Eurasian Coalition
on Male Health

REPORT

Assessment of the Availability of PrEP, the Main Barriers to Implementing PrEP, and Scaling Up PrEP in the EECA Region

Eurasian Coalition
on Male Health

Assessment of the Availability of PrEP, the Main Barriers to Implementing PrEP, and Scaling Up PrEP in the EECA Region

Report

Prepared by:
M. Kornilova,
Independent Consultant;
G. Roshchupkin,
Community Health Systems Coordinator,
Eurasian Coalition on Male Health

Table of Content

List of Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Treatment
ARV	Antiretroviral
CBO	Community-Based Organization
CDC	US Centers for Disease Control and Prevention
ECOM	Eurasian Coalition on Male Health
EECA	Eastern Europe and Central Asia
EU	European Union
FTC	Emtricitabine
GF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HBV	Hepatitis B
HIV	Human Immunodeficiency Virus
KP	Key Population
MSM	Men Having Sex with Men
MoH	Ministry of Health
NGO	Non-Governmental Organization
PEPFAR	President's Emergency Plan for AIDS Relief
PLH	People Living with HIV
PrEP	Pre-Exposure Prophylaxis of HIV
STI	Sexually Transmitted Infections
TDF	Tenofovir
UN	United Nations
UNAIDS	Joint United Nations Program on HIV/AIDS
WHO	World Health Organization

Executive summary

This report presents the results of an assessment on the availability of pre-exposure prophylaxis (PrEP) in the countries of Eastern Europe and Central Asia (EECA). This assessment was conducted by the Eurasian Coalition on Male Health (ECOM) between July and September 2018. The study was aimed at collecting information on and forming an overview of ongoing PrEP projects, learning about plans for scaling up of these projects, identifying the main obstacles and barriers that hinder the initiation and scale-up of PrEP in the region, and at developing recommendation on how to address these barriers.

The assessment utilized different methods to collect information, such as an on-line structured questionnaire, in-depth interviews with key participants, and a desk review of national strategies, guidelines and other official documents regulating access to PrEP in the countries assessed. The participants of the assessment represented various actors working in the field of HIV services: non-governmental organizations (NGOs), including those led by representatives of key populations (KP) (community-based organizations (CBO)), medical facilities that provide HIV treatment and care, and United Nations (UN) agencies. Seventeen countries were assessed: Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Macedonia, Moldova, Russia, Slovakia, Ukraine, and Uzbekistan.

As a result of this assessment, we identified the following:

- The availability of PrEP in the EECA region is poor. Only two countries out of 17, Georgia and Ukraine, have fully developed ongoing pilot projects, each providing 100 annual PrEP courses for men who have sex with men (MSM) and trans* people. At the time of assessment (September 2018), Moldova had just began a PrEP pilot project prioritizing HIV discordant couples as the primary target group. In addition, three other countries announced that they plan to start piloting PrEP in 2019: Kazakhstan, Russia and Kyrgyzstan.

- The remaining 11 countries assessed in the study declared a general interest in PrEP, but have not developed clear plans for piloting this initiative, nor have identified sources of funding for even a small program.

- Truvada and corresponding generic combinations of the drug are registered in all the countries surveyed, but required for using Truvada as PrEP clinical protocols developed only in Georgia, Ukraine and Moldova. A short, schematic description of providing PrEP is included in the Ministry of Health (MoH) Guidelines on HIV Prevention and Treatment in Armenia, but, in its current form, cannot be considered as a full-value protocol.

- PrEP is part of the National HIV Strategy in 3 countries: Georgia, Moldova and Armenia. However, as the example of Armenia shows, the formal inclusion of this intervention in policy guidance documents does not guarantee the actual establishment of the service, as there are no clients receiving PrEP in Armenia yet.

- The main barriers to the initiation and implementation of PrEP programs are the lack of demand due to low levels of knowledge and experience with PrEP, and the significant disconnect between potential clients and key gatekeepers such as medical practitioners and health officials. These are the core issues that need to be urgently addressed by spreading knowledge and information about PrEP through all means possible. Comprehensive information about what PrEP is and about why it is needed and effective, must be available to and reach all target audiences, including KP, medical practitioners, other HIV service providers and, of course, decision makers.

- There is also a need for both country- and regional-level advocacy efforts to push governments and international stakeholders to include PrEP in national strategies and legislative documents guiding the HIV response, and to allocate technical and financial resources to make PrEP available in the region for all who need it and would like to receive it following promotional campaigns.

- Experience from pilot projects suggests that PrEP needs to be geared more closely towards clients. This means that PrEP and related services should be available not only in HIV and medical facilities, but also in community NGOs serving the targeted populations. To achieve this, stronger working collaboration between governmental and community-based entities is required. This entails collaboration that goes beyond mutual referral of clients, and that includes actual joint work and the establishment of sustainable mechanisms of national (private and governmental) support and funding for community NGOs and advocacy groups.

Based on the results of the assessment, no insurmountable barriers were identified that would make PrEP implementation impossible in any of the countries assessed. The implementation and scaling up of PrEP programs in the EECA region is realistic in the short term, provided there is support for comprehensive informational and advocacy campaigns, high demand from the community, endorsement from professionals in the field, well-developed, mutual cooperation between governmental and non-governmental structures, and, where necessary, international technical and financial support.

