Hepatitis C Elimination Program

Georgia

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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 men who have sex with men**
- **4–12% among health care workers**

Georgia - pilot country for HCV elimination

- **Small country, optimal site for piloting**
- **High burden of HCV infection**
- **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

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

Strategy 2 – Prevent HCV Transmission

Objective 2.1. Decrease HCV incidence among PWID by promoting harm reduction

Intensify HCV detection efforts among PWID

- Introduce guidance for HCV testing and confirmatory testing with RNA (or HCV core antigen) for those entering NSP/OST -

  Begin with a pilot program to assess feasibility and effectiveness
- Provide VCT at NSP/OST service points through community-based outreach testing and mobile ambulances
- Provide antibody and RNA testing results to those PWID who test positive
- Establish effective referral mechanisms to full laboratory diagnostic services and linkage to care through case management and social services.

Intensify HCV prevention efforts among PWID

- Scale up comprehensive NSP services at the drop-in center and mobile ambulances and through involvement of peers
- Scale up OST services (e.g., increased coverage, financial and geographic access, take home doses, psycho-social support, and maintenance OST in prisons)
- Conduct education activities for preventing infection/re-infection among PWID

Improve care and treatment for PWID living with HCV

- Provide treatment of PWID at demonstration NSP and OST service points
- Support treatment through peer support and through individual and group counseling (patient schools).
- Link PWID released from prison to community harm reduction services

HCV Elimination program steps

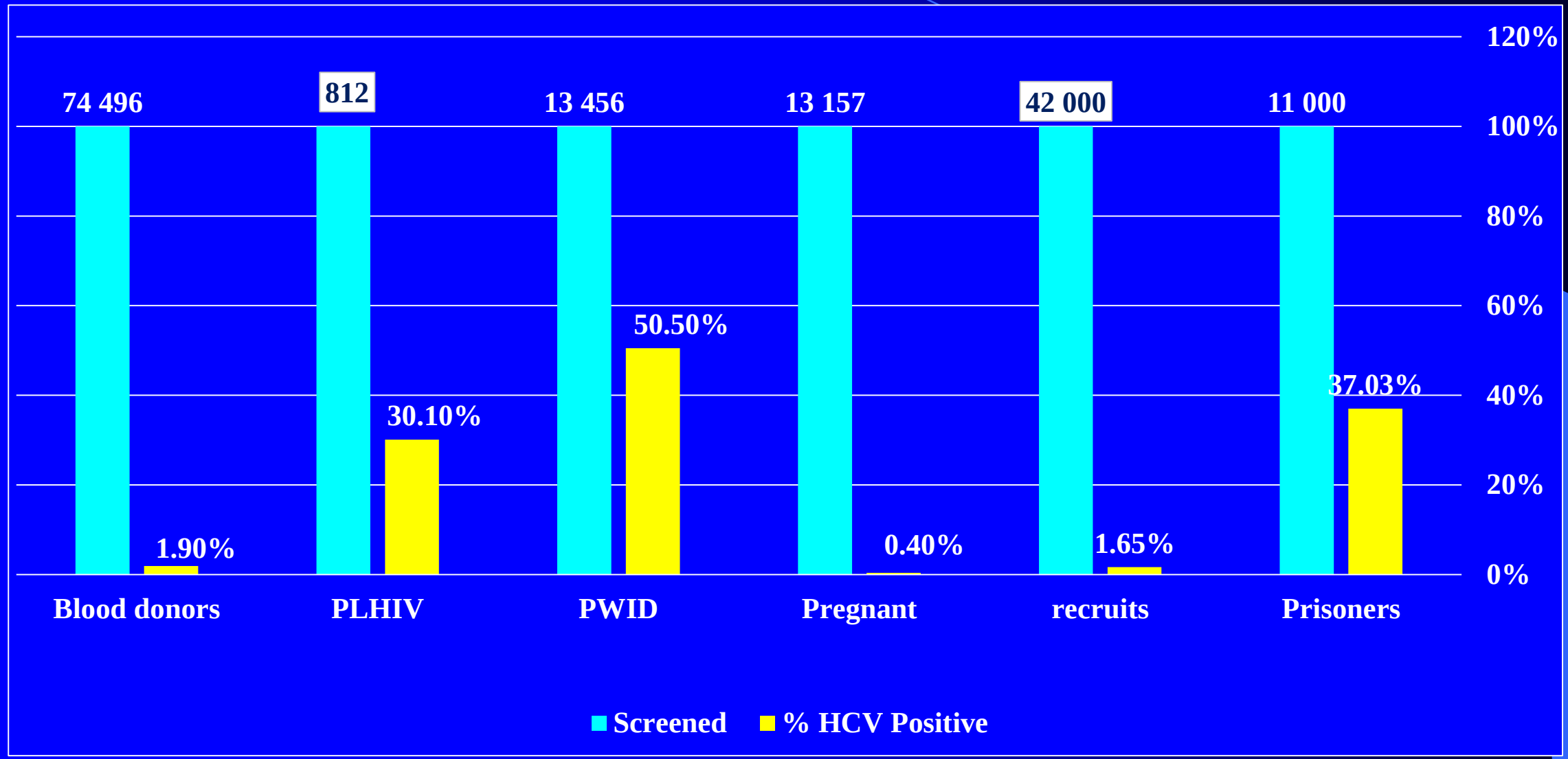
- **Technical Advisory Group (TAG) of international experts was formed and met to provide guidance, and monitor progress of HCV elimination program**
- **The treatment program was initiated in 4 sites in Tbilisi, the capital, in May 2015**
- **Currently 17 HCV treatment centers operating including 95 specialized physicians authorized to provide HCV treatment services throughout the country**
- **All HCV treatment centers have the capacity of providing point-of-care and laboratory based anti-HCV testing, viral load determination, and genotyping.**

