



საქართველოს რეპროდუქციული  
ბრუნდობიდან ღვაწნიდთა,  
შრომის, ჯანმრთელობისა და  
სოციალური ღვაწვის სანიონსტრო



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

# Hepatitis C Elimination Program

Monthly Progress Report- January 2020

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## Introduction

In April 2016, The Government of Georgia and the company "Gilead" signed a long-term agreement on the continuous provision for zero price of the new generation of hepatitis C medicines by Gilead Science Inc., until the elimination of hepatitis C in Georgia.

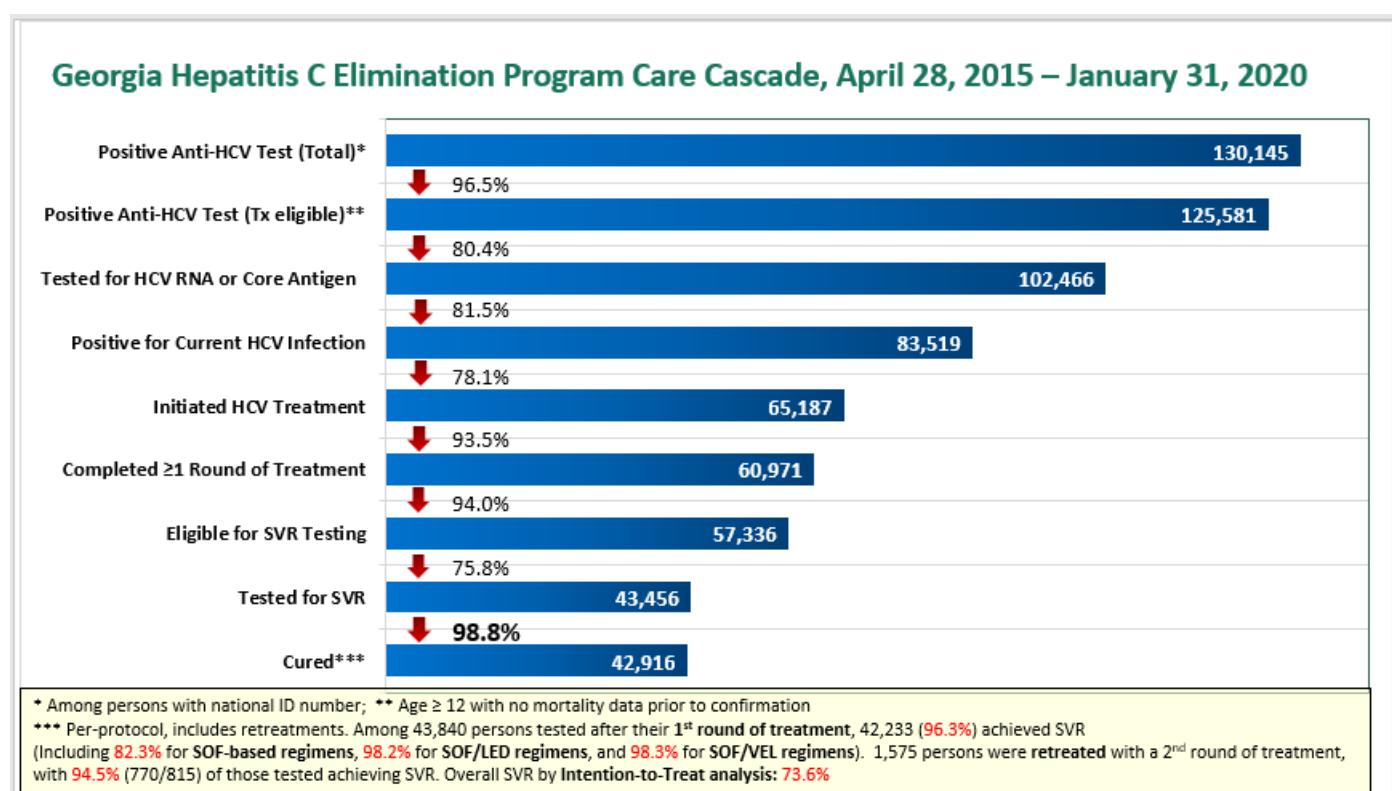
In August 2016, a long-term strategy for elimination of hepatitis C (2016-2020) was developed to achieve the ultimate goal of eliminating the hepatitis C. Strategy sets forth the following targets, to be reached by 2020:

