



GEORGIA

Hepatitis C Profile



MINISTRY OF LABOUR,
HEALTH AND SOCIAL
AFFAIRS OF GEORGIA



NATIONAL CENTER FOR
DISEASE CONTROL AND
PUBLIC HEALTH

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 – 3,720,400 (January 1, 2016).

	2011-2012	2013	2014	2015
GDP per capita (USD)	3231-3523	3,600	3,681	3,767
Government expenditure on health as % of GDP	1.70%	2.00%	2.40%	2.80%
Health expenditure:				
Public funding	18.3% - 21.4%	28.90%	30%	32%
Private funding	78.8% - 75.8%	69.10%	66%	66%
International Aid	2.8% - 2.8%	3.10%	3%	2%
	Launch of Universal Health Care Program, targeting 2.4 million uninsured populations. 100% of Georgian population is covered with basic benefit package			
Key Statistics	2012	2013	2014	2015
Birth Rate	12.7 per 1000	12.9 per 1000	16.3 per 1000	15.9 per 1000
Mortality Rate	11.0 per 1000	10.8 per 1000	13.2 per 1000	13.2 per 1000
Life Expectancy at Birth	74.7 years	75.2 years	72.9 years	72.9 years
Maternal Mortality Rate per 100,000 live births	22.8	27.7	31.5	32.1
Infant Mortality Rate per 1000 live births	10.8	10.5	8.2	8.6
Under 5 Mortality Rate	12.4	12	9.3	10.2

HCV Epidemiology

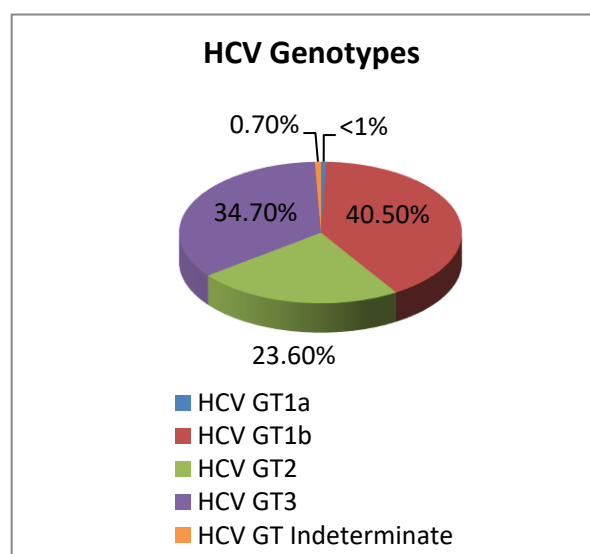
Based on available data, Georgia is among the countries with high hepatitis C (HCV) Prevalence, however, the reasons of the high burden of the disease has not been studied sufficiently. Collapse of the health care system in 1990s, sub-optimal quality standards of health services had negative influence 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

There are no precise data available on HCV prevalence in Georgian prisons as no sero-prevalence study has been conducted. Data collected during the free HCV screening offered to prisoners as part of the prison-based HCV treatment program demonstrated a prevalence of ~48%. In the mortality structure among prison population deaths associated with HIV/AIDS and viral hepatitis are the third highest with 17.53% (including liver cirrhosis and cancer), only after cardiovascular and respiratory disease mortality rates. The HCV prevalence among HIV infected people is reported as 48,6% and as 73,4% among HIV infected PWID.

According to the Latest population-based survey, conducted by the National Center for Disease Control and Public Health (NCDC) and US Centers for Disease Control and Prevention (CDC) 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



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

Distribution of HCV genotypes by years has changed substantially in Georgia: According to the data of the population-based HCV seroprevalence survey, which was conducted in collaboration with CDC between May-August, 2015, 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.

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 2014 Government of Georgia covers treatment of HCV infected patients with Pegylated Interferon + Ribavirin (Peg/Riba) regimen at the penitentiary system.

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

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

- 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 has been established at a price of 92.88 USD per vial of Peg/Riba. This has dramatically lowered a price for 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 experienced in the HCV treatment and monitoring are mainly consolidated in Tbilisi. The expertise in this area outside Tbilisi is limited, but they have experience of managing infectious diseases and in 2015 they received basic training on HCV care and management using new Directly Acting Antiviral drugs (DAAs).

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.

