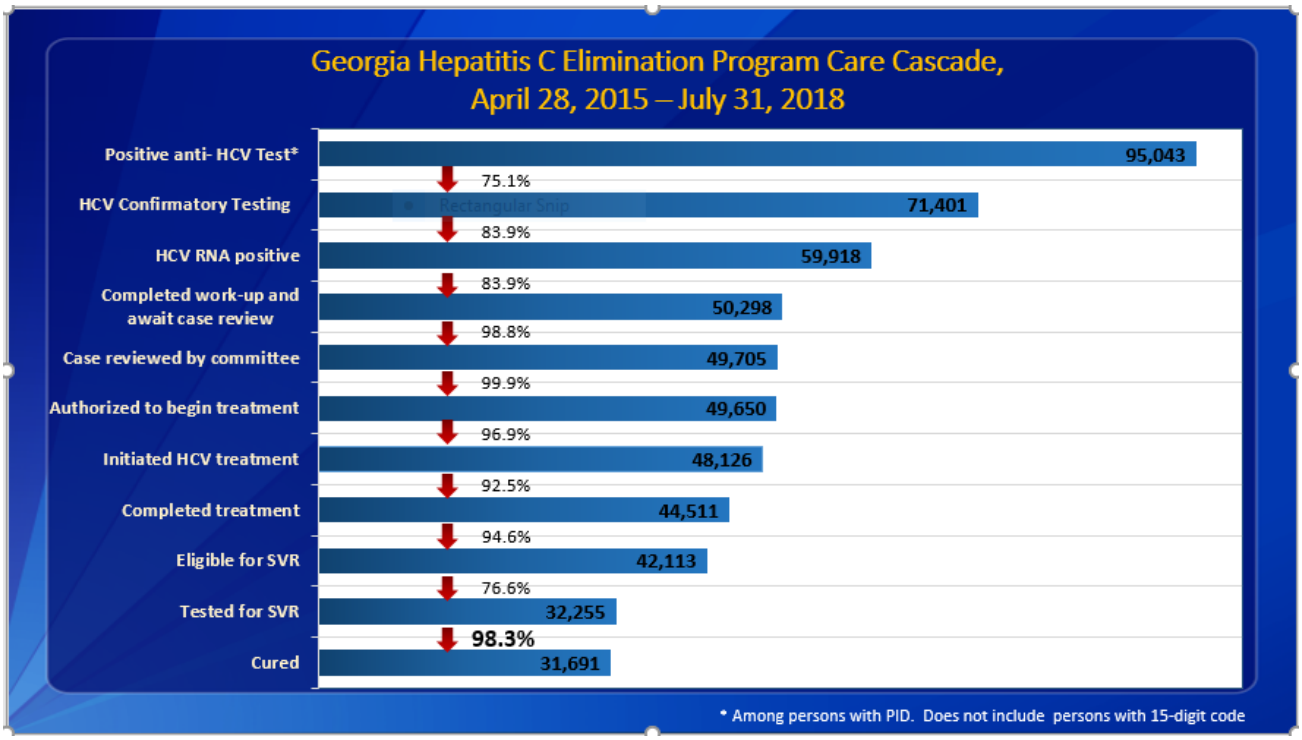
We would like to share activities of July 2018 regarding HCV Elimination Program in Georgia.

