

HCV Country Profile

November, 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

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 – 3,723,500 (January 1, 2019).

	2011-2012	2013	2014	2015	2016	2017	2018
GDP per capita (USD)	3843.7 - 4249.8	4341.4	4483.3	3754.9	3857.3	4046.8	4345.5*
Government expenditure on health as % of GDP	1.7%	2.0%	2.4%	2.9%	3.1%	2.9%	2.8%*
Health expenditure							
Public funding	18.4% - 20.6%	24.3%	28.2%	36.3%	37%	38%	40%*
Private funding	79.1% - 77.1%	73.4%	69.9%	61.9%	62%	60%	59%*
International Aid	2.5% - 2.3%	2.3%	1.9%	1.8%	1%	2%	1%*
Key Statistics							
Birth Rate per 1000	13.6 - 16.3	15.9	15.2	14.3	14.8	14.6	13.7
Mortality Rate per 1000	13.3 - 13.2	13.1	13.2	13.2	13.6	12.8	12.5
Life Expectancy at Birth (years)	72.1	72.5	72.8	73.0	72.7	73.5	74.0
Maternal Mortality Ratio (per 100,000 live births)	27.6 - 22.8	32.2	31.5	32.2	23.0	13.1	27.4
Infant Mortality Rate (per 1000 births)	11.0 - 10.8	10.5	9.5	8.6	9.0	9.6	8.1
Under5 Mortality Rate (per 1000 live births)	12.0 - 12.4	12.0	9.3	10.2	10.7	11.1	9.8

* Preliminary data

HCV Epidemiology

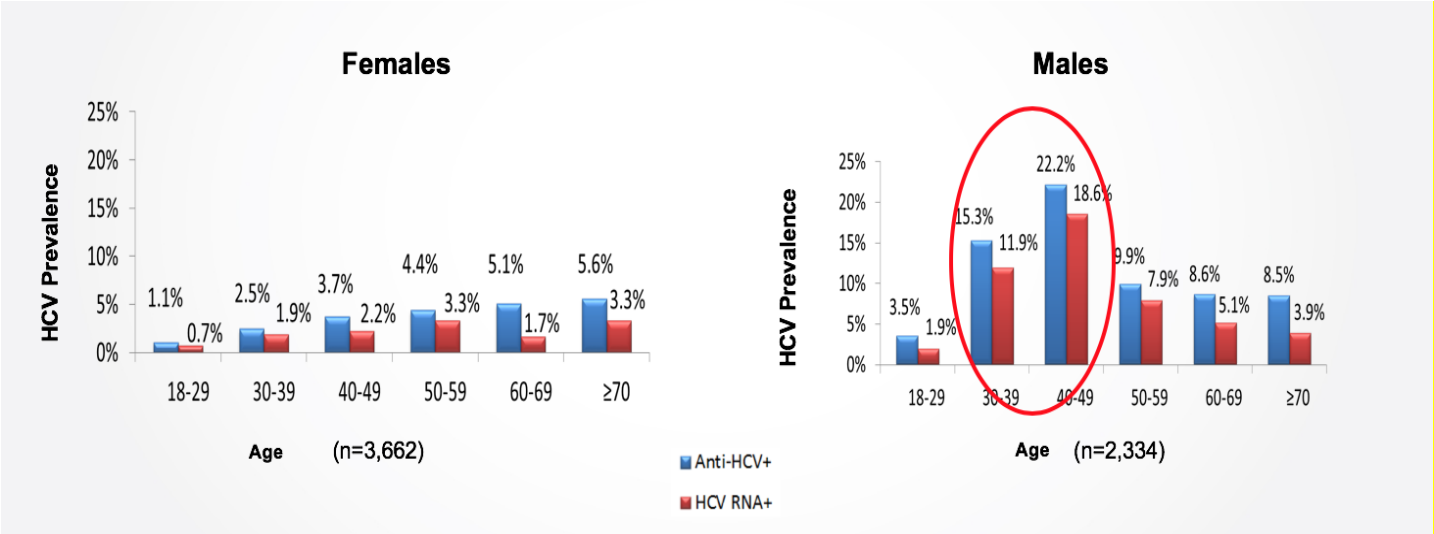
Based on available data, Georgia is among the countries with high hepatitis C (HCV) Prevalence, however, the reasons of the high burden of the disease has not been studied sufficiently. Collapse of the health care system in early 1990s, sub-optimal quality standards of health services had negative influence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

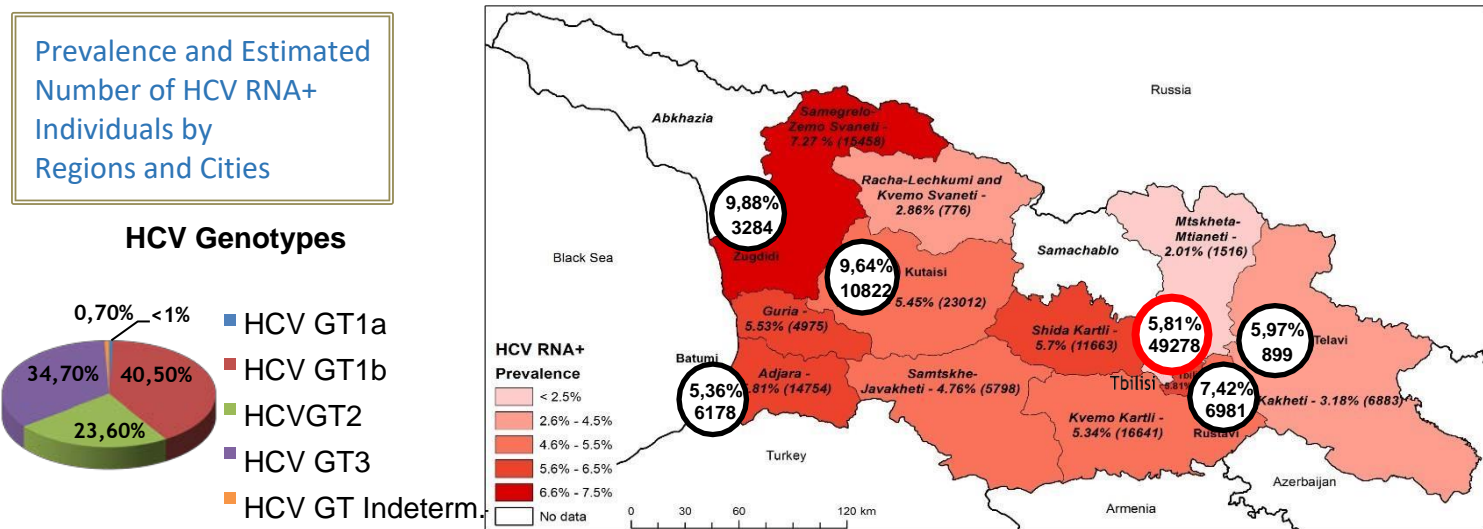
Men who have sex with men (MSM) - Tbilisi	7.1%	BSSamongmenwhohavesexwithmenintwocities of Georgia,2015
MSM - Batumi	18.9%	
Health care workers	5%	Butsashvili M et al. 2012

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%andthe prevalenceofactive diseaseis 5.4%.

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



According to HCV serosurvey, infection is concentrated in males particularly of age groups 30-49. The Highest HCV prevalence is among 30-39 year-old (11.9% HCV RNA+) and 40-49 year-old males (18.6% HCV RNA+)



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*

The genetic characteristic of hepatitis C virus in Georgia has some peculiarities. Particularly, Hepatitis C virus (HCV) recombinant form RF1_2k/1b is common in Georgia. According to the studies provided by the Infectious Diseases, AIDS and Clinical Immunology Research center, clinic “Mrcheveli” and the National Center for Disease Control and Public Health, this virus contains genomic fragments of genotype 2 and genotype 1 and is misclassified as genotype 2 by standard genotyping. To confirm and characterize presence of suspected HCV RF1_2k/1b strains among Georgian population whole Genome Sequencing of HCV recombinant forms were performed at Genome Center of the National Center for Disease Control and Public Health of Georgia as part of HCV elimination program of Georgia. Specimens were provided by Infectious Diseases, AIDS, and clinical Immunology Research center, Tbilisi Georgia. The study confirmed presence of RF1_2k/1b recombinant strain in ethnic Georgian population and revealed that out of 685 HCV genotype 2 patients enrolled in the study 502 (73.2%) had RF1_2k/1b strain and 183 (26.7%) had either HCV 2a, 2k, or 2c subtypes.

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.

**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
Cepheid Xpert FS HCV viral load	2019

**Timing of implementation of HCV
antiviral treatment approaches in
Georgia**

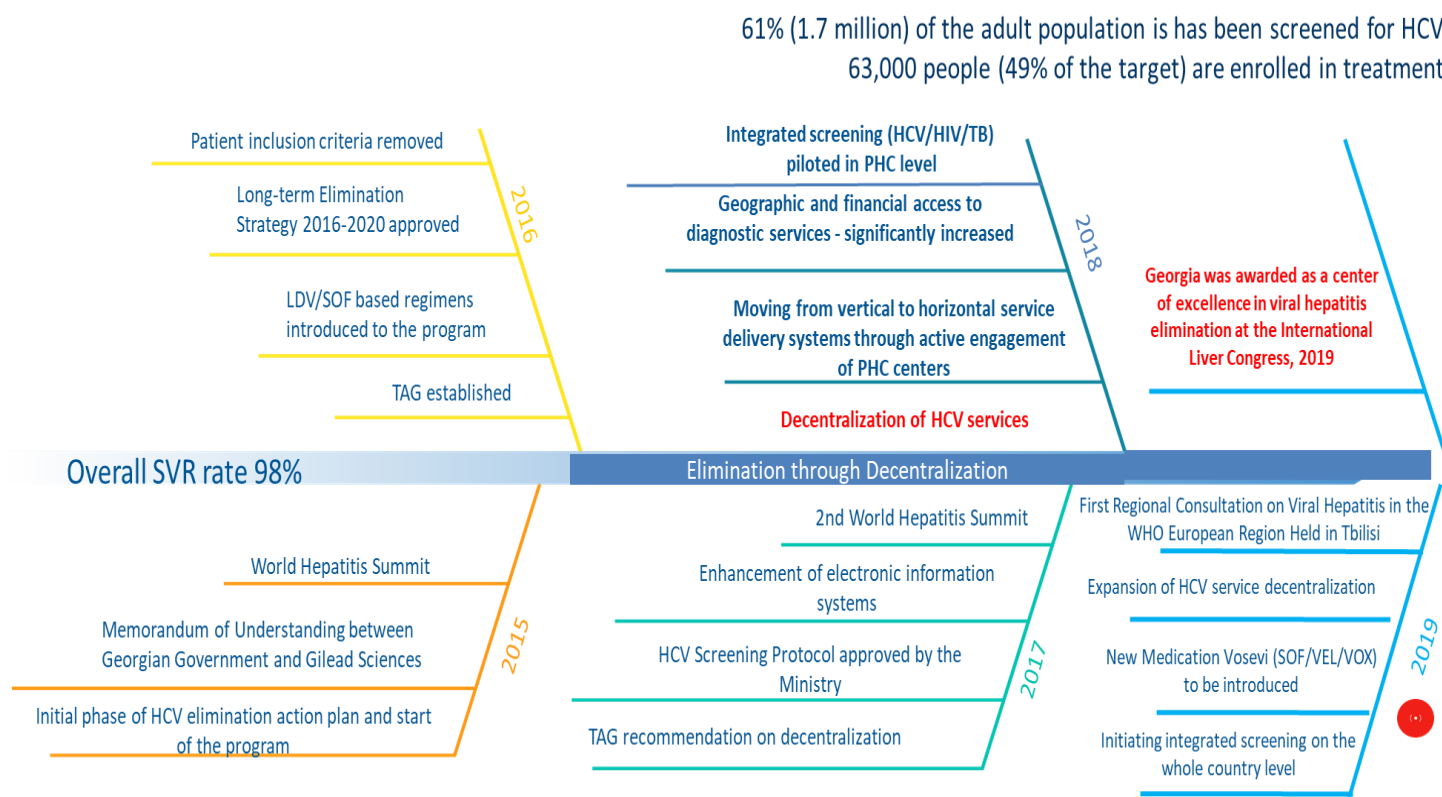
Treatment approach	Year of implementation
Interferon monotherapy	1996
Interferon alpha + ribavirin	1998
Pegylated interferon alpha	2001
Pegylated interferon alpha + ribavirin	2002
Pegylated interferon alpha + ribavirin + telaprevir or Boceprevir	2011
Sofosbuvir + pegylated interferon alpha + ribavirin	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 2019-2020

HCV Care and Treatment (Historical Milestones)

- Until 2014 diagnostics and treatment of Hepatitis C in general population were neither financed by the state 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 with Pegylated Interferon + Ribavirin (Peg/Riba) - 150 per year since 2011.
- Starting from 2013 (till September 2015), Government of Georgia covered treatment of HCV infected patients with Pegylated Interferon + Ribavirin (Peg/Riba) regimen at the penitentiary system.
- In 2014, Ministry of Internally Displaced Persons 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 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 were mainly consolidated in Tbilisi. The expertise in this area was limited outside the capital city, but there were medical professionals specialized in infectious diseases who received basic training on HCV care and management using new direct-acting antiviral drugs (DAAs) since 2015.

