

MODULE 2

COMMUNITY
EDUCATORS AND
ADVOCATES



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

JULY 2017



WHO/HIV/2017.24

© **World Health Organization 2017**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 2: Community educators and advocates. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Layout by L'IV Com Sàrl, Villars-sous-Yens, Switzerland.

Cover Photos: © JohnRaeNYC

Contents

INTRODUCTION	2
THE COMMUNITY EDUCATORS AND ADVOCATES MODULE	4
Stakeholders' concerns and responses	4
1. Community-based organizations (CBOs)	4
2. People with HIV	5
3. Men who have sex with men	6
4. Transgender men and women	6
5. Sex workers	7
6. People who inject drugs	7
7. Health care workers providing (or considering providing) PrEP	8
8. Ministries of health	8
9. Leaders	9
Approaches to providing information about and advocacy for PrEP	10
Stigma	14
FURTHER READING	15
REFERENCES	16

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 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 suppressed 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 experiences of transgender men and women are often obscured because they have been included with men who have sex with men, whose situation is different. Table 4 addresses some of the concerns and questions about PrEP raised often by transgender men and women.

TABLE 4. FAQs ON PREP RAISED BY TRANSGENDER MEN AND WOMEN

CONCERN / QUESTION	RESPONSE
Does PrEP work for transgender women?	Yes, PrEP works for transgender women when used as recommended, once daily. Results of the experiences of transgender women in the iPrEx study (8) showed that in a group of 339 transgender women there were no infections if more than four PrEP tablets were taken per week. However, overall adherence to PrEP was less for transgender women compared to other groups, especially during periods of higher possible exposure to HIV.
Does PrEP interfere with gender affirming hormones?	No. Gender affirming hormones are processed in the body by the liver, whereas PrEP medicines are processed in the kidneys. Interferences between sex hormones and ART have not been observed.

5. Sex workers

Sex workers bear a disproportionate burden of HIV infection in places where their work is criminalized. Where sex work is not criminalized, sex workers are often better able to protect themselves through the careful use of condoms. Condoms are the mainstay of preserving sexual health among sex workers. PrEP could provide an additional prevention tool (9). Table 5 addresses some of the main questions and concerns about PrEP raised often by sex workers.

TABLE 5. FAQs ON PREP RAISED BY SEX WORKERS

CONCERN / QUESTION	RESPONSE
Will PrEP influence condom use by sex workers?	Condom use with clients is the mainstay of maintaining sexual health for many sex workers. Unlike condom use, PrEP does not prevent other STIs or pregnancy. PrEP roll-out should not undermine sex workers' ability to negotiate and demand consistent condom use with clients. PrEP demonstration projects have not shown a drop in condom usage (10). Many sex workers do not use condoms with their primary partners (for example, spouses). Others sometimes struggle to negotiate condom use when they are new to sex work. The ability of some sex workers to negotiate safer sex can be compromised by restrictive and adverse social and legal environments. In such circumstances, PrEP can serve as an added layer of protection. PrEP can also provide additional protection in case of condom breakage or slippage, or when sexual violence occurs.
Will PrEP affect advocacy for the decriminalization of sex work?	Decriminalization of sex work is important to allow workers to protect themselves from violence, rape and STIs. PrEP users often feel empowered by being able to control their HIV risk.
Will sex workers be coerced to take PrEP?	All use of PrEP medicines must be voluntary. Advocacy and communication messages must highlight that taking PrEP is always a voluntary choice.

6. People who inject drugs

People who inject drugs carry a disproportionate burden of HIV infection in many places. WHO recommends a package of effective HIV services to be provided for all people who inject drugs including harm reduction (in particular opioid substitution therapy and needle and syringe programmes). When these interventions are available, the risk of HIV transmission is significantly reduced. Providing these services should be a priority.

People who use and/or inject drugs may also be at risk of sexual transmission of HIV. In particular, this may be the case among people who use amphetamine type stimulants and engage in higher risk sexual practices (including among some subgroups of men who have sex with men in some settings). There may also be a link with sex work and not being empowered to use condoms consistently with all clients or with intimate partners.

