Hepatitis C Elimination Program
Georgia

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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 ≥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

**Females**

- 18-29: 0.7%
- 30-39: 1.9%
- 40-49: 4.3%
- 50-59: 4.4%
- 60-69: 3.3%
- ≥70: 1.7%

**Males**

- 18-29: 1.9%
- 30-39: 11.9%
- 40-49: 22.7%
- 50-59: 18.6%
- 60-69: 10.1%
- ≥70: 7.9%

HCV Prevalence by City

- Zugdidi: 14.0%
- Kutaisi: 12.8%
- Tbilisi: 9.6%
- Rustavi: 9.4%
- Telavi: 8.8%
- Batumi: 8.0%

(n=2,414)
Anti-HCV risk factors

All Anti-HCV+ Participants

- IDU only: 46.7%
- Blood transfusion only: 33.6%
- Both: 15.1%
- Neither reported: 4.6%

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

- Diagnosed: 90%
- Treated: 95%
- Cured: 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 convayed 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

Total Number of Eligible Patients

<table>
<thead>
<tr>
<th>Stage</th>
<th>Percent</th>
<th>Total Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV RNA tested</td>
<td>92.8%</td>
<td>43,821</td>
</tr>
<tr>
<td>HCV RNA Positive</td>
<td>93.9%</td>
<td>40,676</td>
</tr>
<tr>
<td>Completed work-up and await case review</td>
<td>96.4%</td>
<td>38,197</td>
</tr>
<tr>
<td>Case reviewed by committee</td>
<td>99.9%</td>
<td>36,831</td>
</tr>
<tr>
<td>Authorized to begin treatment</td>
<td>98.4%</td>
<td>36,188</td>
</tr>
<tr>
<td>Completed treatment</td>
<td>88.0%</td>
<td>31,840</td>
</tr>
<tr>
<td>Cured**</td>
<td></td>
<td>18,732</td>
</tr>
</tbody>
</table>

** 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

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**Treatment Outcomes in Patients with Complete SVR Data Receiving Sofosbuvir-Based Regimens**

Apr 28, 2015 – Dec 31, 2016 (n=4774)

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

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)**

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

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

### Barriers and Challenges
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

Barriers to HCV Care and Treatment among PWID, Georgia
**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, 2016–2020

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**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)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never missed a dose of any treatment</td>
<td>187</td>
<td>81.30%</td>
</tr>
<tr>
<td>Never delayed a medical appointment</td>
<td>207</td>
<td>90.40%</td>
</tr>
<tr>
<td>Patient put under DOT</td>
<td>1</td>
<td>0.40%</td>
</tr>
<tr>
<td>Attended at least 1 support group session</td>
<td>76</td>
<td>33.00%</td>
</tr>
<tr>
<td>Treatment outcome (SVR12)</td>
<td>165/187</td>
<td>88.20%</td>
</tr>
</tbody>
</table>

PWID vs non-PWID

<table>
<thead>
<tr>
<th></th>
<th>PWID</th>
<th>Non - PWID</th>
<th>P</th>
<th>aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>46.2</td>
<td>50.9</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>0.9</td>
<td>12.9</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>75</td>
<td>55</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>SVR</td>
<td>88.5</td>
<td>83.2</td>
<td></td>
<td>1.10 (0.59 – 2.09)</td>
</tr>
</tbody>
</table>
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, 2nd 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