

Pre-Exposure Prophylaxis (PrEP) in Eastern Europe and Central Asia: first lessons to learn





Pre-Exposure Prophylaxis (PrEP) in Eastern Europe and Central Asia: first lessons to learn

Author: Tinatin Zardiashvili

Acronyms

APH Alliance Public Health

APCOM Asia-Pacific Coalition on Male Health
ARV/ART Anti-Retroviral/Anti-Retroviral Therapy
AIDS Acquired Immunodeficiency Syndrome

CBO Community-based organization

CDC The Centers for Disease Control and Prevention (USA)

CEECA Central, Eastern Europe and Central Asia

CCM Country Coordinating Mechanism

CSO Civil Society Organization

ECDC European Centre for Disease Prevention and Control

ECOM Eurasian Coalition on Health, Rights, Gender and Sexual Diversity

EECA Eastern Europe and Central Asia
EMIS European MSM Internet Survey

GF The Global Fund to Fight AIDS, Tuberculosis and Malaria

HBV Hepatitis-B Virus
HCV Hepatitis-C Virus

HIV Human Immunodeficiency Virus

HDCD Hospital of Dermatologic and Communicable Diseases (Moldova)

IBBS Integrated Bio-Behavioral Survey

KAP Key Affected Population

LGBT Lesbian, Gay, Bisexual and Trans

MoH Ministry of Health

M&E Monitoring and Evaluation

NCDC National Center for Disease Control and Public Health (Georgia)

NGO Non-Governmental Organization

PEPFAR President's Emergency Plan for AIDS Relief

PrEP Pre-Exposure Prophylaxis
STI Sexually Transmittable Disease

SW Sex Worker
TG Trans Gender

UNAIDS Joint United Nations Programme on HIV/AIDS

USD United States Dollar

WHO World Health Organization

Contents

Acronyms	2
INTRODUCTION	4
About the Report	4
Data Collection Process	4
Brief Overview of the Findings	4
ARMENIA	6
Briefly about PrEP in Armenia Today	6
Research Process, Sources and Findings	6
BELARUS	7
Briefly about PrEP in Belarus Today	7
Initiation	7
Pilot Project Arrangements	7
Lessons Learned at this Stage	8
GEORGIA	9
Briefly about PrEP in Georgia Today	S
Initiation	9
Implementation	9
Sustainability Arrangements	10
Challenges	10
Lessons Learned	10
MOLDOVA	12
Briefly about PrEP in Moldova Today	12
Initiation	12
Implementation	12
M&E Arrangements	14
Sustainability Arrangements	14
Challenges	14
Lessons Learned	14
UKRAINE	16
Briefly about PrEP in Ukraine Today	16
Initiation	
Implementation	16
Pilot Project	16
Scale Up Project	17
Innovation: PrEPster Web-Site	18
Sustainability Arrangements	18
Challenges	18
Lessons Learned	18
Δημογος	73

INTRODUCTION

About the Report

The given report presents cases of introducing the pre-exposure prophylaxis (PrEP) for HIV in five countries of the Eastern European region, specifically, in Armenia, Belarus, Georgia, Moldova and Ukraine.

The qualitative research to collect information and to describe the cases has been commissioned by ECOM - Eurasian Coalition on Health, Rights, Gender and Sexual Diversity, international network of LGBT community organizations and other NGOs working in the area of gay men's, other MSM's, and trans people's sexual health and rights in the region of Central and Eastern Europe and Central Asia (CEECA).

ECOM's mission is to create favourable conditions to ensure that men who have sexual relations with other men and transgender people have access to services in the field of sexual and reproductive health, mainly to HIV prevention, treatment, care and support, based on respect for their human rights. One of ECOM targets is to support the introduction of the HIV pre-exposure prophylaxis in the region.

With support from ViiV Healthcare Foundation and other partners, ECOM realizes a project "PrEPare EECA" which along to other activities, includes assessment of the current situation in the region and collection of best practices of PrEP introduction in the region.

Data Collection Process

In order to describe the cases presented in this report, we have performed a mixed study involving a desk review, interviews and e-mail communication with the PrEP stakeholders.

A desk reviews included all available reports, documents and presentations collected through PrEP projects' stakeholders (Annex-2). Initial list of the interviews was provided by ECOM and afterwards, the snow ball method has been applied in selecting other interviewees. Thus, nearly half of our respondents were identified by those respondents who were in the initial list mentioned above. For each country, we aimed to speak at least with one representative from each sector, i.e. state institutions, CBOs and international organizations, also with the PrEP project staff members, whereas it was applicable.

Depending on availability and preference of our respondents, some preferred a written format, so they have answered our questions via e-mails. With majority of the respondents we had a skype-interviews.

In the interview, we followed a data collection framework specifically developed for this research (Annex-3).

Brief Overview of the Findings

The five cases described in this report represent five different processes of initiation and establishing the PrEP services in the countries, which are completely different in terms of the political context, health system's organization, HIV epidemiological situation and financial arrangements for HIV prevention programs. Despite of these differences, there are some similarities: all countries have initiated PrEP service between 2015-2019, firstly, in respond to WHO recommendation in 2015 which presented strong evidence base for the effectiveness of this method. Secondly, in respond to growing HIV-incidence among KAPs, including but not limited to MSM.

The main challenge for initiation PrEP services was the creation of demand in gay men's, other MSM's, and trans people's communities. No matter, who initialised the PrEP, the state institution, for example, in Georgia, Armenia and Moldova, or it has been promoted by active advocacy by NGOs, as in Ukraine, or by joint efforts of international and local organizations, as it happened in Belarus, the main issue in all five countries is a low community awareness and, consequently, the low demand on the services.

Another issue is retaining the users, who are not often ready for regular uptake of the medicine and regular visits for clinical monitoring. The needs assessment study in Moldova, for example, showed that communities were very enthusiastic to start PrEP after hearing the benefits and effectiveness of the method, however, after deeper questions, it became clear that they were not ready for regular uptake and visiting medical facilities on a regular basis. In all five countries, the users feel very uncomfortable visiting the specialised HIV units or AIDS centres.

The described cases proved that delegating some components of the PrEP service to the community organizations provides more information to potential users and creates the diversity in places for testing and distributing the medicines, which positively affects the recruitment process and adherence to PrEP. After piloting medical-facility based model in Georgia and the first evaluation of the pilot project in Moldova, the countries came to the decision to expand the community participation. Moldova has recruited only 8 users in 2018 through medical-facility based

model, and in one month after activating the community component, they have recruited additional 8 users. Another strategy planned by the countries in order to positively influence a demand is revising clinical protocols by adding on-demand uptake as an alternative for the daily regimen. This is already planned by Georgia and Moldova and under consideration in Ukraine.

The experience of the countries showed that essential element to ensure PrEP's sustainability is a normative base. When the country explicitly considers PrEP as one of the HIV-prevention methods, there is much bigger chance to receive a state financing for it, for example, as it happened in Georgia and Moldova, where medical components are fully or partially covered by the state budget. These are two countries, along with Armenia, where PrEP is included in National HIV Strategy as HIV-prevention. However, Armenia chosen different way of PrEP's institutionalization: it is a paid service provide at the National AIDS Centre. In countries with bigger population and consequently with a higher number of potential users, i.e. in Ukraine, official legalization may not be sufficient to resolve financial issues related to the cost of the medicines, laboratory tests, and counselling.