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.

The road towards HCV Elimination

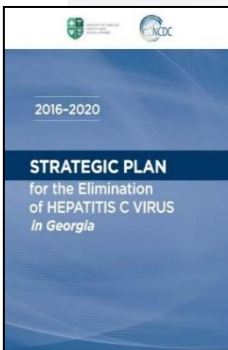


- Over the past several years the Government of Georgia substantially stepped up its efforts against hepatitis C by implementing national programs such as free of charge hepatitis C treatment for HIV/HCV co-infection patients (funded under the Global Fund HIV Program since 2011); Free of charge hepatitis 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 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, 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.
- First results towards elimination of HCV in Georgia was discussed during the EASL congress in Vienna, World Hepatitis Summit in Glasgow, WHO Regional Committee for Europe 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, 2015. 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.
- 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.
- 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 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, 63 proposals were reviewed and 55 were approved by the Scientific Committee by the end of October, 2019. Clinical guideline for management of HCV infection was elaborated by the Clinical Committee.

- **The 2nd Technical Advisory group 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.
- **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 approved by the MoLHSA 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.
- The 6th National Hepatitis C Elimination workshop, was conducted on March 6-7, 2019 in Tbilisi. The main goal was to review the progress on implementation of the HCV elimination Plan and discuss the strategy to strengthen screening and linkage to care.
- On **the 4th TAG meeting**, which was conducted on 28-30 November 2018, the group evaluated current accomplishments and revised 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.
- In April 2019 EASL meeting in Vienna was dedicated to Georgia and country was awarded with the status of the **Center of Excellence**.

The National HCV Elimination Strategy



Goal

Elimination of HCV by ensuring prevention, diagnostics and treatment of the disease

Targets

90-95-95

By 2020

- ✓ **90% of people living with HCV are diagnosed (n=135,000)**
- ✓ **95% of those diagnosed are treated (n=128,250)**
- ✓ **95% of those treated are cured (n=122,000)**

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

2) Prevent HCV transmission

3) Identify persons infected with HCV

4) Improve HCV laboratory diagnostics

5) Provide HCV care and treatment

6) Improve HCV Surveillance

Recent progress by different directions of the Elimination Strategy

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

➤ Educational, awareness raising activities, 2019

- Mass media awareness campaign: More than 200 TV reporting, TV and radio shows with invited guests and articles
- Social media educational campaign: Hepatitis C Facebook page (More than 120 000 reaches and 16,826 likes)
- NCDC webpage used for information and communication purposes
- Street advertisement and dissemination of printed educational materials
- SMS Texting communication

➤ Screening and communication campaigns

- Community and organized settings (i.e. Metallurgical Plant, Land transport Agency, etc.) throughout the country
- Sport events, Festival and Concerts

➤ Hepatitis C Screening Program at Public Service Halls:

- HCV Screening and education materials provided at Public Service Halls at 13 cities of Georgia
- Printed education materials distributed, video clips broadcasted on the screens and invitations on HVC screening printed on tickets
- More than 150 Students from local universities were trained and involved in promotion activities

➤ Hepatitis C Cured Patient Association, 2019:

- Association involved in communication strategic planning
- Collaborative community based activities carried out throughout the country

➤ Personal Communication Activities, 2019:

- Public discussions and seminars with the participation of the NCDC, Local Government, PH centers, service providers and the patient association for primary health care workers, HCV patients, vulnerable groups and general populations
- Annually on 28th of July Georgia is celebrating World Hepatitis Day with wide range of activities during the whole week.

Prevent HCV Transmission: Blood Safety

- Confirmatory testing was introduced for all anti-HCV positive blood donations within the State Safe Blood Program
- Two nucleic acid testing (NAT) systems have been purchased with support of Global Fund. Centralized NAT testing will start later this year and will be scaled up nationwide over the next two years
- Awareness is being raised on unpaid blood donations in the general population
- Percentage of voluntary donations has increased from 5% to 30% during the last decade
- Prevalence of HCV screening positive donations decreased from 1.4% to 0.5% during the last five years
- Draft law and standards on quality and safety of blood and blood components have been developed
- EU Twinning Project on strengthening blood safety system has been granted to Georgia. The project will start from January 2020 and will be implemented through partnership with two European Member States (Lithuania and Netherlands)

Prevent HCV Transmission: Infection Control

- Publishing and implementation of new Infection prevention and control (IPC) guidelines
- Development and publishing of IPC guidelines for dental settings
- Organization of trainings for medical personnel, public health workers, and dentists on the unified educational curriculum
- Continue infection prevention monitoring control and ensure sustainability of the process
- Conduct research/assessment of the risk of HCV transmission in non-traditional healthcare and community settings
- IPC training needs to be expanded and should include professional medical associations
- Professional medical associations should develop a curriculum on infection prevention and control and train their association members
- The Universal Health Care (UHC) program can be leveraged to increase IPC practices in health facilities that wish to be included in the program by meeting the quality criteria

Identify persons infected with HCV

- HCV screening in more than 1000 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 1.7 million Georgian adult citizens screened as registered in the unified electronic screening registry

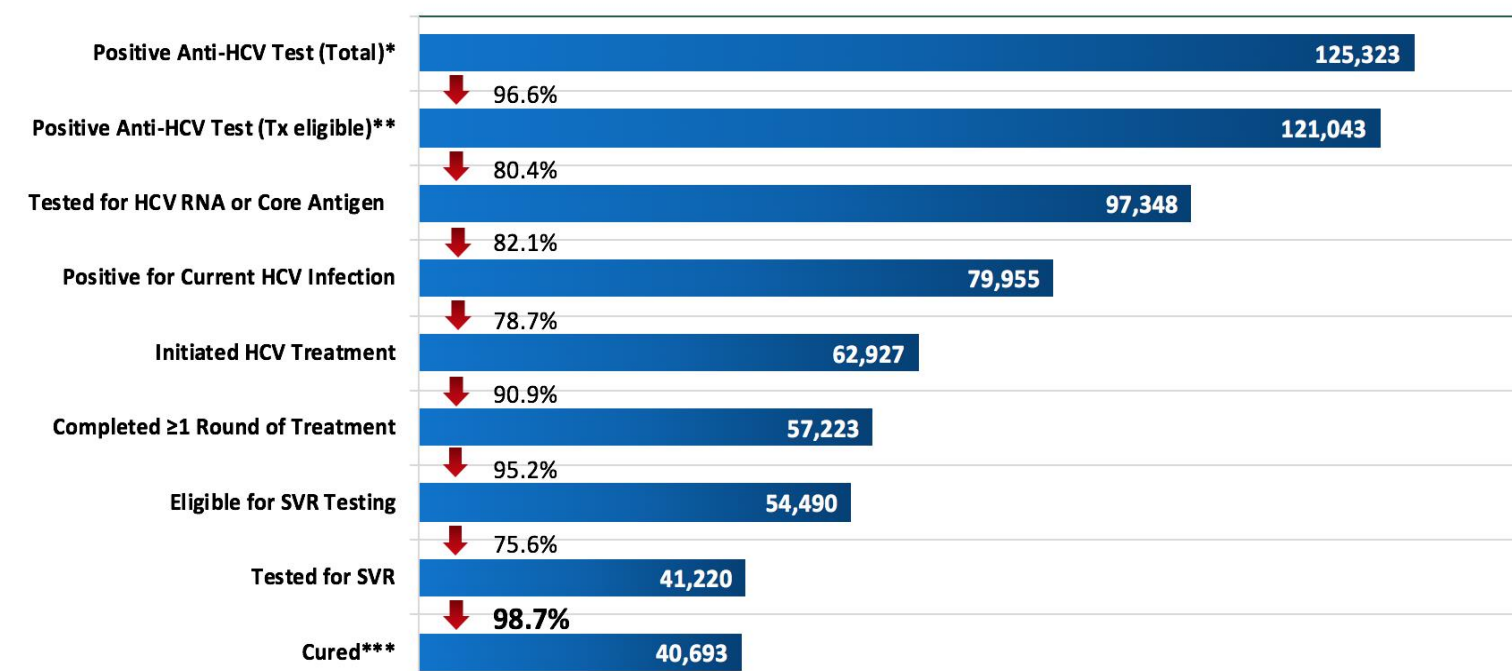
Improve HCV laboratory diagnostics

- Conduct assessment of HCV rapid tests to ensure only high quality tests are being used and develop standardized protocol for validation and verification of HCV rapid diagnostic tests
- HCV sequencing has been implemented Laboratory testing using the Global Hepatitis Outbreak and Surveillance Technology (GHOST)
- A new HCV diagnostic methodology- XPERT® FINGERSTICK HCV VIRAL LOAD ASSAY- has been implemented since October 2019
- Since 2017, the national EQA program has been implemented regarding HCV diagnostics including Genexpert platforms and in the future this program will be expanded to blood banks
- HCV core Antigen testing has been implemented since December 2017
- The performance of HCV core Ag testing has been validated
- Present the data to the scientific committee to simplify the HCVcore Ag testing algorithm
- Plans to mandate proficiency testing in order to identify weaknesses and prepare recommendations
- Plans to implement comprehensive external quality assessments of laboratories throughout the country at least once a year

