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

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HCV Burden in Georgia

Population – 3.7 million

GDP per capita (USD) in 2016 - \$3,853

HCV Prevalence among different population groups:

- ✓ PWID: 66.2% (Bio-Behavioral Surveillance Survey, 2015)
- ✓ TB Patients: 21% (Lomtadze et al, 2013)
- \checkmark 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)



National HCV Seroprevalence Survey 2015

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%)

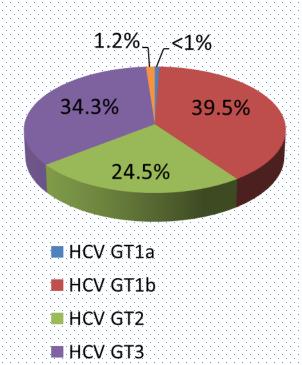


Nationwide HCV prevalence

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

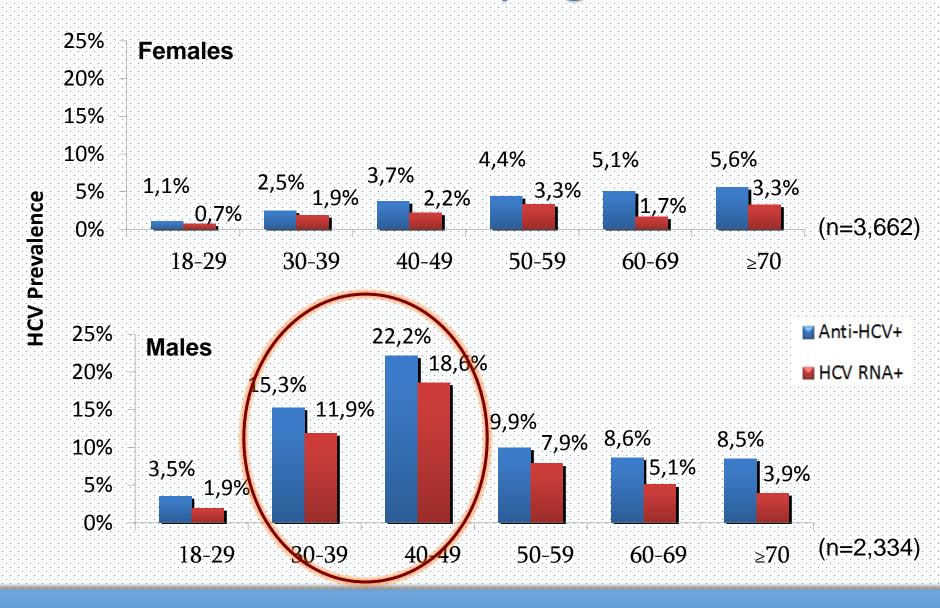
Characteristic	n	%	Estimated # nationwide ≥18 years
Anti-HCV+	433	7.7%	215,000
HCV RNA+	311	5.4%	150,000

