



**Minutes of the 92nd CCM meeting
January 29, 2019**

**Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and
Social Affairs of Georgia**

Participants

#	CCM Members/Alternates	
1	David Sergeenko	CCM Chair, Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
2	Amiran Gamkrelidze	NCDC&PH, General Director PR of the GF grants
3	Akaki Abutidze	On behalf of Mr. Tengiz Tsertsvadze, General Director, Infectious Diseases, AIDS and Clinical Immunology Research Center SR of HIV grant
4	Zaza Avaliani	National Center of Tuberculosis and Lung Diseases, Director SR of TB grant
5	Eka Kavtiashvili	On behalf of Mr. Khatuna Todadze, Center for Mental Health and Prevention of Addiction
6	Nino Kasradze	Ministry of Education, Science, Culture and Sport Chief Specialist of the Strategic Planning Unit of Strategic

		Development Department
7	Guram Amiridze	Alternate member of Mr Levan Kakava, Deputy Minister of Internal Affairs
8	Irine Javakhadze	Ministry of Finance, Budget department/State and consolidated Budget Formulation Division, Chief Specialist
9	Marijan Ivanusa	WHO Representative /Head of WHO Country Office in Georgia
10	Nino Mamulashvili	WHO Country Office, Programs Coordinator, alternate member
11	Lela Bakradze	UNFPA, Assistant Representative
12	Archimandrite Adam – Vakhtang Akhaladze	Head of Public Health Department, Patriarchate of Georgia
13	Zurab Vadachkoria	Rector of Tbilisi State Medical University
14	Elguja Meladze	Employers’ Association of Georgia, President
15	Konstantine Labartkava	CBO New Vector, KAP IDU Board Chairman SR of HIV grant
16	Gocha Gabodze	Alternate members of Mr. Davit Kakhaveri, Equality Movement KAP MSM Community SR of HIV grant

17	Lasha Tvaliashvili	CBO Real Vision Real People PLHIV community
18	Irma Kirtadze	Alternate member of Ms. Mzia Tabatadze, NGO Alternative Georgia
19	Zaza Kartchkhadze	NGO New Way SR of HIV grant
20	Nino Qajaia	Alternate member to Ms. Lela Tsakadze NGO Winners Club, Founder, TB KAP
21	David Jikia	Alternate member of Mr. Nikoloz Mirzashvili, Former TB Patient, Patients Union
22	Giorgi Magradze	Georgian Health Promotion and Education Foundation, TB NGO
#	Guests/Observers/speakers	
23	Tamar Zurashvili	Policy and Advocacy Specialist
24	Nana Nabakhtevili	LFA, UNOPS, Finance Expert
25	Nino Samvelidze	EU, Programs Manager
26	Marina Darakhvelidze	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
27	Thea Jikia	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia, Drugs Agency
28	Irma Khonelidze	NCDCPH, Deputy Director General, GFATM PIU, Director

29	Ketevan Stvilia	NCDCPH, Deputy Director General, GFATM PIU, HIV Program Coordinator
30	Eliso Bichashvili	Ministry of Justice, Medical Department of Special Penitentiary Service, Coordinator of Primary Healthcare Services Unit
31	Vivian Cox	“Stop TB Partnership”, MDR TB clinical consultant
32	Nino Lomtadze	NCTLD, Head of TB Surveillance and Strategic Department
33	David Otiashvili	Alternative Georgia
34	Konstantine Rukhadze	CBO “New Vector” GENPUD, KAP IDU
35	Kakha Kvashilava	Georgia Harm Reduction Network
#	Secretariat	
36	Irina Grdzeldze	Executive Secretary
37	Natia Khonelidze	Administrative Assistant

Agenda

15:00 – 15:10	<p>Opening speech /remarks/ endorsement of the agenda</p> <p>Mr. David Sergeenko - CCM Chair, Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia</p>
15:10 – 15:15	<p>Addressing the members with the request to declare the presence of the Conflict of Interest</p> <p>Secretariat</p>
15:15 – 15:20	<p>The change of the representation of the Ministry of Education, Science, Culture and Sports at the CCM/admission to CCM membership of Ms. Nino Kasradze, Head Specialist of the Strategic Planning Unit of the Strategic Development Department/Voting</p> <p>Ms Irina Grdzeldze – CCM Executive Secretary</p>
15:20 – 15:40	<p>Updates of TB treatment guidelines according to WHO 2018 December recommendations</p> <p>Ms. Vivian Cox – “Stop TB Partnership”, MDR TB clinical consultant</p>

