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Achievements and gaps to provide pre-exposure prophylaxis (PrEP) for women across the European Region – Results from a European survey study

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ABSTRACT

Introduction: The use of pre-exposure prophylaxis (PrEP) is a safe and effective prevention option to all people at substantial risk of HIV acquisition, irrespective of gender. However, in most European countries PrEP services focus on key populations, in particular men who have sex with men (MSM). This study aims to explore PrEP availability and implementation for women across the European region.

Methods: An online survey was sent to all members of Women Against Viruses in Europe (WAVE) from 50 countries in September 2019. It consisted of 19 questions, including both multiple choice and free text answers.

Results: In total, responses from 34 countries were included in the study (Western Europe n = 12, Central Europe = 12, Eastern Europe n = 6). PrEP was accessible in 30 WHO European countries. More than half of them stated that PrEP was available for all groups at-risk of HIV acquisition (n = 18), while in many countries PrEP was only available to MSM and transgender persons. Two-thirds of country respondents confirmed the availability of a national guideline for PrEP (n = 23), of which six countries had specific recommendations for PrEP in women. The most cited obstacles for PrEP access were lack of information about PrEP, lack of political support, and high cost for the individual. Fifteen country respondents stated that there were specific obstacles for PrEP access for women, such as guidelines prioritizing MSM, women not being seen as a target population for PrEP, and lack of knowledge about which subgroup of women would benefit most from PrEP. Seven countries had made efforts to encourage women's access to PrEP, most of which were individually based or initiated by local NGOs.

Conclusions: PrEP is an important addition to HIV combination prevention. Women's access to PrEP in Europe remains limited. Women are often not included in the guidelines or targeted with education or information, resulting in a general lack of information about the use of PrEP for women.

Introduction

In 2018, nearly 50 000 women were newly diagnosed with HIV, representing 36% of the 140 000 new HIV diagnoses overall in the WHO European region. The majority of these newly HIV diagnosed women were in the Centre and East of the region, where an increase in new HIV diagnoses among both men and women was observed between 2009 and 2018. Heterosexual sex was the most commonly reported HIV acquisition mode among women in the region.[1] Over half of the newly diagnosed women were diagnosed late, highlighting that women need more attention in Europe's prevention and testing effort to reduce infections amongst women and children and enable the goal of ending AIDS by 2030.[1,2]

Many prevention strategies available to women at risk of HIV acquisition through sex depend on the male partner, i.e. condoms, antiretroviral therapy or male circumcision.[3] Pre-exposure prophylaxis

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(PrEP) is the use of an antiretroviral medication taken by those who are HIV negative but who are at risk of acquiring HIV.[4] In 2015, the WHO recommended that PrEP should be offered as a prevention option to all people at substantial risk of HIV acquisition, irrespective of gender.[4] These recommendations were based on a systematic review and meta-analysis of documenting the effectiveness and safety of PrEP across heterogeneous populations when taken with high adherence, with no difference in effectiveness by sex. For event-driven PrEP regimens, the evidence was less conclusive.[5] Several recent studies have been published with further information on PrEP effectiveness and safety for women, including studies of alternative PrEP agents, including long acting injectables and vaginal rings.[6–9] Current safety data also support the use of PrEP in pregnant and breastfeeding women.[10,11] Thus, PrEP offers women an efficacious, female-controlled HIV prevention choice.[12]

Truvada (tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC)) was authorized by the European Medicines Agency (EMA) in 2016 to be used as PrEP.[13] France was the first European country to make PrEP nationally available and reimbursed by its health care system.[14] Recent surveillance data from the European Centre for Disease prevention and Control (ECDC) show that there has been a marked increase in the number of countries in the WHO European Region implementing PrEP, either as part of national healthcare provision or through pilot or research projects.[14,15] However, these data also highlight that availability of PrEP in Europe is complex and fragmented, and in many countries PrEP services focus on key populations, in particular men who have sex with men (MSM) and, to a lesser extent, transgender women.[12,14,16]

Several systematic reviews summarizing the current knowledge on the efficacy, safety and barriers to PrEP use among women have been published.[12,17,18] Most of these focus on the use of PrEP internationally, with limited information on the implementation and access to PrEP for women living in the European region. Women Against Viruses in Europe (WAVE) within the European AIDS Clinical Society (EACS) (http://www.eacsociety.org/wave/about-wave/wave.html) was established in 2014 to promote the health and wellbeing of women living with HIV (WLWH) and HIV prevention for women in Europe. The initiative involves health care professionals, researchers and community representatives. WAVE endeavours to promote equality of access to care, including HIV prevention for women, and contributing to the body of evidence for using such prophylaxis for women.[19,20] Therefore, in 2019 a survey conducted within WAVE, exploring PrEP availability and implementation for women across the European region was performed with an aim to describe the current situation and encourage future opportunities.