Access to harm reduction remains the mainstay of HIV prevention for people who inject drugs. However, this population should not be excluded from PrEP services. PrEP can be considered for people who use drugs for whom harm reduction services – sterile injecting equipment and opioid substitution therapy – are not relevant, such as people using amphetamine type stimulants and if they have substantial HIV risk. Table 6 addresses a key question about PrEP raised often by people who inject drugs.

TABLE 6. FAQ ON PREP RAISED BY PEOPLE WHO INJECT DRUGS

CONCERN / QUESTION	RESPONSE
Does PrEP work to prevent the acquisition of HIV from injection drug use?	Access to clean injection equipment is the basis of HIV prevention among people who inject drugs. PrEP does not prevent other blood-borne infections, for example from the hepatitis B or C virus. Needle syringe programmes provide multiple benefits and are the first priority in the prevention of HIV infection from injection drug use. The use of PrEP could provide additional protection where access to and consistent use of sterile injecting equipment may be compromised. People who use or inject drugs may, however, be at increased risk of HIV from sexual transmission and should in this instance be included in PrEP programmes.

7. Health care workers providing (or considering providing) PrEP

Health care workers play a key role in introducing PrEP. The *Clinical module* for health care workers in this implementation tool aims to provide specific medical information related to the delivery of PrEP. Table 7 addresses some broader concerns and questions frequently raised by health care workers when considering or providing PrEP.

TABLE 7. FAQs ON PREP RAISED BY HEALTH CARE WORKERS

CONCERN / QUESTION	RESPONSE
Can PrEP increase the burden of drug resistance?	Consistent use of PrEP prevents HIV infection, and a person who does not acquire HIV infection will not develop HIV drug resistance. HIV testing every three months will also reduce the risk of drug resistance. Modelling suggests that PrEP contributes less than 5% to the total burden of drug resistance from antiretroviral use. The relative contribution of ART to drug resistance far exceeds that from PrEP; therefore, preventing new HIV infections by using PrEP would decrease overall levels of HIV drug resistance (11–13).
What are the risks of hepatitis B flares after stopping PrEP?	TDF used in PrEP is an effective medicine for the treatment of hepatitis B virus (HBV) infection. People with HBV may have a flare of their infection if they stop PrEP. This risk occurs primarily among people with HBV treatment indications: elevated transaminases (AST or ALT), elevated HBV DNA levels, low platelet count or signs of liver cirrhosis. Starting and stopping PrEP has been shown to be safe for people with active HBV infection and normal or near normal AST and ALT (14, 15). Testing for hepatitis B is suggested among PrEP users. Vaccination is effective and will benefit people who are hepatitis B susceptible and can be offered as part of a PrEP programme.
Will low adherence limit PrEP uptake and effectiveness?	Adherence to PrEP has tended to be higher in open-label demonstration projects that have provided PrEP to people together with information about its safety and the high efficacy it provides when used as directed. PrEP adherence has been shown to be high among people who may gain most from taking it and who understand the HIV risks they face and how PrEP can benefit them (16, 17).
Will PrEP increase the burden of STIs?	PrEP prevents HIV but does not prevent syphilis, gonorrhoea, chlamydia or other STIs. Consistent condom use protects against gonorrhoea transmission; it also protects, but less so, 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 (7). It is not yet known if PrEP will increase or decrease STI rates. PrEP provides opportunities to diagnose and treat STI cases, which is the mainstay of STI prevention.

8. Ministries of health

Ministries of health play a key role in the introduction of PrEP in national health programmes. Before rolling out a PrEP intervention in a country, the ministry of health will consider how: people who would benefit most from PrEP use are identified; settings and services where PrEP could be integrated are selected; the funds needed to cover the costs are allocated; health care workers are trained; and monitoring systems are in place. Table 8 addresses some of the main concerns and questions frequently raised about PrEP by staff at ministries of health.