1. Statistics

1.1 Georgia Hepatitis C Elimination Program Care Cascade April 28, 2015 – April 30, 2018

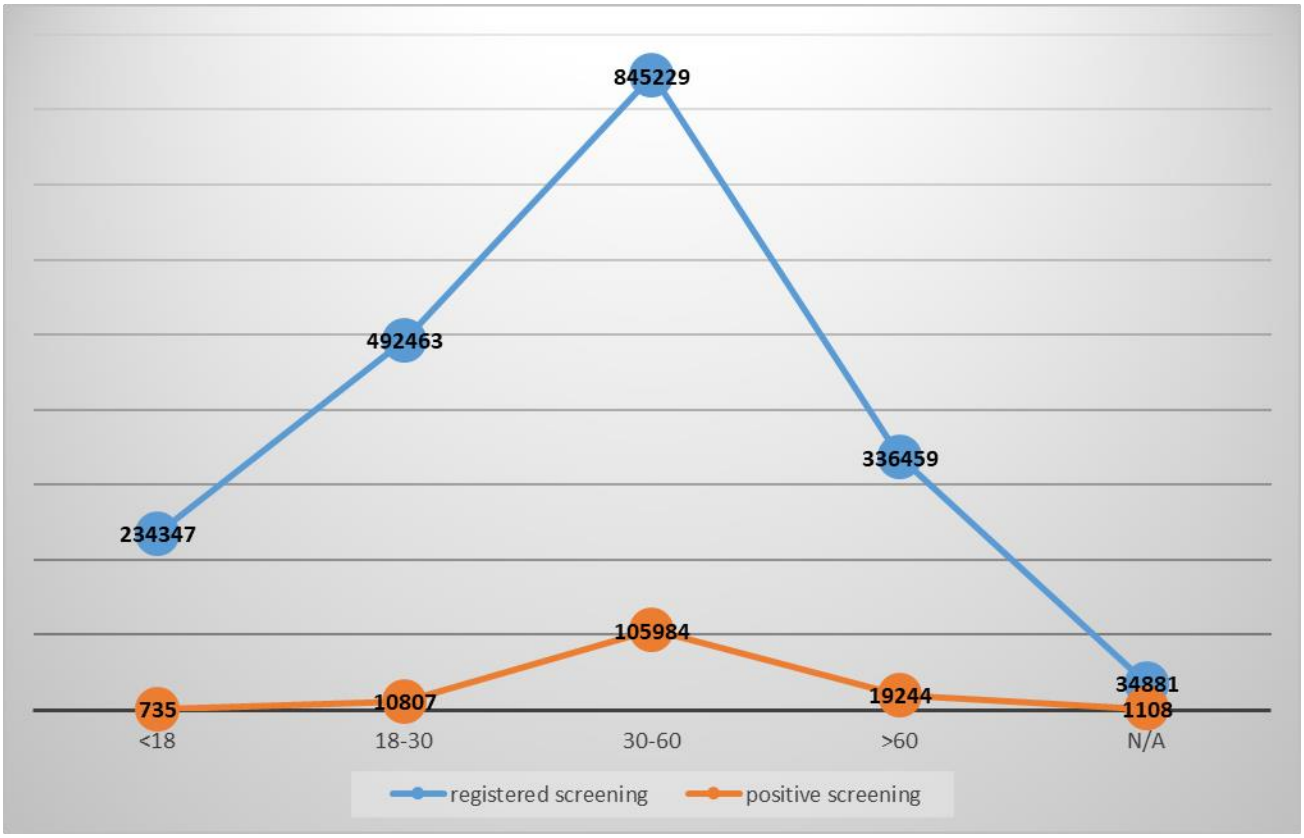
* Due to technical issues, the updated care cascade will be provided in July, 2018



