

## Pre-exposure prophylaxis (PrEP) for HIV prevention



### KEY POINTS

- Pre-exposure prophylaxis (PrEP) is a daily course of antiretroviral drugs (ARVs) taken by HIV-negative people to protect themselves from infection.
- Evidence shows that, when taken consistently and correctly, PrEP reduces the chances of HIV infection to near-zero.
- PrEP is cost effective, and there is growing demand for it from people at higher risk of HIV infection, but the scale and coverage currently remains limited.
- PrEP does not protect against other STIs so needs to be delivered as part of a comprehensive package of HIV/STI prevention services.
- PrEP's effectiveness decreases rapidly if not taken regularly as prescribed, so addressing the barriers preventing adherence is key to success.

Explore this page to find out more about [the evidence on PrEP](#), [landmark trials](#), [where PrEP is being implemented](#), [the scale-up challenges of PrEP](#) and [the future: next-generation PrEP](#).

Pre-exposure prophylaxis (PrEP) normally comes in the form of a daily course of antiretroviral drugs (ARVs) that are taken orally and can protect HIV-negative people from HIV before potential exposure to the virus.

More than 15 trials of oral PrEP have shown that, when taken consistently and correctly, PrEP is very effective and reduces the chances of HIV infection to near-zero.<sup>1 2 3 4</sup> This has led some to describe PrEP as a 'game changer' for HIV prevention.<sup>5 6 7</sup>

While PrEP can provide very effective protection against HIV, it does not provide protection against

other sexually transmitted infections (STIs) and blood-borne illnesses such as Hepatitis C, syphilis, and gonorrhoea. The effectiveness of PrEP is closely linked to adherence – if someone taking PrEP regularly misses some daily doses, their risk of HIV infection will increase substantially. It is therefore important that any programme offering PrEP provides it as part of a combination package of prevention initiatives, based on an individual's circumstances – with support and advice on the importance of PrEP adherence.

In 2015, recognising that PrEP has potential population-wide benefits, the World Health Organization (WHO) released new guidelines recommending that PrEP should be offered as a choice to people who are at substantial risk of HIV infection as part of a combination HIV prevention programme.<sup>8</sup> Previously, PrEP was only recommended for certain key affected populations such as [sex workers](#), [men who have sex with men](#) (sometimes referred to as [MSM](#)), [people who inject drugs](#) (sometimes referred to as [PWID](#)).<sup>9</sup> WHO broadly defines priority populations for PrEP as groups with an HIV incidence of about 3 per 100 person-years or higher.<sup>10</sup> In high-prevalence, generalised settings this may include young people, adolescents and women.

The United Nations General Assembly's 2016 Political Declaration on HIV and AIDS includes a commitment to providing three million people at higher risk of HIV infection with PrEP by 2020. However, by the end of 2017 only 350,000 people have ever taken PrEP, while the number of people currently PrEP is likely to be lower as many people only take PrEP for a short period. Around two thirds of PrEP users live in the United States of America (USA), , although access is expanding in a number of other countries and a significant number of people are also thought to be accessing PrEP through the internet.<sup>11</sup>

There is a serious discrepancy between who would benefit most from PrEP and who is currently accessing. There are many challenges associated with PrEP implementation and scale-up, as well as issues relating to individual adherence.

As of 2019, Truvada, a single pill that is a combination of ARVs tenofovir and emtricitabine, is approved for use as PrEP. Solo tenofovir has been tested as PrEP in two major studies: Partners PrEP, involving serodiscordant heterosexual couples (where one person is HIV positive and one is HIV negative), and the Bangkok Tenofovir Study involving people who inject drugs.<sup>12</sup> Other ARVs such as Maraviroc are also being studied as possible PrEP alternatives.<sup>13</sup>

## PrEP: the evidence

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The argument is over about PrEP. If you take the drug, it works, not only in a clinical trial but in the field.

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- *Anthony Fauci, Director, US National Institute of Allergy and Infectious Diseases (NIAID)* <sup>14</sup>

PrEP has been shown to reduce the risk of HIV infection from unprotected sex by over 90%, and from injecting drugs by more than 70%.<sup>15</sup> These statistics include individuals with lower adherence levels so the actual level of protection for those fully adhering is higher and near 100%.

For people facing limited options to protect themselves against HIV or for those who can't or don't want to use a condom, PrEP allows them to discreetly take control of their HIV risk.<sup>16</sup>

A number of high-profile trials have shown how PrEP can be an effective HIV prevention option in a number of different settings.

