The birth of the HCV elimination in Georgia: the focus on strategic information

Amiran Gamkrelidze, MD, PhD, Professor
Director General
National Center for Disease Control and Public Health
HCV Burden in Georgia

- **Population – 3.7 million**
- **GDP per capita (USD) in 2016 - $3,853**

HCV Prevalence among different population groups:

- TB Patients: **21%** (Lomtadze et al, 2013)
- MSM: Tbilisi – **7.1%**, Batumi – **18.9%** (BSS, 2015)
- Blood donors: **7.3%** (Tbilisi blood donors 1998)
  - **7.8%** (Tbilisi, Batumi, Poti blood donors 1997-1999)
  - **2% overall** (“Safe Blood” Georgia State Program, 2012)
- STI patients: **11.3%** (Tsertsvadze, 2008)
- Healthcare workers: **5%** (Butsashvili M et al. 2012)

Old Estimate of prevalence among general population – **6.7%** *(population-based survey in the capital city Tbilisi, 2001-2002)*
Background

Rationale

• Existing HCV prevalence data in Georgia were:
  • 10+ years old
  • Geographically limited (Tbilisi only)
  • Focused on specific high-risk groups (PWID, prison inmates)

• HCV elimination plan required baseline national prevalence data to:
  • Plan prevention, care & treatment services
  • Measure progress over time toward elimination

Methods

Sample chosen using a stratified, multi-stage cluster design with systematic sampling

Sample: 7,000 adults, ≥18 years of age

Sample size calculated based on:
• Estimated HCV prevalence (6.7%, Tbilisi survey)
• Projected 70% response rate
• Desired precision of estimates (95% confidence interval ± 1%)
**Nationwide HCV prevalence**

- Total number of interviews – **6330** (90% response rate)
- Total number of blood samples – **6010** (86% response rate)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
<th>Estimated # nationwide ≥18 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HCV+</td>
<td>433</td>
<td>7.7%</td>
<td>215,000</td>
</tr>
<tr>
<td>HCV RNA+</td>
<td>311</td>
<td>5.4%</td>
<td>150,000</td>
</tr>
</tbody>
</table>

**HCV Genotype Distribution**

- HCV GT1a: 34.3%
- HCV GT1b: 39.5%
- HCV GT2: 24.5%
- HCV GT Indeterminate: 1.2%
- <1%
HCV Prevalence by Age and Gender

**Females**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Anti-HCV+</th>
<th>HCV RNA+</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29</td>
<td>1.1%</td>
<td>0.7%</td>
</tr>
<tr>
<td>30-39</td>
<td>2.5%</td>
<td>1.9%</td>
</tr>
<tr>
<td>40-49</td>
<td>3.7%</td>
<td>2.2%</td>
</tr>
<tr>
<td>50-59</td>
<td>4.4%</td>
<td>3.3%</td>
</tr>
<tr>
<td>60-69</td>
<td>5.1%</td>
<td>1.7%</td>
</tr>
<tr>
<td>≥70</td>
<td>5.6%</td>
<td>3.3%</td>
</tr>
</tbody>
</table>

(n=3,662)

**Males**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Anti-HCV+</th>
<th>HCV RNA+</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29</td>
<td>3.5%</td>
<td>1.9%</td>
</tr>
<tr>
<td>30-39</td>
<td>15.3%</td>
<td>11.9%</td>
</tr>
<tr>
<td>40-49</td>
<td>22.2%</td>
<td>18.6%</td>
</tr>
<tr>
<td>50-59</td>
<td>9.9%</td>
<td>7.9%</td>
</tr>
<tr>
<td>60-69</td>
<td>8.6%</td>
<td>5.1%</td>
</tr>
<tr>
<td>≥70</td>
<td>8.5%</td>
<td>3.9%</td>
</tr>
</tbody>
</table>

(n=2,334)
HCV prevalence by age
comparison of screening and survey results

National Center for Disease Control and Public Health
www.NCDC.ge
Characteristics associated with anti-HCV+ status

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Crude OR (95% CI)</th>
<th>AOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>3.5 (2.5, 4.8)</td>
<td></td>
</tr>
<tr>
<td>Urban residence</td>
<td>1.8 (1.4, 2.5)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>3.9 (2.2, 6.8)</td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>6.5 (3.9, 11.1)</td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>3.0 (1.61, 5.91)</td>
<td></td>
</tr>
<tr>
<td>60+</td>
<td>2.9 (1.6, 5.4)</td>
<td></td>
</tr>
<tr>
<td>History of incarceration</td>
<td>11.3 (7.5, 17.1)</td>
<td></td>
</tr>
<tr>
<td>History of injection drug use</td>
<td>37.6 (23.5, 60.0)</td>
<td>21.4 (12.3, 37.4)</td>
</tr>
<tr>
<td>History of blood transfusion</td>
<td>3.8 (2.6, 5.5)</td>
<td>4.5 (2.8, 7.2)</td>
</tr>
</tbody>
</table>
Anti-HCV prevalence in major cities and regions of Georgia
Prevalence and Estimated Number of HCV RNA+ Individuals by Regions and Cities

