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 – 3,716,900 (January 1, 2020).

	2013	***2014***	***2015***	***2016***	***2017***	***2018***	***2019***
GDP per capita (USD)	4341.4	4483.3	4012.6	4062.1	4358.5	4722.0	4763.5
Government expenditure on health as % of GDP	2.0%	2.4%	2.9%	3.1%	2.9%	2.8%	-
Health expenditure:							
Public funding	24.3%	28.2%	36.3%	37%	38%	40%	-
Private funding	73.4%	69.9%	61.9%	62%	60%	59%	-
International Aid	2.3%	1.9%	1.8%	1%	2%	1%	-
Key Statistics							
Birth Rate	13.4	16.3	15.9	15.2	14.3	13.7	13.0
Mortality Rate	13.1	13.2	13.2	13.6	12.8	12.5	12.5
Life Expectancy at Birth	72.5	72.8	73.0	72.7	73.5	74.0	74.1
Maternal Mortality Ratio (per 100,000 live births)	32.2	31.5	32.2	23.0	13.1	27.4	28.9
Infant Mortality Rate (per 1000 live births)	13.2	9.5	8.6	9.0	9.6	8.1	7.9
Under 5 Mortality Rate	15.6	10.9	10.2	10.7	11.1	9.8	9.4

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 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.

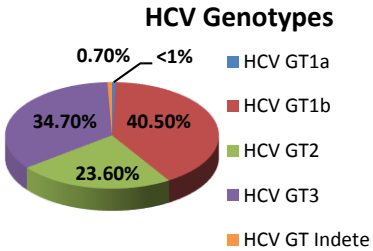
General population	**Prevalence**	**Source**
Surveys among blood donors	1) 7.3% 2) 7.8% 3) 2% overall	1) Tbilisi blood donors 1998 2) Tbilisi, Batumi, Poti blood donors 1997-1999 3) "Safe Blood" Georgia State Program, 2012
Population-based surveys	6.7%	Tbilisi population-based survey 2001-2002
	7.7% Anti-HCV+ 5.4% HCV RNA+	**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

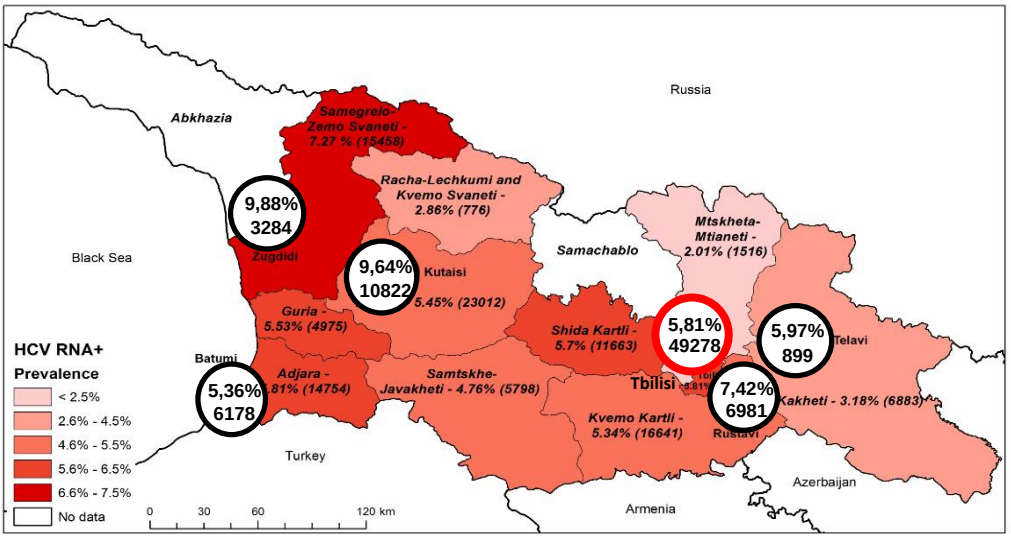
Men who have sex with men (MSM) - Tbilisi	7.1%	BSS among men who have sex with men in two cities of Georgia, 2015
MSM - batumi	18.9%	
Health care workers	5%	Butsashvili M et al. 2012

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) in 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)†	HIV Co-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 covered by private insurance schemes, treatment was fully dependent on patient's ability to pay out of pocket.
- The Global Fund HIV Program covered HCV treatment for HIV/HCV co-infected patients – 150 per year since 2011.
- Starting from 2013, Government of Georgia covered treatment of HCV infected patients with Pegylated Interferon + Ribavirin (Peg/Riba) regimen at the penitentiary system.
- In 2014, Ministry of Labour, Health and Social Affairs (MoLHSA) negotiated preferential pricing of Peg/Riba for the general population. The new price for standard dual therapy established at a price of 92.88 USD per vial of Peg/Riba. This dramatically lowered the cost of HCV standard treatment regimens 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.