## Landmark PrEP trials

Started in 2007, the iPrEx study was the first to offer PrEP. Oral PrEP was provided to 2,500 men who have sex with men at 11 sites in six countries on four continents (Brazil, Ecuador, Peru, South Africa, Thailand and the USA). It found that the HIV infection rate in HIV-negative gay men who were given PrEP was reduced by 44%, compared with men taking a placebo. Crucially, among those who took PrEP seven days-a-week as prescribed, the risk of infection was reduced by 99%.<sup>17</sup> Similarly, the IPERGAY study, which offered oral PrEP at six hospitals in France and Canada, reported an 86% reduction in the HIV infection rate compared to those taking a placebo.<sup>18</sup>

The Partners PrEP trial recruited around 4,750 heterosexual couples in which one partner was living with HIV across [Kenya](#) and [Uganda](#). The risk of HIV infection was reduced by 62% among those who took oral tenofovir and 73% among those who received Truvada.<sup>19</sup> The TDF2 Study Phase II/III trial evaluated daily oral Truvada in 1,200 heterosexual men and women in Botswana and found it reduced the risk of HIV infection by 62%.<sup>20</sup>

Additionally, a number of trials have shown the effectiveness of PrEP in preventing HIV infection among women at a high risk of HIV.<sup>21</sup> The FEM-PrEP Phase III trial evaluated the safety and effectiveness of once-daily oral Truvada for HIV prevention in 1,950 women aged 18-35 years in Kenya, South Africa and Tanzania. A lack of adherence meant PrEP was not found to reduce HIV risk (see Challenges section further down this page).<sup>22</sup>

There has been one high-profile trial involving people who inject drugs. The Bangkok Tenofovir Study Phase II/III trial involved around 2,400 people in Thailand who inject drugs. Daily oral PrEP was found to halve the risk of HIV infection (49% efficacy).<sup>23</sup>

Full details of all current, planned, and completed PrEP demonstration projects, clinical trials, implementation initiatives and end user studies are listed by AVAC's Global PrEP Use Tracker.<sup>24</sup>

### Does PrEP use increase risk behaviour?

A number of studies are examining whether people on PrEP are less likely to use a condom, which could lead to an increase in other sexually transmitted infections (STIs).

The PROUD Study conducted in the [United Kingdom \(UK\)](#) reported no difference in condom usage or levels of STIs between people given PrEP and people that didn't take the drug.<sup>25</sup>

However a study that took place between 2010 to 2015 among men who have sex with men in Montréal, Canada did find an association. Increased rates of STIs were observed in the first 12 months of taking PrEP, compared to the 12 months prior.<sup>26</sup>

A 2019 evidence review analysing 20 PrEP studies and trials among gay men and other men who have sex with men also found high rates of STIs among people on PrEP, ranging from 33% to 100%. Although this suggests there are high rates of STIs among gay men and other men who have sex with

men who are taking PrEP, evidence as to whether PrEP is responsible for this high rate is unclear. The issue is further complicated by the fact that accessing PrEP means people will be tested for HIV and other STIs before initiating it, leading to an increase in STI diagnoses.

This suggests that, if people are engaging in high-risk sex that increases their likelihood of having an STI, they are also likely to be exposed to HIV and so would greatly benefit from PrEP, along with interventions designed to increase condom use.[27](#) [28](#)

## Cost effectiveness

PrEP drug costs are lower than HIV treatment costs, both per-dose and for the duration of use. Moreover, PrEP is prescribed to be taken consistently, but only when someone is at heightened risk of HIV, whereas, should someone acquire HIV, they will need to be on antiretroviral treatment (ART) for their entire life in order to stay healthy.[29](#) With an estimated cost of less than 5% of an HIV programme's total budget, PrEP is considered by UNAIDS to be a key component of a Fast-Tracked response.[30](#)

PrEP can also create links between individuals and other sexual and reproductive health services such as STI testing, prevention tools such as condoms, lube and harm reduction, family planning services, and services to prevent or respond to gender-based violence.

