

# Pre-exposure prophylaxis for HIV prevention in Europe

Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia – 2016 progress report

## Dublin Declaration

This ECDC evidence brief summarises key issues and priorities for action in Europe. It draws on country data reported to ECDC for Dublin Declaration monitoring in 2016. In addition, this brief draws on data from a collaborative ECDC and Hornet Gay Social Network rapid survey of a non-representative sample of men who have sex with men in Europe about PrEP use.



Following ECDC's 2010, 2012 and 2014 progress reports, a new series of thematic reports and evidence briefs present the main findings, discuss key issues, and assesses the progress made since 2014 in Europe's response to HIV.

## Key messages

- Pre-exposure prophylaxis (PrEP) can reduce the risk of infections in HIV-seronegative persons at substantial risk, as long as it is taken as prescribed.
- Use of PrEP as an additional prevention option has the potential to reduce HIV transmission and contribute to reversing the increase in new infections in Europe.
- France is the only country in Europe currently providing PrEP through public health services, but a number of other countries are implementing or planning to implement PrEP demonstration projects.
- Use of antiretroviral medication for PrEP has been approved in the European Union, but countries cite the cost of drugs as a key barrier to provision of PrEP by public health services.

## Introduction

Pre-exposure prophylaxis (PrEP) is the use of an antiretroviral medication by people who are uninfected to prevent the acquisition of HIV. The efficacy of PrEP has been shown in a number of randomised controlled trials including iPREX (Pre-exposure Prophylaxis Initiative), Partners PrEP, PROUD and ANRS-IPERGAY (French Research Agency trial) [1-4]. Two of these trials were conducted in Europe – PROUD in the United Kingdom and ANRS-IPERGAY in France.

In 2015, the World Health Organization recommended that PrEP should be offered as an additional prevention option for people at substantial risk of HIV infection based on the results of these trials [5]. Current guidelines recommend that PrEP be made available to populations at high risk of acquiring HIV infection [5,6]. Eligibility criteria may need to be adapted as population groups at high risk of HIV differ between countries in Europe.

PrEP is a rapidly evolving area with new regulations and guidance being developed to reflect new available evidence. In July 2016, the European Medicines Agency recommended granting market authorisation in the European Union for use of the antiretroviral medication Truvada<sup>1</sup> for PrEP, to reduce the risk of sexually-acquired HIV infection in adults at high risk [7]. This recommendation was approved by the European Commission in August 2016. This evidence brief summarises key issues and priorities for action in Europe. It draws on data on PrEP reported to ECDC by 47 countries for Dublin Declaration monitoring in early 2016, and refers to subsequent developments as of August 2016.

