



MINISTRY OF LABOUR
HEALTH AND
SOCIAL AFFAIRS



2016–2020

STRATEGIC PLAN

for the Elimination
of HEPATITIS C VIRUS
in Georgia

STRATEGIC PLAN FOR THE ELIMINATION OF HEPATITIS C VIRUS IN GEORGIA, 2016-2020

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OVERALL

MoLHSA: Davit Sergeenko, Valeri Kvaratskhelia, Eka Adamia

NCDC: Amiran Gamkrelidze, Irma Khonelidze, Paata Imnadze, Maia Tsereteli, Davit Baliashvili, Giorgi Khatelishvili

IDACIRC: Tengiz Tsertsvadze, Nikoloz Chkhartishvili

NGO HRU: Maia Butsashvili

U.S. CDC, South Caucus Office, Tbilisi, Georgia: Lia Gvinjilia, Juliette Morgan

U.S. CDC, Division of Viral Hepatitis: John Ward, Francisco Averhoff, Kiren Mitruka, Muazzam Nasrullah, Nancy Glass, Rachel Wilson, Anna Koscelski

University Research Co. Representation in Georgia: Tamar Gabunia

World Health Organization Headquarter and Regional Office for Europe

Surveillance Panel

NGO HRU: Maia Butsashvili

NCDC: Khatuna Zakhshvili, Maia Tsereteli, Tsira Merabishvili, Davit Baliashvili, Irma Burjanadze, Ana Aslanikashvili

IDACIRC: Nino Badridze, Akaki Abutidze

U.S. CDC, Division of Viral Hepatitis: Geoff Beckett, Scott Holmberg

Harm Reduction Panel

Global Fund HIV Program, NCDC: Ketevan Stvilia, Alexander Asatiani, Giorgi Soselia

Georgian Harm Reduction Network: Marine Gogia, Paata Sabelashvili

IDU Community: Koka Labartkava

U.S. CDC, Division of Viral Hepatitis: Alice Asher, Eyasu Teshale

Safe Blood Panel

NCDC: Eter Kipiani, Ekaterine Kavtaradze, Vladimer Getia, Sofio Dolbadze

MoLHSA: Babi Turkia

IDACIRC: Ketevan Shermadini

Blood Bank: Levan Avalishvili, Marina Abashidze

Infection Control Panel

NCDC: David Tsereteli, Giorgi Chakhunashvili

MoLHSA: Marina Baidauri

State Regulation Agency for Medical Activities: Tariel Kashia

Mediclub Georgia: Nia Giuashvili

Georgian Dental Association: Ketii Gogilashvili

Clinic "Helsicore": Gela Arabidze

Information, Education, Communication Panel

MoLHSA: Nino Mamaladze, Irina Tskhomelidze

NCDC: Maia Shishniashvili, Nino Mamukashvili, Marina Topuridze

U.S. CDC, Division of Viral Hepatitis: Cynthia Jorgensen

Clinical Management and Treatment Panel

IDACIRC: Tengiz Tsertsvadze, Nikoloz Chkhartishvili, Vakhtang Kerashvili, Elza Vashakidze, Marina Kvitashvili, Maia Jamutashvili, Gia Beitrishvili, Shorena Dvali

Hepatology Clinic HEPA: Lali Sharvadze

Clinic Mrcheveli: Davit Metreveli

U.S. CDC, Division of Viral Hepatitis: Claudia Vellozzi, Aaron Harris, Alexander Millman