All countries have different arrangements in terms of covering the PrEP medicines, laboratory tests, and community-based support (the demand creation, recruiting, and adherence counselling and support), however, the community-based support remains as most fragile in terms of sustainability.

Our research demonstrated that the Global Fund is a main source of financing in most countries for PrEP medicines and express tests, partly for the clinical tests and especially for the community-based support.

The four cases we provide in this report are organized in the standard format with briefly emphasising current situation, then describing the process of initiation and implementation, sustainability arrangements, main barriers and the lessons learned. The countries are represented in alphabetical order. However, the Annex 1 allows the reader to follow initiation of the PrEP in these countries chronologically as well as to compare the status of the similar events or developments.

The cases can be interesting for the wide range of the readers: professionals, who are interested how PrEP service is organized in different countries, for the community representatives. To those countries, who are about starting PrEP services, this report provides five different scenarios with the challenges and ways to overcome, so likewise Belarus, they can take into consideration all lessons learned and design their pilots basing on the evidence shared by Georgia, Moldova and Ukraine.

ARMENIA

Briefly about PrEP in Armenia Today

There is PrEP service in Armenia, but there was no any pilot program on developing PrEP service in the country. Our research showed that there are no concrete thoughts about expanding PrEP in Armenia in the nearest future. PrEP is recognised as one of the HIV prevention methods by mentioning it in the National HIV Strategy. The National Centre for AIDS Prevention offers PrEP as paid service. The national protocol recommends the usage of TDF or TDF+FTC. Clients can get PrEP at the National Centre for AIDS Prevention, where they also can receive a consultation, but the service, as mentioned above, is not free of charge. As of February 2019, there were 5 clients using PrEP in Armenia.

Research Process, Sources and Findings

Despite Armenia was, possibly, the first country in the region introduced PrEP, it was difficult to reach out to the stakeholders from the Ministry of Health and AIDS Centre for learning the national experience. We were able to reach out only one representative of the community for the interview and exchanged a few e-mails with one representative of the MoH and one representative of the NGO. Therefore the main sources of information for this brief overview were a) an ECOM's <u>research</u> by Marina Kornilova and b) Community leader, who mentioned that there are no major changes to a situation or further developments since the report was developed at the end of 2018.

According to M. Kornilova, 'the situation in Armenia is unusual, as PrEP is part of the National Strategy on HIV¹, but there is no guarantee for the provision of PrEP free of charge'. The report also says that National ARV treatment guidelines, by MoH, schematically and very briefly describe PrEP as one of HIV prevention methods. According to M. Kornilova, the total price for screening, medical tests, counselling and prescription of Truvada was equivalent to 215 USD in 2018. By September 2018, there were no clients enrolled in PrEP.

According to another source, as of February 2019, AIDS Centre has 5 clients for PrEP and the price of PrEP was equivalent to 50 USD per month and included the medicine, clinical testing and counselling.

It can only be assumed that the reason for low number of service users should be not only high price, but lack of awareness and information among potential users of PrEP as well as low interest from the government and medical specialists.

Usually, the pilot of PrEP aims the service delivery system development and testing. So, for Armenia, it will be actual only in case if the government plans to provide PrEP free of charge or at the affordable price under the national program to cover the percentage and variety of key populations in accordance with the WHO recommendations. It looks like now there is no such goal in Armenia, respectively there are no reasons for conducting such a pilot. Moreover, most stakeholders are pretty sure that the inclusion of a few paragraphs about PrEP in the national HIV strategy, development of a brief clinical protocol and setting up a paid medical service at the national AIDS Centre means that the country has already initiated and implemented PrEP. They could not understand the meaning of the questions about the plans of PrEP piloting in the country.

Our respondent assumed that the future of PrEP in Armenia largely depends on financial arrangements of HIV treatment and prevention in Armenia after transitioning from the GF grant. Other barriers underscored by the community are the unreliability of statistical data, not showing a real picture of HIV-incidence among MSM. It may also be determined by a high level of stigma and discrimination towards MSM from the wider population and also by religious leaders and even medical personnel. In such context, most MSMs are hiding their sexual behaviour causing a bias in statistical data.

The community expert interviewed, mentioned the readiness of CBOs to promote PrEP in Armenia and support the pilot project, however, they realize that they, most probably, lack appropriate knowledge and competence in doing so. The community expert considers involvement in regional HIV-initiatives as one of the ways out from the existing situation and sees it as an opportunity to learn and grow. The relationships between community organizations and the MoH are quite strong and effective, therefore, if the community knows what and how to do in terms of PrEP expansion, they can achieve some progress in the nearest future.

¹ National Program on HIV/AIDS prevention in the Republic of Armenia in 2017-2021

BELARUS

Briefly about PrEP in Belarus Today

At the moment of this research, Belarus does not have yet any protocol, national guidance or pilot project on using PrEP for HIV prevention. However, the country is in the active planning process to start a pilot project in 2020. A long preceding work has been done by the local office of WHO, MoH and NGO "Vstrecha" to disseminate information, to initiate a process and to find a donor. The PrEP pilot in Belarus will be part of the regional initiative funded by the Global Fund and led by Alliance Public Health ("Sustainability of services for KAP in EECA region", #SoS_project). Sub-recipient of the grant will be a state agency, titled as Republican Scientific and Practical Center of Medical Technologies, Informatization, Management and Economics of Public Health. Currently, an international technical support project is in the process of state registration at the Ministry of Economics. After the project is registered, the working group will start specifying the project activities and drafting of the clinical protocols.

Initiation

Stakeholders found difficult to attribute initiation of PrEP in Belarus to one specific sector or organization, it was rather a collective initiative by the community, state and international organizations.

The process was kicked off by joint efforts of WHO local office and local NGO Vstrecha, with active contribution from the state agency which is in charge of HIV prevention and treatment (the Republican Scientific and Practical Centre of Medical Technologies, Informatization, Management and Economics of Public Health).

The process of initiation started soon after the WHO recommendation on PrEP was issued in 2015. Two other international organizations, UNAIDS and ECOM have also contributed to successfully opening a dialogue about PrEP service in Belarus, by organizing informational meetings and presentations. NGO Vstrecha has prepared and published <u>articles</u> on their web-site about PrEP to inform and educate community representatives on benefits of PrEP method.

Apart from strong evidence of PrEP effectiveness in the prevention of HIV provided by WHO, main justification for the need of introducing PrEP in Belarus were increasing HIV incidence among MSM and low rates of using condoms by high-risk groups² (EMIS and IBBS 2016 researches). At the same time, as mentioned by the respondents, in 2016-2017 there were anecdotal cases of unofficial use of PrEP by MSM community members, which proved the exiting demand and need to start a pilot. IBBS study results in 2017 provided addition prove of the need to act. According to the Republican Scientific and Practical Centre of Medical Technologies, Informatization, Management and Economics of Public Health, presentation and discussion of alarming IBBS results on the CCM meeting pushed stakeholders for the action.

As explained by the respondents, MSM community is not in a priority list in the Ministry of Health and there was a very low chance that the state would fund a PrEP initiative, so the stakeholders started to look for international funding opportunities. In parallel to the grant searching, the WHO local office has organized study tours for public health managers and community representatives to see successful models of PrEP projects in the region and abroad. MoH representatives participated in the regional meeting on PrEP in Germany. WHO has also organized a series of training for medical personnel and community representatives in Belarus. Such an approach has sensitized MoH and ensured political support from the state agencies to further promote PrEP, to get involved in the planning of the pilot project.

