

# Hepatitis C Elimination Program

## Georgia

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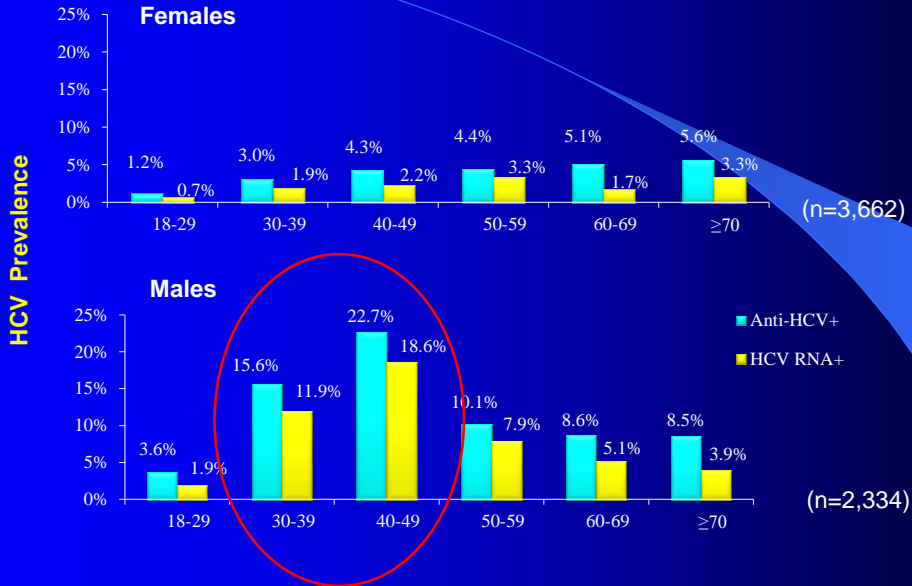
Health Research Union (HRU)/Clinic NEOLAB  
National HCV Committee, MOH



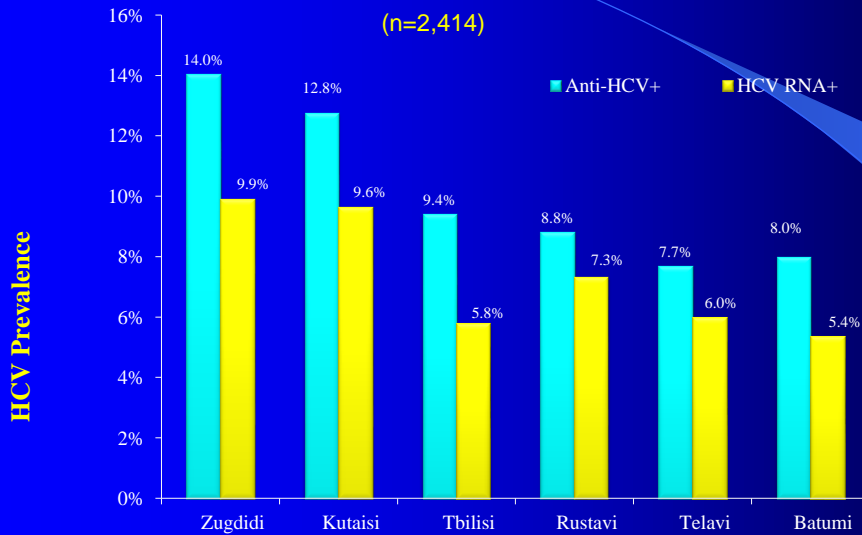
## High prevalence of HCV in Georgia

- **Georgia is a lower-middle income country located in Eastern Europe, with a population of 3.7 million**
- **Recent national serosurvey in 2015 (with US CDC support) estimated 7.7% anti-HCV prevalence**
- **Chronic HCV infection (RNA positive) - among 5.4% (estimated 150,000 adults aged  $\geq 18$  years living with HCV)**
- **57–92% seroprevalence - people who inject drugs (PWID)**
- **17% among MSM**
- **4–12% - health care workers**