Background

There is a lack of published empirical studies describing the demand, distribution and use of pre-exposure prophylaxis (PrEP) in Eastern Europe Central Asia (EECA). From what is known to date, PrEP as well as treatment as prevention are not adequately addressed in this part of the world. In 2015, the World Health Organization updated its guidelines on the use of antiretroviral therapy (ART) in managing HIV infection to include the use of PrEP (i.e.tenofovir disoproxil fumarate and emtricitabine, marketed as "Truvada" in the global market) in high-risk populations[I]. The effectiveness of PrEP as a method of HIV prevention among MSM has already been proven, and the drug is currently is being evaluated as a method of HIV prevention among other key populations (KP), such people injecting drugs, sex workers and regular sexual partners of people living with HIV (PLH). The 2010 iPrEx study conducted in the United States demonstrated the effectiveness of a daily dose of oral tenofovir and emtricitabine as PrEP against HIV in human subjects[II]. Furthermore, the 2015 French IPERGAY study demonstrated a similar effectiveness of an on-demand regimen of oral tenofovir and emtricitabine[III]. Cost-effectiveness studies in the United States have shown a substantial decrease in HIV incidence when PrEP is being used, and recognized that PrEP is economically efficient despite the current high costs of the drug in that country[IV,V]. Available data examining the acceptability of PrEP among high risk populations demonstrates a general willingness to use PrEP[VI,VII].

The goal of this assessment is to evaluate the use of PrEP as an HIV prophylaxis among KP, with a primary focus on MSM in EECA. An additional objective of this assessment was to explore the factors that prevent the selected countries of the region from using PrEP as a tool for HIV prevention, such as barriers to the procurement of supplies and medications (ARTs, PrEP); provision of services (e.g., testing, counseling, follow-up care); knowledge gaps; role of stigma and discrimination; and barriers to accessing the services. The evidence synthesized through this assessment will provide a basis for advocacy efforts and for scaling up the use of PrEP in the region, and will also inform programming and research focused on PrEP.

Goals and Objectives of the Assessment

Goal #1:
Evaluate the use of PrEP as a method of HIV prevention in the selected countries of the EECA region; and assess various aspects related to the implementation and scale-up of PrEP programs.

Goal #2:
Identify legislative, structural, and community barriers, as well as other factors, such as the lack of knowledge, information gaps, stigma and discrimination, low adherence, and access to services, that affect the use of PrEP as an HIV prevention measure.

Goal #3:
Identify ways of addressing barriers to the implementation and scale up of PrEP programs, and develop recommendations to support advocacy efforts and to inform programmatic decisions.

Methods

The assessment utilized a mixed method of data collection. It consisted of three phases: an on-line structured questionnaire, followed by semi-structured in-depth interviews, and finally a desk review of the relevant documents.

The on-line study consisted of 46 questions accessible through the on-line platform SurveyMonkey. The questionnaire was available in two languages: Russian and English. Participants could choose their preferred language to answer the questions. The questionnaire consisted of one-choice, multiple-choice and open-ended questions and was aimed at collecting as much preliminary information on the availability of PrEP in EECA countries as possible. All respondents were requested to provide their contact details for the follow-up in-depth interviews. Those who did so, participated in an additional question-and-answer session carried out over the telephone or through on-line conversations. Respondents were also requested to provide any documentation related to PrEP for the desk review. This documentation included clinical protocols, normative documents regulating the provision of medications, or legislative acts that officially include PrEP as an HIV prevention intervention.

Respondents represented a wide range of people involved in the provision of HIV-related services and included representatives of NGOs, government, UN organizations, service providers and clients.

The following countries were included in the assessment (17 in total): Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Macedonia, Moldova, Russia, Slovakia, Ukraine, and Uzbekistan.

Results

Availability of PrEP in the region of Eastern Europe and Central Asia (EECA). General overview

Despite the fact that PrEP was proven to be a highly effective HIV prevention intervention 6 years ago, its availability in the region surveyed remains extremely limited. Only two countries out of the 17 surveyed in the assessment have fully-developed, ongoing pilot projects: Georgia and Ukraine; one additional country, Moldova, had just began piloting PrEP at the time the assessment was carried out. PrEP is officially included in the National HIV Strategy in Armenia and mentioned as a method of HIV prevention in MoH guidelines, but is only available in AIDS Centers as a paid service. There is not a single client receiving PrEP in Armenia, and there are no national targets regarding coverage with PrEP services.

Another example is Slovakia, where PrEP is available only at the client's expense, however, community NGOs provide support in purchasing the medication at a more affordable cost and in linking up clients with trusted doctors who carry out medical check-ups before and during the admission of the drugs. Nevertheless, these efforts cannot be considered as a sustainable service, since they depend solely on the level of the client's own awareness, responsibility and financial capacity.

Several countries have declared that they are interested in and have made plans for implementing pilot projects, but these plans are generally vague and are not reflected in any financial or legislative changes. This means that there is generally no donor, governmental, or any other kind of support available for making PrEP accessible to all in need.

However, pilot projects are currently being developed in Georgia, Ukraine, and Moldova. These pilot projects consist of several phases. In Georgia, the first stage of PrEP implementation, carried out before the actual start of the pilot program in 2017 included a training session for those involved in the pilot, a needs assessment conducted among Georgian MSM, as well as capacity building for local NGOs. The same preparatory measures were implemented in Ukraine. So far, Moldova has only trained medical specialists involved in the provision of PrEP, however, there are plans to train community representatives in 2019 with technical support from UNAIDS. In Central Asian countries, there seems to be less interest in PrEP. Nevertheless, the state medical systems of Kazakhstan and Kyrgyzstan have already made the first steps toward starting their PrEP pilot projects in 2019.

Challenges regarding the introduction of PrEP in EECA may include the cost of the intervention, as well as the high levels of stigma and discrimination towards PLH and key populations in the region. However, with HIV incidence in EECA having increased by 57% between 2010 and 2015[VIII], antiretroviral treatment (ART) alone will not stop the epidemic. This is especially true due to the ineffective centralized system of procurement and supply management for antiretroviral (ARV) medications, which contributes to the low level of coverage with ART in the region, which is far from reaching the 90-90-90 target. Given its proven effectiveness, the provision of PrEP to key populations can be a significant step in controlling the explosive growth of the HIV epidemic in EECA countries.