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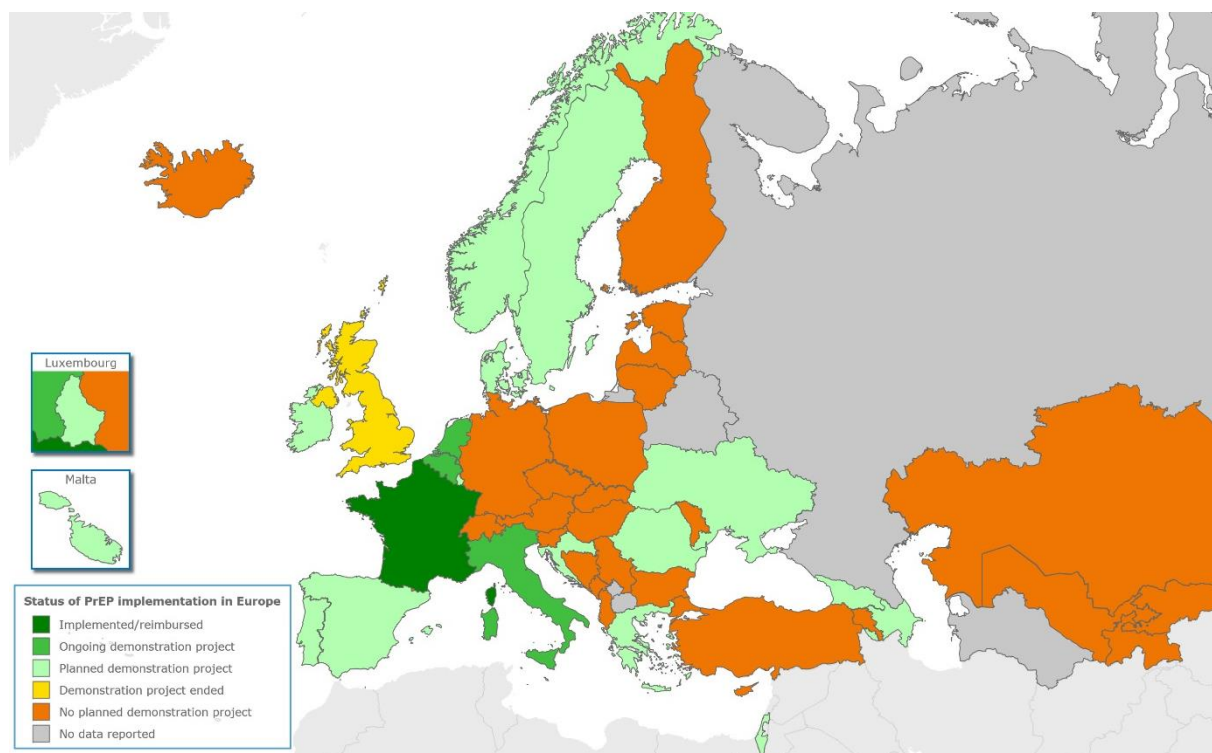
## What is the status of PrEP in Europe?

Only one country provides PrEP through its public health service. In France, the National Agency for Drug Safety has authorised a Recommendation for Temporary Use (RTU) of Truvada for PrEP for three years, which can be renewed for a further three years before a final decision is taken. Under the RTU, which took effect in January 2016, use of Truvada for PrEP is fully covered by the national health insurance system. As of July 2016, 1 077 people were reported to be receiving PrEP through the public health system, with 90 clinics offering PrEP assessment and prescription, and civil society organisations playing an important role in supporting PrEP use. However, the number is likely to be higher as some clinics do not report data.

PrEP demonstration projects are completed in one country and ongoing in three countries. The demonstration project in the United Kingdom, which targeted men who have sex with men at high risk of HIV, has ended, but a decision has yet to be made about how PrEP provision through the public health system will be funded. There are ongoing demonstration projects in Belgium, Italy and the Netherlands, all of which are being implemented in healthcare settings. The target populations are men who have sex with men at high risk of HIV in Belgium, men who have sex with men and transgender people at high risk of HIV in the Netherlands, and sero-discordant heterosexual couples in Italy.

In Europe and Central Asia, PrEP demonstration projects are planned in a further 15 countries. These countries are Azerbaijan, Croatia, Denmark, Georgia, Greece, Ireland, Israel, Luxembourg, Malta, Norway, Romania, Portugal, Spain, Sweden and Ukraine. Most of these planned demonstration projects will target men who have sex with men who are at high risk of HIV, and will be implemented in healthcare settings. Denmark is planning demonstration project implementation in a community setting and Ireland is planning one through a joint healthcare and community setting partnership. Ireland, Romania and Ukraine report that national policy and clinical guidelines for PrEP are under development.

**Figure 1. Status of PrEP implementation in Europe and Central Asia as of August 2016**



**Relatively few countries have initiatives to educate stakeholders about the use of PrEP for HIV prevention.** Most of these countries (Table 1) are implementing or planning demonstration projects. A number of additional countries report that initiatives to educate different stakeholders are planned.