- 90% of HCV infected persons will be tested for their infection,
- 95% of people with chronic infection will receive treatment, and
- 95% of persons receiving treatment will be cured of HCV

This report reflects the Hep C elimination program progress in January 2020. The report was prepared by the Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia in collaboration with the National Center for Disease Control and Prevention.

## 1 Statistics

### 1.1 Georgia Hepatitis C Elimination Program Care Cascade, April 28, 2015 – January 31, 2020

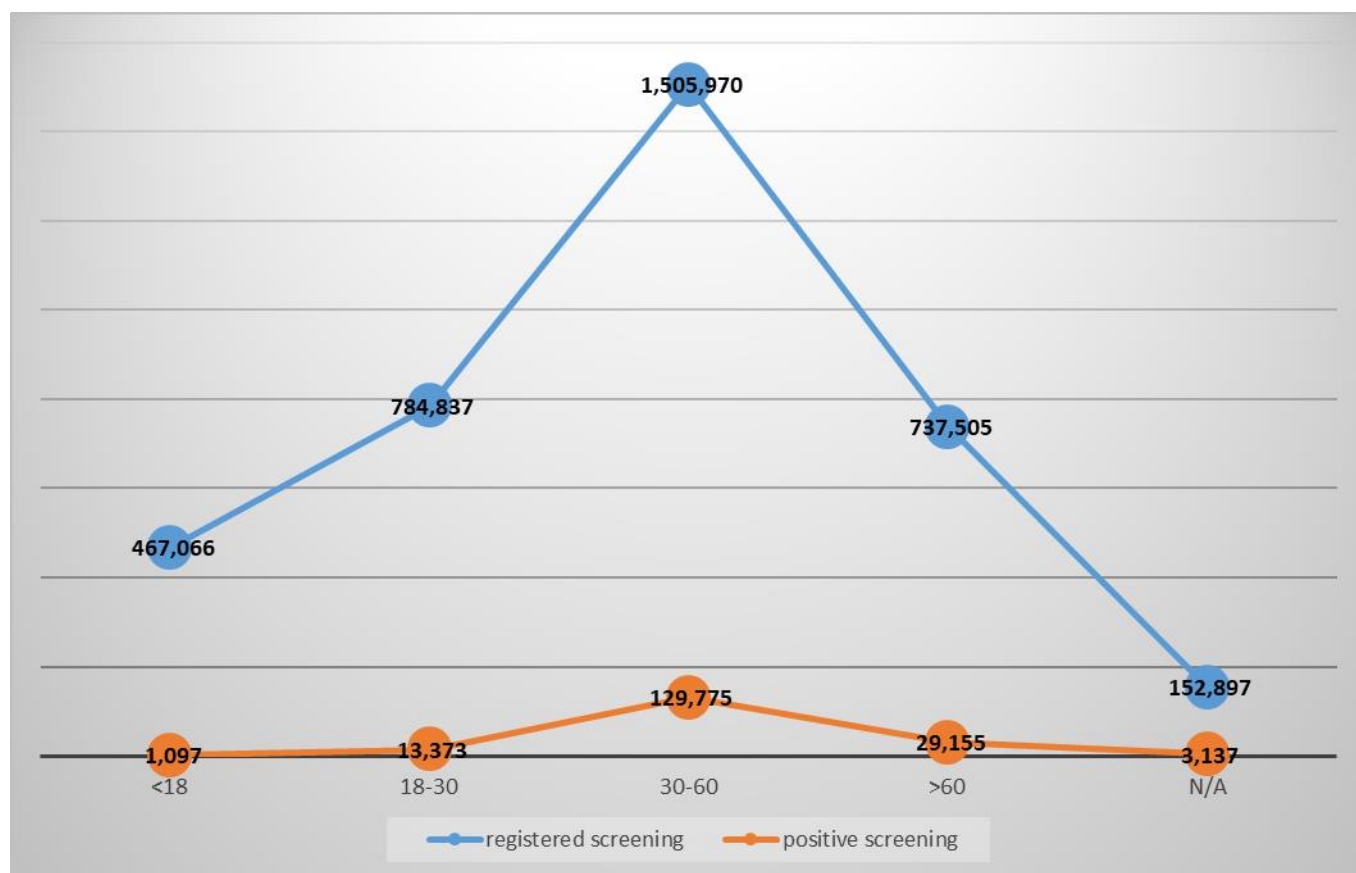


## 2 Update on programmatic activities

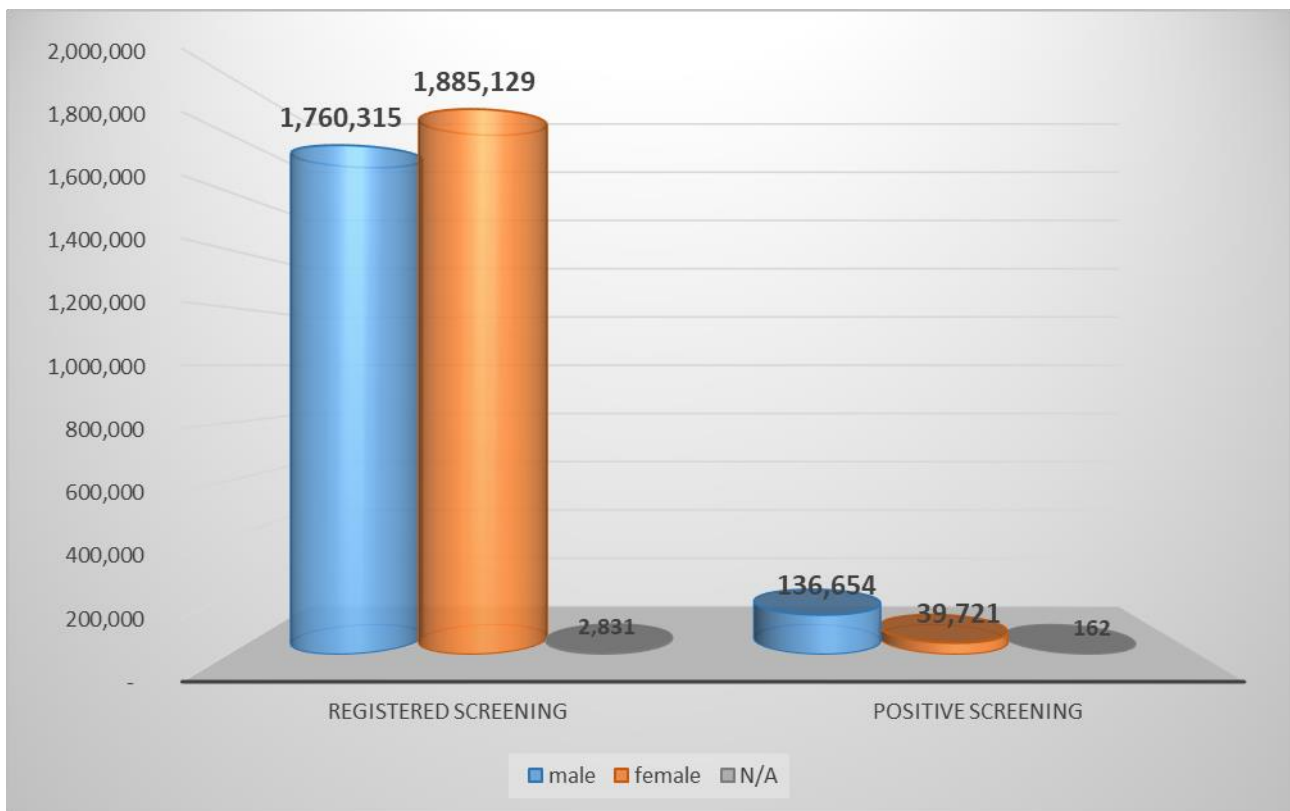
### 2.1 Information about screening activities