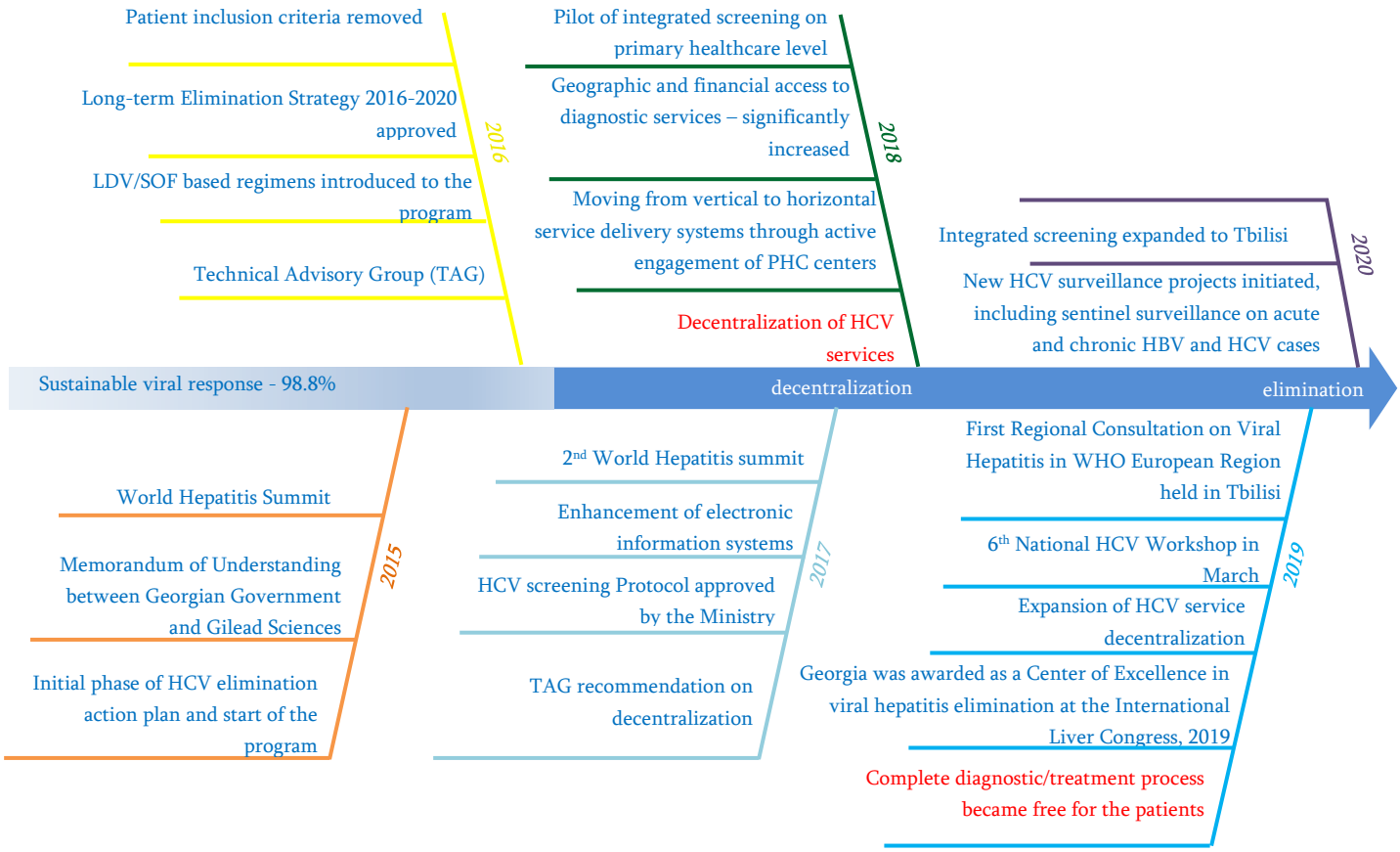
Major diagnostic methods implemented in Georgia