Finance and Logistics Panel

MoLHSA: Ketevan Goginashvili, Ekaterine Adamia

Laboratory Diagnostics and Quality Assurance Panel

NeoLab: George Kamkamidze

NCDC: Maia Alkhazashvili, Gvantsa Chanturia, Nazi Chitadze

IDACIRC: Marika Karchava, Lana Gatsserelia

U.S. CDC, South Caucus Office, Tbilisi, Georgia: Beth Skaggs

U.S. CDC, Division of Viral Hepatitis: Jan Drobeniuc

LIST OF ABBREVIATIONS

| | |
|---------|---|
| AIDS | Acquired Immunodeficiency Syndrome |
| ARV | Antiretroviral |
| BBS | Bio-behavioural survey |
| BTS | Blood Transfusion Service |
| BCC | Behaviour change communication |
| CDC | Centers for Disease Control and Prevention |
| CBO | Community-based organisation |
| CSO | Civil society organization |
| ECHO | Extension for Community Healthcare Outcomes |
| EIDSS | Electronic Integrated Disease Surveillance System |
| FSW | Female sex worker |
| GFATM | The Global Fund to Fight AIDS, Tuberculosis and Malaria |
| HBV | Hepatitis B virus |
| HCV | Hepatitis C virus |
| HIV | Human immunodeficiency virus |
| IBSS | Integrated bio-behavioural surveillance study |
| IDACIRC | Infectious Disease, AIDS and Clinical Immunology Research |
| IDU | Injecting drug use |
| IEC | Information, Education & Communication |
| IPC | Infection prevention and control measures |
| KAP | Key affected populations |
| M&E | Monitoring and evaluation |
| LIFER | Liver Institute and Foundation for Education and Research |
| MDM | Médecins du Monde France |
| MoLHSA | Ministry of Labour, Health and Social Affairs |
| MSM | Men who have sex with men |
| NCDC | The National Centre for Disease Control and Public Health |
| NSP | Needle and syringe program |
| NGO | Non-governmental organization |
| HCV NSP | National HCV Strategic Plan |
| OI | Opportunistic infection |
| OST | Opioid substitution therapy |
| PCR | Polymerase chain reaction |
| PDI | Peer driven intervention |
| PIT | Provider initiated testing |
| PWID | People who inject drugs |
| PWUD | People who use drugs |
| PLHIV | People living with HIV |
| QA | Quality assurance |
| STI | Sexually transmitted infection |
| SW | Sex worker |
| TAG | Technical Advisory Group |
| TTI | Transfusion-Transmissible Infections |

| | |
|--------|--|
| TB | Tuberculosis |
| UN | United Nations |
| UNAIDS | The Joint United Nations Programme on HIV/AIDS |
| VCT | Voluntary counselling and testing |
| WHO | World Health Organization |

EXECUTIVE SUMMARY

Globally, there are an estimated 130-150 million people living with hepatitis C virus (HCV), and more than 700,000 people die every year from HCV-associated hepatic diseases. 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. New cases of HCV also are on the rise, with most occurring among persons who inject drugs (PWID). HCV is a preventable and curable blood-borne infection. However, because acute infection is often asymptomatic, most persons remain unaware of their infection status until decades later, when they experience life-threatening complications (e.g., liver cancer and cirrhosis). In response to this HCV epidemic, the Government of Georgia committed to eliminating HCV in their country by 2020 (defined as 90% reduction in infection prevalence), a goal that is now achievable due to recent availability of highly effective, direct acting antivirals (DAAs) capable of curing >90% of persons treated. In addition, the country proposed the following elimination goals: a) testing 90% of HCV-infected persons for their infection; b) treating 95% of people with chronic HCV infection; and c) curing 95% of persons treated of their HCV infection.

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. Furthermore, the Government of Georgia (including the Ministry of Labour, Health, and Social Affairs [MoLHSA] and the National Center for Disease Control [NCDC]) convened a Technical Advisory Group (TAG) composed of international experts in the field of viral hepatitis (e.g., representatives from the U.S. Centers for Disease Control and Prevention [CDC], World Health Organization [WHO], and other international partners). The group, which first met in November 2015, was tasked with developing strategies, objectives, and actions that would help Georgia eliminate HCV. One of TAG's primary recommendations was development of a strategic HCV Elimination Plan accompanied by targets and indicators to promote program monitoring and evaluation.

This Strategic Plan for the Elimination of Hepatitis C in Georgia represents the first such plan of its kind. Georgia will continue to collaborate with outside experts to implement the activities outlined in the Elimination Plan, which serves as a roadmap for other countries committed to eliminating HCV-associated morbidity and mortality and preventing new infections. The Elimination Plan will be updated as needed to accommodate advances in the field of HCV prevention and address emerging challenges.

