National Hepatitis C Virus Elimination Progress Report, Georgia

January 1, 2017 – June 30, 2018

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ACKNOWLEDGEMENTS

LIST OF ABBREVIATIONS

AASLD	American Association for the Study of Liver Diseases
BBSS	Bio-Behavioural Surveillance Survey
CME	Continuing medical education
DAA	Direct acting antivirals
DVH	Division of Viral Hepatitis
EASL	European Association for the Study of the Liver
EQA	External quality assessment
FIND	Foundation for Innovative Diagnostics
FTD	First time donors
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GHRN	Georgia Harm Reduction Network
GMP	Good Manufacturing Practice
HBV	Hepatitis V virus
HCC	Hepatocellular carcinoma
HCV	Hepatitis C virus
HCVcAg	Hepatitis C virus core antigen
HCW	Health-care workers
HIV	Human Immunodeficiency virus
HRU	Health Research Union
IDACIRC	Infection Diseases, AIDS and Clinical Immunology Research Center
IPC	Infection prevention and control
NCDC	Georgia's National Center for Disease Control and Public Health
NSP	Needle and syringe program
OST	Opioid substitution treatment
PCP	Primary-care physicians
PCR	Polymerase chain reaction

PHC	Primary health centers
PWID	Persons who inject drugs
RAMA	Regulation Agency for Medical Activities
RIQAS	Randox International Quality Assessment Scheme
SOPs	Standard operating procedures
SSA	Social Service Agency
SVR	Sustained virologic response
TSMU	Tbilisi State Medical University
TTI	Transfusion transmissible infections
U.S. CDC	United States Centers for Disease Control and Prevention
VCT	Voluntary counseling and testing

INTRODUCTION

Since 2015, Georgia has been working towards the country-wide elimination of hepatitis C virus (HCV) infection, defined as a 90% reduction in HCV prevalence by 2020. Progress towards the 2020 HCV elimination goal hinges on scaling up best practices, leveraging existing efforts and resources, and improving coordination across various national programs (e.g., the HIV state program and harm reduction programs), agencies (e.g., the Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs , Social Service Agency [SSA], and Georgia's National Center for Disease Control and Public Health [NCDC]) as well as among health-care providers.

This report highlights the impact of various policy changes and initiatives occurring from January 1, 2017 through June 30, 2018 aimed at improving HCV outcomes across the continuum of HCV care. This report supplements the findings in the *National Hepatitis C Virus Elimination Progress Report, 2015–2017*[*]and includes the following:

- Highlights of accomplishments and key findings
- Challenges remaining to the achievement of the HCV elimination goals
- Tables containing monitoring and evaluation data on key performance indicators for the reporting period
- Appendices (1-4)

The information contained in this current progress report mirrors the following six elimination strategies presented in the larger *Strategic Plan for the Elimination of Hepatitis C Virus in Georgia, 2016–2020*[†].

1. Improve Advocacy, Awareness, Education, and Partnerships for HCV-Associated Resource Mobilization
2. Prevent HCV Transmission through Harm Reduction, Blood Safety, and Infection Prevention and Control
3. Identify and Link to Care Persons Infected with HCV
4. Improve HCV laboratory diagnostics
5. Provide Comprehensive HCV Care and Treatment
6. Improve HCV Surveillance

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[*]Available from: http://www.ncdc.ge/Pages/User/Documents.aspx?ID=33a11d14-e71c-4b28-ad39-d6670090664c
[†]Available from:
https://www.moh.gov.ge/uploads/files/2017/akordeoni/failebi/Georgia_HCV_Elimination_Strategy_2016-2020.pdf

STRATEGY-SPECIFIC PROGRESS MADE TOWARDS HCV ELIMINATION

Strategy 1. Improve Advocacy, Awareness, Education, and Partnerships for HCV-Associated Resource Mobilization

Georgia currently has strong governmental and societal support for awareness and prevention initiatives, and MoLHSA implemented and continued to support several strategies during this reporting period. A top priority for the government during this time was to promote and support primary-care physicians (PCP) in their efforts to raise awareness among the general population and identify, diagnose, and treat patients with hepatitis C infection.

Key Accomplishments and Findings

- Implementation of a social media campaign; HCV-related blog posts, banners, and TV shows; and training and seminars to raise awareness in the general population as well as high-risk subgroups. "Get Treated" and "Defeat C" were the primary communication campaign slogans for 2017.
- A mobile communication strategy was developed that involved using brief text messages. From July through November 2017, brief text messages were sent in three phases, initially targeting 30–60 year-old males (approximately 500,000 persons) in July 2017, the general population (approximately 1.8 million people) in October 2017, and persons in high-risk populations (nearly 500,000 persons) in November 2017.
- The HCV screening summer campaign, conducted during July through August 2017 in collaboration with the students from Tbilisi State Medical University (TSMU), involved visiting approximately 48,000 households in Tbilisi; households were provided printed educational materials and were verbally encouraged to seek HCV screening at one of the 13 outpatient clinics located in the capital city.
- The Hepatitis C Cured Patient Association was established in March 2018.
- A website (c.moh.gov.ge) was developed to provide up-to-date information about the elimination program for the general population, patients, health-care professionals, elimination-program providers, advocates, and international partners.
- Data from a small-scale Facebook survey among the general population and a qualitative survey from a subgroup of persons who inject drugs (PWID) revealed that most respondents had a moderate knowledge about how people become infected with hepatitis C and how to prevent transmission; however, 90% of surveyed PWID incorrectly believed that HCV clearance upon treatment provided protection against future infections.[‡]

[‡] http://hrn.ge/assets/uploads/AIV%20and%20HSV%2002.11.18/PDI_PWIDS_2017.pdf

Strategy 2. Prevent HCV Transmission through Harm Reduction, Blood Safety, and Infection Prevention and Control

Preventing new HCV infections is crucial to achieving the elimination goal. Although increased awareness of the risks associated with hepatitis C transmission can support prevention efforts, improvement is needed in other areas, including greater integration of HCV services at harm-reduction sites, continued provision of services and monitoring of coverage provided at needle and syringe programs (NSP) and opioid substitution treatment (OST) programs, and more robust blood bank and infection-prevention control practices.

Harm Reduction

Key Accomplishments and Findings

- Four projects with a primary focus on PWID were launched in 2018:
    - Implementation of the Foundation for Innovative Diagnostics (FIND)'s pilot project to investigate the feasibility, acceptability, effectiveness, and cost-effectiveness of three models of HCV viremia testing for confirmation and linkage to care among PWID
    - Implementation of HCV treatment in four harm-reduction (HR) centers
    - Evaluation of integrated HCV treatment programs within Georgia's HR centers
    - A study of barriers and facilitators to enrollment in Georgia's HCV elimination program among PWID
- HCV prevalence was 63.2% among PWID according to the Bio-Behavioral Surveillance Survey (BBSS) conducted in 2017.
- HCV screening efforts at NSP sites have substantially increased the total number of PWID aware of their HCV infection status, from 13,736 in 2014 (baseline) to 21,371 in 2017. The proportion of PWID testing positive for anti-HCV was 32% in 2017 compared to relatively stable seropositivity percentages observed in previous 3 years (47% in 2014, 50% in 2015, and 44% in 2016)
- Based on available data from the national screening and treatment databases, of 2,586 anti-HCV positive persons registered as beneficiaries of HR program, 1,525 received confirmatory testing; 88.3% (1,347/1,525) had chronic HCV infection. A total of 869 persons, identified as current or former PWID, initiated treatment, and 96% (465/482) of those were cured of their HCV infection.
- According to data from the Georgia Harm Reduction Network (GHRN), PWID aged 30–49 years had the highest rates of screening during the reporting period. Yet the proportion of HCV-antibody positive PWID is higher among persons aged 50–59 years, highlighting the need to better target screening and testing towards specific age sub-groups.
- In July 2017, the OST program supported by the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) was fully transitioned to state-based funding, resulting in the elimination of co-payment requirements for patients that resulted in a considerable increase in the number of PWIDs enrolled in OST (7,381 by the end of 2017).

Blood Safety

Key Accomplishments and Findings

- Beginning in March 2018, all blood-collection centers were mandated to refer anti-HCV positive samples from blood donors to the Lugar Center for diagnosis of chronic HCV infection.
- From January through December 2017, a total of 2,812 randomly selected blood aliquots from the blood banks participating in the state program were submitted to the Lugar Center for retrospective testing for HCV, HIV, HBV and syphilis. Overall, 9 (0.3%) of these samples were found to have discrepant HCV antibody testing results.
- Twelve laboratories participated in the Randox International Quality Assessment Scheme (RIQAS)[§]/Randox Professional Testing (PT) program for transfusion transmitted infections (TTI) testing. Of these 12 laboratories, three had zero errors for all four TTI markers; "no error" reports were received from two laboratories.
- Experts organized by the European Commission's Technical Assistance and Information Exchange (TAIEX) instrument conducted a workshop and study tours for two blood banks to help Georgia harmonize national blood-safety regulations with European directives.
- An active communication campaign was conducted to promote voluntary blood donations.
- A slight reduction in HCV prevalence occurred in 2017 among the donor population, from 1.8% in 2016 to 1.4% in 2017, with highest prevalence observed in middle-aged donors (2.8% in the 40–49 age group and 2.3% among those aged 50–59 years).
- HCV prevalence was 3.1% in first-time donors (FTD) and 0.4% in repeat donors, with the highest prevalence observed among paid FTD (5.8%).
- Of blood donors previously tested anti-HCV negative, 33 screened positive in 2017.
- Of the 125 donors with confirmed active HCV infection, 12 were identified as repeat donors.

Infection Prevention and Control

Key Accomplishments and Findings

- The national Infection Prevention & Control (IPC) guideline Technical Work Group (TWG) initiated development of comprehensive IPC guidelines and of implementation of a toolkit. The IPC guidelines were divided into two modules, with the adoption of the IPC guideline Module 1 by the Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs anticipated by the end of 2018, and development of Module 2 is ongoing through 2019. The following topics are included in the Module 1 of IPC guidelines:

  - Introduction to standard precautions
  - Hand hygiene
  - Personal protective equipment
  - Injection safety
  - Sharps injury and prevention

[§] RIQAS-the largest global External Quality Assurance (EQA) scheme aimed to help clinical laboratories meet their quality requirements and provide the best possible patient care https://www.randox.com/riqas-external-quality-assessment/

- o Laundry
- o Environmental cleaning and disinfection
- o Decontamination and sterilization
- An assessment team comprised of representatives from the Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs, NCDC, and the State Regulatory Agency for Medical Activities visited 66 hospitals with intensive-care units.
- The percentage of health-care facilities compliant with national guidelines increased from 0% at the baseline assessment in 2017 to 18% at the follow-up visits (n=12 hospitals).
- Substantial improvement was seen in the safety of health-care injections, with the proportion of hospitals compliant with this indicator increasing from 29% (baseline) to 67%.
- The percentage of health-care facilities receiving IPC training on the topics of injection and sharps safety increased from 62% (n=40 hospitals) to 95% (n=63 hospitals).
- All surveyed facilities had appointed an IPC focal point, and all had an active IPC committee.
- Full compliance with national legislation requirements on sterilization and disinfection has been reported from only 54% (n=36) of clinics.
- Safe-injection practices were implemented in 67% (n=44) of clinics.

- From January 2017 through May 2018, on-the-job trainings on IPC policies and precautions were conducted for 190 physicians and nurses, 92 dentists (trained by the Georgian Dental Association), and approximately 2,100 staff members from non-medical facilities (e.g., beauty salons, tattoo salons, and other facilities performing cosmetic procedures or providing non-traditional health-care services).

Strategy 3. Identify and Link to Care Persons Infected with HCV

Diagnosis of persons infected with HCV is critical to achieving elimination. Georgia aims to screen and link to care persons in certain risk groups (e.g., PWID), hospitalized patients, persons living in areas with high HCV prevalence, and members of the general public. Screening involves an initial HCV test, with referral for confirmation of chronic HCV infection using either PCR or core antigen (HCVcAg) testing. No cost is incurred by the patient. To improve the identification of HCV-infected persons, NCDC has planned a telephone survey for those not linked to care to gain a better understanding of the nature of patient-level factors impeding access to such care and will use survey data to inform interventions designed to improve linkage to care. Novel models such as the Samegrelo-Zemo Svaneti triple screening pilot project [HCV, TB, and HIV] employed in high prevalence areas with financial support from GFATM also can improve identification of HCV-infected persons. Such efforts require coordination at the regional and local levels, including engagement of the local government, public health centers, HCV-care providers, and primary health-care facilities participating in the universal health care and village doctor state programs.

Key Accomplishments and Findings
- HCV antibody testing in Georgia is provided free-of-charge, and access has expanded greatly, with HCV screening available at more than 1,000 sites across the country.

- From December 2017 (when the Lugar Center began conducting HCVcAg confirmatory testing) through March 2018, regulatory changes were made to improve access and HCV confirmatory testing.
- As of June 30, 2018, a total of 1,175,291 persons have been screened for HCV and are registered in the unified national screening registry.
- Among persons receiving HCV testing, most were screened during inpatient hospitalization (44%; n=496,228); other groups of persons receiving HCV screening included blood donors (18%; n=203,376), and pregnant women (8.5%; n=96,135).
- As of June 30, 2018, the prevalence of hepatitis C remained high at 8.3% (n=93,181) among the 1,125,808 persons registered in the elimination program.
- Of 93,181 persons who tested positive for anti-HCV, more than 24,000 (26%) had not received confirmatory testing and were not linked to HCV care; the Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs, in partnership with NCDC, has developed strategies to follow-up these individuals and link them to confirmatory testing and care.
- In April 2018, Georgia initiated a pilot project in one region (Samegrelo-Zemo Svaneti) to test the potential for integrating hepatitis C, HIV, and TB screening services at the primary health-care facility level by engaging primary health-care providers in the detection and referral or management of all three diseases under one umbrella.

    o From April through June 2018, a total of 38,900 persons had been screened for HCV in the Samegrelo-Zemo Svaneti region, of which 1,179 (3%) tested anti-HCV positive.

- Free HCV antibody screening services became available at specially designated areas in 12 Public Service Halls across the country operating under the Ministry of Justice.

Strategy 4. Improve HCV Laboratory Diagnostics

Several strategies have been developed and evaluated over the past 2 years to simplify and facilitate HCV diagnosis in Georgia by broadening the landscape of existing and approved assays for diagnosing active HCV infection. Access to confirmatory tests for active HCV infection was recognized as a barrier to scaling up testing and treatment services during this reporting period. Although the diagnosis rate has improved over the last 3 years, Georgia has not yet met the HCV diagnosis target of 90%; as of June 30, 2018, this rate was 43%. Another key activity taking place within this reporting period was the development of a quality assurance system for HCV diagnostics throughout the country.

Key Accomplishments and Findings
- Establishment of the HCV Elimination Program prompted clinical laboratories throughout the country to initiate the registration and licensing process. As of December 2017, more than 500 laboratory service providers were registered in the Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs database.
- In March 2017, the Lugar Center established the first National External Quality Assurance (EQA) program for HCV viral load and genotyping. A simplified algorithm for laboratory diagnostics and management of care was implemented in March 2018.

- All enrolled laboratories (n=16, including the HCV reference laboratory) successfully passed the EQA panel in 2017, confirming the validity of the testing results. The cumulative 2017 EQA Program results for quantitative HCV RNA viral load were "excellent" in 78.9 %; "good" in 17.7%; and "acceptable" in 3.6% laboratories. All laboratories accurately detected genotype.
- Preliminary results of the collaborative study, Hepatitis C Elimination through Access to Diagnostics (HEAD Start) demonstrated that collecting blood from anti-HCV screened positive PWID for HCV confirmation testing at HR centers improved access to such testing. Of persons having blood drawn at HR centers (with testing either done on site [Group 1; n=182) or sent to Lugar Center for centralized testing [Group 2; n=71), 100% completed HCV confirmatory testing; in contrast, only 87% (55/63) of persons referred to service providers for their blood draw and HCV confirmatory testing (Group 3) completed such testing.

Strategy 5. Provide Comprehensive HCV Care and Treatment

Georgia's elimination program aims to treat 95% of patients diagnosed with chronic HCV infection (an estimated 135,000 of the 150,000 persons living with chronic HCV infection) by 2020. For this reporting period, only one third of HCV-infected persons (approximately 47,000) had been or were enrolled in the treatment program. To accelerate identification of infected persons and access to treatment, priority was given to decentralizing HCV services to primary health-care and HR sites. A robust information system, ELIM-C, allows for tracking and monitoring all patients receiving treatment through the program. Successful decentralization of care and treatment requires simplification of treatment algorithms and patient management. The scale-up of HCV care decentralization (planned for August 2018) will require an increase in the capacity and reach of the information technology (IT) system to all primary health-care and HR sites. IT support is critical to the success of every aspect of the HCV care decentralization effort, including: screening, diagnostics, treatment, and drug distribution.

Key Accomplishments and Findings

- The number of treatment centers has increased since the launch of the elimination program, from four centers in April 2015 to 32 centers by June 30, 2018. A total of 27 HCV provider clinics were enrolled in the program during 2017, with five more joining through June 30, 2018.
- On December 8, 2017, a "Decentralization of HCV Care Services" meeting was held at Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs to discuss the major challenges and opportunities associated with this approach.
- In June 2018, a total of 10 PHC facilities (two sites in Tbilisi and eight sites in regions) were selected for decentralization of HCV care and treatment services. These PHC clinics were prioritized for services because they are located a substantial distance from HCV service providers in regions/districts with known or suspected high prevalence of HCV infection serving a large number of patients under the universal healthcare program.
- Preparatory work on piloting a new model combining both simplified testing and management and integration of HCV treatment in primary health-care settings started in late December 2017. Four primary health-care clinics were participating in the pilot project by May 2018, and a total of 22 patients were enrolled by June 30, 2018.

- A special Continuing Medical Education (CME) training program for primary care physicians has been developed and approved by the Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs
- For the first phase of decentralization, PHCs will provide care only to HCV treatment-naïve patients with mild fibrosis using the simplified diagnostics and treatment monitoring algorithm, while persons with more advanced liver fibrosis (FIB4 > 1.45) will be referred to specialized clinics.
- Ministry of Internally Displaced Persons from the Occupied Territories Labour, Health, and Social Affairs has begun improving access for PWID by decentralizing HCV treatment, offering therapy in three HR centers as of October 2018 with expansion to additional centers planned for the near future.
- As of June 30, 2018, a total of 49,350 HCV-infected persons were enrolled in the treatment program.
- Monthly patient enrollment in the treatment program slowed during 2017 and the first 6 months of 2018 to approximately 1,000 patients per month.
- Sustained viral response (SVR) reached 98.2% (31,158/31,715) among patients eligible and tested for SVR; the SVR rate calculated using an "intent to treat" analysis (which took into account persons who completed treatment but did not receive SVR testing) was 75.4%.

Strategy 6. Improve HCV Surveillance

Surveillance plays a critical role in HCV prevention and control. Georgia recognizes the advantages of an effective surveillance system for planning, resource allocation, and monitoring of public health programs. However, the current surveillance system does not adequately capture and promptly identify seroconversion cases of HCV infection among the populations at risk such as PWIDs and persons receiving dialysis. Active since the program's inception, the national treatment database can be utilized as a tool for surveillance. Strengthening the HCV program's information system, which supports both clinical and program policy decisions, will help ensure availability of reliable data. Linkage of the HCV treatment database to other data sources (e.g., the national screening registry, E-health, and the SSA financial module) facilitates the collection of accurate and integrated information for each person screened, diagnosed, and registered in the national HCV elimination program.

Key Accomplishments and Findings
- An assessment study for HCV-attributable primary liver cancer was initiated during this period.
- The first day of the annual National Spring HCV Workshop (March 2018) was dedicated to an in-depth discussion of the challenges and opportunities associated with surveillance.
- In 2018, a study (Descriptive, Retrospective Study on the Prevalence of Acute Viral Hepatitis in Georgia) was undertaken to describe all types of viral hepatitis and unspecified jaundice cases by health-care facility in 2017 as recorded in the E-health system, an electronic medical record system.

- Surveillance data on HCV reinfection collected among PWID in Tbilisi through a joint effort between Medecins du Monde (France) and the local NGO Health Research Union from July 2015 through December 2017 indicates an incidence rate of 1.2 per 100 person-years[**].
- Preliminary findings of a project to analyze cases of HCV among children < 18 years of age in Georgia reveal that from April 2015 through March 2018, out of a total of 103,399 children aged 0–18 years who were screened, 322 (0.3%) tested anti-HCV positive.