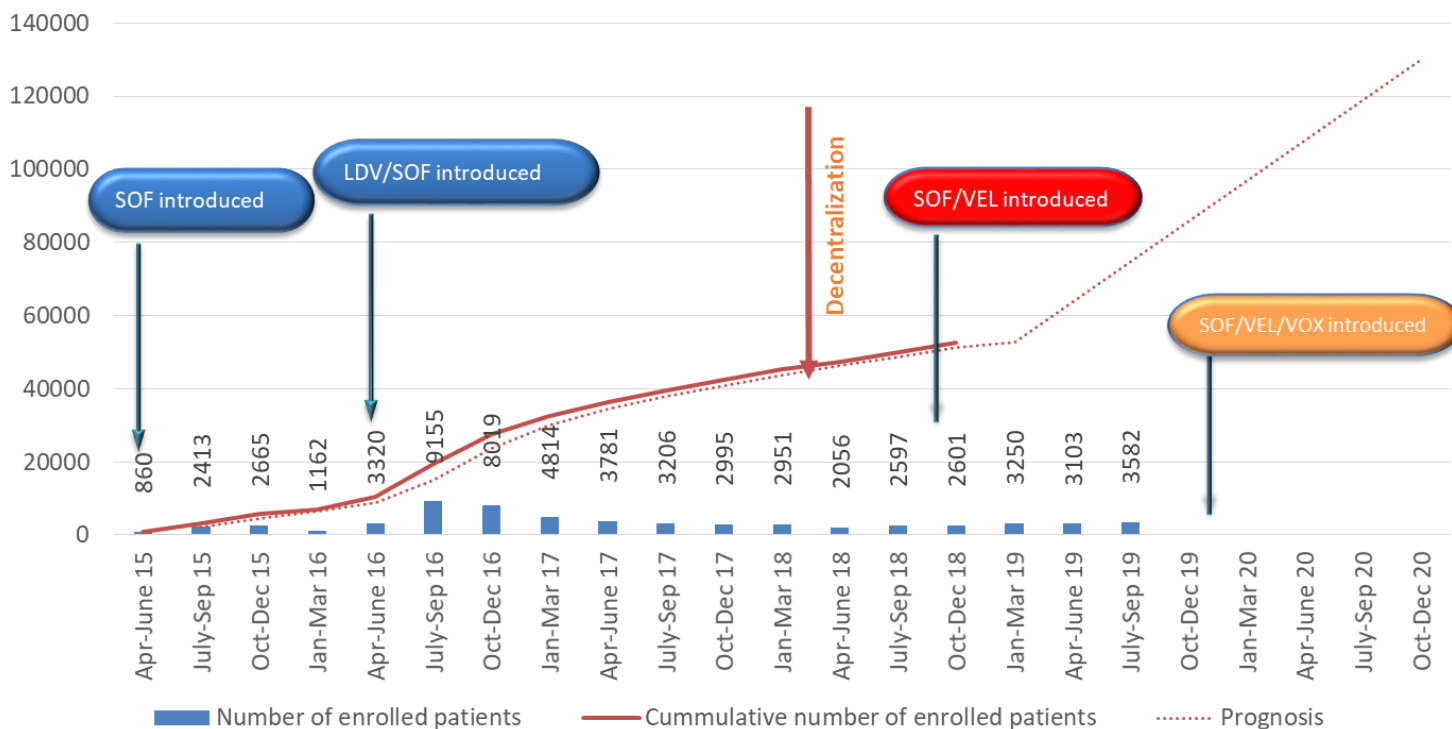
Provide HCV care and treatment

Starting with 4 sites in 2015, currently 42 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 2019, **62,927** patients initiated the treatment, with overall cure rate – **98.7%**

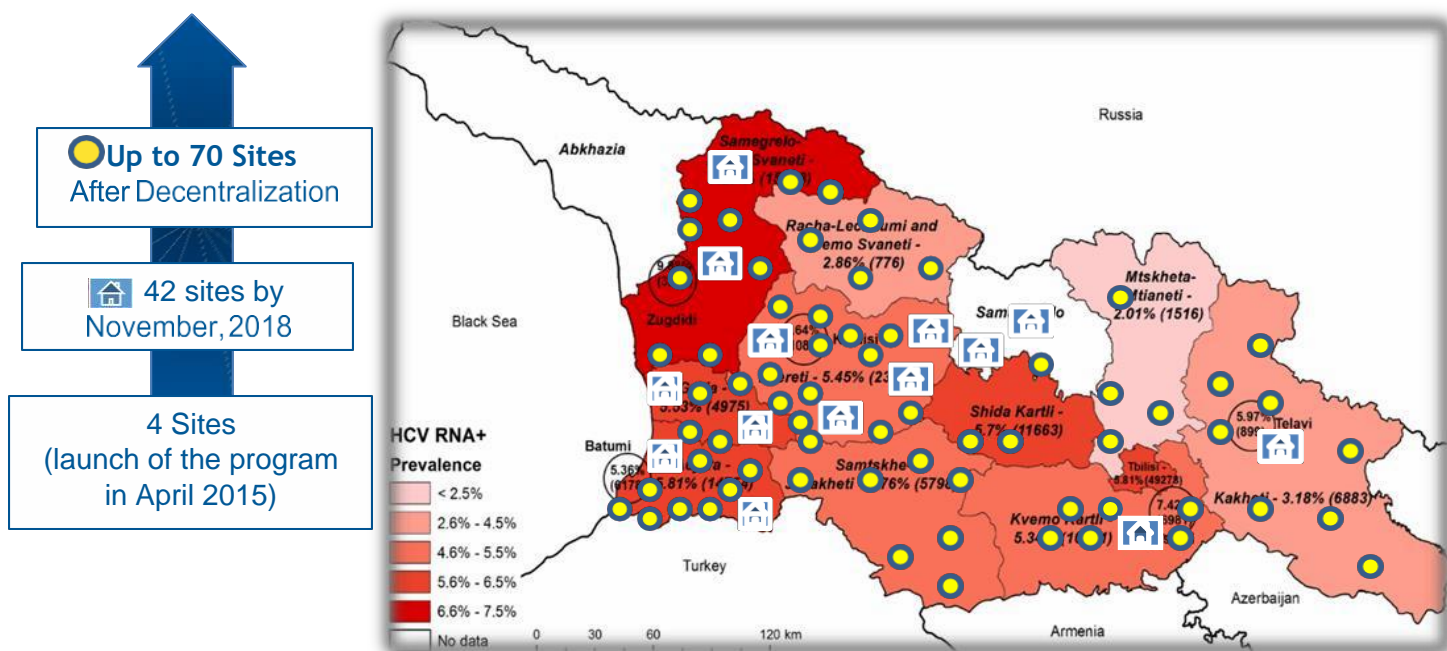
Georgia Hepatitis C Elimination Program Care Cascade, April 28, 2015 – October 31, 2019



Enrollment in the HCV Treatment Program



Decentralization of HCV Services



Improve HCV surveillance

- The case-definitions have been reviewed
- Acute HCV case reporting became obligatory
- Each acute HCV case will be individually investigated
- The pilot project on monitoring re-infection started in 2019
- Activities for enhancing surveillance in the young population are in the planning phase

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

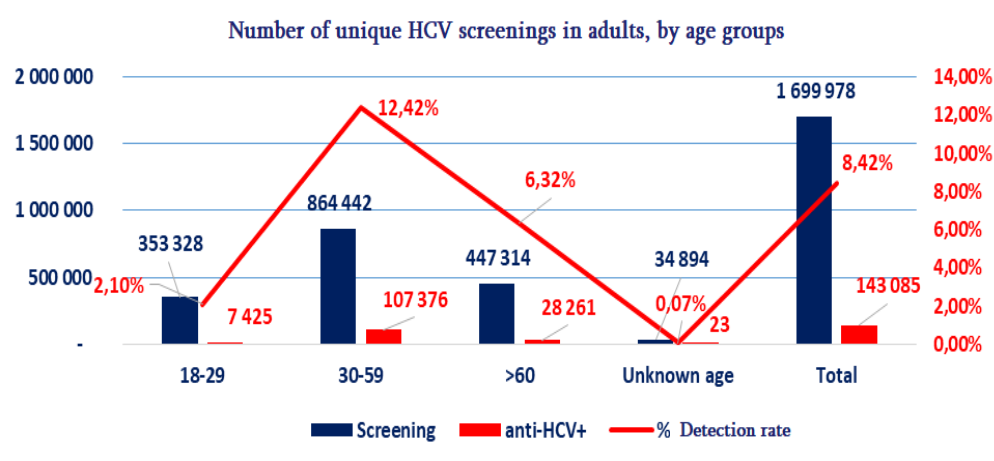
- ✓ Current or past injection/intranasal drugs users
- ✓ Men who have sex with man
- ✓ Prisoners
- ✓ Sex workers
- ✓ Hospitalized patients
- ✓ HIV infected persons
- ✓ TB patients
- ✓ STI patients
- ✓ Blood donors
- ✓ Recipients of blood or blood products
- ✓ Persons ever on dialysis
- ✓ Persons with hemophilia
- ✓ 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

Recent updates in the State HCV Program

From the launching of the State Hepatitis C Elimination Program, screening and the treatment of HCV patients is free for the citizens of Georgia. In the diagnostic component of the program there was 30-70% share of co-payment from the patient, which was gradually decreased and from August 2019 the whole process became free.

Unified Electronic HCV Screening Module

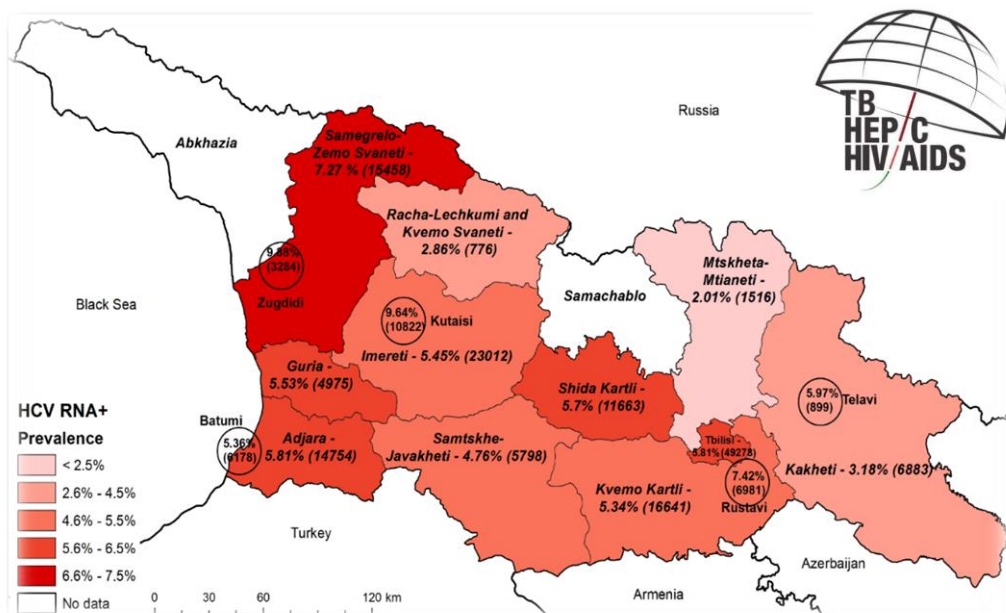
A unified electronic HCV screening module was created to capture data from all national HCV screening programs. Screening providers enter the data into the module on-site. The module is using personal IDs based on a link with Public Registry that allows to synchronize HCV-related data from different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



As of November 2019, over 3,3 million screenings were registered in the database. More than 1.7 million adults were tested with positivity rate 8.4%.

Integration of HCV, TB and HIV Detection at PHC level

- Pilot project in Samegrelo-Zemo Svaneti region was launched in November, 2017
- Integrated HCV/HIV/TB screening protocol approved - **Target for screening - 40% of local population**
- 454 doctors and nurses trained
- Integrated multidisciplinary service monitoring groups established
- Municipal programs supporting pilot implementation approved

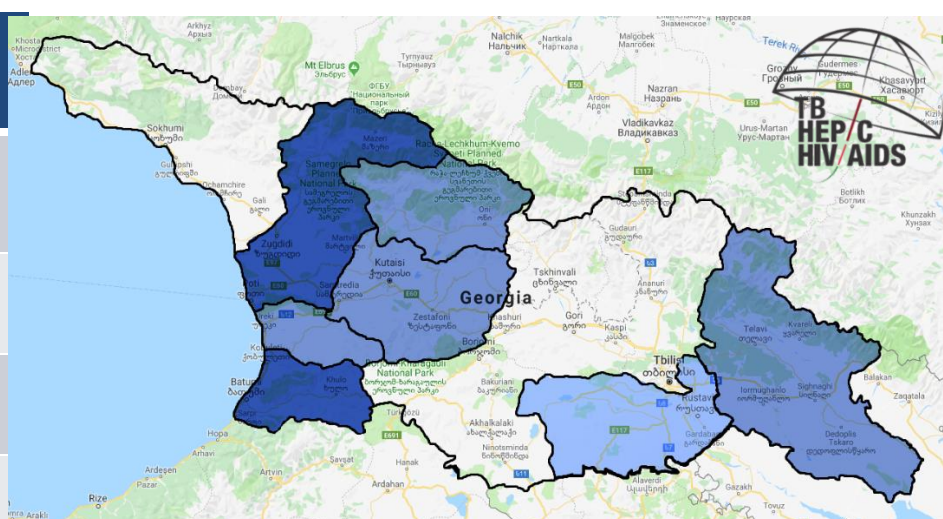


88 178 persons were screened from April to November, 2018 on HCV, HIV and TB among which:

- Anti-HCV+ 2279cases
- Anti-HIV+ 37 cases
- Presumptive TB 192 cases

Due to the successful implementation of the project, the number of screened individuals has increased significantly. The project has since expanded in several regions of Georgia and is expected to be countrywide by the end of the year.

