



Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia

Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia – 2018/19 progress report

November 2019

Dublin Declaration

This evidence brief summarises key issues and priorities for action in Europe and Central Asia on PrEP. It is largely based on data collected in 2018 and 2019 by the European Centre for Disease Prevention and Control (ECDC) to monitor implementation of the 2004 Dublin Declaration. The monitoring questionnaire was



disseminated to the 53 countries that are part of the WHO European Region, plus Kosovo¹ and Liechtenstein via an online survey.

Key messages

- PrEP (pre-exposure prophylaxis) is very effective at preventing HIV acquisition when taken as prescribed. It is an essential element in the 'combination prevention' necessary to reach the Sustainable Development Goal of ending the AIDS epidemic by 2030.
- Since 2016, there has been an increase in the number of countries in the WHO European Region implementing PrEP, either as part of national healthcare provision or in demonstration projects.
- There is evidence of considerable 'informal' use of PrEP by people who access it online or by other means. Not all of them inform their sexual health specialists, which means that they may not be properly monitored and run the risk of possible implications for their health.
- Given the current levels of risk for HIV acquisition, improved access to PrEP and greater progress in its implementation can have a positive impact on HIV incidence, especially in the Centre and East sub-regions of Europe where implementation is very low.
- Improved data collection and surveillance on PrEP uptake and outcomes and the sharing of best practices (particularly regarding feasibility, cost and technical matters) is needed to support the roll-out of PrEP in the Region.

Introduction

The international community has committed to the Sustainable Development Goal (SDG) target of ending the AIDS epidemic by 2030. Pre-exposure prophylaxis (PrEP) is the use of an antiretroviral medication by people who are uninfected to prevent their acquisition of HIV. The efficacy of PrEP is well-documented [1] [2] [3] With the publication of the PROUD [2] and Ipergay [3] studies in 2015, ECDC encouraged EU Member States to give consideration to integrating PrEP into their existing HIV prevention package for those most at-risk of HIV infection [4]. In 2015, based on the results of trials, the World Health Organization (WHO) recommended that PrEP should be offered as an additional prevention option for people at substantial risk of HIV infection [5].

To achieve the SDGs, UNAIDS has recommended as one of its global targets that three million people should be on PrEP by 2020, with a focus on key populations and people at high risk in high prevalence settings [6]. UNAIDS also recommends outreach and new media are disseminating information widely in an effort to create demand for PrEP alongside other prevention technologies. PrEP is seen as an essential element in combination prevention.

Suggested citation: European Centre for Disease Prevention and Control. Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia – 2018/19 progress report. Stockholm: ECDC; 2019.

This report was coordinated by Teymur Noori and Anastasia Pharris. ECDC would like to thank Rosalie Hayes, Yusef Azad, Cheryl Gowar, Alison Brown and Valerie Delpech for their support in the production of the report.

¹ This designation is without prejudice to positions on status and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence

In July 2016, the European Medicines Agency recommended granting market authorisation in the European Union for use of the antiretroviral medication Truvada² for PrEP, to reduce the risk of sexually-acquired HIV infection in adults at high risk. This recommendation was approved by the European Commission in August 2016.

That same year ECDC published the first Evidence Brief on 'Pre-exposure prophylaxis for HIV prevention in Europe', drawing on data from the Dublin Declaration monitoring process in 2016 [7]. However, the situation with regard to PrEP implementation in Europe is fast-moving. Ongoing developments include increasing civil society activism and greater access of national health systems to generic PrEP (emtricitabine and tenofovir). This Evidence Brief draws on data from 2018 and 2019 to provide an updated picture of PrEP implementation in the European Region.

Additional data sources

To ensure that the most up-to-date data are used in what is a rapidly changing environment as regards PrEP implementation in Europe, data from the 2018 round of Dublin Declaration monitoring have been supplemented from a variety of other sources. Use has been made of data from a shorter 2019 survey undertaken for Dublin Declaration monitoring which also included questions on PrEP. Findings are also included from a collaborative ECDC and Hornet Gay Social Network rapid survey of a non-representative sample of 12 053 HIV-negative gay men in Europe asked about PrEP use in 2017 [8]. Data were also included from the European Men-Who-Have-Sex-With-Men Internet Survey (EMIS-2017), which involved around 127 000 MSM respondents from 47 of the 55 countries in Europe and Central Asia and was conducted between October 2017 and January 2018 [9].