As a result of the advocacy and fundraising efforts for PrEP and regional consultations, it has been decided to include a pilot initiative of PrEP project in Belarus in the regional Global Fund-supported <u>program</u> "Sustainability of services for KAP in EECA region".

The program applies an operational research approach, which means that based on the pilot, most effective model of PrEP delivery will be developed. The model will be presented to the state with the suggestion to take over its financing and administration. However, there are no sustainability arrangements or plans developed at the moment.

Pilot Project Arrangements

The pilot PrEP project will target 100 persons (MSM first of all) in Minsk city, one-year courses are planned for the implementation in 2020. The planned pilot is funded from the regional Global Fund program "Sustainability of services for KAP in EECA region". As of September 1st, 2019, the project was undertaking the registration process at the Ministry of Economics.

² EMIS 2010 : the European men-who-have-sex-with-men internet survey Findings from 38 countries / The EMIS Network. – Stockholm : European Centre for Disease Prevention and Control; 2013. – http://www.emis-project.eu/

National specialists are currently in the process of developing all relevant documents and protocol. WHO provides technical support and training to the national specialists, both from NGO and clinicians. PrEP will be distributed through infectious disease hospital since in Belarus the provision of antiretroviral drugs requires special license. However, the primary counselling of clients and further monitoring of their adherence will be done with the significant involvement of NGO "Vstrecha".

The country has already designated a working group of the project consisting of the specialists from different sectors. The group will design the project details, develop protocols, define roles, and develop the client's route from recruiting to enrolment and further monitoring. The group is going to start its work immediately after the registration of the Global fund grant in the Ministry of Economics.

Interviewed stakeholders representing CBO and government sectors are recognising the need for sustainability and institutionalization arrangements, however, there are no specific plans at the moment. These arrangements will be developed along with the project of implementation.

Lessons Learned at this Stage

Although the project has not started yet, the stakeholders in Belarus already performed a needs assessment among MSM on PrEP services. The research showed that potential users need deeper knowledge and understanding of PrEP. It happens quite often when MSM express willingness to use PrEP after they learn about the benefits of this prevention method, however, when they realize that enrolment in PrEP means a long term administration of the antiretroviral medicine and regular monitoring in a medical setting by undertaking medical tests, they change their mind about using PrEP. This is a lesson learned by HIV program stakeholders via needs assessment survey, which motivated them to think about creative approaches in educating the potential users of PrEP.

Belarusian stakeholders involved in PrEP initiation are planning to consider the lessons learned by other Eastern European countries as well, such as Ukraine, Moldova and Georgia. They are aware that most beneficiaries prefer not to visit AIDS centres for medical tests, counselling and for receiving the medicines. The PrEP project partners planned to not medicalize the process and largely involve NGO "Vstrecha" in recruitment, counselling and follow up processes. As an option for piloting, "Vstrecha" has already identified a local policlinic located nearby their office, so recruited users will undertake all required clinical tests in the policlinic. The respondents mentioned that distribution of PrEP medication will be available at an alternative location.

GEORGIA

Briefly about PrEP in Georgia Today

In Georgia, PrEP is part of a Global Fund-supported programme since August 2017. The primary recipient of the grant in the country is the National Centre for Disease Control and Public Health (NCDC)³. Implementing organizations for PrEP component are the Infectious Disease, AIDS and Clinical Immunology Research Centre (National AIDS Center) and community-based NGO Equality Movement.

Since 2015, PrEP is included in the National Strategic Plan (for 2015-2018) as part of the standard HIV prevention package. This actually ensured national funding for PrEP for a later stage, during transition period from the Global Fund's financing. As of July 2019, the medical component (clinical consultation, clinical tests and PrEP medication) are covered by National HIV/AIDS program.

The first pilot project has covered 100 users in the capital, Tbilisi. The scale up started in 2019 by increasing geographic coverage of the service by adding two big towns in west Georgia, Batumi and Kutaisi. As of August 31, 2019, PrEP service has 218 PrEP users. Initially established medical facility-based model now is being modified into the mixed model with more active involvement of the community representatives.

Initiation

National Strategic Plan for HIV/AIDS in Georgia for the period of 2015-2018 included PrEP as a part of the standard HIV-prevention package. This step has ensured further smooth institutionalisation and financial sustainability of the medical component of the service, which legally became state's responsibility.

Preparatory work to introduce PrEP in Georgia started from early 2016. The PrEP service has been introduced and promotes by the group of HIV program stakeholders and experts from different organizations such as NCDC, National AIDS Centre and local NGOs, Equality Movement⁴, Tanadgoma and Identoba.

The technical support provided by international experts from APCOM⁵ and ECOM⁶ through Global Fund financed CRG initiative helped the PrEP stakeholders to develop a comprehensive protocol for PrEP services in early 2017. The pilot project was officially launched in August 2017.

As explained by the respondents, preceding justifications for introducing the PrEP in Georgia were growing HIV-prevalence among MSM⁷ and recommendation by WHO made in 2015, with strong evidence of method's effectiveness.

Implementation

The pilot project on PrEP in Georgia, targeted on 100 users, was launched in August 2017 as an independent Global Fund supported project implemented by two sub-recipients: the national AIDS Centre and local NGO Equality Movement ('Pre-exposure prophylaxis (PrEP) of HIV infection among MSM and transgender women in Georgia').

According to the ECOM's <u>research</u> by Marina Kornilova, by September 2018 the PrEP service had 100 regular users and majority of them have been on PrEP for approximately 1 year. 25 users dropped out from the service during the first year of a pilot.

Initially, a PrEP delivery model was mainly based in medical facilities, which means that the national AIDS Centre was providing the majority of services, such as laboratory tests, doctor's consultation, adherence follow up and distribution of the medicines. From 2019, potential PrEP users are either referred by the community centres, or they can directly apply to the AIDS Centre.

The role of the community based partner, Equality Movement, is recruitment and the provision of social support through their resource centres. Specifically, the activities include informing community members about the project and encouraging them to participate, screening applicants for eligibility (express HIV testing and questionnaire), providing adherence and risk reduction counselling, and social support, as well as overseeing case management.

³ The national agency under the ministry of labour, health and social affairs.

⁴ Formerly known as LGBT Georgia

⁵ Asia-Pacific Coalition on Male Health

⁶ ECOM - Eurasian Coalition on Health, Rights, Gender and Sexual Diversity

⁷ According to the data from 2015, HVI-prevalence in Tbilisi among MSM was 25% and among general population-0.4%.

According to Kornilova, informational support included an informational brochures for potential users, describing the proven effectiveness of Truvada, and dispelling the most common myths and superstitions about PrEP; Communities have also organized the PrEP users' schools with trusted doctors facilitating discussions and answering questions about PrEP; According to the project stakeholders, spreading information through peers and social networks has worked particularly well for recruiting clients to the project.

The person referred for using PrEP services should be an adult MSM or TG women who are at high risk of acquiring HIV. The risk is assessed by using a special questionnaire. After the screening, the clients are referred to the AIDS centre for assessing a general wellbeing and undertaking a laboratory tests for Hepatitis-B and for assessing a kidney function. If the client satisfies clinical selection criteria, the medication is distributed and then user is being monitored according to the protocol. According to the clinical protocol, PrEP users are suggested a daily uptake of Tenofovir-300 mg or Emtricitabine-200 mg.