Models of service provision in the countries implementing PrEP pilot projects in the EECA region

☐ **Georgia** began a PrEP pilot project in August 2017.

This work is funded by the Global Fund (GF) through the National Center of Disease Control and Prevention. As of today (September 2018), the total number of clients on PrEP is 100 people, and the majority of these clients have already been on PrEP for approximately 1 year. 25 people have dropped out of the program. The target groups of the intervention are MSM and trans* women. Currently, no other KP are enrolled in the program, but they may be considered as the next target for PrEP after 2020. The Georgian model of PrEP delivery is mainly based in medical facilities, meaning that the majority of services are provided at the Infectious Disease, AIDS and Clinical Immunology Research Centre. This is the place where clients receive the drugs, and HIV, Hepatitis B (HBV), and other STI tests, and where monitoring of kidney functions is carried out. Recruitment and the provision of social support are conducted by the community GBT organization, "Equality Movement". These activities include informing community members about the project and encouraging them to participate, screening applicants for eligibility, providing adherence and risk reduction counseling, and social support, as well as overseeing case management.

The project is currently only being implemented in Tbilisi. Only one PrEP regimen is used, a daily uptake of the drug. Informational support consists of informational brochures for patients that describe the proven effectiveness of Truvada, and dispel the most common myths and superstitions about PrEP; "patient's schools" with trusted doctors facilitating discussions and answering questions about PrEP; the use of social networks, mainly Facebook, for advertising the initiative; and peer-to-peer transmission of information about PrEP.

The respondents emphasized that spreading information through peers and social networks has worked particularly well for recruiting clients to the project.

At the time the assessment was conducted, the country was completing the client satisfaction survey, the results of which will be presented at the end of September 2018, and will provide a basis for the further improvement of the project model, in order to make the service delivery model more convenient for a greater number of potential clients. This is especially important in view of the upcoming scale-up of the program. The scale-up is scheduled to be carried out through 2020 and will include the expansion of the program to two other cities: Batumi and Kutaisi, as well as the enrollment of an additional one hundred clients. The scale-up will also pilot a community-based model of PrEP provision with clients able to pick up their medication at the offices of the "Equality Movement" organization. Clinical monitoring of clients who prefer the community-based model of PrEP delivery is currently under discussion and will require some modifications to the clinical protocol.

The scale-up will be funded by the GF until the end of 2020, followed by a shift to government funding. A distinguishing feature of the Georgian case, which differs from other countries in the region, is that PrEP is included in the National Strategic Plan as part of the HIV prevention package. This increases the probability of national funding for PrEP services following the exit of the GF.

Although the pilot project in Georgia can be considered a success, there are still some barriers that need to be resolved before it is scaled up.

The information gap is one such barrier. There is a significant lack of knowledge among KP about PrEP. Meanwhile, there are no funds available for a widespread and long-term informational campaign about PrEP. This creates problems related to demand and to the recruitment of clients for PrEP projects. There are also many misconceptions about the medication that are circulating in the community, which has a high level of mistrust towards pharmacological substances. This gap was addressed to a certain extent through peer-to-peer knowledge exchange and through the distribution of information on social networks (Facebook, dating apps, etc.). The most popular misconceptions were listed and dispelled in printed materials developed by the community organization and through doctor consultations in individual or group (so-called "patient's schools) sessions.

Another big problem is the excessive "medicalization" of the intervention. The medications are currently available in only one medical facility (the Republican AIDS Center). In accordance with the clinical protocol, clients must have blood tests performed every two months, while the pills are distributed monthly. The working hours of the AIDS centers are not convenient for people who have a full-time job. Moreover, there is no separate line or waiting room for PrEP clients, meaning that they must wait in the general queue with other patients, which significantly increases the waiting time. These factors are clearly discouraging and could either prevent people from enrolling in the PrEP program or increase the drop-out rate, which is already high (25 people have already dropped out of the program). These obstacles are being taken into consideration for the planned scale-up phase, when PrEP will be available at the community-based GBT organization "Equality Movement". However, this will only be in Tbilisi, and not at the newly included sites (Kutaisi and Batumi).

There is only one regimen, a daily dose, which is described in the clinical protocol and therefore available under the pilot project. The possibility of introducing an on-demand regimen is under discussion, however, there is no specific timeline on how soon this would be made available. Nevertheless, local experts admit that it is necessary to introduce PrEP on-demand and plan to work on amending the clinical protocols. Currently, the ARV medication used for PrEP is available in Georgian pharmacies, as well as in international online shops. This creates the theoretical possibility of purchasing and using PrEP outside the framework of the pilot project, which may be beneficial for non-Georgians who are temporarily or permanently residing in the country, as all the services provided under the pilot project, including informational support and counseling, are only available to Georgian citizens.

- **Ukraine** began its PrEP pilot project on 29 January, 2018 with the financial support of the President's Emergency Plan for AIDS Relief (PEPFAR).

The project is located in Kyiv and, as of the beginning of September 2018, has reached its ceiling of 100 clients receiving PrEP, not counting 12 clients who dropped out and 1 client who was diagnosed as HIV-positive after 3 months of being on PrEP. The project targets MSM and trans* people and uses a combination of a community-based and a medical facility-based model with a maximum uptake of the community-based model.

The NGO, "Alliance Global", carries out a wide range of activities for the program, including recruitment, behavioral risk assessment, HIV and HBV screening, provision of HBV vaccinations, case management, and the provision of social support for PrEP users. It is possible to receive a number of services directly through the CBO: case managers can pick up medications at the organization, and there is a nurse that comes to the office of the organization to perform medical tests. The program works with five trusted doctors who were trained by the leading medical specialist involved in IPERGAY study.