Availability of PrEP in Europe and Central Asia

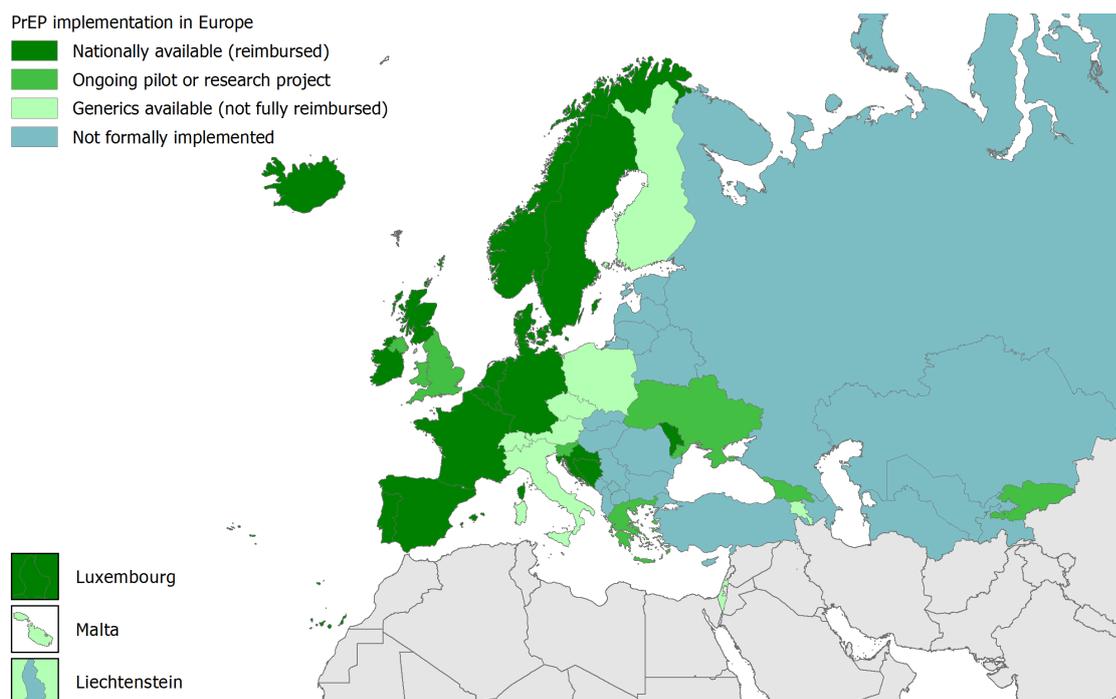
The availability of PrEP in Europe is fragmented, complex and in flux. Figure 1 provides information on where PrEP is made available within a country's health system. It does not take account of online PrEP access, usually of generic PrEP from abroad. Nor does it take account of access to PrEP through private healthcare, usually available at relatively costly patent prices. The three categories of availability are, nationally available (reimbursed), part of an ongoing pilot or research project (also reimbursed), and as generics available in healthcare settings but not reimbursed.

Data collected via Dublin Declaration monitoring provide a snapshot of a rapidly-changing situation as regards state PrEP provision, with substantial diversity across the Region. However, results show that progress has been made since 2016, when only France reported that PrEP was nationally available and reimbursed [7]. By 2019, 16 out of 53 reporting countries reported reimbursed PrEP within their national health service, either through insurance or from the public sector (Belgium, Bosnia and Herzegovina, Croatia, Denmark, France, Germany, Iceland, Ireland, Luxembourg, Moldova, the Netherlands, Norway, Portugal, Spain, Sweden, and Scotland within the United Kingdom).

Nine countries report that generic PrEP is available in healthcare settings, but it is not fully reimbursed (Armenia, Austria, the Czech Republic, Finland, Israel, Italy, Malta, Poland and Switzerland).

Five countries report PrEP availability only through pilot, research or demonstration projects at national or sub-national level (Georgia, Greece, Slovenia, Ukraine, and England, Northern Ireland and Wales within the United Kingdom). It is important to note that the degree of access to PrEP in such projects varies considerably. For example, the United Kingdom saw 6 000 people access PrEP in the 12 months prior to reporting in 2019, while Ukraine saw 125 people access PrEP in the same period.

² Any mention of commercial product or service within ECDC publications is for information only. It should not be displayed in a manner which suggests endorsement by ECDC. For more information see <http://ecdc.europa.eu/en/pages/legalnotice.aspx>

Figure 1. Status of PrEP implementation in Europe and Central Asia, November 2019

In-country geographical variation in access to PrEP

Similar variation is experienced in-country across the Region, reported by 11 countries (Austria, Croatia, the Czech Republic, Estonia, Finland, Germany, Ireland, Poland, Spain, Sweden and the United Kingdom). In Croatia and the Netherlands, PrEP is only available in one city. Spain and Sweden stated that availability depended on the region/county, while in the United Kingdom there are differences in the degree of access across the four constituent nations – although available to all who need it in Scotland, Wales and Northern Ireland, PrEP availability is currently limited in England as there is a cap on the numbers who can access the PrEP IMPACT implementation trial.

Developing and implementing guidelines on PrEP

In 2019, 21 countries stated that PrEP guidelines had been developed or are being implemented³; five countries stated that PrEP guidelines had been developed but are not yet being implemented⁴ and 21 countries stated that no PrEP guidelines had been developed as yet⁵.