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

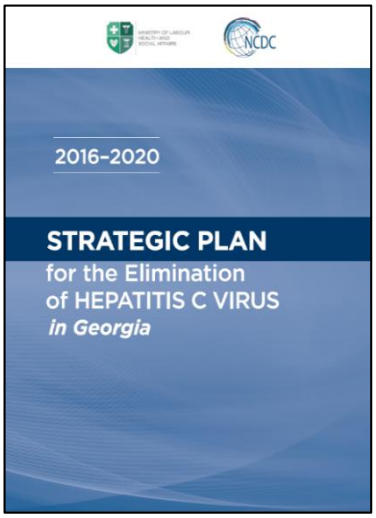
Treatment approach	Year of implementation
Interferon alpha monotherapy	1996
Interferon alpha + ribavirin	1998
Pegilated interferon alpha	2001
Pegilated interferon alpha + ribavirin	2002
Pegilated interferon alpha + ribavirin + telaprevir or Boceprevir	2011
Sofosbuvir + pegilatedinterferon alpha + ribavirin	2014
Sofosbuvir + ribavirin	2014
Sofosbuvir + ledipasvir	2015
Sofosbuvir + daclatasvir	2015
Ombitasvir + paritaprevir + ritonavir + dasabuvir	2015
Sofosbuvir + Velpatasvir	2018
Sofosbuvir + Velpatasvir + Voxilaprevir	2020

Progress towards elimination



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

- Over the past 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 pegilated interferon and ribavirin for the general population.
- In February 2014, MoLHSA (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 Sciences, Inc. 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 MoLHSA, a special commission on HCV was established that was 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 was 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, **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 Sciences, Inc. 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 transfussion were identified as main risk-factors.
- Progress towards elimination of HCV in Georgia was discussed during the ILC 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, MoLHSA and NCDC conducted the **3rd National HCV Elimination workshop** on April 6-8, 2016 in Tbilisi. National and international experts discussed results of national serosurvey, 1st phase of elimination program and Elimination Strategy for 2016-2020.

Georgian HCV Elimination Strategy (2016-2020) goals:

- ✓ *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.*

- 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, 70 proposals were reviewed and 62 were approved by the Scientific Committee by the end of July, 2020. Clinical guideline for management of HCV infection was elaborated by the Clinical Committee.
- Progress towards elimination of HCV in Georgia was discussed at the ILC 2016 in Barcelona. Memorandum of Understanding for 10 years was signed between the Georgian Government and pharmaceutical company Gilead Sciences, Inc.

- 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.
- **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. Protocol was approved by the MoLHSA in May 2017.
- A pilot project – **Integration of HCV, TB and HIV Detection at PHC level** 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. Following the successful example of this region, a similar project was implemented in other regions in the country.

- 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 ILC 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 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 ILC 2018 in Paris.
- 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.
- During 11-13 February 2019 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.
- Georgia was awarded as a **Center of Excellence in viral hepatitis elimination** at ILC 2019 in Vienna.
- On the **5th TAG meeting** in November 2019 the group recommended development of the new strategic document which will also include hepatitis B elimination and integration of disease management into the universal healthcare plan.
- In August 2019 patient's copayment in diagnostic component of the HCV state program was abolished and the complete process became free of charge.
- In 2020 'follow-up' program was initiated to track screening-positive individuals who did not refer to further services (i.e. did not get confirmatory testing and, respectively, did not get enrolled in the treatment program).

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

Prevent HCV transmission

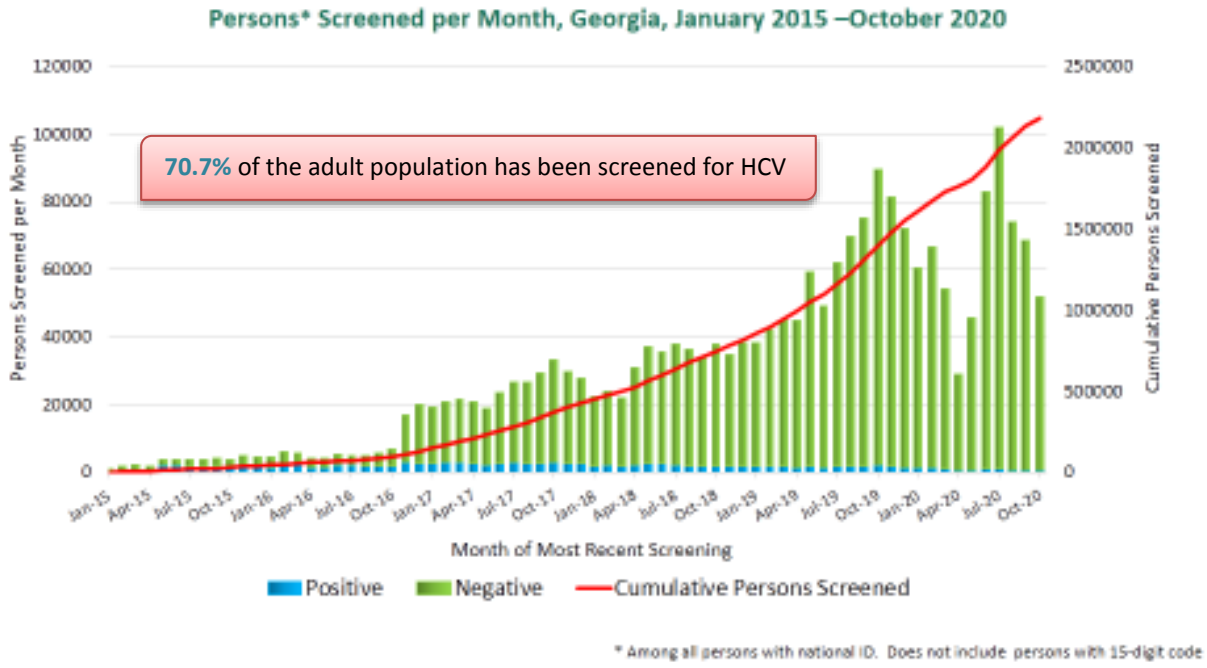
- IPC training course for physicians and nurses developed, trainings performed by NCDC
- Throughout the country, all officially registered non-healthcare facilities are being monitored and controlled for compliance on IPC measures
- Point-Prevalence Study performed on antibiotic consumption, HAI and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