Region	Population screened in PHC	Population screened (total)	Screening positive
Samegrelo-zemo Svaneti	124,458	172,774 (70.3%)	HCV 2778 HIV 57 TB 221
Adjara	70,701	161,482 (60.8%)	HCV 765 HIV 59 TB 788
Guria	21,014	64,765 (76.4%)	HCV 263 HIV 8 TB 15
Imereti	25,934	228,485 (58.8%)	HCV 275 HIV 13 TB 27
Racha-Lechkhumi	5,411	18,224 (78.7%)	HCV 94 HIV 0 TB 1
Kakheti	30,369	122,408 (50.7%)	HCV 268 HIV 12 TB 10
Mtskheta-Mtianeti	6,516	35,243 (49.0%)	HCV 42 HIV 2 TB 1
Total	284,403		HCV 4485* HIV 151* TB 1063 **



* Antibody positive

** Preliminary data – suspected cases by questionnaire

Micro-elimination in specific risk-groups

	TB Patients	HIV Infected Individuals	Hemophilia Patients	OST Program Beneficiaries	Dialysis Patients	War Veterans and Their Family Members
Target Population	2 122	4 090	389	9 080	2 979	69 254
Screening Coverage %	94%	98%	99%	87%	89%	51%
Finding Screening Positives %	17%	36%	37%	86%	23%	12%
Confirmatory Pos.	228	821	72	4 925	368	2751
Started treatment	119	749	55	4 141	70	2320
Coverage by treatment %	52%	91%	76%	84%	19%	84%

Important Events and Study Tours

Study Tours Organized by NCDC

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 toward 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.

During the period of 2017-2019 the delegations composed of health professionals from different countries: Ukraine, Azerbaijan, Uzbekistan, Armenia, Moldova, Kirgizstan, Egypt and Afghanistan visited Georgia to get acquainted with the different aspects of ongoing national HCV Elimination program in the Country and learn about our experience through site visits and meetings with the policy makers, experts, public health professionals, clinicians etc.

Important events

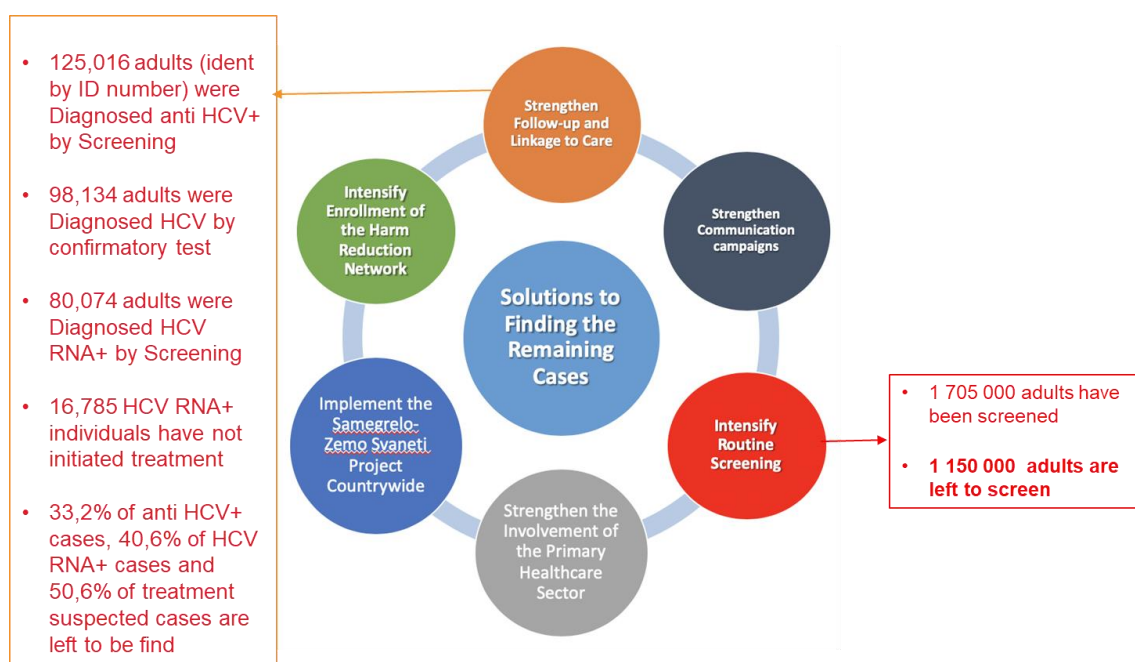
- National Hepatitis C Elimination Workshops - 2014, 2015, 2016, 2017, 2018, 2019
- Technical Advisory Group meetings – 2015, 2016, 2017, 2018, 2019
- The WHO regional consultation on viral hepatitis was held in Tbilisi Georgia – 2019
- EASL side meetings dedicated to Georgian HCV Elimination Program: 2014 – London; 2015 – Vienna; 2016 – Barcelona; 2017 – Amsterdam; 2018 – Paris; 2019 – Vienna
- **Center of Excellence in HCV Elimination** - Georgia was awarded as a center of excellence in viral hepatitis elimination at the International Liver Congress, 2019



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.

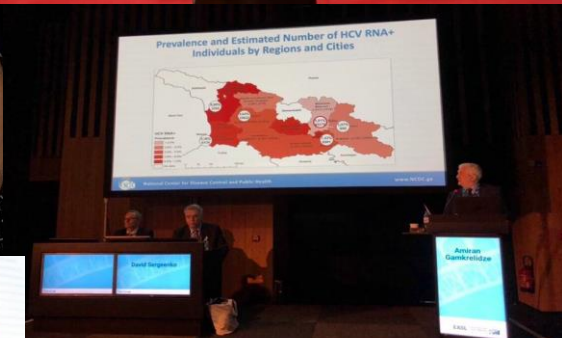
The NOhep Visionaries Programme is a global campaign which engages governments to scale-up successful approaches to elimination and share key learnings, accelerating progress towards eliminating viral hepatitis by 2030.

Future Plans Funding Remaining Cases



Summary and Recommendations

- HCV Elimination program is a major driver for Health System strengthening and advancing Public Health Agenda in Georgia, especially for HIV and TB. HCV elimination program supports the development of other key public health programs such as Safe Blood, Infection Control, Harm Reduction, etc.
- In the first 4,5 years of the HCV Elimination Program, Georgia has scaled up the screening and treatment services achieving impressive results – 61% screening coverage and 49% treatment coverage with 98.7% cure rate
- Enhancing HCV testing and linkage to care and treatment services are critical to reaching by the end of 2020 HCV elimination goals
- Provision of HCV screening, confirmation, care and treatment services at non-specialized settings nearer to patients' homes is critical for achieving the elimination goals
- Decentralization and integration of HCV/HIV/TB services' delivery in primary care or harm reduction settings can result in overcoming barriers to access care and treatment
- In order to achieve HCV elimination goals, screening should be targeted to the specific age groups where the biggest proportion of antibody+ cases to be reveled are still concentrated (male population - 35-55 age group, female population –50 years old and above age group)
- Strengthening the follow up and linkeage to further diagnostic testing and treatment of more than 24,000 antibody+ individuals and 16,000 RNA+ individuals who were lost from the system
- Lessons learned from the Georgia HCV Elimination Program can inform programs in other countries striving to eliminate HCV as a public health threat.





SCIENTIFIC ARTICLES AND PRESENTATIONS 2019

RESEARCH

Open Access

Hepatitis C prevalence and risk factors in Georgia, 2015: setting a baseline for elimination



Liesl M. Hagan^{1*}, Ana Kasradze², Stephanie J. Salyer³, Amiran Gamkrelidze², Maia Alkhazashvili², Gvantsa Chanturia², Nazibrola Chitadze², Roena Sukhiashvili², Marina Shakhnazarova², Steven Russell³, Curtis Blanton³, Giorgi Kuchukhidze², Davit Baliashvili², Susan Hariri¹, Stephen Ko^{1,4}, Paata Imnadze², Jan Drobeniuc¹, Juliette Morgan^{3,5} and Francisco Averhoff¹

Abstract

Background: The country of Georgia launched the world's first Hepatitis C Virus (HCV) Elimination Program in 2015 and set a 90% prevalence reduction goal for 2020. We conducted a nationally representative HCV seroprevalence survey to establish baseline prevalence to measure progress toward elimination over time.

Methods: A cross-sectional seroprevalence survey was conducted in 2015 among adults aged ≥ 18 years using a stratified, multi-stage cluster design ($n = 7000$). Questionnaire variables included demographic, medical, and behavioral risk characteristics and HCV-related knowledge. Blood specimens were tested for antibodies to HCV (anti-HCV) and HCV RNA. Frequencies were computed for HCV prevalence, risk factors, and HCV-related knowledge. Associations between anti-HCV status and potential risk factors were calculated using logistic regression.

Results: National anti-HCV seroprevalence in Georgia was 7.7% (95% confidence interval (CI) = 6.7, 8.9); HCV RNA prevalence was 5.4% (95% CI = 4.6, 6.4). Testing anti-HCV+ was significantly associated with male sex, unemployment, urban residence, history of injection drug use (IDU), incarceration, blood transfusion, tattoos, frequent dental cleanings, medical injections, dialysis, and multiple lifetime sexual partners. History of IDU (adjusted odds ratio (AOR) = 21.4, 95% CI = 12.3, 37.4) and blood transfusion (AOR = 4.5, 95% CI = 2.8, 7.2) were independently, significantly associated with testing anti-HCV+ after controlling for sex, age, urban vs. rural residence, and history of incarceration. Among anti-HCV+ participants, 64.0% were unaware of their HCV status, and 46.7% did not report IDU or blood transfusion as a risk factor.

Conclusions: Georgia has a high HCV burden, and a majority of infected persons are unaware of their status. Ensuring a safe blood supply, implementing innovative screening strategies beyond a risk-based approach, and intensifying prevention efforts among persons who inject drugs are necessary steps to reach Georgia's HCV elimination goal.

Keywords: Hepatitis C virus, HCV, HCV elimination, Georgia, HCV prevention, Global health security

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RESEARCH

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An evaluation of the hepatitis C testing, care and treatment program in the country of Georgia's corrections system, December 2013 – April 2015

Aaron M. Harris^{1*}, Otar Chokoshvili^{2†}, Joshua Biddle³, Kostantine Turashvili⁴, Maia Japaridze⁵, Irma Burjanadze⁶, Tengiz Tsertsvadze², Lali Sharvadze², Marine Karchava², Archil Talakvadze⁷, Ketevan Chakhnashvili⁴, Tamta Demurishvili⁴, Paata Sabelashvili⁸, Monique Foster^{1,9}, Liesl Hagan¹, Maia Butsashvili¹⁰, Juliette Morgan^{5,11} and Francisco Averhoff¹

Abstract

Background: The country of Georgia has a high burden of chronic hepatitis C virus (HCV) infection, and prisoners are disproportionately affected. During 2013, a novel program offering no cost screening and treatment of HCV infection for eligible prisoners was launched.

