

Hepatitis C Research in Georgia

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Burden of Hepatitis C, Georgia

- General population:
6.7% (Tbilisi population survey 2000-2002)
- High risk populations:
 - IDU
 - 57-74% among IDUs (BSS/USAID/GHPP)
 - ~50% among IDUs 2006-2012 (GHRN)
 - 92% among IDUs 2012 (Tbilisi, MDM/HRU)
 - MSM: 17.3 (BSS/CIF)
 - HCW: 5% (HRU)



Gaps and Challenges in HCV control

Prevention:

- Weak national infection control regulations
- Poor infection control policies at the facility level
- Blood safety issues related to 90% of paid and family replacement donors, very low proportion of volunteer donors
- Sustainability of harm reduction interventions in view of phasing out of donor funding
- Harm reduction interventions in prisons



HCV Elimination Program

Global Hepatitis C Elimination Framework

- Treatment as prevention and cure for global eradication of HCV is being discussed among researchers, public health leaders and industry partners
- Currently available DAAs and new drugs in the pipeline set new paradigm for Hepatitis C treatment globally – oral regimes, close to 100% curability rates, fewer side effect
- Pilot hepatitis C elimination model needed to provide evidence to global community to move forward with the elimination interventions



Georgia - pilot country for HCV elimination

- Small country, optimal site for piloting
- High burden of HCV infection, relatively small numbers of patients and thus total cost of treatment programs
- Strong Government commitment in health care
- Established public health system and networks
- Human resource capacity, and developed service delivery networks
- Public-private partnerships and strong civil society organizations
- Established harm reduction and preventive interventions among high risk groups and key affected populations



Elimination strategies

Access to Diagnosis and Treatment

- Comprehensive elimination strategic plan
- Ensure provision of affordable drugs through low price negotiations with pharmaceutical industry
- Ensure universal access to screening, diagnostic and treatment services



Elimination strategies

Prevention

- Develop and endorse national infection control policies and regulations
- Facilitate implementation of facility level infection control policies, including safe injection practices.
- Expand harm reduction programs and interventions
- Promote volunteer blood donations and ensure quality assurance for blood transfusion services.



Elimination strategies

Partnerships

- Strengthen collaboration between the national government, civil society organizations, healthcare professionals and researchers
- Ensure participation of patients and key affected populations in program design and implementation
- Develop strong international partnerships to ensure technical assistance and support for national inte



Elimination strategies

Cross-cutting objectives

- Develop/strengthen human resources for elimination interventions
- Develop a monitoring and evaluation system to measure success and failures
- Generate evidence-based data for replication in other countries and settings
- Develop research agenda in different fields of HCV (epidemiology, basic science)



Key strategies, activities and outcomes before implementation of a nationwide hepatitis C elimination program

- 2011 - Free PEG/RBV treatment for HIV/HCV co-infected persons per year through Global Fund for AIDS, TB, and Malaria
428 persons received treatment
- 2014 - Free HCV screening, diagnostics for all incarcerated persons
Free PEG/RBV treatment for up to 500 incarcerated persons with fibrosis stage F2 (moderate disease) per year
406 persons received treatment
- 2014 - Reduced price (60%) PEG/RBV treatment for 10,000 persons
851 persons received treatment



HCV Elimination Program

- Georgia committed to building its capacity to implement an HCV elimination program.
- The HCV elimination program initially focused on treating HCV-infected persons with severe liver disease (advanced liver fibrosis)
- Providing discounted HCV diagnostic services.



HCV Elimination Program

- Eight clinical sites and two prisons with experience providing interferon-based treatment were assessed and scored based on six domains:
 - leadership and governance,
 - quality of clinical care services,
 - health information systems/management,
 - human resource capacity, access to necessary laboratory tests,
 - drug-procurement procedures.
- Standard World Health Organization–adapted tool was used to assess capacity at four clinical laboratories



Elimination Program - Progress to date

- Agreement on 5,000 free courses of sofosbuvir (Sovaldi) followed by 20,000 free courses of ledipasvir-sofosbuvir (Harvoni) per year through Gilead Science
- Through end of August, 2015, a total of 10 225 persons sought treatment
- Among these, 3392 completed work-up and await case review
- 3024 persons initiated treatment
(sofosbuvir/ribavirin or Sofosbuvir/ribavirin/interferon regimen)
- Data management system “STOP-C” developed to monitor and evaluate HCV continuum of care



HCV Elimination Program

- *Publication*

Mitruka K, Tsertsvadze T, Butsashvili M, Gamkrelidze A, Sabelashvili P, Adamia E, Chokheli M, Drobeniuc J, Hagan L, Harris AM, Jiqia T, Kasradze A, Ko S, Qerashvili V, Sharvadze L, Tskhomelidze I, Kvaratskhelia V, Morgan J, Ward JW, Averhoff F.

Launch of a Nationwide Hepatitis C Elimination Program - Georgia, April 2015. MMWR Morb Mortal Wkly Rep. 2015 Jul 24;64(28):753-7.