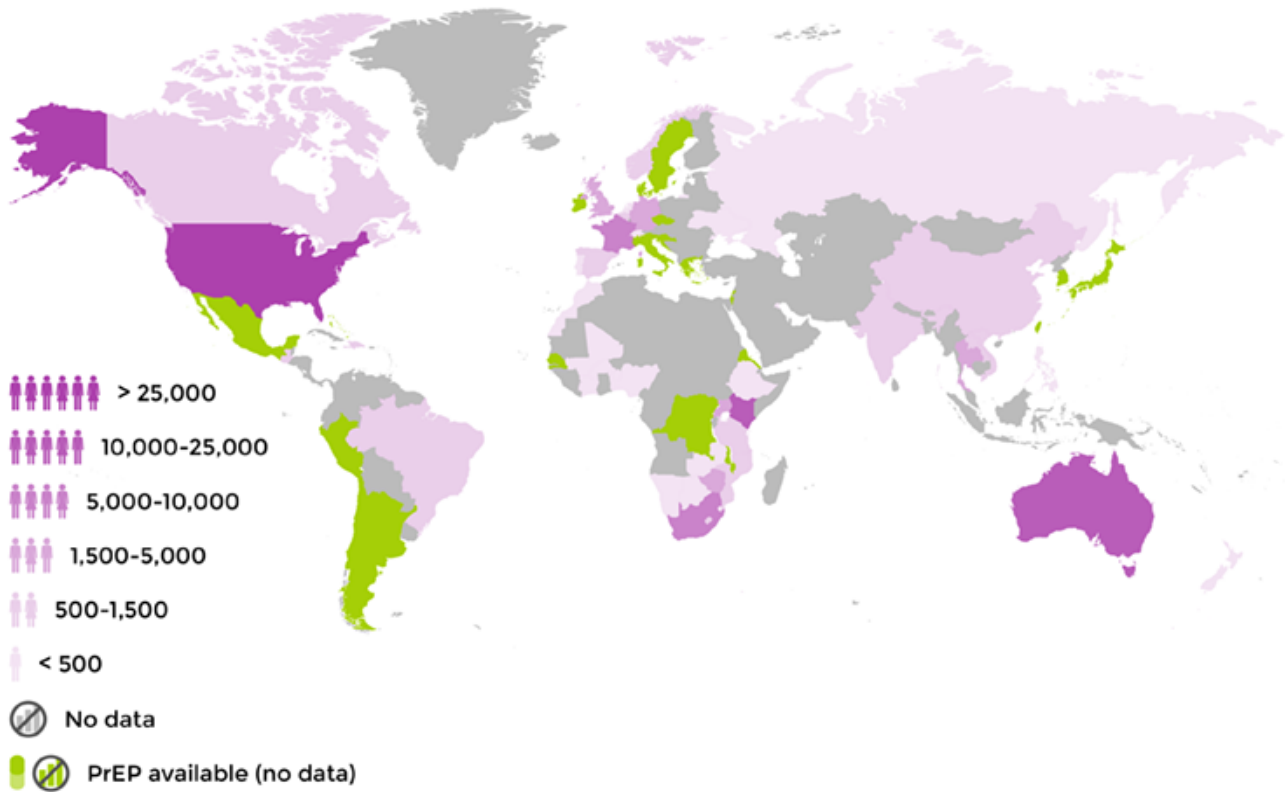
Despite this, the cost of PrEP is an important concern, even in high-income countries. A survey of 31 western and eastern European countries conducted by the European Centre for Disease Prevention and Control found that 21 countries considered the cost of PrEP to be a highly important limiting factor against its implementation; the second most important limiting factor was the cost of service delivery.[31](#)

Ultimately, the cost-effectiveness of PrEP will be determined by the cost of PrEP medication, how efficiently it can be delivered to the people in greatest need, and its impact (see Challenges section for more on costs).

## Where is PrEP being implemented?

As of June 2018, 46 countries had regulatory approval for PrEP. Of these, 39 had included PrEP within their HIV policies, a 40% increase from 2016, mostly in Europe or Africa. However, this does not mean that PrEP is available in all parts of these countries and to everyone who needs it. In 10 of these countries, PrEP is being introduced nationally, and in a further 29 there are smaller-scale PrEP projects, which are being carried out to research how best to offer PrEP services, as well as the cost and acceptability of PrEP, in preparation for PrEP being rolled-out more widely.[32](#) [33](#)

Different countries are targeting different populations. Countries in sub Saharan Africa that are scaling up PrEP such as South Africa, Lesotho and Kenya are focusing on adolescent girls and young women.[34](#) While the USA, most European countries, Australia, Thailand, Brazil, Vietnam and the Philippines largely focus on gay men and other men who have sex with men. South Africa, Kenya and India also have some focus on sex workers.[35](#)



Source: AVAC Global PrEP Initiation Tracker (2018) (from [avac.org](http://avac.org), accessed May 2019)

**Avert** [www.avert.org](http://www.avert.org)

## Big city experiences

### *San Francisco, USA*

San Francisco in the USA was one of the first places to implement PrEP, rolling out the service in 2012.<sup>36</sup>

In November 2014, roughly 600 men who have sex with men enrolled on PrEP at the Magnet sexual health clinic in the Castro neighbourhood of San Francisco. After one year, there were no new HIV infections among the group. Adherence remained high over time – 95% after one month, and 94% in the seventh month reported that they had missed fewer than three doses during the past week.<sup>37</sup> As part of the programme, SMS reminders are sent to new clients to help them adhere to their medication. People can also be connected to health professionals and peers via an online social network if they have any questions. They are also supported to select health insurance plans that cover at least a portion of their PrEP costs.<sup>38</sup>

Steve Gibson, Director of the Magnet clinic, said:

