



6th National Hepatitis C Elimination Workshop

March 6-7, 2019
Tbilisi, Georgia



MINISTRY OF INTERNALLY DISPLACED
PERSONS FROM THE OCCUPIED
TERRITORIES, LABOUR, HEALTH AND
SOCIAL AFFAIRS OF GEORGIA



NATIONAL CENTER
FOR DISEASE CONTROL
AND PUBLIC HEALTH



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LABOUR, HEALTH AND SOCIAL AFFAIRS

NATIONAL CENTER FOR DISEASE CONTROL
AND PUBLIC HEALTH

144, Ak. Tsereteli Ave.
Tbilisi 0119, Georgia
Phone: 2 51 00 11 / 15 05

#99, Kakheti Highway.
Tbilisi 0198, Georgia
Phone: 116 001

info@moh.gov.ge
www.moh.gov.ge
fb.com/mohgovge

ncdc@ncdc.ge
www.ncdc.ge
fb.com/ncdcgeorgia

Country Background

Georgia is located at the crossroads of Western Asia and Eastern Europe; bounded to the west by the Black Sea, to the north by Russia, to the south by Turkey and Armenia, and to the southeast by Azerbaijan. The capital city is Tbilisi. Georgia covers a territory of 69,700 square kilometers (26,911 sq. mi). Population – 3,729,600 (January 1, 2018).

	2011-2012	2013	2014	2015	2016	2017
GDP per capita (USD)	3843.7-4249.8	4341.4	4483.3	3754.9	3857.3	4046.8
Government expenditure on health as % of GDP	1.7%	2.0%	2.4%	2.9%	3.1%	-
Health expenditure:						
Public funding	18.4% - 20.6%	24.30%	28.2%	36.3%	37%	-
Private funding	79.1% - 77.1%	73.4%	69.9%	61.9%	62%	-
International Aid	2.5% - 2.3%	2.3%	1.9%	1.8%	1%	-
Key Statistics						
Birth Rate	13.6 per 1000	13.4 per 1000	16.3 per 1000	15.9 per 1000	15.2 per 1000	14.3 per 1000
Mortality Rate	13.3 per 1000	13.1 per 1000	13.2 per 1000	13.2 per 1000	13.6 per 1000	12.8 per 1000
Life Expectancy at Birth	72.1 years	72.5 years	72.8 years	73.0 years	72.7 years	73.5 years
Maternal Mortality Ratio (per 100,000 live births)	25.2	27.7	31.5	32.2	23.0	13.1*
Infant Mortality Rate (per 1000 births)	14.2	13.2	9.5	8.6	9.0	9.6
Under 5 Mortality Rate (per 1000 live births)	16.2	15.6	10.9	10.2	10.7	11.1

* Preliminary data

HCV Epidemiology

Based on available data, Georgia is among the countries with high hepatitis C (HCV) Prevalence, however, the reasons of the high burden of the disease has not been studied sufficiently. Collapse of the health care system in early 1990s, sub-optimal quality standards of health services had negative influence on safe injection practices, infection control and blood safety in health care settings over the years. All these conditions along with the widespread practice of needle sharing among people who inject drugs (PWID) contributed to the spread of HCV in the general population.