2011-2012	2013	2014	2015	2016
The Global Fund Project "Improving management of HIV/HCV Co-infection in Georgia" - Free of Charge Hepatitis C treatment for HIV/HCV co-infected patients with Peg/Riba	<p>State Program "Hepatitis C Treatment in the Prison Population" - Free of Charge Hepatitis C treatment for prisoners;</p> <p>Government negotiates for Peg/Riba treatment course price reduction to \$4,500;</p> <p>MoLHSA negotiated for additional 10,000 treatments for civil population with price reduction of 60%</p>	<p>Prisoner HCV Treatment Program; MoLHSA 10,000 civilians treatment program;</p> <p>1st National workshop on Hepatitis C was conducted, feasibility of elimination was discussed.</p> <p>National commission on Hepatitis C was established</p> <p>The Georgian Government announces Hepatitis C as a high governmental priority</p> <p>Protocol for population-based HCV seroprevalence survey was developed by the CDC</p> <p>Dr. David Sergeenko, the Minister of Labour, Health & Social Affairs of Georgia discussed and started negotiations regarding possibilities of HCV response strengthening and elimination with US partners and Gilead</p> <p>HCV elimination perspectives in Georgia were discussed during the annual meeting of the EASL in London</p>	<p>National Program for Short-term/urgent Measures (1st phase) of Hepatitis C Elimination Action Plan for 2015 is developed and approved by the Georgian Government in April</p> <p>Long-term elimination strategy for 2016-2020 is developed</p> <p>2nd National workshop on Hepatitis C was conducted</p> <p>Memorandum of Understanding between Georgian government and US pharmaceutical company Gilead is prepared and officially signed on April 21, 2015</p> <p>Progress towards elimination of HCV in Georgia is discussed during the annual meeting of EASL in Vienna, World Hepatitis Summit in Glasgow, as well as WHO Euro regional committee in Vilnius and high-level ministerial meeting in Minsk</p> <p>HCV seroprevalence survey is conducted during May-August, 2015</p> <p>Technical Advisory Group meeting is held in Tbilisi, November 3-4</p>	<p>Harvoni is introduced in the elimination program</p> <p>3rd National HCV Elimination Workshop is held in Tbilisi</p> <p>Long-term elimination strategy for 2016-2020 is approved by the government</p> <p>Inclusion criteria are removed – all HCV-positive patients get treatment</p> <p>2nd Technical Advisory Group (TAG) meeting was held in Tbilisi, October 24-25</p>



Georgian 2nd National Workshop on Hepatitis C, March 26, 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-infection 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 MoLHSA (Minister Dr. David Sergeenko) initiated discussion regarding strengthening Hepatitis C response in the country with US partners.
- 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 meeting 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 manufacturing 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 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.
- Georgian delegation with the support of the US CDC and Open Society Foundation Georgia visited Egypt in February 2015 to get familiar with the ongoing Sofosbuvir treatment program and use experience of Egypt in planning elimination strategy for Georgia.

➤ In March 2015 **2nd National HCV Workshop** was organized by MoLHSA, NCDC and IDACIRC with the support of the US CDC and participants from governmental and non-governmental stakeholders, local experts and international experts from CDC, WHO and Emory University. 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.



Official signing of Memorandum of Understanding, April 21, 2015

➤ **Memorandum of Understanding** between the Government of Georgia and US 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, to describe HCV circulating genotypes and identify knowledge and perceptions towards hepatitis and its prevention and treatment. The survey estimated that **7.7%** population is anti-HCV positive and **5.4%** are HCV RNA positive.

➤ **Long-term elimination strategy** for 2016-2020 is developed. To facilitate the process of elaboration, several workshops and a 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.



2nd Technical Advisory group (TAG) meeting, October 24-25, 2016

➤ With Support of CDC, WHO and Eurasian Harm Reduction Network, MoLHSA and NCDC conducted **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 government scaled up screening activities. Since January 2015 through December 2016 more than 470,000 people have been screened for HCV through several programs. Diagnostic yield (positive HCV cases found) within ongoing screening programs varies from 0.4% among pregnant women to 45% among PWIDs.

➤ In August, 2016 the **Scientific Committee (SC)** was 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, 22 proposals were reviewed by the SC by the end of February.



Prime minister Giorgi Kvirikashvili meets patients enrolled in HCV program

➤ **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 elimination program care cascade

Implementation of elimination program started in April 2015 and currently 29 service centers in different cities, and 1 center in penitentiary system, are providing diagnostic and treatment services to program beneficiaries. By the end of December, 2016, **27,595** patients started treatment with different regimens based on Sofosbuvir and Harvoni, **19,778** patients already completed the treatment, and among those with SVR result available, cure rate reached **79.5%** on Sofosbuvir-based regimens and **98.2%** on Harvoni-based regimens.

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.



Minister Davit Sergeenko on World Hepatitis Summit, Glasgow, 2015