[**] https://az659834.vo.msecnd.net/eventsairaueprod/production-ashm-public/b4333167497c40c1a8b1564a8c09363d

STRATEGY-SPECIFIC CHALLENGES TO HCV ELIMINATION
January 1, 2017 through June 30, 2018

Improving Awareness:

- Unknown impact and coverage of HCV communication campaign
- Limited scope of communication campaigns
- Limited understanding of the barriers to enrolling in the screening and treatment program (such data could inform effective communication campaigns)
- Gaps in knowledge regarding the societal factors that drive stigma
- Insufficient resources

Preventing Transmission:

Harm Reduction

- Barriers to monitoring access and treatment among PWID
- Patient-perceived misconceptions regarding side effects associated with antiviral treatment
- Lack of trust regarding perceived confidentiality and anonymity among PWID enrolled in the National Screening Registry.
- Inconsistencies in data between the Harm Reduction Program and the National Screening Registry
- Stigma related to drug use, social factors, and economic factors that affect access to HCV care and treatment for PWID

Blood Safety:

- Decentralization and fragmentation of the blood transfusion service
- Lack of a supervisory body at the central level
- Existence of profit-based and unregulated blood banks
- The predominant practice of paying donors, which compromises blood safety practices
- Lack of standardization of clinical guidelines and deficient testing algorithms for donated blood in some blood banks
- Reliance on semi-automated and rapid-test platforms for testing blood donations
- Lack of effective quality assurance and control systems
- Suboptimal national regulations and non-compliance with European standards

Infection Control:

- Failure to adequately enforce existing regulations that mandate IPC in health-care facilities
- Failure of clinics to fully comply with national legislation requirements on sterilization and disinfection and to employ safe injection practices
- Absence of SOPs to guide management of health-care workers exposed to infectious material
- Failure of institutions to identify, register, and report nosocomial infections
- Lack of implementation of the 2009 IPC curriculum approved for medical universities in 2014

Identifying Infected Persons and Linking them to Care:

- Steadily declining rates of anti-HCV positivity among the screened population
- Suboptimal numbers of anti-HCV positive persons receiving confirmatory testing
- Suboptimal rates of linkage to care among persons with HCV infection confirmed by HCVcAg

Improving Laboratory Diagnostics:

- Lack of a quality assurance system for HCV rapid tests
- No national system for licensing laboratory professionals
- Absence of uniform national standard operating procedures (SOPs) for the country's HCV diagnostic laboratories
- Lack of standardized comprehensive training programs for laboratory personnel on quality and biosafety standards and practices.

Providing Care and Treatment:

- Lack of European Association for the Study of the Liver (EASL) or American Association for the Study of Liver Diseases (AASLD) recommended regimens to guide therapy of patients requiring retreatment after failure to achieve SVR after their initial DAA course
- Limited provider capacity and scarcity of treatment centers in some rural and geographically disparate areas
- Need for simplification of treatment algorithms and patient management
- Need for increased training for PHC doctors and HR staff to improve their knowledge and skills in HCV management
- Need for additional IT support to facilitate full-scale decentralization of HCV care in primary care and HR setttings

Improving Surveillance:

- Issues of timeliness, accuracy, and completeness of data collection associated with current HCV surveillance system
- Failure of current system to adequately capture and promptly identify seroconversion cases of HCV infection among populations at risk (e.g., PWID and persons receiving dialysis)
- Need for a repeat serosurvey to document progress towards elimination (90% reduction in seroprevalence)

Monitoring & Evaluation: Advocacy, Awareness and Education, and Partnerships

Objective	Indicator name	Measurement	Data Source	Value/Result	Remarks
1.1. Educate the public and high-risk groups about viral hepatitis and the importance of testing	1. Levels of awareness among the general public regarding a) HCV transmission b) HCV prevention c) testing and diagnosis d) treatment	**High Awareness** All or most participants aware **Medium Awareness** Some participants aware **Low Awareness** A few or no participants aware		a) High b) Medium c) High d) Medium	*small scale Facebook survey
	2. Levels of awareness among PWID regarding a) HCV transmission b) HCV prevention c) testing and diagnosis d) treatment	**High Awareness** All or most participants aware **Medium Awareness** Some participants aware **Low Awareness** A few or no participants aware	2017 BBSS Qualitative study by GHRN	a) Medium b)Low c) Medium d) Medium	
1.2 Reduce community-level stigma and discrimination associated with HCV infection	3. Level of perceived HCV-related stigma and discrimination experienced among HCV patients in health-care and other settings (e.g., work, housing, school, corrections, and law enforcement)		Qualitative survey among beneficiaries		Data not available

Objective	Indicator name	Measurement		Data source	Value/Result	Remarks	Value/Result (2015-2016)
2A. Decrease HCV incidence among PWID by promoting harm reduction	1. Number and percentage of PWID reached with preventive counseling (Defined Package of Services) * The beneficiary is considered reached if received at least two services from the list of basic package (condom, consultation, information materials, syringe/needle) and one of them has to be syringe/needle	**Numerator** Number of PWID reached with preventive counseling **(N=27,250)**		Harm reduction program records	**52%**		*61%*
		Denominator Estimated number of PWID **(N=52,500)**		Population size estimation of PWIDs in Georgia 2016			
	2. Number and percentage of PWID enrolled in OST	**Numerator** Number of PWID enrolled in OST **(N= 7,381)**		IMPHA Records	**45 %**	IBBS 2017 Opioid dependence was measured using the Rapid Opioid Dependence Screen (RODS) The RODS calculation revealed that 31.4% of those	*20%*
		Denominator Estimated number of opioid user PWID **(N=16,275)**		IBBS			

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks	*Value/Result (2015-2016)*
					who used illicit opioid drugs (93% of the whole sample) had the active phase of opioid dependence. This amounts to 31% of all PWID being dependent on opioids	
	3. Number and percentage of PWID screened for HCV infection at: a. NSP sites and Outreach b. OST service centers c. mobile ambulatories	**Numerator** Number of PWID screened for HCV infection **a. N=11,885 aa. 4,485** **b. N/A** **c. N=9,745**	a) Harm reduction program records aa) National HCV screening registry	**a. 23%** **aa. 8.5%** **b. n/a** **c. 19%**		*a. 48%* *b. n/a* *c. 2%*
		Denominator Estimated number of current PWID **(N=52,500)**	PSE			
	4. Number and percentage of PWID with presence of anti-HCV antibodies	**Numerator** Number of PWID with anti-HCV positivity **(N=6,850)∗** **(N=1,941)∗∗**	∗Harm reduction program records ∗∗National HCV screening registry	**32%** **36.8%**		*44%*

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks	*Value/Result (2015-2016)*
		Denominator Number of PWID tested for HCV infection **(N=21,371)∗** **(N=5,280)∗∗**				
	5. Number and percentage of PWID testing positive on rapid tests who undergo HCV confirmatory testing	**Numerator** Number of PWID tested for HCV RNA or HCV core antigen testing **(N=981)**	Treatment database	**50.5%**		*Data not available Current database doesn't allow tracking of these data*
		Denominator Number of PWID with anti-HCV positive results **(N=1,941)**	National HCV screening registry			
	6. Number and percentage of PWID diagnosed with active HCV infection	**Numerator** Number of PWID diagnosed with chronic HCV infection based on virologic biomarker testing **(N=861)**	Treatment database	**87.7%**		*Data not available*
		Denominator Number of PWID who were tested for HCV RNA or HCV core antigen testing **(N=981)**	National HCV screening registry			

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks	*Value/Result (2015-2016)*
	7. HCV prevalence among PWID by IBBS study		IBBS	**63.2%**	Value is pooled estimate from IBBS 2017. Actual numerator unknown.	*66.2%*
	8. Number and percentage of PWID with active HCV infection started HCV treatment	**Numerator** Number of PWID started HCV treatment **(N=651)**	Treatment database	**75.6%**		*Data cannot be assessed*
		Denominator Number of PWID with diagnosed HCV infection **(N=861)**				
	9. Number and percentage of PWID enrolled in treatment program who completed treatment	**Numerator** Number of PWID completed antiviral treatment **(N=511)**	Treatment database	**78.5%**		*Data cannot be assessed*
		Denominator Number of PWID enrolled in HCV care and treatment **(N=651)**				

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks	*Value/Result (2015-2016)*
	10. Number and percentage of PWID completing treatment who achieved sustained virologic response (SVR)	**Numerator** Number of PWID who achieved SVR **(N=282)**	Treatment database	**95.8%**		*Data cannot be assessed*
		Denominator Number of PWID assessed for SVR at 12-24 weeks after the end of treatment **(N=294)**				
	11. Percentage of PWID reporting use of sterile injecting equipment the last time they injected	**Numerator** Number of PWID reporting use of sterile injecting equipment the last time they injected	IBBS	**91.6%**	Value is estimate from IBBS 2017. Actual numerator unknown.	*80.4%*
		Denominator Estimated number of PWID **(N=52,500)**				

Objective	Indicator name	Measurement	Data source	Value/ Result	Remarks
2B.a Prevent health-care-related transmission of viral hepatitis by improving blood safety	1. Number and percentage of all blood banks participating and operating in the Unified Blood Donor Electronic Database (Donor Database)	**Numerator** Number of blood banks participating and operating in the Donor Database **(N=21)**	Donor Database	**95.5%**	
		Denominator Total number of blood banks holding state license in blood production service **(N=22)**	State Regulation Agency for Medical Activities		
	2. Lead agency is established at central level to oversee and coordinate blood service in the country	Appropriate legislative act	MoLHSA	Not established	
	3. Licensing regulations for the blood banks are established, approved, and published	Appropriate legislative act	Legislative Department of MoLHSA	Not established	
	4. Percentage of all blood banks that have obtained Good Manufacturing Practice (GMP) and/or ISO certificates	**Numerator** Number of blood banks that have obtained GMP and/or ISO certificates	State Programs Department at NCDC		Data not available
		Denominator Total number of blood banks (**N=22**)	State Regulation Agency for Medical Activities		

Objective	Indicator name	Measurement		Data source	Value/ Result	Remarks
	5. Number and percentage of voluntary donations among all blood donors	**Numerator** Number of voluntary donations (**N=20,283**)		Donor Database	**23.1%**	
		Denominator Total number of blood donations (**N=87,881**)		Donor Database		
	6. Percentage of anti-HCV reactive persons among blood donors	**Numerator** Number of blood donors with anti-HCV positive results (**N=727**)		Donor Database	**1.4%**	
		Denominator Total number of unique blood donors (**N=51,799**)		Donor Database		
	7. Percentage of blood donors tested for HCV by NAT and/or other sensitive tests	**Numerator** Number of blood donors tested for HCV confirmation (**N=1,193**)		STOP-C registry C Elimination	**41.7%**	Data for the period 2015-2017
		Denominator Number of seroreactive blood donors (**N=2,860**)		Donor Database C Elimination database		
	8. Percentage of blood donors with confirmed active HCV infection	**Numerator** Number of blood donors tested positive by HCV confirmatory testing (Core Ag, PCR) (**N=904**)		STOP-C C Elimination	**75.8%**	Data for the period 2015-2017
		Denominator Total number of unique blood donors tested for HCV confirmation (**N=1,193**)				

Objective	Indicator name	Measurement	Data source	Value/ Result	Remarks
	9. Degree of the continuity of care (Percentage of HCV confirmed blood donors enrolled in the HCV treatment programs)	**Numerator** Total number of HCV confirmed donors enrolled in the treatment programs **(N=722)**	C Elimination	**79.9%**	
		Denominator Total number of donors with HCV confirmed infection **(N=904)**	STOP-C C Elimination		

Monitoring & Evaluation: Infection Control, 2017

Objectives	Indicator name	Measurement	Data source	Value/Result	Remarks
2C.a Prevent health-care-associated transmission of viral hepatitis by improving infection control in health-care facilities	1. National guidelines on injection safety developed and published online	N/A	Published guidelines	**2**	**Scale indicator:** 0 = not started; 1 = under development; 2 = draft complete; 3 = published.
	2. Policies on needle-stick injuries developed and published online	N/A	Published guidelines	**2**	(see 2C.a.1)
	3. National sterilization and disinfection guidelines developed and published online	N/A		**2**	(see 2C.a.1)
	4. National waste management guidelines revised and published online	N/A	Ministerial decree	**2**	(see 2C.a.1)
	5. Number of medical universities and nursing colleges with IPC curriculum introduced into training program		Survey conducted by NCDC/Ministry	**2**	
			Ministry of Education		
	6. Percentage of health-care facilities provided training with an IPC curriculum	**Numerator** Number of health-care facilities receiving IPC training **(N=62)**	Survey conducted by Ministry/NCDC	**93.9%**	

Objectives	Indicator name	Measurement	Data source	Value/Result	Remarks
		Denominator Number of health-care facilities surveyed **(N=66)**	Survey conducted by Ministry/NCDC		
	7. Degree to which facilities follow national IPC guidelines, needle-stick policies, guidelines on injection safety, national sterilization guidelines, and national waste-management guidelines	**Numerator** Number of health-care facilities compliant with national guidelines **(N=12)**	Survey conducted by Ministry/NCDC	**18.0%**	
		Denominator Number of health-care facilities surveyed **(N=66)**	Survey conducted by Ministry/NCDC		
	8. Percentage of health-care facilities with an appointed IPC focal person	**Numerator:** Number of health-care facilities with appointed IPC focal person **(N=66)**	Survey conducted by Ministry/NCDC	**100%**	
		Denominator:	Survey conducted by Ministry/NCDC		

Objectives	Indicator name	Measurement	Data source	Value/Result	Remarks
		Number of health-care facilities surveyed **(N=66)**			
	9. Percentage of health-care facilities with functional IPC committees	**Numerator:** Number of health-care facilities with active IPC committees **(N=66)**	Survey conducted by Ministry/NCDC	**100%**	
		Denominator: Number of health-care facilities surveyed **(N=66)**	Survey conducted by Ministry/NCDC		
	10. Percentage of health-care facilities displaying IPC awareness materials	**Numerator** Number of health-care facilities displaying awareness materials **(N=60)**	Survey conducted by Ministry/NCDC	**90.9%**	
		Denominator Health-care facilities where the survey was conducted **(N=66)**	Survey conducted by Ministry/NCDC Training records		

Objectives	Indicator name	Measurement	Data source	Value/Result	Remarks
2C.b Prevent HCV transmission in non-traditional health-care and other community settings	1. State regulations and policies of IPC in non-medical facilities are updated and published online		Published State regulations and regional public health centers	**3**	**Scale indicator:** 0 = not started; 1 = under development; 2 = draft complete; 3 = published.
	2. Percentage of non-medical facilities where SOPs are available	**Numerator** Number of non-medical facilities where SOPs are available **(N=416)**	Survey conducted by Ministry/NCDC and regional public health centers	**100%**	Data shown for Tbilisi. Nationwide data has changed since last survey, and newer data is not available.
		Denominator Total number of sampled surveyed non-medical facilities **(N=416)**	Survey conducted by Ministry/NCDC and regional public health centers Training records		
	3. Number of non-medical facility staff trained in IPC		Ministry/NCDC and regional public health centers Training records	**1500**	

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks
3.1 Increase the number of people diagnosed with HCV infection through expanded screening and testing	1. A national screening guideline/protocol established, approved by national authorities, and published		Published guidelines	**3**	Scale indicators are as follow: 0 = not started; 1 = under development; 2 = draft complete; 3 = published.
3.2 Expand HCV testing to reach high-risk populations better	2. Number of persons tested for hepatitis C antibody 1) Total 2) Prisoners 3) People living with HIV/AIDS 4) Pregnant women at ANC clinics 5) TB patients 6) Hemodialysis patients 7) Inpatients 8) PWIDs		Screening registry	**1) 744,983** **2) 4,127** **3) 1,220** **4) 43,097** **5) 414** **6) 1,912** **7) 378,762** **8) 5,280**	

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks
	3.The proportion of anti-HCV positive persons 1) Total 2) Prisoners 3) People living with HIV/AIDS 4) Pregnant women at ANC clinics 5) TB patients 6) Hemodialysis patients 7) Inpatients 8) PWIDs	**Numerator** Number of persons with HCV seropositivity	Screening registry	1) **5.0%** (37,351) 2) **12.6%** (521) 3) **30.6%** (1,220) 4) **0.6%** (243) 5) **18%** (75) 6) **16.7%** (320) 7) **3.8%** (14,521) 8) **36.8%**(1,941)	
		Denominator Number of persons screened for Hepatitis C	Screening registry		
	4. Number and percentage of children born to HCV-positive women screened for hepatitis C	**Numerator** Number of children born to HCV-infected mothers and screened for hepatitis C			Data not available
		Denominator Total number of children born to HCV-positive women during the reporting period			

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks
4.1 Improve laboratory detection of HCV infection	1. Proportion of HCV confirmatory testing sites (laboratories and point of care diagnostic sites) enrolled in the national hepatitis C EQA program	**Numerator** Number of laboratories performing HCV confirmatory testing that are enrolled in national/international hepatitis C EQA program **(N=16)** **Denominator** Total number of laboratories performing HCV confirmatory testing in Georgia **(N=16*)**	NCDC Lugar Center, Ministry	**100%**	*Denominator includes the reference lab-Lugar Center
	2. Proportion of HCV confirmatory testing sites that participated on 3 EQA challenges per year	**Numerator** Number of laboratories performing HCV confirmatory testing that participated on 3 National/international EQA challenges per year **(N=12)** **Denominator** Total number of laboratories performing HCV confirmatory testing enrolled in hepatitis C EQA program **(N=16)**	NCDC Lugar Center EQA Program	**75%**	
	3. Quality Management System standards for certification are defined, approved, and published		Published QMS standards, Ministry		Ongoing

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks
	4. Proportion of labs providing HCV lab services certified according to national laboratory quality management system (QMS) standards	**Numerator** Number of laboratories performing hepatitis C laboratory services that are certified according to national QMS standards **Denominator** Total number of laboratories performing hepatitis C laboratory services	Ministry		Not applicable until national laboratory QMS standards are approved

Objective	Indicator name	Measurement	Data Source	Value/Result	*Value/Result (2015-2016)*
5.1. Promote universal access to HCV care and treatment	1. Proportion of anti-HCV positive persons assessed for viraemic HCV infection	**Numerator** Number of HCV antibody positive persons tested for viraemic HCV infection **(N=51,205)**	Elimination C STOP-C databases Screening registry	**63%**	**65.5%**
		Denominator Number of people with a presence of anti-HCV antibodies **(N=81,242)**	Screening registry		
	2. Proportion of persons diagnosed with chronic HCV infection	**Numerator** Number of persons diagnosed with chronic HCV infection based on virologic biomarker testing **(N=46,573)**	Elimination C STOP-C databases Screening registry	**91%**	**95.3%**
		Denominator Number of persons tested for viraemia after a positive serological result **(N=51,205)** ◊ Target of identifying **90%** of persons infected with hepatitis C infection: **N=135,000**	Elimination C STOP-C databases Screening registry National sero-prevalence survey conducted in **2015**	**◊34.5%**	**◊26.9%**

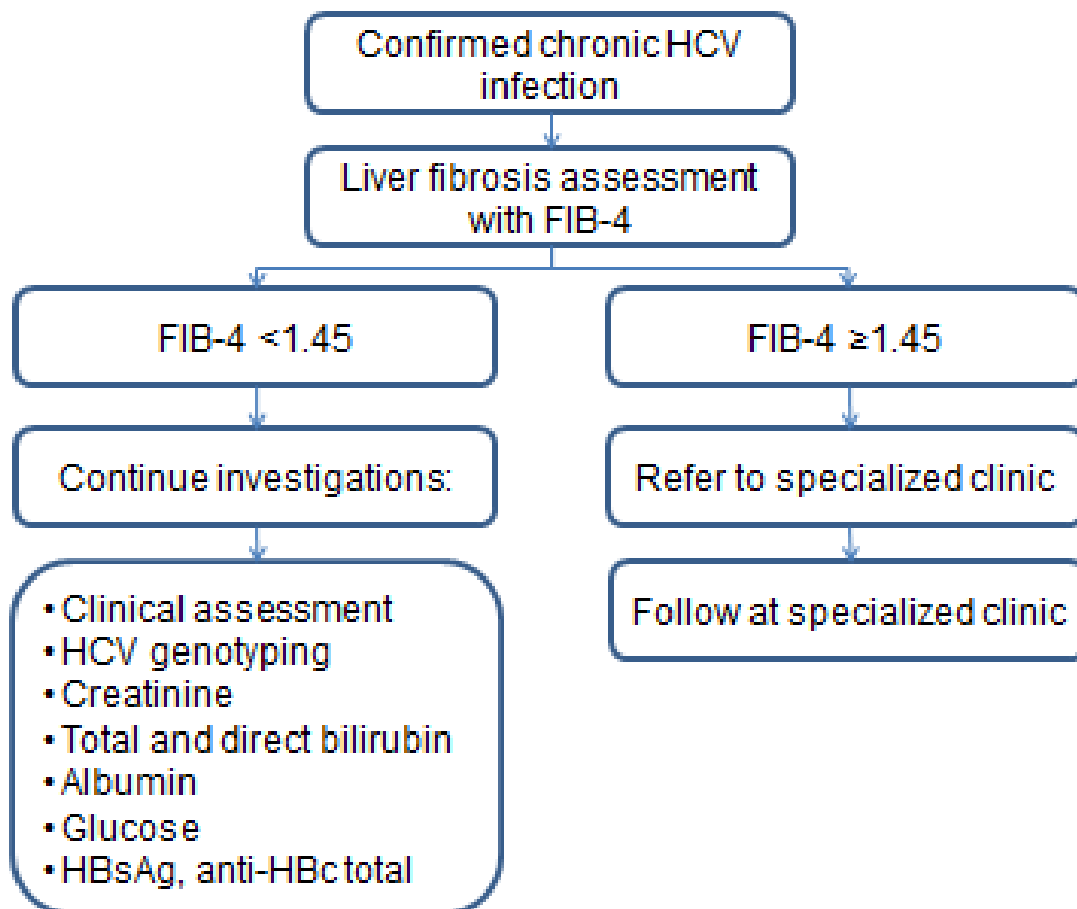| Objective	Indicator name	Measurement	Data Source	Value/Result	*Value/Result (2015-2016)*
	3. Proportion of persons with chronic HCV infection initiated antiviral therapy	**Numerator** Number of persons diagnosed with chronic HCV infection who initiated antiviral therapy **(N=42,391)**	Elimination C and STOP-C databases	**91%**	**76%**
		Denominator Number of persons diagnosed with chronic HCV infection **(N=46,573)**	Elimination C STOP-C databases Screening registry		
		◊Target of treating **95%** of persons with chronic HCV infection: **N=128,250**	National sero-prevalence survey conducted in **2015**	◊**33%**	◊**21.5%**
	4. Proportion of patients engaged in antiviral therapy who have completed treatment	**Numerator** Number of patients with chronic HCV infection who have completed treatment **(N=37,948)**	Elimination C and STOP-C databases	**89.5%**	**71.7%**
		Denominator Number of patients diagnosed with chronic HCV infection who initiated treatment **(N=42,391)**	Elimination C and STOP-C databases		