Methods

Data collection and analysis

The survey was designed and finalised by a steering group consisting of PrEP activists and clinicians. Surveys were sent initially to all WAVE members, i.e. healthcare professionals, members of the community, advocacy groups and others. To ensure inclusion of all regions, people from countries known to have an interest in women and HIV but who were not WAVE members were approached personally by the WAVE Scientific Committee members.

An invitation email to participate in the WAVE survey on PrEP and women was sent to 1965 people from 51 countries on September 10, 2019. A reminder was sent 3 weeks later. Invitees were encouraged to collaborate with other people in their country working with PrEP and to send one response from their country. Thus, the aim was not for the survey to be answered by all invited participants, but rather those who are prescribing PrEP in the country, i.e. those thought of as being in a good position to give relevant and trustful answers because of their expertise. If more than one response was received from the same country, the respondents were contacted and asked to provide one consensus response. The survey was an online questionnaire, taking approximately 15 minutes to complete. It consisted of 19 questions, including both multiple choice and free text answers.

Results were analysed using the European Centre for Disease Prevention (ECDC) geographical division of the WHO European region, grouping countries into three sub-regions based on geographic and broad epidemiological patterns: West, East, and Centre.[21] The quantitative results are presented descriptively, while the qualitative text from the open questions is used to elaborate and illustrate aspects of the quantitative results.

Individual consent was provided by respondents completing the survey. Ethical approval was not required as no patient data was used and no biomedical intervention performed.

Results

Of the 1965 invitation emails sent, 30% (n = 590) opened the email, and 4.4% (n = 86) clicked on the link and opened the survey. In total, 38 respondents completed the survey, of which 4 responses where received from the same country. Thus, responses from the following 34 countries are included in the study; 16 from the West (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland, the United Kingdom), 6 from the East (Belarus, Kyrgyzstan, Lithuania, Moldova, Russia, Ukraine), and 12 from the Centre (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Hungary, Poland, Romania, Serbia, Slovenia, Turkey). Based on the number of countries completing the survey the response rate was 67% (34 out of 51 countries).

PrEP accessibility in Europe

Of the 34 countries within the WHO European Region included in the survey, 30 (88%) reported yes to the question of whether PrEP was accessible in their country. The countries who reported that PrEP was accessible were then asked in which way people could access it in their country (Fig. 1). Based on these responses, access to PrEP was divided into four main categories; (i) PrEP reimbursed within the national health service, (ii) PrEP available in health care settings or by purchasing it legally online, but not fully reimbursed, (iii) PrEP available only through clinical trials, by purchasing it illegally online, or via the underground market, and (iiii) PrEP not available by any means.

(i) Eight countries (24%) reported that PrEP was available for free at the point of care, either either through the public sector or insurance (Bosnia and Herzegovina (only Sarajevo), Croatia, Denmark, France, the Netherlands, Moldova, Portugal, and Ukraine). Five of these countries commented that reimbursed PrEP was available with a medical prescription provided by an HIV specialist, after candidates were screened for HIV and sexual transmitted infections (STIs) and counselled on minimising risk-taking behaviour.

(ii) Seventeen countries (50%) reported that PrEP was available in health care settings or by purchasing it legally online, but not fully reimbursed (Austria, Belgium, Czech Republic, Finland, Germany, Hungary, Ireland, Israel, Italy, Lithuania, Poland, Russia, Serbia, Slovenia, Sweden, Switzerland, and the United Kingdom). In Scotland, Wales and in Northern Ireland PrEP was free at point of care but in England it was still officially only available via a clinical trial. The cost of PrEP in all mentioned countries varied considerably depending on how much was subsidised by social services or insurance. For example, the cost for PrEP in Germany was €10 per prescription, while it was almost €200 in Russia.