Implementation of the pilot project is being carried out based on the local protocol approved by the Kyiv City Department of Health. The regimen used, as dictated by the clinical protocol, is a daily uptake of the drug. An on-demand regimen has not been discussed, as the project is funded by PEPFAR through the US Centers of Disease Control and Prevention (CDC), and at the time of the development and approval of the clinical protocol, only a daily uptake regimen was approved in the US.

There are plans for a significant scale up of the PrEP program throughout the country. Through the support of the GF and PEPFAR, there is a possibility to procure PrEP courses for 3500 new clients. However, there are still no available funds for a nation-wide informational campaign or for the provision of social support for the thousands of prospective new clients. Many other questions remain: how to ensure medical follow-up, if there is no money allocated to covering the clinical monitoring component; who will support the massive capacity building efforts required among medical professionals and among NGOs? There are presently no national clinical guidelines for PrEP. The guidelines that currently exist were developed at the local level and can only be used in the medical facility where they were developed (for now, this means only in the City Clinical Hosital #5, Kyiv). There is no national strategy yet which would ensure the legal status of PrEP as an essential component of HIV prevention. Under these circumstances, it is not very clear how such a massive scale up, from 100 to 3500 clients, will be achievable.

As of the end of September 2018, the pilot project in Ukraine had not yet been evaluated. However, the respondents who participated in this assessment have underlined almost the same barriers as previously described in the Georgian project. The lack of information among potential clients creates a lack of demand. In addition, according

to the opinions of the respondents, the excessive medicalization of the intervention does not create a positive environment for recruiting new clients or for retaining ones already participating in the project. Respondents also mentioned that there is a long way to go in order to change the attitudes of service providers, especially those who work in the medical field, so that they treat PrEP users not as a patients, but as clients of prevention programs.

Another noteworthy initiative in Ukraine, which began in July 2018, is carried out by The PrEPster[1] team. It is aimed at helping to spread knowledge about PrEP among medical professionals through the development and distribution of a Q&A booklet about PrEP, and at enabling people to purchase PrEP via an on-line service at a negotiated price (it currently costs approximately USD 25 per month for the purchase of a 6 month course). This price was fixed with the manufacturers of generic TDF/3TC and is the same cost for orders made through the PrEPster web-site as in other European countries (e.g. Great Britain). Customs legislation permits the duty free import of goods, including medications, for personal use at an amount no greater than 150 euros. Once again, this represents a good opportunity for non-citizens and for those, who are not part of the on-going pilot project, but who want to receive PrEP now.

☐ The latest country to join the "PrEP club" is **Moldova**.

At the time the assessment was carried out, Moldova had already launched a PrEP initiative free of charge. PrEP is available in all 8 facilities (HIV units) that provide ART throughout the country. Next year, the unrecognized state of Transnistria will also be included in the initiative. The medical staff of all of the HIV units underwent training on the clinical aspects of PrEP in May-June 2018. A national clinical PrEP protocol has been developed (which is also available in Russian for Transnistria) and the medications have been procured. As in the case of Georgia and Ukraine, a daily uptake is the only regimen used. The primary target group are HIV-negative partners in HIV discordant couples whose sex partners have not started ART or have not yet reached viral suppression. MSM are the secondary target group being considered for this program. As of August 2018, only two clients were enrolled in the program. Currently, Moldova is only using a medical facility-based model of service provision. The involvement of community NGOs is envisaged to being in 2019 with the support of UNAIDS. However, the exact form of their participation is not clear yet.

Georgia, Ukraine and Moldova are the only three countries in the region that have PrEP programs free of charge, even though they are limited in scale. Other countries that participated in the assessment, including those that are European Union (EU) members, do not have PrEP programs provided through their national healthcare systems. It is possible to purchase medications either in local pharmacies or on-line. However, all expenses related to the procurement of the medications, as well as the costs of clinical tests and check-ups before and during the admission of the drugs, must be covered by the client him/herself. Moreover, there is no kind of medical insurance, which would cover the costs for PrEP and related services.

1 The PrEPster is a UK based support service for PrEP users.

The situation in Armenia is unusual, as PrEP is part of the National Strategy on HIV, but there is no guarantee for the provision of PrEP free of charge. Instead of issuing a special protocol, PrEP in Armenia is regulated based on a separate chapter in the ARV treatment guidelines issued by the MoH. PrEP is offered by the AIDS Centre on a paid basis only. Clients have to pay approximately 215 USD for screening, medical tests, consultations and for the prescription of Truvada. The price is very high for the country, where the average monthly salary is 260 USD. So far, no clients have expressed an interest in the governmental PrEP service in Armenia.

Other elements affecting access to PrEP in countries that do not have PrEP programs offered through their healthcare systems

The countries covered in the assessment use different approaches to introducing PrEP, which are mainly focused on creating opportunities to purchase the medication at a lower cost or on linking clients to "trusted" doctors who can provide basic counseling services and monitor blood tests. One such examples is Slovakia where the brand Truvada and local generic drugs are available in pharmacies, however the prices for these drugs are as high as EUR 413 for Truvada and EUR 275 for a generic combination of tenofovir/emtricitabin. Under these circumstances, a local CBO has established a service for procuring the medications at a much lower cost (EUR 70 including shipment) from Germany through the Czech Republic.

There are also services, such as Dynamics International and Green Cross pharmacies, which were established with the aim of helping people purchase the drugs at a price lower than they are offered on the regular market. However, the custom regulations of different countries are not always friendly to those who would like to import medications even for personal use. For example, Hungary only allows a one-time tax-free shipment of medications, which essentially prevents the use of these services for those wishing to purchase PrEP on a regular basis.