National HCV Survey, NCDC/US CDC

- Stratified, multistage cluster survey designed to select a nationally representative sample of 7,000 adults, launched in six major cities (including Tbilisi) and 10 rural regions in May 2015.
- Household visits
- Serum samples for anti-HCV antibody
(if positive, HCV RNA and genotyping)
- Data on behavioral risk factors
- The survey will allow calculation of independent HCV prevalence estimates for the six major cities and most rural areas surveyed once analyzed by fall 2015



HCV Research Projects, HRU

- Evaluation of risk factors of transmission of blood-borne diseases among dental health care workers in Georgia
Fogarty International Center, NIH
- Unraveling the Paradox of HCV Transmission between Cohabiting Sexual Partners
Fogarty International Center, NIH



HCV Research Projects, HRU

Influence of immunogenetic factors on the course of hepatitis C virus infection

Rustaveli Foundation

Genotype distribution (IDUs vs non-IDUs)

242 non-IDUs - genotype distribution:

- Genotype 1 – 40.96%
- Genotype 2 – 18.6%
- Genotype 3 – 40.5%

Prevalence of mixed genotypes was significantly higher ($p < 0.01$) among IDUs (9%) vs. non-IDUs (1.7%).

200 IDUs - genotype distribution:

Genotype 1 – 26%,
Genotype 2 – 21%
Genotype 3 – 53%

The difference between these two subgroups was statistically significant ($p < 0.005$).

Kamkamidze G, Butsashvili M, Kajaia M, Kandelaki G,
Chubinshvili O, Presented at Clinical Virology Symposium,
April 2015, Daytona, Florida



HCV Research Projects, HRU

Prevalence and awareness of blood borne pathogens among health care workers of Georgia

Civilian Research and Development Foundation (CRDF)

Fogarty International Center, NIH

Publications

Butsashvili M, Kamkamidze G, Kajaia M, Morse DL, Triner W, Dehovitz J, McNutt LA. Occupational exposure to body fluids among health care workers in Georgia, Occup Med (Lond). 2012 Dec;62(8):620-6

Butsashvili M, Kamkamidze G, Kajaia M, Morse DL, Triner W, Dehovitz J, McNutt LA

Needing to adjust for confounding in risk factor studies of hepatitis C
Submitted



HCV Research Projects, HRU

Framing potential research in the area of immunogenetic, viral and behavioral risk factors of clinical course of HCV infection in Georgia

ANRS

Butsashvili M, Kamkamidze G, Kajaia M, Orne-Gilemann J, Dabis F.
Predictive values of serum biomarkers for fibrosis assessment among patients with hepatitis C

- *Presented at AASLD Special Conference on hepatitis C, New York City, Sept, 2014*



HCV Research Projects, HRU

- Blood borne viruses (HCV, HBV, HIV) among health care workers of Georgian Maternity hospitals
NATO Science and Security Programme

Publication

Butsashvili M, Kamkamidze G, Umikashvili L, Gvinjilia L, Kankadze K, Berdzuli N. Knowledge of health care-associated infections among Georgian obstetricians and gynecologists.

J Infect Dev Ctries. 2010 Jun 3;4(5):329-33.



HCV Research Projects, HRU

HCV infection among injecting drug users in Georgia

Medicins du Monde (MDM)

Publications:

- Luhmann N, Champagnat J, Golovin S, Maistat L, Agustian E, Inaridze I, Myint WM, Butsashvili M, Bouscaillou J.

Access to hepatitis C treatment for people who inject drugs in low and middle income settings: Evidence from 5 countries in Eastern Europe and Asia.

Int J Drug Policy. 2015 Aug 22.

- Bouscaillou J, Champagnat J, Luhmann N, Avril E, Inaridze I, Miollany V, Labartkava K, Kirtadze I, Butsashvili M, Kamkamidze G, Pataut D.

Hepatitis C among people who inject drugs in Tbilisi, Georgia: an urgent need for prevention and treatment.

Int J Drug Policy. 2014 Sep;25(5):871-8.



HCV Research Projects, HRU

CD4 and CD8 T cell responses in HIV and HCV
Infected patients

INTAS

Publication

Barbakadze G, Kamkamidze G, Butsashvili M, Kiladze M, Jatchvliani D.

The role of specific CD4+ T helper cell response in the course of hepatitis C virus infection. Sb Lek. 2003;104(1):79-83.



- **High incidence of the hepatitis C virus recombinant 2k/1b in Georgia: Recommendations for testing and treatment.**

Karchava M, Waldenström J, Parker M, Hallack R, Sharvadze L, Gatserelia L, Chkhartishvili N, Dvali N, Dzigua L, Dolmazashvili E, Norder, Tsertsvadze T



Future Research, HRU

- Estimating the nosocomial risk of hepatitis C virus (HCV) infection among young Georgian women
- Behavioral, socio-economic and medical factors associated with HCV treatment outcome