(iii) Five countries (15%) reported that PrEP was only available through clinical trials, by purchasing it illegally online, via the underground market, or by procuring it from someone living with HIV but non-adherent to their medication (Bulgaria, Cyprus,

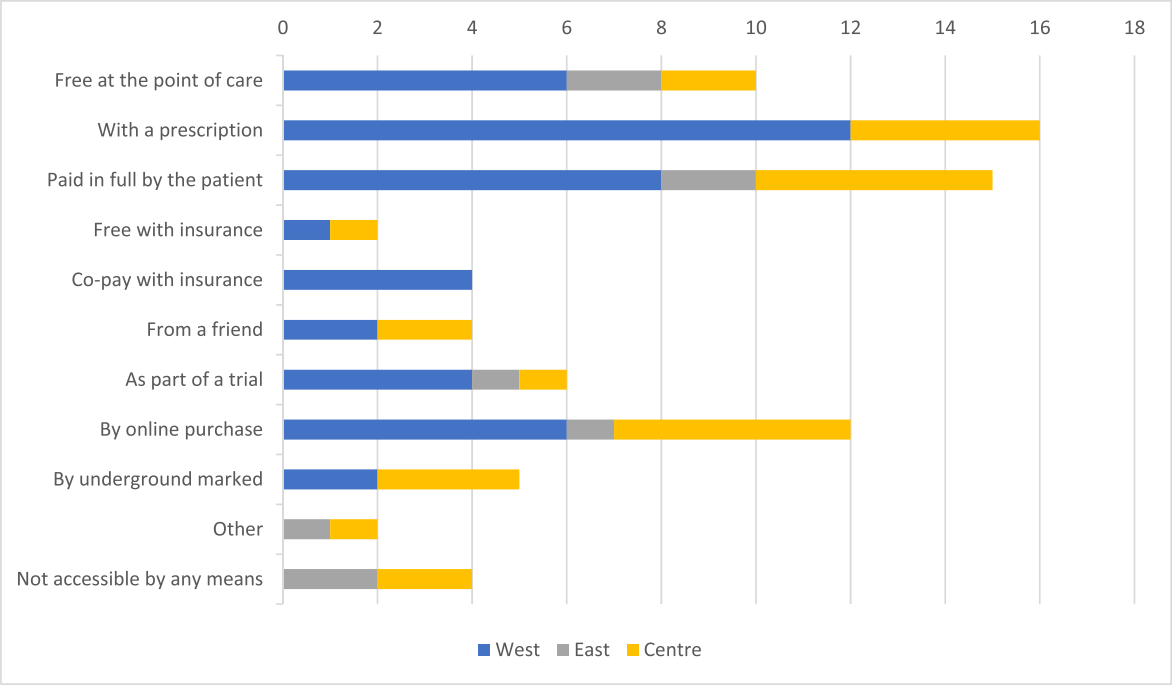

Fig. 1. Main ways of accessing PrEP in the included 34 European countries reporting.

Greece, Romania, and Spain). The respondent from Spain commented that some individuals got PrEP for free by asking for PEP.

(iiii) Four countries (12%) reported that PrEP was not accessible by any means (Albania, Belarus, Kyrgyzstan, and Turkey).

Importing PrEP

Eleven country respondents answered yes to the question of whether importing PrEP via post was legal in their country (32% of the participating countries; Denmark, Finland, Hungary, Kyrgyzstan, Lithuania, Poland, Russia, Switzerland, Turkey, Ukraine, and United Kingdom), but only within the European Union and only for personal use. A prescription was also needed in Turkey and Lithuania. Thirteen (38%) countries reported that it was illegal to import PrEP via post (Albania, Austria, Belarus, Bosnia and Herzegovina, Czech Republic, France, Ireland, Israel, Italy, the Netherlands, Portugal, Serbia, and Slovenia), but the respondents from Israel and Slovenia commented that this was not enforced. Ten (29%) countries responded that they did not know whether importing PrEP via post was legal or illegal (Belgium, Bulgaria, Croatia, Cyprus, Germany, Greece, Moldova, Romania, Spain, and Sweden).

National guidelines

Almost two-thirds of country respondents confirmed the existence of a national guideline for PrEP (n = 23 (68%); Austria, Bosnia and Herzegovina, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Moldova, the Netherlands, Poland, Portugal, Russia, Spain, Sweden, Switzerland, Turkey, Ukraine, and the United Kingdom). Twenty of those countries reported having prescription guidelines (i.e. guidelines relating to the drug prescription itself). Austria, Bosnia Herzegovina, and Belgium reported having provision guidelines (i.e. guidelines relating to the social/political part of PrEP roll out and attitude towards offering PrEP). Eleven countries reported that they did not currently have national guidelines (Albania, Belarus, Bulgaria, Croatia, Cyprus, Greece, Kyrgyzstan, Lithuania, Romania, Serbia, and Slovenia), four of which, however, had guidelines in development but not yet approved by the relevant authority (Belarus, Greece, Lithuania, and Romania). The guidelines in Croatia were approved as of September 2018. Slovenia did not have national guidelines but did use the EACS guidelines.