HCV Genotype Distribution



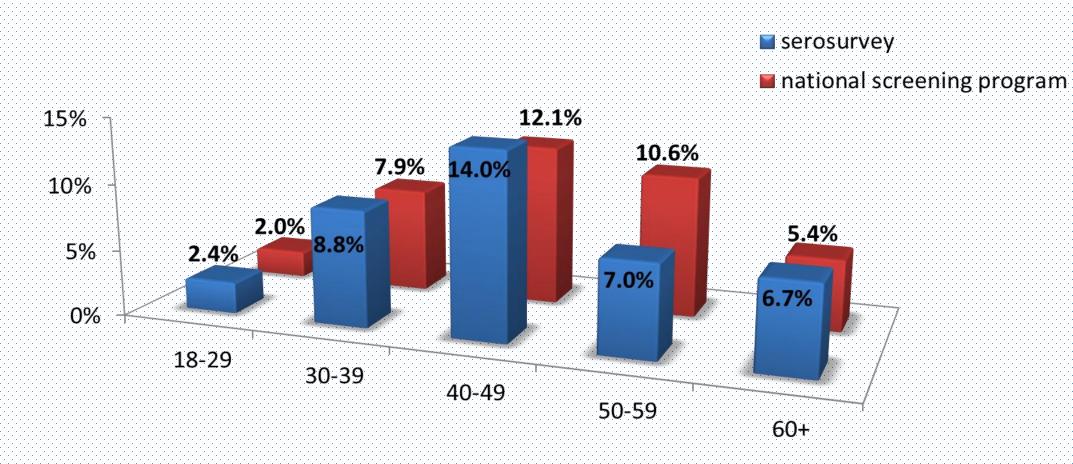
HCV GT Indeterminate

HCV Prevalence by Age and Gender





HCV prevalence by age comparison of screening and survey results



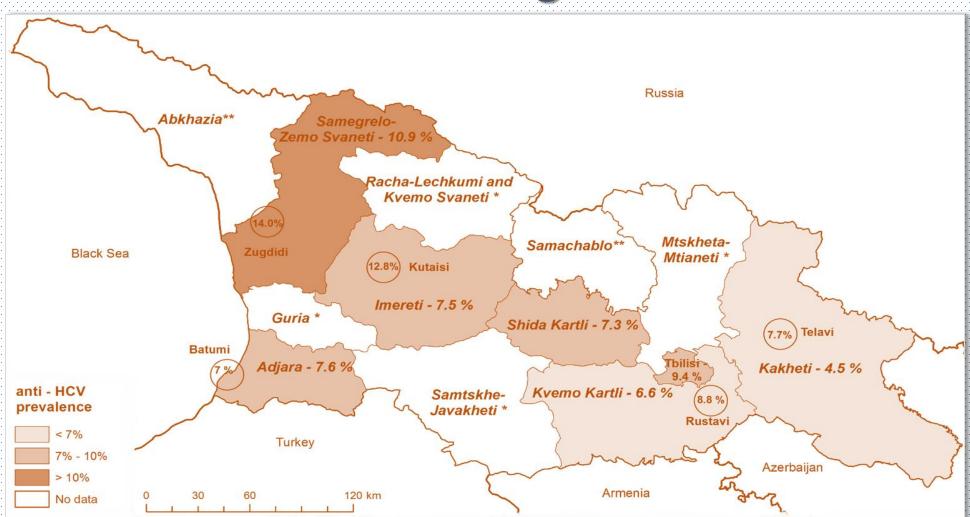


Characteristics associated with anti-HCV+ status

Characteristic	Crude OR (95% CI)	AOR (95% CI)	
Male gender	3.5 (2.5, 4.8)		
Urban residence	1.8 (1.4, 2.5)		
Age			
18-29	1		
30-39	3.9 (2.2, 6.8)		
40-49	6.5 (3.9, 11.1)		
50-59	3.0 (1.61, 5.91)		
60+	2.9 (1.6, 5.4)		
History of incarceration	11.3 (7.5, 17.1)		
History of injection drug use	37.6 (23.5, 60.0)	21.4 (12.3, 37.4)	
History of blood transfusion	3.8 (2.6, 5.5)	4.5 (2.8, 7.2)	