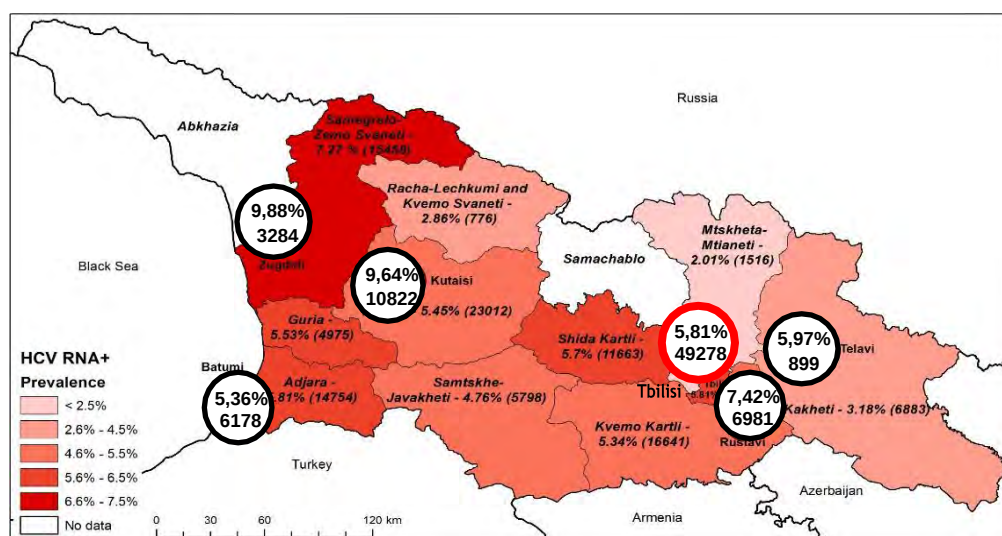
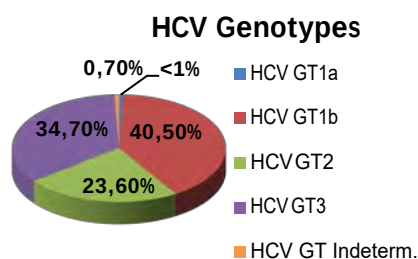
General population	Prevalence	Source
Surveys among blood donors	1) 7.3% 2) 7.8% 3) 2% overall	1) Tbilisi blood donors 1998 2) Tbilisi, Batumi, Poti blood donors 1997-1999 3) "Safe Blood" Georgia State Program, 2012
Population-based surveys	6.7% 7.7% Anti-HCV+ 5.4% HCV RNA+	Tbilisi population-based survey 2001-2002 National Population survey, 2015
High risk populations		
PWID	1) 70% 2) 50% 3) 66.2%	1) ever-IVDU 2002 (Tbilisi) 2) PWID 2006-2012 (Georgian Harm Reduction Network) 3) PWID (BSS, Curatio International Foundation)
HIV infected PWID	73.4%	Chkhartishvili N et al. 2014
Other		
STI patients	11.3%	Tsertsvadze, 2008
TB patients	21%	Lomtadze et al. 2013

Men who have sex with men (MSM) - Tbilisi	7.1%	BSS among men who have sex with men in two cities of Georgia, 2015
MSM - batumi	18.9%	
Health care workers	5%	Butsashvili M et al. 2012

According to the Latest population-based seroprevalence survey, conducted by the National Center for Disease Control and Public Health (NCDC) and US Centers for Disease Control and Prevention (CDC) between May-August, 2015, estimated national seroprevalence of hepatitis C is 7.7% and the prevalence of active disease is 5.4%.

Characteristic	n	Weighted %	Estimated number of adults >18
Anti-HCV+	425	7.7%	215,000
HCV RNA+	311	5.4%	150,300

Prevalence and Estimated Number of HCV RNA+ Individuals by Regions and Cities



HCV Genotypes in Georgia

Distribution of HCV genotypes by years has changed substantially in Georgia: according to the data of the 2015 population-based HCV seroprevalence survey, proportion of genotype 1 is 39.5%, much less compared to the proportion in 2002 that was estimated at 62%, while proportion of genotype 2 has increased. The genotype 3 is the most widespread after genotype 1 followed by genotype 2.

Genotype	General pop (2002)*	General pop (2003-2013)**	General pop (2015) ***	IDU (2012)†	HIVCo-infected
HCV GT 1b	62%	43%	40.5%	22%	42%
HCV GT 2	11%	24%	23.6%	20%	18%
HCV GT 3	27%	33%	34.7%	66%	35%

*Source: Stvilia, et al: J Urban Health; 83(2):2006:289-298; ** Georgian Infectious Diseases, AIDS and Clinical Immunology Research Center data for 2003-2013; *** 2015 seroprevalence survey. in appx. 2% GT is indeterminate; †Bouscaillou, J., et al. (2014). : Int J Drug Policy; Karchava, et al: Georgia Medical News: 2009 Dec: (177): 51-55

HCV Care and Treatment

- Until 2014 diagnostics and treatment of Hepatitis C in general population were neither financed by the state nor private insurance schemes, treatment was fully dependent on patient's ability to pay out of pocket.
 - The Global Fund HIV Program has been covering HCV treatment for HIV/HCV co-infected patients – 150 per year since 2011.
 - Starting from 2013, Government of Georgia covers treatment of HCV infected patients with Pegylated Interferon + Ribavirin (Peg/Riba) regimen at the penitentiary system.
- In 2014, Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia negotiated preferential pricing of Peg/Riba for the general population. The new price for standard dual therapy has been established at a price of 92.88 USD per vial of Peg/Riba. This has dramatically lowered the cost of HCV standard treatment regimen to 1115 and 2230 USD for Genotypes 2, 3 and Genotype 1 respectively. Prior to initiation of the above programs, approximately 150-200 patients received the HCV treatment in the private sector per year.
- Specialists who are experienced in the HCV treatment and monitoring are mainly consolidated in Tbilisi. The expertise in this area is limited outside the Capital city, but there are medical professionals specialized in infectious diseases who received basic training on HCV care and management using new direct-acting antiviral drugs (DAAs) in 2015.