- Samegrelo-Zemo Svaneti: 7.27% (15,458)
- Tbilisi: 5.81% (49,278)
- Kvemo Kartli: 5.34% (16,641)
- Racha-Lechkumi and Kvemo Svaneti: 2.86% (776)
- Shida Kartli: 5.7% (11,663)
- Mtsheta-Mtianeti: 2.01% (1,516)
- Samachablo:
- Zugdidi: 9.88% (3,284)
- Guria: 5.53% (4,975)
- Imereti: 5.45% (2,3012)
- Adjarra: 6.81% (14,754)
- Samtskhe-Javakheti: 4.76% (5,798)
- Abkhazia:
- Batumi:
- Black Sea:
- Armenia:
- Turkey:
- Russia:
- Azerbaijan:
- Kakheti: 3.18% (6,883)
- Kakheti: 3.68% (6,981)

National Center for Disease Control and Public Health
www.NCDC.ge
Main Findings

- **215,000 anti-HCV positive persons**

- **IDU and Blood Transfusion – Most common risk factors**

- **Highest prevalence regions** – Samegrelo, Achara, Imereti, Tbilisi

- **Men between 30-50 years old – Highest prevalence**

- **Large proportion of individuals – unknown risk factors**

- **Only about 1/3 of anti-HCV positive persons knew their HCV status**
Road towards HCV Elimination

- Free of Charge Hep C treatment with peg/riba regimens for HIV/HCV co-infected patients
- Free of Charge Hep C treatment with peg/riba regimens for prisoners
- 60% Discount program for civilians
- Additional 10,000 treatments with peg/riba regimens with price reduction for civil population
- Negotiations with CDC, Gilead and other US partners
- HCV elimination perspectives - annual meeting at the EASL London
- National Committee

2011 - 2012
2013
2014
Road towards HCV Elimination (2)

- National program for short-term/urgent measures of HCV elimination action plan
- 1st Technical Advisory Group (TAG) meeting
- LDV/SOF based regimens introduced to the program
- 2nd National Workshop
- 3rd National Workshop
- 2nd TAG meeting
- 4th National Workshop
- Special session on EASL meeting
- Electronic Screening Module created
- Memorandum of Understanding between Georgian Government and Gilead
- World Hepatitis Summit
- Patient inclusion criteria removed
- Long-term Elimination Strategy approved 2016-2020
- Screening Protocol approved by the Ministry
- Special session dedicated to Georgia on EASL meeting in Amsterdam
- Long-term elimination plan 2016-2020
Why Georgia?

► Small size of the country (69,700 km²) with population of **3.7 million** people
► High prevalence of HCV infection in general population
► 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
► 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

National Center for Disease Control and Public Health
www.NCDC.ge
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

✓ 95% of those diagnosed are treated

✓ 95% of those treated are cured
Strategic plan for the elimination of HCV

**Recent progress**

<table>
<thead>
<tr>
<th>Objective</th>
<th>Strategies</th>
</tr>
</thead>
</table>
| Promote advocacy, awareness and education, and partnerships for HCV associated resource mobilization | • Massive awareness raising campaigns  
• Short text messages (SMS) regularly sent to the population to invite them to the HCV screening  
• HCV Hotline established at NCDC |
| Prevent HCV transmission | • Infection control and prevention monitoring and evaluation in medical and non-medical facilities have been strengthened significantly  
• Regular screening activities among PWID and their sexual partners |
| Identify Persons Infected with HCV | • Enhancement of screening through extending it to the more than 500 centers countrywide, including inpatient and outpatient settings, pharmacies and public places, such as public service halls  
• Development of unified electronic screening module that combines screening data from all sources |
| Improve HCV Laboratory Diagnostics | • Research activities for the simplification of HCV diagnostics, including studies on HCV cAg and various PCR approaches  
• Introduction of external quality assessment in NCDC referral laboratory (Lugar Center) |
| Provide HCV Care and Treatment | • More than 40,000 patients already completed treatment in 32 service providers countrywide  
• Overall SVR rate – 95%  
• SVR rate for Ledipasvir/Sofosbuvir regimens only – 98% |
| Improve HCV Surveillance | • Identification and Characterization of HCV-Attributable Hepatocellular Carcinoma – in collaboration with US CDC  
• HCV prevalence survey in IDPs in Georgia |
Since 2015, more than 1 million persons have been screened