# HCV Prevalence by Age and Gender

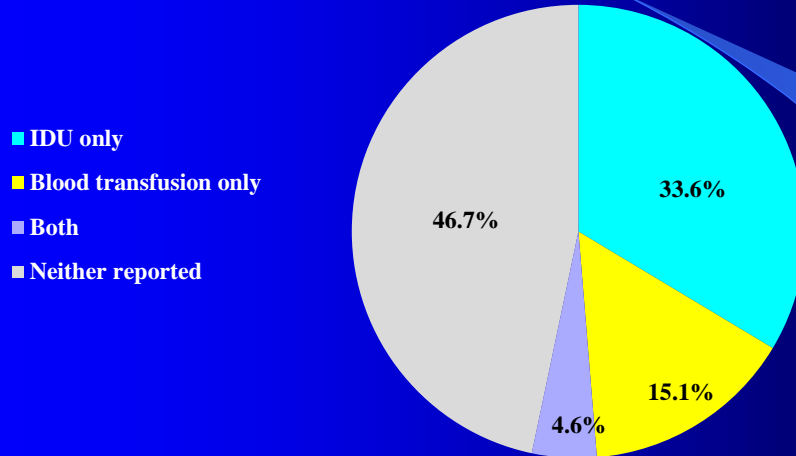


# HCV Prevalence by City



## Anti-HCV risk factors

All Anti-HCV+ Participants



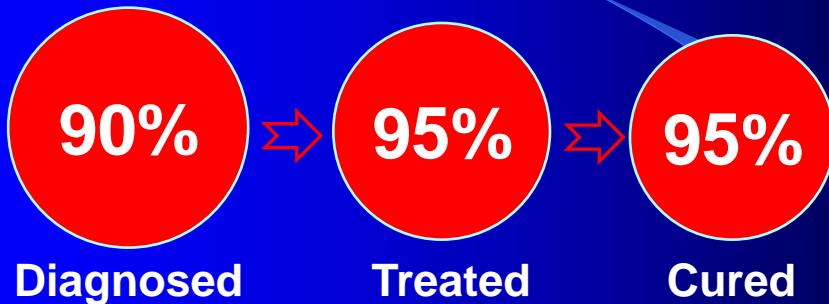
## Georgia - pilot country for HCV elimination

- Small country, optimal site for piloting
- High burden of HCV infection, relatively small numbers of patients and thus total cost of treatment programs is relatively low
- Strong Government commitment to address the problem
- Human resource capacity, and developed service delivery networks
- Strong civil society organizations
- Established harm reduction and preventive interventions for high risk groups and key affected populations
- Partnership with and technical assistance from the Centers for Disease Control and Prevention (CDC)
- Commitment of Gilead Sciences to donate DAAs in support of the program

## Assessment of clinical and laboratory capacities HCV Elimination Program

- US CDC team with Georgian experts assessed several clinical sites with experience providing interferon-based treatment and scored them based on six domains:
  - Leadership and governance,
  - Quality of clinical care services,
  - Health information systems/management,
  - Human resource capacity,
  - Access to necessary laboratory tests,
  - Drug-procurement procedures.
- Standard WHO tool (adapted) was used to assess capacity of clinical laboratories

## Targets: 90-95-95



## HCV Elimination Strategic Plan

### Strategies proposed to achieve elimination include:

- Assessing the burden of disease and risk factors for transmission in the country
- Ensuring prevention of transmission in healthcare and non-healthcare settings
- Identification of all persons living with HCV infection
- Access to high quality diagnostics and treatment services for HCV infected individuals

## HCV Elimination program steps

- Technical Advisory Group (TAG) of international experts was formed and met to provide guidance, and monitor progress of HCV elimination program
- The treatment program was initiated in 4 sites in Tbilisi, the capital, in May 2015
- Currently 28 HCV treatment centers operating including 139 physicians authorized to provide HCV treatment services throughout the country
- All treatment centers have the capacity of providing point-of-care and laboratory based anti-HCV testing, viral load determination, and genotyping.