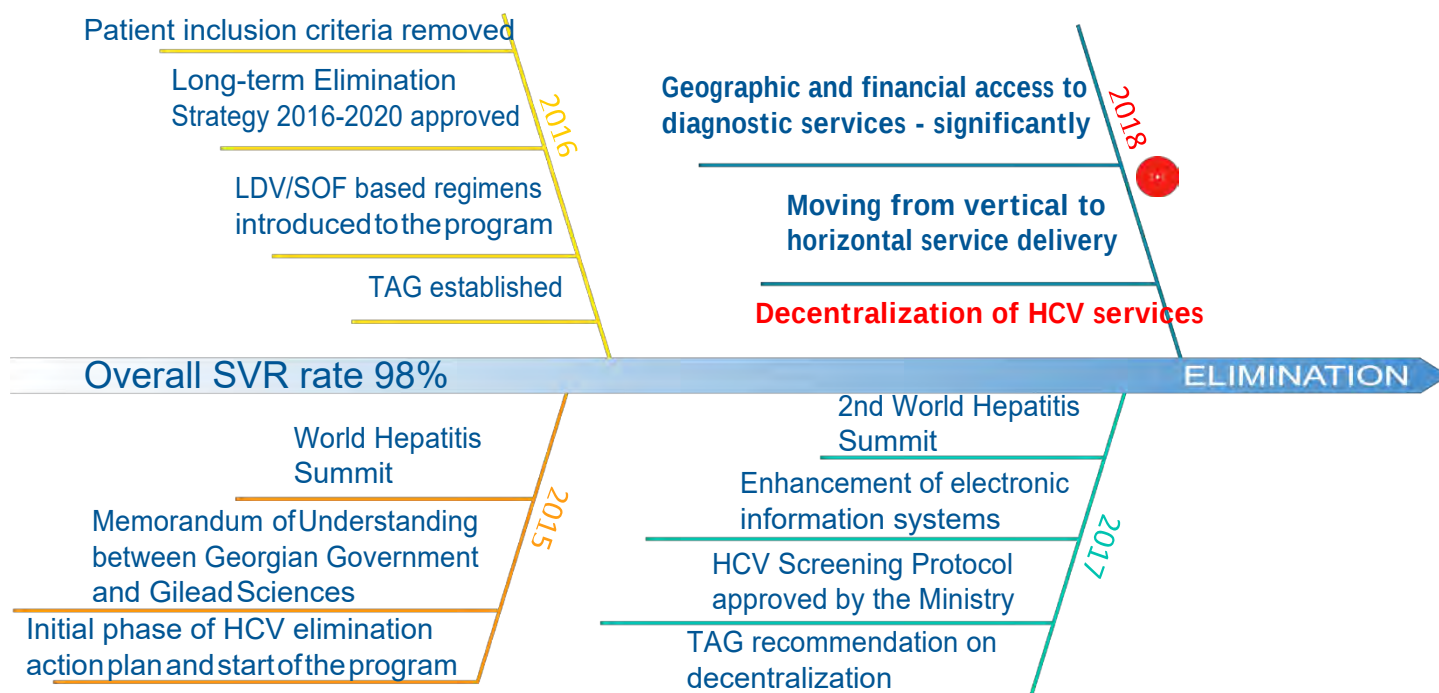
Major diagnostic methods implemented in Georgia

Method	Year of implementation
ELISA	1984
Western Blot	1985
Qualitative PCR	1995
Quantitative PCR	1996
HCV Genotyping	2003
HCV RNA quantitative tests using real-time PCR	2006
Transient liver elastography and other noninvasive markers	2007
IL28B Genotyping	2010
NS5B and 5'UTR/Core region sequencing	2010
HCV core antigen testing for confirmation of active infection	2017
Cepheid Xpert HCV viral load	2017