Nevertheless, even in countries with liberal customs legislation, creating demand for PrEP is always the first issue.

Plans for scaling up PrEP in the region

Although the assessment showed that there is a high level of interest in PrEP in nearly all of the countries surveyed, only three have developed plans for launching PrEP pilot projects from 2018. In Kazakhstan, an agreement with the donor is at its final stage. The project will be led by the National AIDS Centre in collaboration with AFEW International. Although the exact model of service provision has not yet been determined, previous experience suggests that the medical facility-based model of PrEP provision will be chosen, with CBO involved in providing information to the community, recruiting clients, and providing social support and adherence and risk reduction counseling. According to the current plans, the procurement of medications will also be carried out through the NGO, which will then deliver them to the medical facility for further distribution to the PrEP clients.

The second country to announce that a PrEP pilot project will be launched in the second half of 2019 is Russia. However, based on information from the country, it is possible that the introduction phase may take longer than expected, as Truvada has only been approved for use in HIV treatment regimens; approval for its use as a prevention intervention requires additional paperwork (an amendment to the medication registration portfolio) at the ministerial level. So far, no clinical protocol has been developed, nor has any target group been identified (discordant couples and/or MSM are the focus of current discussions). Moreover, knowledge about PrEP among KP and medical professionals is quite limited. Nevertheless, given that announcements have been made by federal-level research institutions (Federal AIDS Center, the National Research Center of Phthisiopulmonology and Infectious Diseases), and that the federal budget has been proposed as a source of funding, the PrEP pilot project in Russia may become a reality.

At the end of September 2018, Kyrgyzstan received confirmation of funding for a PrEP pilot project and began developing the plan for it. According to the plan, the first phase of the project will consist of determining the primary target group for the intervention by conducting focus groups among different KP. In 2019, the Republican AIDS Centre will procure the medications and begin implementing the intervention among one or several target populations depending on the results of the focus groups and the interest expressed by KP.

Other countries reported that there is a general interest in piloting PrEP initiatives, but any plans to do so are very vague, as there is currently no funding available from national budgets, donors, or other sources. Governments in these countries are not ready to start sponsoring such initiatives as there is no pressure from advocacy work by either medical professionals or KP. The current level of knowledge about PrEP among medical specialists and communities in the region is too low to adequately create demand for the drug or to ensure that stakeholders are advocating for its availability. Existing data demonstrates that PrEP is cost-efficient, particularly among populations with low access to ART and a high risk of HIV infection[IX]. Nevertheless, in countries where not all PLH receive ART, PrEP is seen as a controversial drug and raises ethical questions ("why should we spend our limited money on PrEP, if there are many PLH who still do not have access to ART?").

Conclusions

Although progress has been made in the region, with three countries initiating PrEP pilot projects, there is still a long way to go before PrEP is made available to everyone who needs and wants to use this method of HIV prevention. The current assessment demonstrates that there are some positive factors which help make the implementation of PrEP programs feasible almost everywhere in the region. Truvada and a generic version of the drug are registered and being sold everywhere in the region. Although it is not registered as a medication for HIV prevention in Russia, it can still be used for research purposes. All of the countries surveyed in the assessment have expressed an interest in launching PrEP, and a number have mentioned that they already have plans to begin PrEP programs in 2019-2020. Clinical recommendations on PrEP have not been developed outside of the countries that are already implementing PrEP interventions. However, experience shows that clinical guidelines can be developed relatively quickly, as the World Health Organization (WHO) and CDC have already published recommendations on PrEP, and protocols from the pilot project of more experienced countries are available and can be easily adopted for any local needs.

It is possible to buy a generic combination of tenofovir/emtricitabin at a lower price through specially developed on-line services (Dynamics International and Green Cross pharmacies), but in order to do this one has to know about PrEP, find a doctor who can help with the initial and follow-up medical examinations, and be sufficiently motivated to adhere to this method of HIV prevention. Currently, the level of self-use of PrEP in EECA countries is very low.

The following barriers to the implementation and scale up of PrEP programs were identified during this assessment. Strong, continuous efforts are necessary to overcome these multiple and diverse barriers.

Barrier #1. Information gap

One of the biggest and most significant barriers is not the lack of availability of PrEP drugs, but rather a severe lack of knowledge about PrEP as an HIV prevention intervention among gay men, other MSM, trans* people and other KP that could potentially benefit from PrEP. This lack of information alone creates the largest obstacle to seeing the benefits of PrEP in EECA countries. Even when potential users have “heard something about PrEP”, they often have many misconceptions and misbeliefs. This is true even among specialists working in HIV services. The most common misconception is that PrEP is only offered in clinical trials and that its effectiveness has not yet been proven. Other common misconceptions are that the medication causes strong side effects, and that STIs are spread

because PrEP users are engaging more often in unprotected sex. Dispelling these misconceptions and increasing knowledge about PrEP among the community is one of the first steps that needs to be taken before beginning any further activities.

Barrier #2. No demand from potential clients

Even in places where there are no programs in place that ensure the provision of PrEP through the healthcare system, it is always possible to undergo the necessary tests in commercial laboratories, find relevant specialists to provide consultations, and to purchase the medication at affordable prices at the client's own expense. According to respondents, however, MSM and trans* people do not use this opportunity to protect themselves from HIV infection. The reason for this is partly due to a lack of information, however, disseminating information alone will not automatically increase demand. PrEP, as with many other highly effective public health interventions (i.e. vaccinations, family planning, etc.), needs a positive image to convince potential users that they can benefit from this service. Using positive role models and basic marketing strategies to promote PrEP may be an effective way to popularize the intervention. In turn, clearly and proactively showing authorities that there is demand for the intervention may push governing bodies to allocate sufficient resources to PrEP programs.