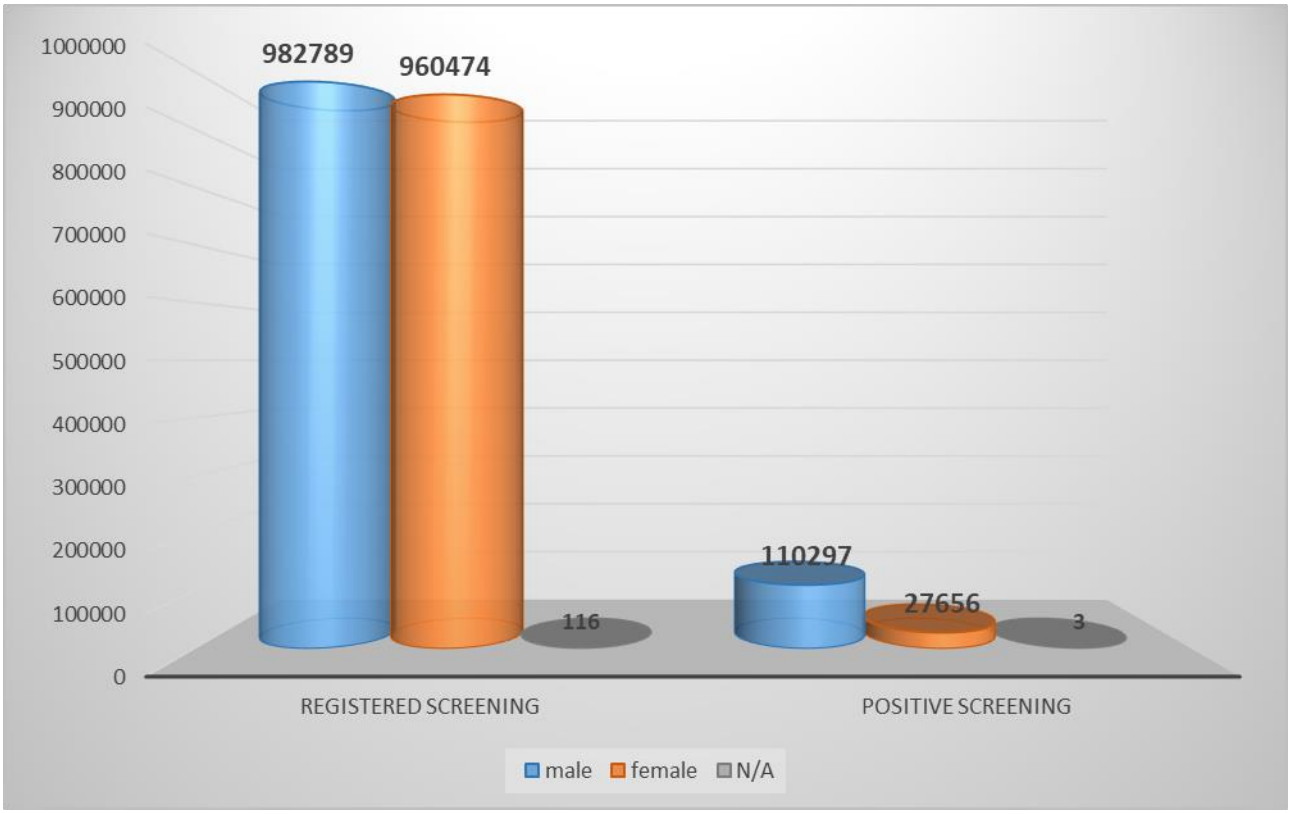
1.2 Information about screening activities

- Total number of registered screening is 1 862 276
- Total number of positive screening among the registered ones is 134 633 (7.10%)
- Distribution by age and gender among the positive screenings:

Screening by age



Screening by gender



1.3.Information about drugs

Total number of disbursed Sovaldi bottles: **39 478**
Sovaldi bottles delivered to service Providers: **34 586**
Sovaldi bottles donated to the Republic of Belarus: **1 500**
Sovaldi bottles donated to the Republic of Armenia: **3 000**
Sovaldi bottles remaining in central stock: **393 (validity period is expired, since sovaldi regimens in practice are almost no longer used for treatment)**

Total number of disbursed Harvoni bottles: **168 440 (including 40 000 new (2018) arrival)**
Harvoni bottles delivered to service Providers**: 133 135**
Harvoni bottles remaining in central stock: **35 305** (**7137 among them expired as of April 30th)**

2. Information about Elimination Program Data System

- A new IT system for care and treatment (ELIM-C 2.0) is being created by US CDC and CITI IT team in order to replace the existing ELIM C treatment system;
- Comprehensive system for drug storage management is also being created, which will be integrated in the renewed IT system for care and treatment;

- In testing mode, all data from the old system has been moved into the new system;
- Technical works are being carried out for launching a new system from August 6, 2018 throughout the country.
- All existing Hep C care providers will be trained before the launching of the new system. Training sites will be in Tbilisi and regions of Georgia (Kutaisi, Zugdidi).

3. Other activities

Two working meetings with participation of US CDC, NCDC and MoLHSA were held at the Ministry in July. During the first meeting, Minister, Dr. David Sergeenko overviewed main achievements and challenges of HCV elimination program. Monthly screening has been dramatically improved. HCV Core Ag testing significantly increased the number of confirmation tests in terms of hospitalized patients, however, patients' enrolment into the program and strengthening data system still remain the main challenges. Dr. Sergeenko requested to create monthly KPI (Key Performance Indicators) of screened patients in order to have an impact on the monthly program enrollment rate. US CDC will ensure incorporation of the KPI into the data system from September 2018.

Another important initiative, that was discussed between the parties was expansion of Hep C care and treatment in Autonomous Republic of Abkhazia. After internal discussions with the State Minister for Reconciliation and Civil Equality of Georgia, further activities will be defined. Council of Europe agreed to host the meeting of Georgian and Abkhaz Representatives on a neutral territory.