Objective	Indicator name	Measurement	Data Source	Value/Result	*Value/Result (2015-2016)*
	5. Proportion of patients achieving SVR to HCV therapy	**Numerator** Number of patients who completed treatment and achieved SVR (undetectable viral load 12-24 weeks after the end of treatment) **(N=26,692)**	Elimination C and STOP-C databases	**98.2% (Per-protocol) 75.7% (Intention-to-treat)**	**84.1%**
		Denominator Number of patients who completed antiviral therapy and were assessed for SVR 12-24 weeks post treatment **(N=27,181)** ◊ Target of curing 95% of persons treated for their HCV infection: **N=121,838**	Elimination C and STOP-C databases	**◊21.9%**	**◊4.4%**
	6. Number of physicians providing HCV services OR provider/resident ratio	**Numerator** Number of physicians providing HCV services: **139**	Ministry	**4.6 per 100,000 residents**	**4.6 per 100,000 residents**
		Denominator Estimated resident population: **3,010,200**			
	7. Number of a) Primary Health-care Centers b) Harm Reduction Sites providing HCV care and treatment			**0**	**0**

Objective	Indicator name	Measurement	Data source	Value/Result	Remarks
6.1 Estimate the national burden of chronic viral hepatitis C	1. The incidence of HCV infection	**Numerator** Total number of new infections with HCV defined as anti-HCV positive per year	Prospective cohort study of the reinfection rate among treated and cured PWID	**1.2** per year*	*incidence of reinfection assessed in selected high-risk persons in the context of a research project (2/169 person-years of follow-up)
		Denominator Total population minus people living with hepatitis C			
	2. Number of deaths attributable to HCV-associated cirrhosis or hepatocellular carcinoma (HCC)	Number of deaths from HCC and cirrhosis attributable to HCV infection	Death Registry/Cancer registry HCC (ICD-10 code C22.0) Cirrhosis (ICD-10 codes K74.3, K74.4, K74.5, K74.6)		

Simplified HCV Diagnostic Algorithm for

Decentralization HCV care at Primary Healthcare Level of the

Hepatitis C Elimination Program in Georgia

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                    ┌─────────────────────────┐
                    │  Confirmed chronic HCV  │
                    │        infection        │
                    └─────────────────────────┘
                                 │
                    ┌─────────────────────────┐
                    │ Liver fibrosis assessment│
                    │       with FIB-4        │
                    └─────────────────────────┘
                     │                       │
        ┌────────────────────┐    ┌────────────────────┐
        │    FIB-4 <1.45     │    │    FIB-4 ≥1.45     │
        └────────────────────┘    └────────────────────┘
                 │                           │
        ┌────────────────────┐    ┌────────────────────┐
        │ Continue investigations: │ Refer to specialized clinic │
        └────────────────────┘    └────────────────────┘
                 │                           │
        ┌────────────────────┐    ┌────────────────────┐
        │ • Clinical assessment │  │ Follow at specialized clinic │
        │ • HCV genotyping    │    └────────────────────┘
        │ • Creatinine        │
        │ • Total and direct bilirubin │
        │ • Albumin           │
        │ • Glucose           │
        │ • HBsAg, anti-HBc total │
        └────────────────────┘
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Simplified HCV Treatment Monitoring Algorithm for Decentralization HCV care at Primary Healthcare Level of the Hepatitis C Elimination Program in Georgia

Simplified treatment monitoring procedures				
Measurements	Treatment Duration (weeks)			After treatment completion (weeks)
	4	8	12	12 or 24
Clinical assessment	X	X	X	X
HCV RNA quantitative				X
Complete blood count	X*	X*	X*	
ALT	X	X	X	

* only for patients receiving Ribavirin containing regimens

Appendix 2.

Simplified Treatment Component for

Decentralization HCV care at Primary Healthcare Level of the

Hepatitis C Elimination Program in Georgia

Treatment of Patients Infected with HCV Genotype 1 or HCV Genotype 4

Daily Sofosbuvir 400mg / Ledipasvir 90mg (1 pill)   Recommendation A1

Treatment duration – 12 weeks

NOTE: This regimen is recommended for treatment **naïve** patients with **no** or **mild** fibrosis

Treatment of Patients Infected with HCV Genotype 2 or HCV Genotype 3

Daily Sofosbuvir 400mg / Ledipasvir 90mg (1 pill)   Recommendation A1

Daily weight-based ribavirin (1000 or 1200 mg in patients <75 kg or ≥75 kg, respectively)

Treatment duration – 12 weeks

NOTE: This regimen is recommended for treatment **naïve** patients with **no** or **mild** fibrosis

Appendix 3.
Scientific Meeting Presentations of the HCV Elimination Program

Abstracts

1. **Real-world effectiveness of ledipasvir/sofosbuvir in hepatitis C virus genotype 1, 2 and 3 infection: single-center experience within Georgian hepatitis C elimination program**

Abstract Presented at EASL, 2018; Paris, France
Authors:
Tengiz Tsertsvadze,[1,2] Nikoloz Chkhartishvili,[1] Akaki Abutidze,[1] Giorgi Korkotashvili,[1] Marina Ezugbaia, [1] Vakhtang Kerashvili,[1] Lana Gatserelia,[1] Lali Sharvadze[1,2].
1 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia
2 Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia

Background and Aims: In April 2015, Georgia, in partnership with US CDC and Gilead Sciences, launched the world's first hepatitis C elimination program. Since March 2016 ledipasvir/sofosbuvir (LDV/SOF) has become available which is recommended for the treatment of all HCV genotypes within Georgia's elimination program. We report on real-world effectiveness of LDV/SOF-based regimens for various genotypes in Georgia.

Methods: Data from the leading Georgian center – Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC) were analyzed. IDACIRC is the country's single largest provider of hepatitis C care treating 33% of all persons enrolled in elimination program countrywide. The primary endpoint was achievement of sustained virologic response (SVR) defined undetectable plasma HCV RNA at least 12 weeks after completion of treatment. Advanced liver fibrosis/cirrhosis was defined as liver stiffness of >9.5 kPa by transient elastography or FIB4 score >3.25. A total of 4962 persons started treatment with LDV/SOF at IDACIRC between March 2016 – June 2017, among them 3908 were assessed for SVR and were included in the analysis.

Results: Among 3908 persons included 1756 (44.9%) had genotype 1, 1039 (26.6%) – genotype 2 and 1113 (28.5%) – genotype 3; 545 (13.9%) patients had advanced liver fibrosis/cirrhosis. 1698 (43.4%) patients received LDV/SOF for 12 weeks, 2130 (53.5%) were treated with LDV/SOF in combination with ribavirin (RBV) for 12 weeks and 80 (2.1%) received LDV/SOF/RBV for 24 weeks. The overall SVR rate was 99.4% (3885/3908), including 99.6% (1749/1756) in genotype 1, 99.8% (1037/1039) in genotype 2 and 98.7% (1099/1113) in genotype 3. Overall 99.7% (3354/3363) of patients without advanced liver fibrosis/cirrhosis achieved SVR vs. 97.4% (531/545) of patients with advanced liver fibrosis/cirrhosis (p<0.0001). Further analysis by genotype and advanced liver fibrosis/cirrhosis status showed statistically significant differences in genotype 1 (98.4% SVR advanced fibrosis/cirrhosis vs. 99.8% SVR without advanced fibrosis/cirrhosis, p=0.0014); and genotype 3 (94.3% SVR advanced fibrosis/cirrhosis and 99.5% SVR without advanced fibrosis/cirrhosis, p<0.0001). In genotype 2 patients 99.2% of patients with advanced fibrosis/cirrhosis achieved SVR compared to 99.9% among patients without advanced fibrosis/cirrhosis (p=0.47).

Conclusions: LDV/SOF-based treatment was highly effective in this real-world cohort, including in patients with advanced liver fibrosis/cirrhosis. Extremely high cure rates were observed in all genotypes. Combination of LDV/SOF/RBV appears to be an effective treatment option not only for genotype 1, but for genotype 2 and 3 infections as well.

2. **Reversal of liver damage among HCV infected persons with advanced liver disease: Two-year follow-up from the HCV elimination program, Georgia.**

Abstract Presented at ASM Clinical virology symposium, 2018; West palm beach, Florida, USA.

Authors:

M. Butsashvili [*][1] , G. Kamkamidze [2], D. Metreveli[3], A. Gamkrelidze [4], M. Zakalashvili3, V. Kerashvili [5], E. Dolmazashvili [6], A. Gamezardashvili [1] ;

1 Health Research Union, Tbilisi, Georgia; 2 Clinic NeoLab, Tbilisi, Georgia; 3 Clinic Mrcheveli, Tbilisi, Georgia; 4 National Center for Disease Control and Public Health of Georgia, Tbilisi, Georgia; 5 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia; 6 Clinic Hepa, Tbilisi, Georgia

Background and Aims: Limited data are available on the impact of treatment among HCV patients with advanced liver fibrosis treated with Direct Acting Antivirals (DAAs). The goal of the study is to assess the long-term health outcome among patients with advanced liver fibrosis treated with DAAs after achieving sustained viral response (SVR). We report on two years of data.

Methods: Patients were recruited from four centers that provide care and treatment services for the largest number of patients under the HCV elimination program in Georgia. Eligibility criteria for enrollment in the cohort includes: treated with DAAs in Georgia through the HCV elimination program; having advanced liver fibrosis level by elastography (>=F3) or FIB4 score (>=3.25); beginning treatment during May - December 2015; and achieving SVR at week 24 post treatment. We compared baseline and post treatment changes in fibrosis level (in kpa or FIB4 score), ALT, AST, platelet count (PLT), spleen size an existence of ascites among enrolled patients.

Results: 420 patients who were recruited for the cohort met the eligibility criteria. Mean age of participants was 52 years (range 30-82) and the majority 363/420 (86%) were male. The mean fibrosis level among those measured by elastography decreased significantly (Mean difference 20.6 kpa, p.05). Among those with ascites at baseline (n=9), 7 (77%) experienced resolution, while among the 412 without ascites at baseline 7 (1.7%) were noted to have ascites during the follow-up examination.

Conclusions: Significant improvement of clinical and laboratory parameters was observed 2 years after treatment completion among patients with advanced liver fibrosis treated with DAAs and achieving SVR.

3. **Long-term health outcome among HCV patients with advanced liver fibrosis treated through HCV elimination program in Georgia**

Abstract Presented at ASM Clinical virology symposium, 2018; West palm beach, Florida, USA.

Authors:

M. Butsashvili [*][1] , G. Kamkamidze [2], D. Metreveli[3], A. Gamkrelidze [4], M. Zakalashvili3, V. Kerashvili [5], E. Dolmazashvili [6], A. Gamezardashvili [1] ;

1 Health Research Union, Tbilisi, Georgia; 2 Clinic NeoLab, Tbilisi, Georgia; 3 Clinic Mrcheveli, Tbilisi, Georgia; 4 National Center for Disease Control and Public Health of Georgia, Tbilisi, Georgia; 5 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia; 6 Clinic Hepa, Tbilisi, Georgia

Background and Aims: Limited data are available estimating long-term treatment outcome among HCV patients with advanced liver fibrosis treated with Direct Acting Antivirals (DAAs). The goal of the study was to evaluate long-term health outcome among patients with advanced liver fibrosis treated with DAAs after achieving sustained viral response (SVR).

Methods: The study sites were four main service centers providing care and treatment for HCV patients within HCV elimination program in Tbilisi, the capital of Georgia. The study cohort included patients treated with DAAs through elimination program, having advanced liver fibrosis level by elastography

(>=F3) or FIB4 score (>=3.25) and achieving SVR at week 12-24 post treatment. Random sample of patients treated during May-December 2015 was enrolled. We compared baseline and post treatment changes in fibrosis level (in kpa or FIB4 score), ALT, AST, platelet count (PLT), hemoglobin level (Hb), spleen size and existence of ascites.

Results: 420 patients were included in the study by the time of data analysis. Mean age of participants was 52 years (range 30-82) and the majority were male (86.6%). Statistically significant changes of all variables were observed, except spleen size. The mean fibrosis level for those measured by elastography decreased significantly (Mean difference 20.6kpa, 95% CI:19.5-21.6). Among those whose fibrosis was measured by FIB4, the mean difference was 1.4 (95% CI:1.2-1.6). ALT and AST levels decreased by 79 and 57 IU/ml, respectively (95% CI:72.4-87.3 and 52.2-62.1); PLT count increased by 22000 per microliter (95%CI:17.9-27.7); spleen size decreased by 0.6 and 0.3 cm (95% CI: -0.2.9-8.3 and 2.1-4.0). Ascites was resolved among 80% of those having ascitic fluid at baseline and developed among 1.5% of those not having ascites before the treatment (RR 0.8; 95%CI:0.20-0.31).

Conclusions: Significant improvement of clinical and laboratory parameters was observed 2 years after treatment completion among patients with advanced liver fibrosis treated with DAAs and achieving SVR.

4. **Low HCV reinfection rate after treatment in people who infect drugs (PWID) from a prospective cohort in Tbilisi, Georgia**

Abstract Presented at 7th International Symposium on Hepatitis Care in Substance Users, 2018; Cascais, Portugal.

Authors:
Bouscaillou J [1], Kikvidze T [2], Le Pluart D [1], Butsashvili M [3], Labartkava K [4], Kamkamidze G [3], Inaridze I [2], Kharshiladze D [2], Avril E [5], Lacombe K [6], Boyd A [7], Luhmann N [1]

1 Médecins du Monde France; 2 Médecins du Monde Georgia; 3 Clinic Neolab Georgia; 4 New Vector Georgia; 5 Gaia Paris France; 6 Hospital Saint-Antoine, Service de Maladies Infectieuses et Tropicales, Paris, France; 7 INSERM, Sorbonne Université, Institut Pierre Louis d'Épidémiologie et de Santé Publique, Paris, France.

Background and Aims: People who inject drugs (PWID) are often excluded from HCV treatment programs because of concerns that ongoing drug use could give rise to reinfection after treatment. This study assesses the incidence of HCV reinfection after treatment among PWID in Georgia.

Methods: PWID participants of this study were treated in the framework of Georgia's national HCV elimination program, and received a peer-driven intervention during treatment aimed to reduce at-risk behaviors for reinfection. PWID achieving SVR after HCV treatment were followed at 6 and 12 months post-treatment. A control group of PWID with negative HCV-RNA during initial screening who were seeking care at the same community-based needle and syringe program were also followed at 6 and 12 months post-screening. HCV-RNA measurements and socio-behavioral questionnaires were obtained during visits. HCV incidence rates were calculated for each group.

Results: From July 2015 to December 2017, 169 PWID (81.6% of all HCV participants having been cured) cured after treatment and 19 "control PWID" were included and followed during a median 12.3 and 16.7 months, respectively. The two groups were no different in terms of age, sex, education, housing, and occupation (p>0.05). Reported injecting drug use during the last 6 months was 56.8% in the post-treatment group and 36.8% in the control group (p=0.14). Two people in each group became HCV-RNA positive, corresponding to an incidence rate of 1.2 per 100 person-years in the post-treatment group and 8.3 per 100 person-years in the control group (incidence rate ratio=0.14, 95%CI=0.01–1.97).

Conclusions: In this pilot project, our study demonstrates a low incidence rate for HCV reinfection among PWID in Georgia receiving a peer-driven prevention intervention during treatment. Concerns about reinfection should not be a reason for their exclusion from HCV treatment programs.

5. **Attitude of staff regarding integrated hepatitis C treatment at eight harm reduction centers in Georgia**

Abstract Presented at INHSU 2018, Lisbon, Portugal

Authors:
Butsashvili M[1], Kamkamidze G[1], Kajaia M[1], Gulbiani L[1], Gamezardashvili A[1], Gvinjilia L[2], Kuchuloria T[2], Shadaker S[2], Nasrullah M[3]
1 Health Research Union Tbilisi, Georgia; 2 CDC Foundation; 3 Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia, United States

Background and Aims: Georgia, a country with a large burden of hepatitis C virus (HCV), launched an HCV elimination program in 2015. People who inject drugs (PWID) are at highest risk of transmission as documented by the national HCV seroprevalence survey. To improve linkage to care among PWID, the Ministry of Labor, Health, and Social Affairs decided to pilot HCV treatment integration with harm reduction (HR) services. However, there was concern about potential resistance of employees at HR centers to the inherent added responsibilities. The aim of this study was to evaluate attitudes and readiness of HR centers' staff for integrated HCV treatment.

Methods: A self-administered questionnaire was used with questions regarding awareness of the HCV elimination program, and perceived feasibility and barriers of implementing HCV integrated care at HR centers. Managers, social workers, counselors, laboratory technicians, and nurses were surveyed from eight harm reduction centers at six regions including the capital of Georgia, Tbilisi.

Results: Of a total 115 respondents surveyed, 49% (n=56) were female. The vast majority of surveyed individuals (96% [n=110]) believe HCV treatment should be integrated with HR services. Perceived benefits included convenience for PWIDs (74% [n=85]), improving trust in the elimination program (67% [n=77]), improving linkage to HCV care (76% [n=87]), and improving treatment compliance (56% [n=64]). Most (86% [n=99]) respondents thought that PWIDs would prefer to have HCV treatment at HR centers compared to specialized clinics. Insufficient administrative and technical resources were reported as major barriers to starting HCV treatment at HR centers by 26% (n=30) and 62.6% (n=72) of respondents, respectively.

Conclusions: The study showed the readiness and willingness of HR centers' staff to integrate HCV treatment with other HR services at their facilities, as well as perceived barriers.

6. **Outcomes of hepatitis C antiviral treatment among PWIDs in Georgia**

Abstract Presented at 4th CEE meeting on Viral Hepatitis and HIV,2018; Prague, Check Republic.

Authors:
Gamezardashvili A, Abzianidze T, Kajaia M, Gulbiani L, Barbakadze G, Kamkamidze G, Butsashvili M
Health Research Union Tbilisi, Georgia

Background and Aims: PWIDs are vulnerable and stigmatized population and treatment adherence is a challenge in this target group. Some physicians consider that the treatment of hepatitis C in this group is not reasonable due to poor adherence and non-compliance to treatment regimens that have negative

impact on treatment outcome. The goal of our study was to evaluate the adherence and outcomes of HCV antiviral treatment with direct acting antivirals (DAA) among PWIDs.

Methods: The study subjects were selected from clinic NEOLAB - one of the major treatment providers of HCV elimination program in Georgia. The random sample of HCV patients having recorded injection drug use as a mode of HCV transmission in medical chart was selected. Totally 160 individuals were enrolled in the study. The study instrument was medical chart review, where socio-demographic, clinical and treatment monitoring data are recorded. The treatment adherence was measured by HCV viral load at week 4 and timely show ups at appointments. The treatment data of 200 patients with no history of injection drug use were taken for comparison.

Results: Among 160 study subjects 159 (99.3%) were males. Average age was 44.5 years (range 22-62 years). 17 (10.6%) individuals were on methadone substitution therapy. According to the quantitative PCR-test conducted at week 4 of treatment 95.6% % of study subjects (153 individuals) had undetectable level of HCV RNA. Among 6 individuals RNA was decreased at least by 2log. As for control group, 97% had cleared the virus at week 4. No statistically significant difference was observed. 91% of study subjects timely showed up at clinical appointments. This indicator was 88% among controls.

Conclusions: Our study revealed that PWIDs have high level of treatment adherence and accordingly, PWIDs should be enrolled in HCV treatment programs without any hesitation.