Settings for the provision of PrEP

Countries were asked about the settings in which PrEP is available (see Figure 2). The most common setting for PrEP provision is the public infectious disease clinic, cited by 18 countries⁶. The other most frequently reported setting is a research setting, including pilots or demonstration projects – cited by 15 countries.⁷ Twelve countries mentioned private providers⁸ and twelve countries mentioned the internet⁹. There was less provision in primary care (Kyrgyzstan, the Netherlands and Sweden) and in public sexual health clinics (France, the Netherlands and Sweden). No provision was reported for Drug Treatment Centres.

³ Armenia, Belgium, Croatia, Czech Republic, France, Georgia, Germany, Israel, Italy, Kyrgyzstan, Luxembourg, Moldova, Monaco, the Netherlands, Norway, Poland, Slovenia, Sweden, Switzerland, Ukraine and Uzbekistan.

⁴ Austria, Denmark, Finland, Ireland, and Spain.

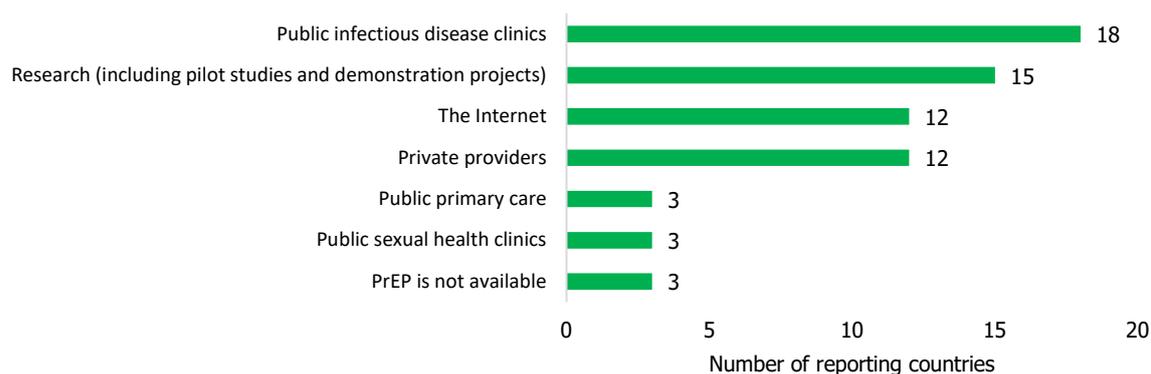
⁵ Albania, Azerbaijan, Belarus, Bosnia & Herzegovina, Bulgaria, Cyprus, Estonia, Greece, Hungary, Iceland, Kazakhstan, Latvia, Liechtenstein, Lithuania, Montenegro, Romania, Russia, Serbia, Slovakia, Tajikistan and the United Kingdom.

⁶ Albania, Belgium, Croatia, Czech Republic, Denmark, Estonia, France, Hungary, Israel, Kyrgyzstan, Liechtenstein, Luxembourg, Moldova, Monaco, Norway, Poland, Slovakia and Sweden.

⁷ Austria, Denmark, France, Georgia, Germany, Ireland, Italy, the Netherlands, Russia, Slovenia, Spain, Switzerland, Tajikistan, Ukraine and the United Kingdom.

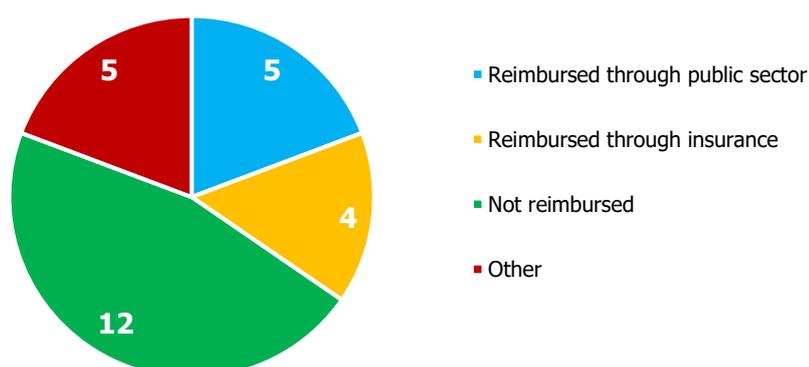
⁸ Austria, Finland, France, Germany, Hungary, Italy, Poland, Russia, Serbia, Spain, Switzerland and the United Kingdom

⁹ Cyprus, Denmark, Greece, Ireland, Israel, Italy, Luxembourg, Poland, Slovenia, Spain, Switzerland and the United Kingdom

Figure 2. Settings for the provision of PrEP in Europe and Central Asia (n=31), March 2019

How is PrEP paid for?