## International Collaboration

- **Project ECHO (Extension for Community Healthcare Outcomes) at the University of New Mexico and the Liver Institute for Education and Research (L.I.F.E.R.), Boston MA., - training and clinical case management support for HCV providers in Georgia**
- **Physicians from 4 major HCV treatment centers in Tbilisi participated in interactive Tele-ECHO clinics, presented complex cases and were provided guidance for HCV patient management**
- **Standardized HCV treatment guidelines for Georgia were developed in collaboration with national HCV treatment experts and experts from Project ECHO/L.I.F.E.R.**



## Patient Pathway

1. Screening positive → diagnostic standard
2. Documents submitted to MoLHSA HCV Committee
3. If the Committee approves the treatment, drugs are delivered to the clinic
4. Medical centers are equipped with a room with camera and safe box and patient is conveyed to that room once every two weeks for pill count and refill

## Testing Algorithm

### Step 1

- HCV seropositive patients tested by HCV RNA Real-time PCR assay (Quantitative)

### Step 2

- CBC, ALT AST
- FIB4 - patient's age, ALT, AST, & platelet count
- Liver Elastography – if FIB4 = 1.45 – 3.25
- Genotype, HBsAg, antiHBc, creatinine, albumin, ALP, GGT, INR, ultrasound

Treatment monitoring tests (including HCV RNA) depending on treatment regimen and duration

## Data management system to monitor and evaluate HCV continuum of care

- All test results of patients included in treatment program entered from screening to SVR
- Tracking of patients by unique National ID number
- Monitoring of medication release

# Treatment regimens

## Phase 1 of elimination program

Sofosbuvir/PEG IFN/Ribavirin – 12 weeks

Sofosbuvir/Ribavirin – 12-24 weeks (by genotype)

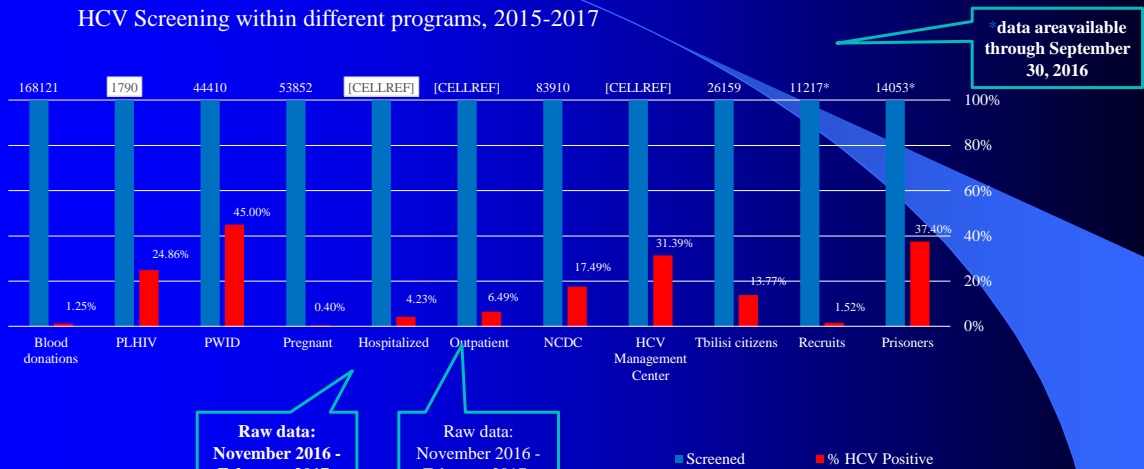
## Phase 2 of elimination program

Sofosbuvir/Ledipasvir w/o Ribavirin – 12-24 weeks (*Gen 1,2,3*)

Sofosbuvir/PEG IFN/Ribavirin – 12 weeks (*Gen 3 cirrhosis*)