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
- In October 2018, HCV screening was established 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.

Unified Electronic HCV Screening Module

Screening data from all national HCV screening programs is gathered within the unified electronic HCV screening module. 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.

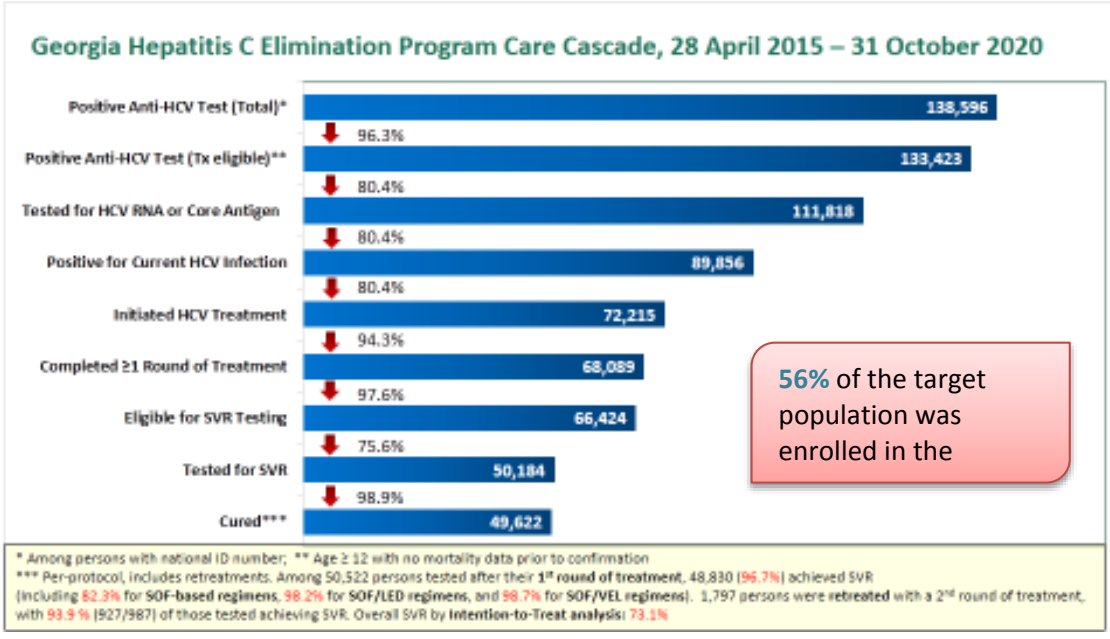


Improve HCV Laboratory Diagnostics

- 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-aroundtime

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 October 2020, 68,089 patients completed the treatment, with overall cure rate – 98.9%.



- Sentinel surveillance of acute and chronic hepatitis B and C was established in 4 infectious disease hospitals in major cities.
- To assess the impact of wide-scale screening, diagnostic and treatment interventions as part of the national hepatitis C program on disease prevalence and to evaluate the changes of hepatitis B prevalence since 2015, repeat seroprevalence survey is planned in 2020.
- Ongoing surveillance projects:
  - ✓ Viral Hepatitis C and B Surveillance Capacity Building
  - ✓ HCV surveillance capacity building - follow up of children born to HCV-infected mothers in Georgia within Hepatitis C Elimination Program
  - ✓ Strengthening HCV and HBV outbreak detection capacity within harm reduction setting in Georgia by utilizing GHOST technology
  - ✓ Evaluation of HCV transmission through endoscopy procedures

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.

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 km^2) 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.

For additional information, please contact:

Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
144, Akaki Tsereteli Avenue
Tbilisi 0119, Georgia
Phone: (+995 032)2510011

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

National Center for Disease Control and Public Health of Georgia
3, Alekseevka Settlement
Tbilisi 0109, Georgia
Phone: 116001

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