The first pilot initiative has only covered the capital, Tbilisi. Starting from September 2019, the project with additional target of 150 users annually, was expanded to the two big towns of west Georgia, Kutaisi and Batumi. As of August 31, 2019 the PrEP in Georgia has 218 users across the country.

The scale up project intends to increase community role in users' recruitment and adherence, which actually means moving towards the mixed model of PrEP delivery. Another change that is under the consideration is to revise a clinical protocol and make available on-demand uptake. Based on evaluation of the first year results, the project management has concluded that above-mentioned modifications could help in overcoming a major challenge of a project, low demand and high rate of drop out.

Monitoring and evaluation of the PrEP component is divided between the two organizations: the clinical component is managed by the national AIDS centre, which collects information for the HIV reporting module. The data from the community component is collected by NCDC, who is a principal recipient for the Global Fund grant in Georgia, and therefore, oversees the M&E system of entire programme.

Sustainability Arrangements

As already mentioned under 'initiation' section, the financial sustainability of the medical component of the PrEP is actually ensured by inclusion of PrEP in the standard HIV-prevention package to be provided by the state funded national HIV programme. From July 1, 2019, as a planned transition action⁸, a medical component of PrEP is covered by the domestic sources.

A community component of providing a social support to the service users is funded by the Global Fund's program until June 2020. The need to look for sustainability options is recognised, which means that the problem is on the agenda of involved stakeholders, however, there is no concrete plan in place yet.

Challenges

As the main challenge for PrEP services in Georgia at the stage of initiation and implementation was relatively low demand in the community and frequent drop out of the users.

Recruiting of users and keeping them adhered to the service without active involvement of the communities proved to be very difficult while implementing the medicalized model of delivery. The pilot project showed that more work is needed by the community organizations in educating the community members.

Other serious impediments were unwillingness of the potential users to visit the AIDS Centre and stigma against MSM and TG among medical personnel. According to the PrEP service barriers assessment <u>research</u> in 2018, most service users felt very uncomfortable while visiting AIDS centre facilities, due to different reasons, such as harsh replicas by the medical staff, also various issues boiling down to the concerns about confidentiality.

Lessons Learned

The Community component is a vital element of the PrEP service, as it can influence recruitment and adherence of the users.

Another important element is awareness raise and education of the potential users. The outreach, peer education and spreading information through social media proved effective.

⁸ Transition plan from the Global Find's financing to the domestic funding is a mandatory plan required by the Global Fund in the process of exiting a country.

Applying mixed model of PrEP service delivery with active participation of the community representatives is an effective step for increasing demand for the service.

Getting effective results in PrEP pilot requires complex, multidisciplinary approach and active involvement of all stakeholders.

MOLDOVA

Briefly about PrEP in Moldova Today

Moldova currently implements three different projects having components on developing and promoting a PrEP service. The first project started on February 2018, it was initiated and run by the state health institution (HIV department at the Hospital of Dermatologic and Communicable Diseases) within the frames of a National HIV Program. Another project is implemented since January 2019 by the NGO Positive Initiative within the #SoS_project funded by the GF and implemented in cooperation with the Alliance of Public Health (Ukraine) aiming at information and awareness raising about PrEP among general public and key target groups, and strengthening sustainability of community participation in the provision of PrEP services. The same purpose is shared by a third project led by NGO GENDERDOC-M with UNAIDS funding, this project also covers training and technical support to PrEP stakeholders.

All three ongoing projects are implemented in close cooperation aiming to find ways to institutionalize community component of PrEP's delivery in Moldova. Agreement to cooperate is stated in the Memorandum of Understanding signed by the parties in June 2019. The need for strong communication campaign and for involving the communities into the PrEP services is one of the lessons learned by the National HIV Program stakeholders, who now aim to transform a medical-facility based model of PrEP service into the mixed model.

Initiation

Initiation of a PrEP service in Moldova can be considered as a somehow unique case, as the process started with the institutionalisation of this prevention service by the national HIV program. The need for PrEP was justified with a strong recommendation made by WHO in 2015 and by unfavourable results of IBBS study⁹ in 2016 specifically, HIV prevalence among MSM has increased from 1,7% to 9% between 2010 and 2016. In terms of MSM sexual behaviour, the study shown that in last 6 month the respondents had 3.1 homosexual partners on average and only 53,5% out of them used condoms consistently. In 2017 the Ministry of Health supported the development of the national clinical protocol in PrEP and enforced it on February 2018. Therefore, the pilot project started in February 2018 and was run by state-funded national HIV program staff. The medication for PrEP was purchased with the GF grant, however, along with transitioning from the Global Fund support, in future, the medication will be purchased with domestic funding.

Implementation

National HIV Program

Since 2018 PrEP is available in all 8 HIV units that provides ART throughout the country. From 2019 the territory of Transnistria is also included in the initiative. Small number of medical personnel underwent training on the clinical aspects of PrEP in May-June 2018.

The pilot service started by applying a medical facility-based model, which means that all clinical tests, counselling and distribution of medication were implemented through the same facilities providing ARV treatment.

The clinical protocol has approved the daily uptake regimen of TDF. Medications were purchased via the Global Fund programme, clinical tests and consultations were covered by the national health system, and therefore, the PrEP service in Moldova is free of charge for any citizen with increased risk of acquiring HIV-infection through different routes.

As of September 1, 2019, the PrEP pilot project recruited and enrolled 8 users (as far as it is known, these are 5 men (MSM or having other HIV-infection risks), 1 SW and 2 women within discordant couples). In 2018 there was only one PrEP service user, and remaining 7 were enrolled in January-August, 2019, 4 out of these 7 users were enrolled in August 2019. It is assumed by the respondents of this study that increased number of users in 2019 is determined by start-up of a second project promoting active engagement of the communities in the recruitment processes (see below the description of the project implemented by NGO Positive Initiative). By the moment, when we were in the process of drafting the given report, NGO GENDERDOC-M has informed us that during September 2019 eight new users registered for the service.

Therefore, despite the fact that since 2018, PrEP is free of charge for any citizen of Moldova, enrolment into the project has been extremely low. The project stakeholders have realised that there is a need to increase a demand on the service through a strong information and awareness raising campaign and engaging the community organizations. After the series of meetings, round tables and small-scale surveys, it has been concluded that spreading of information and educating of the potential users are not enough. Well-informed potential users of PrEP may feel uncomfortable visiting HIV units. Some of them prefer to keep a reason for a visit to medical facility confidential, which might not be always possible, when they are referred to the specialised HIV-unit. Some

⁹ http://www.pas.md/ro/PAS/Studies/Details/72

users/potential users may also be threatened by 'over-medicalization' of the service, especially those who's risky behaviour is only occasional and not somewhat happening regularly.

After analysing the lessons learned, in order to address low demand issue, the National HIV Programme in cooperation with UNAIDS and the community-based NGOs has decided following:

- 1. To develop online informational web-site for general public and high risk groups and enrol in training not only medical personnel, but community representatives;
- 2. To move from medical facility-based model to mixed model. This means to actively involve communities in to the recruitment and counselling, to offer the clinical tests in regular medical facilities/policlinics located nearby the partner NGOs. To make available medicines distribution from NGO's office by medical doctors visiting the offices once or twice a week, depending on actual need.
- 3. To consider revising clinical protocol and to offer alternative regimen of the treatment, which is based on demand.