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The bottom line is that there were no new HIV infections. We've found that the combination of clinical services combined with benefits navigation is what helps ensure that people can start

taking the medication the same day, often costing the client nothing.<sup>39</sup>

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In 2017, PrEP was added to the city's HIV programme. That year, around half of at risk men who have sex with men were estimated to be on PrEP.<sup>40</sup> <sup>41</sup> New HIV diagnoses fell in San Francisco by 43% between 2013 and the end of 2016, a decrease that is associated with increased viral suppression among people living with HIV and the fact that more people are using PrEP.<sup>42</sup>

#### *London, UK*

In London, online PrEP access has been associated with a dramatic reduction in HIV among gay men and other men who have sex with men, with four London sexual health clinics reporting a 40% reduction in new HIV infections among this population between 2015 and 2016.<sup>43</sup>

The reason that so many people have been purchasing PrEP online is that, until 2017, the National Health Service in England (NHS England) only provided access to PrEP through small-scale trials, leading many people in London and beyond to purchase generic versions online.

In 2017, NHS England announced it would provide PrEP to 10,000 people through an implementation study across 200 UK clinics. The study is the first study to assess the cost-effectiveness of a national roll-out of PrEP in the UK.<sup>44</sup>

#### Buying PrEP online

Evidence presented by WHO suggests online purchase of PrEP is happening at a significant scale, not only in Western Europe and North America but in Asia and some parts of Latin America and Africa.<sup>45</sup>

In a 2017 study, researchers offered drug monitoring to people in London purchasing PrEP online in order to verify whether internet-based drug concentrations were consistent with necessary clinical standards. Their analysis found that all generic versions purchased over the internet were similar to, and in some cases slightly higher than, the original formulation of Truvada, which is manufactured by Gilead. Significantly, they also found that no new cases of HIV were seen among participants.

The results from this study are important in reassuring people at risk of HIV who cannot yet access PrEP that it is safe to purchase it from recommended online websites.<sup>46</sup>

#### *Sydney, Australia*

New South Wales was the first state in Australia to trial PrEP at a large scale. It did this via a PrEP trial called EPIC-NSW, which was launched in March 2016. A year later HIV infections among gay men and other men who have sex with men in New South Wales had fallen by almost one-third.

The declines were highest among men living in established gay communities in Sydney (51.8%) and

Australian-born men (48.7%) across the state. The decline in HIV infections was less pronounced among immigrants, with a smaller 21% decline among those born in Asia.[47](#) [48](#)

## Examples of PrEP implementation across the world

### *Brazil*

The PrEP Brazil Study focuses on men who have sex with men and transgender women. It is employing a number of strategies to increase PrEP adherence, including SMS reminders and engagement through social media.[49](#)

Preliminary results of the study showed uptake of PrEP over 50%, and notable increases in awareness of the service and knowledge of high-risk sexual behaviour among participants.[50](#)

Following the success of this study, in May 2017 Brazil announced free access to PrEP to people at substantial risk of HIV infection. It is the only country in Latin America where PrEP is available through the public health service. Between 2017 and 2022, around 50,000 sex workers, gay men and other men who have sex with men and transgender people will be able to access PrEP under the scheme.[51](#) [52](#)

However, the number of people in Brazil who want PrEP may outstrip availability. A 2018 modelling study estimated that PrEP demand among gay men and other men who have sex with men across 11 Brazilian cities would equate to around 66,120 men (aged 15 to 64 years) and could be as high as 97,960. Researchers found PrEP demand to vary considerably by city due to differences in the number of gay men and other men who have sex with men living there and city-specific HIV prevalence.[53](#)

### *Kenya*

Kenya has Africa's largest PrEP programme, with around 25,000 people taking PrEP.

In 2016, Kenya included oral PrEP in its ART guidelines for people at substantial risk of HIV infection. In 2017 it published a PrEP implementation framework, and has been rolling out PrEP across the public health sector since. The framework identifies 19 geographical areas with high HIV prevalence where PrEP should be available. It also names the following population groups as priorities for PrEP access: female sex workers, people in discordant couples, pregnant women, fishing communities around Lake Victoria, adolescents and young people, people in the general population with multiple sexual partners, men who have sex with men, and people who inject drugs.

As part of this work, a PrEP medication supply chain has been integrated into Kenya's existing ART supply chain, which provides medication to more than 3,000 health clinics. Uptake so far has been most successful among couples and female sex workers.[54](#) [55](#)

### *Zimbabwe*

Around 4,000 people are taking PrEP in Zimbabwe, making it the country with the third largest PrEP programme in Africa, behind Kenya and South Africa.[56](#)

In 2009, the Sister with a Voice programme was launched to strengthen [Zimbabwe's](#) HIV response among sex workers. Within this programme, the SAPPH-Ire project ran between 2014 and 2016, offering ART to women who test positive for HIV and PrEP to women who test negative for HIV.