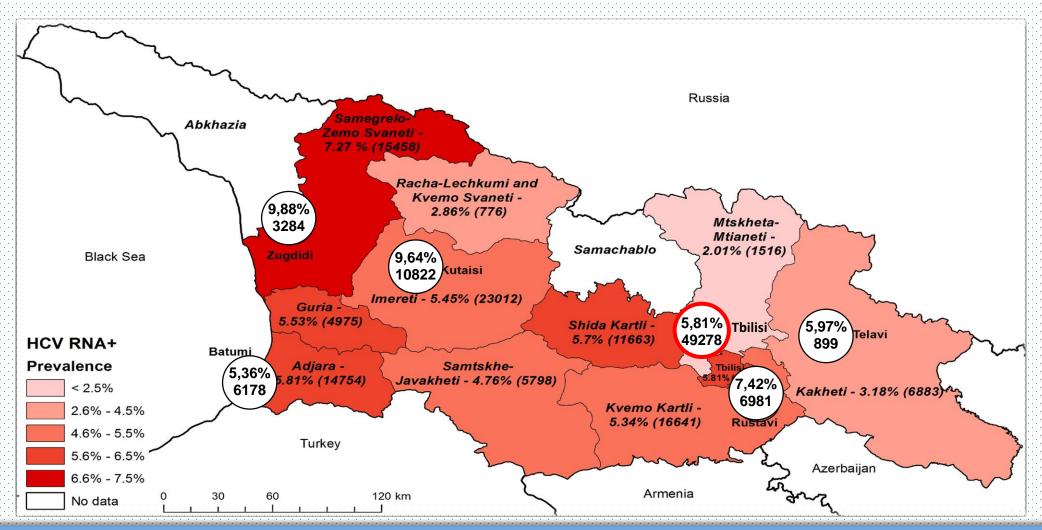


Anti-HCV prevalence in major cities and regions of Georgia





Prevalence and Estimated Number of HCV RNA+ Individuals by Regions and Cities





Main Findings

IDU and Blood Transfusion – Most common risk factors

Highest prevalence regions – Samegrelo, Achara, Imereti, Tbilisi

215,000 anti-HCV positive persons

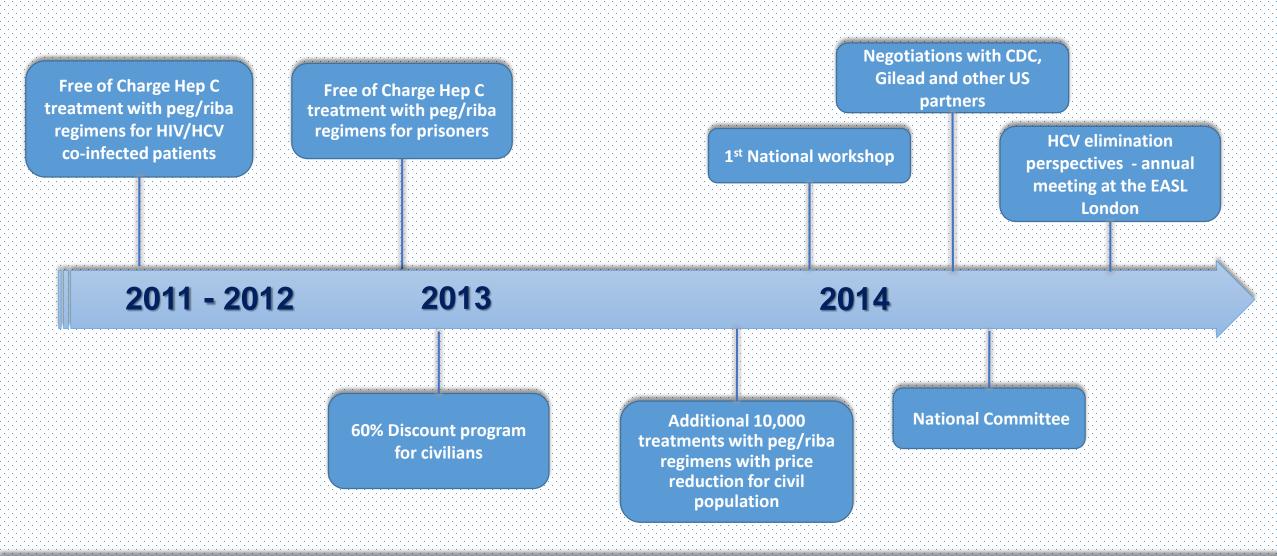
Men between 30-50 years old – Highest prevalence