Two Projects Led by Community-Based NGOs

Project-One

Implemented by NGO "Initiativa Positiva" (sub-recipient of a regional programme led by Alliance for Public Health, 'Sustainability of services for KAP in EECA region' (#sos project). Funded by the Global Fund

This project is part of a Global Fund financed 3 year regional programme titled as Sustainability of services for KAP in EECA region (#sos project). At a regional level the programme is managed by Alliance for Public Health, principal recipient of a grant in Moldova is "Initiativa Positiva". Implementing partners are NGO AFI in Chisinau; NGO Miloserdie in Tighina/Bender and NGO ATIS in Balti. The project aims to address the broader issues related to the sustainability of HIV-services and PrEP is one of the components of the project.

Primary target groups of the PrEP component within this project are: HIV-negative persons who are having HIV-infection risks and with the focus on MSM, SW and discordant couples. Target number of users is 100 persons for 2019-2020.

The project activities include training of community representatives and establishing an alternative route for the potential users. Social workers of a project are actively involved in the recruitment of PrEP service users through outreach and peer education and support activities. Potential users will get a medical counselling at the office of the NGO by visiting medical staff of HIV units. Some express tests will be performed at the office and other laboratory tests will be done at regular policlinics or laboratories. The cost of the laboratory tests will be covered by the project, as the state only covers medical tests that are performed at HIV units. According to some respondents, at a later stage, the project has to develop an effective and functional model of a service delivery that would allow the laboratory tests to be covered by the state and at the same time, to provide an alternative locations to HIV-units (for example, at the policlinics) for the comfort of the service users. Some respondents admitted that PrEP should be promoted through the NGOs and the users have to be educated in a way that they feel comfortable to receive the service at the medical institution.

The project activities also include development of the nationwide information and awareness raising campaign aiming at increased awareness about PrEP among wider population and development of web-site on PrEP for all groups of population. Having in mind existing in the society prejudices related to HIV and sexual behaviour of certain groups, the project has planned an inclusive and gender-sensitive campaign targeting entire population and positioning PrEP not as a service exclusively developed for the KAP's, but for anybody being at risk of HIV, for example, any woman or man having several sexual partners, medical personnel or tattoo specialists, etc.

Project-Two Implemented by NGO GENDERDOC-M Funded by the UNAIDS

The project started in September 2019. It will use same approach to recruitment, testing and enrolling the potential users as by "Initiativa Positiva".

According to the respondent of this study, NGO GENDERDOC-M has already identified a policlinic located nearby the office, they plan to sign a contract with this institution for provision of necessary clinical tests for those potential users, who are recruited by GENDERDOC -M during the counselling sessions. Similar to the first project described above, it is planned to host medical staff once or twice a week at the NGO office, for clinical counselling and distribution of the medication. The user's route will be tested and established by the project during the pilot targeting 100 users for 2019-2020.

Additional activities covered by this project are training for medical personnel and community representatives, also providing technical support to all partners implementing PrEP related activities in the country

Integrated Approach in PrEP Projects implementation

All three projects stakeholders are keen to integrate their activities in relation to PrEP services in order to maximize the effectiveness of the initiative. This intent is documented in the Memorandum of Understanding between the partners, leading implementers of a PrEP components in three different projects, specifically, in June 2019 the partners signed following agreements:

- -UNAIDS and Positive Initiative signed a Memorandum of Understanding on the coordinated planning, financing and evaluation of PrEP related work
- -HDCD, UNAIDS and Positive Initiative signed a protocol on the selection of the NGOs, coordination and monitoring mechanism, and cost estimation for consultancy and adherence services in relation to one PrEP beneficiary.

M&E Arrangements

NGO Positive Initiative has developed software to monitor and evaluate the HIV services provision across the country. After starting a project on PrEP, they are adjusting the software by adding PrEP services and related indicators. The software was transferred to the National HIV Programme and have already been shared with the partner NGOs. At the moment, data is gathered and analysed by NGO Positive Initiative and the National HIV Program is gradually taking over the M&E function.

Sustainability Arrangements

PrEP service has several elements, therefore, we separately describe here sustainability arrangements for each of these elements:

- 1. Routine clinical laboratory tests: these tests are covered by the National HIV Program only in that cases when test are done at HIV units¹⁰. For the users visiting other laboratories based in the city policlinics or hospitals, the clinical tests are not free of charge and during the project lifespan, the cost is covered by the donor funded projects run by NGOs. There are no arrangements yet to resolve this issue.
- 2. Medicines for PrEP: at the moment purchased with the GF grant, but according to the plan of the transition to national funding, the medicines along with ART will be covered by domestic sources and will be free of charge for the clients.
- 3. Social support element is still financed by the donors, however, there is a precedent of the state funding for prevention and harm reduction services channelled through local NGOs. The PrEP stakeholders intend to advocate for including PrEP service into the list of the state funded mandatory services (under the National Health Insurance Company).

Important element of further sustainability arrangements in Moldova can be considered the integrated approach to the management, implementation, and monitoring of the three different projects implemented by 3 different organizations and financed by 3 different sources (including state institution and domestic funding). Such approach indicates readiness of the state institutions in Moldova to take over the PrEP services in future, however, there are no guarantees yet and NGOs need to advocate and work hard for the implementation of their plans in terms of equal sustaining of all elements of PrEP services.

Challenges

Main challenge for PrEP services at the stage of initiation and implementation was lack of demand from potential users. According to the responds representing both, communities and the National AIDS Program, initially applied medical facility based model without involvement of the communities and having no awareness campaigns for the potential users demined such a low demand. Initiated changes in the service delivery process from September 2019 were planed based on the lessons learned.

Lessons Learned

The main lesson learned by Moldovian stakeholders was that even the state level enforcement, availability of financing and medication cannot ensure adequate demand for the PrEP and to create and increase a demand, some additional measures and activities are required.

Awareness raising campaign, education of potential users and training of the communities and medical personnel are inevitable elements of initiation of PrEP services;

¹⁰ HIV department of the Hospital of Dermatological and Communicable Diseases is a state institution, which is managing the National HIV Program through its 8 HIV units across the country.

A mixed model of PrEP service delivery, envisioning an active participation of the communities along with medical professionals, has a good potential to increase a demand;

Inclusion into the clinical protocol both uptake regimen for the PrEP: daily and on-demand, may have a potential to increase a demand and improve adherence of users.

UKRAINE

Briefly about PrEP in Ukraine Today

In 2019, Ukraine stared scaling up the pilot project in PrEP, which began in 2018 in Kiev, with financial support of the President's Emergency Plan for AIDS Relief PEPFAR and The Centers for Disease Control and Prevention $(CDC)^{11}$ and has established medical facility based service with active participation of the community organizations.

The scale up plan covers 24 regions and intends to involve additional 2806 users on top of those users that were engaged by the pilot. As of September 2019, PrEP service has 959 users across the country.

Ongoing project on PrEP is implemented by Alliance Public Health (APH) with financial support of the Global Fund and in partnership with the national AIDS and Public Health Centres and community based organizations.