15:40 – 15:50	<p>The formalization of the relationship between NCTLD and LEPL Drug Agency for medical activities in terms of pharmacovigilance of anti-TB drugs</p> <p>Ms. Nino Lomtadze – National Center for Tuberculosis and Lung Diseases, Head of Surveillance and Strategic Planning Department, Coordinator of the Global Fund TB Program in Georgia</p>
15:50 – 16:00	<p>The role of pharmacokinetic research in clinical management of TB – modern approaches, existing practice (French model), future plans</p> <p>Mr. Zaza Avaliani - National Center of Tuberculosis and Lung Diseases, Director</p> <p>Ms. Nino Lomtadze - National Center for Tuberculosis and Lung Diseases, Head of Surveillance and Strategic Planning Department, Coordinator of the Global Fund TB Program in Georgia</p>
16:00 – 16:15	<p>HIV and TB grants implementation status/grant making process</p> <p>Ms. Irma Khonelidze – NCDCPH Deputy Director, GFATM PIU Project Director</p>
16:15 - 16:25	<p>Report on Oversight activities</p> <p>OC Renewal</p> <p>Ms Irina Grdzeldze – CCM Executive Secretary, Mr. Nikoloz Mirzashvili – Patients’ Union</p>
16:25 – 16:35	<p>Georgia Syringe Vending Machine Trial – implementation status</p> <p>Mr. David Otiashvili – Alternative Georgia, Director</p>
16:35 - 16:45	<p>AOB/announcements</p>
16:45	<p>Closure of the meeting</p>

List of acronyms

aDSM - Active TB drug-safety monitoring and management

AE - Adverse event

AIDS - Acquired Immune Deficiency Syndrome

Bdq - bedaquiline

CBO - Community Based Organization

CCM - Country Coordinating Mechanism

Cs – Cycloserine

Cfz - Clofazimine

COI - Conflict of Interest

CSO - Civil Society Organization

CT – Country Team

Dlm – delamanid

DR-TB - Drug Resistant Tuberculosis

GDF - Global Drug Facility

HIV - Human Immunodeficiency Virus

IDU – Injecting Drug User

KAP – Key Affected Population

LTBI - Latent Tuberculosis Infection

LVX - Levofloxacin

Lzd - linezolid

MSM – Men who have sex with men

NCDCPH – National Center for Disease Control and Public Health

NCTLD – National Center for Tuberculosis and Lung Diseases

NSP – National Strategic Plan

OC – Oversight Committee

PAAC - Policy and Advocacy Advisory Committee

PCR – Program Continuation Request

PIU - Project Implementation Union

PLHIV - People living with HIV

PR – Principal Recipient

PV - Pharmacovigilance

RR TB - Rifampicin-resistant tuberculosis

SAE – Serious Adverse Event

SR – Sub-recipient

SVM – Syringe Vending Machine

TB – Tuberculosis

TDM - Therapeutic Drug Monitoring

TRP – Technical Review Panel

UNFPA - United Nations Population Fund

WHO - World Health Organization

David Sergeenko – greeted the participants and thanked them for coming. The Chairperson requested if there are any topics to be additionally include into the agenda, to make any announcements and to raise topics for discussions beyond the agenda. Dr Sergeenko asked members to declare the presence of the Conflict of Interest if any, fill out the CoI forms.

The agenda of the 92nd CCM meeting was endorsed. The COI forms were filled out and kept at the CCM Office.

David Sergeenko - gave the floor to **Ms. Irina Grdzeldze**.

Irina Grdzeldze – announced that due to structural changes in the Ministry of Education, Science, Culture and Sports at the CCM the Ministry proposed to shift the CCM membership from Mr. Kakha Khandolishvili to the proposed candidate, Ms. Nino Kasradze, Head Specialist of the Strategic Planning Unit of the Strategic Development. Ms. Grdzeldze asked the members to address Ms. Kasradze with questions if any and put the issue to the vote.

Ms. Nino Kasradze was unanimously admitted to the CCM membership by all members presented at the meeting. The membership of Mr. Khandolishvili was ended.

David Sergeenko – congratulated Ms. Kasradze, wished her success and gave the floor to Ms. Vivian Cox.