Methods: The HCV treatment program implemented a voluntary opt-in anti-HCV testing policy to all prisoners. Anti-HCV positive persons received HCV RNA and genotype testing. Transient elastography was also performed on prisoners with positive HCV RNA results. Prisoners with chronic HCV infection who had \geq F2 Metavir stage for liver fibrosis and a prison sentence \geq 6 months were eligible for interferon-based treatment, which was the standard treatment prior to 2015. We conducted an evaluation of the HCV treatment program among prisoners from the program's inception in December 2013 through April 2015 by combining data from personal interviews with corrections staff, prisoner data in the corrections database, and HCV-specific laboratory information.

Results: Of an estimated 30,000 prisoners who were incarcerated at some time during the evaluation period, an estimated 13,500 (45%) received anti-HCV screening, of whom 5175 (38%) tested positive. Of these, 3840 (74%) received HCV RNA testing, 2730 (71%) tested positive, and 880 (32%) met treatment eligibility. Of these, 585 (66%) enrolled; 405 (69%) completed treatment, and 202 (50%) achieved a sustained virologic response at least 12 weeks after treatment completion.

Conclusions: HCV infection prevalence among Georgian prisoners was high. Despite challenges, we determined HCV treatment within Georgian Ministry of Correction facilities was feasible. Efforts to address HCV infection among prison population is one important component of HCV elimination in Georgia.

Keywords: Chronic hepatitis C, HCV infection, Prisons, Global health security, Linkage to care, Incarcerated, Prisoner

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RESEARCH

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The burden of non-communicable diseases and their related risk factors in the country of Georgia, 2015

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Abstract

Background: Non-communicable diseases (NCDs), mainly cardiovascular diseases, are a substantial cause of mortality in the country of Georgia, accounting for approximately 93% of all deaths (standardized mortality rate 630.7 deaths per 100,000 persons per year) and an important threat to health security. We conducted a nationally representative survey examining the prevalence of NCDs and their risk factors as part of a 2015 Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) serosurvey.

Methods: We conducted a cross-sectional serosurvey among adults aged ≥ 18 years using a stratified, multi-stage cluster design ($n = 7000$). We asked participants standardized questions from the Global Adult Tobacco Survey and the WHO STEPwise approach to Surveillance (STEPS) Survey. We also measured blood pressure and Body Mass Index for each participant. Weighted frequencies were computed for NCD and risk factor prevalence and compared to 2010 STEPS results.

Results: Georgians reported high rates of smoking, alcohol use, elevated blood pressure, obesity, diabetes and cardiovascular disease. An estimated 27.1% (95% confidence interval [CI]: 25.3, 28.8%) of adults (51.5% of men and 6.0% of women) reported daily use of tobacco products and 27.5% (95% CI: 25.7, 29.2%) of adults (52.1% of men and 7.0% of women) reported binge drinking within the last 30 days. Physical measurements revealed that 37.5% (95% CI: 35.8, 39.3%) of adults had elevated blood pressure and 33.4% (95% CI: 31.8, 35.0%) had obesity. 5.4% (95% CI: 4.6, 6.2%) of adults had self-reported diagnosed diabetes and 15.3% (95% CI: 14.1, 16.6%) had self-reported diagnosed cardiovascular disease. From 2010 to 2015, the prevalence of obesity increased by 8.3 percentage points (95% CI: 5.9, 10.7%; $p < 0.01$) and the prevalence of elevated blood pressure increased by 4.1 percentage points (95% CI: 1.4, 6.8%; $p < 0.01$).

Conclusions: Georgia has a high NCD burden, and results from the survey showed an increase in obesity and elevated blood pressure since 2010. The prevalence of other major NCDs have remained near levels reported in the 2010 STEPs survey. Comprehensive public health interventions are needed to control the health security threats of major NCDs and their risk factors in the future.

Keywords: Global Health, Non-communicable disease, Risk factors, Survey, Georgia, Global health security

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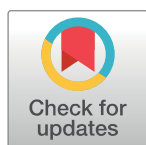
On the way to Hepatitis C elimination in the Republic of Georgia—Barriers and facilitators for people who inject drugs for engaging in the treatment program: A formative qualitative study

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Citation: Chikovani I, Ompad DC, Uchaneishvili M, Sulaberidze L, Sikharulidze K, Hagan H, et al. (2019) On the way to Hepatitis C elimination in the Republic of Georgia—Barriers and facilitators for people who inject drugs for engaging in the treatment program: A formative qualitative study. PLoS ONE 14(4): e0216123. <https://doi.org/10.1371/journal.pone.0216123>

Editor: Jason Blackard, University of Cincinnati College of Medicine, UNITED STATES

Received: July 6, 2018

Accepted: April 15, 2019

Published: April 29, 2019

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Data Availability Statement: Transcripts are uploaded in the Dryad repository (DOI: [10.5061/dryad.67g98n6](https://doi.org/10.5061/dryad.67g98n6)).

Funding: The study was conducted in the frame of the research project funded by the International Science and Technology Center N-G2201 “The Barriers and facilitators to screening and treatment for HCV among drug users in the Republic of Georgia: A formative qualitative study.” Drs. Holly

Abstract

Hepatitis C virus (HCV) infection is a significant public health concern worldwide. Georgia is among the countries with a high burden of HCV infection. People who inject drugs (PWID) have the highest burden of infection in Georgia. In 2015, the Government of Georgia, with partners' support, initiated one of the world's first Hepatitis C Elimination Programs. Despite notable progress, challenges to achieving targets persist. This qualitative study is aimed to better understand some of the barriers and facilitators to HCV testing and treatment services for PWID to inform HCV treatment policies and practices. The study instrument examined social, structural, and individual factors influencing HCV testing and treatment practices. We started with key informant interviews to guide the study instrument development and compare the study findings against health care planners' and health care providers' views. Forty PWID with various HCV testing and treatment experiences were recruited through the snowball method. The study found that along with structural factors such as political commitment, co-financing of diagnostic and monitoring tests, and friendly clinic environments, knowledge about HCV infection and elimination program benefits, and support from family and peers also play facilitating roles in accessing testing and treatment services. On the other hand, inability to co-pay for diagnostic tests, fear of side effects associated with treatment, poor knowledge about HCV infection, and lack of social support hampered testing and treatment practices among PWID. Findings from this study are important for increasing the effectiveness of this unique program that targets a population at high risk of HCV infection.

Impact of hepatitis C virus antibody positivity on mortality and causes of death in people living with HIV in Georgia

Nikoloz Chkhartishvili¹ , Natalia Bolokadze¹,
Nino Rukhadze¹, Natia Dvali¹, Akaki Abutidze¹,
Lali Sharvadze^{1,2} and Tengiz Tsertsvadze^{1,2}

International Journal of STD & AIDS
0(0) 1–9

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DOI: 10.1177/0956462419866055

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Abstract

Hepatitis C co-infection in people living with HIV (PLWH) is common in Georgia. Antiretroviral therapy (ART) is widely available in the country since 2004, and from 2011, patients have unlimited access to hepatitis C virus (HCV) treatment. A retrospective nationwide cohort study included adult PLWH diagnosed between 2004–2016, who were followed up until 31 December 2017. Predictors of mortality were assessed in Cox proportional hazards regression model. A total of 4560 persons contributed 22,322 person-years (PY) of follow-up, including 2058 (45.1%, 10,676 PY) anti-HCV+ patients. After the median 4.1 years of follow-up, 954 persons died, including 615 anti-HCV+ patients. Persons with HCV had higher overall mortality compared to HIV monoinfection (5.76/100 PY vs. 2.91/100 PY, $p < 0.0001$). In multivariable analysis, anti-HCV positivity was significantly associated with mortality (adjusted hazard ratio: 1.42, 95% CI: 1.09–1.85). Among anti-HCV+ persons, liver-related mortality due to viral hepatitis before the availability of HCV therapy (2004–2011) was 2.11 cases per 100 PY and this decreased to 0.79 cases per 100 PY after 2011 ($p < 0.0001$). AIDS remained the leading cause of death prior to and after 2011. Wide availability of ART and anti-HCV therapy translated into a significant decline in mortality including due to liver-related causes. Improving earlier diagnosis will decrease excess AIDS-related mortality among people living with HIV/HCV co-infection.

Keywords

HIV, hepatitis C, antiretroviral therapy, AIDS

Date received: 15 February 2019; revised 19 June 2019; accepted: 5 July 2019

Introduction

Wide-scale availability of antiretroviral therapy (ART) led to significant increase in life expectancy among people living with HIV (PLWH) nearly approaching that of general population.¹ As PLWH live longer, they are more likely to die from non-AIDS complications, including liver-related diseases caused by viral hepatitis.² HIV is known to accelerate the progression of liver disease caused by hepatitis C virus (HCV); in turn HCV is associated with increased risk of mortality among PLWH.^{3–5}

Georgia is a country where the HIV prevalence is low, with an estimated adult prevalence of 0.4%, while 7.7% of adult general population is anti-HCV-positive.^{6,7} Co-infection with HCV is common among PLWH in Georgia with nearly half of them carrying HCV

antibodies.⁸ For many years, Georgia's HIV epidemic was driven by injection drug use (IDU), but recent trends indicate shift to sexual transmission through both heterosexual contacts and male-to-male sex. The country has made a significant progress in HIV treatment and care ensuring universal access to ART since 2004 through the Global Fund support.⁹ This has resulted in significant reduction in all-cause mortality

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Article Navigation

ACCEPTED MANUSCRIPT

Three years of progress towards achieving hepatitis C elimination in the country of Georgia, April 2015 – March 2018

Tengiz Tsertsvadze ✉, Amiran Gamkrelidze, Nikoloz Chkhartishvili ✉, Akaki Abutidze, Lali Sharvadze, Vakhtang Kerashvili, Maia Butsashvili, David Metreveli, Lia Gvinjilia, Shaun Shadaker ... [Show more](#)

Clinical Infectious Diseases, ciz956, <https://doi.org/10.1093/cid/ciz956>

Published: 29 September 2019 **Article history** ▼



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Abstract

Background

In April 2015, in collaboration with U.S. CDC and Gilead Sciences, Georgia embarked on the world's first hepatitis C elimination program. We aimed to assess progress towards elimination targets after three years since the beginning of the elimination program.

Methods

We constructed an HCV care cascade for adults in Georgia, based on the estimated 150,000 persons age ≥ 18 years with active HCV infection. All patients who were

screened or entered the treatment program during April 2015 – March 2018 were included in the analysis. Data on the number of persons screened for HCV was extracted from the national HCV screening database. For treatment component we utilized data from the Georgia National HCV treatment program database. Available treatment options included sofosbuvir (SOF) and ledipasvir/sofosbuvir (LDV/SOF) based regimens.

Results

Since April 2015, a cumulative 974,817 adults were screened for HCV antibodies, 86,624 persons tested positive, of which 61,925 underwent HCV confirmatory testing. Among estimated 150,000 adults living with chronic hepatitis C in Georgia, 52,856 (35.1%) were diagnosed, 45,334 (30.2%) initiated treatment with DAA, and 29,090 (19.4%) achieved sustained virologic response (SVR). Overall 37,256 persons were eligible for SVR assessment, of these only 29,620 (79.5%) returned for evaluation. In the per-protocol analysis, SVR rate achieved was 98.2% (29,090/29,620), and 78.1% (29,090/37,256) in the intent-to-treat analysis.

Conclusions

Georgia has made substantial progress in the path towards eliminating hepatitis C. Scaling-up testing and diagnosis, along with effective linkage to treatment services are needed to achieve the goal of elimination.

Keywords: [HCV](#), [Elimination](#), [cascade](#), [Georgia](#)

Topic: [hepatitis c, chronic](#), [hepatitis c, adult](#), [centers for disease control and prevention \(u.s.\)](#), [hepatitis c antibodies](#), [diagnosis](#), [hepatitis c virus](#), [per protocol analysis](#), [sofosbuvir](#), [ledipasvir](#), [hepatitis c screening](#), [sustained virologic response](#)

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World Hepatitis Day — July 28, 2019

World Hepatitis Day, observed each year on July 28, was established to raise awareness and promote understanding of viral hepatitis around the world. The theme of this year's World Hepatitis Day is "Invest in Eliminating Hepatitis," underscoring the need to increase commitment for hepatitis response. In 2015, an estimated 257 million persons were living with hepatitis B and 71 million with hepatitis C worldwide (1).