INTRODUCTION

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV). Chronic hepatitis C develops in most people infected with HCV and can cause serious complications, such as end-stage liver disease. Although no vaccine is available to protect against hepatitis C, interventions can prevent HCV transmission. HCV infection can be treated with antiviral drugs and, in most cases, successfully cured, reducing the risk of morbidity/mortality and theoretically risk for transmission [1, 2]

Another type of chronic viral hepatitis, hepatitis B, also causes substantial morbidity and mortality worldwide, including in Georgia. Unlike HCV, a vaccine is available to protect people from hepatitis B virus (HBV). Persons already infected with HBV can be treated with antiviral drugs, which although effective in preventing disease progression, do not lead to cure. Further discussion about HBV infection is beyond the scope of this document, but information regarding HBV epidemiology, modes of transmission, prevention, and control worldwide and for the country of Georgia can be found at <http://www.cdc.gov/hepatitis/hbv/>.

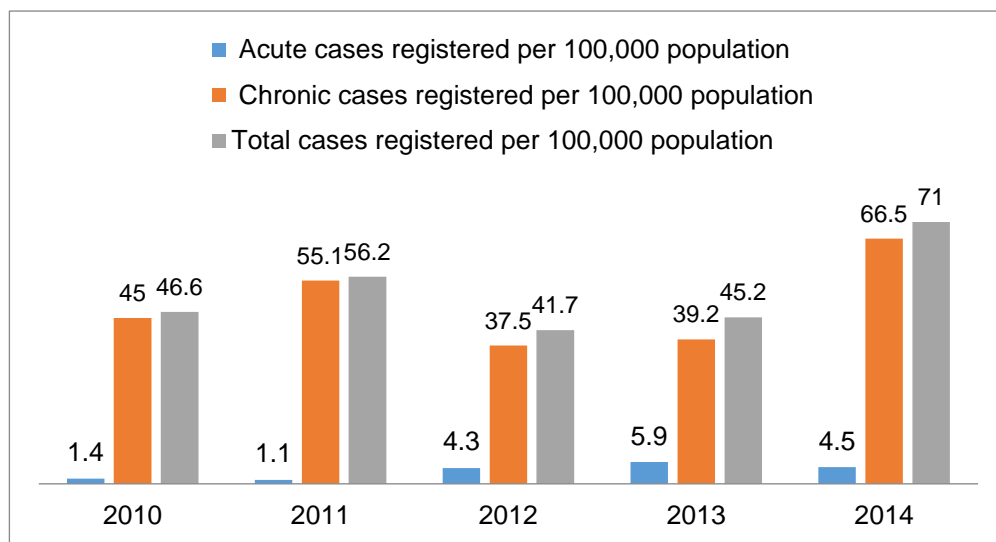
Humans are the only natural reservoir of HCV. Transmission occurs through contact with the blood of an infected person. Important modes of transmission include injection-drug use and healthcare-associated transmission. Hepatitis C is also transmitted perinatally from mother to child, by sharing personal items contaminated with infected blood, and through sexual contact, although infection through these routes is relatively rare [3].

Globally, there are an estimated 130-150 million people living with HCV infection and 700,000 HCV-attributable deaths each year [4, 5]. HCV transmission and mortality are considered epidemic in certain populations of the world. For instance, a concentrated epidemic is occurring in high-risk populations (e.g., persons who inject drugs [PWID]) in most developed countries (e.g., the United States and countries in Western Europe) and is becoming a major source of infection in developing countries and those with transitional economies, accounting for 40% or more of cases globally [6]. Some countries with high HIV prevalence rates are also experiencing an HCV epidemic involving persons who are co-infected with HIV [7]. Rates of HIV/HCV co-infection are highest in areas where injection-drug use is a major route of HIV transmission. The extent to which other countries are experiencing similarly high rates of HCV infection is unknown, as there is a dearth of reliable epidemiologic data globally; for some countries, there are no data available at all.

The prevalence of hepatitis C is high in Georgia (5.4% [RNA positive]) [8], a country with one of the largest burdens of HCV infection globally (Figure 1). Indeed, this infection remains one of the biggest public health threats facing the country. In recognition of this threat, Georgia began offering treatment to a limited number of HCV-infected persons in 2011. Beginning in 2014, when new oral medications that can cure >90% of HCV infections were licensed [9, 10], Georgia engaged partners to develop a comprehensive HCV prevention and control plan; the concept of elimination of HCV transmission and disease emerged during a meeting with these partners. To prepare for the launch of an HCV elimination program, Georgia requested

assistance from the U.S. Centers for Disease Control and Prevention (CDC) to describe HCV epidemiology, evaluate laboratory and healthcare capacity, and conduct program monitoring and evaluation.

