

# WHO EXPANDS RECOMMENDATION ON ORAL PRE-EXPOSURE PROPHYLAXIS OF HIV INFECTION (PrEP)

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## What is PrEP?

Oral pre-exposure prophylaxis of HIV infection – PrEP – is the use of antiretroviral (ARV) drugs by people who do not have HIV infection in order to prevent the acquisition of HIV.

## What does WHO recommend?

The World Health Organization (WHO) now recommends that people at substantial risk of HIV should be offered PrEP.

In 2014 WHO recommended offering PrEP to men who have sex with men (MSM). On the basis of further evidence of the effectiveness and acceptability of PrEP, WHO has now broadened the recommendation to include all population groups at substantial risk of HIV infection. Offering PrEP should be a priority for populations with an HIV incidence of about 3 per 100 person-years or higher. PrEP should be an additional prevention choice in a comprehensive package of services that also includes HIV testing, counselling, male and female condoms, lubricants, ARV treatment for partners with HIV infection, voluntary medical male circumcision and harm reduction interventions for people who use drugs.



### New recommendation

**Oral 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 HIV prevention approaches.**

**STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE**

## Key evidence

High-quality evidence strongly supports use of PrEP by any person at substantial risk of acquiring HIV infection.

- **Risk of drug resistance is low**, occurring in approximately 1 in 1000 PrEP users in clinical trials. Drug resistance occurred almost exclusively among people who already had acute undetected HIV infection when they started PrEP. Therefore, testing for HIV before people start PrEP is essential to avoid drug resistance. Moreover, offering PrEP reduces the number of new HIV infections, each of which would require lifelong therapy, with substantial ongoing risk of drug resistance. Thus, PrEP is expected to decrease the public health burden of HIV drug resistance.
- **No evidence for risk compensation** in sexual practices, such as decreased condom use or more sexual partners, has emerged in any PrEP studies or programmes.
- **PrEP can be used with hormonal contraception.** Recommended PrEP regimens do not appear to alter the effectiveness of hormonal contraception.
- **PrEP can be used during pregnancy.** No increase occurred in adverse pregnancy-related events among women taking PrEP in early pregnancy. This is important because both mother and infant are more vulnerable to HIV acquisition during pregnancy and breastfeeding.
- **PrEP is acceptable.** Various populations report that they find PrEP acceptable, and individuals have shown substantial interest in PrEP as an additional choice for HIV prevention.
- **Twelve trials of the effectiveness** of oral PrEP have been conducted among serodiscordant couples, heterosexual men, women, MSM, people who inject drugs and transgender women. These trials took place in Africa, Asia, Europe, South America and the United States.
- **PrEP works, when taken.** A systematic review and meta-analysis of trials using TDF finds that PrEP is effective. The level of protection did not differ by age, gender, ARV regimen (TDF versus emtricitabine (FTC) + TDF) or mode of acquiring HIV (rectal or penile/vaginal). The level of protection was strongly correlated with adherence.
- **PrEP has an excellent safety profile.** Across 10 randomized controlled trials, rates of any adverse event did not differ between PrEP and a placebo.

- **Adherence can be maintained.** Demonstration projects and experience in every-day settings are proving that people can adhere to daily oral PrEP.

## Will PrEP be cost-effective?

Offering PrEP is expected to be cost-effective where the incidence of HIV is greater than 3 per 100 person-years and perhaps also at lower incidence. Incidence as high as 3 per 100 person-years remains common among young women in some settings in southern Africa, among some sex workers in Africa and among MSM in many countries. Drug costs of PrEP are lower than treatment drug costs, both per-dose and for the duration of use, which is as-needed for PrEP but lifelong for treatment.

## Considerations for PrEP implementation

PrEP should not displace or compete with effective and well-established HIV prevention interventions, such as comprehensive condom programming for sex workers and MSM 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. The decision to use PrEP should always be made by the individual.

### Where will PrEP offer the most benefit?

Countries with high HIV incidence in certain geographical areas or

specific populations may consider introducing PrEP as an additional prevention option. In these high incidence populations, programmes can use simple screening questions to identify, and then offer PrEP to, people who would benefit most from PrEP. Implementation in low- and middle-income settings has been limited to date, but increasing experience in demonstration projects can guide wider implementation. WHO is developing PrEP implementation guidance that will be published in 2016.

### Key elements of PrEP services

- **Offer PrEP as part of combination HIV prevention approaches.** Continued advocacy for and investment in effective combination HIV prevention services is essential.
- **Involve communities and support an enabling environment.** The full participation of communities is critical to developing and implementing services. In many places community-based organizations have taken the lead in limiting the spread of HIV infection. Countries should support these organizations to lead PrEP implementation and to provide accurate information about PrEP.
- **Provide training.** Health-care providers should be trained and supported to provide culturally appropriate PrEP services to persons at substantial risk for HIV, especially young women and people from key populations.
- **Ensure HIV testing.** HIV testing is required before starting PrEP and regularly while taking PrEP. Using quality-assured HIV testing is

important, and referral of people who test positive to HIV treatment and prevention services is essential.

- **Monitor renal function.** Given the use of TDF-based PrEP regimens creatinine testing is desirable before starting PrEP and quarterly during PrEP use for the first 12 months, then annually thereafter.
- **Test for hepatitis B infection.** Hepatitis B (HBV) is endemic in much of the world where HIV prevalence is highest. Testing PrEP users for HBV surface antigen is desirable, with HBV vaccination for those who are uninfected. WHO recommends TDF or entecavir for treatment of liver disease due to HBV. If PrEP is stopped in such people, continuing an alternative therapy for HBV should be considered.
- **Encourage adherence for effectiveness.** Demonstration projects have shown that most people can use daily oral PrEP effectively. Effective PrEP use is different from adherence to HIV treatment in that PrEP can be started and stopped as a person moves through "seasons of risk", whereas treatment is lifelong. Ways to increase PrEP adherence include informing people that PrEP is highly effective when taken and that PrEP is safe; the great majority of PrEP users have no side-effects. Support groups, including those using social media, may help with adherence by enabling PrEP users to share experience and challenges.

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## POLICY BRIEF

## WHO EXPANDS ITS RECOMMENDATION ON THE USE OF ORAL PrEP