Vivian Cox - presented to the audience main WHO DR TB treatment guidelines revision as of December 2018 and its implications for Georgia National TB Program (presentation attached). Ms. Cox underlined the prompt adaption and implementation of the WHO recommendations in the country and leading position of Georgia in the region in terms of TB treatment. She also highlighted the fact that the planning

work aimed at revision of national treatment guidelines based on WHO recommendations is already ongoing. Prioritization of drugs to treat drug-resistant tuberculosis and lengths of treatment of DR TB were under the main focus of the presentation. Dr. Cox presented to the audience the priority drugs for treatment of RR TB and MDR TB (2016) where second line drugs are injectable agents (group B). In 2016 the new drugs, Bdq and Dlm were first included into that list (group D). The analysis of the data from clinical research since 2016 served as basis for the reprioritization of the drugs in the latest 2018 recommendations. The newer drugs, Bdq and Dlm were moved up in prioritization. In contrast with 2016 guidelines the injectable drugs were deprioritized significantly and they will be used only in minimal number of DR TB patients based on toxicity of the drugs and lack of evidence on how well they work. While speaking on the duration of the treatment it was noted that growing body of evidence shows that the good outcomes can be achieved with the shortened duration. Thus according to new recommendations for uncomplicated MDR-TB, duration may be shortened to 9 months using the same priority drugs, for more complex MDR-TB, new duration is 18-20 months, modified depending on patient response. The main implications for Georgia were presented as follows:

1. *Majority of patients diagnosed with DR-TB can be treated with all oral treatment regimens* which allow avoiding the logistics and toxicities associated with injectable agents and provide a chance to improve treatment outcomes by using the most effective drugs with best scientific evidence for their use.
2. *Treatment duration will be shortened to 9-20 months for most patients* which reduces costs associated with treatment and provides a chance to improve adherence to treatment and treatment completion.

The National guidelines revisions developed jointly with guideline development working group to be submitted to the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia reflects two main directions: modified fully oral shorter regimen for pulmonary RR-/MDR-TB: 9 months Bdq/Lzd/Lfx/Cfz/Cs, with Dlm first drug to substitute in case of toxicity (1); Longer 20 month regimens for all other patients, e.g. quinolone resistance, extensive TB disease: Backbone of Bdq/Lzd/Lfx/Cfz, with additional drugs based on treatment history and drug resistance patterns (2). It was noted that backbone for treatment includes Lzd which can be applied for children as well.

Additional national guideline revisions include: attention to patient support during and after treatment completion: post-treatment rehabilitation; enhanced efforts to find all TB cases and treat latent TB infection: systematic screening for Active TB Disease guidelines and latent TB infection guidance in national guidelines

The guidance is updated on: surgical management of TB cases; TB meningitis and other forms of extrapulmonary TB; laboratory monitoring (including therapeutic drug monitoring); resistance testing to DR-TB drugs.

The following steps of implementation process were presented:

Guidelines: finalization, submission for approval by MoH, printing and distribution.

Training: at NCTLD for TB physicians and regional coordinator, then cascade of training for TB physicians and regional coordinators outside Tbilisi.

LTBI screening and treatment: implementation plan needed to expand in a step wise fashion after guideline finalization and approval.

Laboratory: expand capacity to support diagnosis and monitoring on treatment.

Pharmacy and supply: finalize forecasting for second line drugs, 2019-2020.

In conclusion, Dr. Cox noted that Georgia is well positioned for adapting WHO guidelines very quickly. The country already has experience in using new drugs. The implementation of new guidelines will contribute greatly to sustainability of achieved progress and further improvement of outcomes.

David Sergeenko – thanked Dr. Cox for interesting presentation. Apart from the aspects to be considered by the specialists there are some issues that needs to be underlined. In the countries with universal access to TB treatment including Georgia adherence to the treatment represents the main challenge. Two important factors of the updated guidelines: shifting to oral drugs and shortened regimens will definitely improve the adherence. As for, Bdq the country already has the experience of its use which is very helpful. The presented issue needs to be considered in the working format. Despite the fact that the treatment regimen is shortened, the comprehensive forecast of the financial implications of using new drugs should be done. Provided that the total cost is equal or less than the sum envisaged by this year budget the prompt implementation will start. The obstacles with regard to national guidelines revision and translation into Georgian language are not anticipated. The Chairperson opened the floor for discussion.