TABLE 8. FAQs ON PREP RAISED BY MINISTRY OF HEALTH STAFF

CONCERN / QUESTION	RESPONSE
How strong is the evidence of the effectiveness of PrEP?	WHO conducted a systematic review of PrEP evidence, the results of which are available in the <i>review of evidence annex</i> at the end of this implementation tool. This review demonstrates the effectiveness of PrEP in the prevention of HIV transmission in a range of populations and settings.
How is it best to provide PrEP?	PrEP services can be nurse-led with support from peer counsellors. PrEP can be integrated into existing clinical services that offer HIV testing, STI screening, other prevention services and ART (or referral for ART). For example, PrEP could be integrated into clinical services for key populations and contraceptive services for women in settings with a very high HIV burden.
How can people at substantial risk of acquiring HIV be identified?	The module on <i>strategic planning</i> in this implementation tool provides examples of approaches that can be used to identify places and groups where the burden of HIV is substantial and where PrEP implementation could be considered.
Will PrEP increase the burden of drug resistance?	Consistent use of PrEP prevents HIV infection, and a person who does not acquire HIV infection will not develop HIV drug resistance. HIV testing every three months will also contribute to preventing the risk of drug resistance. Modelling has shown that PrEP contributes less than 5% to the total burden of drug resistance from antiretroviral use. The relative contribution of ART to drug resistance far exceeds that from PrEP; therefore, preventing new HIV infections by using PrEP will decrease overall levels of HIV drug resistance (11–13).
How can scarce health resources be appropriately allocated to cover PrEP?	PrEP is less expensive than HIV treatment because treatment requires more medicines over a longer period of time and more laboratory testing. In some settings PrEP is expected to be cost-saving if offered to people who would otherwise have a greater than three per 100 person-year risk of acquiring HIV infection. This saving comes from providing PrEP to people for periods of substantial risk and avoiding the costs of lifelong ART for HIV.

9. Leaders

Leaders who are already tackling multiple health and social problems and economic challenges may be hesitant to think about HIV. PrEP may be seen as an expensive programme that does not bring the social benefits of other approaches to sexual health. Leadership is needed to ensure that medicines regulatory authorities and public health officials review the evidence for offering immediate ART to all people with HIV and offering PrEP to people who do not have HIV but face substantial risk of acquiring it. Leadership is also necessary to commit the resources required for effective implementation of these policies as well as to inspire public health authorities to develop and prioritize comprehensive strategic plans for decreasing HIV transmission and HIV-related illness and death. Table 9 addresses a key question about PrEP frequently raised by leaders.

TABLE 9. FAQ ON PREP RAISED BY LEADERS

CONCERN / QUESTION	RESPONSE
What rationale can leaders use to convincingly and effectively integrate PrEP into overall national HIV plans?	PrEP is effective in preventing HIV infection. It provides an additional prevention option for communities and people who continue to experience high HIV incidence. Where incidence remains high, successfully preventing new HIV infections may be cost-saving in the long term.

Approaches to providing information about and advocacy for PrEP

A range of approaches can be considered to increase awareness about and demand for PrEP and to advocate for the provision of PrEP to people and communities at substantial HIV risk.

i. Mass media

Print and digital mass media can increase general awareness of PrEP in the community. However, the choice whether to use PrEP is personal and people will usually not rely only on mass media sources to guide such decisions. Word of mouth is often a key source of information for people making health-related choices. PrEP must always be presented as a personal choice. Therefore, it is essential that mass media messages focus on the product and not on the person, so as not to stigmatize, especially when mobilizing key populations.

Mass media can be used to increase awareness about PrEP, including:

- Science news that raises awareness about key PrEP and other prevention studies
- Human interest stories portraying the experiences of people taking PrEP
- News stories on country-specific experiences of providing PrEP

ii. Posters and handouts

Posters and handouts in this section are presented as examples and do not necessarily reflect the views or policies of the WHO. Posters and handouts (see examples in Figures 1-8) can be valuable in building familiarity with PrEP. It is helpful to use a variety of images that appeal to diverse populations. Many programmes have developed PrEP materials following consultations with their communities to find images and messages most relevant to them. It is essential not to be overly ambitious with these materials and to avoid prescriptive statements about right and wrong behaviour. There is little evidence that posters directly influence behaviour; rather, behaviour changes through interpersonal interactions. Yet, such posters build familiarity and can prompt questions. Hence, they may be useful in clinic waiting rooms, workplaces, educational establishments and schools.