FIGURE 1. NATIONAL RATES OF REPORTED ACUTE AND CHRONIC HCV CASES PER 100,000 POPULATION — GEORGIA, 2010–2014



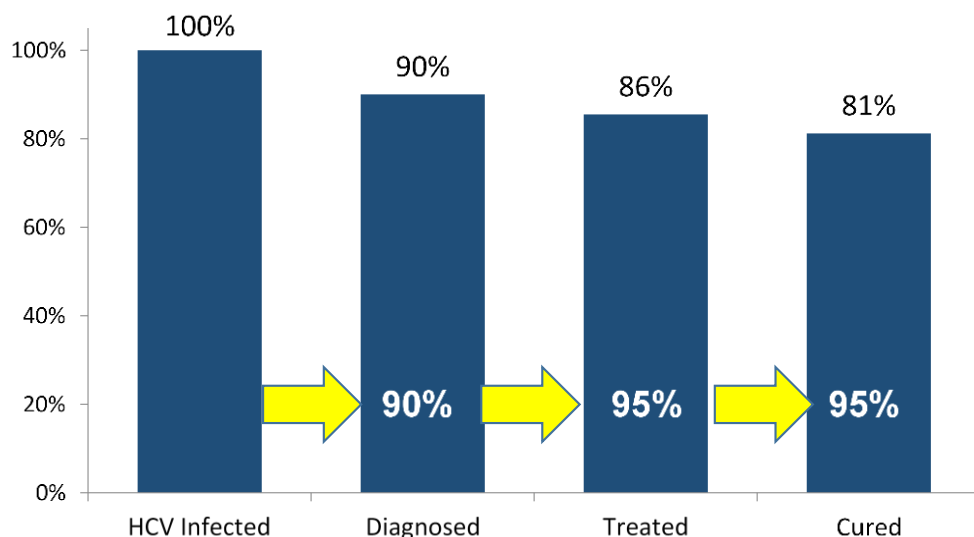
On April 28, 2015, with strong political will, a partnership with and technical assistance from CDC, and commitment from Gilead Sciences to donate direct acting antiviral (DAA) medications, the country of Georgia embarked on the world’s first HCV elimination program [11]. This program provides HCV screening at testing sites throughout the country and offers curative treatment at no cost to infected persons. The initial phase of the program prioritized treatment for HCV-infected persons with advanced liver disease and at highest risk for HCV-associated morbidity and mortality. The initial treatment regimens consisted of sofosbuvir in combination with pegylated interferon and ribavirin, although beginning in mid-February 2016, patients began receiving the newer ledipasvir/sofosbuvir DAA regimen. Georgia has been committed to increasing technical and financial resources to implement evidence-based interventions for preventing and managing HCV as the program has evolved.

Georgia recognized that a more comprehensive estimate of the burden of HCV infection in the country was needed to inform evidence-based screening, treatment, and prevention interventions and strategies; these data would also be critical to the development of an HCV elimination plan and would provide a baseline against which progress could be measured over time. As a result, the country conducted a nationally representative, cross-sectional household serosurvey among persons aged ≥ 18 years during May through August 2015 in major cities and rural regions of the country (Georgia Ministry of Labor, Health, and Social Affairs [MoLHSA], unpublished data, 2016).

To achieve its elimination goal, the country of Georgia has set forth the following 2020 targets: a) identifying 90% of HCV-infected persons; b) treating 95% of people with chronic HCV infection; and c) curing 95% of persons treated of their HCV infection (Figure 2). The country set an overall goal of 90% reduction in prevalence (i.e., from 5% to 0.5%) during the same time period. Given that an estimated

150,000 patients are living with chronic HCV infection, reaching all three elimination targets would require testing over one million Georgians, diagnosing about 133,000 patients, treating approximately 126,000 patients, and curing about 120,000 patients (Figure 2). Since the baseline prevalence of active HCV infection is approximately 5% in the adult population, a 90% reduction in prevalence equates to a 0.5% prevalence. Achievement of these goals is expected to reduce mortality by at least 65%.