Timing of implementation of HCV antiviral treatment approaches in Georgia

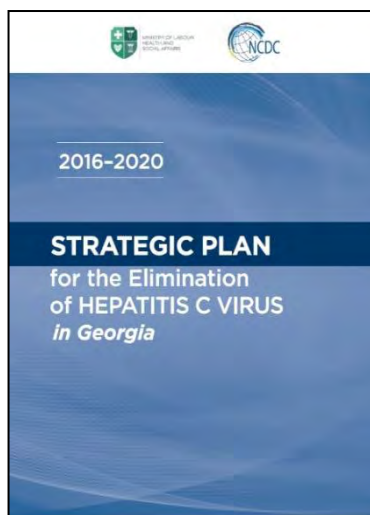
Treatment approach	Year of implementation
Interferon alpha monotherapy	1996
Interferon alpha + ribavirin	1998
Pegylated interferon alpha	2001
Pegylated interferon alpha + ribavirin	2002
Pegylated interferon alpha + ribavirin + telaprevir or Boceprevir	2011
Sofosbuvir + pegylated interferon alpha + ribavirin	2014
Sofosbuvir + ribavirin	2014
Sofosbuvir + ledipasvir	2015
Sofosbuvir + daclatasvir	2015
Ombitasvir + paritaprevir + ritonavir + dasabuvir	2015
Sofosbuvir + Velpatasvir	December, 2018
Sofosbuvir + Velpatasvir + voxilaprevir	To be implemented in 2019

Progress towards elimination



The Government of Georgia declared intention to eliminate hepatitis C in Georgia and this initiative already received strong international support. The national Hepatitis C elimination program became operational in 2015.

- Over the past several years the Government of Georgia substantially stepped up its efforts against hepatitis C by implementing national programs such as free of charge hepatitis C treatment for HIV/HCV co-infected patients (funded under the Global Fund HIV Program since 2011); Free of charge hepatitis C treatment at the penitentiary system and 60% price reduction on combination of pegylated interferon and ribavirin for the general population.
 - In February 2014, Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia (Minister Dr. David Sergeenko) initiated discussion with US partners regarding strengthening of the hepatitis C response in the country.
 - In March 2014, the **1st National Workshop on Hepatitis C**, organized by CDC, MoLHSA, NCDC, Georgian Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC), Bristol University, and Emory University, developed the first concept of hepatitis C elimination in Georgia. The concept was endorsed by the Government of Georgia and declared intention of eliminating HCV infection in the country. In April 2014, the concept was discussed at the WHO supported hepatitis summit in Geneva and later CDC helped to organize dedicated satellite meeting on hepatitis C elimination in Georgia during the 49th annual International Liver Congress (ILC) of the European Association for the Study of the Liver (EASL) in London.
 - In 2014, the Georgian Government started negotiation with pharmaceutical company Gilead which is one of the global leaders in research and manufacturing of potent DAAs, including Sofosbuvir and fixed-dose combination of Ledipasvir/Sofosbuvir regarding possible elimination of HCV in Georgia.
- Under the Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia, a special commission on HCV was established that is in charge of overall coordination of national HCV elimination movement. In addition, a working group of experts was created to elaborate national strategy and action plan for HCV elimination. National Program for Short-term/urgent Measures of Hepatitis C Elimination Action Plan for Georgia has been developed.
- With support of the CDC and Open Society Foundation Georgia Georgian delegation visited Egypt in February 2015 to get familiar with the ongoing Sofosbuvir treatment program and use Egypt's experience in the
 - Planning of elimination strategy for Georgia.



➤ In March 2015, a **2nd National HCV Workshop** was organized. Short term/urgent measures of Hepatitis C elimination Action Plan for 2015 was discussed and finalized during the workshop and later in April was approved by the Georgian Government.

➤ **Memorandum of Understanding** between the Government of Georgia and pharmaceutical company Gilead was prepared and officially signed on April 21, 2015.

➤ **Population-based HCV seroprevalence survey** was conducted in May-August, 2015. It aimed to estimate the prevalence of HCV infection in the general population, to assess risk factors for HCV infection in Georgia, describe circulating HCV genotypes and identify knowledge and perceptions towards

hepatitis, its prevention and treatment. The survey estimated that **7.7%** of population are anti-HCV positive and **5.4%** are HCV RNA positive. Injection drug use and history of blood transfusion were identified as main risk-factors.

➤ Progress towards elimination of HCV in Georgia was discussed during the EASL congress in Vienna, World Hepatitis Summit in Glasgow, WHO Euro regional committee in Vilnius and high-level ministerial meeting in Minsk in 2015.

➤ **Long-term elimination strategy** for 2016-2020 was developed. To facilitate the process of elaboration, workshops and meetings were organized with support of CDC and WHO. **The Technical Advisory Group (TAG)** composed of 12 international experts was established with support of the CDC and the first meeting was held in Tbilisi on November 3-4. After the meeting, TAG provided a set of recommendations on long-term elimination strategy. **Strategy was approved by the Georgian government on August 18, 2016.**

➤ The **2nd Technical Advisory group (TAG) meeting** was held in Tbilisi on October 24-25, 2016. Recent progress towards elimination, monitoring and evaluation indicators and priorities for 2017 were discussed and TAG provided recommendations related to HCV care and treatment, screening, prevention and other directions of HCV elimination strategy.