Large proportion of individuals – unknown risk factors

Only about 1/3 of anti-HCV positive persons knew their HCV status

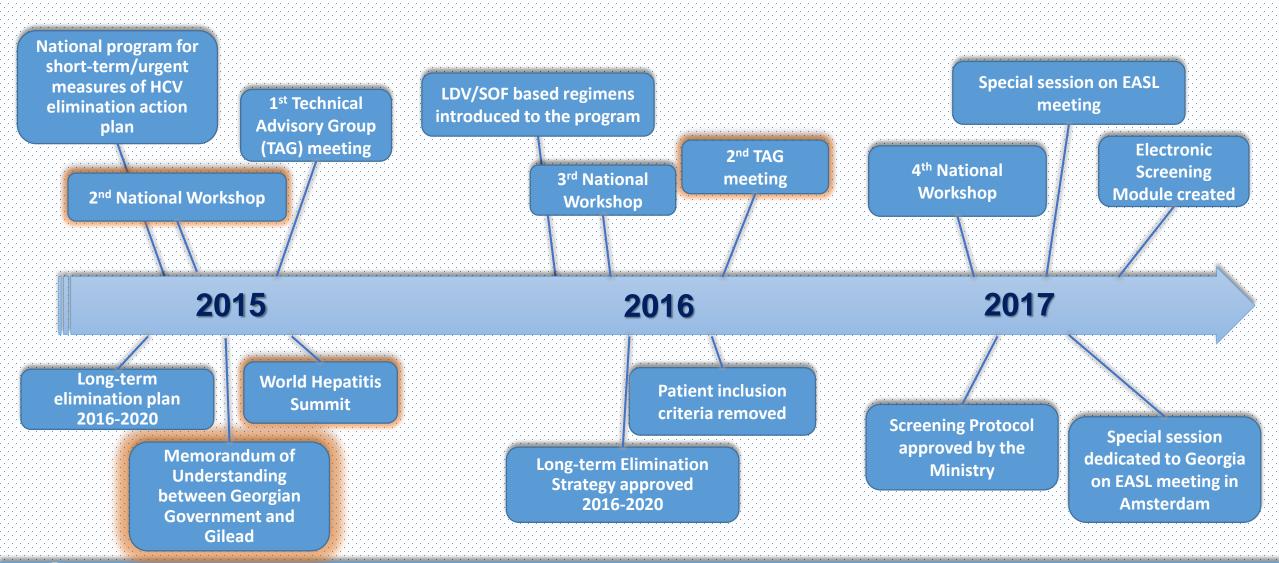


Road towards HCV Elimination





Road towards HCV Elimination (2)





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



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

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

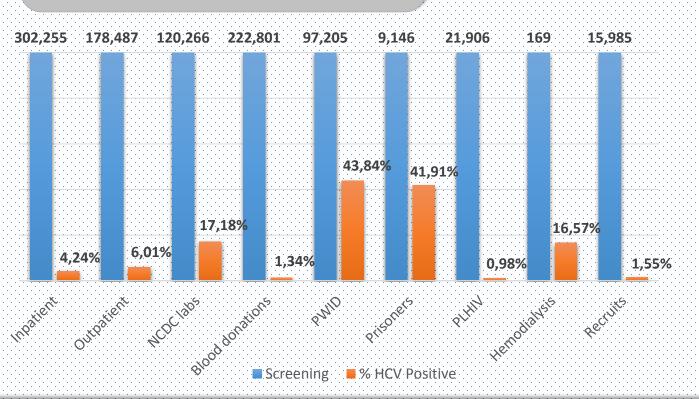
- •Identification and Characterization of HCV-Attributable Hepatocellular Carcinoma in collaboration with US CDC
- •HCV prevalence survey in IDPs in Georgia