7. **NS5A RASs among HCV RF1_2k/1b patient failed on ledipasvir/sofosbuvir/ribavirin combination within Georgian hepatitis C elimination program.**

Authors:
Marine Karchava[1,2], Mariam Svanidze [1,2], Nikoloz Chkhartishvili[1], Natia Dvali[1], Lana Gatserelia[1,2], Lela Dzigua[1], Lali Sharvadze[1,2,3], Tengiz Tsertsvadze[1,2,3]
1 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia
2 Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia
3 Clinic Hepa, Tbilisi, Georgia

Background and Aims: Georgia has one of the highest HCV prevalence as well as highest frequency of recombinant strain RF1_2k/1b in the world. Effectiveness of different DAAs among RF1_2k/1b patients was evaluated in a study conducted in 2015 in Georgia. Which reported significantly higher cure rates among RF1_2k/1b patients treated with sofosbuvir/ribavirin in combination with interferon and especially ledipasvir/sofosbuvir/ribavirin compared to standard HCV genotype 2 treatments with 12 or 20 weeks of sofosbuvir/ribavirin. Even though SVR rates among RF1_2k/1b patients are high within Georgia's national hepatitis C elimination program, virologic failure still occurs and failing patients are subjected to retreatment with alternative DAA regimens. Most data on the clinical impact of NS5A RASs concern HCV genotype 1 and 3 infections. However, the clinical role of NS5A RASs among HCV genotype 2 patients is still debatable. Moreover, no information is currently available on development and clinical significance of NS5A RASs among RF1_2k/1b patients. Taking into account the sharing of HCV genotype 1 and genotype 2 sequences in RF1_2k/1b genome, as well as low genetic barrier for developing NS5A RASs among HCV genotype 1 NS5A sequence, emergence of NS5A RASs can be responsible for treatment failure among RF1_2k/1b patients.

Methods: We report occurrence of NS5A RASs among HCV infected 70 years old male patient, who was enrolled in hepatitis C elimination program in 2017. Patient has F3 liver fibrosis by metavir (kPa-11.1) and hepatocellular carcinoma. Baseline HCV viral load was 4 280 000 Iu/ml and was infected with HCV G2 by

conventional 5'UTR/Core genotyping. Patient received 12 week of ledipasvir/sofosbuvir/ribavirin and relapsed after treatment completion. NS5A region sequencing was performed using home based semi nested sequencing assay with the following primers: HCV-NS5a_6082_F1: ARTGGATGAACCGRCTRATAGCSTT (6082-6106), HCV-NS5a_6652_R: CCCGWBAYGTARTGGAARTC (6652-6633) and HCV-NS5a_6120_F2: AACCAYGTYTCCCCYACRCACTA (6120-6142). HCV NS5A sequence was analyzed by Geno2pheno [HCV] tool available at http://hcv.geno2pheno.org/index.php.

Results: 520 basepair long NS5A sequence was obtained. Based on the Geno2pheno [HCV] tool, NS5A sequence has similarity to reference D90208 at 90.1% and subtype is 1b. Following polymorphisms were identified: K6R, S17T, L31M, L34IV, T56AT, A92V, Y93H, D126V, F127G, H128V, of which 31M and 93H causing either resistance or reduced susceptibility to all NS5A drugs (Daclatasvir, Elbasvir, Ledipasvir, Ombitasvir, Velpatasvir) except Pibrentasvir.

Conclusions: In conclusion, this case study demonstrates, for the first time, occurrence of L31M and Y93H RASs among RF1_2k/1b patients failing on ledipasvir/sofosbuvir/ribavirin therapy. Which indicates that emergence of these RASs among RF1_2k/1b patients could cause DAA treatment failure. Therefore, performing NS5A sequencing on RF1_2k/1b patients failing on ledipasvir/sofosbuvir/ribavirin therapy could be extremely important for achieving individual and public health benefit.

8. **Factors associated with sustained viral response among HCV genotype 2 patients treated with direct acting antivirals within HCV elimination program in Georgia**

Abstract Presented at 4th CEE meeting on Viral Hepatitis and HIV,2018; Prague, Check Republic.

Authors:
Butsasvili M, Gulbiani L, Kajaia M, Gamezardashvili A, Abzianidze T, Pachkoria E, Kochlamazashvili M, Mgaloblishvili T, Kamkamidze G
Health Research Union Tbilisi, Georgia/Clinic Neolab

Background and Aims: Georgia has a high burden of HCV infection; a 2015 national serosurvey found that an estimated 5.4% of adults are currently infected with HCV. On April 28, 2015, Georgia launched the world's first National HCV Elimination Program that included free of charge treatment with DAAs for all HCV infected persons. The DAAs for the elimination program are donated by Gilead Sciences, and sofosbuvir was the first DAA available for the program. Later sofosbuvir/ledipasvir became available. Objective of this study was to assess the real-world data of treatment outcome among patients with HCV genotype2 treated with direct acting antivirals.

Methods: Study enrolled genotype2 patients, enrolled in HCV elimination program in Georgia and treated at one of the leading clinics providing HCV care services. These patients were treated with sofosbuvir or sofosbuvir/ledipasvir in combination with ribavirin. We analysed demographic and clinical data of patients achieving sustained viral response (SVR) by the time of analysis. Fibrosis level of patients was measured by liver elastography or FIB4 score (>=F3 and >3.25 were considered as high fibrosis level, respectively) Bivariate and logistic regression analysis was used to assess the association between SVR and several other factors.

Results: A total of 817 genotype 2 patients were eligible for the analysis; there were more males (88.9%). Females had higher chance of achieving SVR compared to males (98.9% vs 94.5%, p<0.05). Patients treated with sofosbuvir/ledipasvir and ribavirin combination were more likely to achieve SVR (97.6% as opposed to 77.8% of those treated with sofosbuvir and ribavirin). 99.4% of patients with low fibrosis level cleared the virus with 87.1% of those having high fibrosis level (p<0.0001). There was no

statistically significant difference in cure rate of patients by the following variables: ever using injection drugs, socio-economic status, diabetes and body mass index. After adjustment, independent predictors of SVR were treatment regimen and liver fibrosis level.

Conclusions: Real-world experience among HCV genotype2 patients demonstrated very high SVR rate for those treated with sofosbuvir/ledipasvir and ribavirin combination.

9. **Approaches to providing hepatitis C viremia testing to people who inject drugs in Georgia**

Abstract Presented at 4th CEE meeting on Viral Hepatitis and HIV,2018; Prague, Check Republic.
Authors:
Chihota V, Japaridze M, Shilton S, Ruiz R, Francois Lamoury O'Brien J, Khonelidze I, Butsashvili M, Alkazashvili M, Marinucci F

Background and Aims: In line with the WHO hepatitis C virus (HCV) elimination targets, Georgia embarked on an elimination programme in 2015. However, a large proportion of infected persons remain unaware of their infection. To expand the treatment more widely to those at high risk of HCV infection, people who inject drugs (PWID) are prioritized for test and treat strategies. Though anti-HCV screening for PWID has been implemented at point-of-service, access to confirmatory viremia testing remains a major barrier. We evaluated two novel approaches to improve access to viremia testing among PWID attending for care at harm reduction sites (HRS).

Methods: This is an ongoing non-randomized interventional study where HRS are assigned to one of three arms i) at four HRS, decentralized testing (Arm 1) where blood draw, viremia testing and results provision is done on-site on the same day, ii) at two HRS a centralized viremia testing approach is implemented (Arm 2) with blood draw on site and testing at a centralized lab. Test results are made available at HRS at a follow up visit, iii) at two HRS testing is done as per standard of care (Arm 3) where patients are referred to a treatment centre for testing and results provided at the treatment centre. Arm 1 and Arm 2 are using "HRS-based-approaches" as participants have blood drawn and receive test results at HRS. Participants are eligible for the study if they tested anti-HCV positive on the same day and did not have confirmed diagnosis. The proportion of participants who received their HCV viremia test result are compared across the three arms. We assess time to reporting of results.

Results: Between 21 May and 30 June 2018, 305 participants were enrolled [183(60%) in Arm 1, 57(19%) in Arm 2; 65(21%) in Arm 3]. Participants were predominantly male (95%), median age 42 years and 81% were currently injecting drugs. 289 (95%) participants reported having taken an HIV test and of these 288(99.7%) self-reported being negative and one did not know their status. To date all participants enrolled in Arm 1 and 2 have had blood drawn for viremia testing and similarly all participants enrolled in Arm 3 were referred to treatment centers for testing. To date, 280 participants who had a confirmatory viremia test done and of these, 248(88.6) received their results (183 in Arm 1, 57 in Arm 2 and 8 Arm 3). Of those with results, 215(86.7%) were positive while 33(13.3%) were negative. On average participants received their results the same day (on average within 3 hours) in Arm 1, 5 days in Arm 2 and 14 days in Arm 3 from the time they had blood drawn for testing.

Conclusions: Providing blood draw for HCV confirmatory viremia testing at HRS where PWIDs attend for care/needle provision improves access to HCV confirmatory viremia testing. The "HRS based approaches" resulted in a larger proportion of participants receiving their confirmatory test results and the turnaround time was shortest where blood draw at HRS was combined with on-site testing.

10. **Characteristics of patients with missing sustained virologic response (SVR) data, elimination program in Georgia**

Abstract Presented at International Viral Hepatitis Elimination Meeting (IVHEM) 2018 Amsterdam, Netherlands.

Authors:

Lasha Gulbiani, Maia Butsashvili, Maia Kajaia, Marika Kochlamazashvili, Tinatin Abzianidze, Elene Pachkoria, Ana Gamezardashvili, George Kamkamidze

Health Research Union/Clinic Neolab

Background and Aims: The HCV Elimination Program in Georgia, starting in 2015, set the ambitious goal of curing 95% of patients treated, defined as achieving sustained virologic response (SVR). Unfortunately, loss to follow-up may lead to biased interpretation of results if the missing tests to ascertain SVR status belong to a group of patients whose response to treatment influences the observed outcomes. Objective of this study was to compare characteristics of HCV patients having SVR test at 12-24 weeks after completion of antiviral treatment to patients lost to follow up and not having SVR test.

Methods: Data were extracted from elimination program database of clinic NeoLab, one of the major implementers of HCV elimination program. Socio-demographic, behavioral and clinical data of all patients treated with direct acting antiviral (DAA) treatment are entered in this database. Characteristics of patients who had SVR test at 12-24 weeks after treatment were compared to those who did not show up for SVR visit.

Results: Overall, 2296 DAA treated patients reached the point of 24 weeks after completion of treatment and were eligible for the analysis (patients who died or stopped the treatment were excluded from the analysis). Majority were males (88.3%). Gender was significantly associated with having SVR test (11.8% of males did not show up for SVR test vs 5.3% of females. PR=0.418. 95% CI:0.26-0.65). Other variables with statistically significant association with SVR test were: 1). Alcohol consumption before the treatment (8.8% of non-users and 12.8% of users did not have SVR test); 2) History of injection drug use (9.3% of those who never used drugs vs 13.3% of PWID did not come to SVR visit); 3) Fibrosis level (patients with advanced fibrosis by liver elastography or FIB4 test were less likely to have SVR test compared to those with lower fibrosis level (PR=0.66; 95% CI:0.48-0.90). Age, socio-economic status, genotype and residence (rural vs urban) were not significantly associated with compliance to SVR visit schedule.

Conclusions: There were differences between the groups of patients who had or did not have SVR test. Activities to improve patients' compliance to the follow-up visit should be planned, particularly in the groups of people with lowest show up rate.

11. **Effective Treatment of RF1_2k/1b Patients By Ledipasvir/Sofosbuvir/Ribavirin within Georgian National Hepatitis C Elimination Program.**

Abstract Presented at AASLD Liver Meeting 2018; San Francisco, CA, USA.

Authors:

Marine Karchava[1,2], Nikoloz Chkhartishvili[1], Lali Sharvadze[1,2,3], Akaki Abutidze[1,2], Natia Dvali[1], Lana Gatserelia[1,2], Lela Dzigua[1], Natalia Bolokadze[1,3], Adam Kotorashvili[4], Paata Imnadze[4], Amiran Gamkrelidze[4], Muazzam Nasrullah[5], Francisco Averhoff[6], Tengiz Tsertsvadze[1,2,3]

1 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia; 2 Hepatology Clinic- Hepa, Tbilisi, Georgia; 3 Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia; 4 National Center for Diseases Control and Public Health, Tbilisi, Georgia; 5 South Caucasus CDC Office, Tbilisi, Georgia; 6 Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, CDC, Atlanta, GA, USA

Background and Aims: HCVRF1_2k/1b strain is common in ethnic Georgians. This chimera virus contains genomic fragments of genotype 2 and genotype 1 and is misclassified as genotype 2 if only structural region is studied. We aimed to evaluate impact of RF1_2k/1b strain on DAA treatment outcomes within Georgian national hepatitis C elimination program.

Methods: Study included 381 patients with HCV genotype 2 as determined by 5'UTR/Core genotyping assay. NS5B sequencing was also performed for genotype clarification. Confirmation of breakpoint positions among selected RF1_2k/1b patients was performed by whole genome sequencing. Study patients were treated with either SOF/RBV or LDV/SOF/RBV regimens.

Results: Treatment response rates among HCV genotype 2 patients receiving HCV care within national hepatitis C elimination program were evaluated. Of total 381 patients enrolled 287 (75.3%; 95% CI: 70.7-79.6%) had RF1_2k/1b strain and 94 had HCV 2a, 2k, or 2c subtypes. Of total patients 336 (88.2%) were male, median age was 49.9 (IQR-42.1-55.3%) and liver cirrhosis was observed among 77 (20.2%). As of May 2018, SVR was accessed for 284. It was achieved in 97.2% (70/72) of genotype 2 and 89.2% (189/212) of RF_2k/1b patients (p=0.05), with a total SVR rate of 91.2% (259/284). Highest SVR rate was observed among patients treated with LDV/SOF/RBV among both genotypes (99.5%).

For patients with cirrhosis SVR in genotype 2 was 93.3% (14/15) compared to 85.0% (34/40) in RF1_2k/1b (p=0.66). Among non-cirrhotic patients, genotype 2 also had better response (SVR 98.2% [56/57]) as compared to RF1_2k/1b (SVR 90.1% [155/172]), (p=0.05). Statistically significant difference was observed in response rates to SOF/RBV (94.2% genotype 2 vs. 64.6% RF1_2k/1b, p=0.02). Among patients with RF1_2k/1b LDV/SOF/RBV was superior (SVR 100.0 % [147/147]) to SOF/RBV (SVR 64.6% [42/65], p<0.0001).

Conclusions: High prevalence of RF1_2k/1b strain can significantly affect treatment outcomes. In our study, LDV/SOF/RBV found to have significantly higher SVR in patients infected with RF1_2k/1b strain as compared to standard HCV genotype 2 treatments with SOF/RBV. There is need for reassessing existing modalities for the management of HCV genotype 2 infections, especially in areas with high prevalence of RF1_2k/1b strain.

12. **Three years of progress towards achieving hepatitis C elimination in the country of Georgia, April 2015 – March 2018**

Abstract Presented at AASLD Liver Meeting 2018; San Francisco, CA, USA.

Authors:
Tengiz Tsertsvadze,[1,2] Amiran Gamkrelidze,[3] Nikoloz Chkhartishvili,[1] Akaki Abutidze,[1] Lali Sharvadze,[2,4] Vakhtang Kerashvili,[1] Maia Butsashvili,[5] David Metreveli,[6] Lia Gvinjilia,[7] Shaun Shadaker,[8] Muazzam Nasrullah,[8] Ekaterine Adamia,[9] Stefan Zeuzem,[10] Nezam Afdhal,[11] Sanjeev Arora,[12] Karla Thornton,[13] Francisco Averhoff[8]

1 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia; 2 Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia; 3 National Center for Disease Control and Public Health, Tbilisi, Georgia; 4 Hepatology clinic HEPA, Tbilisi, Georgia; 5 Health Research Union, Tbilisi, Georgia; 6 Medical Center Mrcheveli, Tbilisi, Georgia; 7 CDC Foundation, Tbilisi, Georgia; 8 Centers for

Disease Control and Prevention, Division of Viral Hepatitis National Center for HIV, Hepatitis, STD&TB Prevention, Atlanta, USA; 9 Ministry of Labour, Health and Social Affairs of Georgia, Tbilisi, Georgia; 10 Goethe University Hospital, Frankfurt, Germany; 11 Beth Israel Deaconess Medical Center Liver Center, Boston, USA; 12 University of New Mexico, Albuquerque, USA

Background and Aims: In April 2015, in collaboration with U.S. CDC and commitment from Gilead Sciences to donate direct acting antivirals (DAAs), Georgia embarked on the world's first hepatitis C elimination program. The country set forth 90-95-95 targets to be achieved by 2020: a) diagnose 90% of HCV-infected persons, b) treat 95% of those diagnosed, and c) cure 95% of those treated. We aimed to assess the three years progress in reaching the elimination targets.

Methods: A hepatitis C care cascade was constructed from available data. A national serosurvey in 2015 estimated that 150,000 persons ≥ 18 years of age were infected with HCV in the country. The number of HCV infected persons, diagnosed, treated, and cured were obtained from the national hepatitis C elimination program treatment databases for the period from April 28, 2015 through March 31, 2018. Persons assessed for SVR were included in treatment efficacy analysis. SVR rates were stratified by HCV genotype and degree of liver fibrosis; advanced fibrosis was defined as FIB-4 score >3.25 or ≥F3 by METAVIR fibrosis score on transient elastography.

Results: Among estimated 150,000 adults living with HCV in Georgia, 52,856 (35.1%) were diagnosed and registered in the treatment program. A total of 45,334 (30.2%) initiated treatment with a DAA. Of 29,620 who completed treatment and were assessed for SVR, 29,090 (98.2%) achieved SVR (Figure). Most of the 29,620 persons with complete SVR data, 85.6% (n=25,362) were treated with ledipasvir/sofosbuvir (LDV/SOF) based regimens, while 4,258 (14.4%) received sofosbuvir (SOF)-based treatment. The overall SVR rate was 98.2%.The SVR rate was 97.3% among persons with advanced fibrosis, and was comparable to the SVR rate among persons without advanced fibrosis (98.7%). High cure rates were achieved among all HCV genotypes: 98.5% in genotype 1, 98.3% in genotype 2 and 97.7% in difficult to treat genotype 3.

Conclusions: Georgia hepatitis C elimination program has achieved high cure rates for patients with genotype 1, 2, and 3, including patients with advanced fibrosis even without newer generation DAAs. Scaling-up testing and diagnosis, along with effective linkage to treatment services and prevention interventions are needed to achieve the elimination goals.

Figure. Hepatitis C care cascade as of March 31, 2018
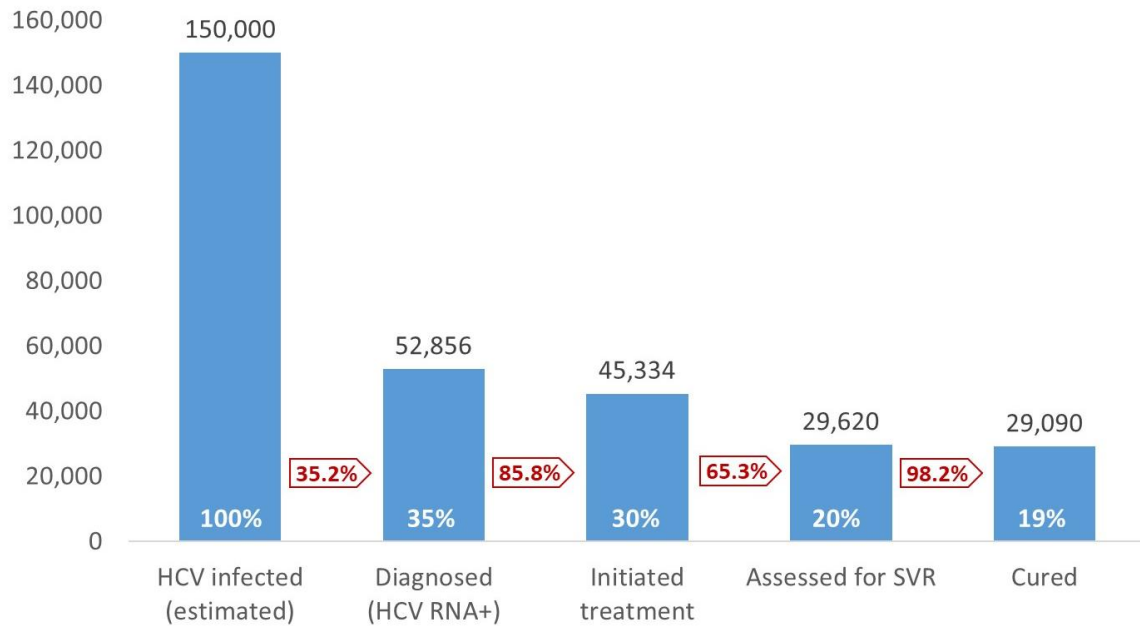
13. HCV screening among the population of Georgia within the National Elimination Program

Authors:
Davit Sergeenko[1], Maia Lagvilava[1], Ana Aslanikashvili[2], Maia Tsereteli[2], Davit Baliashvili[3], Vladimer Getia[2], Alexander Turdziladze[2], Irma Khonelidze[2], Maia Alkhazashvili[2], Ekaterine Adamia[1], Paata Imnadze[2], Amiran Gamkrelidze[2]
1 Ministry of Labour, Health and Social Affairs, Tbilisi, Georgia; 2 National Center for Disease Control and Public Health, Tbilisi, Georgia; 3 Emory University, Rollins School of Public Health, Department of Epidemiology, Atlanta, Georgia, USA
Background and Aims: Georgia is high hepatitis C (HCV) prevalence country. According to the latest nationwide seroprevalence study conducted in 2015, 7.7% of the population is anti-HCV antibody positive and 5.4% has chronic hepatitis C infection. Since the launch of the National HCV Elimination Program in 2015, the country of Georgia has stepped up its efforts to achieve the goals of the National HCV Strategy and identify 90% of the HCV infected population by 2020. Therefore, screening campaigns became massive and rigorous in the country, with the active involvement from public and private organizations. Over 800 sites provide HCV screening across the country free-of-charge, following the National HCV Screening Protocol approved by the Ministry of Health. Full coverage is achieved among blood donors, pregnant women, hospitalized patients and military recruits.
Methods: This analysis was prepared based on the data from the unified electronic HCV screening database, which is being used by all screening provider sites. The database is administered by the National Center for Disease Control and Public Health and it captures information of each HCV screening

performed in the country. We looked at the numbers of screened individuals by different populations, as well as positivity rates among them.