Positivity rate ~ 6%

### Unified Electronic Screening Module

- Real time monitoring of screening progress and data linkage with treatment databases
- Simplified process of getting medical services
- Easy data exchange capabilities for validation of different results
- Data standardization for better analysis
- Proper and effective validation mechanisms to avoid mistakes in business rules and data entry
- Notification and reminder systems
- Robust reporting capabilities
- Comprehensive data for improved policy making process
44% HCV AB prevalence among PWID in 2016 and 35% in 2017 (January-November)

12% HCV AB prevalence among sexual partners of PWIDs in both, 2016 and 2017 (January-November)

- HCV screening (RDT) as a part of the Needle and Syringe Program (NSP) is available for PWID at 14 Stationary Harm Reduction centers countrywide
- Six mobile ambulatories support geographic coverage expansion (up to 66 cities) of the evidence-based prevention and screening programs
- Peer education and case management activities undertaken at 13 Stationary Harm Reduction centers
- Since 2016, HCV Screening is available for Sexual partners of PWID
- Patient Schools and expansion of case management intervention to be introduced in 2018
- Upcoming pilot project supported by FIND will allow decentralization of HCV confirmation (VL) testing and improve linkage to care at 4 HR centers
- HCV integrated treatment site was opened at OST Center in Tbilisi, operational from 2017
Enrollment in the HCV treatment program

Since April 2015, more than 40,000 patients enrolled in the program.
**People-centred care is focused on and organized around the health needs and expectations of people and communities rather than on patients or diseases.**

**Strategic Framework**

- To raise awareness among all stakeholders including general public on all three diseases in the region;
- To develop the sustainable local public-private partnership for effective integration of TB/HIC/HCV screening and early disease detection;
- To strengthen PHC through development of integrated TB/HIC/HCV screening model with detailed protocol;
- To map the service providers at the regional level and establish effective referral systems to specialized clinics;
- To build the providers’ capacity and increase the stakeholders’ engagement in service quality monitoring;
- To generate the evidence-based recommendations for program expansion to promote service integration nationwide.

**Pilot project in Samegrelo-Zemo Svaneti Region was launched in September, 2017**

**Integration of HCV, TB and HIV Detection at PHC level**
HCV Elimination Program Management
Ministry of Labour, Health and Social Affairs of Georgia

State Committee
Clinical Committee
Scientific Committee

National Center for Disease Control and Public Health
Screening providers - 570
Healthcare providers - 32

Social Service Agency
Hepatitis Management Center
- Tbilisi
Hepatitis Management Center - Zugdidi

www.NCDC.ge
Georgia HCV Elimination Scientific Committee

- Established in August, 2016
- Membership
  - Ministry of Labour, Health and Social Affairs
  - NCDC,
  - Infectious Diseases, AIDS and Clinical Immunology Research Center,
  - Clinic “Hepa”,
  - Clinic “Neolab”,
  - Clinic “Mrcheveli”
  - US CDC
- Open to non-members (e.g.: NGOs, Universities, other)
  - Requires member sponsorship
  - Bristol U, FIND, Boston U
- Received 33 proposals Aug 2016 - Jul 2017
  - 33 reviewed, 25 approved
Project ECHO to Regional Facilities

(About 20 TeleECHO clinic sessions conducted through 4 hubs, June 2016 – June 30, 2017)

TBILISI

**ECHO Hubs**

Infectious Diseases and AIDS Center; Clinic HEPA; Clinic NeoLab; Clinic Mrcheveli

- **Tbilisi**
  - 3 sites
- **Batumi**
  - 1 site
- **Kutaisi**
  - 3 sites
- **Zugdidi**
  - 1 site
- **Rustavi**
  - 1 site
- **Gori**
  - 1 site

**Expert Panel:**

Tengiz Tsertsvadze (Head of Clinical Group)
Vakhtang Kerashvili (ID Center), Elza Vashakidze (Tbilisi State Medical University),
Lali Sharvadze (Hepa), Maia Butsashvili (NeoLab), George Kamkamidze (NeoLab),
David Metreveli (Mrcheveli), Maia Zhamutashvili (Mrcheveli), Jaba Zarkua (Mrcheveli), Mamuka Zakalashvili (Mrcheveli)

National Center for Disease Control and Public Health

www.NCDC.ge
Important events

• National Hepatitis C Elimination Workshops - 2014, 2015, 2016, 2017
• Technical Advisory Group meetings –2015, 2016, 2017 (Nov 30- Dec 1)

• EASL side meetings dedicated to Georgian HCV Elimination Program
  2014 – London
  2015 – Vienna
  2016 – Barcelona
  2017 – Amsterdam, 8 abstracts from Georgia approved by EASL committee
Acknowledgements

Ministry of Labour, Health and Social Affairs

US Centers for Disease Control and Prevention (CDC)

Gilead Sciences, Inc.

WHO, WHO Euro

TAG Members

LIFER

ECHO

National Center for Disease Control and Public Health
Thank you!