Six countries reported having specific recommendation for PrEP in women (Austria, France, Germany, Ireland, Ukraine, and the United Kingdom). The comments from France and Austria state that these recommendations were related only to women highly exposed to HIV such as sex workers or women with multiple partners. Among the countries with no specific guidelines for women (n = 20), the comments from Finland, Moldova, Spain and Sweden highlighted that their guidelines were not gender-specific but targeted to individuals at most risk of HIV acquisition. The country respondent from Spain highlighted in the comments that there where specific recommendations on the use of PrEP in pregnant women. Eight country representative reported that they did not know whether there were any national guidelines with specific recommendations for PrEP in women.

Populations prioritized and eligible for PrEP

Of the 30 countries with access to PrEP, 18 (60%) reported that PrEP was accessible for all groups at-risk of HIV acquisition irrespective of gender or sexuality (Austria, Bosnia and Herzegovina, Belgium, Czech Republic, Finland, France, Germany, Hungary, Ireland, Italy, Moldova, Poland, Portugal, Russia, Slovenia, Switzerland, Ukraine, and United Kingdom). However, comments show that provision of PrEP in many countries were guided by specific criteria, i.e. access only for individuals with a high risk or PrEP only being available at major hospitals and/or only after an assessment by an infectious disease/HIV specialist. Among the countries where PrEP was not available to all groups (n = 12), the comments were that PrEP was only accessible for groups deemed at-risk specifically MSM and transgender individuals.

Number of people accessing PrEP via any means

The respondents were asked to provide an estimate on the number of people accessing PrEP by any means and also how those numbers where obtained. Overall, the total estimated number of people accessing PrEP via any means varied across the European Region, from <10 in Moldova

and Lithuania to over 30,000 in France. The number of people accessing PrEP in the East and Centre of the Region is relatively low, and limited official data exists. One exception is Poland, where it is estimated that approximately 1500–2000 people are accessing PrEP. Numbers were obtained through inquiry or surveys at the clinical departments responsible for PrEP treatment.

Formal clinical follow-up

Of the 30 countries where PrEP was accessible 25 (83%) reported that there was a formal clinical follow-up advice for PrEP users. Four countries reported that there was no formal clinical follow-up. In Cyprus and Greece PrEP is only accessible through clinical trials or by purchasing it illegally online, while the respondents from Lithuania and Serbia did not know if there is any formal follow-up for PrEP users.

The most common model of care for PrEP users was a follow-up every three months (n = 18 (72%)), with each visit including an adherence review, drug side-effect review and testing for HIV, hepatitis and sexually transmitted infections (STIs). It was less common to include a pregnancy test, general health promotion advice, and drug and alcohol services, if needed (Table 1).

Table 1
Clinical follow-up among countries reporting PrEP accessibility.

	All countries	West	East	Centre
	n=30	n=16	n=4	n=10
Formal follow-up of PrEP users, n (%)				
Yes	25 (83)	15 (94)	3 (75)	7 (70)
No	3 (10)	1 (6)	0	2 (20)
Unknown	2 (7)	0	1 (25)	1 (10)

Content of clinical follow-up in countries reporting formal clinical follow-up	**An adherence review**	**A side effects review**	**An HIV test**	**An HCV Test**	**Tests for bacterial STIs**	**A Serum creatinine/eGFR/urinalysis for kidneys**	**A pregnancy test, for women not using reliable contraception**	**A pregnancy test, for women using reliable contraception**	**Health promotion advice**
Center region									
Bosnia and Herzegovinia									
Croatia									
Czech Republic									
Hungary									
Poland									
Romania									
Slovenia									
Eastern region									
Moldova									
Russia									
Ukraine									
Western region									
Austria									
Belgium									
Denmark									
Finland									
France									
Germany									
Ireland									
Isreal									
Italy									
The Netherlands									
Portugal									
Spain									
Sweden									
Switzerland									
United Kingdom									