Konstantine Labartkava – as a representative of IDUs community and CBO New Vector stated that the organization is implementing Harm Reduction Program and earned a very high level of trust form the side of beneficiaries. The latest tendencies of organizational activities are directed towards offering integrated services to beneficiaries. He referred to successfully implemented project “Provision of Support for Patients with Resistant Tuberculosis to Provide Improvement in Treatment” when direct involvement of the community, creation of multi-disciplinary groups, uniting former patients, identification of the reasons for treatment interruption rather than medical, such as social and psychological and other activities brought successful outcomes. Due to collaborative activities the rate of interrupted treatment was reduced from 13% to 5%. Mr. Labartkava expressed special gratitude towards Prof. Zaza Avaliani and all NCTLD team for best cooperation and support and expressed his hope for continued cooperation.

Irma Khonelidze – stated that financial forecast for new drug is on-going in collaboration with GDF, NCTLD and with involvement of Dr. Cox. The work will be completed by the end of the week. The preliminary estimates show that costs associated with implementation of new regimen will not exceed the budget sum. The latest order for TB drugs made in November in some extent envisages procurement of new drugs. Ms. Khonelidze expressed her hope that taking into consideration the implementation steps the country will be able to adapt a new regimen starting from the 2nd quarter of current year.

David Sergeenko – summarized the discussion, thanked all for expressing their views and stated that the work will be continued in working format.

The CCM agreed on the following: the work on updated guidelines to be continued in working format within relevant institutions.

David Sergeenko - gave the floor to Ms. Lomtadze.

Nino Lomtadze – stated that according to the Ministerial Decree #01-18/5 on mandatory recording and reporting of the SAEs for all DR-TB patients, issued in May 2016, NCTLD became responsible body for aDSM. The form for collection information on anti-TB drugs was developed. With assistance of donor organizations and Association of Phthisiologists and Pulmonologists the medical workers were provided with all relevant trainings.

Currently the paper-based data are collected at NCTLD. The form is accompanied by detailed instruction on its use. The staff of NCTLD is entering the data into an Excel file and makes analysis (AE, severity of AE, drugs causing AE, impact of AE on TB treatment, which medicines for management of AE needed).

The rapporteur noted that Drug Agency became a full member WHO collaborating Uppsala Monitoring Center (WHO-UMC). The quality and quantity of the reports prepared by NCTLD greatly contributed to this important fact. While speaking on NTP and Drug Agency cooperation Dr. Lomtadze focused on the following: the productive cooperation established between these two institutions needs to be formalized. The main vision of this formalized cooperation is as follows: NCTLD has direct access to WigiFlow for entering data and access to its analytical portal while Drugs Agency finally validates the data from NCTLD. Dr. Lomtadze noted that this issue will be discussed in details at the TB Council meeting.

Thea Jikia – thanked NCTLD for great contribution. Ms. Jikia stressed that high quality of reports from TB Center allowed Drug Agency to become a full member of Uppsala in 2018. Drug Agency will make all efforts to get the access levels requested by NCTLD which will make their cooperation more effective. Finally, Ms Jikia noted that currently transitional period is in place and radical development in the field of Pharmacovigilance is on the way.

Irma Khonelidze – underlined the importance of development of PV field. She stressed that with support of the Global Fund representatives of NCTLD and Drug Agency participated in the comprehensive training on PV held in Uppsala. This year if such need exists one more participant can be added. This issue will be further discussed in working format and agreed with the Global Fund.

David Sergeenko – referred back to the period when Bdq was firstly introduced in the country and the challenges associated with the PV and expressed his satisfaction with regard of on-going progress in this field.

The CCM agreed on the following: the work on formalization of the relationship between NCTLD and LEPL Drug Agency in terms of pharmacovigilance of anti-TB drugs to be continued in working format within relevant institutions.

David Sergeenko – gave the floor to Mr. Avaliani.

Zaza Avaliani– outlined the role of pharmacokinetic research in clinical management of TB, modern approaches and planned activities. Mr. Avaliani stated that number of innovative approaches are supported by and implemented within the Global Funds project and expressed his gratitude towards Mr. Amiran Gamkrelidze and Ms. Irma Khonelidze for best cooperation. In addition, the project financed by 5% Initiative provides another opportunity to support innovations in TB management.