**Table 1. Countries reporting that initiatives are underway to educate stakeholders about PrEP**

Stakeholder	Number of countries
Policy makers	8
Health ministries	7
Physicians	8
Public health professionals	8
HIV prevention programmes	9
Potential PrEP users	8

**There is little data on off-licence use of PrEP.** Most countries (37) report that they have no survey-based information on off-licence use of antiretroviral medication for PrEP. In Italy, a survey of 1 405 people living with HIV performed at 32 HIV centres in early 2014, found that 1% had shared their treatment with friends or partners as PrEP, and 9% reported PrEP use in their immediate circle. In Switzerland, the 2014 GaySurvey found that 1.5% of surveyed men who have sex with men reported having used PrEP; of these, the majority had been prescribed PrEP off-licence by their doctor and none reported having bought it on the internet.

But there is anecdotal evidence that people at high risk of HIV infection are being prescribed Truvada for PrEP or are purchasing it online. Ten countries – Austria, Belgium, Croatia, the Czech Republic, Germany, Ireland, Malta, the Netherlands, Romania and the United Kingdom – reported that there is anecdotal information about online purchase or doctors prescribing Truvada for PrEP, or individuals seeking post-exposure prophylaxis (PEP) but using the medicines for PrEP. This information is consistent with the findings of a recent survey about PrEP use among men who have sex with men, and a survey of informal PrEP use conducted in France in 2014 [8] among users of the services of the community organisation AIDES. This found that 4.6% of 2 668 people reported informal PrEP use, of whom 74% were men who have sex with men.

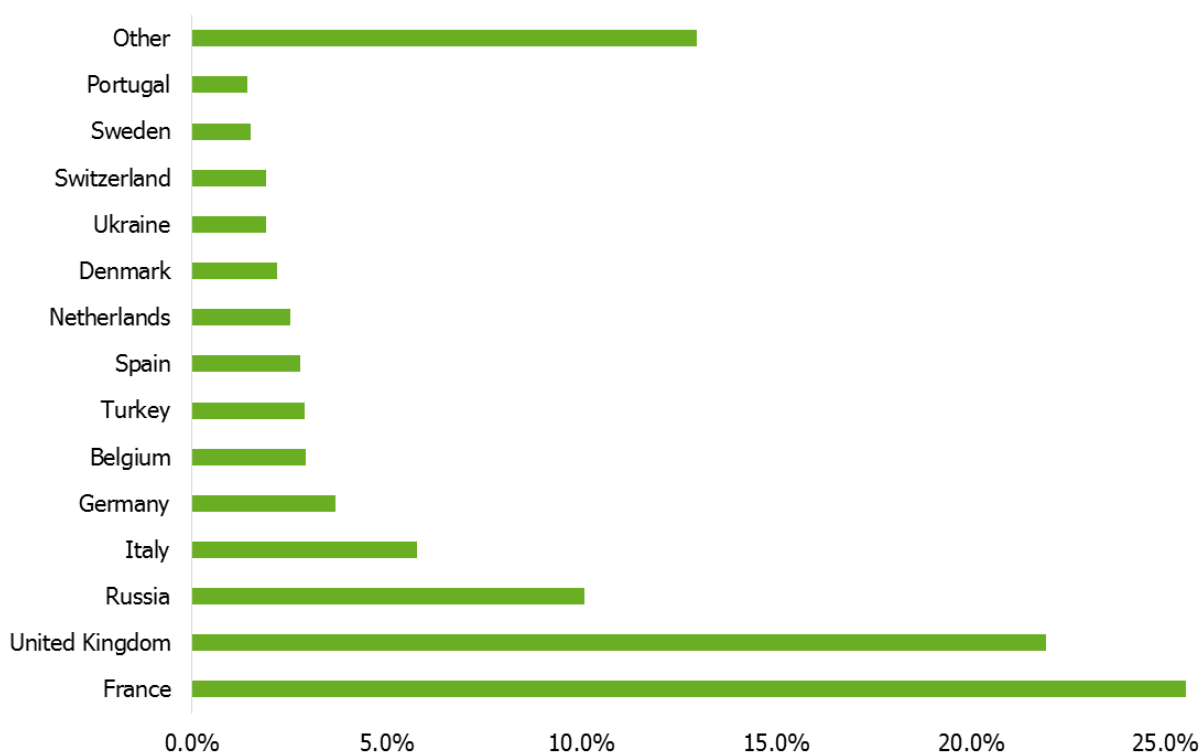
**There are some concerns about informal use of PrEP.** Concerns highlighted by countries include how to promote adherence and provide follow-up care, as well as how to ensure that people are purchasing genuine drugs and reduce the risks associated with stock outs of drugs. The United Kingdom has developed advice on clinical monitoring and PROUD clinics are providing clinical support to individuals who are buying PrEP online.