Results: Since the launch of the Elimination Program in April 2015 through April 2018, more than 1.2 million individuals have been screened on HCV, with the overall positivity rate – 9%. Positivity rates vary through the population groups, with the lowest rate among pregnant women (0.5%) to the highest prevalence in state opioid-substitution therapy beneficiaries (91.3%) (Figure 1). Infection is also highly prevalent in people with hemophilia (62.5%) and people living with HIV (39.7%).

Conclusions: More than one third of the adult population has been screened in Georgia and about half of estimated number of anti-HCV positive adult population were identified. Although, to reach the national strategy goals, it is required to increase screening coverage and reach the people who have never been tested, as well as raise awareness among population and improve infection control in medical and non-medical facilities to prevent transmission and reduce the number of new infections.

Figure 1. HCV screening in different population groups (April 2015 – April 2018)
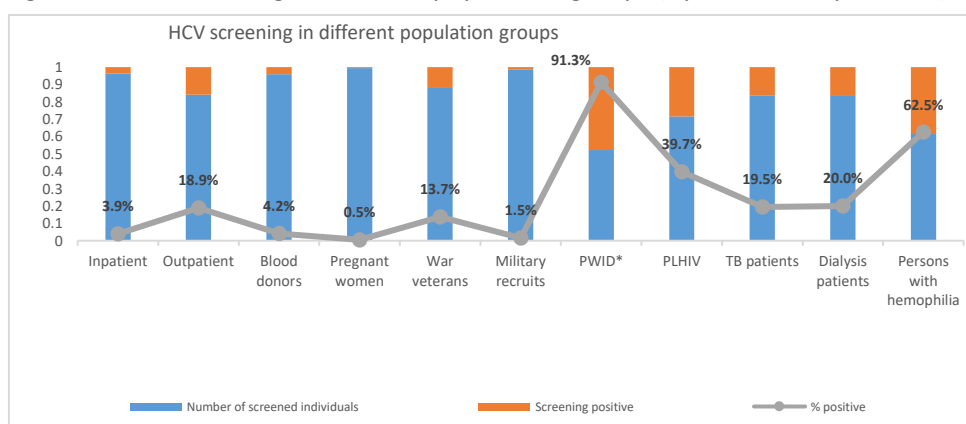
* State Opioid-Substitution Program beneficiaries screened on HCV

14. Emergence of NS5A RASs among HCV RF1_2k/1b patients treated within Georgian hepatitis C elimination program: a case report

Abstract Presented at AASLD Liver Meeting 2018; San Francisco, CA, USA.

Authors:
Tengiz Tsertsvadze [1,2,3], Marine Karchava[1,2], Mariam Svanidze[1,2] Lali Sharvadze [1,2,3]
1 Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia; 2 Hepatology Clinic-Hepa, Tbilisi, Georgia; 3 Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia

Background and Aims: Georgian guidelines recommend treating HCV genotype 2 patients exclusively with Ledipasvir/Sofosbuvir/Ribavirin (LDV/SOF/RBV) due to the high prevalence of RF1_2k/1b strain in the country. Even though this combination yielded high cure rates at 98.8%, virologic failure still occurs.

The clinical impact of NS5A RASs among HCV genotype 2 patients is debatable. Moreover, no information is available on significance of NS5A RASs among RF1_2k/1b patients. Considering specifics of RF1_2k/1b strain, namely insertion of 1b sequence in NS5A genome, also low genetic barrier for developing NS5A RASs among 1b, emergence of NS5A RASs can be responsible for treatment failure. Thus, we aimed to identify if NS5A RASs cause failure among HCV genotype 2 patients within Georgian national hepatitis C elimination program.

Methods: We report occurrence of NS5A RASs among two patients treated with LDV/SOF/RBV. First patient was a 70 years old male with F3 liver fibrosis (kPa-11.1) and hepatocellular carcinoma. Baseline HCV viral load (VL) was 4 280 000 Iu/ml. Second patient was a 59 years old female, with a F3 liver fibrosis (kPa-10.6) and HCV VL 3 000 000 Iu/ml. Both patients were infected with genotype 2 by 5'UTR/Core genotyping. NS5A sequencing on both baseline and post-treatment specimens was performed using home based semi-nested sequencing assay and analyzed by Geno2pheno [HCV] tool available at http://hcv.geno2pheno.org/index.php. Whole genome sequencing was performed to confirm infection with RF1_2k/1b strain.

Results: Quality, 520 base pair long NS5A sequences were obtained, indicating NS5A sequence similarity to subtype 1b for both patients. Whole genome sequencing revealed infection by RF1_2k/1b and recombinant breakpoint position at 3175 bp within NS2 region. Analysis of post treatment NS5A sequences revealed emergence of L31M and Y93H RASs compare to baseline. These major RASs caused resistance or reduced susceptibility to all NS5A drugs (Daclatasvir, Elbasvir, Ledipasvir, Ombitasvir, Velpatasvir) except Pibrentasvir in both patients.

Conclusions: These cases demonstrate, for the first time, emergence of L31M and Y93H RASs among RF1_2k/1b patients failing on LDV/SOF/RBV therapy. Therefore, NS5A sequencing for HCV genotype 2 patients failing LDV/SOF/RBV combination could be extremely important, especially for high RF1_2k/1b prevalent regions in order to achieve individual and public health benefit within hepatitis C elimination programs.

POSTER REFERENCE NUMBER: 15

Increasing Hepatitis C disease awareness, diagnostic and linkage to care into harm reduction program in Georgia

M.Gogia, MD, MPH; K.Stvilia, MD, G.JIKIA, MD, MPH; MPH; K.Kvashilava; S. Asatiani; Member organizations of Georgian Harm Reduction network

BACKGROUND

HIV and HCV remain significant public health challenges in Georgia. The most affected risk groups for both infections are PWIDs. Prevalence of HCV in PWIDs that varies between **50-92%** illustrates high magnitude of the problem. HCV screening was accessible in harm reduction program since 2006, but due to high cost the treatment was not affordable, especially for key populations. Georgian harm reduction network-GHRN was actively involved into a long advocacy process demanding free treatment for HCV patient PWIDs. Under strong civic pressure Government had to act and National HCV elimination program took a start from 2015 with aims to eliminate HCV by 2025 in country.

New model practices of the harm reduction programs including tandem testing on HIV and HCV allowed increasing the number of PWIDs tested for HCV twice in 2016 (26,025) in comparison to 2014. 42.6% of testing was conducted through outreach testing by mobile ambulatories. 10,926 PWIDs were referred to HCV treatment sites, however, lack of effective linkages between the harm reduction and HCV treatment databases complicates work of case managers for follow up support of PWIDs enrolled in care and can't generate the complete data of GHRN work.

METHODS

In order to react proactively towards its new role for the hepatitis C elimination, GHRN has developed new targeted interventions which were aligned with HIV prevention interventions supported by the GFATM HIV program. The emphasis was placed on increased HIV/HCV tandem screening of PWID population through expanding outreach capacities of the program. For avoiding stigma and self-stigma factors HCV testing was offered to general population as well by harm reduction sites. Mobile ambulatories expanded the program coverage to 32 cities allowing testing of additional 11,101 PWIDs in 2016.

Diagram N1 Increased HCV testing at harm reduction program
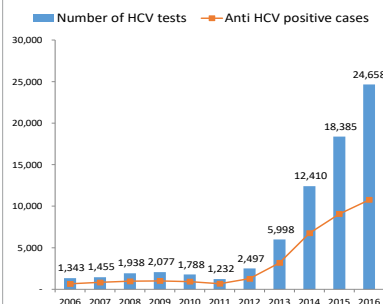
RESULTS

GHRN with support of other international organizations started piloting of patients' schools and peer driven interventions (PDI). HIV and HCV Tandem testing was supported by the GFATM HIV program. Collaboration with Police was initiated to gain their support for outreach work. HCV education module was included in existing PDI educational programs, informational-education flyers and brochures about HCV were delivered to PDI program participants as well. Case managers that were mostly people living with viral hepatitis were ensuring linkage of screening positive PWIDs to HCV treatment sites.

Recent HCV data at harm reduction program		
Activity	Year	Number
HCV cases among PWIDs included in HCV treatment program	2015- 2016	2,377
Detected HCV cases among PWIDs	2017 (6 months)	4908
Number of HCV cases (PWIDs) supported to be included in HCV treatment	2017 (6 months)	2067
HCV positive cases among general population screened by harm reduction sites	2017 (6 months)	1223

CONCLUSIONS

Capacities of the harm reduction programs can effectively be used for early detection, linkage to treatment services for HCV positive PWIDs. Proper risk counseling and disease awareness activities are inevitably important to decrease the risk of re-infection among PWIDs. Strong Integration between HCV and HIV programs ensures cost-effectiveness of both interventions. Unified screening and treatment databases are critical for success of the elimination program. Besides, initiation of HCV national program enabled initiation dialogue with Police officials to smooth attitude to harm reduction program.

REFERENCES

The harm reduction project is a part of National HIV prevention program supported by the Global Fund. National Center for Disease Control and Public Health is a Principal Recipient of the Global Fund Grant and Georgian Harm Reduction Network (GHRN) is Sub-Recipient and of this grant. The authors want to thank all of the NGOs that are members of GHRN and were directly involved in service delivery process: Step to Future (Gori,Telavi) Ketevan Bidzinashvili, Kakhi Gemazashvili; New Way (Tbilisi, Kutaisi, Samtredia) Dali Usharidze, Zaza Karchkhadze Nana Darsavelidze; New Vector (Tbilisi, Rustavi) Koka Labartkava; Lasha Abesadze; Qsenoni (Zugdidi) Nino Janashia; Imedi (Batumi) Zoria Tsurtsumia; Hepa plus (Tbilisi) Manana Sologashvili; Fenix (Ozurgeti) Otari Jijieshvili; Ordu (Poti),Vakhtang Gamsakhurdia; Aceso (Tbilisi) Irakli Kirtadze.

CONFLICTS OF INTEREST

There is no conflict of interest depicted by the authors

Contact Information
NAME Guranda JIkia
TEL NO +995 595 142888
EMAIL gjikia@hrn.ge

Hepatitis C Screening Within the National Elimination Program in the Country of Georgia

A. GAMKRELIDZE[1], A. TURDZILADZE[1], V. GETIA[1], M. ALKHAZASHVILI [1], M. TSERETELI [1], A. ASLANIKASHVILI [1], D. BALIASHVILI [2] and P. IMNADZE [1]
1National Center for Disease Control and Public Health, Tbilisi, Georgia
2Emory University, Rollins School of Public Health

INTRODUCTION

Georgia is among the countries with high hepatitis C (HCV) prevalence.

Based on the nationwide seroprevalence survey conducted in 2015, 7.7% of the total population is hepatitis C antibody positive and the prevalence of active disease is 5.4%.

In 2015, Georgia launched the large-scale public health program with the ambitious goal to eliminate hepatitis C by 2020.

Georgia's National Hepatitis C Elimination Strategy (2016-2020) sets forth the following targets:

✓ identify 90% of hepatitis C infected people,
✓ treat 95% of the identified individuals and
✓ Achieve sustained virologic response in 95% of those treated.

AIM

Georgia has significantly scaled up the screening activities during recent years. HCV screening is provided free-of-charge in more than 600 centers countrywide, including inpatient and outpatient facilities, prisons, Georgian Harm Reduction Network sites, Public Health Centers, pharmacies, etc.

METHOD

Screening is performed according to the National Screening Protocol approved by the Georgian Government.

Universal coverage with hepatitis C screening is ensured for certain population groups, such as pregnant women, blood donors, hospitalized patients and recruits. Screening-related data for these groups are entered in corresponding databases.

Unified electronic HCV screening module was created to capture the data from all national HCV screening programs. Outpatient screening providers enter the data into the module on-site. The module is using personal IDs based on a link with Public Registry that allows to synchronize HCV-related data from different databases, such as HCV treatment database, unified electronic blood donor module, hospitalized patient's electronic module and birth registry.

For individuals with high-risk behavior personal ID number is replaced with the 15-digit code which allows to enter screening data without disclosing the identity.
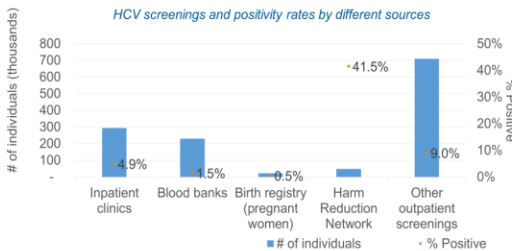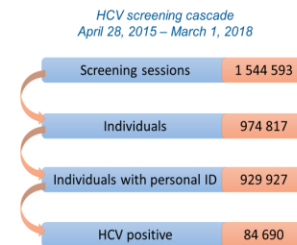
RESULTS

As of March 2018, 1 544 593 screening tests were registered in the electronic screening module, of which 8.2% were positive.

974 817 individuals were screened with 10.6% positivity rate.

The proportion of positive results were considerably higher in males compared to females with the positivity rates of 16.9% and 4.1%, respectively.

Infection was mainly concentrated in 30-59 age group (78.0% of all screening positive cases) which reflects the 2015 seroprevalence study findings.

HCV screening cascade
April 28, 2015 – March 1, 2018

Screening sessions	1 544 593
Individuals	974 817
Individuals with personal ID	929 927
HCV positive	84 690

HCV screenings and positivity rates by different sources

The charts demonstrate the numbers of screenings registered in the electronic HCV screening module from April 2015 to March 2018.

HCV screenings and positivity rates in different population groups
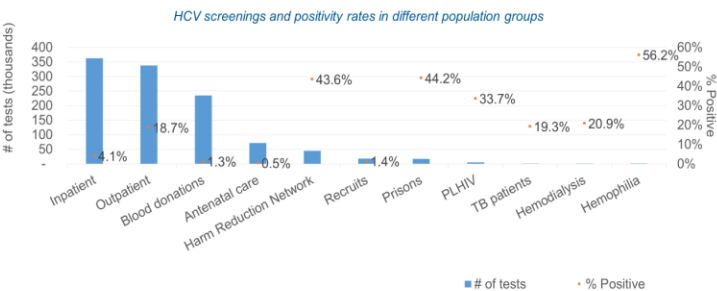
CONCLUSIONS

HCV prevalence is high in Georgia, especially in certain population groups with high risk behaviour.

Georgia has markedly strengthened hepatitis C screening interventions and has already covered significant part of its population.

Although, to reach the set goals, screening activities need to be expanded further. Extending screening over the total population is still a challenge and requires a multisectoral approach.

ACKNOWLEDGEMENTS

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CONTACT INFORMATION

National Center for Disease Control and Public Health
pr.ncdc@ncdc.ge
www.ncdc.ge

PROGRESS TOWARD HEPATITIS C VIRUS ELIMINATION THROUGH PROVISION OF CARE AND TREATMENT SERVICES, GEORGIA, 2015-2017

D.SERGEENKO[1], A. GAMKRELIDZE[2], T. TSERTSVADZE[3], G. KAMKAMIDZE[4], D. METREVELI[5], L. SHARVADZE[6], M. TSERETELI[7], A. ASLANIKASHVILI[8], E. ADAMIA[9], L. GVINJILIA[10], M. NASRULLAH[11], T. KUCHULORIA[12], F. AVERHOFF[13]

1Ministry of Labor, Health and Social Affairs of Georgia; Minister; 2National Center for Disease Control and Public Health; Director General; National Center for Disease Control and Public Health; 3Infection Diseases, Aids, and Clinical Immunology Research Center; Director; 4Tbilisi State Medical University; Health Research Union 5Medical Center Mrcheveli; Head of Department 6Hepatology Clinic Hepa; Hepatology Clinic Hepa; 7National Center for Disease Control and Public Health; Head of Department Hiv/Aids, Hepatitis, Sti & Tb; 8National Center for Disease Control and Public Health; Ncdc; 9Ministry of Labour, Health and Social Affairs; State Programs Department; 10Cdc Foundation; Cdc Foundation; 11Centers for Disease Control and Prevention; Division of Viral Hepatitis, National Center for Hiv/Aids, Viral Hepatitis, Std and Tb Prevention; 12Cdc South Caucasus Office; Georgia Hepatitis C Elimination Program; 13Centers for Disease Control and Prevention; Division of Viral Hepatitis National Center for Hiv/Aids, Viral Hepatitis, Std, and Tb Prevention.

INTRODUCTION

The country of Georgia has high burden of hepatitis C virus (HCV) infection. The nationwide seroprevalence survey conducted in 2015, indicated 5.4% of adults (approximately 150,000 persons) with active HCV infection (RNA positive).

AIM

In April 2015, the Georgian government, in collaboration with CDC, Gilead Sciences and other partners embarked on a national program to eliminate HCV by 2020, defined as decreasing prevalence of active infection by 90%; a key strategy is scaling up HCV treatment by ensuring access to free of charge treatment for all infected persons.

METHOD

- Data from all screening and treatment sites are collected and analyzed by the Georgia National Center for Disease Control and Public Health and Ministry officials.
- All data from treatment providers are entered into a web-based database.
- A unified electronic screening registry captures data from all national and local HCV screening programs throughout Georgia.
- Data from the screening and treatment programs are linked by a unique identification number.
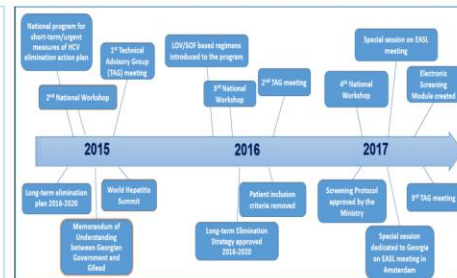- these data were analyzed to describe the national cascade of care.

RESULTS

- From April 28, 2015 through October 31, 2017, more than 1.4 million HCV, screening sessions were performed and 45,225 HCV infected (RNA positive) individuals were registered for the treatment program.
- Among those who registered, 40,420 (89.4%) individuals initiated treatment, approximately 27% of the estimated 150,000 persons living with HCV in the country.
- Of those who initiated treatment, 36,012 (81%) completed treatment.
- Among individuals with available data on sustained virologic response (SVR) i.e., cure (n=32,835), the overall SVR was 98.2%.
- 14 Harm reduction centers across the country provide HCV services to ensure the high coverage among people who inject drugs and their sexual partners.
- Significant progress has been reached in infection prevention and control in medical and non-medical facilities, as well as in blood safety regulations.
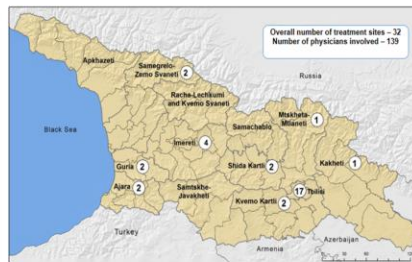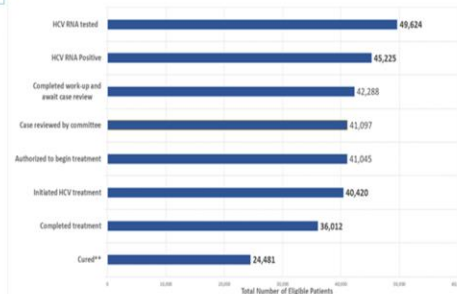

Road towards HCV Elimination

Geographic distribution of HCV treatment provider sites

Georgia Hepatitis C Elimination Program Care Cascade
April 28, 2015 – October 31, 2017
** of 32,835 patients eligible for SVR assessment, 24,930–were tested, 24,481 (98.2%) achieved SVR, 7.905 (24%) missing data

CONCLUSIONS

- In the first 30 months of the HCV Elimination Program, Georgia has scaled up the screening and treatment services achieving impressive cure rates.
- These activities represent a key step towards reaching the established national HCV elimination goals.
- The Georgia HCV Elimination Program has made substantial progress since its launch in April 2015; the country has demonstrated the ability to scale up HCV care and treatment services rapidly.
- Enhancing HCV testing and linkage to care and treatment services are critical to reaching the 2020 HCV elimination goal.
- Lessons learned from the Georgia elimination program can inform programs in other countries striving to eliminate HCV as a public health threat.