Barrier #3. Lack of commitment from medical professionals and health officials

Lack of awareness about PrEP, and the common misconception that "PrEP will open the door to unprotected sex" results in a lack of advocacy support from people developing national HIV responses and policies. Another problem highlighted by respondents from several countries (Russia, Bulgaria and Ukraine) is the challenge of achieving a proper balance between addressing treatment needs and developing effective prevention interventions. Many respondents stated that it is difficult to respond to the question whether it is ethical to provide the ARV drug for prevention purposes when not all PLH are receiving treatment (although recent studies show that PrEP is significantly reducing the incidence of HIV[x]).

Barrier #4. Limited funding

All three PrEP pilot projects that are currently being implemented are funded by international donors. Scaling up the Georgian and Ukrainian projects will also be carried out with funding from the GF and PEPFAR. Although governments are gradually assuming responsibility for the funding of prevention interventions, they are not yet ready to invest state and municipal funds in PrEP programs, and do not yet have a strategy on how to create a supportive environment for those who can pay for PrEP themselves.

All respondents from countries that would like to introduce PrEP programs stated there is a problem with finding funding even for small-scale PrEP projects. Given that the main, traditional international donors, such as the GF and PEPFAR, are planning to exit the region, finding additional funding will not be easy. This also applies to the individual, but important, elements of the PrEP program, which go beyond simply distributing the medication (i.e. creating demand, providing social support and encouraging adherence, capacity building, etc.).

Barrier # 5. Excessive medicalization of the intervention

This was one of the most common responses given by respondents from countries that already have experience with PrEP. Using the term "medicalization", the respondents noted that:

- the provision of services through medical facilities often automatically entails the feeling of being a patient, as there is generally no separate premises for PrEP clients and HIV-positive patients; and that
- there is a need to regularly adjust one's personal schedule to the working hours of the clinic, and make visits too frequently to pick up medications and perform blood tests.

The fact that a majority of healthy people (who are a target population of PrEP programs) do not generally tend to visit healthcare facilities unless there is a real reason for it, the medicalization of prevention services, and PrEP is not an exception, is a strong reason for the resistance to enroll in PrEP programs and a frequent cause of drop-outs from programs. The respondents have proposed a simple solution to these problems: moving services to community-based facilities, such as community NGOs, thereby bringing PrEP closer to clients.

Barrier #6. Stigma and discrimination

Stigma is a particular issue related to PrEP, as the intervention is most commonly used by and associated with MSM, which can create an uncomfortable situation in some instances, if a client comes to receive his drugs and the doctor knows that he is an MSM. In countries that are hostile to LGBT people, this situation can be even more problematic and can lead to a reluctance to be enrolled in PrEP programs in order to avoid discrimination and the disclosure of sensitive confidential information from medical facilities.

Barrier #7. Insufficient political and legislative support

PrEP is a part of national strategies regulating the HIV response in only three countries (Georgia, Moldova, and Armenia). This is becoming more and more important in view of the upcoming phase out of the GF from CEECA countries. The absence of any provisions on PrEP in national strategies puts the sustainability of this intervention at risk in countries that have already begun PrEP programs.

Recommendations on Addressing Barriers.

All participants have been asked to provide recommendations and their opinions on what would help to facilitate the availability of PrEP and the scaling-up of this intervention in their respective countries and in the region as a whole. These recommendations were analyzed and the most common and feasible ones are presented below. The vast majority of the recommendations are provided by respondents from countries implementing PrEP pilot projects.

1. Create an informed and conscious demand for PrEP in the community

This is the first step that should be taken before any further activities. A service may be excellent, but if the clients do not know about the benefits of the interventions offered, they will not use them. If the target population does not know what PrEP is and why they would need it, they will not start requesting and using it.

This can be done through continuous distribution of accurate information about PrEP, its advantages and about what makes it different from traditional HIV prevention methods. The most obvious way to do this would be through widespread, national informational campaigns, and by posting advertisements on popular informational resources (i.e. dating applications for MSM, magazines, and social networks, such as Facebook, VK, Instagram, Telegram). Potential clients should be informed about this method of HIV prevention, its effectiveness, have a clear understanding of whether this method would work for them, and should know how to obtain it.

2. Dispel myths and misconceptions about PrEP.

This recommendation implies not only the dissemination of information, but also more in-depth, thorough and detailed work with clients, medical professionals and other HIV service providers on dispelling myths and misconceptions that they may have about PrEP. The most common misconceptions are that: PrEP is still a medication for clinical trials and that its safety and effectiveness are still being tested; there are multiple, frequent, and severe side-effects; and that PrEP is encouraging risky behavioral practices. Dispelling these misconceptions is an important task requiring thorough work to counter each of these myths by providing evidence-based information targeting the different audiences involved. The Georgian experience, for instance, shows that developing special

materials aimed at dispelling popular myths surrounding PrEP, as well as arranging "PrEP schools" facilitated by trusted and experienced medical practitioners could be effective ways to address the problem.

3. Increase cooperation between community activists and medical professionals from different countries to exchange knowledge on successful experiences implementing PrEP programs

Collecting and presenting success stories about the implementation of PrEP programs is a relatively simple, but powerful strategy that uses the peer-to-peer approach at the country level and allows people to learn from the experiences of others. In the EECA region, there are already two successful pilot projects from which other countries that are ready to pilot their own initiatives can learn. The experiences of Western European countries, such as France, Belgium and the United Kingdom, can also be shared with the help of specialists from these countries. Inviting the PrEP coordinator from the European Centers for Disease Control and the medical doctor directly involved in the IPERGAY study to the preparation stage of the Ukrainian project was a big asset to the development of the implementation strategy and to building the capacity of the people involved in the project's implementation.