Offered at 14 locations, community-based adherence support was provided to both groups. Each woman in the programme selects a 'sister', another woman in the programme with whom she attends monthly peer group sessions. Their HIV status is kept confidential unless they choose to disclose it, and the programme sisters support each other with medication adherence. SMS reminders are used to encourage women to attend both clinic and medication refill appointments. [57](#)

Another key component of the programme was legal advice provided to participants by peer educators. The peer educators inform sex workers of their basic rights and how they can legally protect themselves against violations of those rights.[58](#)

Also operating in Zimbabwe is DREAMS, a multi-country programme that focuses on reducing HIV among adolescent girls and young women. A two-year study, which began in 2017/18, will follow young women in Zimbabwe who sell sex who are being offered oral PrEP through the DREAMS programme in partnership with Sisters with a Voice. The study will establish whether PrEP, in combination with a range of other HIV prevention services, reduces new infections among this group.[59](#)

### *Thailand*

As with many countries in Asia and the Pacific, Thailand's epidemic is concentrated among gay men and other men who have sex with men, transgender people, sex workers and people who use drugs.

The Thai government has been carrying out a number of PrEP pilot projects including the 5-year COPE4YMSM study, which targets at risk young men who have sex with men and transgender women (18-26 year old), and PrEP-30 (also known as PrEP-15), which offers free PrEP to Thai and non-Thai people regardless of gender and age.

It is estimated that between 6,800 and 7,300 were on PrEP in Thailand as of 2018. In the same year the government began scaling-up a number of PrEP projects to make PrEP available within the national health system. PrEP for people at substantial risk of HIV has also been included in Thailand's core HIV prevention package and included in the country's universal health coverage scheme.[60](#) [61](#)

## PrEP models

### Key population-led services

Enabling people from population groups that are most affected by HIV such as sex workers or gay men to design and deliver PrEP programmes to people within their community has proven to be an effective delivery method.

For example, between January 2016 and December 2017 the Princess PrEP programme in Thailand paid and trained transgender women and men who have sex with men to link their peers to local community health centres in order to access PrEP. Those attending the service were tested for HIV and if negative were given a course of PrEP along with condoms and lube then followed-up with appointments after one and three months then every three months after that.

Princess PrEP has been more successful in delivering PrEP to transgender women and men who have sex than similar public health sector schemes. At 1, 3, 6, 9 and 12 months, retention was 74.2%, 64.0%, 56.2%, 46.7% and 43.9% respectively, although it was lower among transgender women than men who have sex with men at every stages in the process. The proportion of people having



condomless sex did not change over the 12-month period. However, new syphilis was diagnosed in 4.9% of those on PrEP at six months and 3.0% after a year, compared to 7.0% when the study began. Among those adhering to PrEP there was one new case of HIV, compared to six among non-adherers.[62](#) [63](#)

## Integrated services

Including PrEP in other health services can also be a way to ensure people most at risk to HIV are able to benefit from it.

For example, the DREAMS programme, which operates in ten African countries, offers PrEP as part of a core package of social, economic and biomedical HIV prevention services aimed at adolescent girls and young women. In some countries, young women can access PrEP alongside a range of sexual and reproductive health services such as contraception and family planning advice.[64](#)

In Detroit in the USA, the Ruth Ellis Health and Wellness Center offers PrEP to transgender women attending services for gender-affirming hormone therapy. As blood tests are needed for both PrEP and hormone therapy they are taken at the same time and adherence support for both medications is also integrated.[65](#)

## Nurse-led models and task-shifting

Task shifting involves training health workers such as nurses to undertake jobs previously done by doctors in order to relieve the strain on human resources.

This is now being used to scale-up of PrEP in a cost-effective way. For example, the EPIC-NSW trial in Australia uses nurses to provide PrEP in 10 local health districts.

A senior doctor who regularly reviews patient records manages each nurse. Anyone in the trial who shows signs of a medical issue, such as side effects or kidney issues, is referred to a doctor. Although registered nurses are able to begin people on PrEP under the programme, most clinics are still using doctors for the initial appointment, after which responsibility transfers to nurses who then carry out regular follow-up appointments.[66](#) [67](#)

Similarly, the San Francisco AIDS Foundation uses a nurse-led model to provide free PrEP to transgender and cisgender men at its Strut sexual health clinic. Using this model has enabled around 1,250 people to be screened for PrEP, of whom 95% enrolled (as of 2016).[68](#)

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Community based organisations can step up to the plate and offer PrEP. There are other organisations that have pharmacists who actually deliver PrEP. It makes sense to step back and think, ‘Who else in your organisation can participate in this?’ It doesn’t necessarily have to be a physician-centred model every time. We know that PrEP is easy, safe, effective, and needed, so we just need

to do it.