ACKNOWLEDGEMENTS

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DOI: http://dx.doi.org/10.15585/mmwr.mm6629a2

CONTACT INFORMATION

Sofo Belkania, MoLHSA; Email: sbelkania@moh.gov.ge; Tel: +995599 223232.

High agreement with HCV RNA in screening and DAA treatment monitoring indicates that cost-effective HCV core Ag test can also be enlisted in the fight to eliminate hepatitis C

Nazibrola Chitadze [1], Maia Alkhazashvili[1], Gvantsa Chanturia[1], Roena Sukhiashvili[1], George Kamkamidze[2], Beth Skaggs[4], Francisco Averhoff[3], Jan Drobeniuc[3], Gavin Cloherty[5], Amiran Gamkrelidze[1]

[1]National Center for Disease Control and Public Health, Tbilisi, Georgia; [2]Clinic NeoLab Tbilisi, Georgia; [3]Division of Viral Hepatitis, Centers for Disease Control and Prevention, Atlanta, GA, USA; [4]Division of Global Health Protection, Centers for Disease Control and Prevention, Atlanta, GA; [5]Abbott Diagnostics, Abbott Park, IL, United States.

INTRODUCTION

- In light of recent advances in HCV therapy, simplification of diagnosis confirmation, pre- treatment diagnostic workup and treatment monitoring is required to ensure broad access to interferon-free therapies.

- HCV core antigen (HCVcAg) is a serologic marker of HCV infection highly concordant with HCV RNA testing- the current standard of care.

AIM

- The aim of this study was to assess feasibility of the HCVcAg test as a high throughput and cost-effective alternative to HCV NAT to determine active HCV infection in screening and DAA treatment monitoring program.

METHOD

The study consisted of two arms:
1) Evaluation of a new HCV screening algorithm that will include reflex HCVcAg testing for confirmation of active infection in anti-HCV-positive participants; and
2) Feasibility of HCVcAg test for monitoring patients on DAA therapy.

- The first arm included 4,235 samples obtained from regular screening sites of the hepatitis C elimination program in Georgia- Blood Banks, Harm Reduction Networks (HRN), Provider Clinics, Screening centers, and from the National Seroprevalence Survey (NSS).
- In the second arm a total of 976 samples were collected at Baseline, Week 4, End of Treatment (EOT), and 12 weeks post treatment, submitted by three provider clinics in Georgia.
- HCV RNA and genotype testing was conducted at the clinics using standard of care Nucleic Acid Test (NAT).
- Specimens were tested with the ARCHITECT HCVcAg assay at the Georgia NCDC R. Lugar Center for Public Health Research.
- Percent agreement between HCVcAg and HCV RNA results was calculated based on qualitative results.

RESULTS

- Overall agreement between HCVcAg and HCV RNA among participants subjected to HCV screening was 97.9% (1258/1284) excluding HCVcAg grey zone samples (n-=10). Due to limited sample volume, repeat testing of GZ samples was not performed or indeterminate (*Figure* 1).

- The agreement between HCVcAg and HCV RNA in the Pre-Treatment specimens was 98.3% (414/421), and in specimens from the 4 week monitoring point was 96.5% (334/346). At EOT and 12 weeks post treatment, the agreement between HCVcAg and HCV RNA was 98.9% (186/188) and 100% (21/21), respectively (Figure 2,3,4,5).

HCV core Ag and HCV RNA Agreement in screening Samples

		HCV RNA		Total
		Pos	Neg	
HCVcAg	Reactive	938	2	940
	Gz-Reactive	7	3	10
	Nonreactive	24	320	344
	Total	969	325	1294

*Percent Agreement: 938+320/1284=97.9%
(*GZ samples were not included in the calculation)
Figure 1.

HCV core Ag and HCV RNA Agreement in Pre- treatment Samples

		HCV RNA		Total
		Pos	Neg	
HCVcAg	Reactive	414	0	414
	Nonreactive	7	0	7
		421	0	421

Percent Agreement: 414+0/421=98.3%
Figure 2.

HCV core Ag and HCV RNA Agreement in Week 4 Treatment Samples

		HCV RNA		Total
		Pos	Neg	
HCVcAg	Reactive	1	13	14
	Nonreactive	1	331	332
		2	344	346

Percent Agreement: 1+331/346=95.9%
Figure 3.

HCV core Ag and HCV RNA Agreement in EOT samples

		HCV RNA		Total
		Pos	Neg	
HCVcAg	Reactive	1	1	2
	Nonreactive	1	185	186
		2	186	188

Percent Agreement: 1+185/188= 98.9%
Figure 4.

HCV core Ag and HCV RNA Agreement in SVR samples

		HCV RNA		Total
		Pos	Neg	
HCVcAg	Reactive	2	0	2
	Nonreactive	0	19	9
		2	19	21

Percent Agreement: 2+19/21=100%
Figure 5.

CONCLUSIONS

- The observed percent agreement between HCV RNA and HCVcAg in the new HCV screening algorithm, and among patients who underwent Pre-Treatment testing selected for DAA therapy, were similar- 97.9% and 98.3% respectively. Among patients who received DAA therapy, the agreement between HCVcAg and HCV RNA exceeded 98% at the EOT, and reached 100% at the 12 week post treatment.

- These data suggest that the HCVcAg can be used as an alternative to HCV RNA to determine active infection in anti-HCV screening positive population, and for the DAA treatment monitoring.

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ACKNOWLEDGEMENTS

CONTACT INFORMATION

Nazibrola Chitadze, MD,
Head of Serology laboratory; R. G. Lugar Center for Public Health Research, National Center for Disease Control and Public Health (NCDC) www.ncdc.ge
9 M. Asatiani st., 0177, Tbilisi, Georgia
Office phone: (995-32) 2243424 ext. 2006; Cell phone: +995 591228527
E-mail: nazi@ncdc.ge; chitazenuki@gmail.com

Effectiveness of Sofosbuvir and Ledipasvir/sofosbuvir based regimens in hepatitis C virus genotype 3 infection: real-world data from Georgian hepatitis C elimination program

T. Tsertsvadze [1,2], N. Chkhartishvili [1], A. Abutidze [1], L. Sharvadze [2,3], V. Kerashvili [1], G. Kamkamidze [4], M. Zakalashvili [5], B. Skaggs [6], L. Gvinjilia [7], S. Shadaker [7], M. Nasrullah [8], A. Gamkrelidze [9], V. Kvaratskhelia [10], S. Zeuzem [11], N. Afdhal [12], S. Arora [13], K. Thornton [13], F. Averhoff [8]

[1]Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia [2]Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia [3]Hepatology Clinic Hepa, Tbilisi, Georgia [4]NeoLab, Tbilisi, Georgia [5]Medical Center Mrcheveli, Tbilisi, Georgia [6]South Caucasus Office of the U.S. Centers for Disease Control (CDC) [7]CDC Foundation, Tbilisi, Georgia [8]Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, CDC, Atlanta, GA, USA [9]National Center for Disease Control and Public Health, Tbilisi, Georgia [10]Ministry of Labour, Health and Social Affairs of Georgia, Tbilisi, Georgia [11] Goethe University Hospital, Frankfurt, Germany [12]Harvard Medical School, Boston, MA, USA [13] University of New Mexico, Albuquerque, NM, USA

INTRODUCTION

HCV genotype 3, which is considered as the most difficult to treat, accounts for 34% of all HCV infections in the country of Georgia. [1]

In April 2015 in collaboration with US CDC and commitment from Gilead Sciences to donate direct acting antivirals (DAAs) Georgia launched the world first national hepatitis C elimination program. [2]

AIM

The aim of this study was to evaluate the effectiveness of sofosbuvir (SOF)-based and ledipasvir/sofosbuvir (LDV/SOF)-based regimens among HCV genotype 3 patients treated within the Georgian elimination program.

METHOD

Data were obtained from the Georgia's hepatitis C elimination program treatment database.

SOF was prescribed either in combination with pegylated interferon (IFN) and ribavirin (RBV), or only with RBV. LDV/SOF plus RBV became recommended regimen for HCV Genotype 3 in Georgia.

Analysis included 7,857 HCV genotype 3 patients who completed treatment and were assessed for sustained virologic response (SVR) by April 30, 2017.

Advanced fibrosis/cirrhosis was defined as F≥3 by METAVIR score based on elastography and/or FIB-4 score >3.25.

RESULTS

Of 7,857 patients included 2,428 (30.9%) had advanced fibrosis/cirrhosis, 1143 (14.5%) received IFN/SOF/RBV for 12 weeks, 807 (10.3%) received SOF/RBV for 24 weeks and 5907 (75.2%) received LDV/SOF/RBV for either 12 or 24 weeks.

The IFN/SOF/RBV arm had an overall SVR rate of 96.1% (1099/1143) and this regimen was more effective in patients with no advanced fibrosis/cirrhosis versus patients with advanced fibrosis/cirrhosis (97.4% vs. 95.0%, p=0.04).

SOF/RBV achieved SVR in 80.3% (648/807) of patients, with higher rates also observed in patients without advanced fibrosis/cirrhosis (88.5% vs.77.0%, p<0.0001).

Patients receiving LDV/SOF/RBV achieved SVR rate of 97.9% (5783/5907) with higher cure rate among patients without advanced fibrosis/cirrhosis vs. patients with advanced fibrosis/cirrhosis (98.5% vs. 95.6%, p<0.0001).

IFN and LDV/SOF based regimens were more effective than SOF/RBV in both patients with or without advanced fibrosis/cirrhosis (p<0.001).

LDV/SOF/RBV arm achieved higher cure rate compared to patients receiving IFN/SOF/RBV (p=0.0004).

SVR Rates among HCV Genotype 3 Patients
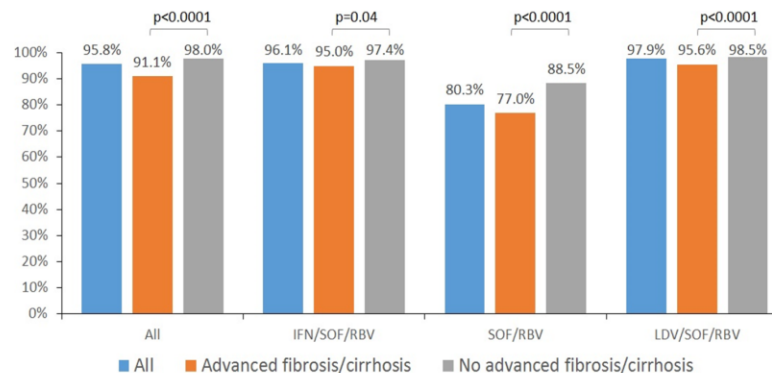
CONCLUSIONS

Overall SVR in genotype 3 patients was up to 98% in LDV/SOF/RBV regimens, which was more effective than SOF/RBV (80% SVR) and IFN/SOF/RBV (96% SVR) in Georgia.

LDV/SOF and RBV may be considered as effective treatment option for HCV genotype 3 infection even in patients with advanced disease.

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Authors are grateful to the U.S. Centers for Disease Control and Prevention (CDC) for exceptional technical assistance necessary for initiation and implementation of National Hepatitis C Elimination Program

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CONTACT INFORMATION

Tengiz Tsertsvadze, MD, PhD
Director General, Infectious Diseases, AIDS and Clinical Immunology Research Center
Professor of Medicine, Ivane Javakhishvili Tbilisi State University
16 Al. Kazbegi Avenue
Tbilisi 0160, Georgia
tengizt@gol.ge

Interim evaluation and projected impact of the hepatitis C virus elimination program in Georgia

J.G. WALKER[1], L. GVINJILIA[2], M. NASRULLAH[3], A. GAMKRELIDZE[4], J. MORGAN[5], and P. VICKERMAN[1]

1. Population Health Sciences, University of Bristol; 2. CDC Foundation, Tbilisi, Georgia; 3. Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, CDC; 4. National Center for Disease Control and Public Health of Georgia, Tbilisi, Georgia; 5. Global Disease Detection, Division of Global Health Protection, South Caucasus CDC Office, Tbilisi, Georgia

INTRODUCTION

Georgia has one of the highest hepatitis C virus (HCV) prevalence rates in the world, with >5% of the adult population (~150,000 people) chronically infected[1]. In April 2015, the Georgian government, in collaboration with CDC and other partners, launched a national program to eliminate HCV through scaling up HCV treatment and prevention interventions, with the aim of achieving a 90% reduction in prevalence by 2020[2].

AIM

We evaluate the impact of the HCV treatment program in Georgia as of 31 October 2017, and assess the feasibility of achieving the elimination goal by 2020. We estimate what treatment rate is needed to achieve a 90% reduction in prevalence by 2020, and when elimination will be reached with the current rate of treatment, or the 90-95 target treatment rate (90% of estimated cases diagnosed and 95% of diagnosed cases treated).

METHOD

We developed a dynamic model of HCV transmission incorporating the changing demographics of people who inject drugs (PWID) and the general population in Georgia (Figure 1). The model includes 9 age classes with time-varying, age and gender-specific recruitment rates to injecting drug use, and age-specific injection cessation rates (Figure 1C), and accounts for liver disease progression and death attributable to HCV (Figure 1B).

We used Markov Chain Monte Carlo Approximate Bayesian Computation (MCMC-ABC) in R[3,4] to calibrate the model to PWID age distributions and HCV prevalence by age, gender, and PWID status from the 2015 national sero-survey and PWID surveys 1997-2015[5]. Harm reduction coverage is included with efficacy estimates for OST from a systematic review[6], and the impact of NSP fit to the decline in HCV prevalence seen in young PWID.

Final parameter sets were used to understand the past and future epidemic dynamics, project the interim impact of treatments undertaken as part of the ongoing Georgia HCV elimination program, and to estimate the treatment rate required to reduce HCV prevalence by 90% by 2020. We calculated an SVR12 rate accounting for loss to follow up for the baseline analysis, and used intent to treat and per protocol SVR rates as upper and lower bounds.

Figure 1: Schematic of model compartments: infection status (A), liver disease (B), age and PWID status (C). Gender not shown.
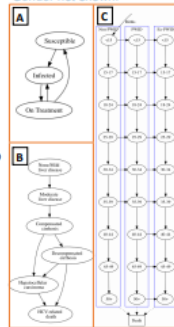
RESULTS

HCV epidemic dynamics
The model fits current epidemic patterns amongst PWID and the general population (Figure 2). Successive sero-surveys of PWID since 1997 show average age of PWID increasing and recruitment to injecting decreasing; the model suggests this means that the population of active PWID in Georgia is declining from a peak in the late 1990s (Figure 3).

Baseline projections
In the absence of any treatment intervention, the model predicts that incidence and prevalence will decline in the general population and in PWID, while HCV-related mortality increases (Table 1).

Interim impact
From May 2015, a treatment rate of at least 2050/month would have been required to reach a 90% reduction in prevalence by the end of 2020. In this time period, 40,420 patients were treated, an average of ~1,350 per month, with 1000/month in August-October 2017, reducing HCV prevalence by 28%. The 40,420 treatments are predicted to avert 2654 (1143 - 4419) deaths due to HCV and 16035 (5592 - 37026) new HCV infections by 2030.

Impact by 2020 – reaching elimination
At the current treatment rate of 1000 patients/month, a 53% (34 - 69%) reduction in adult prevalence and 52% (32 - 69%) reduction in incidence will be reached by 2020, and a 90% reduction reached during the year 2025 (Figures 4 & 5). Scaling up to reach the 90-95 target (2311/month) will achieve 81% (58 - 92%) reduction in adult prevalence and 80% (52 - 92%) reduction in incidence by 2020, and 90% reduction in 2021. Reaching a 90% reduction in prevalence and incidence by 2020 will require scale up to 3300 treatments/month (2000 – >4000, Figure 5).
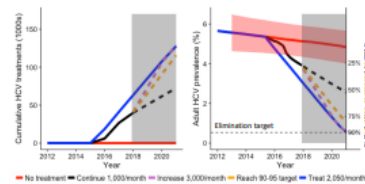

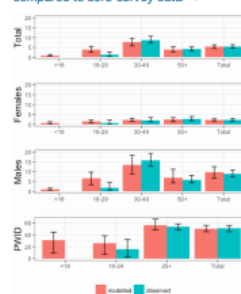Figure 2: Modelled estimates of HCV prevalence in 2015 by group and age, compared to sero-survey data[1,5]

Figure 3: Projected population size of current, former, and ever (current + former) PWID over time. Points show available estimates for adult PWID[1,7,8], point marked x was used for fitting.
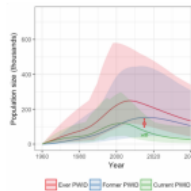
Table 1: Projected change in prevalence, incidence, and HCV-related mortality in the absence of intervention, from 2015- 2030. Incidence is per 100 person-years.

	2015	2030
Overall incidence	0.2 (0.07-0.39)	0.13 (0.04-0.27)
PWID incidence	2.69 (0.07-10.04)	1.99 (0.04-8.63)
HCV-related deaths	607 (165-1159)	711 (265-1251)
Prevalence, all ages	4.2% (3.51-4.92%)	2.91% (1.94-4.43%)

Figure 4: Projected HCV treatment numbers (left) and corresponding change in HCV prevalence (right). The red line shows no treatment, with uncertainty bounds, the blue line shows the treatment rate required from program initiation to reach the prevalence target by 2020, and the black, purple, and orange lines show the rate of treatment achieved as of October 2017 and projected treatment rates (within grey box) of 1000/month, 2311/month (to reach the 90-95 target), and 3,000/month.

Figure 5: Year in which 90% prevalence reduction will be reached, by treatment rate from November 2017, with alternative SVR rates.

CONCLUSIONS

The Georgia HCV elimination program has accomplished an impressive scale up of treatment, which has already reduced HCV prevalence and incidence, and averted deaths due to HCV. However, treatment initiation has fallen short of the target and monthly treatment rates now need to be tripled to achieve a 90% reduction in prevalence by 2020.
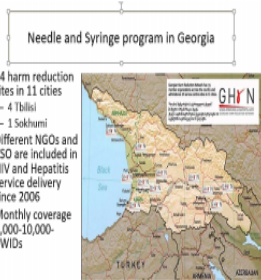
ACKNOWLEDGEMENTS

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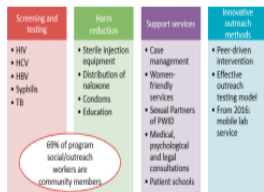
CONTACT INFORMATION

Any questions? E-mail Dr. Josephine Walker: j.g.walker@bristol.ac.uk

M.Gogia, MD, MPH; K.Stvilia, MD, MHA, I.Khonelidze, MD, MPA; Kh.Kutateladze, MD; S.Asatiani MD, MBA; G.Jikia, MD, MPH;

Georgian Harm Reduction Network, Shartava av. 24, apt 7, Tbilisi, Georgia. mgogia@hrn.ge

National Center for Disease Control and Public Health. Asariani str 9, Tbilisi, Georgia

Background:

HIV and HCV remain significant public health challenges in Georgia. The most affected risk groups for both infections are PWIDs. Prevalence of HCV in PWIDs that varies between 50-92% illustrates high magnitude of the problem. HCV screening was accessible in harm reduction program since 2006, but due to high cost the treatment was not affordable, especially for key populations. Accordingly no diagnostic and linkage to care services existed in harm reduction program. Georgian harm reduction network-GHRN was actively involved into a long advocacy process demanding free treatment for HCV patient PWIDs. Under strong civil society pressure Government had to act and National HCV elimination program took a start from 2015 with aims to eliminate HCV by 2020 in country. Additional barrier was strict drug law

Needle and Syringe program in Georgia

- 14 harm reduction sites in 11 cities
  - 4 Tbilisi
  - 1 Sokhumi
- Different NGOs and CSO are included in HIV and Hepatitis service delivery since 2006
- Monthly coverage 8,000-10,000- PWIDs

A number of services are provided by GHRN

Screening and testing	Harm reduction	Support services	Innovative outreach methods
• HIV • HCV • HBV • Syphilis • TB	• Sterile injection equipment • Distribution of naloxone • Condoms • Education	• Case management • Women-friendly services • Sexual Partners of PWID • Medical, psychological and legal consultations • Patient schools	• Peer-driven intervention • Effective outreach testing model • From 2016: mobile lab service

69% of program social/outreach workers are community members

Methods:

In order to react proactively towards its new role for the hepatitis C elimination, GHRN has developed new targeted interventions which were aligned with HIV prevention interventions supported by the GFATM HIV program. The emphasis was placed on increased HIV/HCV tandem
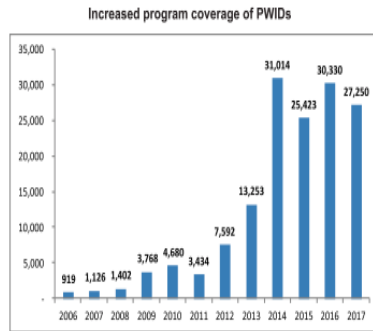
For avoiding stigma and self-stigma factors HCV testing was offered to general population as well. Mobile ambulatories expanded the program coverage to 32 cities allowing testing of additional 11,101 PWIDs in 2016.

Case managers that were mostly people living with viral hepatitis were ensuring linkage of screening positive PWIDs to HCV treatment sites. GHRN with support of other international organizations started piloting of patients' schools and peer driven interventions (PDI). HIV and HCV Tandem testing was supported by the GFATM HIV program.