# HCV Screening – Current Status

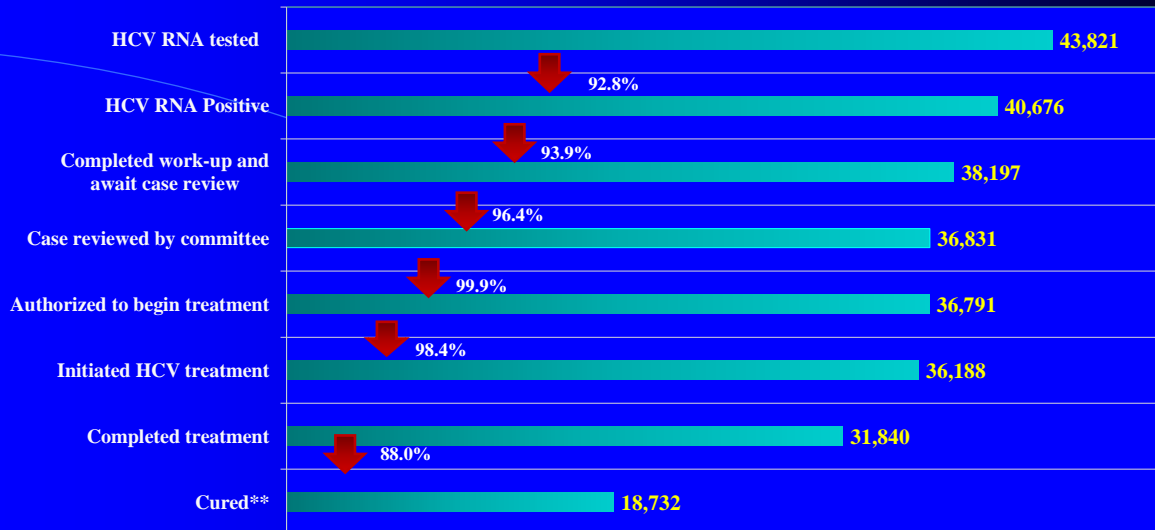
HCV Screening within different programs, 2015-2017



Since May, 2015, more than **550,000** tests were performed with **10%** positivity rate



## Georgia Hepatitis C Elimination Program Care Cascade April 28, 2015 – June 30, 2017



\*\* of 27,864 (87.5%) patients eligible for SVR assessment, 19,800—were tested, 18,732 (94.6%) achieved SVR, 8,064 (25.3%) missing data

## Treatment Outcomes in Patients with Complete SVR Data Receiving Sofosbuvir-Based Regimens Apr 28, 2015 – Dec 31, 2016 (n=4774)

	SVR Rate				
	G1	G2	G3	G4	TOTAL
<b>12 weeks IFN/SOF/RBV</b>	<b>80.3%</b> (724/902)	<b>95.4%</b> (230/241)	<b>96.2%</b> (1099/1143)	<b>66.7%</b> (2/3)	<b>89.8%</b> (2055/2289)
<b>12 weeks SOF/RBV</b>	<b>27.3%</b> (3/11)	<b>77.3%</b> (273/353)	<b>0%</b> (0/1)	—	<b>75.6%</b> (276/365)
<b>20 weeks SOF/RBV</b>	<b>33.3%</b> (1/3)	<b>75.7%</b> (296/391)	<b>0%</b> (0/2)	—	<b>75%</b> (297/396)
<b>24 weeks SOF/RBV</b>	<b>53.9%</b> (382/709)	<b>36.4%</b> (4/11)	<b>81.6%</b> (579/710)	<b>50%</b> (2/4)	<b>67.4%</b> (967/1434)
<b>48 weeks SOF/RBV</b>	<b>61.2%</b> (85/139)	<b>77.2%</b> (44/57)	<b>73.4%</b> (69/94)	—	<b>68.3%</b> (198/290)
<b>TOTAL</b>	<b>67.8%</b> (1195/1764)	<b>80.4%</b> (847/1053)	<b>89.6%</b> (1747/1950)	<b>57.1%</b> (4/7)	<b>79.5%</b> (3793/4774)

Source: Georgia's HCV Elimination Program Treatment Database

## Treatment Outcomes in Patients with Complete SVR Data Receiving Sofosbuvir/Ledipasvir Based Regimens March, 2016 – December 31, 2016 (n=1592)

	SVR Rate				
	G1	G2	G3	G4	TOTAL
12 weeks SOF/LDV	<b>98.5%</b> (824/837)	<b>100%</b> (8/8)	<b>100%</b> (1/1)	–	<b>98.5%</b> (833/846)
24 weeks SOF/LDV	<b>98.9%</b> (88/89)	–	–	–	<b>98.9%</b> (88/89)
12 weeks SOF/LDV/RBV	<b>95.3%</b> (143/150)	<b>99.2%</b> (248/250)	<b>97.5%</b> (232/238)	<b>100%</b> (4/4)	<b>97.7%</b> (627/642)
24 weeks SOF/LDV/RBV	<b>100%</b> (4/4)	–	<b>100%</b> (11/11)	–	<b>100%</b> (15/15)
<b>TOTAL</b>	<b>98.1%</b> (1059/1080)	<b>99.2%</b> (256/258)	<b>97.6%</b> (244/250)	<b>100%</b> (4/4)	<b>98.2%</b> (1563/1592)

