

## ECDC EVIDENCE BRIEF

### 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 – 2020/2021 progress report

July 2022

#### 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 between March and September 2021 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 Kosovo<sup>1</sup> and Liechtenstein via an online survey.

#### Key messages

- When taken as prescribed, PrEP (pre-exposure prophylaxis) is very effective at preventing HIV-negative people from acquiring HIV. It is an essential element in the 'combination prevention' necessary to reach the United Nations (UN) Sustainable Development Goal of ending the AIDS epidemic by 2030.
- Since 2018/2019, there has been an increase in the number of countries in the World Health Organization (WHO) European Region implementing PrEP, either as part of national healthcare provision or in implementation studies.
- Greater access to PrEP and progress in PrEP implementation are needed to reach the Sustainable Development Goal of ending the AIDS epidemic by 2030.
- Certain key populations, such as people who inject drugs, prisoners and undocumented migrants, remain ineligible for PrEP in many countries in the European Region
- Improved data collection and surveillance on PrEP uptake are vital for obtaining a proper understanding of who has access PrEP. In addition, best practices need to be shared, especially those relating to feasibility, cost and technical matters, in order 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 HIV/AIDS epidemic by 2030. Pre-exposure prophylaxis (PrEP) is the use of an antiretroviral medication by people who are HIV-negative to prevent their acquisition of HIV. The efficacy of PrEP is well-documented [1,2,3]. With the publication of the PROUD [3] and Ipergay [4] studies in 2015, ECDC encouraged European Union (EU) Member States to consider integrating PrEP into their existing HIV prevention package for those most at risk of HIV infection [4]. In 2015, WHO 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].

To achieve the SDGs, UNAIDS recommends that three million people worldwide use PrEP annually, with a focus on key populations and those at greatest risk in high-prevalence settings [6]. As regards PrEP implementation in Europe, the situation is fast-moving. Developments include increasing levels of civil society activism and greater access to generic PrEP (emtricitabine and tenofovir) by national health systems. This Evidence Brief draws on data collected during the 2021 Dublin Declaration monitoring to provide an updated picture of PrEP implementation in the European Region.

<sup>1</sup> 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

## Additional data sources

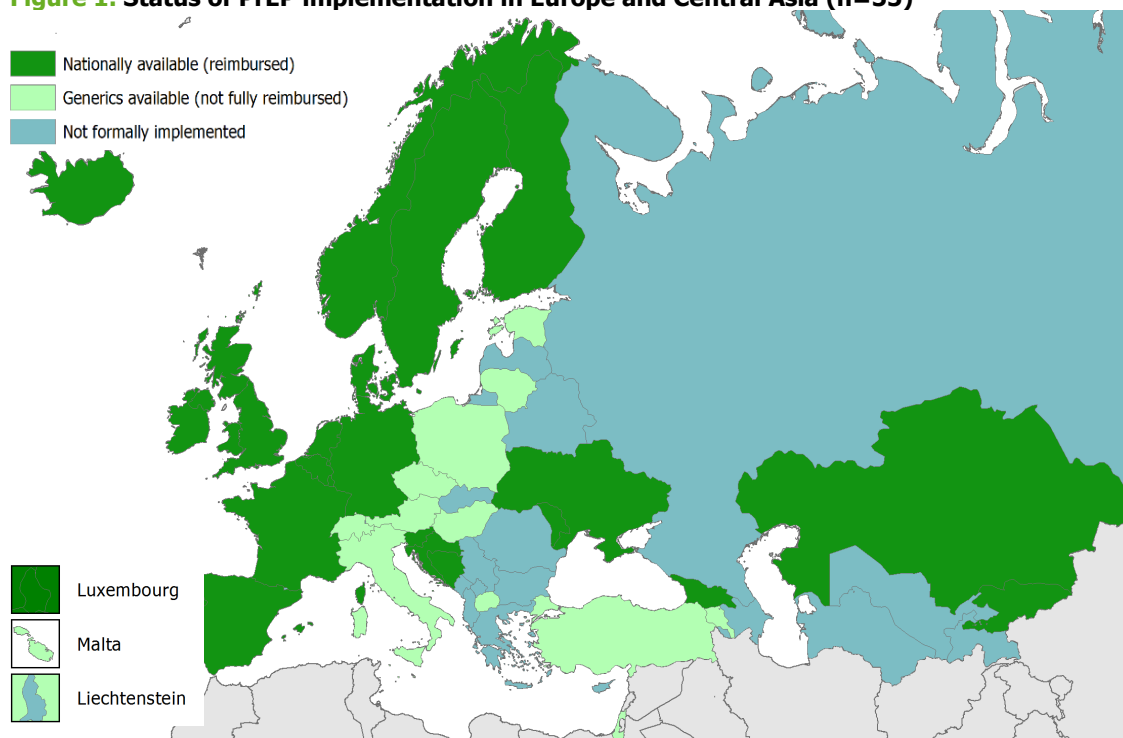
In this report, progress on PrEP provision is analysed through comparison with existing data sets. Earlier rounds of data collection were supplemented with data extracted from a variety of other sources. These include findings from a collaborative ECDC and Horner Gay Social Network rapid survey of a non-representative sample of 12 053 HIV-negative gay men in Europe regarding PrEP use in 2017 [8] and data from the European Men-Who-Have-Sex-With-Men (MSM) Internet Survey (2017), conducted between October 2018 and January 2018 and involving around 127 000 MSM from 48 European countries [9].