## PrEP use among men who have sex with men in Europe

In April 2016, ECDC collaborated with the Hornet Gay Social Network on a rapid survey of a non-representative sample of men who have sex with men in Europe about PrEP use. The objective was to collect information about current use of PrEP and intentions to use PrEP in future.

Over three days, 8 543 people responded to the survey (Figure 2); the high proportions of responses from France, the United Kingdom and Russia to some extent, reflect the reach of Hornet in these countries. Among the 8 048 respondents who did not report being HIV positive, 793 or 10% reported that they are currently taking PrEP.

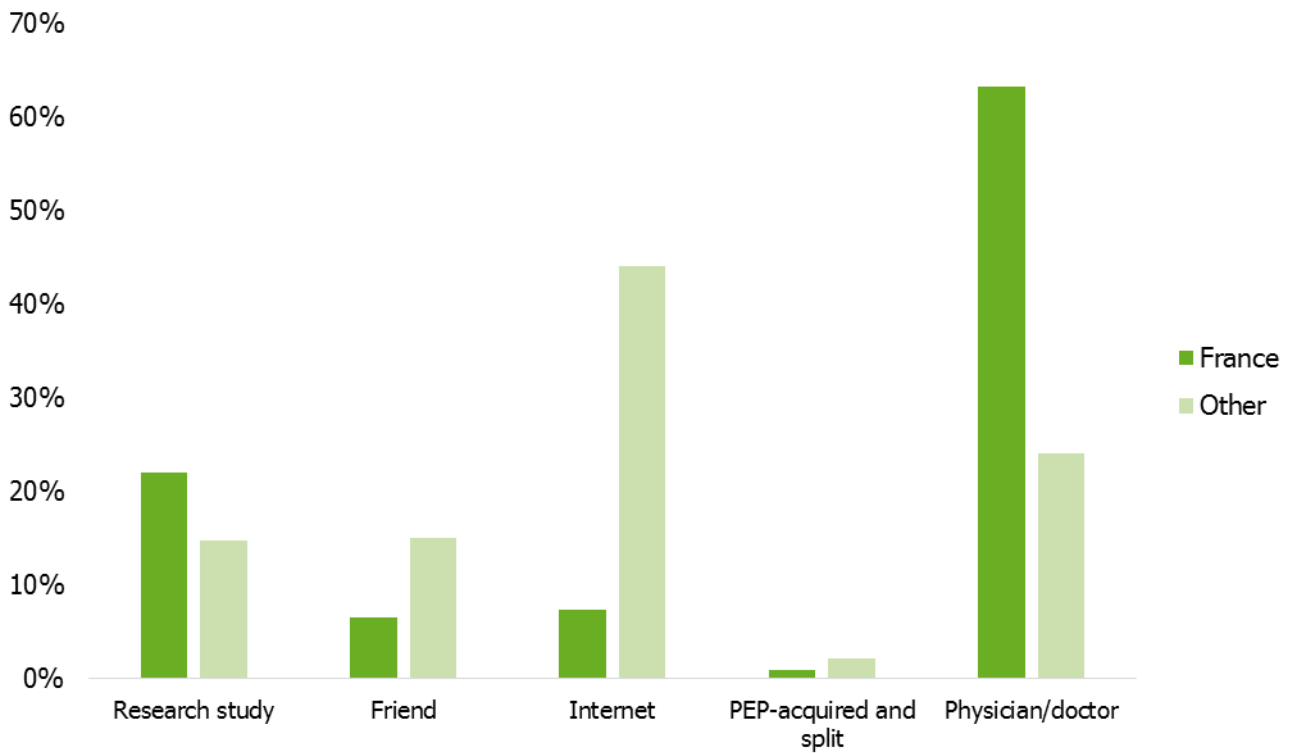
**Figure 2. Percentage of respondents to PrEP survey by country (N=8 543)**