Twenty-six countries responded to the question as to whether and how PrEP is reimbursed (Figure 3). Twelve countries said that PrEP was not reimbursed. Four countries stated that it was reimbursed through insurance (Croatia, France, Germany and Israel) and five said it was reimbursed through the public sector (Belgium, Luxembourg, the Netherlands, Norway and Sweden). Five countries reported 'Other', explaining that access was via a research project (Slovenia and the United Kingdom) or via external donors (Kyrgyzstan, Georgia, Ukraine).

Figure 3. How PrEP is paid for in the countries of Europe and Central Asia (n=24), as of March 2019

Uptake of PrEP in Europe and Central Asia

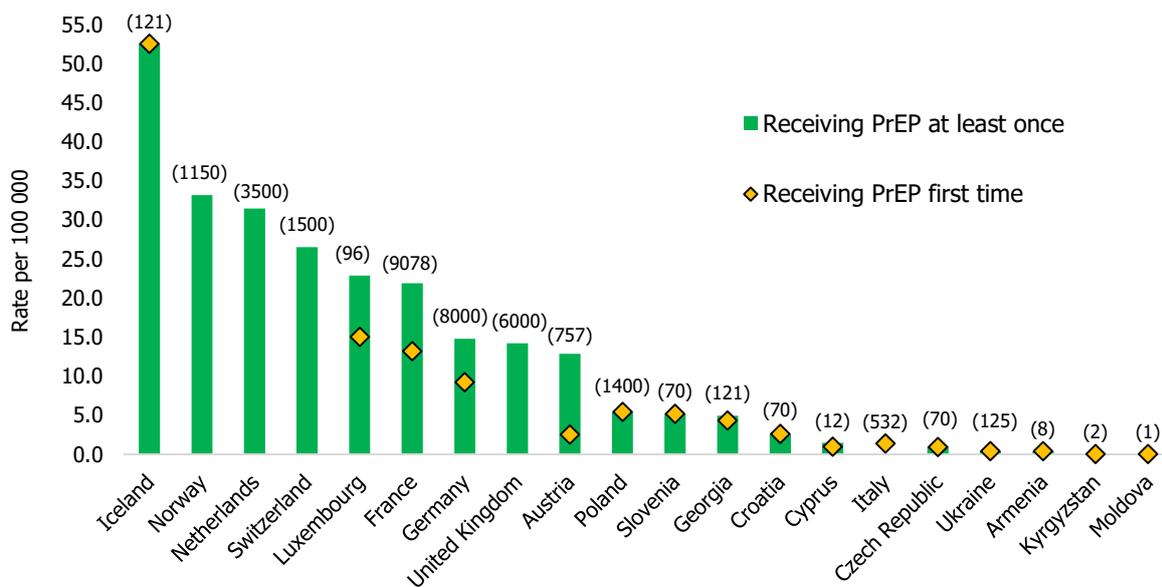
Twenty countries were able to report numbers receiving PrEP for the first time in the last 12 months and/or numbers receiving PrEP at least once in the last 12 months. Italy, Norway, the Netherlands, Switzerland and the United Kingdom were only able to report one of these indicators.

Ireland, Israel, Belgium, Denmark, Portugal, Spain and Sweden reported PrEP provision in their country but were unable to provide any data on numbers receiving PrEP.

Fifteen of the 20 countries provided data disaggregated by gender and probable transmission route, with 12 reporting that over 90% of PrEP users are MSM. The exceptions were Armenia, Kyrgyzstan and Moldova where reported PrEP users were exclusively female. Numbers reported for demographics other than MSM were in single figures.

The number and rate of people using PrEP at least once varied substantially between countries and ranged from one PrEP user (Moldova) to 9 078 PrEP users (France) and a rate of 0.04–52.5 per 100 000 adult population (aged 15–64 years). In most countries for which data were provided, the majority of PrEP users had received PrEP for the first time in the last 12 months.

Figure 4. Number of people receiving PrEP in Europe and Central Asia (n=20), reported in 2019¹⁰