## Availability of PrEP in Europe and Central Asia

Figure 1 provides information on which countries made PrEP available through their health system in 2021. It does not account for online PrEP access, usually of generic PrEP sourced from abroad, or access via private healthcare where PrEP is usually available at relatively costly patent prices. The two categories of availability are nationally available (reimbursed) and generics, available in healthcare settings but not reimbursed.

PrEP implementation has improved substantially since 2016, when only one country, France, reported that PrEP was nationally available and reimbursed [7]. In 2021, 22 of the 55 reporting countries indicated that reimbursed PrEP was available from their national health service, either through insurance or paid by the public sector (Belgium, Bosnia and Herzegovina, Croatia, Denmark, France, Georgia, Germany, Netherlands, Norway, Iceland, Ireland, Kazakhstan, Kyrgyzstan, Luxembourg, Moldova, Portugal, Slovenia, Spain, Sweden, Ukraine, Northern Macedonia, and the United Kingdom). In addition, fourteen countries reported that generic PrEP was available in healthcare settings, although it is not fully reimbursed

**Figure 1. Status of PrEP implementation in Europe and Central Asia (n=55)**



In 2021, 20 countries stated that PrEP guidelines had been developed and are being implemented<sup>2</sup>; ten countries stated that PrEP guidelines had been developed<sup>3</sup>; one country stated that PrEP guidelines had been developed but were not yet being implemented<sup>4</sup> and eleven countries stated that no PrEP guidelines had been developed as yet<sup>5</sup>. Thirteen countries did not provide a response<sup>6</sup>.

<sup>2</sup> Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland and United Kingdom.

<sup>3</sup> Albania, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Ukraine and Uzbekistan.