The following was under the focus of the rapporteur:

Therapeutic Drug Monitoring (TDM) performed through pharmacokinetic research represents a tool for optimization of TB treatment and possibly for TB elimination. TDM provides an opportunity to select a concrete effective and safe dose of a medicine for a concrete patient. The role of TDM is especially important for the following groups of the patients: sensitive TB patients with unsuccessful standard treatment despite full adherence to the treatment; patients with acute gastroenterological problems; patients receiving drugs characterized with drug – interaction; patients with kidney diseases and being on dialysis; patients with HIV and Hepatitis C co-infection; patients having diabetes; patients receiving 2nd line treatment.

Afterwards Prof. Avaliani focused on the adverse events. According to PV data of NCTLD, 75% of DR TB patients has at least one AE and 19% has at least one SAE. 82% of these cases can be associated with anti-TB drugs. National and International guidelines on drug toxicity management are empirical thus termination of all anti-TB drugs for a long period of time is quite common while the concrete reason of the toxicity can be just one specific drug. Implementation of pharmacokinetic study in the country will dramatically increase the efficacy of the treatment.

It is notable that TDM is actively used in Europe and the USA. The French TB treatment Program differs from Georgia NTP just with this one principle which was revealed within the framework of 5% Initiative project as well. Within the framework of the project 2 clinicians and 2 laboratory workers from NCTLD were sent to France where they altogether with other issues worked on PK. Thus the basis for continued collaboration with French partners, other international organizations was set up. Finally, Prof. Avaliani expressed hope that this proposal will be accepted and supported by the Global Fund project.

David Sergeenko – thanked Prof. Avaliani and opened the floor for discussion. Dr. Sergeenko explained to the audience the concept of TDM and noted that pharmacokinetic research is a routine study, especially while using injectable antibiotics. The Chairperson summarized the discussion and noted that the proposed initiative is important and appropriate. The estimates of the needed resources e.g equipment infrastructure should be done.

The CCM agreed on the following: the work on this direction to be continued, the estimates to be done.

David Sergeenko – gave the floor to Ms. Khonelidze.

Irma Khonelidze – presented to the audience the status of grant making process. She reminded to the audience that HIV and TB PCRs were submitted to the Global Fund in August 2018. The Global Fund informed the country that the Global Fund's Technical Review Panel has recommended Georgia's Funding Requests to proceed to grant-making. Thus the grant-making process has been launched. The timelines set up with the purpose to enable smooth translation of funding requests to disbursement-ready grants were presented:

HIV grant. End date of current grant - June 30, 2019. The required documents are planned to be submitted within coming days. The grant negotiations will be held in the week of February 11, 2019. The LFA will be involved in detailed discussions and will make its conclusion on presented documentation. The next step is submission of the request for approval to Grant Approval Committee at its meeting planned for March 2019 and further to the Global Fund Board for making final decision in April 2019. The proposed schedule allows proceeding with necessary tender procedures with program implementers. The proposal needs to be submitted to the Cabinet of Ministers for approval. Once approval is secured the Grant Agreement will be signed by all parties.

TB grant. End date of current grant is December, 2019. The same process as for HIV grant is planned to be undertaken starting from the 3rd quarter of current year. The exact dates to be agreed.

Afterwards Ms. Khonelidze focused on the issue of transition of preventive services and the volume of the transition. This issue is reflected in the 2019-2022 HIV NSP endorsed by the CCM in July 2018. During the planning phase the consideration toward necessity for adding additional funds for this component emerged. The final conclusion will be made during the coming days. Thus it is anticipated that the revision of the program split will become necessary. This issue will be discussed within PAAC format and then agreed with the CCM.

Ms. Khonelidze provided the audience with information on the meeting initiated by the Global Fund and aimed at presentation and sharing experience on two initiatives on-going in Georgia within TB Program: HIV/HepC/TB pilot program in Samegrelo – Zemo Svaneti Region and ECHO project. The meeting was held in November 2018 and the CTs from different regions were participating at the meeting. Hep C elimination program had served as a trigger for launching and development of TB ECHO project. TB consiliums are being shifted to the format of ECHO. ECHO is successfully launched with Adjara zero TB initiative project. Two sessions have been already held and the 3rd one for case managers will be held next Friday. The Information on this initiative attracted vivid interest of the participants of the meeting. Mr. Zaza Avaliani has been already contacted with the request to see the project on site.

As for HIV/HepC/TB pilot program, the Global Fund finds it desirable to make an assessment of this model and to develop a business model as an example for other countries.

David Sergeenko – thanked Ms. Khonelidze for providing updates, addressed the members with the request to raise the questions if any.