FIGURE 1. TIMELINE OF HIV PREVENTION TOOL FOR MEN WHO HAVE SEX WITH MEN, DEVELOPED BY APCOM, AN ALLIANCE OF DIVERSE STAKEHOLDERS FOCUSED ON MALE SEXUAL HEALTH ACROSS ASIA AND THE PACIFIC

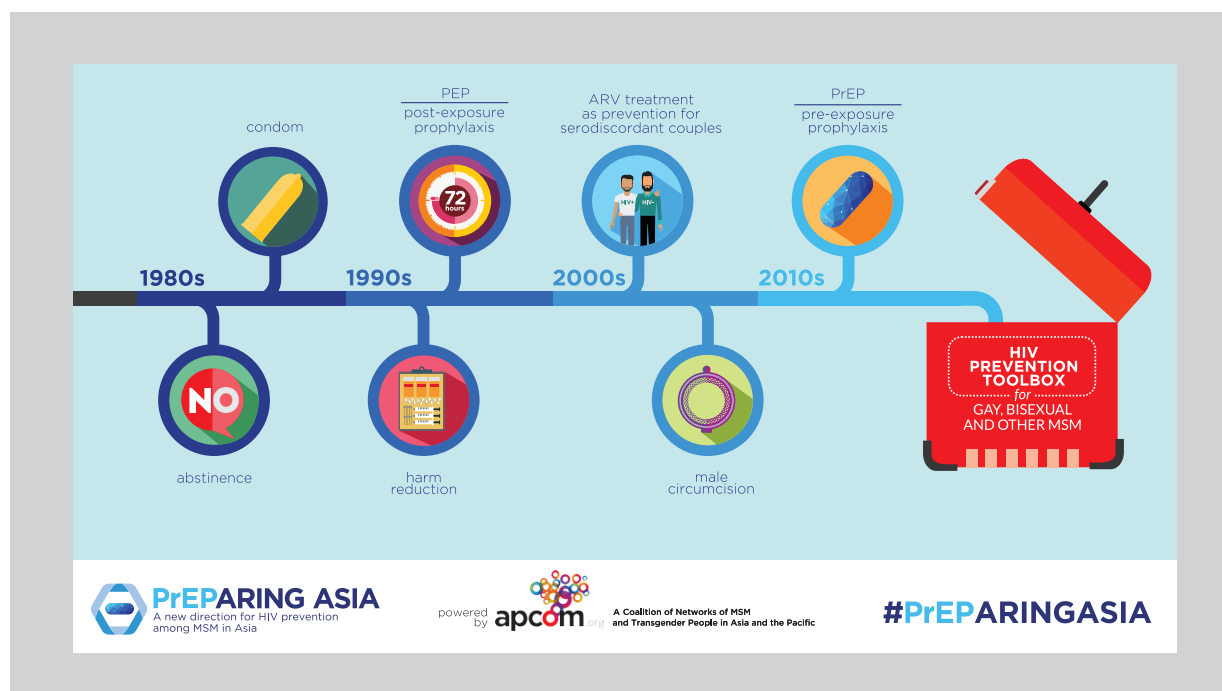


FIGURE 2. FRENCH ADVERT FOR PREP DEVELOPED BY AIDES, FRANCE'S LEADING COMMUNITY-BASED ORGANIZATION WORKING ON HIV ISSUES



© Maya Lambert for AIDES.