<sup>4</sup> Slovenia

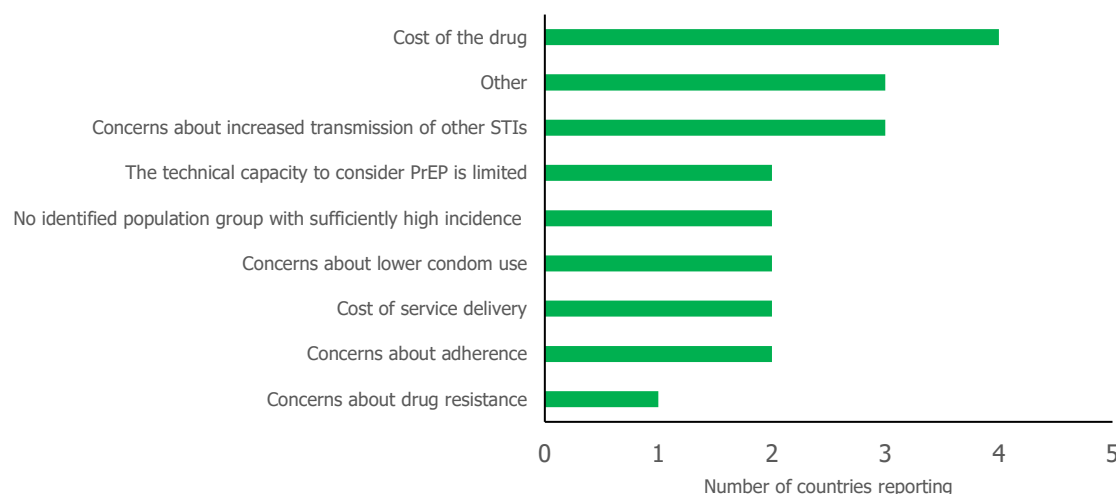
<sup>5</sup> Azerbaijan, Bulgaria, Cyprus, Greece, Hungary, Latvia, Lithuania, Malta, Monaco, Romania and Turkey.

<sup>6</sup> Andorra, Bosnia & Herzegovina, Israel, Kosovo, Liechtenstein, Luxembourg, Montenegro, North Macedonia, Russia, San Marino, Serbia, Slovakia and Turkmenistan.

### Barriers to PrEP implementation

The eleven countries that had not yet developed PrEP guidelines reported a number of barriers which are preventing or limiting PrEP implementation (Figure 2). Given the low number of countries citing each barrier, it is important not to overinterpret these responses. The cost of the drug remains the most cited barrier to PrEP implementation, as has been the case since 2016, with four of the eleven countries reporting this as a barrier to PrEP implementation in 2021. The second most cited barrier to PrEP implementation was the concern about increased transmission of other sexually transmitted infections (STIs). Other barriers reported by the countries include limitations on the technical capacity to consider PrEP, concerns about reduced use of condoms and cost of service delivery.

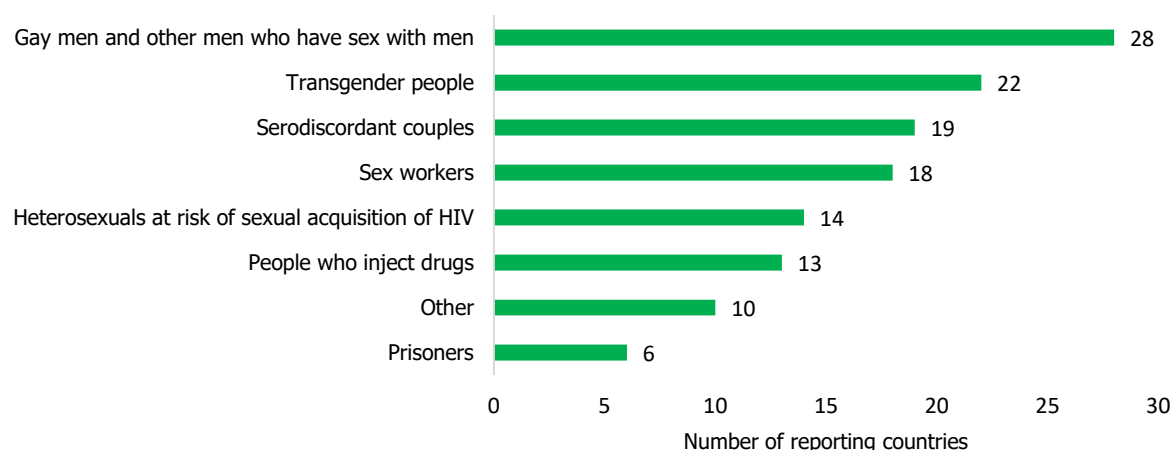
**Figure 2. Issues preventing or limiting PrEP implementation across Europe and Central Asia (n=11)**



### PrEP eligibility criteria

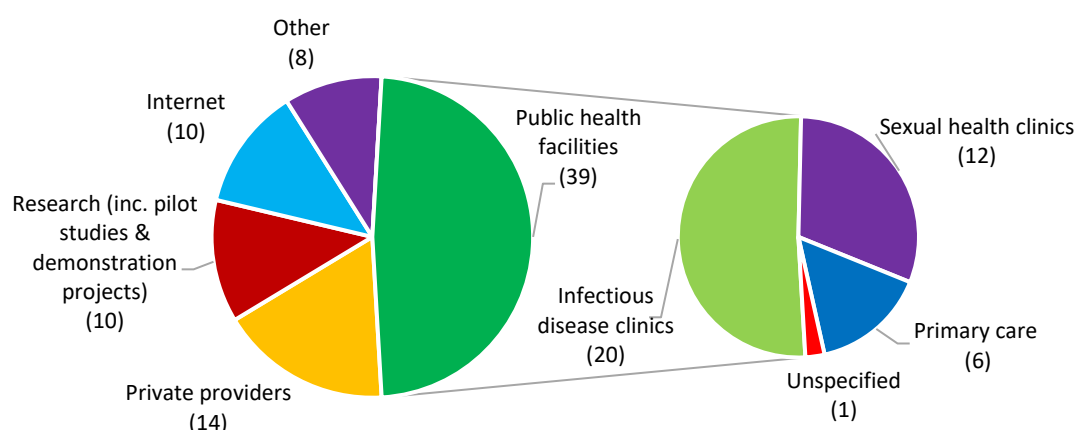
Countries were asked which key populations were eligible for PrEP (Figure 3). In 2021, 28 of 30 countries reported that gay, bisexual and other men who have sex with men are eligible for PrEP. Prisoners were only reported as being eligible for PrEP in a very small number of countries - only six of the 28 countries specifically referred to prisoners as eligible. In 2021, all key populations saw an increase in the number of countries reporting them to be eligible for PrEP, with the exception of gay, bisexual and other men who have sex with men.

**Figure 3. Populations deemed eligible for PrEP across Europe and Central Asia (n=30)**



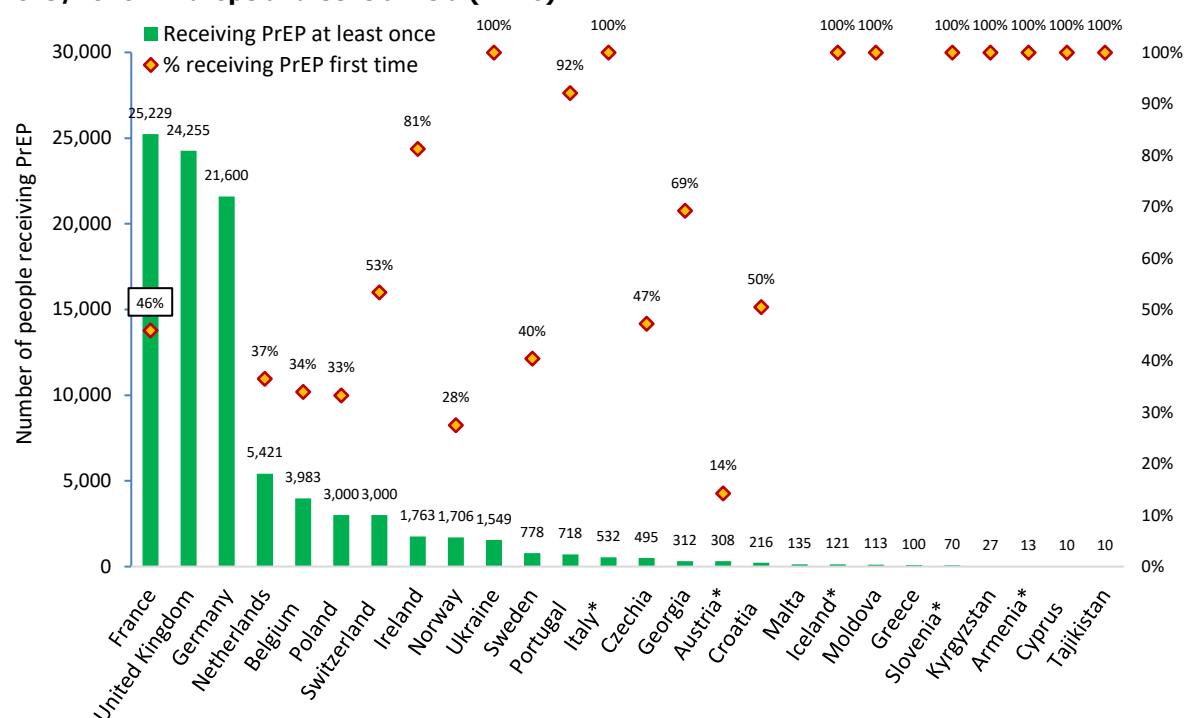
### Settings for the provision of PrEP

Countries were asked about the settings in which PrEP is available (Figure 4). In 2021, the most common setting reported for PrEP provision was the public infectious disease clinic, cited by 20 countries. The second most frequently reported setting was private providers, cited by 14 countries. Twelve countries mentioned sexual health clinics and 10 countries mentioned the internet. There was less provision of PrEP in primary care facilities, (only six of the 30 countries reported having this).

**Figure 4. Settings in which PrEP is available across Europe and Central Asia (n=30)**

## PrEP uptake in Europe and Central Asia

In 2021, 26 countries were able to report numbers receiving PrEP for the first time during the last 12 months and/or numbers receiving PrEP at least once in the last 12 months (Figure 5). The number and rate of people using PrEP at least once varied substantially among countries, ranging from 10 PrEP users (Cyprus and Tajikistan) to 25 229 PrEP users (France). In most countries for which data were provided, the majority of PrEP users were recent initiates and had received PrEP for the first time in the last 12 months.

**Figure 5. Number of people receiving PrEP and percentage receiving PrEP for the first time in 2019/2020 in Europe and Central Asia (n=26)**

\* Data from 2019

## Accessibility of PrEP

### Who can prescribe PrEP?

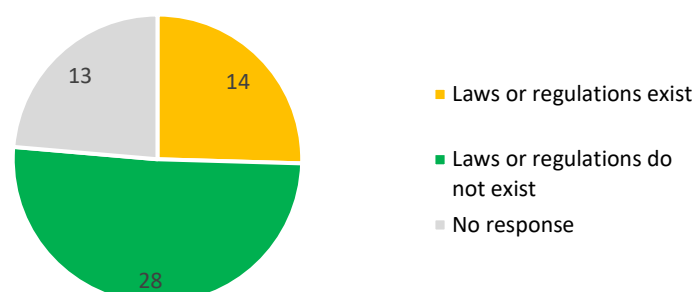
Thirty-one countries responded to the question concerning restrictions on who can prescribe PrEP. In all of the countries that responded doctors can prescribe PrEP. However, one country specified that it could only be prescribed by specialist doctors at HIV centres. Members of the nursing profession, such as nurse practitioners and midwives, were only able to prescribe PrEP in two of the 31 countries, and pharmacists were not able to prescribe PrEP in any of the 31 countries.

**Table 1. Professionals with the authority to prescribe PrEP across Europe and Central Asia (n=31)**

Profession	Number of countries
Doctors	31
Clinical officers	4
Members of the nursing profession (e.g. midwives, nurse practitioners and registered nurses)	2
Other	1
Pharmacists	0

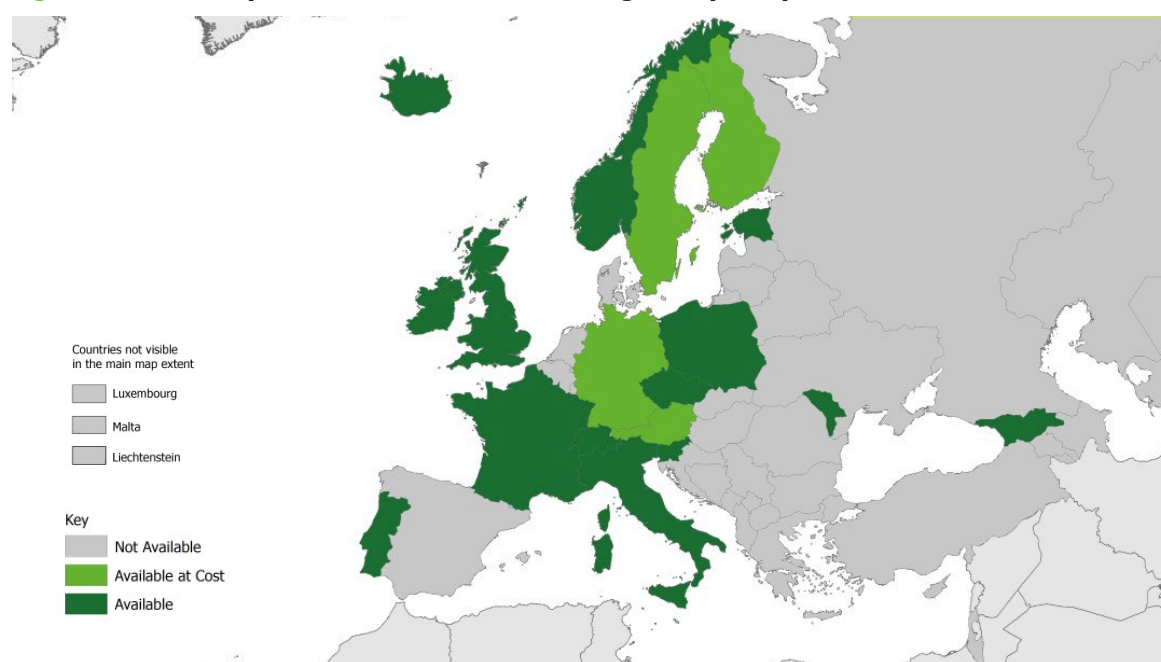
### *Prohibition of online purchase of PrEP*

In 2021, 14 countries reported having laws or regulations which prohibit individuals from purchasing PrEP online. This figure has increased since 2020, when 12 countries reported such laws. While one country reported that they no longer have prohibitions on accessing PrEP online, three countries reported new laws against the online purchase of PrEP. One of the 14 countries restricting the online purchase of PrEP reported that individuals were allowed to purchase PrEP online from an EU country, however purchasing online from outside of the EU was not permitted.

**Figure 6. Countries with laws or regulations prohibiting individuals from purchasing PrEP online from abroad (n=55)**

### *Availability of PrEP for undocumented migrants*

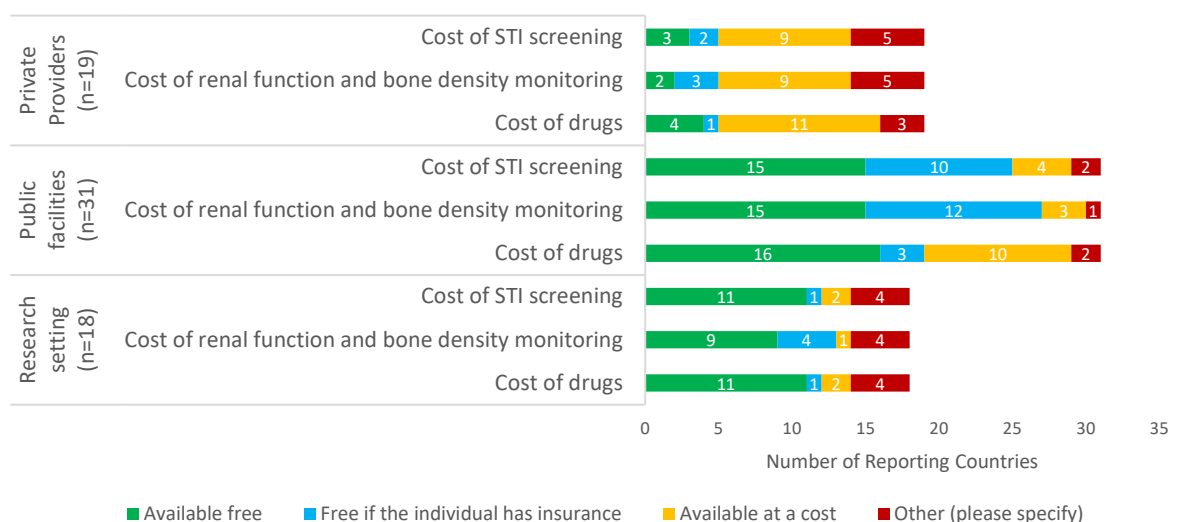
In 2021, only 15 countries reported that PrEP was available for undocumented migrants. An additional four countries reported that PrEP was only available for undocumented migrants through private practices or at cost.

**Figure 7. Availability of PrEP for undocumented migrants (n=55)**

## The cost of accessing PrEP

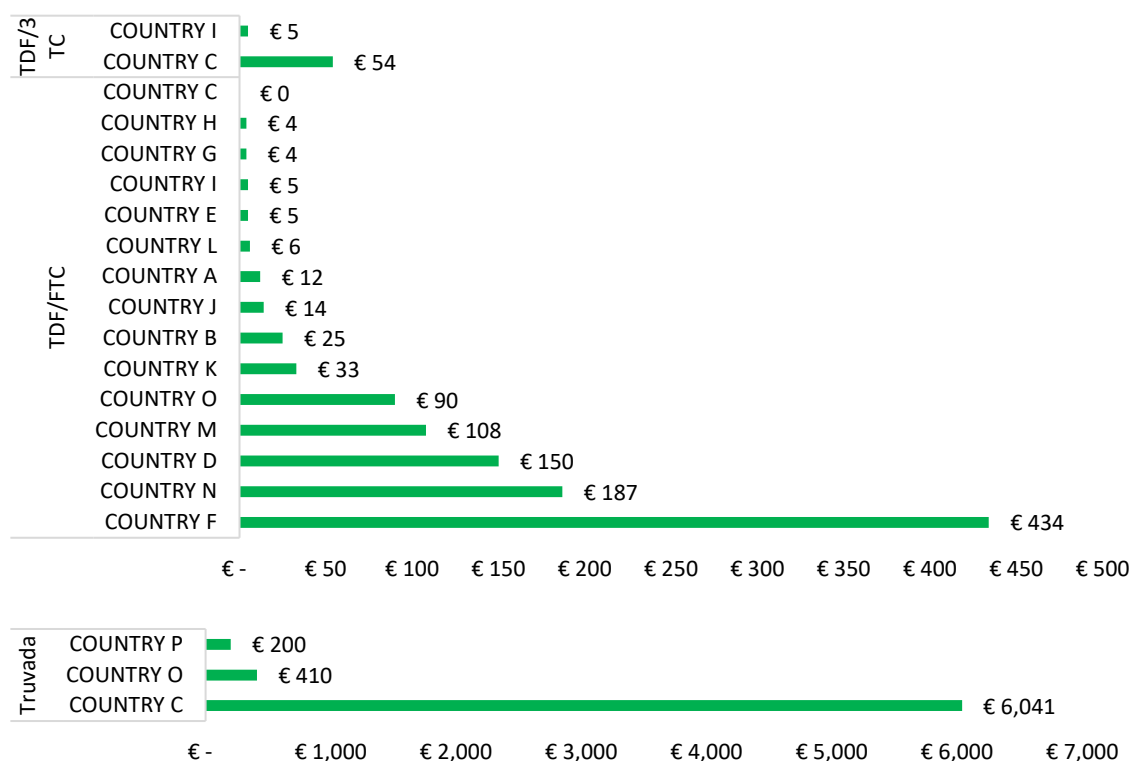
Thirty-one countries provided data on the cost of accessing PrEP. Ten of them said that PrEP was not reimbursed at public facilities. Three countries stated that it was reimbursed through insurance (Croatia, Germany, Malta) and 14 said it was reimbursed through the public sector (Denmark, Finland, France, Georgia, Iceland, Ireland, Kazakhstan, Kyrgyzstan, Moldova, Netherlands, Norway, Slovenia, Spain, United Kingdom). Two countries reported 'Other', explaining that access to free PrEP is restricted to certain clinics (Ukraine) and that there is no official programme for reimbursing PrEP (Austria).

**Figure 8. Cost to the individual when receiving PrEP in different settings across Europe and Central Asia**



Countries in Europe and Central Asia were able to purchase PrEP at different prices. For example, for 28–30 tablets of generic PrEP (TDF/3TC and TDF/FTC), the lowest purchase price reported was EUR 0 (donation from the private sector) and the highest was EUR 434. Truvada was generally more expensive, with the highest purchase price being EUR 6 041 and the lowest EUR 200.

**Figure 9. Cost of PrEP (28–30 tablets), as purchased by governments across Europe and Central Asia (n=16)<sup>7</sup>**



<sup>7</sup> This data has been anonymised due to its commercial sensitivity.



## Conclusions

The provision of PrEP in Europe and Central Asia has significantly increased since 2016, however, there is still a great deal of variation among the countries. Data collected via Dublin Declaration monitoring on state provision of PrEP provides a snapshot of a rapidly changing situation. In 2021, 21 countries reported that they were now providing and reimbursing PrEP within their national health system. However, even within these countries, PrEP is not always available everywhere and some countries have restrictions on who is eligible for PrEP. While progress has been made on increasing PrEP accessibility in Europe and Central Asia, wider scale implementation of PrEP is necessary to accelerate progress towards the UN Sustainable Development Goal 3.3: ending the AIDS epidemic by 2030.

In addition, PrEP is still mainly provided in medicalised settings, with infectious disease clinics being the most common setting and most countries allowing only doctors to prescribe PrEP. Research indicates that this may create barriers to access for target groups [10]. Therefore, countries are encouraged to explore how PrEP could be provided through community-based organisations.

PrEP may also be inaccessible to undocumented migrants in countries where it is only available to migrants through private clinics or at-cost, since this creates a financial barrier to care [11].

In countries without national PrEP guidelines, cost is the most cited barrier to PrEP implementation and this has been the case since 2016. However, there is a low response rate to questions concerning barriers to implementation, and a range of issues are cited, including concerns about reduced use of condoms and increased transmission of other STIs, limitations on the technical capacity to consider PrEP, and cost of service delivery. It is important to understand barriers preventing the implementation of PrEP programmes in order to facilitate improvements in availability, and this should be a priority for countries.

In order to facilitate PrEP implementation across Europe and Central Asia, ECDC has developed minimum standards on the principles of PrEP programming, monitoring and surveillance [12]. Countries should consider these standards when developing and implementing national guidelines, and they are also encouraged to place a stronger focus on increasing PrEP accessibility for all key populations.

## Priorities for action

- Greater access to PrEP and progress in PrEP implementation are needed to reach the Sustainable Development Goal of ending the AIDS epidemic by 2030. To achieve this progress, it would be helpful for countries to gain a better understanding of the barriers within their country to implementing PrEP programmes.
- PrEP eligibility requirements may restrict certain individuals from accessing PrEP. Countries should review PrEP eligibility, taking into account the HIV prevalence and all relevant key populations.
- Countries are encouraged to share experiences on feasibility of implementation, costs and technical capacity with those countries that have not implemented national PrEP guidelines.
- Strong surveillance systems would enable data on PrEP eligibility, uptake, duration on PrEP and outcomes to be captured. Consistent data collection across the Region should be encouraged. In particular, the extent of informal online access to PrEP and the relevant health outcomes should be added to existing monitoring.

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