Figure 2. Projected Cascade of HCV Care Based on 90-95-95 Targets



BURDEN OF HCV INFECTION IN GEORGIA

The prevalence of HCV infection in Georgia is among the highest in the world. Findings from the national population-based serosurvey conducted in 2015 by the National Center for Disease Control and Public Health (NCDC) and CDC revealed that 7.7% (95% confidence interval [CI]: 6.7-8.9) of adults have evidence of HCV infection (i.e., are anti-HCV positive); chronic HCV infection (i.e., RNA positivity) was found among 5.4% (95% CI: 4.6-6.4) of those tested, which translates to an estimated 150,000 persons living with HCV in Georgia (MoLHSA, unpublished data, 2016). Genotype 1 is the most prevalent HCV genotype in Georgia. The 2015 population-based survey revealed 39.5% prevalence of genotype 1b (<1% prevalence of genotype 1a), followed by genotype 3 (34.3%) and genotype 2 (24.5%) (MoLHSA, unpublished data, 2016). In addition to the prevailing HCV 1, 2, and 3 genotypes, HCV recombinant strain RF1_2k/1b is common (76%) among HCV genotype 2 patients according to a 2011 study [12].

Although epidemiologic patterns of HCV in Georgia are not completely understood, contributing factors to the high disease burden include transmission associated with poor infection control in healthcare settings and inadequate blood-bank practices, problems likely exacerbated by the collapse of the Georgian

healthcare system during the 1990s. Poor infection-control practices in healthcare settings is also thought to be an important cause of HBV transmission in Georgia. A study in one hemodialysis center in Tbilisi found that 67% (109) of 162 patients tested positive for HCV infection [13].

Injection-drug use is a major public health problem in Georgia and has accelerated the HCV epidemic through shared use of needles, syringes, and other injection equipment among the estimated 50,000 PWID living in the country [14]. According to the Behavioral Surveillance Survey (BSS) conducted during 2014–2015, 66.2% of Georgian PWIDs are HCV-infected [15], and the 2015 serosurvey identified history of injection-drug use as a major risk factor for HCV transmission. Other groups of persons who may be at risk for HCV include men who have sex with men (MSM) (prevalence ranging from 7.1% to 18.9% depending on city) and blood donors (Table 1). Prisoners also have higher rates of HCV; HCV testing during 2004–2008 revealed 52% anti-HCV positivity among 2,031 prisoners in detention facilities.

TABLE 1: HCV PREVALENCE IN GEORGIA

| Target Group | HCV Prevalence | Source |
|-----------------------------------|----------------|--|
| General Population | | |
| Population-based survey | 7.7% | National population-based survey 2015 |
| Surveys among blood donors | 7.3% | Tbilisi blood donors 1998 |
| | 7.8% | Tbilisi, Batumi, Poti blood donors 1997-1999 |
| | 2% overall | “Safe Blood” Georgia State Program, 2012 |

| High-Risk Populations | | |
|--|-------------------|--|
| PWID | 63% | Ever-IDU 1999 (Tbilisi, Batumi, Poti) |
| | 70% | Ever-IDU 2002 (Tbilisi) |
| | 50% | IDU 2006-2012 (Georgian Harm Reduction Network) |
| | 66.2% | IDU 2014 (BSS, Curatio International Foundation) |
| HIV-infected PWID | 73.4% | Chkhartishvili et al. 2014 |
| Other Populations | | |
| Patients with sexually-transmitted infections | 11.3% | Tsertsvadze, 2008 |
| TB patients | 21% | Lomtadze et al. 2013 |
| Men who have sex with men (MSM) | 7.1% (Tbilisi) | Behavioral Surveillance Survey (BSS) among MSM in Tbilisi, Georgia, 2015 |
| | 18.9% (Batumi) | BSS among MSM in Batumi, Georgia, 2015 |
| Healthcare workers | 5% | Butsashvili et al. 2012 |

DEVELOPMENT OF GEORGIA'S STRATEGIC PLAN FOR THE ELIMINATION OF HCV

To achieve the country's HCV elimination goals, the Strategic Plan for Elimination of Hepatitis C in Georgia was developed by the Georgian Ministry of Labour, Health, and Social Affairs (MoLHSA) in close collaboration with experts from CDC, the World Health Organization (WHO), and other international partners. On November 3-4, 2015, MoLHSA collaborated with these partners to convene Georgia's first external Hepatitis Technical Advisory Group (TAG) meeting. A total of 11 national and international experts in the field of viral hepatitis prevention and control served as TAG members. One of the key recommendations resulting from this TAG meeting was development of a national HCV Elimination Plan; TAG members and representatives from the Georgia MoLHSA then met to discuss aspects of the draft elimination plan in the context of proposed goals for HCV elimination in the country of Georgia.