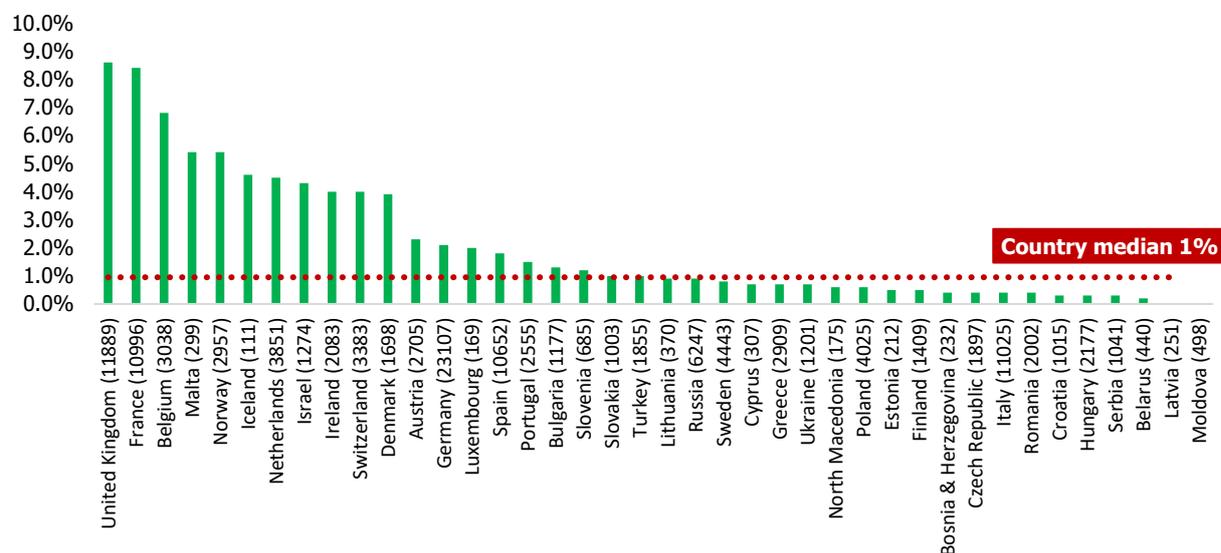


PrEP use among men who have sex with men (MSM) in Europe

Prevalence of PrEP use amongst MSM

In EMIS-2017, the percentage of respondents currently taking PrEP ranged across countries from 0% to 8.6%. Among the 40 countries included in Figure 5, the median proportion of non-HIV-diagnosed respondents currently taking PrEP daily or on demand is 1%.

Figure 5. Proportion of non-HIV diagnosed EMIS respondents currently taking PrEP daily or on demand in EMIS reporting countries (n=112 939), EMIS-2017



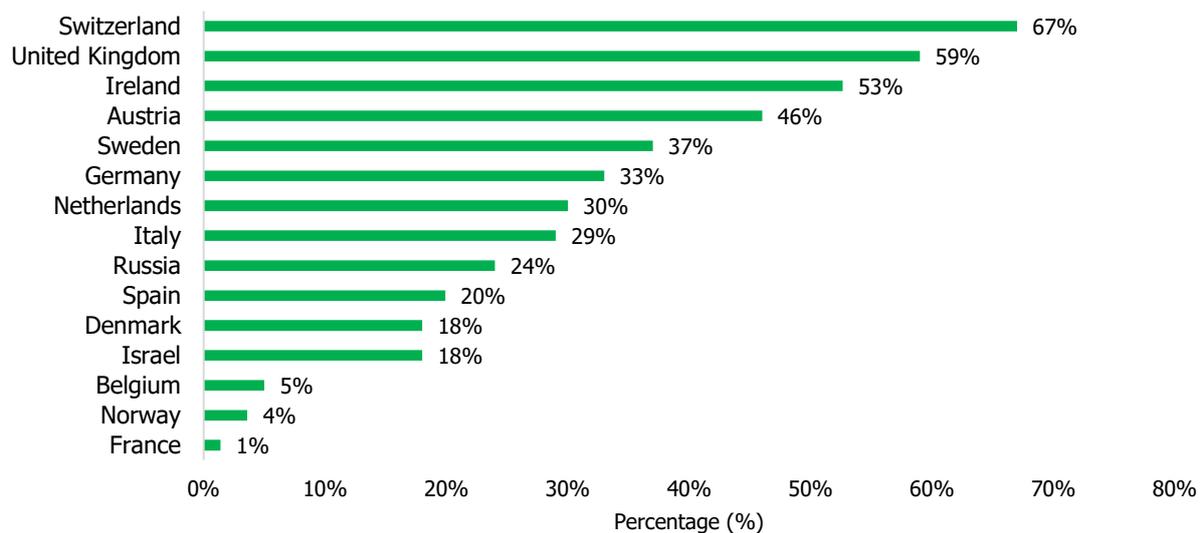
Source: EMIS-2017 [9].

¹⁰ Data labels describe actual numbers using PrEP at least once in the last 12 months. Italy was unable to provide an estimate for the number of people receiving PrEP at least once in the last 12 months, so the data label describes numbers using PrEP for the first time in the last 12 months.

'Informal'/online PrEP access

EMIS-2017 data show substantial variation between countries in online use of PrEP (Figure 6), including in countries with very similar overall rates of PrEP use (see Figure 5). The United Kingdom, with 8.6% PrEP use, has 59% of respondents using online PrEP whereas France, with very similar PrEP uptake at 8.4%, has only 1% of that number accessing their PrEP online. This can be explained by variation in whether and how PrEP is accessed in different countries. France was the first European country to make PrEP nationally available and reimbursed in their health system. In England (which accounts for 84% of the UK population), other than online, PrEP can only be accessed via an ongoing trial with a cap on numbers.