HCV Screening Among Different Target Groups

Since 2015, more than 1 million persons have been screened

Positivity rate ~ 6%

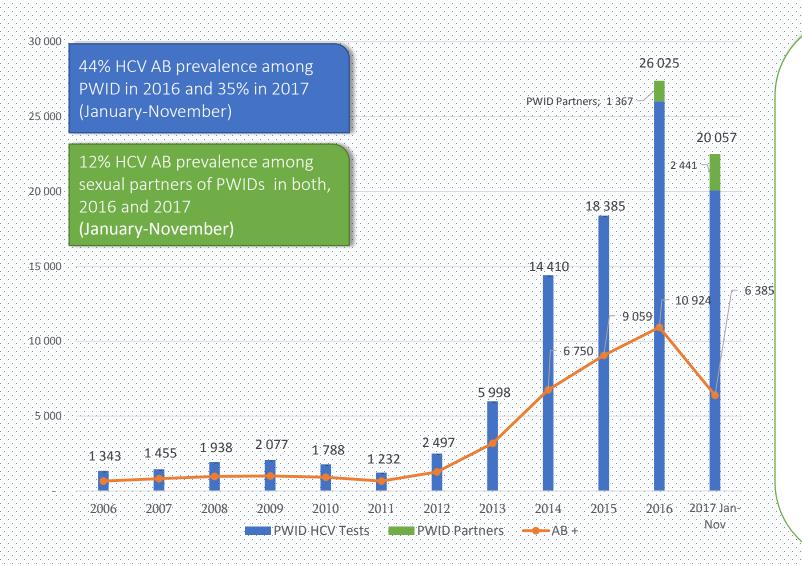


Unified Electronic Screening Module

- 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



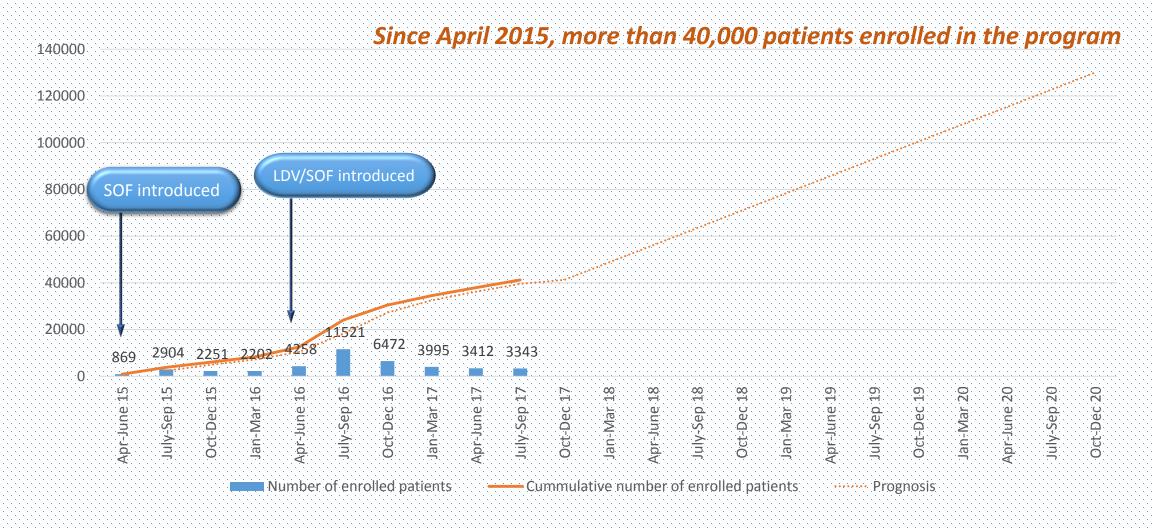
Number of HCV testing sessions among PWIDs by years



- 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 of 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



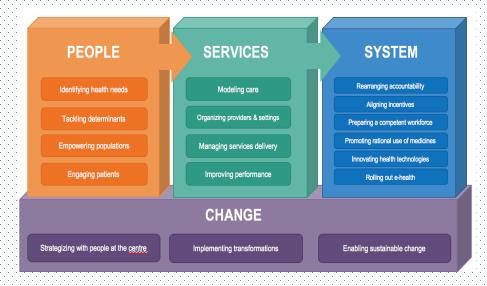
Enrollment in the HCV treatment program





Integration of HCV, TB and HIV Detection at PHC level

Strategic Framework



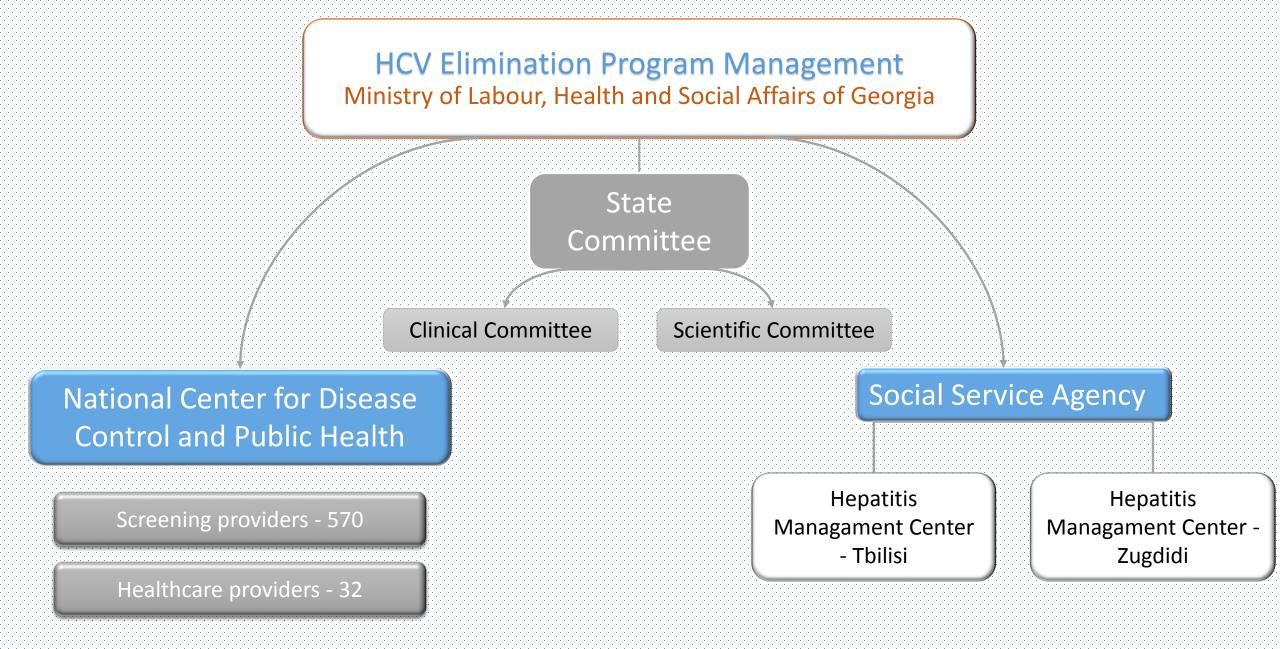
«People-centred care is focused on and organized around the health needs and expectations of people and communities rather than on patients or diseases»