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- Pierre-Cedric Crouch, director of nursing at Strut.[69](#)

## 'Demedicalised' services

A common argument is that PrEP needs to be 'demedicalised', which means it needs to be offered in non-clinical contexts in the same way that condoms, lubricant are and HIV testing are.[70](#) [71](#) This a growing area of research with trials expected in the next few years.

## PrEP scale-up challenges

### Availability


The availability of PrEP is currently extremely limited. Although UNAIDS has indicated that 3 million people at substantial risk of HIV infection should be on PrEP by 2020, only 350,000 people have ever taken it and the number of those currently accessing it is even lower.[72](#)

One of the reasons for this is that national regulatory approval for PrEP, which legalises the use of medicines, is limited to a small but growing number of countries. The United States approved the use of PrEP in 2012 and clinical guidelines were issued in 2014. In January 2016, France began offering PrEP within its national healthcare system..[73](#)

In December 2015, South Africa became the first African country to issue full regulatory approval of PrEP and to include PrEP in its national HIV programme. It was followed swiftly by Kenya. Other national regulatory authorities have also approved PrEP including Australia, Canada, Belgium, Brazil, Lesotho, Portugal,, Uganda and Zimbabwe.[74](#) [75](#) The European Medicines Agency has also granted market authorisation for PrEP to be marketed across all countries in the European Union.[76](#)

In countries with regulatory approval for PrEP, the availability of the drug may still be restricted by several factors. People may only be able to access PrEP through a demonstration or implementation project. In addition, where there are no national clinical guidelines or policies on PrEP some doctors may feel unable to prescribe it. This forces people who want PrEP to buy it online and leads others to miss out. Even in places where everything is currently in place, the drug may still not be made available for free under a national health system. A study, which charted primary care clinicians' knowledge of, and attitudes towards, PrEP in the USA between 2009 and 2015, found their awareness of PrEP increased from 24% in 2009 to 66% in 2015. Overall, 91% of clinicians indicated a willingness to prescribe PrEP to at least one group at high risk of HIV, with 63% indicating support for public funding of PrEP by the end of the study period.[77](#)

To increase access to PrEP in California USA, a company called Nurx is allowing people to get a prescription for PrEP via a mobile app without having to see a doctor. The information put into this app is reviewed by a doctor remotely who decides whether the treatment is suitable for the person. Before they can receive their prescription, they must also have blood and urine tests.[78](#)



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## Awareness and demand generation

Many people who could benefit from PrEP are still unaware of its existence.

One study surveying awareness and acceptability of PrEP among men who have sex with men in Scotland, Wales, Northern Ireland and the Republic of Ireland found that only one third (34.5%) were aware of PrEP. Men who tested for HIV every six months were most likely to be aware of PrEP.<sup>79</sup>

A US-based study among adolescent men who have sex with men found that only 16% of survey participants were aware of PrEP, also that those who reported more regular conversations about HIV with the parents were more likely to be aware of PrEP. Among those who were aware of PrEP, more meaningful (or higher quality) communication with a parent was associated with adolescents feeling more in control with regard to using PrEP.<sup>80</sup>

Another US-based study among young black men who have sex with men, one of the most vulnerable groups for HIV in the USA, found awareness and uptake of PrEP to be low, echoing the treatment disparities that this group experienced earlier in the HIV response.<sup>81</sup>

Similarly, only 39% of men who have sex with men surveyed in [Thailand](#) said that they would definitely use PrEP. Those participants who perceived themselves to be at higher risk of HIV were more motivated to take PrEP, whereas younger and less educated participants and those engaging in transactional sex were less likely to take it.<sup>82</sup> In the UK, around half of men who have sex with men have shown an interest in taking PrEP.<sup>83</sup>

In contrast, in Latin America demonstration projects and qualitative research finds a high awareness and willingness to use PrEP among men who have sex with men, transgender women and sex workers, especially if PrEP is accessible in the public sector for free or at an affordable price.<sup>84 85</sup>

Findings from in-depth interviews with female sex workers as part of the Treatment And Prevention for Sex workers (TAPS) Demonstration Project in South Africa, looked at people's lived experiences and perceptions of taking up and using PrEP. A lack of trust in the existence and/or effectiveness of PrEP influenced the motivation of women to access PrEP and to keep using it.<sup>86</sup>

It is important to note that people most at risk to HIV may have legitimate concerns about PrEP while

others may be more willing to take it. For example, the Global Forum on MSM & HIV (MSMGF), a network of gay and men who have sex with men sexual health and rights advocates, is campaigning for the immediate implementation of PrEP for men who have sex with men. In contrast, some sex workers have warned how access to PrEP could subject them to greater pressure from clients to agree to condomless sex, increasing their risk of other STIs.[87 88](#)