FIGURE 3. KENYAN POSTER FOR SENSITIZING COUPLES ABOUT PREP FOR THE PARTNERS SCALE-UP PROJECT



FIGURE 4. POSTER DEVELOPED BY THE SOUTH AFRICAN NATIONAL DEPARTMENT OF HEALTH

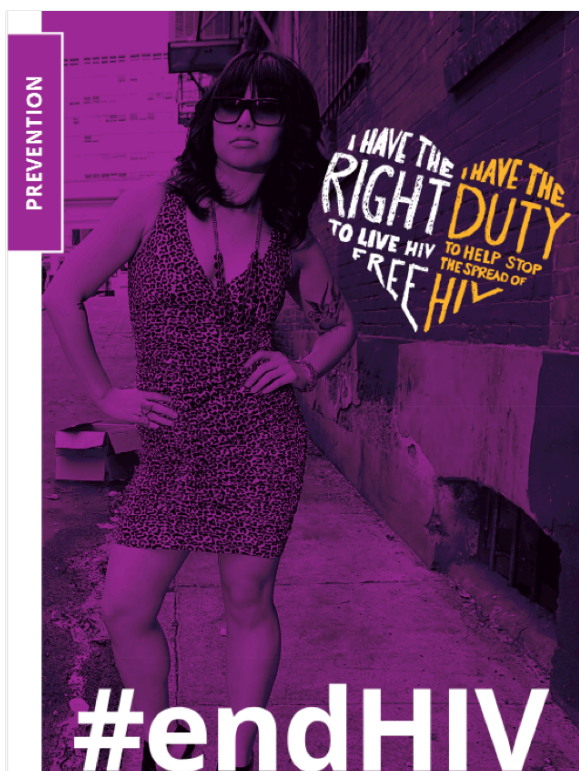


FIGURE 5. PALM CARD DEVELOPED BY THE SOUTH AFRICAN NATIONAL DEPARTMENT OF HEALTH

TAKEN DAILY, PrEP IS AN ADDITIONAL PREVENTION OPTION FOR HIV-NEGATIVE PEOPLE

What is PrEP?
PrEP or pre-exposure prophylaxis comes in the form of a pill, it is 200 mg of emtrici-tabine and 300 mg of tenofovir, mixed together.

Why should I take PrEP?
PrEP helps to prevent HIV for HIV-negative people.

How should I take PrEP?
You take one PrEP pill once a day with or without food. It helps to take the pill at the same time each day so that you do not forget. If you forget to take the pill, take it as soon as you remember but do not take more than 1 pill in one day.

Where should I keep PrEP?
PrEP should be kept in a cool dry place, away from children. Keep in a tightly closed container.