With Support of CDC, WHO and Eurasian Harm Reduction Network, Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia and NCDC conducted the **3rd National HCV Elimination workshop** on April 6-8, 2016 in Tbilisi. National and international experts discussed results of the national serosurvey, 1st phase of elimination program and Elimination Strategy for 2016- 2020.

➤ In August, 2016 the **Clinical and Scientific Committees** were established with the aim of providing the volunteer leadership for the transparency and coordination of the research activities within Hepatitis C Elimination Program in Georgia. In total, 52 proposals were reviewed and 44 were approved by the Scientific Committee by the end of October, 2018. Clinical guideline for management of HCV infection was elaborated by the Clinical Committee.

➤ Progress towards elimination of HCV in Georgia was discussed at the EASL congress 2016 in Barcelona. Memorandum of Understanding for 10 years was signed between the Georgian Government and pharmaceutical company Gilead.

➤ The **4th National HCV elimination workshop** was conducted on March 9-10, 2017. The main subject of the workshop was to review the progress on implementation of the Hepatitis C Elimination Plan 2016-2020, to evaluate the work accomplished during the two years and to discuss the important aspects of Georgian Hepatitis C Elimination Program with particular emphasis on screening, treatment and linkage to care.

Georgian HCV Elimination Strategy goals to be achieved by 2020:

- ✓ *testing 90% of HCV-infected persons for their infection*
- ✓ *treating 95% of people with chronic HCV infection*
- ✓ *curing 95% of persons treated of their HCV infection.*

HCV Screening Protocol was approved by the Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia in May 2017

- The **3rd TAG meeting** was organized on November 30 - December 1, 2017. TAG members observed the ongoing processes and provided new recommendations to facilitate the progress.
- Special session on the EASL congress 2017 in Amsterdam was dedicated to Georgia HCV Elimination Program.
- Georgia was awarded the title of **NOhep Visionary** for the European Region at the 2017 World Hepatitis Summit in Sao Paulo, Brazil.
- The **5th National HCV Elimination workshop** was held on March 7 and 9, 2018 with the main focus on the plan of decentralization for HCV services.
- NCDC supported the establishment of the 'Cured Hepatitis C Patients' Association' which aims to facilitate the HCV Elimination Program by raising awareness, reducing the hepatitis C-associated stigma and discrimination among the population.
- HCV elimination progress in Georgia was traditionally discussed on a special session - Overcoming the Challenges with Innovation during EASL congress 2018 in Paris.
- During 11-13 February the First Regional Consultation on Viral Hepatitis in the WHO European Region - "Progress on the Way to Elimination" was conducted in Tbilisi, which aimed to review the countries' progress, exchange good practices and identify challenges in order to overcome them in response to viral hepatitis, including national planning, surveillance and monitoring, prevention, testing and strengthening laboratory capacity, improving access to diagnostics and treatment and optimizing viral hepatitis management strategies in line with the updated WHO guidelines.
- On the 4th TAG meeting which was conducted on 28-30 December, 2018, the group evaluated current accomplishments and devised new recommendations to aid progress.

Recent progress by different directions of the Elimination Strategy

Promote advocacy, awareness and education, and partnerships for HCV associated resource mobilization

- Multi-Sectoral communication working group created
- Joint strategic communication action plan developed
- Communication slogan, message box and branding developed, reviewed and implemented in joint communication activities
- More than 200 media activities – TV and radio reporting, TV shows with invited guests and articles in printed media
- Short text messages regularly sent to entire population as a reminder to get screened
- Active Social media educational campaign - Hepatitis C Facebook page (with up to 120 000 reaches and 16,486 likes)

Prevent HCV transmission

- Renewed IPC guideline will be finalized by January, 2019
- IPC training course for physicians and nurses developed, trainings performed by NCDC
- Throughout the country, all officially registered non-healthcare facilities are being monitored and controlled for compliance on IPC measures
- Point-Prevalence Study performed on antibiotic consumption, HAI and AMR in 10 clinics
- *Sanford Guide for Antimicrobial Therapy 2018* has been translated into Georgian and published, 3,000 copies will be distributed among the medical facilities; official electronic version of the guide will be available online

- Confirmatory testing of all anti-HCV positive blood donations – improved linkage to in-depth diagnostic and treatment services
- Introduction of Unified Electronic Donor Database – established infection traceability
- Expert mission organized by the European Commission's Technical Assistance and Information Exchange Instrument (TAIEX) – recommendations developed and presented to Georgian health authorities
- Decision signed by the European Commission to grant Georgia a Twinning Assistance in Blood Safety field aiming to approximate national blood regulations to EU respective directives