*Source: Georgia's HCV Elimination Program Treatment Database*

## Barriers and Challenges

## Barriers to HCV Care and Treatment among PWID, Georgia

### Hepatitis C among PWID in Georgia

- Estimated 40,000 active PWID (1.5% of the population aged 15-64)
  - HCV antibody prevalence 66.2% - 92% and 89% of them chronically infected
  - PWID bear a significant burden of HCV in country (25%)
  - Male prisoner study showed that 70% of respondents reported ever using drugs; of these, 41% reported drug use while in prison
- Incidence of HCV in PWID at least 3 times higher than in the general population
- During 2015-2016, 13,400 former or current IDUs screened, of which 6795 (50.5%) tested positive for HCV infection

**Strategy 2 – Prevent HCV Transmission**  
**Objective 2.1. Decrease HCV incidence among PWID by promoting harm reduction\***

- Intensify HCV detection efforts among PWID
- Intensify HCV prevention efforts among PWID
- Improve care and treatment for PWID living with HCV

\* Strategic Plan for the Elimination of Hepatitis C Virus in Georgia, 20

**Peer support intervention for PWIDs on treatment for HCV**  
*(MDM project)*

- **Objectives:**
  - Facilitating PWIDs access and retention in the national programme
  - Overcoming providers and PWIDs concerns about HCV treatment (enhance uptake, adherence, prevent reinfections)
  - Being affordable and easy to scale-up
- **Descriptive operational research to assess the effectiveness of the intervention**
  - Primary outcome: SVR12 rate
  - Secondary outcomes:
    - Adherence and tolerance
    - Behaviors at risk of reinfection
    - Satisfaction

### Results of people having completed the treatment (n=230)

Never missed a dose of any treatment	187	81.30%
Never delayed a medical appointment	207	90.40%
Patient put under DOT	1	0.40%
Attended at least 1 support group session	76	33.00%
Treatment outcome (SVR12)	165/187	88.20%

### PWID vs non-PWID

	PWID	Non - PWID	P	aOR (95% CI)
Age	46.2	50.9	<0.001	
Female gender	0.9	12.9	<0.001	
Cirrhosis	75	55	<0.001	
<b>SVR</b>	<b>88.5</b>	<b>83.2</b>		<b>1.10 (0.59 – 2.09)</b>

## **Integrating HCV care with Harm Reduction (HR) services for PWID**

- Hepatitis C treatment effectiveness for PWID can be improved if delivered in an integrated and multidisciplinary approach
- Integrated services in HR can mitigate stigma and improve HCV treatment outcomes
- In 2017 Ministry of Health started piloting integration process in HR;
  - One HR center in Tbilisi providing HCV treatment, 2<sup>nd</sup> will be approved soon

## **Evaluation of integrated HCV treatment program in harm reduction centers of Georgia**

*Supported by CDC*

### *Objectives of the project are to evaluate:*

- The effectiveness of integration of HCV treatment into HR centers
- Treatment outcome, compliance and side effects among patients treated at harm reduction centers
- Patient satisfaction
- Referral from OST and NSP sites to other service centers

## Challenge related to treatment of patients with Gen 2

- High prevalence of recombinant strain 2k/1b
- Conventional genotyping assays documenting as genotype 2 or mix 1&2
- If treated as genotype 2, low SVR

*Treatment of gen2 patients with SOF/LED/RBV regimen*

## Barrier related to co-payment for diagnostic tests

### Activities

- Decreasing number of tests for inclusion in the program and for treatment monitoring
- Trying to replace PCR by HCV core Ag testing

## Challenges related to detection of new cases

### Activities

- Unified electronic screening module – screening data from different programs will be accumulated in one registry
- Scale up screening in outpatient settings – incentivizing primary health care personnel
- Large-scale information campaign about HCV screening targeted at general population
- SMS notifications targeted to males above 30 years old
- Piloting integrated HCV-HIV-TB Screening, diagnosis and treatment approach in Samegrelo-Zemo Svaneti region

Thank you