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

- To raise awareness among all stakeholders including general public on all thee 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







Georgia HCV Elimination Clinical Committee

The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America Present

HCV Guidance:
Recommendations for

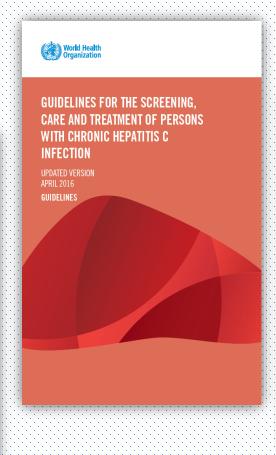
Testing, Managing, and Treating Hepatitis C

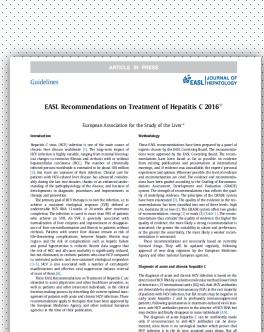
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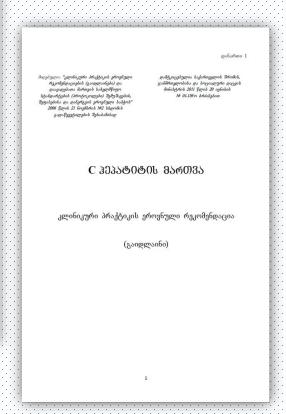
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Please die this article in press as: , . EASL Recommendations on Treatment of Hepatitis C 2016. J Hepatol (2016), http://dx.doi

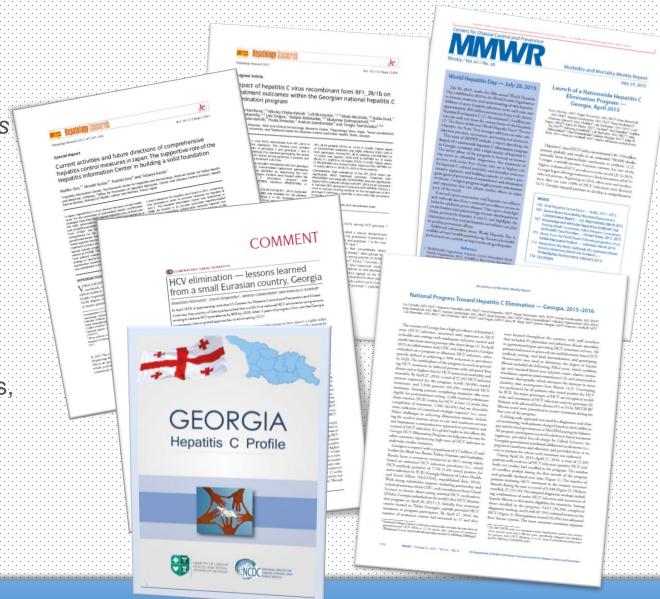
patients with acute hepatitis C will be anti-HCV positive at diagnosis. In these case, caute hepatitis C can be superted if the clinical signs and symptoms are compatible with acute hepatiti-(alanine aminotransferase [ALT] > 100 times the upper limit of normal, and jaundice) in the absence of a history of chronic lives disease or other causes of acute hepatitis, and/or if a likely recen-





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)



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!