PrEP Information

THE WE ARE GENERATION THAT WILL END HIV

I HAVE THE RIGHT DUTY TO LIVE HIV FREE TO HELP STOP THE SPREAD OF HIV

May2016v3

1

PrEP

THE WE ARE GENERATION THAT WILL END HIV

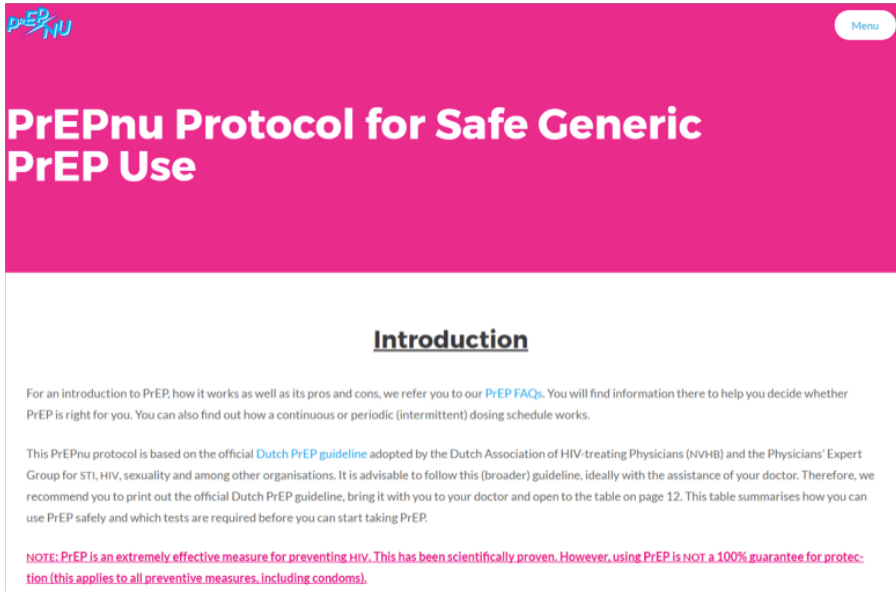
TAKEN DAILY, PrEP IS AN EXTRA PREVENTION OPTION FOR HIV-NEGATIVE PEOPLE



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

FIGURE 6. INFORMATION ON GENERIC USE OF PREP ON A WEB PORTAL DEVELOPED BY PREPNU, A COMMUNITY INITIATIVE FROM THE NETHERLANDS FOCUSED ON EDUCATING THE DUTCH LGBT COMMUNITY



PrEPnu Protocol for Safe Generic PrEP Use


Introduction

For an introduction to PrEP, how it works as well as its pros and cons, we refer you to our [PrEP FAQs](#). You will find information there to help you decide whether PrEP is right for you. You can also find out how a continuous or periodic (intermittent) dosing schedule works.

This PrEPnu protocol is based on the official [Dutch PrEP guideline](#) adopted by the Dutch Association of HIV-treating Physicians (NVHB) and the Physicians' Expert Group for STI, HIV, sexuality and among other organisations. It is advisable to follow this (broader) guideline, ideally with the assistance of your doctor. Therefore, we recommend you to print out the official Dutch PrEP guideline, bring it with you to your doctor and open to the table on page 12. This table summarises how you can use PrEP safely and which tests are required before you can start taking PrEP.

NOTE: PrEP is an extremely effective measure for preventing HIV. This has been scientifically proven. However, using PrEP is NOT a 100% guarantee for protection (this applies to all preventive measures, including condoms).

**FIGURE 7. ADVERTISEMENT DEVELOPED BY APCOM #SHARETHEWORDS
[HTTPS://APCOM.ORG/2015/09/10/PrEP101](https://apcom.org/2015/09/10/PrEP101)**



PrEP is like
taking anti-malaria pill.

It's a good strategy before you embark on your exotic adventure.

apcom.org Learn more about PrEP at apcom.org/PrEPARINGASIA

FIGURE 8. KENYAN ADVERTISEMENT ON FACEBOOK GROUP ([HTTPS://WWW.FACEBOOK.COM/PrePKENYA/](https://www.facebook.com/PrePKENYA/))



iii. Social media

Internet-based social media (Figure 8) and dating and peer-to-peer apps are a cheap and widely available means to reach potential PrEP users. Social media can play a key role in disseminating important scientific information. Information on the high effectiveness of PrEP and stories from early adopters of PrEP may encourage people who could benefit from PrEP to seek PrEP services (18).

iv. PrEP-user champions

PrEP users who are willing to speak publicly are very effective at addressing stigma. They speak from a position of power, expressing in their own words the reasons why they chose to use PrEP to protect themselves, their partners and their community.

Stigma

People at risk of acquiring HIV infection often experience stigma from multiple sources. Adolescent girls and young women may have special concerns about being judged negatively, which could make them hesitant to access sexual health services or could interfere with their effective use of PrEP and other protective practices. Also, young women sometimes report bad experiences with judgmental providers when seeking contraception, which could discourage them from seeking PrEP. The behaviour of men who have sex with men, transgender people, sex workers and people who inject drugs are criminalized in many places, sometimes making them reluctant to seek HIV-related or other sexual health services. Transgender individuals, too, are subject to stigma, discrimination and violence. Cultural sensitivity, which involves having an open and genuine interest in the experiences of individuals and their expression of their identity, is essential. Extreme care must be taken that PrEP roll-out does not have a negative impact by increasing stigma.

An approach centred on cultural humility is critically important.

Further reading

Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf?ua=1).