4. Provide health officials and specialists from medical institutions and NGOs with technical support on planning and implementing successful PrEP programs

Although there are sufficient resources and peer-reviewed literature on PrEP, many health managers and medical practitioners in the region are unaware of this. Most of the resources are only available in English, and few people in the region know this language well enough to be able to read these materials. This issue can be resolved by translating and distributing the most relevant publications. Another recommendation is to make pocket leaflets ("cue cards") with basic, core facts about PrEP, eligibility criteria for PrEP offering, key messages activists and organizations can address to communities (potential clients), as well as with parameters for clinical monitoring.

Another way to disseminate information to health managers and practitioners is to conduct thematic round tables, webinars and workshops, in a way that many professionals as needed will be reached.

Pharmaceutical companies could be potential allies, as they also have an interest in ensuring that the products they produce are known and recognizable.

5. Improve advocacy for PrEP

Civil society representatives should be able to conduct a dialogue with policy makers and advocate for the inclusion of PrEP in national

and international HIV prevention strategies. Ensuring that PrEP is well understood and supported by national and international health leaders may be the only chance to introduce PrEP quickly, especially in countries with a highly centralized system of decision-making. This is also relevant for countries that are already piloting PrEP. Taking into consideration the reduction in funding from international donors, engaging governments is a way to ensure the sustainability of funding available for PrEP, as well as to maintain support services and capacity building.

6. Introduce PrEP into strategic and methodological documents guiding the national HIV response, and develop a set of effective M&E indicators to measure the quality and cost-effectiveness of PrEP implementation

Although this will not always guarantee the availability of free services, in many cases this is the first and an essential step to beginning any new initiative. Officially including PrEP as part of the national strategy on HIV prevention is important for protecting the future of the initiative and ensuring its sustainability.

7. Promote a low-threshold and client-centered approach to PrEP implementation

PrEP is a public health intervention, which should be client-oriented, like any other prevention activity. If clients are not satisfied with how the service is provided, they will not use it. The goal of public health professionals is to keep clients in services, which are proven to be effective in preventing new infections. This implies offering different models of service provision, including both medical facility-based and community-based models, avoiding frequent and excessive medical procedures, offering flexible hours of operation that are convenient for clients, developing services for on-line medical consultations, providing social support, case management, and adherence counseling, and offering any additional services that may be attractive to clients (i.e. HBV vaccinations).

8. Address stigma and discrimination

Stigma is one of the factors that makes medical facility-based PrEP programs less desirable than community-based ones. Keeping in mind that we need to keep clients on PrEP in order to achieve the desired public health effect of the intervention, the creation of a stigma-free, friendly, non-judgmental environment is essential. This is also important given that conducting counseling on risk reduction and sexual health is an important part of any PrEP intervention and key to reducing the spread of STIs.

9. Make a regional plan and build a coalition for the promotion of PrEP

It would be extremely helpful to develop a regional coalition/task force of PrEP advocates that includes community leaders, HIV experts

knowledgeable about PrEP, UN representatives, and other relevant stakeholders for the development of a road map for scaling up PrEP in the region.

10. Ensure that the prevention and treatment of STIs are always well integrated in HIV programs, especially in PrEP programs

Although PrEP is a great method of HIV prevention, it does not protect users from other STIs. Given that the presence of other STIs increases the risk of HIV infection, clients and providers should be aware of this and have a clear understanding that one pill cannot prevent other infections if they continue to practice high-risk sexual behavior. STI outbreaks among PrEP users can undermine and discredit all efforts spent on establishing the PrEP program. Conversely, improvements in STI prevention and treatment under PrEP programs can increase the attractiveness of PrEP to clients and boost the cost-efficiency of national health strategies.

11. Recommendations from respondents from EU countries

All respondents from EU member states underlined that clear recommendation from the EU would draw the attention of decision-makers to the problem and would reinforce their efforts in advocating for PrEP.

Recommended Resources

1. WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection
http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/

2. CDC Library on Pre-Exposure Prophylaxis
https://www.cdc.gov/hiv/risk/prep/index.html

3. Pre-Exposure Prophylaxis for HIV Prevention in Europe. Monitoring Implementation of the Dublin Declaration on Partnership to Fight HIV/AIDS un Europe and Central Asia – 2016 progress report
https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/pre-exposure-prophylaxis-hiv-prevention-europe.pdf

4. PrEP Demonstration Project Tools. PrEP Watch
https://www.prepwatch.org/demo-project-tools/

5. Pre_exposure Prophylaxis for HIV Prevention
https://www.avert.org/professionals/hiv-programming/prevention/pre-exposure-prophylaxis

6. AIDS Education and Training Center (AETC), The Ryan White HIV/AIDS Program. Pre-Exposure Prophylaxis. Webinars and on-line training guidelines and toolkits
https://aidsetc.org/topic/pre-exposure-prophylaxis

7. Calabrese, S. K., Magnus, M., Mayer, K. H., Krakower, D. S., Eldahan, A. I., Gaston Hawkins, L. A., … Dovidio, J. F. (2016). Putting PrEP into Practice: Lessons Learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure Prophylaxis and Associated Care. PLoS ONE, 11(6), e0157324.
http://doi.org/10.1371/journal.pone.0157324

8. PreParing: PrEP for Providers and Patients. John Hopkins University. On-line training course.
Available at *https://www.coursera.org/learn/prep*

9. "PrEP in Europe", an online resource and advocacy center on PrEP in Europe
http://www.prepineurope.org/en/resources/

10. "I want PrEP Now", an online support center for PrEP users in UK
https://www.iwantprepnow.co.uk/

11. "The policy of PrEP", AIDS 2018 special session on PrEP
https://www.youtube.com/watch?v=C3ajPwlHdBA