HCV Elimination program steps

- **Stage 1 – during first year patients with advanced fibrosis (FIB 4 > 3.25 or F3 – F4 by liver elastography)**

  SVR 84%
- **Stage 2 – all RNA positive patients are included in treatment program**
- **Up to September 1, 2016, 17700 patients started HCV treatment**

Diagnostic yield within HCV screening program among different target groups, Georgia, 2015-2016 N=175,000



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., provide training and clinical case management support for HCV providers in Georgia
- From February 2016 physicians from the four major HCV care and 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 convoyed to that room once every two weeks for pill count and refill

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)*

Sofosbuvir/Ledipasvir/PEG IFN/Ribavirin – 12 weeks

(Gen 2 SOF treatment experienced)

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

MDM PROGRAM IN GEORGIA

RDS Survey to assess HCV epidemic among PWID in Tbilisi

2012

- **92.1% - HCV antibody positive**
- **83.35 – HCV RNA positive**
- **22.2% - severe liver fibrosis**

Medecins du Monde

New Vector

Clinic Neolab

Since May 2015: Peer support intervention for PWIDs on treatment for HCV

- **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

Model Framework

Step 1
- **Targeted Communication**

Step 2
- **Non-Invasive screening within HR organization**
- (Rapid test, liver Elastometry)

Step 3
- **Medical Assessment**
- **Inclusion in National Treatment Program**

Step 4
- **HCV Treatment**

Step 5
- **Post-Treatment Follow up**

Peer Support

Costs not included in the national treatment program (diagnostics+side effect management) is covered by MDM

Socio-demographics (N=245)

Age	N	%
<40	44	17.96%
40 to 50	115	46.94%
50+	86	35.1 %
Sex		
Female	2	0.80%
Male	243	99.20%
Education		
Secondary	62	25.3%
Higher	183	74.7%
Occupation		
Employed	85	34.70%
Unemployed	160	65.30%
Incomes		
<700 GEL	194	79.20%
700+ GEL	51	20.82%

Drug use		
Age first injection	(Mean) 18.5	(SD) 3.02
OST	59	24.10%
Has injected the last month	122	49.80%
Drugs injected last month		
Subutex	76	62.30%
Vint	53	43.40%
Heroin	32	26.20%
Methadon	10	8.20%
Krokodil	7	5.70%
Morphine	4	3.30%
Opium/poppy	2	1.60%
Tropicamid	1	0.80%
Frequency of injection last month		
Every day	10	8.20%
Every week	56	45.90%
Not Every week	56	45.90%

Liver disease		
Level of fibrosis	n	%
F2-F3	2	0.80%
F3	91	37.10%
F3-F4	18	7.40%
F4	120	49.00%
F3+ at fib4 (Fibroscan failures)	14	5.70%
Genotype		
1	45	18.50%
2	63	25.90%
3	126	51.90%
Mixed	9	3.70%
Associated factor of fibrosis		
Heavy alcohol consumption	60	26.00%
Cannabis	114	46.50%
HBV	11	4.50%
Past HCV treatment	10	4.20%

Outcome among 230 people having completed the treatment		
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%

Reinfection project

Hypothesis

The peer-support intervention delivered to PWIDs during the treatment project decrease the risk of reinfection after treatment through a sustained improvement of at risk behaviors

Objectives

- To assess the effectiveness of the intervention to improve the behaviors at risk of reinfection
- To assess the incidence of HCV reinfection after treatment in PWIDs (and associated factors)
- To study the liver disease evolution after treatment

  (and associated factors)