Oral pre-exposure prophylaxis – Putting a new choice in context. Geneva: UNAIDS; 2015 (http://www.unaids.org/sites/default/files/media_asset/UNAIDS_JC2764_en.pdf).

References

1. Kojima N, Klausner JD. Is Emtricitabine-Tenofovir Disoproxil Fumarate Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection Safer Than Aspirin? *Open Forum Infect Dis.* 2016;3(1):ofv221.
2. Grohskopf LA, Chillag KL, Gvetadze R, Liu AY, Thompson M, Mayer KH, et al. Randomized Trial of Clinical Safety of Daily Oral Tenofovir Disoproxil Fumarate (TDF) Among HIV-uninfected Men Who Have Sex With Men (MSM) in the United States. *J Acquir Immune Defic Syndr.* 2013.
3. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med.* 2010;363(27):2587-99.
4. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet.* 2016;387(10013):53-60.
5. Molina JM, Capitant C, Spire B, Pialoux G, Cotte L, Charreau I, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med.* 2015;373(23):2237-46.
6. Smith DK, Herbst JH, Zhang X, Rose CE. Condom effectiveness for HIV prevention by consistency of use among men who have sex with men in the United States. *J Acquir Immune Defic Syndr.* 2015;68(3):337-44.
7. Mayer K, Levine K, Maloney K, Zaslow S, Krakower D, Grasso C, et al. Increasing HIV Suppression, PrEP Use and STDs in Boston MSM Accessing Primary Care. Presented at: CROI 2016; Boston, Massachusetts, USA; 2016.
8. Deutsch MB, Glidden DV, Sevelius J, Keatley J, McMahan V, Guanira J, et al. HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. *Lancet HIV.* 2015;2(12):e512-9.
9. Cowan FM, Delany-Moretlwe S. Promise and pitfalls of pre-exposure prophylaxis for female sex workers. *Curr Opin HIV AIDS.* 2016;11(1):27-34.
10. Fonner VA, Dalglis SL, Kennedy CE, Baggaley R, O'Reilly KR, Koechlin FM, et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS.* 2016;30(12):1973-83.
11. Abbas UL, Glaubius R, Hood G, Mellors JW. Antiretroviral treatment, preexposure prophylaxis, and drug resistance in sub-Saharan Africa: a consensus among mathematical models. *J Infect Dis.* 2014;209(1):164-6.
12. Abbas UL, Glaubius R, Mubayi A, Hood G, Mellors JW. Antiretroviral therapy and pre-exposure prophylaxis: combined impact on HIV transmission and drug resistance in South Africa. *J Infect Dis.* 2013;208(2):224-34.
13. van de Vijver DA, Nichols BE, Abbas UL, Boucher CA, Cambiano V, Eaton JW, et al. Preexposure prophylaxis will have a limited impact on HIV-1 drug resistance in sub-Saharan Africa: a comparison of mathematical models. *AIDS.* 2013.
14. Peterson L, Taylor D, Roddy R, Belai G, Phillips P, Nanda K, et al. Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial. *PLoS Clin Trials.* 2007;2(5):e27.
15. Solomon MM, Schechter M, Liu AY, McMahan VM, Guanira JV, Hance RJ, et al. The safety of tenofovir-emtricitabine for HIV pre-exposure prophylaxis (PrEP) in individuals with active hepatitis B. *J Acquir Immune Defic Syndr.* 2015.
16. Grant RM, Anderson PL, McMahan V, Liu A, Amico KR, Mehrotra M, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis.* 2014.
17. Liu AY, Cohen SE, Vittinghoff E, Anderson PL, Doblecki-Lewis S, Bacon O, et al. Preexposure Prophylaxis for HIV Infection Integrated With Municipal- and Community-Based Sexual Health Services. *JAMA Intern Med.* 2015:1-11.
18. Grov C, Rendina HJ, Jimenez R, Parsons JT. Using Online Settings to Identify Gay and Bisexual Men Willing to Take or With Experience Taking PrEP: Implications for Researchers and Providers. *AIDS Educ Prev.* 2016;28(5):378-92.



For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv