

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 – 2022 progress report

February 2023

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 February and August 2022 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 55 countries in Europe and Central Asia (the 53 countries in the WHO European region, plus Kosovo¹ and Liechtenstein), including the 30 countries of the European Union/European Economic area (EU/EEA) via an online survey.

Key messages

- Pre-exposure prophylaxis (PrEP) is very effective at preventing novel HIV infections when taken as prescribed. It is an important element in the 'combination prevention' necessary to reach the United Nations (UN) Sustainable Development Goal of ending the AIDS epidemic by 2030.
- Since 2016, PrEP has been increasingly available through healthcare systems in countries in the World Health Organization (WHO) European Region, but in 2022 17 countries (five in the EU) had not yet formally implemented PrEP in their healthcare systems.
- Certain key populations, such as people who inject drugs, prisoners, and undocumented migrants, remain ineligible for PrEP in many countries in the WHO European Region.
- PrEP is mostly provided in clinical settings, such as infectious disease clinics and sexual health clinics, and in most countries in the WHO European Region requires a prescription from a medical doctor.
- Improved data collection and surveillance on PrEP uptake are vital for obtaining a proper understanding of who has access to PrEP. In addition, sharing of best practices, especially those relating to feasibility, cost, and technical matters, would support expanded provision 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 released an opinion that European Union Member States should consider integrating PrEP into their existing HIV prevention package for those most at risk of HIV infection [4]. In 2015, the World Health Organization (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].

The situation regarding PrEP implementation and availability in Europe is fast-moving and evolves with advances in medical sciences. Continuing developments include

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.

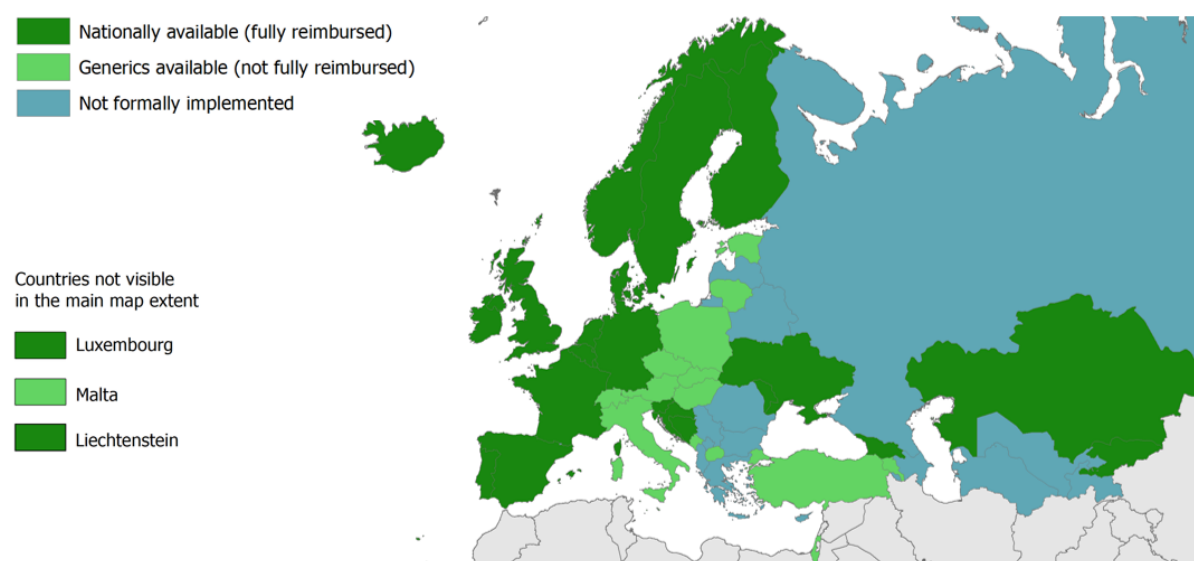
increasing levels of civil society activism and greater access to generic PrEP (emtricitabine and tenofovir) by national health systems. This evidence brief draws on data collected during the 2022 Dublin Declaration monitoring to provide an updated picture of PrEP implementation in the European region.

Availability of PrEP in Europe and Central Asia

Figure 1 provides information on which countries have made PrEP available through their health system in 2022. It does not account for online PrEP access, use of generic PrEP sourced from abroad, or access via private healthcare where PrEP is usually available at relatively high patent prices. The two categories of availability are nationally available (reimbursed) and generics available in healthcare settings (but not reimbursed).

PrEP implementation in Europe and Central Asia has improved substantially since 2016, but at the time of data collection 17 of 55 countries (five EU countries) had not yet formally implemented PrEP through their healthcare systems. In 2022, 23 countries reported that PrEP was available and reimbursed through their healthcare system, either through insurance or paid by the public sector². In addition, 15 countries reported that generic PrEP was available in healthcare settings, although not fully reimbursed.

Figure 1. Status of PrEP implementation in Europe and Central Asia in 2022 (n=55)



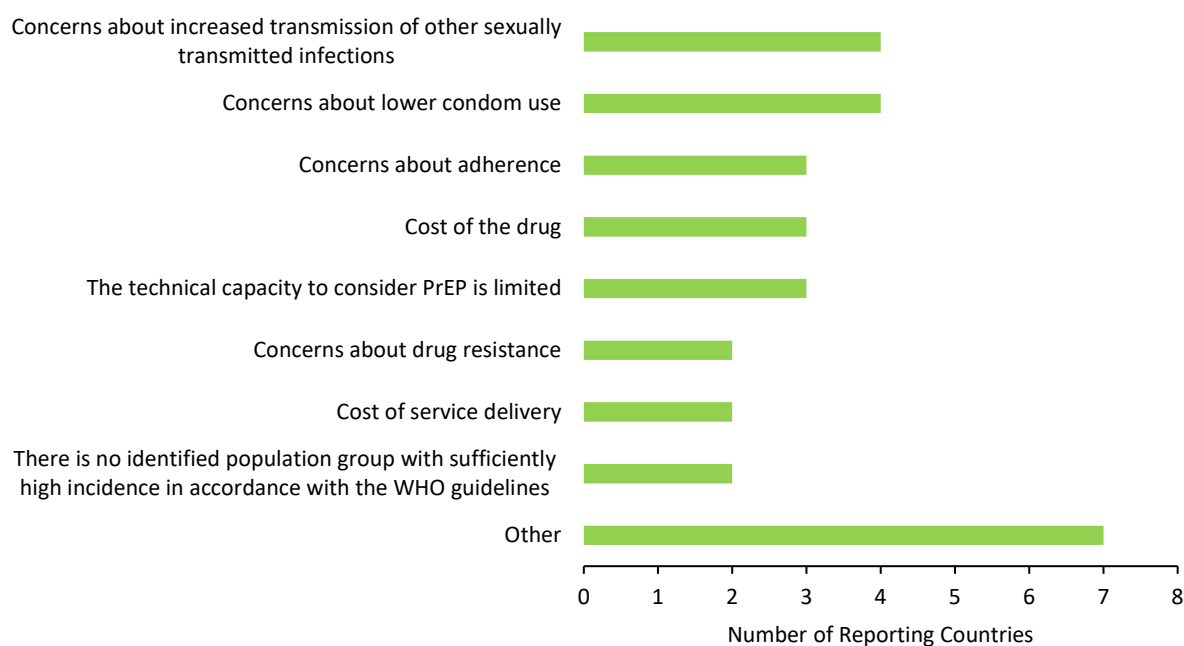
National PrEP guidelines

In 2022, 30 countries stated that PrEP guidelines had been developed and are being implemented; five countries stated that PrEP guidelines had been developed (no information as to whether or not they are implemented); one country stated that PrEP guidelines had been developed but were not yet being implemented and 15 countries stated that no PrEP guidelines had been developed. Four countries did not provide a response.

Barriers to PrEP implementation

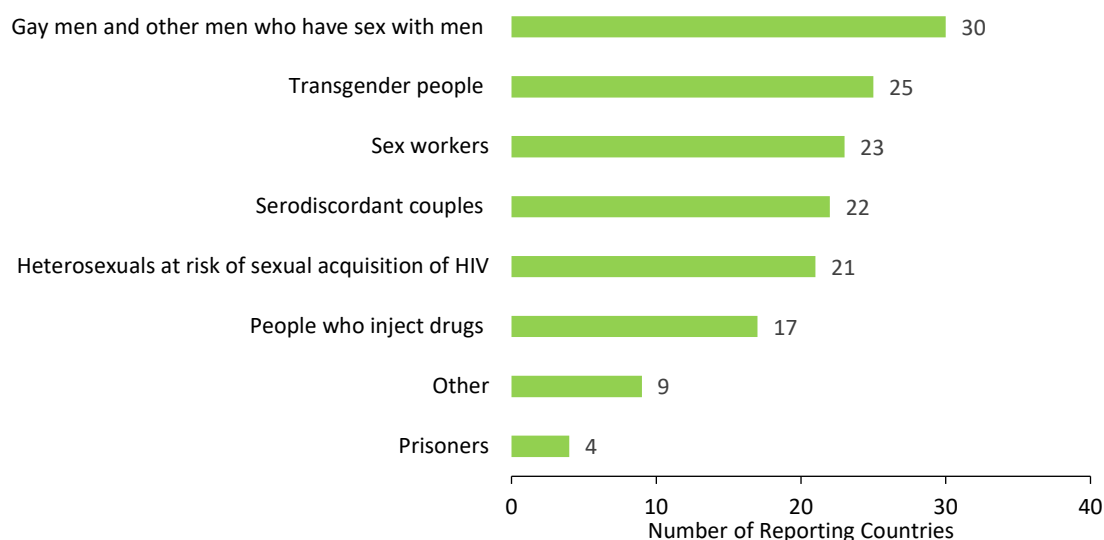
The 15 countries which have not yet developed PrEP guidelines reported a number of barriers that are preventing or limiting PrEP implementation (Figure 2). Key concerns reported by the countries include concerns about increased transmission of other STIs, concerns about lower condom use, concerns about drug costs and concerns about adherence. Seven countries reported 'other' concerns, which included legal barriers, impacts of the COVID-19 pandemic and government priorities as barriers to PrEP guideline development and implementation. With low rates of data on these barriers and substantial variation between countries, it is important not to overinterpret these responses.

² Belgium, Bosnia and Herzegovina, Croatia, Denmark, Finland, France, Georgia, Germany, Iceland, Ireland, Kazakhstan, Kyrgyzstan, Liechtenstein, Luxembourg, Monaco, North Macedonia, Norway, Portugal, Slovenia, Spain, Sweden, Ukraine, United Kingdom.

Figure 2. Issues preventing or limiting PrEP implementation across Europe and Central Asia (n=15)

PrEP eligibility for key populations

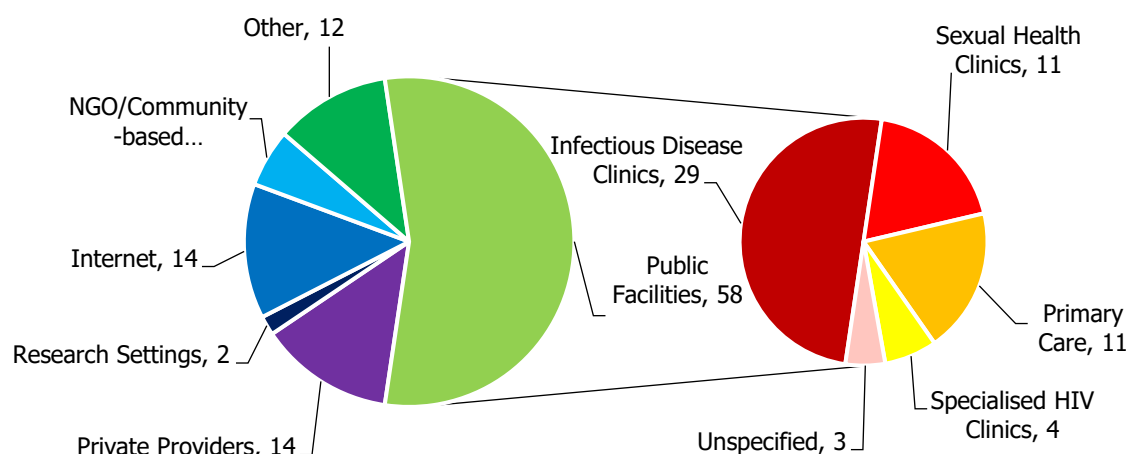
In 2022, 35 countries provided data on which key populations were eligible for PrEP (Figure 3). Gay men and other men who have sex with men were most frequently reported as eligible for PrEP: 30 of 35 countries reported that they are eligible for PrEP. Prisoners were least frequently reported as eligible for PrEP, with only four of 35 countries reporting them eligible.

Figure 3. Populations deemed eligible for PrEP across Europe and Central Asia (n=35)

Settings for the provision of PrEP

Countries were asked about the settings in which PrEP is available (Figure 4), and 49 countries provided responses. In 2022, the setting in which PrEP was reported to be most frequently available was infectious diseases clinics, cited by 29 countries. Other commonly reported settings for PrEP provision included private providers (14), the internet (14), sexual health clinics (11), and primary care (11).

Figure 4. Settings in which PrEP is available across Europe and Central Asia (n=49)

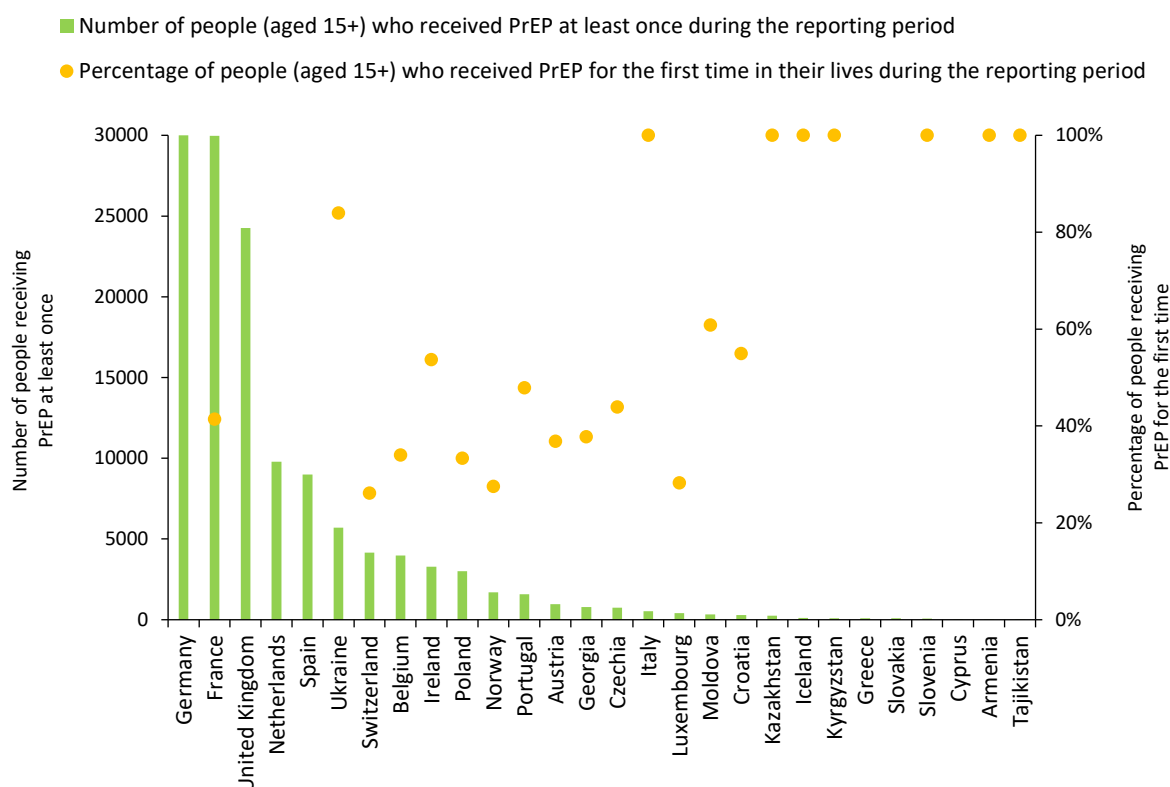


PrEP uptake in Europe and Central Asia

In the 28 countries in Europe and Central Asia which were able to report data, 131 279 people had received PrEP at least once in the last 12 months (Figure 5). The number of people using PrEP at least once varied greatly by country, ranging from 10 PrEP users in Tajikistan to 30 000 in Germany.

Twenty-one of the 28 countries were able to provide data on the number of people using PrEP for the first time in the last 12 months. In most countries which provided data, the majority of PrEP users were recent initiates and had received PrEP for the first time in the last 12 months. Overall, 45% of PrEP users in the 21 countries which were able to report data had used 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 2021³ in Europe and Central Asia (n=28)



³ Period covered by the data presented is 01/01/2021 – 31/12/2021 unless specified. Other periods covered by the data: – 25/03/2019 (Iceland); 08/01/2018 – 31/12/2020 (Slovenia); 01/01/2018 – 31/12/2018 (Greece); 01/01/2019 – 31/12/2019 (Armenia); 03/01/2019 – 29/03/2019 (Poland); 15/01/2019 – 28/02/2019 (Italy); 01/04/2019 – 31/10/2020 (United Kingdom); 01/11/2019 – 31/12/2021 (Spain); 01/01/2020 – 31/12/2020 (Belgium, Norway, Portugal, Tajikistan); 01/07/2020 – 30/06/2021 (France); 01/01/2021 – 21/09/2021 (Switzerland); 01/01/2021 – 01/03/2022 (Austria).

Accessibility of PrEP

Who can prescribe PrEP?

Thirty-seven countries responded to the question concerning who can prescribe PrEP (Table 1). Doctors were able to prescribe PrEP in 36 countries, but four of these countries specified that the prescribing doctor had to be an infectious disease specialist. Five countries⁴ reported that clinical officers were able to prescribe PrEP. Members of the nursing profession were only able to prescribe PrEP in two countries⁵, and pharmacists were not able to prescribe PrEP in any of the 37 countries.

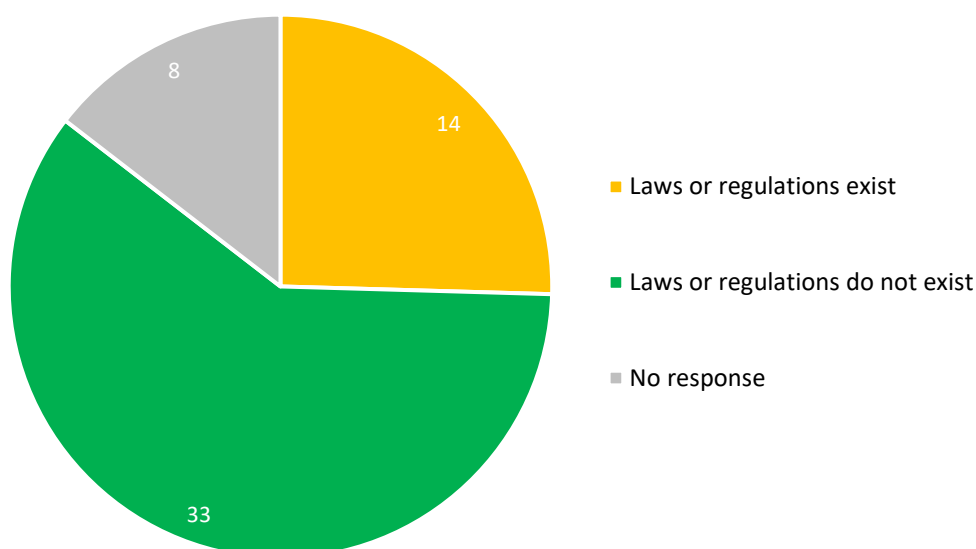
Table 1. Professionals with the authority to prescribe PrEP across Europe and Central Asia (n=37)

Profession	Number of countries
Doctors	36
Clinical officers	5
Members of the nursing profession (ex: registered nurses, nurse practitioners, and midwives)	2
Pharmacists	0

Prohibitions for online purchase of PrEP

In 2022, 14 countries⁶ reported having laws or regulations which prohibit individuals from purchasing PrEP online (Figure 6). One of the 14 countries restricting access to online PrEP from abroad reported that individuals were permitted to purchase PrEP online originating from an EU country, but that purchasing online from outside the EU was not allowed.

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



Availability of PrEP for undocumented migrants

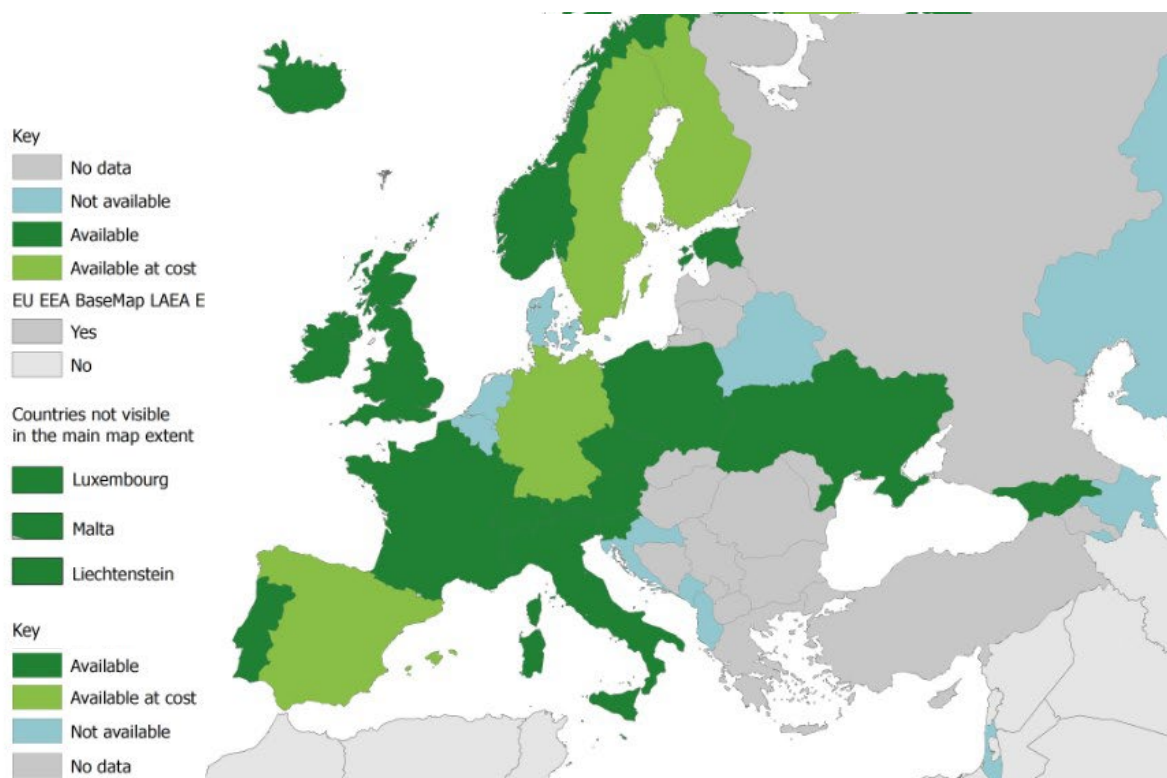
In 2022, 19 countries reported that PrEP was available for undocumented migrants (Figure 7). An additional four countries reported that PrEP was only available for undocumented migrants through private practices or at cost, which may limit the number of undocumented migrants able to access PrEP in these countries. One country reported that PrEP may be available through NGOs, but that PrEP was not formally available for undocumented migrants through its healthcare system.

⁴ Azerbaijan, Kazakhstan, Liechtenstein, Tajikistan, Ukraine.

⁵ Ireland, United Kingdom.

⁶ Austria, Czechia, Denmark, Finland, Germany, Greece, Ireland, Italy, Norway, Portugal, Serbia, Slovenia, Spain, Sweden.

Figure 7. Availability of PrEP for undocumented migrants in 2022 (n=55)

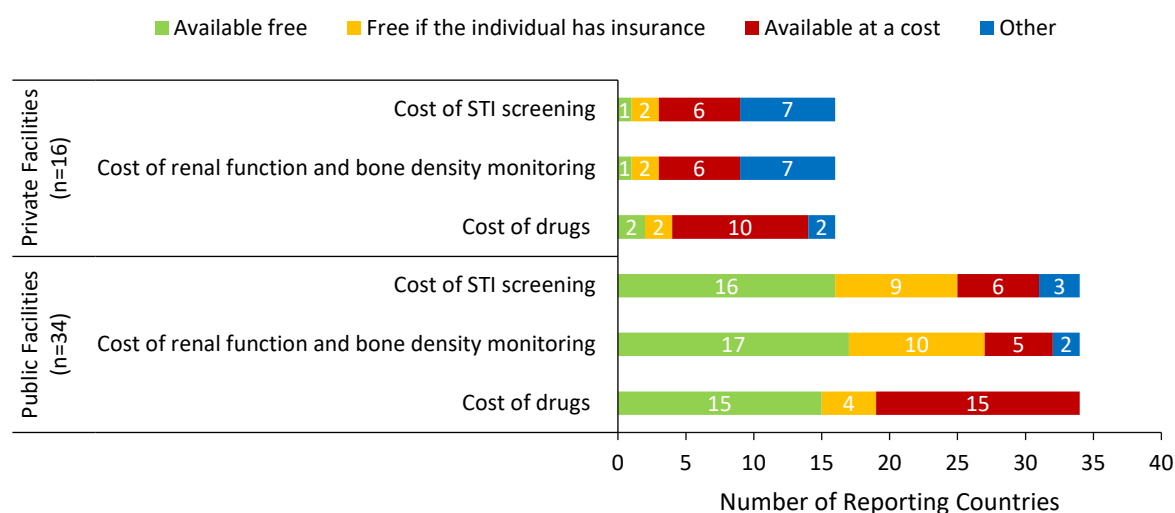


The cost of accessing PrEP

Thirty-five countries provided data on the cost of accessing PrEP, with 34 of the 35 countries able to provide data on costs of accessing PrEP at public facilities (Figure 8). Fifteen of the 34 countries reported that PrEP was available for free at public facilities and four reported that PrEP was free if the individual had insurance. The remaining 15 countries reported that PrEP was only available at cost. Some of the countries where PrEP is only available at cost reported that measures exist to help reduce the financial burden of PrEP, including co-payments, partial reimbursement with national insurance or low-cost options, such as generic drugs or pilot programmes for low-cost drugs.

Individuals accessing PrEP are recommended to have regular renal and bone density screening and STI testing while using PrEP. Six countries reported that STI screening was not available for free at public facilities and five countries reported that renal and bone density monitoring were not available for free at public facilities, which may reduce PrEP accessibility.

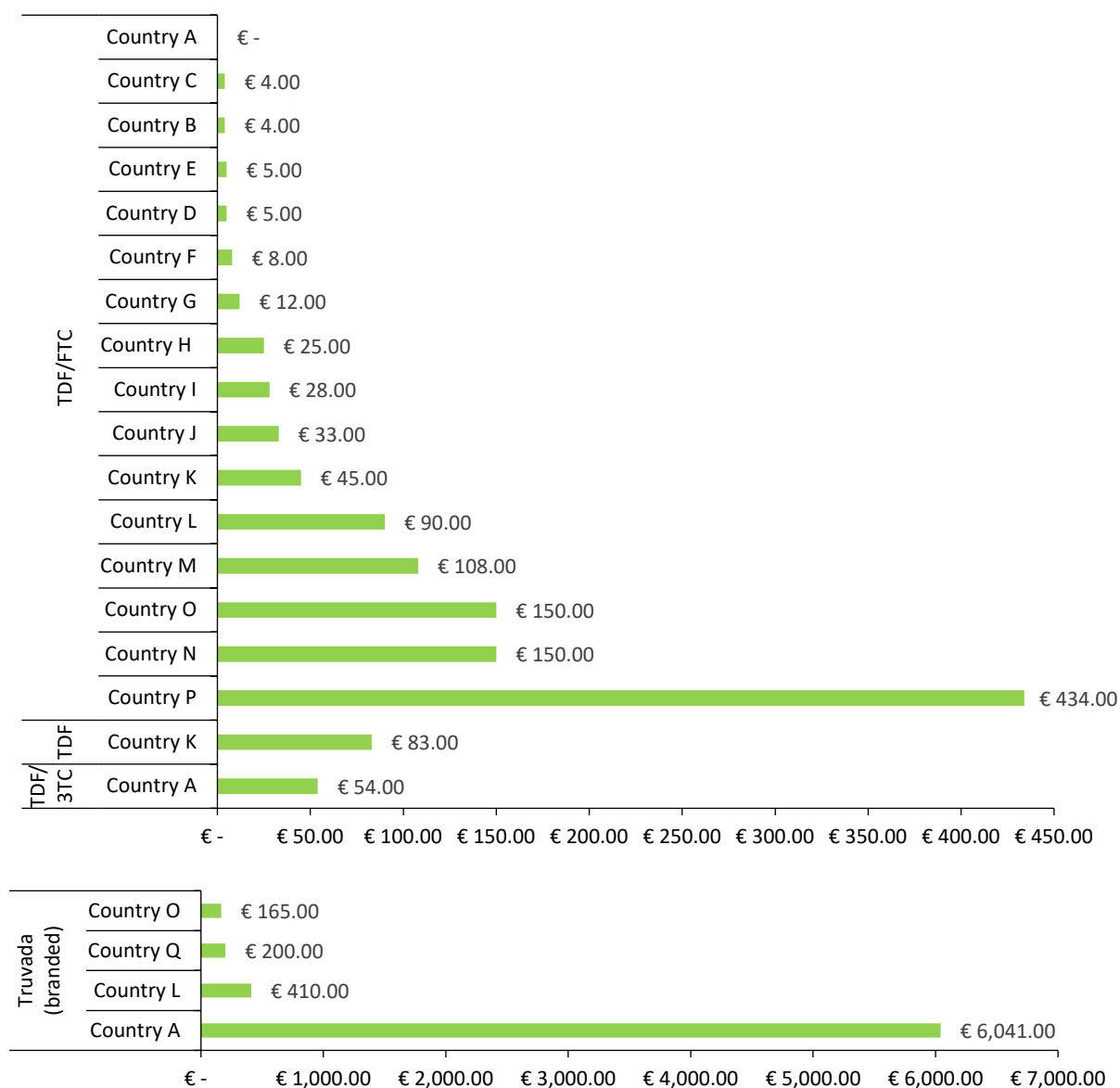
Figure 8. Cost to the individual when receiving PrEP in different settings across Europe and Central Asia (n=35)



Government PrEP purchase price

Countries in Europe and Central Asia were able to purchase PrEP at different prices, with a median price of EUR 30.50 for generic PrEP and EUR 305.00 for branded PrEP (Figure 9). The lowest purchase price reported for 28–30 tablets of TDF/FTC, a generic version of PrEP, was EUR 0 (a donation from the private sector) and the highest purchase price was EUR 434.00. Truvada was generally more expensive than the generic forms of PrEP: the lowest government purchase price for 28–30 tablets of Truvada was EUR 165.00 and the highest purchase price was EUR 6 041.00.

Figure 9. Cost of PrEP (28–30 tablets) as purchased by governments across Europe and Central Asia (n=17) in 2022^{7,8}



Conclusions

The provision of PrEP in Europe and Central Asia has significantly increased since 2016, but there is still a great deal of variation among countries in terms of the scale of implementation. Data on the state of the provision of PrEP provide a snapshot of a rapidly changing situation. In 2022, 30 countries in the WHO European Region had developed and implemented national PrEP guidelines, and PrEP was available for free through the healthcare system of 23 countries. However, even within these, PrEP is not always available everywhere and some countries have restrictions around who is eligible for PrEP. In particular, PrEP remains inaccessible for certain key populations, including prisoners and undocumented migrants. While progress has been made on increasing PrEP

⁷ These data have been anonymised due to commercial sensitivity.

⁸ Abbreviations of commonly prescribed generic PrEP drugs: TDF – tenofovir disoproxil fumarate; 3TC – Lamivudine; FTC – Emtricitabine.

accessibility in Europe and Central Asia, wider scale implementation of PrEP is necessary to accelerate progress towards the UN Sustainable Development Goal 3.3 of ending the AIDS epidemic by 2030.

In addition, while some countries have reported PrEP availability in NGO/community-based settings, PrEP is still mainly provided in medicalised settings, with infectious disease clinics being the most common and most countries allowing only doctors to prescribe PrEP. Research indicates that this may create barriers to access for target groups [6].

PrEP may also be inaccessible to undocumented migrants in countries where it is only available to migrants through private clinics or at-cost, as this creates a financial barrier to care [7].

In the 15 countries without national PrEP guidelines, various barriers to PrEP implementation have been identified, including concerns about: increased transmission of other STIs, lower condom use, drug costs, and adherence. It is important to understand the specific barriers to preventing the implementation of PrEP programmes in individual countries in order to facilitate improvements in availability.

To facilitate PrEP implementation across Europe and Central Asia, ECDC has developed operational guidance on PrEP with accompanying country case studies where implementation experiences are shared, and has developed minimum standards on the principles of PrEP programming, monitoring, and surveillance [8]. Countries should consider these standards when developing and implementing national guidelines, and are also encouraged to place a stronger focus on increasing PrEP accessibility for all key populations.

Priorities for action

- National guidelines are a useful tool in guiding the implementation of national PrEP programmes. Countries without national guidelines, or in countries with guidelines that are not implemented, are encouraged to gain a better understanding of the barriers within their country to the development and implementation of national PrEP guidelines or programmes.
- 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, countries are encouraged to share experiences on feasibility of implementation, costs and technical capacity with those countries that have not implemented PrEP through their healthcare system.
- Countries are encouraged to remove restrictions on who can access PrEP and review and expand the settings in which PrEP is available, to reach a wider population – for example, they are encouraged to explore how PrEP could be provided through community-based organisations.
- Strong surveillance and monitoring systems would enable data on PrEP eligibility, uptake, duration on PrEP, and outcomes to be captured. Consistent data collection across the region would improve data comparability. In particular, adding the extent of informal online access to PrEP and the relevant health outcomes to existing monitoring would improve the understanding of who has access to PrEP.

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