Persons who inject drugs are at highest risk for hepatitis C virus (HCV) infection. Globally, an estimated 15.6 million persons aged 15–64 years inject drugs, 52% of whom are HCV-antibody positive (2). This issue of *MMWR* features a report on the progress in the country of Georgia toward prevention and detection of HCV infection, and linkage to treatment, of persons with HCV infection who inject drugs (3). Georgia's hepatitis C elimination program, launched in 2015, was recently named the world's first Centre of Excellence in Viral Hepatitis Elimination by the European Association for the Study of the Liver International Liver Foundation. Access to hepatitis C testing and treatment for persons who inject drugs is critical to achieving elimination in countries where persons who inject drugs account for a significant proportion of HCV infection. Additional information and resources about viral hepatitis are available at <https://www.cdc.gov/hepatitis>.

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Progress in Testing for and Treatment of Hepatitis C Virus Infection Among Persons Who Inject Drugs — Georgia, 2018

Ketevan Stvilia, MD¹; Philip R. Spradling, MD²; Alexander Asatiani, MD¹; Maka Gogia, MD³; Khatuna Kutateladze, MD³; Maia Butsashvili, MD, PhD⁴; Jaba Zarkua, MD⁵; Tengiz Tsertsvadze, MD, PhD⁶; Lali Sharvadze, MD, PhD⁷; Maia Japaridze, MD⁸; Tinatin Kuchuloria, MD, PhD⁹; Lia Gvinjilia, MD, PhD⁹; Irinka Tskhomelidze, MPH⁹; Amiran Gamkrelidze, MD, PhD¹; Irma Khonelidze, MPA¹; David Sergeenko, MD, PhD¹⁰; Shaun Shadaker, MPH²; Francisco Averhoff, MD²; Muazzam Nasrullah, MD, PhD²

In April 2015, the country of Georgia, with a high prevalence of hepatitis C virus (HCV) infection (5.4% of the adult population, approximately 150,000 persons), embarked on the world's first national elimination program (1,2). Nearly 40% of these infections are attributed to injection drug use, and an estimated 2% of the adult population currently inject drugs, among the highest prevalence of injection drug use in the world (3,4). Since 2006, needle and syringe programs (NSPs) have been offering HCV antibody testing to persons who inject drugs and, since 2015, referring clients with positive test results to the national treatment program. This report summarizes the results of these efforts. Following implementation of the elimination program, the number of HCV antibody

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tests conducted at NSPs increased from an average of 3,638 per year during 2006–2014 to an average of 21,551 during 2015–2018. In 2017, to enable tracking of clinical outcomes among persons who inject drugs, NSPs began encouraging clients to voluntarily provide their national identification number (NIN), which all citizens must use to access health care treatment services. During 2017–2018, a total of 2,780 NSP clients with positive test results for HCV antibody were identified in the treatment database by their NIN. Of 494 who completed treatment and were tested for HCV RNA ≥ 12 weeks after completing treatment, 482 (97.6%) were cured of HCV infection. Following the launch of the elimination program, Georgia has made much progress in hepatitis C screening among persons who inject drugs; recent data demonstrate high cure rates achieved in this population. Testing at NSPs is an effective strategy for identifying persons with HCV infection. Tracking clients referred from NSPs through treatment completion allows for monitoring the effectiveness of linkage to care and treatment outcomes in this population at high risk, a key to achieving hepatitis C elimination in Georgia. The program in Georgia might serve as a model for other countries.

The Georgian Harm Reduction Network began operating and receiving hepatitis C testing data from NSPs in 2006. As of 2016, 16 NSPs were operating in 13 cities across Georgia. During 2017–2018, with additional resources provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria, two additional NSP centers and eight mobile NSP units became operational, increasing coverage to approximately 50 of 79

municipalities countrywide. The Georgian Harm Reduction Network also provides diverse services* to persons who inject drugs to improve their health outcomes (5).

Persons who inject drugs and who test positive with a rapid HCV antibody test at NSPs are offered case management support and referred to authorized treatment sites for testing to confirm active HCV infection.[†] Since 2017, those persons who agree to treatment referral are asked to provide their 11-digit NIN to the NSP so that further clinical management can be confirmed and documented in the national program treatment database. Once at the treatment center, those patients with confirmed infection are enrolled in the treatment program and, if eligible for treatment, prescribed a direct-acting antiviral regimen according to national treatment guidelines (6). Within 12–24 weeks of completing treatment, patients are instructed to return to the treatment site for HCV RNA testing to determine whether sustained viral response (i.e., virologic cure) was achieved. Demographics, diagnostics, and treatment outcomes are recorded in real-time in the national program treatment database.

For this analysis, program records from the Georgian Harm Reduction Network were reviewed to ascertain annual HCV

* Services provided though the Georgian Harm Reduction Network include distribution of sterile injecting equipment, condoms, and naloxone; voluntary counselling and testing for hepatitis C, human immunodeficiency virus, hepatitis B, and syphilis; peer-to-peer education; raising prevention awareness among persons who inject drugs; and advocacy for increased access to NSPs.

[†] Positive for HCV RNA or HCV core antigen.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. *MMWR Morb Mortal Wkly Rep* 2019;68:[inclusive page numbers].

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antibody screening and positivity frequencies at NSPs during January 2006–December 2018 among persons who inject drugs; age group and sex distribution data were available from NSPs for 2015–2018. NSPs entered testing and service provision data into a database, which were validated by data management specialists at the Georgian Harm Reduction Network. Deduplication of test results was not conducted during 2006–2013 because of insufficient resources; during 2014–2018, deduplication of results was performed for each calendar year. Data for HCV antibody-positive persons who inject drugs who provided their NIN to NSPs during January 1, 2017–December 31, 2018, were linked to the national program treatment database to ascertain the hepatitis C care cascade, which summarizes the sequential steps in care. Because this analysis constituted a program evaluation, institutional review board oversight was not indicated.

During 2006–2018, NSPs provided 118,943 HCV antibody tests to persons who inject drugs, 48,228 (40.5%) of which were positive (Figure 1). During the years preceding program implementation (2006–2014), 32,738 (average 3,638 per year) tests were conducted; nearly half (49.6%; 16,247) were positive. Following implementation of the elimination program (2015–2018), the average number of antibody tests performed each year among persons who inject drugs increased approximately 500%, to 21,551. Among the 86,205 HCV antibody tests provided during this period, 31,981 (37.1%)

were positive. Males accounted for 96.1% of tests, and persons aged 30–39 years were the most frequently tested age group (33.7%). In 2018, the HCV antibody prevalence among persons aged 18–29 years was 5.5%, the lowest among all age groups during 2015–2018. HCV antibody positivity was 37.8% among males and 24.0% among females tested at NSPs during 2015–2018.

During 2017–2018, among 12,163 HCV antibody-positive test results from 11,424 clients at NSPs, 2,780 (24.3%) persons were identified by their NIN in the national treatment database, 1,626 (58.5%) of whom received a follow-up diagnostic test for active HCV infection (Figure 2). Among those tested, 1,370 (84.3%) had active HCV infection. Of those with active infection, 1,029 (75.1%) initiated treatment, 892 (86.7%) of whom completed treatment and were eligible for sustained viral response testing. Of these, 494 (55.4%) returned for sustained viral response testing, 482 (97.6%) of whom achieved cure.

Discussion

Hepatitis C testing at NSPs in Georgia is an effective strategy for identifying persons with HCV infection. During the 3 years following the launch of the elimination program in Georgia in 2015, the number of HCV antibody tests performed at NSPs increased nearly fivefold, and the number of persons with positive test results doubled, compared with the number with positive test results during 2006–2014. Further, voluntary

FIGURE 1. Number of tests for hepatitis C virus (HCV) antibody conducted and positive test results among persons who inject drugs — Georgian Harm Reduction Network, Georgia, 2006–2018

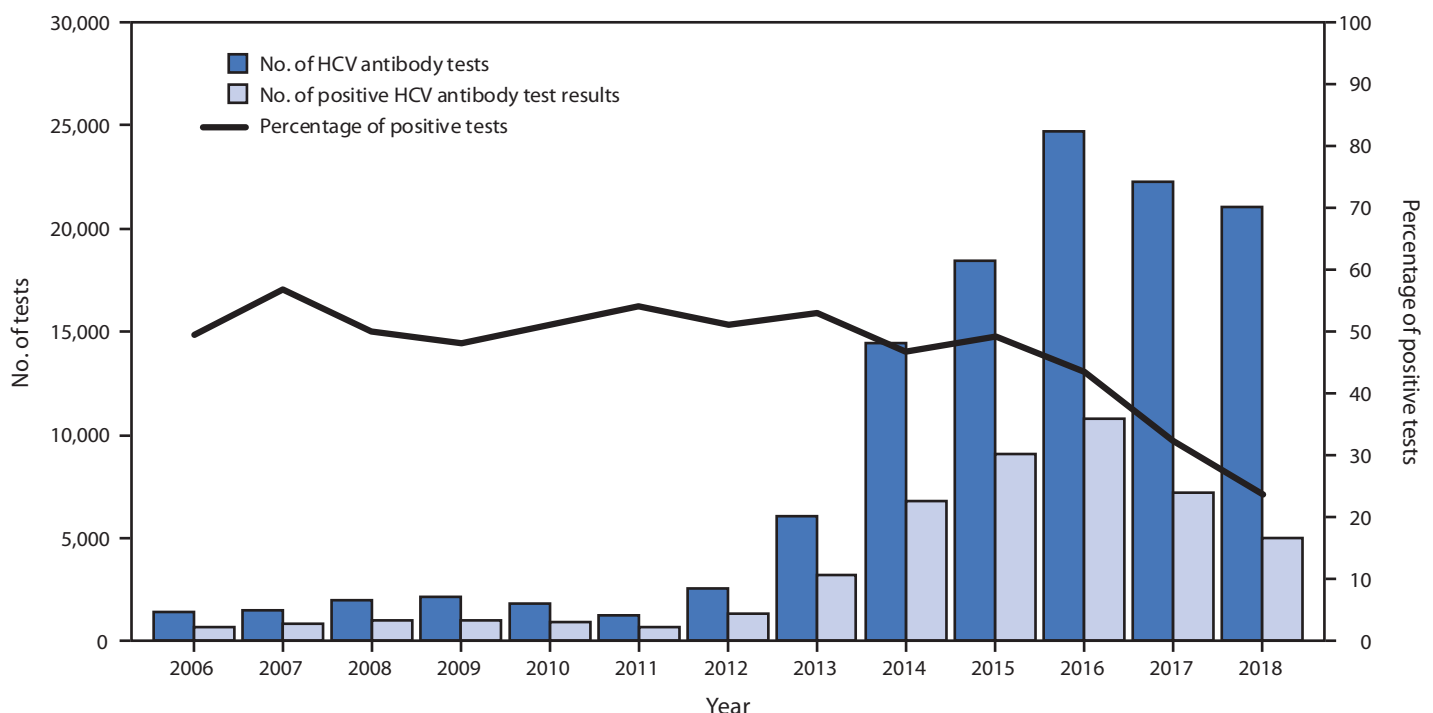
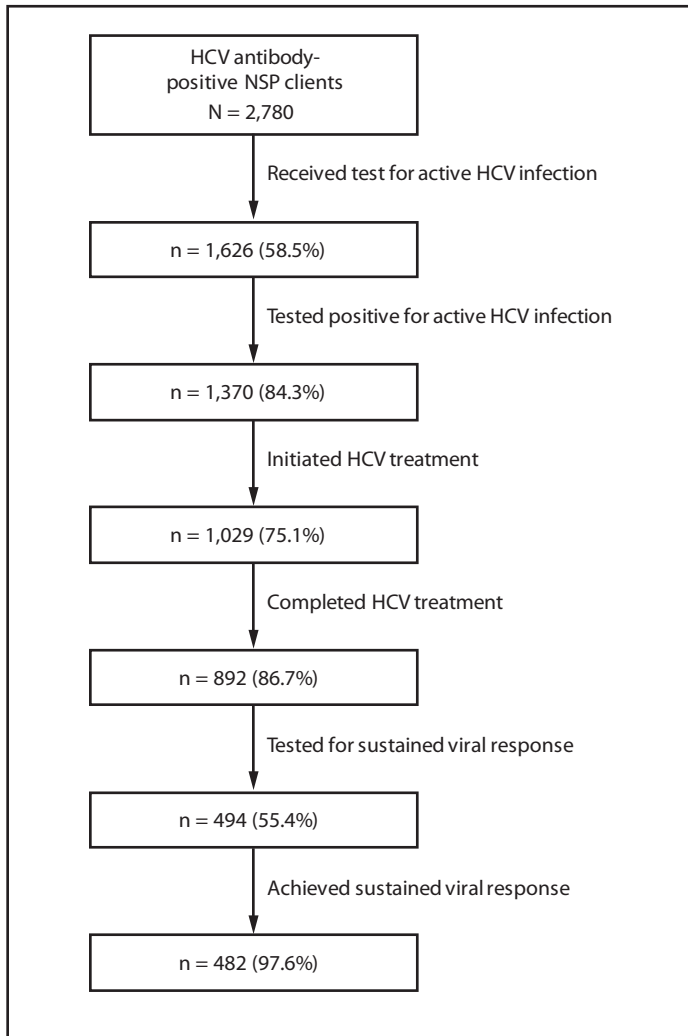