Partnerships between communities most affected by HIV and those providing PrEP must be in place so those most affected by HIV can help design PrEP programmes in ways that will effectively raise awareness, create demand, and help people adhere to PrEP if they start taking it.[89](#)

However, there are differing views on the best way to do this. On one hand, targeted messaging may be more effective in reaching those who would benefit most from PrEP. On the other, such targeting could inadvertently stigmatise potential users.[90](#)

To address this issue, USAID, PEPFAR and OPTIONS have created a free digital tool called The PrEP Communications Accelerator, which supports national governments, programme implementers, and health practitioners to develop marketing and communications that drive demand for PrEP in sub-Saharan Africa. The tool identifies five target audiences for HIV prevention, all of which are high-risk populations across sub-Saharan Africa: adolescent girls and young women, female sex workers, serodiscordant couples, men who have sex with men, and people who inject drugs. The interactive tool provides a customised communications plan for different combinations of audience and setting.[91](#)

## Adherence

Available evidence suggests that four or more doses per week of PrEP yields protection against HIV acquisition by anal sex, although less than daily dosing may not be effective in preventing transmission for women or people who inject drugs.[92](#)

Understanding the rates at which people are able to adhere to PrEP and addressing the barriers preventing adherence will be crucial to the long-term success of this intervention.[93](#)

One study of three cities in the USA reported very different levels of PrEP adherence among men who have sex with men. In San Francisco, 52% of participants took PrEP daily compared to 35% in Washington DC and just 13.5% in Miami.[94](#)

A further 27% of those from Miami, 18% from Washington and 4% from San Francisco only took two doses a week - offering about 70% protection (compared to over 90% if taken daily). Moreover, 11%, 2% and 4% respectively took just one dose a week, offering very little protection; and 4.5%, 2% and 0% of participants had no detectable tenofovir in their blood. A number of factors were attributed to this difference in adherence levels including knowledge and awareness of PrEP, its availability and the participants' lifestyle.[95](#)

Another factor that can affect adherence is exposure to abuse and violence within a relationship. A study carried out among mixed status couples across Africa found that women who had experienced verbal, physical or economic abuse from a partner were more likely to have low PrEP adherence. The reasons given included stress and forgetting, leaving home without pills, and partners throwing pills away.[96](#)

To address PrEP adherence among high-risk men who have sex with men, an approach that uses

cognitive-behavioural therapy (CBT) has been developed in the USA. The 'Life Steps' intervention consists of a number of CBT modules such as creating a PrEP dosing schedule, adhering to daily PrEP, problem-solving barriers to adherence, and sexual risk-reduction techniques. An assessment of Life Steps found that, when supplemented with short videos on PrEP, it had the potential to increase PrEP adherence for this key population.<sup>97</sup>

## Acceptability

Although there has been significant progress in rolling out PrEP for certain groups in certain contexts such as some groups of men who have sex with men in high-income countries, there are concerns that other groups such as women, [young people and adolescents](#) in high prevalence settings are being left behind.<sup>98</sup>

Two trials, FEM-PrEP study and VOICE (Vaginal and Oral Interventions to Control the Epidemic), have attempted to establish how useful PrEP would be to women living in generalised HIV epidemics in East and Southern Africa. The FEM-PrEP study worked with around 2,120 HIV negative women in Kenya, South Africa and Tanzania between 2009 and 2014. Despite all participants having been identified as being of heightened HIV risk, around half of those enrolled in the study felt they had 'no chance' of acquiring HIV in the next 12 weeks. This meant they were unlikely to initiate or adhere to PrEP despite being given access to it. <sup>99 100</sup>

The VOICE trial tested the effectiveness of daily PrEP in oral form or as a vaginal gel. It took place between 2009 and 2012 in 15 clinics in South Africa, Uganda, and Zimbabwe and enrolled around 5,030 HIV negative women. Participants perceived themselves to be at risk for HIV, however many were not supported by partners to take part in the trial and some felt suspicious and confused about taking medication despite being healthy. Again, the trial was stopped early due low adherence.<sup>101</sup>

In relation to young people and adolescents, there are concerns that this age groups' special stage of development could mean that PrEP could affect them in different ways, for example in terms of side-effects, or they may be more likely than older people to engage in higher-risk sex if using PrEP and less likely to adhere to medication. For this reason, many countries are yet to approve PrEP for under 18s, although the USA did approve its use in May 2018.