Identify persons infected with HCV

- HCV screening in more than 700 centers countrywide, including inpatient and outpatient facilities, prisons, Georgian Harm Reduction Network (GHRN) sites, Public Health Centers, etc.
- Regular screening activities among PWID and their sexual partners
- Since October 2018, HCV screening is provided in 12 Public Service Halls in different cities across the country
- High HCV screening coverage in certain groups, e.g. hospitalized patients, blood donors, pregnant women, PLHIV, TB patients, prisoners, military recruits.
- More than 1.4 million Georgian citizens screened as registered in the unified electronic screening registry

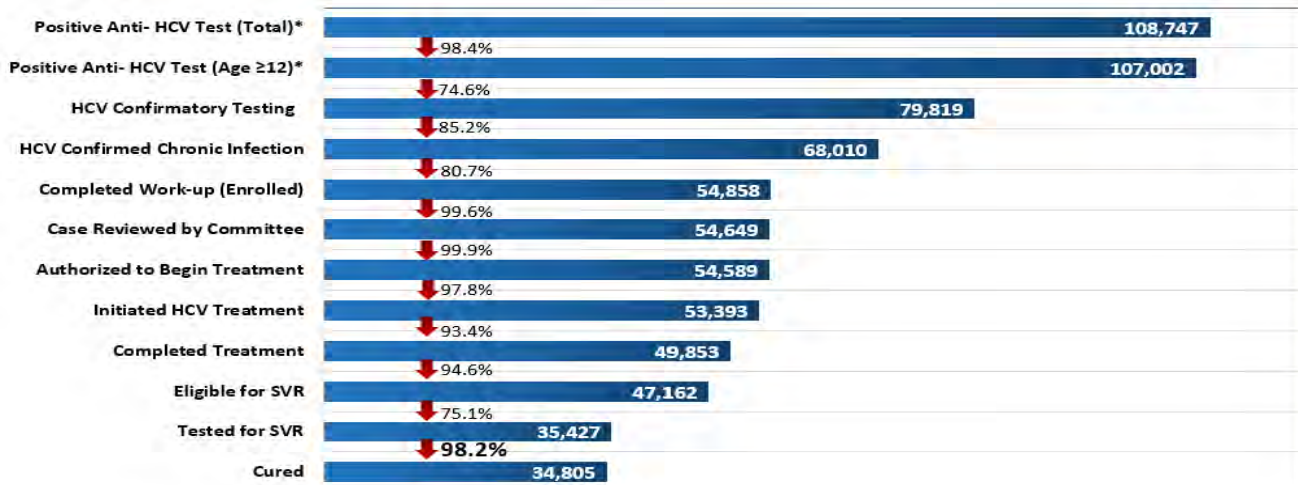
Improve HCV laboratory diagnostics

- Clinical laboratories' registration and licensing process initiated within the HCV Elimination Program
- More than 500 laboratory service providers registered in HCV database
- National External Quality Assurance program introduced at Lugar Center
- 16 PCR Laboratories (14 private and 2 public) within the HCV Elimination Program
- 2000 samples sent to Lugar Center monthly for HCV core Ag testing
- 5-10 days turn-around time

Provide HCV care and treatment

- Starting with 4 sites in 2015, currently 39 service centers in different cities, including 1 center in penitentiary system, are providing diagnostic and treatment services to the elimination program beneficiaries. Since the launch of the program in April 2015 through November 2018, **48,205** patients completed the treatment, with overall cure rate – 98.2%

Georgia Hepatitis C Elimination Program Care Cascade, April 28, 2015 – January 31, 2019



*Among persons with PID. Does not include persons with 15-digit code

- Since December 2018, Sofosbuvir + Velpatasvir based regimen (Epclusa) will be included in the national treatment guideline

Improve HCV surveillance

- The assessment study for HCV-attributable primary liver cancer was initiated
- A study (Descriptive, Retrospective Study on the Prevalence of Acute Viral Hepatitis in Georgia) was conducted to describe all types of viral hepatitis and unspecified jaundice cases reported to the E-Health system in 2017



- Surveillance data on HCV reinfection among PWID in Tbilisi were collected through the joint effort between “Medecins du Monde” (France) and the local NGO Health Research Union
- Project to analyze cases of HCV among children in Georgia was initiated