FIGURE 2. Hepatitis C virus (HCV) testing* and treatment outcomes among persons who inject drugs referred by needle and syringe programs (NSPs) to the national hepatitis C treatment program, as identified by their national identification numbers — Georgia, 2017–2018



* HCV RNA or HCV core antigen.

use of the NIN among persons who inject drugs and receive services at NSPs permitted monitoring the linkage to care and treatment, as well as treatment outcomes, among this population at high risk. The number of tests performed annually at NSPs peaked in 2016, and the percentage of positive test results has been trending down since the launch of the elimination program in 2015. The reasons for the decrease in testing after 2016 are unclear but might represent a decreasing pool of persons who inject drugs and remain unaware of their HCV infection status. The decrease in the proportion of positive test results at NSPs during 2016–2018 suggests that a higher proportion of persons who inject drugs screened in recent years have not yet had exposure to HCV. This interpretation is supported by the finding that among all age groups, those

Summary

What is already known about this topic?

Georgia, with a high prevalence of hepatitis C virus (HCV) infection and a high prevalence of injection drug use, launched a hepatitis C elimination program in 2015. Since 2006, needle and syringe programs (NSPs) have offered HCV antibody testing for persons who inject drugs.

What is added by this report?

Following the launch of the hepatitis C elimination program, the number of HCV antibody tests performed at NSPs has increased fivefold, and the number of persons with positive test results has doubled.

What are the implications for public health practice?

Hepatitis C testing at NSPs is an effective strategy for identifying persons with HCV infection. The program in Georgia might serve as a model for other countries.

aged 18–29 years had the lowest HCV antibody positivity prevalence in 2018 and might attest to the effectiveness of the prevention measures provided by NSPs. Given the estimate of approximately 50,000 persons who inject drugs in Georgia and that nearly 120,000 HCV antibody tests have been conducted at NSPs (with approximately 50,000 positive HCV antibody test results) since 2006, it is likely that the majority of persons who inject drugs in Georgia have been tested at least once for HCV antibody.

Fewer than one fourth of persons who inject drugs agreed to provide their NIN to NSPs for the purpose of tracking clinical outcomes. Stigma related to drug use and fear of adverse legal, social, and economic consequences might discourage persons from disclosing their NIN to NSPs before accessing hepatitis C care and treatment (6). To avoid revealing their injection drug use status in the national registry and treatment database, persons could opt to visit treatment sites without divulging their affiliation with NSP services. At present, no incentives are offered by NSPs to motivate persons to provide their NIN. Without the NIN, persons who inject drugs cannot be tracked throughout the cascade of hepatitis C care, and the degree to which elimination efforts are proceeding in this population is hard to ascertain. A study is currently underway to examine the feasibility and effectiveness of providing screening, care, and treatment services at NSPs.

The findings in this report are subject to at least three limitations. First, data from NSP screening and the treatment programs could not be independently verified and could be subject to data entry errors. Second, resources were unavailable to deduplicate NSP test records before 2014; thus, it is not known whether each HCV antibody test during 2006–2013 represented a single person screened. Finally, because only a small proportion of screening data from NSPs were linked to

treatment data, this analysis could not fully assess the effectiveness of linkage from NSP screening to the national care and treatment program.

Strategies to engage persons who inject drugs in hepatitis C prevention, care, and treatment are needed to ensure elimination in Georgia. Lessons from Georgia could inform other countries with a high prevalence and similar epidemiology of hepatitis C.

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All authors have completed and submitted the ICMJE form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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Excellence in viral hepatitis elimination – Lessons from Georgia

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Globally, there are more than 70 million people living with chronic hepatitis C virus (HCV) infection, and an estimated 257 million people are living with hepatitis B virus (HBV) infection, both of which cause significant morbidity and mortality primarily as consequences of chronic infection, including hepatocellular carcinoma and liver failure.¹ Georgia, a small country in the South Caucasus, has a high prevalence of HCV infection with an estimated 150,000 adults living with hepatitis C, representing 5.4% of the adult population.² Georgia was the first country in the world to undertake the challenge of hepatitis C elimination. A serosurvey in 2015 laid the foundation for the elimination program; the survey not only defined the burden of hepatitis C in the country, but also identified the major risk factors for transmission (injection drug use and receipt of blood products) and the demographic profile of those infected, thus allowing for clear characterization of the epidemic including identifying the most at-risk populations.² The cost of treatment in 2015 was prohibitive, so a key partnership was established with Gilead Sciences, who agreed to support the elimination program by providing free-of-charge treatment directly to the country because of the government's commitment to hepatitis C elimination nationwide.

Georgia launched the hepatitis C elimination program in April, 2015³ and set an ambitious goal of 90% reduction in hepatitis C prevalence by 2020.^{4,5} The initial program focus was on treatment, and through April 2019, nearly 60,000 persons had initiated treatment (Fig. 1). However, because of an appreciation of the importance of prevention, the program embraced a comprehensive approach, developing a strategy that addresses prevention, surveillance, advocacy, education, quality diagnostics, screening, and linkage to care, in addition to treatment.⁶

Further, Georgia has invested in and developed an advanced hepatitis C information system,⁷ which links screening, laboratory diagnostics, and treatment data allowing for near real-time monitoring of the care cascade (Fig. 1) and feedback on the effectiveness of programs and interventions, providing policy-makers with the ability to quickly identify deficiencies and make evidence-based adjustments.

Another critical element of the success of the program has been the country's commitment to scientific excellence. To accomplish this, Georgia has assembled an international group of experts in all aspects of hepatitis C elimination that come together annually as the Technical Advisory Group (TAG)⁷ to review progress and make recommendations to the program. Georgia has also developed a Scientific Committee⁷ that oversees and coordinates the research agenda for the elimination program. The Scientific Committee is also charged with documenting progress, assessing program effectiveness through the monitoring of key performance indicators, developing and testing innovations, and ensuring scientific integrity.

A further key to success has been the country's openness to working with partners and community. One group of key partners are without a doubt the clinicians and patients in Georgia that were early on aggressively advocating for ways to obtain treatment with the new life-saving direct acting antivirals (DAAs). Among the clinicians, providers from the four major infectious diseases hospitals provided critical leadership. The dedicated infectious disease specialists from these four centers were the first to offer treatment in the country, and have been instrumental in the scale-up of the program. The United States Centers for Disease Control and Prevention (CDC), another key partner, has been providing technical assistance to the program since 2013. The program has over time gained additional external partners, ranging from non-governmental organizations, to industry, to academic institutions, to patient advocacy groups (see acknowledgements); each of these partners bring key expertise and perspectives.

Despite the significant progress of the Georgia hepatitis C elimination program since its launch, challenges remain.

Keywords: Hepatitis C; Hepatitis elimination; Monitoring and evaluation; Georgia.
Received 14 June 2019; accepted 19 June 2019

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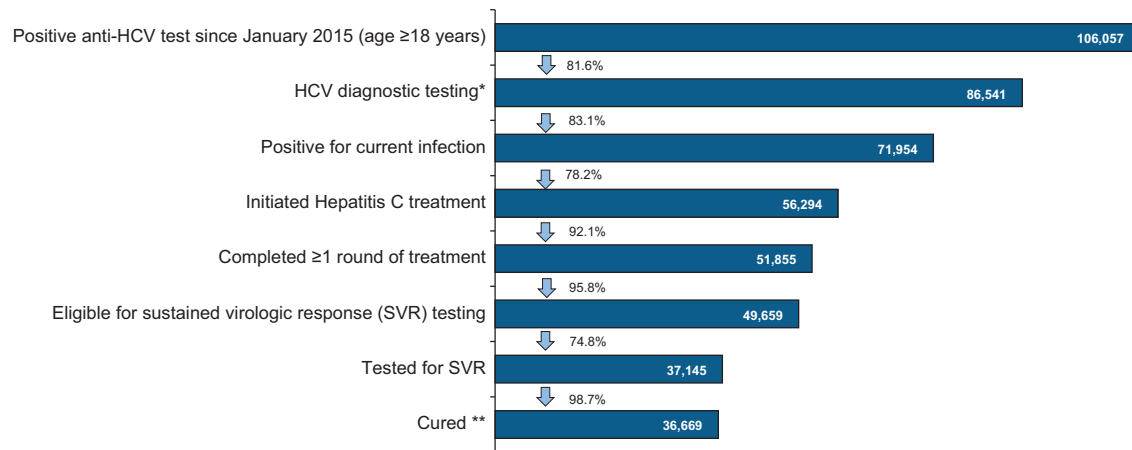


Fig. 1. Georgia hepatitis C elimination program care cascade, April 28, 2015 – April 30, 2019. *Either hepatitis C virus RNA or core antigen testing. **Includes retreatments. Among 37,582 persons tested after their 1st round of treatment, 36,098 (96.1%) achieved SVR. 1,327 persons initiated a 2nd round of treatment, with 94.2% (615/653) of those tested achieving SVR. HCV, hepatitis C virus; SVR, sustained virologic response.

A substantial portion of the estimated 150,000 HCV infected people still need to be identified and linked to care (Fig. 1). The number of patients entering the program has slowed after peaking at more than 4,000 patients per month in late 2016. In response, the government took additional steps to decrease barriers by lowering the cost of diagnostics and by integrating screening, care and treatment services into primary healthcare settings and harm-reduction centers throughout the country. Integration of these services allows infected individuals to receive hepatitis C care and treatment services in familiar and convenient locations, a strategy that has proven effective.^{8,9} Georgia plans to expand services to every district in the country, doubling the number of hepatitis C provider sites. In addition, the program provides services to the most marginalized and at-risk populations including people who inject drugs and incarcerated populations.

In line with the World Health Organization's (WHO's) targets to eliminate viral hepatitis B and C as a public health threat by 2030,^{1,10} many countries have developed and adopted viral hepatitis elimination strategies. However, despite the tremendous progress that has been made in recent years, only 12 of the 194 countries that endorsed the WHO global health sector strategy are on track to reach the WHO elimination targets.¹¹ Georgia was the world's first country to formally launch a national hepatitis C elimination program, although a few other countries, like Australia and Iceland, are now embarking on elimination as well.^{12,13} Georgia embraced a comprehensive hepatitis C elimination program⁶ that includes strategies in place to not only identify those infected with HCV and link them to care and treatment services, but also to safeguard the nation's blood supply, improve access to quality affordable diagnostics, and reduce infection among people who inject drugs and in the healthcare setting.^{4,7,14,15} Georgia's efforts are all the more remarkable as it is not a high-income country.¹⁶ The leadership exhibited by Georgia in hepatitis C elimination is the result of several factors including: the highest levels of political commitment, the allocation of significant resources, and the comprehensive nature of the program.⁶ This has culminated in the great success attained to date, and has led to the country being named as the World's first European Association for the Study of the Liver (EASL)-International Liver Foundation Center of

Excellence in HCV Elimination,¹⁷ meeting all established criteria (Box 1).