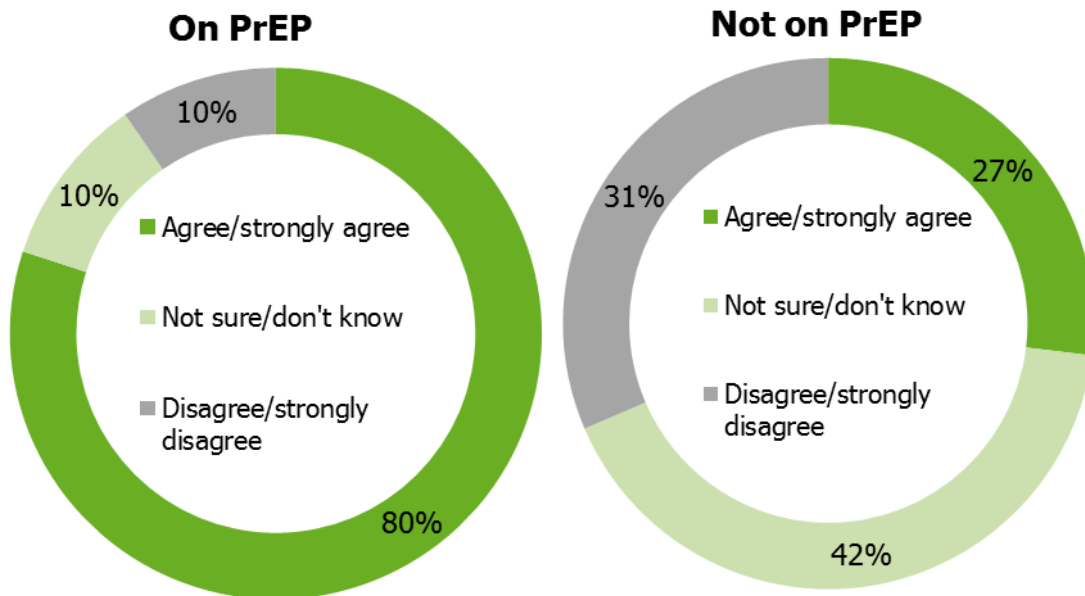
Data source: Hornet (<https://hornetapp.com/>)

Those currently taking PrEP obtain it from a range of sources (Figure 3). Most respondents from France had acquired PrEP through their doctor. Among those outside France who are currently taking PrEP, the main source was the Internet, followed by a doctor’s prescription or a research study. Of those taking PrEP, 69% said their healthcare provider was aware of this. Approximately one in four of those not currently on PrEP agreed with the statement that they were likely to use PrEP in the next six months (Figure 4). It is important to note that, as the survey was based on a convenience sample, the results cannot be generalised.