A number of trials are underway to establish how effective PrEP would be for use by adolescents in different contexts.<sup>102</sup> This includes PEPFAR's [DREAMS initiative](#) [pdf], which is supporting adolescent girls and young women who are at high risk of HIV to access a range of prevention services including PrEP.<sup>103</sup>

It also includes [PlusPills and UChoose](#), both of which are operating in Cape Town, South Africa. PlusPills is looking into the acceptability and use of PrEP among girls and boys between 15 and 19 years of age, while UChoose is examining PrEP delivery through different contraceptive options among girls aged 16 to 17 years.<sup>104</sup>

The findings of PlusPills were presented in 2017. It found no significant evidence of adverse effects for adolescents taking PrEP, however adherence declined significantly over the 12 month study period.<sup>105</sup>

## Package of services

Because PrEP is only fully effective when it is adhered to exactly as prescribed – and also does not

protect against other STIs – it needs to be delivered as part of a comprehensive package of HIV/STI prevention services based on an individual's circumstances. These might include condoms and lubricant, safer sex counselling, frequent STI check-ups and treatment and regular HIV testing.<sup>106</sup>

A range of models for delivering PrEP have been proposed, including STI clinics, primary care clinics, and community-based organisations with links to clinics.<sup>107 108 109</sup> However, each of these options presents challenges.

For example, while STI clinics serve a population at risk of HIV infection, most operate on a drop-in or urgent care basis and do not provide ongoing care and monitoring. Conversely, primary care clinics are experienced with ongoing care, but need to be able to identify people eligible for PrEP and offer risk reduction and adherence counselling.<sup>110</sup>

## Stigma and discrimination

As with other HIV services, stigma and discrimination have a negative effect on uptake and adherence to PrEP.

In some settings, PrEP is associated with high-risk sexual activity. It also has the stigma of being related to HIV (which may also relate to other stigmas, such as homosexuality, sex work, and/or drug use) and the stigma of PrEP being an alternative to condoms (as condom use is often associated with responsible sexual activity).<sup>111</sup> For these reasons, PrEP uptake may be hindered by fears of being seen as engaging in stigmatised behaviours such as same sex sexual activity or drug use.<sup>112</sup>

In serodiscordant couples its use by one partner may also be rejected for fear it may identify the other as HIV positive. For example, a study in Nigeria used telephone interviews, in-depth interviews, online surveys and focus groups to examine people's views of PrEP. Respondents prioritised HIV serodiscordant couples for PrEP. However, the potential for stigma associated with ARV use was seen as something that would significantly discourage uptake.<sup>113</sup> PrEP-related stigma has also been reported by trial participants at a range of sites among different key affected populations spanning several countries. Authorities may also persecute sex workers for the possession of PrEP pills as evidence of sex work.<sup>114</sup>

A study of around 240 US-based, HIV-negative, men who have sex with men found that participants who recently engaged in transactional sex were more likely to report that anticipated stigma from primary and casual partners would deter them from using PrEP, suggesting that those who face multiple stigmas may need more focused interventions to enable them to access PrEP.<sup>115</sup>

## Regulatory approval and costs

In the USA, PrEP can cost as much as US\$ 1,000 per month. However, generic formulations are available for as little as US\$ 5 per month in low-income countries and US\$ 25 per month by internet purchase from approved suppliers.<sup>116</sup>

Manufacturers of generic pharmaceuticals are filing to produce versions of PrEP that will bring the cost down further.<sup>117</sup>

## The future: next generation PrEP

Research is currently underway to find other ways of providing PrEP so that people do not have to remember to take a daily pill.

These ARV-based HIV prevention tools include the dapivirine vaginal ring. This is a silicone ring that works in a similar way to a contraceptive vaginal ring but instead releases an ARV called dapivirine instead. A number of trials have been conducted so far. The Ring Study and ASPIRE operated between 2012 and 2016 involving around 4,500 women in Malawi, South Africa, Uganda and Zimbabwe. It found the rate of new infections reduced by 56% among those who used it as instructed. Two extension studies, [DREAM](#) and [HOPE](#), began in 2016. Interim results suggest a similar reduction at 54%, with full results expect in 2019.[118](#)

Also being tested, although at an earlier stage in development, is long-acting injectable PrEP. These trials ([HPTN 083](#) and [HPTN 084](#)) are working with a wide range of groups including women in high prevalence African countries, gay men and other men who have sex with men and transgender women.

Results from these trials are due in 2021 or 2022. If successful, injectable PrEP could help address the issue of adherence to a large extent as it would only require people to engage every time they needed an injection, for example every other month, rather than having to remember to take a pill every day.[119](#)

*Photo by Jason/ CC BY-NC-ND 2.0*



### Tools and resources:

For information on PrEP and its availability in Asia and the Pacific visit: [www.prepmap.org](http://www.prepmap.org)

For practical guidance on PrEP implementation across a range of settings, see the following WHO manual: WHO (2017) '[WHO implementation tool for pre-exposure prophylaxis \(PrEP\) of HIV infection](#)'

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