Collaboration with Police was initiated to gain their support for outreach work. HCV education module was included in existing PDI educational programs, informational-education flyers and brochures about HCV were delivered to PDI program participants as well.

Increased program coverage of PWIDs

Results:

New model practices of the harm reduction programs including tandem testing on HIV and HCV allowed increasing the number of PWIDs tested for HCV twice in 2016 (26,025) in comparison to 2014 (12,410). 42.6% of testing was conducted through outreach testing by mobile ambulatories. 10,926 PWIDs were referred to HCV treatment sites, HCV education module was included to existing Peer Driven Intervention educational program, informational-education flyers and brochures about HCV were delivered. At harm reduction sites more emphasize was done on

HCV screening among PWIDs amd their sexual partners
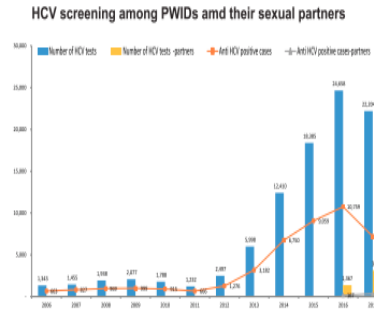
Recent HCV data of harm reduction program

Activity	Year	Number
HCV cases among PWIDs included in HCV treatment program	2015- 2016	2,377
Detected HCV cases among PWIDs	2017 (6 months)	4908
Number of HCV cases (PWIDs) supported to be included in HCV treatment	2017 (6 months)	2067
HCV positive cases among general population screened by harm reduction sites	2017 (6 months)	1223

Conclusions:

Capacities of the harm reduction programs can effectively be used for early detection, linkage to treatment services for HCV positive PWIDs. Proper risk counseling and disease awareness activities are inevitably important to decrease the risk of re-infection among PWIDs. Strong integration between HCV and HIV programs ensures cost-effectiveness of both interventions. Unified screening and treatment databases are critical for success of the elimination program. Besides, initiation of HCV national program enabled

Linkage to care within HePC Elimination program, 2017

Organization	Anti HCV positive	Involved in HCV treatment
New Vector	516	60%
New Way Tbilisi	661	65%
Hepa+	672	40%
Aceso	576	51%
New Way Kutaisi	1193	20%
Qsenoni	708	90%
Imedi	467	40%
Step to Future Telavi	240	38%
Step to Future Gori	499	55%
Ordu	277	43%
Fenix	242	90%
New Way Samtredia	245	47%
New Vector Rustavi	513	50%

BLOOD TRANSFUSION SAFETY AND ELIMINATION OF HEPATITIS C IN GEORGIA

E Bloch[1], E Kipiani[2], L Gvinjilia[3], M Alkhazashvili[2], N Chitadze[2], I Tskhomelidze[3], A Turdziladze[2], V Getia[2], S Keating[4]

[1]Pathology, Johns Hopkins University School of Medicine, Baltimore, United States, [2]National Centers for Disease Control and Public Health, Tbilisi, Georgia, 3 US Centers for Disease Control South Caucasus Office, [4]Blood Systems Research Institute, San Francisco, United States

Background: In response to a national Hepatitis C (HCV) epidemic, the Government of Georgia has initiated a public health program to eliminate HCV by 2020. The program combines screening and treatment with a goal of identifying 90% of HCV-infected individuals, treatment of 95% of those with chronic HCV infection, and attainment of cure in 95% of those treated for HCV infection. Blood transfusion has been identified as a significant mode of transmission for HCV in Georgia.

Aims: To assess blood transfusion operations in Georgia to inform development of a strategic plan and targeted intervention for HCV prevention under the broader goal of improved blood transfusion safety.

Methods: Twenty-two blood banks hold a license to produce blood in Georgia and all are required to use a donor-donation database. Unique donor identification numbers are assigned to the donor and donation, providing access to the donation information, donor demographics and testing records. Data from 2015 to 2017 were extracted from the blood donor database and summarized according to operational indices (e.g. numbers of donations), donor demographics (sex; remunerated, voluntary or replacement; first time or repeat) and infectious marker status (the prevalence of transfusion transmitted infection). Information on the blood banks that participated in the State Safe Blood Program were also available for evaluation.

Results: During this time period, 225,908 donations were recorded. Sixty percent of donations were collected from male donors and 59% of donations were from paid donors. HCV and HIV prevalence results were based on screening with an ELISA assay as reported by the blood bank laboratories. The HCV and HIV prevalence was 0.7% and 0.1% respectively. The HCV positive donations were collected, predominantly, from first-time donors (82% of HCV positive).

Summary/conclusions: Previous studies in Georgia have shown that HCV prevalence is highest among men and in people who inject drugs. Given that the majority of Georgian blood donors were male and constituted paid donors, this constitutes a possible high-risk population for HCV acquisition. Since the window period of HCV screening by ELISA can take 8 weeks or longer, testing approaches in use, which typically comprise serological (antibody) screening alone, lack sufficient sensitivity to detect recent infection in donors, thus failing to interdict transfusion-transmitted HCV. While the goal of the HCV elimination program is to test and treat all HCV infected Georgians, blood transfusion remains to be a risk for transmission but also an opportunity to identify and link HCV positive donors to HCV treatment programs. Work towards transition to HCV antigen screening and ultimately nucleic acid testing of blood donations will shorten the window period, reduce the risk for transfusion transmitted HCV infection and improve access to optimal HCV screening. Linkage of the donor database to an HCV treatment database will improve referral of HCV positive donors to care and treatment services.

Table 1. Overview of Blood collections by year

	2015	2016	2017	Total
Number of Collections	68398	80361	77149	225908
Donor status				
First time	18534	19283	19808	
Repeat	30304	31835	32009	

Table 2: Donor infectious marker positivity by year

	2015 n (%)	2016 n (%)	2017 n (%)
Hepatitis C	993 (2.3%)	823 (1.7%)	581 (1.3%)
Hepatitis B	657 (1.5%)	570 (1.2%)	452 (1.0%)
HIV	58 (0.1%)	68 (0.1%)	41 (0.1%)
T. pallidum	452 (1.0%)	359 (0.7%)	250 (0.5%)
Total	2160 (4.9%)	1820 (3.7%)	1324 (2.9%)

Distribution of Blood Banks in Georgia, 2018

Participate in the state program

State program participants since 2018

Do not participate in the state program

POSTER REFERENCE NUMBER: 13

Hepatitis C diagnostic – barrier to effective Linkage to care within Georgian Hepatitis C elimination program

G.JIKIA, MD, MPH; M.GOGIA, MD, MPH; Member organizations of Georgian Harm Reduction network

BACKGROUND

HIV and HCV remain significant public health challenges in Georgia. With an HCV prevalence of 7.7% and an estimated 150,000 persons living with chronic HCV infection, Georgia has one of the highest burdens of HCV infection in the world. Georgia began laying the groundwork necessary to meet these ambitious HCV elimination goals in 2015 by establishing HCV testing and treatment sites throughout the country and treating those found to be infected with curative DAAs made available free of charge by pharmaceutical company Gilead Sciences. The most affected risk groups for this infection are PWIDs. Prevalence of HCV in PWIDs varies between 50-92%. HCV screening was accessible in harm reduction program since 2006, but due to high cost the treatment was not affordable, especially for key populations. Georgian harm reduction network-GHRN was actively involved into a long advocacy process demanding free treatment for HCV patient PWIDs. In Imereti region out of 1,438 of screened positive cases there were involved only 34% in treatment, Samegrelo announced 985 positive cases, involvement percentage were - 67% - the reasons of refusal were the similar plus restricted geographical access to the treatment clinics and myths about negative effects of the drugs. There are quite a number of reasons of refusal to treat in Adjara region: Stigma and self-stigma and discrimination from Medical personnel are one of the main reasons of low involvement (35-40%).

METHODS

In order to evaluate the involvement of PWIDs in the Hepatitis C elimination Program, GHRN requested the data from 14 NSP drop-in centers that are located in 11 major cities. The data was generated from harm reduction program database and recordings of outreach workers and VCT counselors that were supporting PWID in linkage to care. The data were received from the following regions: Tbilisi, Guria, Imereti, Adjara, Kakheti, Kvemo-Kartli and Shida Kartli.

Diagram N1 HCV testing among PWIDs at harm reduction program

RESULTS

Totally 25,328 HCV testing were performed in 2017, out of them 7,526 were HCV positive. All HCV positive PWIDs were referred to HCV treatment sites by 14 harm reduction sites.
In Tbilisi, out of 2,425 of screened positive HCV cases Only 53% were involved in HepC elimination program. There were defined the following reasons for this: a) lack of money required for co-payment; b) low motivation of drug users to be treated.

Recent HCV data at harm reduction program

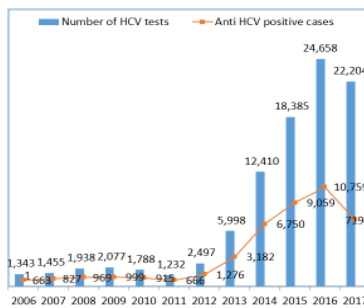| Activity	Year	Number
HCV cases among PWIDs included in HCV treatment program	2015- 2016	2,377
Detected HCV cases among PWIDs	2017	7,194

CONCLUSIONS

The study results demonstrate that free medication is not enough for involvement in the treatment program, free diagnostic is necessary for effective linkage to care especially for high risk groups.
Besides, capacities of harm reduction programs should more effectively be used for linkage to treatment services. Proper risk counseling and disease awareness activities are inevitably important to increase involvement of PWIDs in Hep C elimination program.

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The harm reduction project is a part of National HIV prevention program supported by the Global Fund. National Center for Disease Control and Public Health is a Principal Recipient of the Global Fund Grant and Georgian Harm Reduction Network (GHRN) is Sub-Recipient and of this grant. The authors want to thank all of the NGOs that are members of GHRN and were directly involved in service delivery process: Step to Future (Gori, Telavi) Ketevan Bidzinashvili, Kakhi Gemazashvili; New Way (Tbilisi, Kutaisi, Samtredia) Dali Usharidze, Zaza Karchkhadze Nana Darsavelidze; New Vector (Tbilisi, Rustavi) Koka Labartkava; Lasha Abesadze; Qsenoni (Zugdidi) Nino Janashia; Imedi (Batumi) Zoria Tsurtsumia; Hepa plus (Tbilisi) Manana Sologashvili; Fenix (Ozurgeti) Otari Jijieshvili; Ordu (Poti), Vakhtang Gamsakhurdia; Aceso (Tbilisi) Irakli Kirtadze.

CONFLICTS OF INTEREST

There is no conflict of interest depicted by the authors

Contact Information
NAME: Guranda JIkia
Mobile: +995 595 142 888
EMAIL: gjikia@hrn.ge

Oral Presentations

1. Hepatitis C elimination in Georgia, Lali Sharvadze

   Presented at HCV 26th APASL congress, 2017; Shanghai, China
2. Progress in HCV Care and Treatment: national hepatitis C elimination program of Georgia, Tengiz Tsertsvadze

   Presented at GIMPHA 4th International Health Conference, 2017; Tbilisi, Georgia
3. Real-world effectiveness of ledipasvir/sofosbuvir in hepatitis C virus genotype 1, 2 and 3 infection: single-center experience within Georgian hepatitis C elimination program

   Presented at 3rd CEE Meeting on Viral Hepatitis and Co-infection with HIV_Program,2017 Ljubljana, Slovenia
4. Local situation on HIV and HCV in Georgia, Akaki Abutidze

   Presented at 3rd CEE Meeting on Viral Hepatitis and Co-infection with HIV_Program,2017; Ljubljana, Slovenia
5. Access to DAAs in EECA Achievements of HCV elimination program in Georgia, Marina Gogia

   Presented at 10th Multi-Stakeholder Meeting on Viral Hepatitis and HIV co-infection, 2017; Bucharest, Romania
6. HCV Situation in Georgia and Overview of HCV Research Experience, Tengiz Tsertsvadze

   Presented at National Institute of Allergy and Infectious Diseases of National Institute of Health, 2017; Bethesda, USA
7. US-Georgia Collaboration in HIV/AIDS and Hepatitis C, Tengiz Tsertsvadze

   Presented at National Institute of Allergy and Infectious Diseases of National Institute of Health, 2017; Bethesda, USA
8. Prevention transmission strategies through strengthening health systems, Maia Butsashvili

   Presented at International Viral Hepatitis Elimination Meeting, 2017; Amsterdam, Netherland
9. National Hepatitis C Elimination Program of Georgia, Tengiz Tsertsvadze

   Presented at 10th Paris Hepatology Conference, 2017; Paris, France
10. Elimination of Hepatitis C and slowing HIV epidemic in PWID: Georgian experience, Tengiz Tsertsvadze

    Presented at Slowing the HIV and HCV epidemic for people who inject drugs, 2018; Wilton Park, Steyning, UK
11. Progress towards HCV Elimination, Amiran Gamkrelidze

    Presented at International Liver Congress, 2018; Paris, France
12. Progress towards decentralization and integration of HCV services in primary care, hospitals and harm reduction settings in Georgia, Davit Sergeenko

Presented at International Liver Congress, 2018; Paris, France

13. Challenges and opportunities for decentralization of HCV care and treatment services, Francisco Averhoff

Presented at International Liver Congress, 2018; Paris, France

14. Challenges and opportunities for decentralization of HCV care and treatment services in harm reduction centers, Maia Butsashvili

Presented at International Liver Congress, 2018; Paris, France

15. HCV Elimination Program in Georgia: Overcoming the Challenges with Innovation, Muazzam Nasrullah

Presented at International Liver Congress, 2018; Paris, France

16. Decentralization of HCV Screening, Care and Treatment in Primary Heath Care Settings, Tengiz Tsertsvadze

Presented at International Liver Congress, 2018; Paris, France

17. Scientific Research in HCV Elimination, Tinatin Kuchuloria

Presented at International Liver Congress, 2018; Paris, France

18. Innovative Approaches to Information Technology in Georgia HCV Elimination Program, Lia Gvinjilia

Presented at International Liver Congress, 2018; Paris, France

19. The Role of Civil Society in Viral Hepatitis C Elimination Programme in Georgia, Marina Gogia

Presented at Eastern Europe and Central Asian AIDS conference, 2018; Moscow, Russia

20. Progress in HCV Care and Treatment: national hepatitis C elimination program of Georgia, Tengiz Tsertsavdze

Presented at GIMPHA 4th International Health Conference, 2018; Tbilisi, Georgia

21. Building Health Systems to Deliver People-centered Health Services, Davit Sergeenko

Presented at The 22nd International AIDS Conference (AIDS 2018); Amsterdam, the Netherlands

22. Atittude of staff regarding integrated hepatitis c treatment at eight harm reduction centres in Georgia, Maia Butsashvili

Presented at INHSU 2018; Lisbon, Portugal

23. Approaches to providing hepatitis C viremia testing to people who inject drugs in Georgia, Maia Japaridze

Presented at 4th CEE meeting on Viral Hepatitis and HIV, 2018; Prague, Check Republic

24. Low HCV reinfection rate after treatment in people who infect drugs (PWID) from a prospective cohort in Tbilisi, Georgia, Maia Butsashvili

Presented at 4th CEE meeting on Viral Hepatitis and HIV, 2018; Prague, Check Republic

Appendix 4

Publications Related to the HCV Elimination Program

Abstracts

1. **Measurement of personal risk behavior in occupational risk studies of health care workers**
   Authors:

Butsashvili M.,[1] Kamkamidze G.,[1] Kajaia M.,[1] Nelson K.,[2] Triner W.,[3] McNutt LA.[4]

1 Health Research Union, Tbilisi, Georgia; 2 Johns Hopkins Bloomberg School of Public Health, Baltimore, USA; 3 Department of Emergency Medicine, Albany Medical College, Albany, NY, USA; 4 School of Public Health, University at Albany, State University of New York, Rensselaer, NY, USA.

Abstract:

Risky behaviours, particularly illegal and heavily stigmatized behaviours, are difficult to measure through self-report in both high risk groups and the general population. Underreporting can result in substantially biased estimates of non-injection drug use (IDU) risk of hepatitis C virus (HCV) infection. We hypothesized that asking about the existence of social networks injection drug use may be a useful marker of IDU.

A cross-sectional survey of physicians and nurses was conducted in 2006-2007 in seven hospitals in Georgia. Based on survey responses participants were categorized into three IDU risk groups: ever used injecting drugs (Self IDU), reported a friend, family member or colleague used injecting drugs (Associate IDU), or reported neither (No IDU). Testing on anti-HCV was done using third generation ELISA methods. Both unadjusted and adjusted prevalence ratios between IDU risk groups and HCV prevalence were estimated.

Of the 1312 (82.2%) participants, 10 (0.8%), 75 (5.7%), and 1227 (93.5%) were categorized as Self IDU, Associate IDU and No IDU, respectively; with HCV prevalences of 20%, 9.3% and 4.6%, respectively (p=0.016). The association was due primarily to women's reports. Those who reported some IDU risk were more likely to report other personal risk behaviors (e.g., multiple sex partners) and occupational risk behaviors (eg, frequent exposure to blood and body fluids).

This study represents a start of measurement development by assessing the potential usefulness of a marker to measure of IDU. Improved measurement of stigmatized behaviors is needed for confounding adjustment to improve estimates of occupational risks of bloodborne infections.
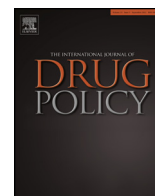
Short Report

Harm reduction-based and peer-supported hepatitis C treatment for people who inject drugs in Georgia

Tamar Kikvidze[a], Niklas Luhmann[b], Elisabeth Avril[b], Maia Butsashvili[c], Konstantine Labartkava[d], Aurélie Etienne[b], Diane Le Pluart[b], Ina Inaridze[a], Ana Gamezardashvili[c], David Kharshiladze[a], Julie Bouscaillou[b],*

[a] Médecins du Monde Georgia, 46 Gutnis Street, Tbilisi, 0103, Georgia
[b] Médecins du Monde France, 62 rue Marcadet, 75018, Paris, France
[c] Clinic Neolab, 47 Tashkenti Street, Tbilisi, 0160, Georgia
[d] New Vector, 9 Mtskheta Street, Tbilisi, 0179, Georgia

ABSTRACT

Backgrounds: Georgia faces high HCV rates (5.4% of chronic cases in general population) with an epidemic concentrated among people who inject drugs (PWID). A National HCV Elimination Program (NHCEP), was launched in April 2015, aiming to eliminate HCV by 2020. To succeed, this program must develop tailored interventions to enroll PWID in treatment.
Intervention: We implemented a pilot intervention to facilitate access to and retention of PWID in the NHCEP, and to prevent reinfection after treatment. Screening was offered at a harm reduction center. PWID with positive results were followed by peer-workers during medical assessment, which lasted 73 days in average, and throughout the treatment by Sofosbuvir and Ribavirin+/− PegInterferon for 12, 24 or 48 weeks delivered at a medical center. Additional prevention sessions and PCR checks were delivered to PWID 6 and 12 months after the confirmation of sustained virologic response.
Results: The pilot intervention screened 554 people in 5 months with 244 starting treatment. The majority of participants (98.0%, n = 239) completed the treatment. The intervention, initially implemented in the capital, was replicated in a rural area.
Conclusion: Peer-supported and strongly integrated, comprehensive HCV care will help PWID reach high uptake and adherence to care.

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Background

Eliminating hepatitis C

The introduction of new highly effective direct-acting antiviral (DAA) therapies has created an opportunity for the global elimination of hepatitis C virus (HCV) (Hepatitis C: only a step away from elimination?, 2015).

People who inject drugs (PWID) account for 10% of HCV cases worldwide (Gower, Estes, Blach, Razavi-Shearer, & Razavi, 2014; Nelson et al., 2011) and 23% of new infections (WHO, 2017). Almost half of chronically infected PWID lives in East/Southeast Asia and Eastern Europe (Nelson et al., 2011), where there is overall limited access to HCV treatment due to the high prices of DAAs (Bailey, Turkova, & Thorne, 2017; Lim et al., 2017). In many Eastern European countries, these exorbitant prices lead to further exclusion of PWID, with reimbursement restrictions in case of drug use, masked as concern about treatment adherence (Marshall et al., 2017).

Interventions adapted to middle-income countries that overcome the barriers to HCV treatment in PWID urgently need to be developed to achieve the WHO targets of testing 90% and treating 80% of chronic HCV cases by 2030 (WHO, 2016).

The Georgian challenge

With 5.4% of chronic HCV infection in the general population (Gvinjilia et al., 2016), Georgia has one of the highest HCV burdens in the world. The country also has a high rate of injecting drug use, with 66.2%–92% of antibody carriers among PWID (Bouscaillou

et al., 2014; Curatio International Foundation, 2015). PWID represent 25% of HCV cases in the country (Luhmann et al., 2015). A National HCV Elimination Program (NHCEP) was launched in April 2015 with strong stakeholders support and a donation of DAAs from Gilead Sciences. The initial phase (2015–2016) of the NHCEP focused on providing 7000 free courses of Sofosbuvir (with Ribavirin+/− PegInterferon) limited to persons with advanced liver fibrosis (F3 or more corresponding to elastometry above 10 kPa or FIB4 > 3.25). The ongoing second phase (2016–2020) intends to treat every person chronically infected with HCV (Gvinjilia et al., 2016). To succeed in eliminating HCV, PWID must be considered a priority target, with a more proactive approach to guarantee their access to treatment.