- ☐ Total number of registered screening is 3 648 275
- ☐ Total number of positive screening among the registered ones is 176 537 (4.84%)
- ☐ Distribution by age and gender among the positive screenings (figures 1 and 2):

2.2. Figure 1. Number of Individuals screened on Hep C and confirmed with the disease per age categories, April 28, 2015 – January 31, 2020



**2.2 Figure 2: Number of individuals screened and found positive on Hep C per gender, April 28, 2015 – January 31, 2020**



## 2.3 Information about drugs (April 28, 2015 – January 31, 2020)

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 are almost no longer used for treatment in practice)**

Total number of disbursed **Harvoni bottles: 173 440**

Harvoni bottles delivered to service Providers: **166 253**

Harvoni bottles remaining in central stock: **50 (+7137 expired as of April 30<sup>th</sup>, 2018)**

Total number of disbursed **Epclusa bottles: 10 976**

Epclusa bottles delivered to service Providers: **10 976**

Epclusa bottles remaining in central stock: **0**

Total number of disbursed **MyHepAll bottles: 4003**

**MyHepAll** bottles delivered to service Providers: **2783**

**MyHepAll** bottles remaining in central stock: **1220**

## 2.4 Information about Elimination Program Data Management System

- Technical support of screening “STOP C” and Hepatitis C treatment systems is ongoing.

## 2.5 Other Activities

### Explanation of the State Auditor’s Report on consumption of Hep C Treatment Drugs by 2018

On Friday, January 10<sup>th</sup> of 2020, the State Audit Office of Georgia issued the Social Service Agency (SSA) Financial audit report. The report covers 2018 period and indicates that by the end of 2018 the SSA had in its stock unused expired Hepatitis C drugs. The amount of expired drugs was as follows:

1. Interferon- 1222 units (State procurement)
2. Ribavirin-5547 units (State procurement)
3. Zepatier -2268 units (Donated by Merck)
4. Sovaldi-16834 units (Donated by Gilead)
5. Harvoni- 205003 units (Donated by Gilead)

These amount of drugs were projected for around 2033 patients to be started on treatment in 2018.

The report refers to the following reasons which resulted in expiration of the above mentioned medicines: Since July 2017 the program experienced reduction in the number of individuals enrolled on treatment compared to 2015 and 2016. In addition, if at the program initiation Sovaldi was the main drug in the treatment scheme, in February 2016 this had been replaced by a newer alternative-Harvoni. With introduction of Harvoni, utilization of Sovaldi, Interferon

and Ribavirin reduced dramatically. Treatment interruption and death of individuals on treatment also played some role in underutilization as compared to planned.

The supply chain management issues, experienced by the program in 2018, has been discussed with the technical advisory group (composed on local and international partners) several times. The needed amount of drugs at the initial stages of the program were based on annual estimated treatment targets reflected in the table below:

Year	Number of Patients - Planned	Number of Patients Actual	Difference
2015	5000	5936	936
2016	20000	21654	1654
2017	20000	14791	(-5209)
2018	20000	10206	(-9794)
TOTAL	65000	52587	12413a

In total, the drugs were expired for an estimated 3% of patients throughout 2015 to 2018. (2033/ estimated 65000 patients). In monetary figures the estimated cost of expired drugs (560 645 083 Gel as indicated in the state audit report) amounts to 5 % of the total estimated amount of **10,373,735,511** imported in 2015-2019.

Please, note that in 2016 and 2017 the estimated costs for Harvoni (by the Revenue Service) was Gel 63833.54 and 75563.60 respectively. In 2018 based on the Levan Samkharauli National Forensics Bureau and amounts to Gel 3314. Therefore, the estimated cost indicated in the report can be misleading unless compared to the total amount of drugs.