The CCM agreed on the following: provided that the necessity for revision of program split emerges the PAAC will issues the recommendation to inform CCM decision.

David Sergeenko - gave the floor to Ms. Grdzeldze.

Irina Grdzeldze – presented to the members the process and the results of the OC renewal process undertaken due to expiration of the 1st two year term of service of the OC members and in line with CCM regulatory documents. The results of the nominations from each sector had been shared with the members in advance of the meeting. The members were asked to provide their opinion regarding the proposed candidates.

The following renewed composition of the Oversight Committee as per nomination of the corresponding sectors was endorsed:

Civil Sector: Mr. Nikoloz Mirzashvili – former TB patient, Patients’ Union; Mr. Lasha Tvaliashvili – representative of HIV community, Real People – Real Vision; Ms. Mzia Tabatadze – Representative of HIV NGOs, Alternative Georgia.

Government Sector: Ms. Eliso Bichashvili – Ministry of Justice, Medical Department of Special Penitentiary Service, Coordinator of Primary Healthcare Services Unit. *Note: The nomination from*

the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia will follow.

Development Partners: Ms. Nino Mamulashvili - WHO Georgia, Country Office, Programs Coordinator.

Afterwards, Ms. Grdzeldze presented to the audience the report on the Oversight Activities and stated that despite the renewal process and some outflow of the OC members the OC activities were not interrupted and were on-going smoothly. The CCM was regularly provided with detail information on the planned and performed activities, dashboards and minutes of all meetings. The meetings dedicated to the discussion of the dashboards were held. 4 site visits were conducted by the OC and the Secretariat, out of this 2 were held in the regions: visits to Equality Movement, Akeso, New Vector Rustavi office, and screening cabinet in Borjomi. Ms. Grdzeldze outlined the details of the visits to the region stating that the minutes will be sent to the members during the coming week.

New Vector Service Center in Rustavi. Date of the visit – January 24, 2019

The Center has been implementing Global Fund financed Needle and Syringe Exchange project since September, 2013 and FIND project since February, 2018. The necessity of existence of substitution therapy Center in Rustavi was specially underlined. The nearest center is located in Tbilisi, which represents an obstacle in terms of receiving services for residents of Rustavi and nearby regions. Dissatisfaction with the quality of 1 ml syringes was expressed. Due to low quality, the quantity of distributed syringes increases which accordingly increases expenditures. The staff noted that there is no interruption in terms of provision of supply material. Though stock of naloxone was depleted on the date of OC visit. They expect its replenishment in the shortest period of time. The staff mentioned the effective and timely communication with PR and SRs and noted that there are no any obstacles with regard to disbursement.

Screening Cabinet in Borjomi. Date of the visit – January 25, 2019

The screening cabinet functions for several months and covers Borjomi, Bakuriani and nearby villages. The number of beneficiaries increased with opening of the cabinet. The Cabinet also makes possible implementation of PDI intervention.

The staff noted that there is no interruption in provision of supply material. The dissatisfaction with regard to the quality of 1 ml syringes was not expressed by the staff as well as by the beneficiaries participating at the meeting. Though the dissatisfaction with the quality of HIV and B tests was expressed.

Participating at the meeting beneficiaries expressed their full satisfaction with the services offered by the cabinet. They asked for continuation of its functioning and shifting to full-time basis and asked to raise this notion before the CCM.

David Sergeenko – addressed the audience with the request to raise any questions, suggestions. The Chairperson gave the floor to Mr. Otiashvili.

David Otiashvili – presented to the audience the implementation status of Syringe Vending Machine Trial project (presentation attached). The following was under the focus of the rapporteur. Mr. Otiashvili

expressed his gratitude towards CCM Chairperson and all CCM for supporting the proposal and issuing a recommendation letter at the stage of the proposal submission. The project is supported by the Ministry of Europe and Foreign Affairs of France, 5% Initiative and the Global Fund. In-country partners: NCDCPH, GHRN. Dr. Otiashvili comprehensively explained the main concept of SVM describing it as an innovative model for NSP intervention. This intervention is effectively implemented in many countries. There is a big body of evidences proving its effectiveness. The benefits of this approach were specified as follows: uninterrupted access 24/7; reaching hidden groups (such as younger PWIDs and women); increased geographical coverage; cost-effectiveness. While speaking on the benefits, it was specially underlined that SVM does not substitute but supplement the standard NSP. While speaking on the aims of the project it was stressed that SVM represents mainly an implementation trial. The assessment of the efficacy was added forming a hybrid design assessing both efficacy and implementation process.