Recent updates in State HCV Elimination Program

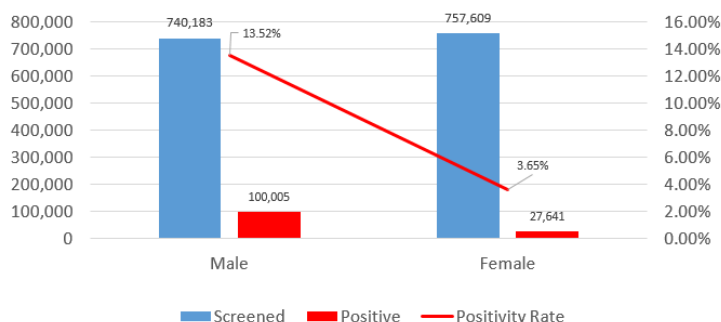
2	HCV Confirmatory testing (HCV cAg/RNA PCR) - became free-of charge
0	HCV genotyping - became free-of charge
1	Diagnostic algorithm was simplified - reduced cost of diagnostic tests
1	HCV testing (screening + confirmation) for all hospitalized patients is performed based on one stop-shop principle
8	Full financial support for certain populations groups (war veterans, socially vulnerable persons) - 70% copayment by government, 30% - by the municipalities
Expanded screening	
Primary healthcare system	
Tandem testing - HCV/HIV/TB	
Public Service Halls	
Decentralization of treatment services to primary healthcare and harm reduction centers - improved geographical accessibility	
Multifunctional information systems in place	
Fully web-based system for patient enrollment - waiting time significantly reduced	

Unified Electronic HCV Screening Module

A unified electronic HCV screening module was created to capture data from all national HCV screening programs. Screening providers enter the data into the module on-site. The module is using personal IDs based on a link with Public Registry that allows to synchronize HCV-related data from different databases, such as HCV treatment database, unified electronic blood donor module, hospitalized patient's electronic module and birth registry.

As of November 2018, over 2.2 million screenings were registered in the database. More than 1.4 million individuals were tested with positivity rate 8.6%.

Screened Individuals by Sex



Screened Individuals by Age Groups



HCV Screening Protocol

HCV screening protocol was developed for medical and public health personnel based on the international guidelines, including the WHO guideline for the screening, care and treatment of persons with chronic hepatitis C infection, nationwide HCV seroprevalence survey (2015) results and Technical Advisory Group recommendations. It was approved by the Government of Georgia on May 6, 2017.

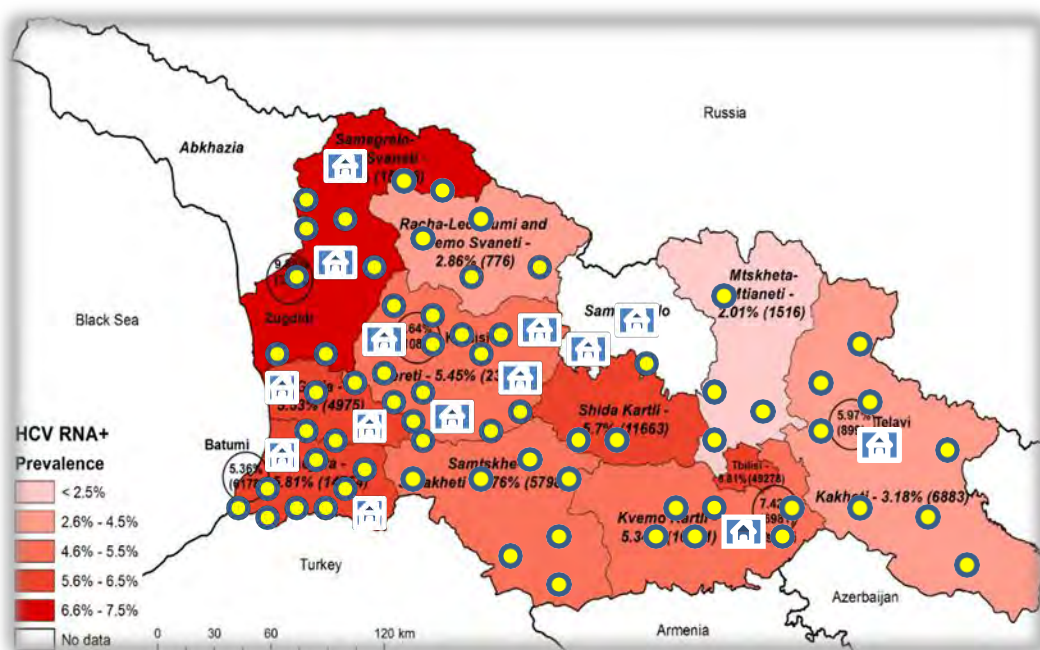
Aims of the protocol are

- To identify population groups that need to be tested on HCV,
- To improve identification of HCV infected persons
- To reach the HCV Elimination Strategy goal – “90% of HCV infected persons have been tested for their infection” by 2020.