The introduction of the Center of Excellence designation allows the EASL-International Liver Foundation to support viral hepatitis elimination efforts around the world. The EASL-International Liver Foundation is seeking to expand the Center of Excellence concept in viral hepatitis elimination to other regions of the world. For governments (e.g. a country or a region) which already fulfill the criteria, the designation provides a standardized framework and process to affirm their

Box 1. European Association for the Study of the Liver-International Liver Foundation Criteria for Center of Excellence in Viral Hepatitis Elimination Designation.

CRITERIA:

A government department, ministry division, unit, or partner etc., prominent within a country's national/state viral hepatitis elimination program can be designated as an EASL-International Liver Foundation Centre of Excellence in Viral Hepatitis Elimination on behalf of the national/state viral hepatitis elimination program based on the fulfilment of the following criteria, as approved by EASL-International Liver Foundation

- A valid estimate of national/state viral hepatitis burden
- A funded comprehensive strategic plan for the national/state elimination of viral hepatitis as a public health threat
- A valid, time-bound, measurable targets for the national/state elimination of viral hepatitis as a public health threat
- Demonstrable progress towards national/state elimination of viral hepatitis through valid indicators
- High quality research outputs in relation to national/state elimination of viral hepatitis
- Demonstrable state of the art viral hepatitis training and educational programming
- Demonstrable partnership between state and non-state actors (academia, private providers, civil society groups, key affected groups and patients advocates) in hepatitis C elimination program planning and implementation
- Clear ability, capacity and readiness to contribute to the achievement of viral hepatitis elimination in other countries/states through technical assistance

commitment towards viral hepatitis elimination. The designation may help elimination programs maintain their momentum during challenging times, such as changes in government or economic downturns that may jeopardize the government's commitment to elimination. For governments which are not meeting the Center of Excellence criteria, but wish to obtain the designation, the EASL-International Liver Foundation may assist by providing technical assistance in support of fulfilling the benchmarks (Box 1). Such a community of designated Centers can serve as a global network of shared best practices and information exchange. Centers can support neighboring countries in launching comprehensive viral hepatitis elimination activities. As a Center of Excellence, Georgia has committed to sharing their experiences with the world, has hosted other countries, including delegations from Egypt and Afghanistan, and is available to provide technical assistance to neighboring countries. As a Center of Excellence, Georgia is working with the EASL-International Liver Foundation to ensure access to information and lessons learned, including their strategic plan, annual progress reports, TAG recommendations, and publications through the development of a website. The Foundation is fully committed to welcoming additional Centers of Excellence throughout the world; a network of viral hepatitis centers of excellence have the potential to contribute tangibly towards the goal of global viral hepatitis elimination by 2030.

Financial support

The authors received no financial support to produce this manuscript.

Conflict of interest

The other authors declare no conflict of interest.

Please refer to the accompanying ICMJE disclosure forms for further details.

Acknowledgements

Partners:

Georgian Harm Reduction Network, Tbilisi, Georgia; World Health Organization, Geneva, Switzerland; Extension for Community Healthcare Outcomes (ECHO), University of New Mexico, New Mexico, USA; Liver Institute and Foundation for Education and Research (LIFER), Boston, Massachusetts, USA; Foundation for Innovative Diagnostics (FIND), Geneva, Switzerland; Médecins du Monde (MDM), Paris, France; Abbott Laboratories, Chicago, Illinois, USA; Bristol University, Bristol, UK; Georgia State University, Atlanta, Georgia, USA; The Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland; Blood System Research Institute, San Francisco, California, USA; Johns Hopkins University, Maryland, USA; Gilead Sciences, Foster City, California, USA.

Disclaimer

The findings and conclusions in this report are those of the authors and not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jhep.2019.06.026>.

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#	Scientific articles and Presentations, 2019		
	Articles	Journal	Authors
1	Deriving the optimal limit of detection for an HCV point-of-care test for viraemic infection: Analysis of a global dataset	J Hepatol. 2019 Jul;71(1):62-70. doi: 10.1016/j.jhep.2019.02.011. Epub 2019 Feb 21.	Freiman JM, Wang J, Easterbrook PJ, Horsburgh CR, Marinucci F, White LF, Kamkamidze G, Krajden M, Loarec A, Njouom R, Nguyen KV, Shiha G, Soliman R, Solomon SS, Tsertsvadze T, Denkinger CM, Linas B
2	The global campaign to eliminate HBV and HCV infection: International Viral Hepatitis Elimination Meeting and core indicators for development towards the 2030 elimination goals	J Virus Erad. 2019 Jan 1;5(1):60-66.	Popping S, Bade D, Boucher C, van der Valk M, El-Sayed M, Sigurour O, Sypsa V, Morgan T, Gamkrelidze A, Mukabatsinda C, Deuffic-Burban S, Ninburg M, Feld J, Hellard M, Ward J
3	Innovative strategies for the elimination of viral hepatitis at a national level: A country case series.	Liver Int. 2019 Oct;39(10):1818-1836. doi: 10.1111/liv.14222. Epub 2019 Sep 4. PMID: 31433902; PMCID: PMC6790606.	Schröeder SE, Pedrana A, Scott N, Wilson D, Kuschel C, Aufegger L, Atun R, Baptista-Leite R, Butsashvili M, El-Sayed M, Getahun A, Hamid S, Hammad R, 't Hoen E, Hutchinson SJ, Lazarus JV, Lesi O, Li W, Binti Mohamed R, Olafsson S, Peck R, Sohn AH, Sonderup M, Spearman CW, Swan T, Thursz M, Walker T, Hellard M, Howell J
4	State of viral hepatitis care in 16 countries of Central and Eastern European Region	Cent Eur J Public Health. 2019 Sep;27(3):212-216. doi: 10.21101/cejph.a5486.	Chkhartishvili N, Holban T, Simonović Babić J, Alexiev I, Matičič M, Kowalska J, Horban A; ECEE Network Group
Oral and Poster Presentations at the International Scientific Conferences, 2019			
1	The road to elimination in Georgia, April 2015- August 2018. David Sergeenko. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
2	The critical role of partnerships in HCV elimination, Georgia, April 2015- August 2018. David Sergeenko. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
3	The HCV care cascade and treatment outcomes, April 2015- August 2018. Tengiz Tsertsvadze. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
4	HCV micro-elimination among people who inject drugs in pursuit of national elimination, April 2015- August 2018. Maia Butsashvili. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
5	Beyond treatment: HCV elimination provides collateral benefits to the health system. April 2015 - August 2018. Francisco Averhoff. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
6	Key role of partnerships in global HCV elimination, April 2015- August 2018. Muazzam Nasrullah. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
7	Key challenges and strategies to reach HCV elimination, April 2015- August 2018. Amiran Gamkrelidze. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
8	Piloting of integrated HCV, TB and HIV screening model at primary care level in Georgia. Irma Khonelidze et al. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
9	Progress towards achieving hepatitis C elimination in the country of Georgia, April 2015- August 2018. Tengiz Tsertsvadze et al. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
10	LDV/SOF/RBV is an effective first-line DAA regimen as well as re-treatment option for RF1_2k/1b patients within Georgian national hepatitis C elimination program. Marika Karchava et al. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		
11	Improvement in liver fibrosis among patients with hepatitis C who achieved sustained viral response after direct acting antivirals treatment, in country of Georgia. Maia Butsashvili et al. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria		

12	Hepatitis C screening among the population of Georgia within the national elimination program. Amiran Gamkrelidze et al. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria
13	HCV care cascade of PWIDs reached within the Global Fund needle and syringe program in Georgia. Ketevan Stvilia et al. The International Liver Congress™, Apr 10-14, 2019, Vienna, Austria
14	HIV, Hepatitis C and harm reduction in Georgia. Maka Gogia. International Forum on Infectious Diseases, Mar 21-24, 2019 Istanbul, Turkey
15	Scaling-up of an effective model of harm reduction-based and peer-supported hepatitis C treatment for PWID in Georgia. Giorgi Soselia. International Harm Reduction Conference 2019, Apr 28 - May 1, Porto, Portugal
16	Progress towards eliminating hepatitis C in Georgia: overcoming challenges through decentralization of services. George Kamkamidze. Translating science to end HIV in Eastern Europe and Central Asia, AIDS 2018 Post-Conference Symposium, Jun 20, 2019, Tbilisi, Georgia
17	Evaluation of hepatitis C treatment outcome among people who inject drugs in Georgia. Lasha Gulbiani et al. 8th International conference on Hepatitis care in substance users 2019, Sep 11 - 13, 2019, Montreal, Canada
18	Hepatitis C treatment integration with harm reduction services in Georgia: preliminary findings. Maia Butsashvili et al. 8th International conference on Hepatitis care in substance users 2019, Sep 11 - 13, 2019, Montreal, Canada
19	Barriers of linkage to hepatitis C care among people who inject drugs in Georgia. Maia Butsashvili et al. 8th International conference on Hepatitis care in substance users 2019, Sep 11 - 13, 2019, Montreal, Canada
20	Approaches to providing hep C viremia testing to PWIDs in Georgia. HEAD start project in Georgia. Maia Japaridze et al. 8th International conference on Hepatitis care in substance users 2019, Sep 11 - 13, 2019, Montreal, Canada
21	HBV/HCV co-infection among patients enrolled in HCV elimination program in Georgia. Maia Butsashvili. The 2nd Transcaucasus Symposium on HBV Infection, Sep 27 - 28, 2019, Tbilisi, Georgia
22	Georgian experience in HCV elimination – is that a way towards HBV elimination? Francisco Averhoff. The 2nd Transcaucasus Symposium on HBV Infection, Sep 27 - 28, 2019, Tbilisi, Georgia
23	Progress towards hepatitis C elimination in Georgia. Tengiz Tsertsvadze. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
24	Integrating HCV care in primary healthcare. Akaki Abutidze. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
25	Longer-term liver outcomes among HIV/HCV co-infected patients after curing hepatitis C. Natalia Bolokadze. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
26	HBV re-activation in HBV/HCV co-infected patients. Lali Sharvadze. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
27	Perspectives of HCV Micro-elimination in HIV/HCV Co-infection in Georgia. Nikoloz Chkhartishvili. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
28	HCV reinfection among HIV patients after DAA therapy in the country of Georgia. Pati Gabunia. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
29	Integrating HCV care in harm reduction services. Maia Butsashvili. International Meeting on HCV Micro-Elimination in HIV/HCV Co-Infection, Oct 14 - 15, 2019, Tbilisi, Georgia
30	Evaluation of the hepatitis C care cascade in the country of Georgia: monitoring 4 years of progress towards elimination. Tengiz Tsertsvadze et al. 17th European AIDS Conference, November 6 - 9, 2019, Basel, Switzerland.
31	Evaluation of the hepatitis C care cascade in the country of Georgia: monitoring 4 years of progress towards elimination, Tengiz Tsertsvadze et al. Nov 8-12, 2019, The Liver Meeting 2019, Boston, USA
32	Management of Hepatitis C in primary healthcare in the country of Georgia. Tengiz Tsertsvadze et al. Nov 8-12, 2019, The Liver Meeting 2019, Boston, USA
33	Factors associated with sustained viral response among patients treated with direct acting antivirals, Georgia elimination program. George Kamkamidze et al. Nov 8-12, 2019, The Liver Meeting 2019, Boston, USA



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