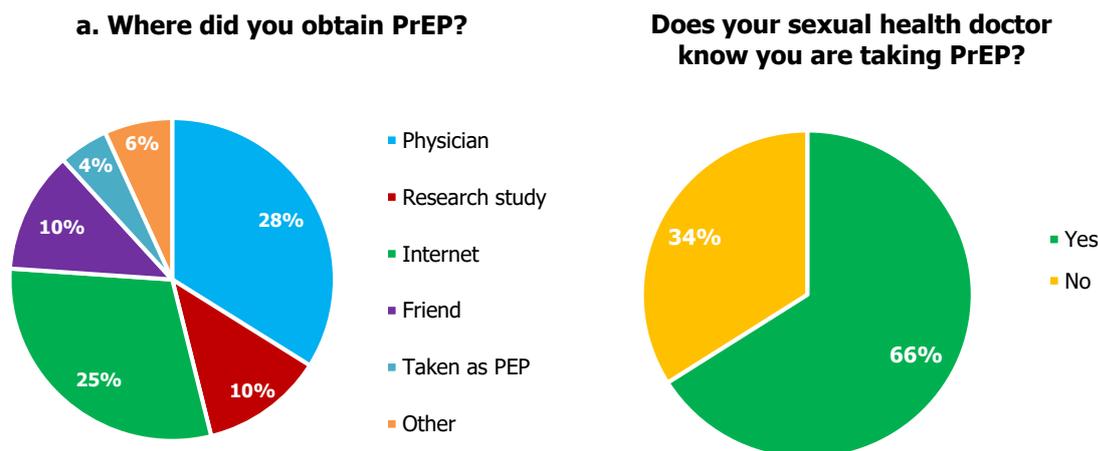
Figure 6. Percentage of those who have ever taken PrEP who accessed it online in EMIS-2017 countries (n=112 939), EMIS-2017



Source: EMIS-2017 [9].

In the Hornet survey, nearly half of men (47%) were accessing PrEP informally (i.e. not via a clinician prescribing in healthcare or research settings) – 24.8% reported that they accessed PrEP via the internet and 10.1% from a friend (see Figure 6a). A third had not disclosed their PrEP use to their sexual health physician/doctor (Figure 6b). The lack of disclosure of PrEP use to clinicians is a concern. For example, it is important that someone taking PrEP is tested appropriately to ensure they are not already living with HIV since there would then be a risk of developing drug resistance. The need for renal function and bone density monitoring should also be considered for certain patients, along with testing for hepatitis B (there are risks in stopping PrEP for those with chronic HBV), as well as regular screening for sexually transmitted infections (STI).

Figure 7. Sources of PrEP access and degree of informal access according to respondents to Hornet-ECDC survey, 2017



Source: Bourne, A. et al. 2019 [8].

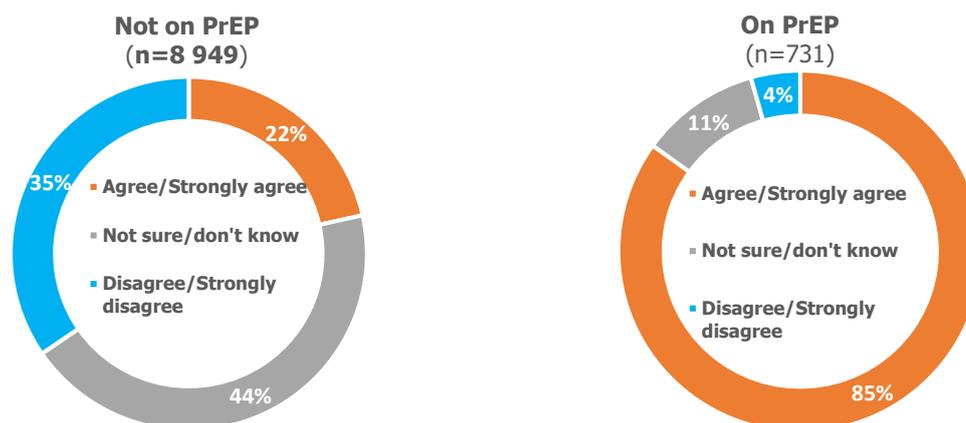
PrEP use and HIV risk among MSM

PrEP use in the Hornet survey was highest among those diagnosed with an STI, those who had accessed post-exposure prophylaxis (PEP) in the previous 12 months and those who had engaged in chemsex¹¹ over the previous three months. This suggests that the MSM taking PrEP are ideal candidates to do so.

Likelihood of future PrEP use

Respondents to the Hornet survey were asked 'To what extent do you agree with the statement: I am very likely to use PrEP in the next 6 months?' Overall, 33.2% of men agreed or strongly agreed that they were likely to use PrEP in the next six months. Of those men not currently using PrEP, 21.5% agreed or strongly agreed that they were likely to use PrEP in the next six months. Of those who were currently using PrEP, 85% agreed or strongly agreed that they were likely to use PrEP in the next six months. This suggests high levels of acceptability among those currently using PrEP, but also the probability of a further increase in usage.