Annex 1: Mapping of PrEP elements in EECA countries

Country	Truvada is registered in the country	TDF/FTC generic combination registered	PrEP is part of the National HIV/AIDS Prevention Strategy	Clinical Protocol on PrEP developed	Healthcare providers are trained on PrEP	Community representatives are trained on PrEP-related topics	Plans to start/ continue PrEP in 2019	On-going Pilot Project
Albania								
Armenia				PrEP mentioned in MoH recommendations				
Azerbaijan								
Belarus								
Bulgaria								
Estonia								
Georgia							Scale up	
Hungary								
Kazakhstan							Under discussion	
Kyrgyzstan							To start in 2019	
Latvia								
Macedonia								
Moldova							Continuation	
Russia	Not for PrEP						To start in 2019	
Slovakia								
Ukraine				Local protocol for one clinical hospital			Scale up	
Uzbekistan								

No Partly Yes No information available

References:

[I]WHO Technical Update on Pre-Exposure Prophylaxis. February 2015. WHO/HIV/2015.4

[II] Grant RM, Lama JR, Anderson PL, et al. Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. The New England journal of medicine. 2010;363(27):2587-2599. doi:10.1056/NEJMoa1011205.

[III] Molina JM, Capitant C, Spire B, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med. 2015 Dec 3;373(23):2237-46. doi: 10.1056/NEJMoa1506273. Epub 2015 Dec 1.

[IV] Chen, A., & Dowdy, D. W. (2014). Clinical Effectiveness and Cost-Effectiveness of HIV Pre-Exposure Prophylaxis in Men Who Have Sex with Men: Risk Calculators for Real-World Decision-Making. PLoS ONE, 9(10), e108742. http://doi.org/10.1371/journal.pone.0108742

[V] Gomez, G. B., Borquez, A., Case, K. K., Wheelock, A., Vassall, A., & Hankins, C. (2013). The Cost and Impact of Scaling Up Pre-exposure Prophylaxis for HIV Prevention: A Systematic Review of Cost-Effectiveness Modelling Studies. PLoS Medicine, 10(3), e1001401. http://doi.org/10.1371/journal.pmed.1001401

[VI] Frankis, J., Young, I., Flowers, P., & McDaid, L. (2016). Who Will Use Pre-Exposure Prophylaxis (PrEP) and Why?: Understanding PrEP Awareness and Acceptability amongst Men Who Have Sex with Men in the UK – A Mixed Methods Study. PLoS ONE, 11(4), e0151385. http://doi.org/10.1371/journal.pone.0151385

[VII] Marieke Bak1 , Anke van Dam2 , Rien Janssens3 Awareness and Acceptability of Pre-Exposure Prophylaxis (PrEP) Among Men Who Have Sex with Men in Kazakhstan: A Mixed Methods Study. Cent Asian J Med Sci. 2018 June;4(2):102-115.

[VIII] HIV and AIDS in Eastern Europe and Central Asia https://www.avert.org/professionals/hiv-around-world/eastern-europe-central-asia

[IX] S.Alistar, P.Grant, E.Bendavid, "Comparative effectiveness and cos-effectiveness of antiretroviral therapy and pre-exposure prophylaxis for HIV prevention in South Africa", BMC Medicine, 2014, 12:46.
Also available online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4003813

[X] LeVasseur, M. T., Goldstein, N. D., Tabb, L. P., Olivieri-Mui, B. L., & Welles, S. L. (2018). The Effect of PrEP on HIV Incidence Among Men Who Have Sex With Men in the Context of Condom Use, Treatment as Prevention, and Seroadaptive Practices. JAIDS Journal of Acquired Immune Deficiency Syndromes, 77(1), 31-40.

Materials Analyzed in the Desk Review:

1. Pre-exposure Prophylaxis of HIV among MSM and Transgender Women in Georgia. Clinical Protocol.
2. The Georgian National HIV/AIDS Strategic Plan for 2016 – 2018. http://www.georgia-ccm.ge/wp-content/uploads/HIV-NSP-2016-20181.pdf
3. Clinical Protocol on Provision of the Medical Service Pre-exposure Prophylaxis of HIV among Adult Men Having Sex with Men and Transgender People. Kyiv, 2017. Available in hard copy in Ukrainian.
4. City Department of HealthCare. Kyiv Municipal Hospital #5. Order #193 on the Integration of the Clinical Protocol on Provision of the Medical Service Pre-exposure Prophylaxis of HIV among Adult Men Having Sex with Men and Transgender People. Available in hard copy in Ukrainian
5. Power Point Presentation" Mid-term Results of PrEP Implementation in Ukraine" made on XI National LGBT Conference in Ukraine. Kyiv, 18 Octover,2018.
6. Ministry of Health and Social Protection of the Republic of Moldova. Clinical National Protocol on Pre-Exposure Prophylaxis of HIV. Chisinau, 2018. Available in hard copy in Romanian.
7. Ministry of health of the Transdnistria Moldovial Republic. Clinical Protocol on Pre-Exposure Prophylaxis of HIV. Tiraspol, 2018. Available in hard copy in Russian.
8. Government of Republic of Armenia. State Targeted Program to Combat HIV/AIDS in republic of Armenia for 2017 -2021. Yerevan,2017 http://www.irtek.am/views/act.aspx?aid=90527
9. Ministry of Health of Republic of Armenia. Clinical Guidelines on HIV Prevention and Treatment. Yerevan, 2017. http://moh.am/uploads/Draft_ART%20GUIDE_24%2007%2017%20(2).pdf
10. Prep Summit: Amsterdam 2018: Presentations and Video Feeds. Available at http://www.prepineurope.org/en/prep-summit-amsterdam-2018-presentations/

Eurasian Coalition on Male Health

www. ecom. ngo
www.fb.com/ecom.ngo
www.twitter.com/ECOMngo
contact@ecom.ngo