It is hypothesized that implementation of SVM will result in: improved 24/7 access to sterile equipment (1); improved access to sterile equipment for those PWIDs, who are not involved in HIV prevention programs and NSPs (2); reduced transmission of HIV and HCV due to acquired safer behavior by various groups of PWIDs (3). Dr. Otiashvili outlined the milestones of the project. Start date – April 2018. End date - April 2021. The preparation phase completed to the date envisaged identification of views, expectations, concerns of potential beneficiaries, service providers, policy makers, residents of nearby areas. The beneficiaries and the staff were interviewed. Installation of first two machines is planned for April, 2019 in Tbilisi. In the process of its operation the comprehensive and regular data collection will be performed. The satisfaction of the beneficiaries will be studied. The study tools include on-line survey. The technology of the SVM also called smart machine allows collection of all necessary data. At the end of the project the beneficiaries and other stakeholders will be questioned again to assess the level of satisfaction and identify bottlenecks. The overarching goal of the project is achieving its sustainability and allowing the country to continue this intervention without donors support.

The stepped-wedge trial design was presented. According to the design by 25th month of project implementation all 10 machines will be operational. It was revealed that adoption of SVM by PWID is quite high. The beneficiaries were interviewed on the subject of desirable dispensed material. 7 types of material were identified (the package for opioid users, the package for stimulators users, the package for prevention of overdose, the packages of male and female condoms, pregnancy test, information material). The survey revealed the favorable locations, the way of taking material. The material used within current Global Fund project will be used. The service will be free of charge. The plastic card will be distributed. The clients of the standard NSP program will receive 6 months cards with twice a day access to the machine. The users not having contact with standard program will receive temporary cards with valid period of 1 month which can be prolonged to 6 months. The beneficiaries need to visit Center in order to reactivate the cards after expiration of validity period. Thus the coverage of beneficiaries will be increased. In order to achieve adoption of the machines by the residents of nearby areas the model of the machine was differentiated. The machine will not be only for drug users but will have wider use as an apparatus supporting health for general population. Thus as per negotiations with pharmaceutical company, PSP some sections will be allotted for selling PSP production. The general population will not have an access to the production for beneficiaries and the material will be covered with non-transparent stickers. The locations in Tbilisi were identified the list was submitted to Tbilisi City Hall with request for rent-free usage of 1sq m of land for non-commercial use. Mr Otiashvili addressed the Ministry with the request of support as the land slot can be donated to the MoH on the basis of the request from MoH to

the Ministry of Economics. Mr. Otiashvili addressed the Ministry with request to support this initiative. The barter agreement with PSP will be concluded. PSP will be providing the machines with electricity.

David Sergeenko – thanked Mr. Otiashvili for interesting presentation. The Chairperson stated that some details presented by Mr. Otiashvili e.g disposal of land slot needs to be further elaborated and structured in working format with involvement of legal advisors to facilitate/inform final CCM decision. The communication and making decision can be done in e-format.

Ketevan Stvilia – addressed Mr. Otiashvili to take into consideration HIV testing of IDUs. The plastic cards can be used as a tool ensuring complementarity of the SVMs to standard program.

David Otiashvili – responded that this factor is taken into consideration. He added that Advisory Board has been established and briefly outlined its scope of work.

The CCM agreed on the following: the details requiring further consideration to be elaborated and structured for informing the CCM decision.

David Sergeenko – open the floor for announcements.

Konstantine Labartkava – raised the following issues:

- 1) Naloxone program. He expressed deep concern with regard to availability and accessibility to this medicine and asked for solution of this acute problem. The role of the Harm Reduction Centers was highly emphasized.
- 2) Pharmacy drug abuse. He stated that despite measures undertaken the situation is still challenging and requires immediate corrective measures. The Civil Sector is considering putting in place radical measures.
- 3) Substitution Programs. Mr. Labartkava highly emphasized and expressed gratitude for successful take-over of methadone program. He stated that the demand for subutex is high. The Government makes its contribution but it is not sufficient. Mr. Labartkava focused on commercial subutex programs and expressed his deep concern with regard to its non-appropriate implementation. He asked the Ministry with the request to mobilize additional resources for free of charge programs. The press-conference covering this issue is planned.
- 4) Integration of services on the basis of harm reduction centers. The importance of integration of State Hepatitis C program on the base of the service centers was underlined. The staff is making all efforts for reaching beneficiaries, the mobile ambulatories are functional. Provision of integrated HIV/TB/Hep C preventive services to beneficiaries is of paramount importance and there is a plan to continue working in this direction. There is a request towards the Ministry for mobilizing greatly needed additional material or financial resources for joint successful implementation of this approach. The community is ready to take an active role in identification and overcoming of all challenges.