**Figure 3. Where do men who have sex with men acquire PrEP? (N=529)**



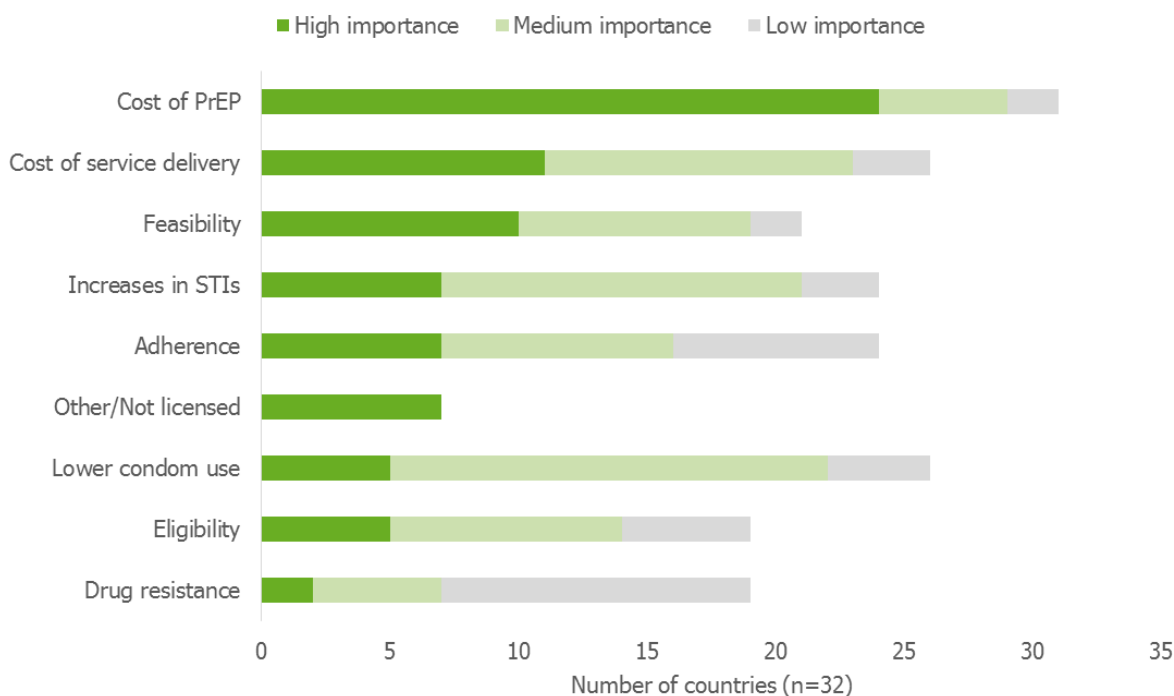
**Figure 4. To what extent do you agree with the following statement 'I am very likely to use PrEP in the next 6 months?' (N=7 159)**



## What are the main barriers to PrEP implementation in Europe?

**Cost of drugs, cost of service delivery and feasibility are the main obstacles to PrEP implementation.** Thirty-one countries identified the cost of drugs as an issue preventing or limiting PrEP implementation, and 24 of these countries rated the issue of high importance. In addition, 23 countries identified the cost of service delivery as an issue of high or medium importance, and 19 countries identified feasibility as an issue of high or medium importance. Countries also have concerns about the impact of PrEP on transmission of other sexually-transmitted infections, on condom use, eligibility criteria, adherence and compliance (Figure 5).

**Figure 5. Issues preventing or limiting PrEP implementation in Europe**



## What needs to be done?

There is a clear need to improve the effectiveness of HIV prevention for key populations in the region, in particular for men who have sex with men, transgender people and others at high risk of sexually-acquired HIV infection. Men who have sex with men are the only population in the EU/EEA where the number of new HIV infections continues to increase and, in 2014, sex between men accounted for 42% of all newly-diagnosed cases of HIV [9]. The use of PrEP as an additional prevention option within a combination prevention approach would provide an opportunity to reduce transmission of the virus, and could reverse the increase in new infections among this and other populations who are most at risk.

Although many countries in Europe are starting to consider PrEP as an additional prevention option, some do not currently have any plans for PrEP. This may change following the recommendation from the European Medicines Agency [7] and approval by the European Commission, but a recent ECDC expert meeting on considerations for PrEP implementation in Europe [10], and data reported to ECDC by countries for Dublin Declaration monitoring, suggest that there are a number of obstacles other than licensing that may limit PrEP implementation in the region.

### Options for action include:

- Developing better data on the populations and the number of people who could benefit from PrEP and establish clear eligibility criteria to maximise feasibility and public health benefit.
- Evaluating demonstration projects and implementation to identify optimal options for service delivery in a range of health system settings in Europe.
- Sharing experience and effective approaches to planning and implementation of PrEP and to address the main barriers to PrEP implementation.
- Strengthening monitoring of formal and informal PrEP use.
- Strengthening monitoring of PrEP impact on new HIV and STI infections.

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