During the meeting, Dr. Francisco Averhoff summarized the outcomes of the rural site visit in Zugdidi, Senaki and Batumi within the PHC pilot project of decentralization care and treatment. He mentioned that Samegrelo-Zemo Svaneti has more resources to tackle the problems and agreed that engagement of local governments and clinicians in Samegrelo (high prevalence areas) should be the focus. In overall the Program should be more focused on the regional approach. Also, it was admitted that Samegrelo-Zemo Svaneti and Adjara regions (PHCs, NCDC labs, and decentralization sites) should be represented at the TAG meeting.

The upcoming TAG meeting will be held on November 28-30, 2018. The meeting venue will be the same. CDC will support New TAG members to be identified, regional data and regional presentations to be a focus. CDC and NCDC develop and modify draft agenda.

The 16th Scientific Committee Meeting of the Hepatitis C Elimination Program

The 16th Scientific Committee Meeting of HCV Elimination program was held on July 13 at the Infectious Disease, AIDS and Clinical Immunology Research Center, with participation of MoLHSA, US CDC, IDACIRC, NeoLab, University of Bristol and other relevant stakeholders. At

the committee meeting were presented HCV program care cascade, research progress report, new proposals and HCV Elimination Program related topics.

Among discussed topics was a concept - Rates and risk factors for HCV reinfection within the national hepatitis C elimination program: implications for program success, which was presented by Dr. Tengiz Tsertsvadze.

The risk of HCV reinfection after successful DAA based treatment is considered as one of the major challenges for controlling and ultimately eliminating hepatitis C. This issue is particularly important for Georgia's elimination program. The program already treated more than 45,000 thousand persons achieving very high cure rates. Reinfection can compromise this accomplishment. Therefore, determining the extent of the problem and designing interventions to prevent reinfection will be crucial for sustaining success.

The problem of HCV reinfection among people who inject drugs (PWID) is explored within CDC supported Georgian PWID cohort study, through cost-share contribution from Hepa clinic/Infectious Diseases and AIDS Center (IDACIRC). However, this may not be sufficient for comprehensive assessment of situation related to HCV reinfection, because PWID cohort study is limited to capital city of Tbilisi only and according to population-based HCV survey conducted in Georgia in 2015, PWID account for less than 40% of HCV infections. Therefore, determining rates and risk factors for reinfection among larger population is needed.

Dr. Tsertsvadze proposed to conduct representative survey of people who achieved sustained virologic response (SVR) within the national hepatitis C elimination program. Specific aims include:

- To determine rate of HCV reinfection among persons successfully treated within national hepatitis C elimination program.
- To identify risk factors associated with HCV reinfection.
- Demographic and epidemiologic characteristics, previous clinical and laboratory data including cirrhosis, treatment history, GT, etc.
- Analysis will be limited to persons who achieved SVR within elimination program
- Sampling frame will be identified from the program database among people with SVR
- Stratified cluster sampling will be conducted accounting for geographic location, sex, and age

Based on preliminary estimates 800 persons will need to be enrolled. Incentives will be used to encourage participation. Samples will be tested for HCV RNA and genotype (GT). GT results will be compared with the previous results captured by the elimination program database to differentiate between later relapse and re-infection. Questionnaires will include risk factor related questions. Statistical analysis will be conducted. Estimated budget is $44,000.

The presented concept was evaluated positively. Scientific Committee members voted for conditional approval stipulating that the methodology of the proposed study should be revisited before final approval.

Furthermore, Dr. Muazzam Nasrullah, CDC updated the committee on his field visits to the Primary Health Care and Harm Reduction pilot project sites.

-Visited hospitals (Tbilisi) were happy about HCV confirmatory testing turn-around time, sample shipment. IT part is still an issue (only few complaints about slow speed).

- Telavi hospital primary healthcare staff are ready and certified to start HCV care. This site provides services to 37,000 individuals and serves as a tertiary center for Akhmeta and Kvareli as well. Treatment has not been initiated yet. They are waiting for the IT system (referral to be incorporated)

- Two harm reduction sites (one private OST and another New Vector site) were visited. Both sites ready (PHC physicians would be providing treatment services) but waiting for the governmental approval to initiate the treatment .