The PrEP project in Ukraine started operations with the local medical protocol developed for only one hospital of Kiev implementing a pilot. In June 2019 the national clinical protocol has been developed, which is significant step towards institutionalization of the service.

The latest National HIV Strategy in Ukraine has covered 2015-2018 period and PrEP was not part of it, as the document has been developed earlier than WHO issued its recommendation on the PeEP. The National clinical protocol about using PrEP as HIV-prevention method in Ukraine has been approved by the Ministry of Health in June, 2019, which was a progressive step towards institutionalization of PrEP, however, financial sustainability of a project is still at risk.

Initiation

Discussions about introducing the PrEP as HIV-prevention method in Ukraine, like in most Eastern European countries, started soon after WHO made its recommendation in 2015.

Preceding work, before starting a pilot project in January 2018, included round tables, workshops and intensive search for the potential donors. The processes were led by Alliance Public Health in close cooperation with local medical clinics and community based NGOs. Specifically, in 2015 the partners launched the on-line educational course for healthcare providers and organized 1st PrEP Kiev Regional Forum for healthcare providers. From 2016 the partners already began planning of the pilot project in PrEP and transformed Regional PrEP forum into the regular annual event with international participation (ECDC¹², WHO, AIDES¹³). In 2017, PrEP among MSM was included in the City's AIDS program as a Fast Track strategy.

Preceding work also included a research on awareness & acceptability of PrEP among MSM, trainings for community members, NGOs and healthcare providers, establishing community counselling and starting small online advertising campaign.

Justifications for the need of PrEP in Ukraine mainly was an epidemiologic situation in regards of an HIV, especially among KAPs. In this context, the strong evidence about PrEP's effectiveness presented by WHO created a perspective to mitigate an epidemic and reduce expenditures for ART in a long-term period.

Implementation

Pilot Project

The PrEP pilot project started on 29 January, 2018 with the financial support of the President's Emergency Plan for AIDS Relief (PEPFAR). The pilot ended in March 2019.

Geographically the project covered only Kyiv, and, as of the beginning of September 2018, has reached its ceiling of 100 clients receiving PrEP. 12 clients dropped out from the service and one client was diagnosed HIV after 3 months of being on PrEP.

The project targeted MSM and trans-people and introduced a mix of a community-based and a medical facility-based models.

¹¹ a federal agency that conducts and supports health promotion, prevention and preparedness activities in the United States

¹² European Centre for Disease Prevention and Control

 $^{^{13}}$ a French community-based non-profit organisation that was founded in 1984 by Daniel Defert following the death of his partner Michel Foucault. The name is a play on "aides" and the English word "AIDS"

The NGO, "Alliance Global", carried 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.

The pilot allowed to provide some services directly through the community organization, for example picking up medications, to undertake some medical tests administered by the visiting nurse. The program worked with five trusted doctors who were trained by the leading medical specialist.

The PrEP services under the pilot project have followed the local protocol approved by the Kyiv City Department of Health. This protocol recommended daily uptake of the medicine. According to ECOM's <u>research</u> by Marina Kornilova, 'an on-demand regimen has not been discussed, as the project was 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'.

At the moment of conducting the above-mentioned research (September 2018), the respondents who participated in the assessment said that the lack of information among potential clients created a lack of demand. Among other barriers were mentioned excessive medicalization of the intervention, creating unpleasant environment for recruiting and retaining the users. Respondents of ECOM's study also mentioned that attitude of service providers and medical personnel has to be changed as they treated PrEP users like patients, and not as clients of prevention program.

According to the data received from Alliance Global and APH, in total the pilot project has involved 148 MSM, out of them, positive results for HIV had 8 persons, 5 for HBV, 4 for HCV, 21 were diagnosed with syphilis and 19- with gonorrhea and chlamydia. 24 participants dropped out from the service.

The tighten budget of the pilot project did not allow stakeholders to conduct the training of medical personnel and community representatives and informational campaign at the required extent.

In 2018 one of the partners, menZDRAV Foundation conducted a study 'PrEP for Life: Awareness and acceptability of PrEP among MSM and TG in Kiev, Ukraine. The study helped to better understand the needs and attitudes of the PrEP users, both, actual and potential.

The study explored the following reasons for a lack of interest in PrEP: need for daily administration (83.2%); concerns about side effects (78.4%); risk of other STIs (71.2%); and out-of-pocket costs (65.6%). Among potential barriers to use PrEP, participants noted side effects (63.8%), cost expenses (60.3%) and necessity of a daily regimen (52.6%). According to participants, PrEP should be free of charge (53.2%) or partially free (35.8%). 50.9% preferred to receive the PrEP medicines at LGBT-community centres and 19.7%- through

The study results largely helped the PrEP stakeholders to readjust a scale up project to the needs of the potential users.

Scale Up Project

The scale up project expanded PrEP services up to 24 regions ('oblast') and is implemented by the APH with financial support of the Global Fund. Implementing partners are NGO Global Alliance, regional and city AIDS centres, regional Public Health Centres L.V. Gromashevsky Institute of Epidemiology and Infectous Disease of the NAMS of Ukraine¹⁴ and 24 other NGOs/CBOs operating across the country. 11 NGOs out of all 25 CBOs involved in the project, are providing social support only to MSM population.

The scale up project offers 2806 annual courses of TDF / FTC to MSM, HIV-negative partners of discordant couples and other persons who are at high risk of enquiring an HIV.

As of September 1, 2019, total 980 persons were tested on HIV, among them 5 persons with HIV-positive results were identified. The project has total 959 users, out of them - 765 are male, 192 - females and 2 - transgender persons. An average age of the first time users is 32.

Recruitment of the users is done by both, NGOs and medical institutions, however, it is important that those who are recruited at the medical institution are referred to the respective NGOs for the social support and counselling.

The scale up project has significantly expanded informational campaign led by NGOs. The activities includes: spreading PrEP related information through social media and other resources owned by partner NGOs (web-sites, resource centers, testing points and etc). Distribution of information leaflets to communities during various events and in clubs.

¹⁴ State institution under the Ministry of Health

The project has developed a web-portal (http://Prep.com.ua/) that allow not only to spread an information, but also to recruit the users. According to the data provided by NGO Global Alliance, between January and June, 2019 this web-site had 42,213 hits, 30,249 site users with unique ID and 768 users, who registered for starting Prep.

Innovation: PrEPster Web-Site

In the ECOM's research by Marina Kornilova, we found a description of an interesting initiative:

"Another noteworthy initiative in Ukraine, which began in July 2018, is carried out by The PrEPster 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."

Unfortunately, we were not able to obtain any information about popularity of the web-site and number of its users, however, this resource may be useful for those countries who are looking for innovative ways to ensure PrEP availability for the local citizens, tourists or expatriates.

Sustainability Arrangements

Ukraine has enforced a National <u>clinical protocol</u> on PrEP in June 2019, which can be considered as important step towards institutional sustainability of this service in the country. However, financial aspects of the services in future are still not clarified.