Intervention: a model of care for PWID to facilitate access and adherence to treatment

Aim of the project

To facilitate access to and retention of PWID in the NHCEP and to prevent reinfection after treatment, Médecins du Monde (an international, medical non-governmental organization), alongside New Vector (a Georgian self-support organization of PWID) and Neolab (a medical center) developed and implemented a peer-support intervention. The overall aim of the project was to provide a model to scale-up to other regions of Georgia in the framework of the NHCEP.

The project took place in Tbilisi, the capital of Georgia, during the initial phase of the NHCEP. During this phase and until recently, HCV treatment delivery was only possible in authorized medical centers (MC).

The project was evaluated in the context of an effectiveness-implementation research (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) that received ethical clearance from the Georgian Institutional Review Board of the Health Research Union, Tbilisi. Each participant included in the project signed a written informed consent. Medical costs that were not included under NHCEP (e.g. management of the adverse events) were reimbursed by Médecins du Monde.

Conceptual framework

In addition to stigma, being denied social support, criminalization and discrimination, patient and provider-related barriers contribute to suboptimal hepatitis C treatment uptake and retention among PWID (Doyle et al., 2015; Harris & Rhodes, 2013; Rich et al., 2016). The intervention aims to overcome the following obstacles: (1) due to referral-associated delays, inflexible hours, geographical distance, waiting time, as well as the prejudiced attitudes of some health professionals, PWID are not likely to seek HCV testing if delivered only in specialized services; (2) in case of a positive result, linkage to care can be made difficult by the long medical assessment required before starting treatment (the PCR test, which confirms the infection, needs to be done in centralized laboratories, and until now, the choice of treatment combination is based on knowing the genotype and the level of liver fibrosis); (3) health providers are concerned that poor treatment adherence in PWID, related to their supposed instability and the occurrence of unusual side effects, will lead to suboptimal efficacy; and finally (4) the risk of reinfection due to continued injecting drug use after treatment that would negate the benefit of treatment is a major reason stated by health authorities for excluding PWID from treatment programs.

Intervention content (Table 1)

Screening within a harm reduction center (HRC)

The screening process was offered at a HRC usually delivering prevention services to about 2600 PWID in Tbilisi. Eligibility to treatment was defined for the initial phase of the NHCEP by a positive viral load and severe liver fibrosis (defined as fibrosis F3 or more according to FIB-4 score or liver elastometry). The usual clients were invited to the HRC to undergo a HCV rapid test (which can only identify people having HCV antibodies, not those who have actually confirm chronic infection) and a liver elastometry (which can be performed using a device that is highly mobile). People with HCV antibodies and liver fibrosis F3 or more were sent to the medical center (MC) for further assessment. To avoid missing cases eligible to treatment, PWID with F2-F3 or inconclusive

Table 1
Pathway of participants.

PROJECT STEP	HARM REDUCTION CENTER	MEDICAL CENTER
Throughout the project	Peer workers: - Are in contact with the patient and the navigator throughout the process - Deliver an individual support in addition to the regular appointments: mediation with medical staff, help with paperwork, etc. - Track the patients dropping out of medical follow-up	Navigator: - Schedules PWID medical appointments - Orientates PWID within the medical center - Relays relevant information from the medical staff to the peer workers and vice et versa
SCREENING	- Noninvasive screening: HCV rapid andibody test and liver elastometry - Initial interview with peer worker (general information and social assessment)	
MEDICAL ASSESSMENT		- HCV confirmation (PCR) - Pretreatment assessment (FIB4, genotype, ultrasonography, etc.)
TREATMENT	- Counseling by peer worker at treatment initiation: messages on adherence, side effects, drug interactions, etc. - Patients' group discussions (monthly) - Multidisciplinary meetings involving peer workers and medical staff	- Bi-monthly medical appointments
12 weeks POST-TEATMENT	- Counseling by peer worker at the end of treatment: messages on the risk of reinfection and liver disease progression after treatment - Reminders to get a PCR check on 12th week after the end of treatment	- PCR check on 12th week after the end of treatment
POST TEATMENT	- Counseling by peer worker regarding reinfection 6 and 12 months after the PCR check on 12th week after the end of treatment	- PCR checks 6 and 12 months (right after the counseling session with the peer worker)

elastometry results were also sent to the MC for a second assessment (elastometry performed by a different person and FIB-4 score) .

Besides facilitating the recruitment of PWID by offering screening in a low threshold HRC, the objective of this process was to avoid unnecessary invasive procedures (blood sampling for PCR) and related costs for the majority who would be ineligible for treatment and, at the same time, to be sufficiently sensitive so as not to miss any cases.

Case management through peer support and patient navigation

In this pilot, the medical assessment, treatment and follow-up were performed in a MC authorized to deliver HCV treatment (Sofosbuvir, Ribavirin+/− PegInterferon for 12, 24 or 48 weeks according to genotype, treatment experience and cirrhosis status). The peer-support intervention consisted of three mandatory face-to-face sessions and personalized support, plus the organization and moderation of patient group discussions at the HRC.

The initial interview with a peer took place at the time of the screening of each patient pre-assessed as eligible. The aim of this first meeting was to provide general information about the program (registration process, steps of the treatment program, etc.), to assess each patient's situation, in particular in terms of social support needs, and to organize a personalized follow-up. A second face-to-face was delivered by peers just after treatment initiation and addressed the questions of adherence, side effects and their management, as well as treatment contraindication and drug interactions. The last face-to-face was delivered just after the end of treatment. Individuals with negative results received information about liver disease progression and post-treatment follow-up (including the importance of a viral load check 12 weeks after the end of treatment), and concerning behaviors carrying a risk of reinfection. Additional meetings or phone calls with peers could also be arranged at the patient's request. Further support included helping with paperwork or mediating with medical staff, etc.

Patient group discussions were organized at least once a month at the HRC and were moderated by peers to enable patients to share information about their treatment experience (how to maintain adherence, how to deal with side effects, etc.) and to ask specific questions. Patients at different stages of treatment, including those who had not yet started, also participated.

Finally, the peer workers were responsible for tracking patients dropping out of the intervention. In the MC, a full-time navigator was in charge of scheduling PWID medical appointments and had a key role as a mediator between the medical staff and the team of peers. If needed, individual cases were reviewed by peer workers and medical staff during multidisciplinary meetings.

Six peers already working at the HRC were involved, each one followed approximately 40 PWID. Prior to the intervention, peer workers had received three-day training delivered by a medical doctor from the MC partner and a harm reduction specialist, and one-week on-the-job skill enhancement relating to counseling methods delivered by a professional social worker.

Standardized material was provided to guide the peer-support intervention. The tools (three check lists for the face-to-face sessions, a peer-worker file, a group discussions grid, and a notebook for PWID in treatment) were specifically developed by medical experts of Médecins du Monde, then tested and adapted by the peer workers (Supplementary material).

Reinfection prevention

Changing behaviors at risk of HCV transmission was part of the three face-to-face sessions described above, which were also used to deliver standardized messages regarding reinfection, as well as personalized advice based on practices reported. After treatment completion, PWID were invited to two additional visits 6 and 12 months after the confirmation of sustained virologic response. These visits were composed of a counseling session with a peer worker and a PCR check. Messages regarding reinfection were specifically developed for these sessions, following the analysis of behavioral questionnaires completed at treatment initiation. Specific drug consumption related risks were identified in the project population, as providing assistance to one another during drug preparation or drug injection, and purchase of ready to use pre-filled syringes.

Cascade of care in the project (Fig. 1)

In a five-months period (May to September 2015), 554 of the ~2600 of HRC usual clients (an estimated 21%) came to be screened to enter the NHCEP. Cascade of care was as follows:

- 97% (n = 338) of the 350 persons referred by the HRC (i.e. with positive rapid test, and elastometry result ≥F2-F3 or inconclusive) actually attended the MC for eligibility confirmation.
- 98% (n = 333) of these 338 patients completed the pre-treatment assessment, which took 73 days on average. Eligibility was confirmed for 244 who initiated treatment.
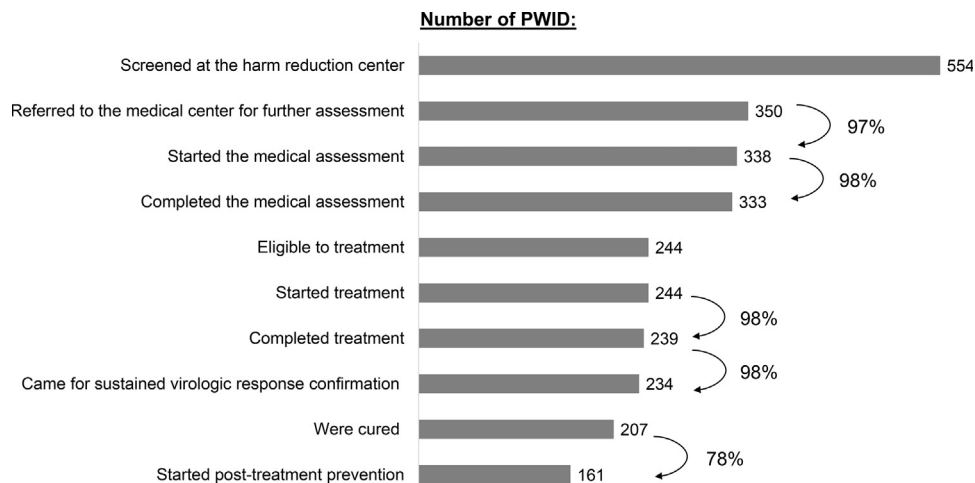
Number of PWID:

Screened at the harm reduction center	554
Referred to the medical center for further assessment	350 — 97%
Started the medical assessment	338 — 98%
Completed the medical assessment	333
Eligible to treatment	244
Started treatment	244 — 98%
Completed treatment	239 — 98%
Came for sustained virologic response confirmation	234
Were cured	207 — 78%
Started post-treatment prevention	161

Fig. 1. Cascade of care.

- 98% (n = 239) of the 244 participants who started treatment completed the treatment
- 98% (n = 234) of them came for the PCR check 12 weeks after treatment (88.5% reached sustained virologic response, n = 207). Incarceration was one of the reasons for dropping out of the intervention at this step.
- Finally, 78% (n = 161) of those identified as cured at the end of treatment came for at least one post-treatment prevention session and PCR check
- The intervention, initially implemented in Tbilisi, capital of Georgia, is being replicated in another area of Georgia, in partnership with another local harm reduction organization .

Conclusion

Our findings demonstrated that a simple peer-support intervention implemented in a HRC produced excellent treatment uptake and retention among PWID based in Tbilisi, Georgia. Further, our work contributed to securing recognition of PWID as a priority group for prevention and treatment within the national program. Moving forward, we suggest additional key actions to increase equitable access to HCV treatment in Georgia. First, we advocate for further decentralization and integration of HCV care services, which would allow adoption of a multidisciplinary approach to PWID treatment that is fully integrated into HRC. This is likely to obtain even better results in terms of linkage to and retention in care and may appeal to the most vulnerable (Ho et al., 2015). In addition, ensuring that ongoing public-awareness campaigns incorporate messages to help PWID recognize their risk of HCV on the one hand and to improve public understanding of addiction on the other, would help reduce stigma. Also, drug addiction should be addressed as a health issue and not a crime: restrictive legislation towards PWID that applies in the country still represents a major obstacle to care and prevention in general (Grebely, Dore, Morin, Rockstroh, & Klein, 2017). Finally, access to effective interventions to prevent reinfection after treatment in PWID is crucial to reach elimination. In fact, the coverage of harm reduction services was still suboptimal when the NHCEP started (51% of PWID had access to needle and syringe programs and 9% to OST in 2015) (Alavidze et al., 2016).

Georgia, as the other middle-income countries developing their HCV control strategy, must prioritize PWID, with specific interventions for screening and support during treatment. Based on our findings, scaling up this model of care nationally appears to be a way to improve PWID access to treatment and to make progress towards the country's goal of eliminating HCV.

Conflict of interest

The authors have declared that no competing interests exist.

Acknowledgements

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.drugpo.2017.11.014.

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Assessment of HIV Knowledge, Attitude and Behaviour among Hepatitis C-Infected Patients Who Inject Drugs in Tbilisi, Georgia

Gogia M.*, Gogochashvili S., Sologashvili M., Revishvili M., Lawlor C

Non-government organisation "Hepa plus" Tbilisi, Georgia, 2017

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ABSTRACT

Blood-borne infectious disease is a growing problem among injecting drug users in Georgia, with growing populations of HIV and HCV-infected people. Despite harm minimisation activity in Georgia since 2005, there are still knowledge gaps around drug user knowledge, attitudes and behaviours. Through compiling and comparing qualitative and quantitive studies, it was shown that HIV knowledge was suboptimal in injecting drug users, and differed between age groups. High amounts of stigma existed around HIV, more than can be accounted for by just injecting drug use alone. Despite education, risk behaviours were still practiced. Differences were demonstrated between risk behaviour severity and infectious status. The study shows many areas for program development and gives valuable insight for similar programs and the need for responsive, personalised, dynamic harm minimisation programs.

INTRODUCTION

In Georgia in 2016 there were an estimated 52,500 injecting drugs users (IDUs)[1], 1.41% of the total population. Georgia is a low HIV/AIDS prevalence country with an estimated infected number of 12,000[2]. Conversely, hepatitis C is highly prevalent (high prevalence country), with 7.7%[3] of the population showing exposure (just under 290,000 people), with 66.2% of IDUs having hepatitis C[4]. The reasons for this transmission has not been properly studied. Harm minimisation services for hepatitis and HIV have been active in Georgia since 2005. The purpose of this paper is to study knowledge, attitudes and risk behaviours related to HIV among hepatitis C infected injecting drug users in Georgia. It is hypothesised that knowledge about HIV/AIDS in injecting drug users with hepatitis C in Georgia is insufficient, and contributes to risk behaviour.

This study was conducted by the NGO "HEPA PLUS'' and was funded by the International East-West AIDS Foundation (AFEW International). The organisation focusses on hepatitis C, mainly IDUs. Since 2011, "HEPA PLUS" has been actively involved in advocacy campaigns related to the availability of hepatitis C treatment and diagnosis, as well as developing, updating and implementing a strategic plan related to the availability of hepatitis C treatment and diagnosis. The organisation is funded by The Global Fund, and the program is supported by Gilead.

MATERIALS AND METHODS

The study was conducted over 7 months from February 1 to August 30, 2017. The study had two arms; a qualitative in-depth interview and focus group arm, and a comparative quantitative arm which has been previously compiled by the organisation and evaluated 5 years of program activity. The qualitative arm involved 60 IDUs with hepatitis C, and compared the quantitative results of 139 participants, 35 of which were HCV-infected. None of the participants of both arms had HIV. There was no overlap between the arms. Age range was for interview was 25 to 55, and for focus groups, 29 to 65. After ethics approval, respondents were recruited by program officials until required number was reached. The qualitative arm involved in-depth interviews of 30 HCV-positive and HIV-negative IDUs, and the focus groups, 30 people, in 4 groups, with the same infected status. The interviews and focus groups assessed responses to certain conversation topics to gauge HIV knowledge, attitudes and risk behaviours and were led by trained researchers.

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Selection criteria included: age 18 years or above, IDU, or IDU history, hepatitis C infected, or in treatment program in the last year, voluntary involvement, and Georgian speaking.

RESULTS

Despite HIV knowledge being available through TV, internet and harm reduction services, level of knowledge was still low. Most participants did not know the difference between HIV and AIDS. Participants knew that HIV was not transmitted by non-sexual and non-blood-related activities, such as hugging, kissing and hand holding, but they did not know the virus cannot be transmitted through utensils and linen. The majority of respondents partook in a risky behaviour, despite knowing the link between their infection status and the risk behaviour. Most of the participants had shared injections, cotton or pottery.

Most participants knew about the high risk for sexual transmission during unprotected sex, but there was still a high rate of unprotected sex. Participants were unable to rationalise their behaviour, with only three respondents stating they undertake risky behaviours while intoxicated.

Most respondents believed that HIV could be transmitted through shaving or sharing toothbrushes, as well as at beauty salons and the dentist. This led many to not share these instruments at home, as well as other common items, such as linen, cutlery and crockery.

Many participants had experience living with an HIV-infected individuals and were confident they would not have issues co-habiting with an infected person. Lack of knowledge was associated with negative attitudes, but many participants stated that if a close contact was to become infected, they would offer empathy and support. Some stated they would be willing to start a family if they loved HIV-infected person.

There was a high level of self-stigmatisation in relation to hepatitis C. Many had tried to protect their status from family and employers. Stigma around HIV was higher, with many males stating they would not marry or start a family with an HIV-positive person, but would be willing to offer support. Responses from women were much broader, ranging from total acceptance to complete separation.

There was no difference in knowledge between males and females, but females had less riskier sexual behaviours. Men often knew their HCV status, yet would still have unprotected

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sex, with some believing it could not be sexually transmitted. Both groups had equal HIV risk, but women knew less about the difference between HIV and AIDS. Injecting risk behaviour was also similar, with the vast majority sharing instruments. As stated, women had wider responses to HIV-infected people, with one stating that they would socially block an infected family member, five women stating HIV-infected people were equal members of society, and three stating they would be willing to marry and start a family if they loved an HIV-infected person.

Interview participants showed no significant difference between the younger (26-35) group, and the older (36-55) group in terms of knowledge, though four participants in the younger group could differentiated HIV and AIDS. The younger group were also more able to independently and easily obtain HIV information. There was no difference between the groups in terms of risk behaviours, stigma towards HIV and satisfaction with NGO services (though more older people used services).

Focus group analysis showed a difference in knowledge, with the oldest group (56 and older) having less knowledge, but they were also less likely to partake in risky sexual behaviour. The middle age focus group (36-55) expressed the greatest amount of fear and sympathy towards the HIV-infected, whereas the younger group (25-35) expressed less stigma.

There were statistically significant differences between HCV-positive and negative people. HCV-positive people more frequently shared water for injection (33% v. 7%, p<0.001), sharing of utensils (43% v. 9%, p<0.001), sharing of cotton (10% v. 1%, p=0.039) and drug sharing (41% v. 12%, P<0.001).

Though there were differences in sexual partner HIV status, condom use, worry about HIV, and knowledge of their own HIV status between HCV-infected and non-infected participants, none of these differences were statistically significant.

Most respondents used the available NGO services and all respondents viewed it as satisfactory. They positively evaluated the Gilead-sponsored hepatitis C program, as well as the education provided. Participants found it difficult to name specific needs, but many mentioned the need for 24-hour needle and syringe exchange. Appreciated services included free dispensation of naloxone and anonymous, daily services.

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DISCUSSION

The results of this study show that hepatitis C is somewhat accepted in Georgian society, while HIV/AIDs is extremely stigmatised. There could be various reasons for this, including the high prevalence among the population, availability of treatment options, and optimism about the outcomes of treatment, and could lead to decrease in information seeking. Conversely, HIV treatment is limited to most people, and HIV knowledge was incomplete in most respondents. IDU beneficiaries infected with hepatitis C had a positive attitude towards people with HIV/AIDS, although stigma did still exist to some extent.

Our research has shown that access to information about HIV/AIDS among IDUs with HCV was high, but this knowledge did not always create a risk behaviour change. Although most of the beneficiaries accessed services, there seemed to be little effect on changing risky behaviours. All IDUs infected with Hepatitis C had risky behaviours in the past, and the majority of them continued risky behaviours.

Differences between male and female respondents were demonstrated, with female respondents generally having a more tolerant attitude towards HIV-infected people. Female sexual behaviour was less risky.

People infected with HCV are also somewhat stigmatised, and self-stigma creates a degree of denial about their equal status in family and community. The power of this stigma is such that, despite two years of elimination efforts in Georgia, three respondents stated that they do not participate in programs for fear of employment termination.

Social advertisements in fighting HIV are shown in our research to be extremely important. Attention should be given to the possibility of living together with an HIV-infected person and to increase acceptance of this disease, as is happening towards hepatitis C.

Based on the analysis of quantitative research it is clear that the respondents who did not have HCV were characterised by less risky behaviour in terms of injecting drug use. However, there was no difference in terms of risky sexual behaviour.

CONCLUSION

Our study on the knowledge, attitudes and behaviours related to HIV of injecting drug users without HIV in Georgia revealed interesting results and points for further future program

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development. In reference to HIV knowledge, as predicted, knowledge was incomplete, with participants being generally overly wary about sharing common equipment with HIV infected people. Interestingly though, this often didn't translate to a change in drug risk. Stigma was generally high around HIV, much more so than HCV, possibly related to higher prevalence. Knowledge of risk of sexual transmission could provide direction for future HIV risk education, and in terms of knowledge, while there was no difference between genders, there was between ages. The results are interesting, and show the need for innovative ways to harm minimise and reduce person risk, and could lead programs to be more responsive and personalised in their approaches to harm minimisation, education and service provision.

LIMITATIONS

Our study was limited due to selection bias and small sample size. The use of focus groups possibly altered the responses of some participants in a group setting.

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