Green = included in follow-up. Red = not included in follow-up

Obstacles to PrEP use

Lack of information about PrEP was the most reported obstacle in the West and East, while PrEP not being commonly discussed as a prevention method was the main obstacle in the Centre of the Region (data not shown). Of the eight countries with reimbursed PrEP, seven countries (Croatia, Denmark, France, the Netherlands, Moldova, Portugal, and Ukraine) stated that lack of information about PrEP was the main barrier for PrEP use. The high cost for the individual (n = 12 (71%)), lack of political support (n = 11 (65%)), and lack of information about PrEP (n = 10 (59%)) were the main obstacles in the 17 countries, where PrEP was accessible, but not reimbursed. In the five countries where PrEP was not officially legally accessible, the main obstacles were lack of political support (n = 3 (60%)), PrEP not being commonly discussed (n = 3 (60%) and PrEP not being officially available (n = 4 (80%)). The most commonly cited obstacles for use of PrEP in the four countries where PrEP was not available were lack of information about PrEP (n = 3 (75%)), lack of political support (n = 3 (75%)), and high cost for the individual (n = 2 (50%)) (See Fig. 2).

Fifteen countries (47%) answered yes to the question of whether there were specific obstacles to PrEP access for women in their country (Austria, Croatia, Denmark, France, Germany, Greece, Israel, the Netherlands, Poland, Portugal, Spain, Sweden, Turkey, Ukraine, and the United Kingdom). Comments were that women are not included in PrEP guidelines nor targeted in clinical studies as they are generally not seen to be at risk for HIV acquisition.

Efforts to encourage women's access to PrEP

Seven countries reported that there were organized efforts to encourage women's access to PrEP in their country (Belarus, Moldova, Poland, Russia, Switzerland, Turkey, and United Kingdom). The comments show that most of these efforts were organised by community-based organisations and NGOs, targeting sex workers, women who were injecting drugs and/or transgender women. For example, in the United Kingdom, the Sophia Forum has developed a website with information on PrEP for women (http://womenandprep.org.uk/), while in Moldova a consortium of NGOs have advocated to pilot community PrEP for all at-risk groups, including sex workers, women injecting drugs and transgender women (https://prepster.info/prep4women/). In Belarus and Poland, there was an effort to increase awareness and knowledge in outpatient clinics and among gynaecologists.

Discussion

This survey study was conducted among EACS members and explored PrEP availability and implementation for women across the European region with the aim of identifying the next steps to make PrEP a successful prevention tool not only for men, but also for women. The results show that knowledge about PrEP, availability and cost varies considerably across the WHO European Region, and overall women's access to PrEP in WHO Europe remains limited. Women are in many countries not seen as a group at risk of HIV acquisition, and therefore not included in guidelines. They are not either targeted with education or information, which results in a general lack of information about the use of PrEP. As highlighted in this study, implementation of PrEP and models of care have in many countries focused on MSM, and recent data from the ECDC estimates that less than 10% of PrEP users in Europe are women (including transgender women) or heterosexual men.[15]

Provision of PrEP for women is most likely limited by multiple factors, including challenges in identifying women with an increased HIV risk.[22] Overall, there is a lack of knowledge about which sub-group of women would benefit the most from PrEP. The EACS guidelines state that "*PrEP may be considered in HIV-negative heterosexual women and men who are inconsistent in their use of condoms and have multiple sexual partners where some of whom are likely to have HIV infection and not being on treatment*".[23] Having a history of partner violence, being recently diagnosed with a STI, and living in a high prevalence area, have also been cited in the literature as characteristics associated with PrEP eligibility among women.[22,24] Perceptions of HIV risk have been reported to be highly gendered and one challenge may be that many women do not consider themselves at risk of HIV acquisition[25,26], particularly if they consider themselves to be in a monogamous relationship. A holistic discourse about HIV risk and risk perception that includes partner, structural and community influences may thus be particularly important for women's uptake of PrEP.[25] Access to PrEP should be based on the actual risk of HIV acquisition, not on the risk group *per se*, so that individuals, irrespective of gender, who, in the opinion of their physician, have a high risk of HIV acquisition should be eligible for PrEP.