David Sergeenko – reiterated the readiness for discussion of any issues in working format, responded to the issues raised and stated:

- 1) Naloxone program. Withdrawal of naloxone from the list of prescription drugs is not considered due to the character of this drug which needs to be prescribed and accompanied with a detailed

instruction of its use to avoid harmful effect. The Chairperson agreed with the role of Harm Reduction Centers ensuring accessibility for the beneficiaries and providing them with appropriate trainings. The Chairperson stressed that the naloxone is provided to the centers by the Government thus its contribution makes provision of the services possible.

- 2) Pharmacy drug abuse which can be divided into two lots: intravenous and tableted forms. The use of intravenous substances has been dramatically decreased since 2014 when due to legislative changes non-prescribed issue of certain drugs became the subject of criminal sanctions. As for tablet form of psychotropic drugs it still remains a problem despite series of measures undertaken. Nowadays there is a consideration towards using the same approach as for intravenous drugs.
- 3) Substitution programs. Methadone substitution program was successfully taken over by the Government. The numbers of beneficiaries increased due to increased accessibility resulted from abolishment of co-funding requirements, the number of sites was hugely increased. Funding of subutex programs can not be seen as a measure of addressing the problem use as stated by Mr. Labartkava. Herewith. Mr. Sergeenko referred to the methods of reacting to the problem as stated by the rapporteur and called on upon constructive and systematic ways e.g development of petition, initiation of legislation package.
- 4) Harm reduction/Hep C program/integration of services. The Chairperson highly emphasized integration of Hep C services at the harm reduction centers and noted that mobile ambulatories represent the government's contribution.

Mr. Sergeenko responded to the same concerns articulated by another representative of community, Mr. Rukhadze. He stated that while recognizing the importance of the services the government makes growing contribution which resulted in significant expansion of the services. The dynamic of the remarkable progress achieved in the recent years was presented one more time. The Chairperson urged the representatives of the community to effective collaboration, developing the concept of qualitative expansion of the services and re-confirmed readiness for best cooperation in the working format.

The representatives of the community thanked Mr. Sergeenko for such a constructive approach.

Kakha Kvashilava – provided brief information on the Regional Project "Sustainability of services for key populations in Eastern Europe and Central Asia region". On April 27, 2018 the consortium of regional organizations from Eastern Europe and Central Asia (EECA) submitted a joint proposal to the Global Fund on regional program on sustainability of services for key populations in Eastern Europe and Central Asia region. The consortium members are: Alliance for Public Health, All-Ukrainian Network of PLWH, Central Asian PLWHA Association and Eurasian Key Populations Health Network. Technical partners: TB People, as well as partners from Belarus, Georgia, Moldova, Kazakhstan, Kyrgyzstan, the Russian Federation, Tajikistan, Uzbekistan and Ukraine. Technical partner from Georgia is Georgian Harm Reduction Network. Project starts date: January 2019, duration – three years. The main aim of the project is to ensure the sustainability of HIV/AIDS services post Global Fund, budget advocacy and advocacy for high quality ARV treatment, fight against stigma and discrimination to improve access to services.

David Sergeenko - thanked the attendees and announced the meeting as closed.

Decisions:

- To admit to CCM Membership Ms. Nino Kasradze. The membership of Mr. Khandolishvili was ended.
- To endorse the following composition of the Oversight Committee

Civil Sector: Mr. Nikoloz Mirzashvili – former TB patient, Patients’ Union; Mr. Lasha Tvaliashvili – representative of HIV community, Real People – Real Vision; Ms. Mzia Tabatadze – Representative of HIV NGOs, Alternative Georgia

Government Sector: Ms. Eliso Bichashvili – Ministry of Justice, Medical Department of Special Penitentiary Service, Coordinator of Primary Healthcare Services Unit.

Development Partners: Ms. Nino Mamulashvili - WHO Georgia, Country Office, Programs Coordinator.

David Sergeenko

Natia Khonelidze

CCM Chair

CCM Administrative Assistant