The latest National Strategy on HIV/AIDS covered the period of 2014-2018 and has already expired. As explained by the respondents, due to some political reasons, the new strategy has not been yet enforced. According to the decision by CCM, a new strategy on HIV, TB and viral hepatitis is being developed, the document will cover the period till 2030 and will have a legal power. The process of discussing a new strategy still in the process and it is not known, when it may be enforced. Described situation puts financial and institutional sustainability of the PrEP project under the risk. According to the respondents, institutionalization of the PrEP is not among priorities of the Ministry of Health, which is implementing large scale decentralisation reform of the National health system, which has coincided with the Global Fund's plan to exit EECA countries in the nearest few years. It looks like in such a challenging transition period, PrEP service in Ukraine will still largely depend on the external funding.

Medication for the PrEP is ensured by the GF by the end of 2021, HIV-tests are ensured by the state funding, the laboratory tests are partly ensured and the scale up project is already experiencing deficit of the funds in some regions, and the social component of the service is covered by the end of 2019. The stakeholders are actively looking for the external funding.

Challenges

- Poor knowledge about PrEP and negative attitude towards users at medical institutions, especially in the regions:
- The lack of financial resources to undertake required medical tests in some regions
- Low motivation for daily PrEP uptake (especially, in the context when community members are well-aware about on-demand/event-driven uptake method.
- Unwillingness of the potential users to visit AIDS centres and to disclose /passport data.

Lessons Learned

Mixed model of PrEP delivery with active participation of the communities in recruitment and social support, by providing optional locations for medical testing and medicines distribution, proved to be effective.

Recruitment of the users is a long-term process and requires extensive work by the communities.

Providing an option for PrEP uptake regimens (daily vs on-demand), has a potential to increase demand and reduce drop outs.

	Georgia	Ukraine	Moldova	Belarus
When was PrEP pilot initiated	In 2015-2016	In 2015-2017	In 2015-2017	2015-2018
Who initiated PrEP in the country	National Centre for Disease Control and Public Health (NCDC) The Infectious Disease, AIDS and Clinical Immunology Research Centre (National AIDS Centre) NGO Equality Movement	The group of stakeholders representing, local, international and community-based organizations led by the Alliance Public Health	The National HIV program administered by HIV department of the hospital of dermatological and communicable diseases (HDCD) In partnership with NGOs Initiative Positiva GENDERDOC-M	WHO country office in Belarus & Communities in partnership with Republican Scientific and Practical Center of Medical Technologies, Informatization, Management and Economics of Public Health
Main justification for a need of PrEP in the country	-Strong evidence of effectiveness presented by WHO; -High and Increasing HIV-prevalence among MSM (25% as of 2015, when 0.4% was among general population);	-Strong evidence of effectiveness presented by WHO; -Epidemiological situation in terms of HIV among KAPs -Some individuals were already using PrEP in the country by self-administering pills	-Strong evidence of effectiveness presented by WHO; -IBBS results, 2016.	-Strong evidence of effectiveness presented by WHO; -Growing HIV-incidence among MSM in Belarus and low rates of using condom among highrist groups (IBSS, 2017) -Some individuals were already using PrEP in the country by selfadministering pills
The role of the communities in PrEP initiation	-Active participation in IBBS results distribution -Active participation in CCM work -Calling for the action.	-Advocated for PrEP - Cooperated with local and international organizations in looking for the donors for PrEP pilot in the country	-Active participation in IBBS results distribution -Raised awareness about HIV incidence among KAP's and advocated for PrEP	-Active participation in IBBS results distribution -Active participation in CCM work -Awareness raising work about PrEP among MSM and other KAPs -Needs assessment research among communities.
When PrEP-pilot starte	August 2017	January 29,2018	January 2018	2020 the month is not specified
Who were implementing parties	NCDC The Infectious Disease, AIDS and Clinical Immunology Research Centre (National AIDS Centre) CBO Equality Movement	Alliance Public Health (APH) CBO Alliance Global Hospital # 5, Kiev L.V. Gromashevsky Institute of Epidemiology and Infectous Disease of the NAMS of Ukraine, AIDS centre, Kiev	National HIV Program administered by HIV department of HDCD NGO "Initiativa Posityva" NGO "GENDERDOC -M"	-NGO Vstrecha -The Republican Scientific and Practical Center of Medical Technologies, Informatization, Management and Economics of Public Health
Other partners	NGO Tanadgoma NGO Identoba The Global Fund (CRG fund) ECOM APCOM	NGO MenZDRAV The Global Fund PEPFAR	NGO "AFI" – Chisinau; NGO "Miloserdie" – Tighina/Bender; NGO "ATIS" – Balti. 14 local NGOs across the country holding a permission to perform HIV testing. 8 HIV units across the country UNAIDS	WHO country office in Belarus UNAIDS NGO Vstrecha
Scale Up	September 2018 Ongoing till June 2022 Same implementing partners Donor- The Global Fund plus domestic funding	January, 2019 Ongoing till December 2019 Donor- The Global Fund Same implementing partners & Regional and city AIDS centres Regional Public Health Centres 24 NGOs/CBOs	January 2019 NGO "Initiativa Posityva", Donor- The Global Fund September 2019 NGO GENDERDOC-M Donor-UNAIDS	NA

How the demand was created	-Raising awareness among the communities through outreach, peer work and other educating methods; -Training of the medical personnel; -Training of the communities	-Informational camping targeted to the communities -Training of small group of medical personnel -Training of the communities	Up to date -Trained medical professionals (small number) -Trained social workers and outreaches of the partner NGOs -Initiated awareness raising campaign target on wider population In future -To develop a web-site (PrEP info resource for all groups) -To train more medical personnel -To train communities; -To promote a mixed model with increased role of the communities -To revise a clinical protocol by including on-demand regimen	In the process of planning
Target groups	MSM Transgender women	-MSM -TG + sex workers -HIV-negative partners in discordant couples	Any HIV-negative person who is at risk of acquiring an HIV (including but not limited to MSM, SW, TG and discordant couples)	MSM (maybe discordant couples at a later stage, details are not known yet)
Number of PrEP Users	Aug 2017-Aug 2018: 100 Aug 2019-June,2022: plus 150 annually As of September 1, 2019: 218	2018: 100 2019: plus 2806 users As of September 1, 2019: 959	Pilot: target was not specified, Scale up: targeting 200 clients annually in 2019-2020 As of September 30, 2019-16 users	First year: 100 No users
What service model was established?	Medical facility based initially, which is now in a process of transforming into the mixed model	Mixed model of service delivery, medical facility-based with active involvement of the community	Medical facility based initially, which is now in a process of transforming into the mixed model	Planning to have a mixed model: medical-facility based with community involvement.
Which uptake regimen is applied?	Daily: Tenofovir/Emtricitabine 300/200 mg Considering to add to the protocol on- demand regimen	Daily: once a day TDF/FTC (generic)	Daily: once a day TDF/FTC (generic) Considering to add to the protocol on- demand regimen	Not known yet. Daily and maybe on-demand too?
What are financing sources for PrEP service/projects	The Global Fund National budget covers medical component from July 2019	Pilot- PEPFAR/CDC Scale up- The Global Fund National budget covers HIV-testing	National HIV programme (medicines and tests) The Global Fund and UNAIDS (social workers, outreaches, information and awareness raising campaign)	Global Fund supported regional programme: "Sustainability of services for KAP in EECA region"