Results from several studies suggest that women, when provided with

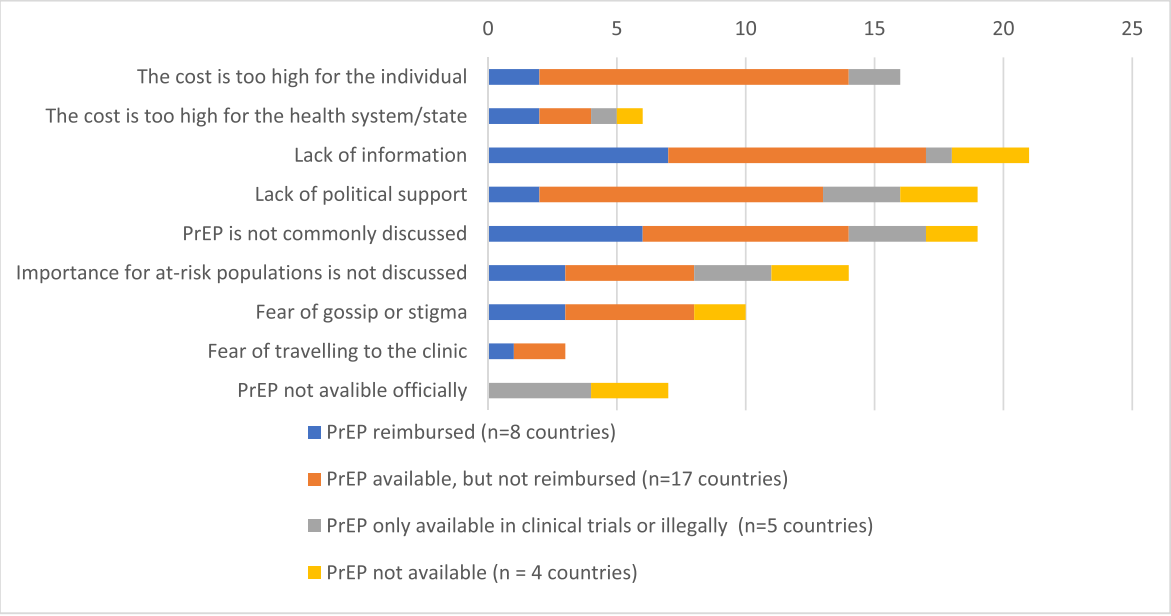

Fig. 2. Obstacles to PrEP use in the 34 countries reporting.

information on the effectiveness of PrEP, are generally keen to take it.[22,25,27,28] However, one challenge to PrEP provision for women is that the awareness of PrEP is generally low among women.[29] In a recent study among 109 African-American women attending a family planning clinic, 80% reported that they were unaware of PrEP being available and 70% reported that they would probably or definitely like to use it.[27] Similar results were reported in a study by Raiman et al.,[30] where two-thirds of HIV-negative cis-women presenting for HIV/STD testing and meeting US criteria for PrEP use were unaware of PrEP.

A barrier mentioned in our study is a lack of availability and general knowledge about PrEP in many of the included countries. Women who may be at risk of HIV may not be accessing specialised clinics unless they have a condition which warrants examination.[17] Moreover, cultural, social and religious norms, such as patriarchal values and culturally prescribed gender roles, may contribute to women's lack of knowledge about PrEP and access to PrEP services.[31,32] Thus, integrating PrEP into primary health and reproductive health services for women may enhance access and awareness of PrEP among women.[12] Goals for the future must include making it available and visible for women at risk of HIV acquisition. This would include improved knowledge but also requires support to overcome barriers such as cost, low self-esteem and stigma, which still remain significant for women.

To our knowledge, this is the first study to explore PrEP access for women in Europe. It has several limitations. First, only 34 out of 51 countries within the WHO European Region responded to the survey. Although the survey invitation was sent to all members of WAVE, the aim was not for all invited participants to answer the survey, but to get one response per country completed by those who are prescribing PrEP in the country. Thus, the invitation targeted clinicians, researchers and community activists thought of as being in a good position to give relevant and trustful answers because of their expertise. However, it is unclear if the respondents have been able to capture fully accurate data on PrEP at a national level. Thus, our findings reflect clinician and community activists' knowledge on PrEP for women in the responding country, rather than state-provided data from health authorities. Second, there is much variability in terms of the implementation of PrEP across Europe, making it difficult to describe the details of our results across the whole region. Finally, the survey included several open text answer options, making it difficult to categorize the different responses. However, the open text responses provided details elaborating the quantitative data.

Conclusion

Awareness and accessibility of PrEP for women in Europe are still very limited and not as equitable as for MSM. There is a general lack of information about the use of PrEP in women. Thus, it seems to be crucial to enhance the understanding of how to increase PrEP awareness among women and healthcare professionals, to improve knowledge about PrEP for women and enable the development of a successful prevention tool specifically designed for women.

Contributors

BC, YG and KAP had the original concept of the study. JK, MV, MJPE, and GC contributed to the design of the study and the collection of data. EM wrote the first draft of the manuscript with KAP, all other authors contributed to the interpretation of data, writing of the report, and approved the final version.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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