Population subgroups with high risks of HCV infection

- ✓ Current or past injection/intranasal drugs users
- ✓ Men who have sex with man
- ✓ Prisoners
- ✓ Sex workers
- ✓ Hospitalized patients
- ✓ HIV infected persons
- ✓ TB patients
- ✓ STI patients
- ✓ Blood donors
- ✓ Recipients of blood or blood products
- ✓ Persons ever on dialysis
- ✓ Persons with haemophilia
- ✓ Persons who have undergone tattooing, piercing or scarification procedures
- ✓ Pregnant women
- ✓ Children (≥18 months) born to HCV infected women
- ✓ Medical staff
- ✓ All individuals attending medical facilities
- ✓ Policemen
- ✓ Persons with history of medical/dental intervention
- ✓ Persons with unspecified liver disease and/or chronic hepatitis, including elevated ALT

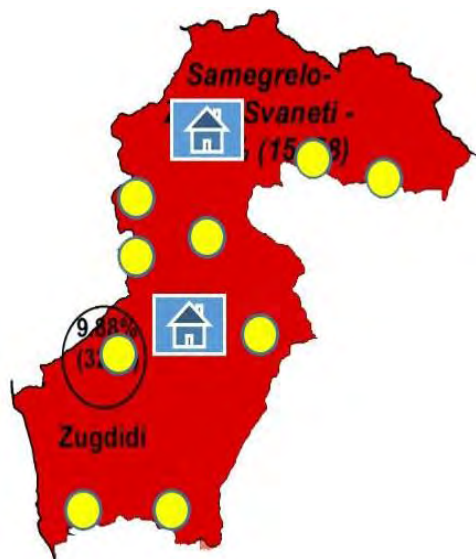
Decentralization of HCV services



Integration of HCV, TB and HIV Detection at PHC level

A pilot project was initiated in September 2017 to improve case detection of Hepatitis C, Tuberculosis and HIV infection at the primary healthcare level in the Samegrelo-Zemo Svaneti region in the country of Georgia.





Samegrelo-Zemo Svaneti region has the highest prevalence of hepatitis C in the country with the 9.88% HCV RNA prevalence in the biggest city of the region – Zugdidi.

In 8 months of project implementation

- ✓ Integrated TB/HIV/HCV screening protocol approved
- ✓ 454 doctors and nurses trained
- ✓ Integrated multidisciplinary service monitoring groups established
- ✓ Municipal programs supporting pilot implementation approved
- ✓ 89,602 persons were screened on HCV, HIV and TB
- 2350 anti-HCV+ cases
- 37 anti-HIV+ cases
- 177 Presumptive TB cases

Following the Samegrelo-Zemo Svaneti example, a similar project has been initiated in the Adjara region

Guria, Racha-Lechkhumi and Kvemo Svaneti, Kutaisi, Kharagauli will be introduced to the program next

Study tours

NCDC provides study tours for the interested audience to introduce the State HCV Elimination program, its management and organization, showing the steps taken to achieve the progress towards the elimination goals.

Meetings are organized with different stakeholders – the Ministry, HCV Management Centers, HCV screening and treatment provider centers, NCDC referral laboratory (Richard Lugar Center for Public Health Research), Public Health Centers, etc.

NOhep VISIONARIES Program

Georgia was awarded the title of NOhep Visionary for the European Region at the World Hepatitis Summit in Sao Paulo, Brazil, on November 1st, 2017. Georgia joined five other countries including Brazil, Bangladesh, Egypt, The Gambia and Mongolia to launch the NOhep Visionaries Programme worldwide.

The NOhep Visionaries Programme is a global campaign which engages governments to scale-up successful approaches to elimination and share key learnings, accelerating progress towards eliminating viral hepatitis by 2030.

Why is Elimination of Hepatitis C in Georgia Feasible and Achievable?

- High prevalence of HCV infection in general population;
- Small size of the country (69,700 km²) with population of 3.7 million people;
- Strong Governmental commitment towards elimination of HCV;
- Availability of all modern HCV diagnostic and treatment methods;
- Strong human resource capacity in the field of viral hepatitis, and particularly in hepatitis C;
- Adherence to principles of evidence-based medicine for hepatitis C as evidenced by the availability of national guidelines for many years;
- Existence of effective systems for implementing large-scale national and international health programs, including through multi-sectoral approach;
- Availability of logistic and control mechanisms within existing national HIV/AIDS, Tuberculosis and hepatitis C treatment programs that effectively prevent leakage of medicines to local and/or neighboring markets;
- Best practice experience in the field of HIV/AIDS that can be replicated for hepatitis C programs. Namely, achievement of universal access to antiretroviral therapy that remains unique in the Eastern European region for more than a decade;