Any sustainability considerations for future?	For Medical Component: ensured by the domestic funding For Community Component: not clear how to ensure it from 2022.	Not yet	To include a social support for PrEP users into the list of services covered by the state (e.g., the fund of prevention and harm reduction of the National Health Insurance Fund) The arrangements for medication and tests are already in place and are/will be funded by the state budget.	Not yet
The role of the communities in PrEP-pilot implementation	-Informing community members about the project and encouraging them to participate; -Screening applicants for eligibility providing adherence and risk reduction counselling -Providing social support Overseeing case management	-Advocacy for initiation and scaling up PrEP -Active cooperation with all stakeholders; -Developing a mixed model of PrED delivery with active participation of CBOs	-Outreach and peer-to- peer work; -Elaboration and implementation of the information and awareness raising campaign; -Active promotion of community-based model, looking for international donors and other sustainability options for PrEP component	NA
Barriers for PrEP implementation and institutionalization	Low demand Unwillingness of the potential clients to visit AIDS centre Misconceptions about PrEP among communities Homo and transhobic attitude among medical personnel and wider population Lack of alternative locations for distribution of medicines Geographical coverage (until 2019 was available only in the capital, Tbilisi)	Lack of financial resources Lack of relevant knowledge among medical personnel	Medical-facility based model creates a barrier to enrolling and retaining of some potential users. A medical facility based model with no involvement of the communities, lack of information and awareness raising campaign resulted in extremely low demand on PrEP by potential users. Community based PrEP planned to be introduced in the end of 2019.	NA
Has it become a part of national strategies? When, how?	PrEP is included in the National Strategic Plan as part of the HIV prevention package since 2015. This increases the probability of national funding for PrEP services following the exit of the GF.	Not yet	The first step of PrEP initiation in Moldova was its legal institutionalization in 2018 by developing a National Protocol and including its implementation in national HIV program. Community element has started in 2019 as a promotion tool for PrEP.	NA
Other mechanisms of institutionalization (already in place or planned, or envisioned)	Financial sustainability of the mecial component is ensured by inclusion of the PrEP service in HIV prevention package (see above) Sustainability of the community component still has to be resolved by June 2022, when component funding expires.	Clinical protocol on PrEP was developed and endorsed by MoH in June 2019	Complimentary adherence and prevention services might be included in state funded complementary health services list.	Training of medical personnel, development of national protocols, sharing experience of other EE countries.

Arrangements for organizational and financial sustainability of PrEP service	Partners are now looking for the ways how to institutionalize the community component of PrEP, no clear plan yet.	At this stage, and in the following few years, all aspects of PrEP (medicines, laboratory tests and community support) are largely depended on the external support	To integrate a PrEP element in already existing HIV services financed by state budget	NA
The role of the communities in institutionalization process	-Active partnership with all stakeholders. T	-Advocacy for the funding. -Advocacy for developing a National clinical protocol -Advocacy for including PrEP into the National HIV Strategy	-Advocacy for initiation and sustainability, as well as application of a community element for initial PrEP promotion in Moldova	NA
Lessons learned	Nothing specific at this stage yet	NA	In order to create a demand, it is vital to apply mixed model and both regimen for uptake, also to train medical personnel and communities and educate high risk groups. It is vital to have a well-planned awareness raising campaigns and online educational resources.	It is important to make sure that community members completely understand how PrEP works. There are many people, who change mind on PrEP after realizing that it requires lifelong administration of the medicine and permanent monitoring through medical tests. Demand- At this stage-biggest issue is how to create demand. There are no gay clubs or other platforms for spreading information. The project has to address this issue, but not known yet-how.

Annexes:

Annex-1 Matrix: Briefly about PrEP Pilots in Belarus, Georgia, Moldova and Ukraine (Matrix)

Annex-2. The list of reviewed materials

- 1. Assessment of the Availability of PrEP, the Main Barriers to Implementing PrEP, and Scaling Up PrEP in the EECA Region, Marina Kornilova, Gennady Roshchupkin; ECOM 2018
- 2. National Program on HIV/AIDS prevention in the Republic of Armenia in 2017-2021
- 3. Clinical Protocol of HIV Prevention, Armenia
- 4. EMIS 2010 : the European men-who-have-sex-with-men internet survey Findings from 38 countries / The EMIS Network. Stockholm : European Centre for Disease Prevention and Control; 2013. http://www.emis-project.eu/
- 5. The barriers to the access to PrEP for MSM and TG in Georgia, George Soselia, report, September, 2018
- 6. IBBS 2016, Moldova, English summary (grey report provided by the respondent)
- 7. The Power Point Presentations prepared for different conferences, provided by the respondents from Georgia, Ukraine, Moldova and by the ECOM.
- 8. https://www.vstrecha.by/stati/zdorove/2544-prep-10-prostykh-voprosov-o-tom-chto-eto-takoe-i-zachem-nuzhno-ob-etom-znat.html
- 9. http://aph.org.ua/en/our-works/eastern-europe-and-central-asia/resservices/?fbclid=lwAR3SkAhuJzq-ESNx2RNPzxntC0FSpWjAW0FFux9JxGU9AU4hNica0KRk6Us
- https://zakon.rada.gov.ua/rada/show/v0003828-15?fbclid=lwAR0jU9x-BXOTeQ00KfkbtFGvb8RuJz9aQ0oDpuvXr6Ma3WakgVxhqXSelHs
- 11. http://www.armaids.am/en/statistics/stat_2019/stat_september_2019.html?fbclid=lwAR2G3hWAGnJixfFvUtHInhwWxgZ_tleYC8aSJilNOdcr50rL-ToBlrU34
- 12. http://www.pas.md/ro/PAS/Studies/Details/72

Annex 3: Data collection framework

1. Initiation of a process

- -when PrEp was initiated in your country?
- -who was (were) the initiator(s)? (donor, local NGOs, communities, other)
- -what was a main justification for a need of PrEP programme in your country (what epidemic situation, in what population)?
- -what was a main reason for starting a PrEp in your country (concrete targets: number of clients in the pilot project, what populations, what service system expected to be develop)?
- -what was the role of the communities in initiation (concrete functions the community organizations were expected to implement, how the coordination between community and medical organizations has been planned to be organized)? -any barriers, mistakes/regrets or lessons learned related to PrEP initiation in your country?

2. Piloting process

- -when the project started?
- -how the project started?
- -who was (were) implementers? (which organization (s))
- -how the demand in the target populations and among medical professionals on this programme was created?
- -how the project works? (activities, logistics, partnerships, role distribution, how the target groups are reached; who are main targets; which medicines; purchasing process/problems in supply?) (please create an organigram where possible)
- -was the attempt to promote a PrEP successful? (some quantitative data, if available)
- -if yes, why and how the success was achieved, if not, why and what would you do differently?
- -what are financing mechanisms, sources of a project? (% from donors, % from national sources, % from other sources)
- -any sustainability considerations for future?
- -cooperation between stakeholders, which stakeholders (NGO, state, academic and other scientific organizations engaged, UN and other internationals, other)
- -what was the role and effectiveness of the communities in implementation?
- -any barriers, mistakes/regrets or lessons learned related to PrEP implementation process in your country?

3. Institutionalization process

- -has it become a part of national strategies? how?
- -other mechanisms of institutionalization (already in place or planned, or envisioned)
- -any plans/thoughts to achieve organizational and financial sustainability?
- -what was the role of the communities in institutionalization process?
- -any barriers, mistakes/regrets or lessons learned related to PrEP Institutionalization process in your country?

Last question: Please tell us anything that you consider important, but has not been covered by my questions and our discussion.