Figure 8. Percentage of respondents to Hornet survey agreeing with the statement 'I am very likely to use PrEP in the next 6 months' - 2017



Source: Bourne, A. et al. 2019 [8].

¹¹ Defined within the study as 'the use of mephedrone, gamma hydroxybutyrate/gamma butyrolactone, ketamine or crystal methamphetamine during sex with men (otherwise known as 'chemsex') within the previous three months'.

Improving access to PrEP

Educating stakeholders on PrEP

In 2018, countries were asked about any initiatives underway to educate key stakeholders on the use of PrEP as an effective prevention intervention. The findings are summarised in Table 1.

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

Stakeholder	Countries in 2016	Countries in 2018
Policy makers	8	12
Health ministries	7	11
Physicians	8	13
Public health professionals	8	13
HIV prevention programmes	9	17
Potential PrEP users	8	17

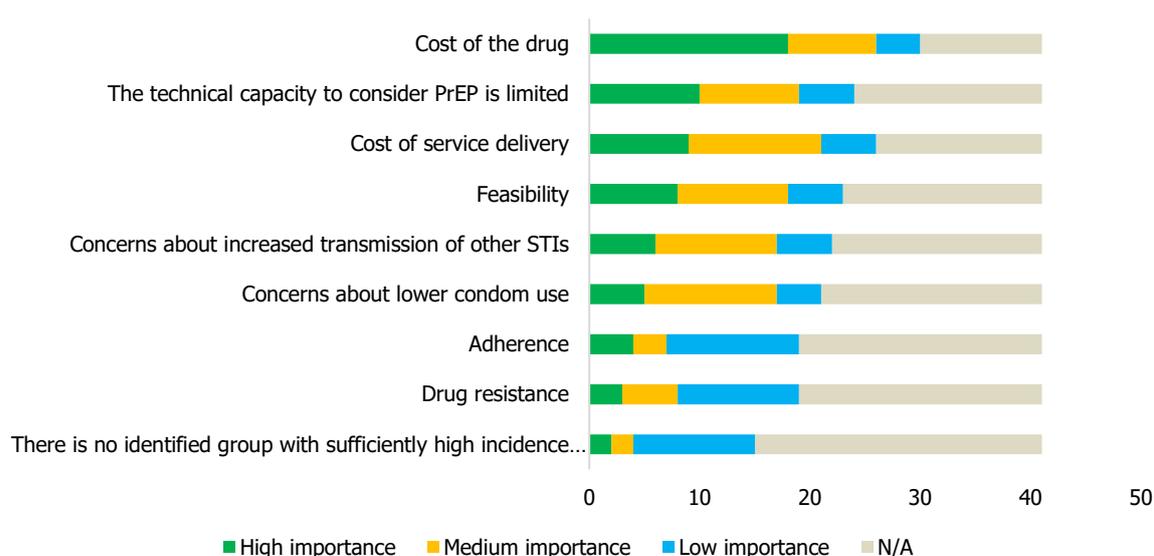
Across every stakeholder group, there has been an increase in the number of countries undertaking educational initiatives concerning PrEP compared to 2016. Unsurprisingly, these different responses were all variations on the same core set of countries which had clearly decided to undertake PrEP education for a range of stakeholders. The majority of these countries were in the West sub-region, but there were some in the Central sub-region (Albania, Czech Republic, Poland) and some in the East sub-region (Georgia, Kyrgyzstan, Ukraine).

Barriers to PrEP implementation

The most commonly cited barrier to implementation of PrEP in Europe was the cost of the drug, with 30 countries mentioning this and 18 of them stating it was of high importance (in 2016, the figures were 31 countries identified it as an issue and 24 saying it was of high importance). Twenty-one countries mentioned the cost of service delivery, with nine rating it of high importance and 12 of medium importance. Technical capacity was the third most commonly-mentioned barrier, with 24 countries mentioning this, ten rating it as of high importance and nine of medium importance. The full response is summarised in Figure 9.

Overall, between 2016 and 2018 there have been only modest changes in the issues limiting implementation of PrEP. The barriers most commonly cited and highlighted as being of greater importance are those relating to cost and service delivery rather than concerns about the impact on sexual behaviour and epidemiology. Nevertheless, concerns about condom use, drug resistance, adherence and STIs are all mentioned by some countries.