Table below indicated amount of drugs imported in the country and estimated costs in 2015-2018.

		<b>Sovaldi</b>	<b>Harvoni</b>	<b>Epclusa</b>	<b>Total Estimated Monetary Value in Gel</b>
2015	Amount of Drugs (bottles)	25,000			
	Estimated costs	1,050,725,286.40			1,050,725,286.40
2016	Amount of drugs(bottles)	13,500	84,912		
	Estimated costs	584,110,695.00	5,420,233,133.00		6,004,343,828.00
2017	Amount of drugs (bottles)		42,088		
	Estimated costs		3,180,320,797.00		3,180,320,797.00
2018	Amount of drugs (bottles)		40,000	2,048	
	Estimated costs		132,560,000.00	5,785,600.00	138,345,600.00

<b>Total 2015- 2018</b>	<b>Cost in Gel</b>	<b>1,634,835,981.40</b>	<b>8,733,113,930.00</b>	<b>5,785,600.00</b>	<b>10,373,735,511</b>
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Based in 2017-2018 enrollment experience, in 2019, the stock was projected with a minimum buffer amount that has been fully utilized.

On 20<sup>th</sup> of January, pharmaceutical company Gilead released the statement for the support of the HCV Elimination Program in Georgia. We take this opportunity and on behalf of the Government of Georgia express our deepest gratitude towards Gilead for the continued support and fruitful partnership.

On 21<sup>st</sup> of January US Deputy Ambassador to Georgia H.E. Elisabeth Rude during the meeting with the Minister Ms. Ekaterine Tikaradze, First Deputy Minister Ms. Tamar Gabunia and Director General of NCDC Dr. Amiran Gamkrelidze underlined the importance of the Hepatitis C Elimination program implementation and expressed full support and trust to the government of Georgia.

### **March Workshop**

The March workshop dates are confirmed and the meeting will be held on March 17-18th. A conference call was held between Ministry and CDC to discuss the theme and priority outcomes of the meeting. The main subject of the workshop this year will be the development of new Strategic Plan 2021-2025, including Hepatitis B and possible integration with Universal Health Care.

### **The website for the Georgia Centre of Excellence**

As a part of the EASL – International Liver Foundation Centre of Excellence grant, a website for the Georgia Centre of Excellence in Hepatitis Elimination is under development. The point of contact for the website was nominated and provided to EASLF and website developers.

### **Technical Advisory Group Recommendations**

Dr. Carolyn Wester, DVH/CDC provided the Ministry and NCDC with recommendations from the 5<sup>th</sup> TAG meeting of the HCV Elimination Program in Georgia to advance the progress already attained by Georgian side.

### **Hepatitis C Elimination Scientific committee meeting**

The 27th Hepatitis C Elimination Program Scientific Committee Meeting was held on January 23, 2020. The meeting was attended by the representatives of the Ministry, NCDC, US CDC, IDARCIRC, Clinic Hepa and Neo lab. The meeting agenda included several new studies:

- Retreatment for HCV: A Retrospective Analysis of Pooled National Program Data across Several Countries
- Stigma in Liver Diseases
- Identifying risk factors of HCV transmission in Georgia – a case-control study
- Evaluation of alcohol use behavior among patients cured through HCV elimination program in Georgia
- Performance of centralized NAT and serologic testing of blood donation samples using NAT and serologic test platforms
- Analysis of HCV RNA levels of viral rebound among patients who have completed treatment for HCV to inform the limit of detection necessary to confirm sustained virologic response (SVR)

Dr. Tengiz Tsertsvadze presented programmatic changes within the hepatitis C elimination program, including the introduction of pan-genotypic DAA allowing to remove genotype test from pretreatment diagnostic algorithm. He demonstrated a treatment decision tree for all genotype patients. He reiterated the topic of reinfection and presented



the definition. The Ministry decided that at the first stage free of charge identification of HCV reinfection and treatment will be provided to PWID. Testing and treatment of HCV reinfection will be expanded in other groups in the future.