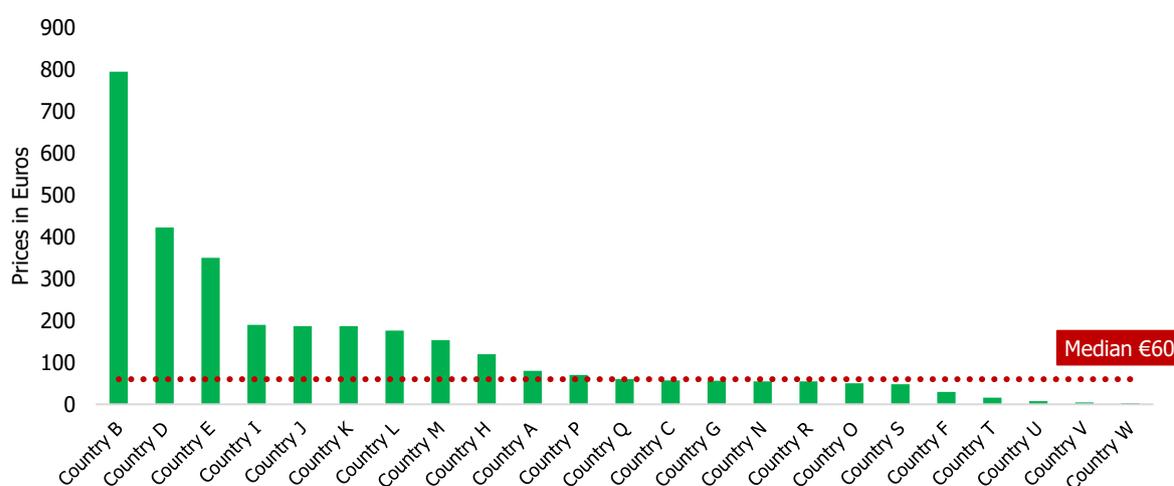
Figure 9. Issues preventing or limiting PrEP implementation in Europe, 2018



As highlighted above, the cost of the drug is frequently cited by governments as a barrier to implementing PrEP. Countries were asked to provide the cost of a monthly supply of PrEP if purchased by their government.

Responses ranged from EUR 3.25 to EUR 795.45, with a median cost of EUR 60 per month (Figure 10). In some countries, only branded PrEP could be purchased as a patent still exists. In others, PrEP is procured via the Global Fund, which reduces the cost dramatically.

Figure 10. The cost of 28–30 tablets of PrEP (one month's supply) purchased by governments, Europe and Central Asia (n=23), reported in April 2019¹²



Conclusions

While provision of PrEP is rapidly increasing, these findings contribute to our understanding of PrEP implementation and use in Europe and Central Asia. Although significant progress has been made since 2016, with 16 countries now providing and reimbursing PrEP within their national health system, PrEP implementation remains variable across the Region.

PrEP is still mainly provided in medicalised settings, with public infectious disease clinics being the most common setting for provision. Since research indicates that this may create barriers to access for target groups [10], countries should explore how PrEP could be provided in community-based organisations which are already serving those who are most at risk of acquiring HIV.

The increase in the availability of reimbursed PrEP, either through the public sector or insurance, across Europe and Central Asia is a positive development. The proliferation of generic PrEP available through healthcare settings may also contribute to increasing accessibility. However, cost will inevitably restrict accessibility in the countries which do not reimburse PrEP or where it is not provided.

Variation in whether and how PrEP is provided also has an impact on the level of use of PrEP purchased online. Informal use of PrEP, obtained either via the internet or from friends, can carry risks if it is not accompanied by appropriate monitoring. Countries should ensure that people accessing PrEP informally are able to access PrEP monitoring services, including renal and bone monitoring for certain patients, testing for hepatitis B and regular STI screening.

Research indicates a positive correlation between the willingness of MSM to use PrEP and an increased risk of acquiring HIV sexually [8]. Recent analysis of the 'PrEP gap' estimates that there are around 500 000 men who have sex with men in the European Union who would be very likely to use PrEP but are currently unable to access it [11]. This figure would probably be much larger if eastern European and Central Asian countries were included. In order to accelerate progress toward SDG 3.3, ending the AIDS epidemic by 2030, much wider-scale implementation of PrEP across Europe and Central Asia will be required.

To facilitate this, minimum standards for the principles of PrEP programming, monitoring and surveillance would be beneficial. ECDC is currently drafting an expert opinion to develop such standards, which are expected to be launched in 2020.

¹² Country names are anonymised due to the sensitive nature of this information.

Options for action

- Further progress in PrEP implementation can have a positive impact on HIV incidence, especially in countries in the Centre and East sub-regions of Europe and Central Asia.
- Knowledge and experience from the various pilots, research and demonstration projects across Europe should be shared in the Region as promptly as possible, to help support effective national implementation.
- There should be a particular focus on sharing experience concerning the feasibility of implementation, costs and technical capacity.
- Opportunities to collaborate with community-based organisations as settings for the provision of PrEP should be explored.
- The extent of informal online access to PrEP and the relevant health outcomes should be monitored.
- Surveillance systems should consider capturing data on PrEP eligibility, uptake, duration of PrEP and outcomes. Consistent data collection across the Region should be encouraged.

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