In spring 2016, data analysis of the population-based serosurvey was completed, and some of the key indicators of the elimination strategy were modified based on updated prevalence data. The monitoring and evaluation framework was further discussed during the 3rd National Hepatitis C Workshop held in Tbilisi, Georgia, on April 6-8, 2016. On June 18, the Liver Institute and Foundation for Education and Research (LIFER) symposium for the Georgia HCV elimination program was conducted, providing a forum for local and international experts to discuss current progress of elimination program and key issues related to HCV diagnostics, care, and treatment.

The National Working Group established at NCDC engaged in several months of intensive discussions regarding establishing realistic, feasible targets that reflect the country's capacity and goals. The Group was composed of representatives from all major stakeholder groups, including governmental and non-governmental agencies, academia, and individual experts. International partners, including CDC and WHO, provided input to promote alignment of the strategies with best-practice recommendations and current international standards. The plan was finalized in close collaboration with the TAG.

Georgia's elimination plan was informed by an analysis of recent trends in disease epidemiology, burden, and existing infrastructure and stakeholder consultations, resulting in well-conceived and comprehensive goals, strategies, objectives, and proposed activities. It is anticipated that this plan will be revised as new insights are gained and challenges emerge.

STRATEGIES FOR HEPATITIS C ELIMINATION IN GEORGIA

| | |
|---|--|
| Strategy 1: Promote advocacy, awareness and education, and partnerships for HCV-associated resource mobilization | <ul style="list-style-type: none">• Educate the public and high-risk groups about viral hepatitis and the importance of testing• Reduce stigma and discrimination associated with hepatitis in healthcare settings and among the general public |
| Strategy 2: Prevent HCV transmission | <ul style="list-style-type: none">• Decrease HCV incidence among PWID by promoting harm reduction• Prevent healthcare-related transmission of viral hepatitis by improving blood safety• Prevent healthcare-associated transmission of viral hepatitis by improving infection control• Prevent HCV in non-traditional healthcare and other community settings |
| Strategy 3: Identify Persons Infected with HCV | <ul style="list-style-type: none">• Increase the number of people diagnosed with HCV infection through expanded screening and testing• Expand HCV testing to better reach high-risk populations |
| Strategy 4: Improve HCV Laboratory Diagnostics | <ul style="list-style-type: none">• Improve laboratory detection of HCV infection |
| Strategy 5: Provide HCV Care and Treatment | <ul style="list-style-type: none">• Promote universal access to HCV care and treatment |
| Strategy 6: Improve HCV Surveillance | <ul style="list-style-type: none">• Estimate the national burden of chronic viral hepatitis |

STRATEGY 1: PROMOTE ADVOCACY, AWARENESS AND EDUCATION, AND PARTNERSHIPS FOR HCV-ASSOCIATED RESOURCE MOBILIZATION

CURRENT ACTIVITIES

The HCV Elimination Program in Georgia receives strong support from the national government, and Georgia has successfully established local and international partnerships in the field of viral hepatitis prevention and control. Local partners include governmental organizations (e.g., MoLHSA; Infectious Disease, AIDS and Clinical Immunology Research [IDACIRC]; and Ministry of Corrections and Legal Assistance [MCLA]) that provide overall program management and coordination; private-sector representatives (e.g., private clinics delivering HCV-associated health services); and non-governmental and community-based organizations that are actively involved in HCV service delivery (e.g., testing and referral), policy dialogue, and long-term elimination planning. These organizations also play a pivotal role in promoting HCV-related communication and education in the community at large. For instance, in addition to supporting Georgia's elimination program by providing newly developed DAAs free of charge since 2015, pharmaceutical company Gilead Sciences has been providing or has agreed to provide support for clinical education, information systems development, and meeting logistics.

CDC has been a pivotal elimination partner, advising the Government of Georgia on HCV control since 2013 and helping the government conceive the concept of HCV elimination based on the country's large burden of disease, highly motivated government and public to address the problem, and small population size (3.7 million). CDC continues to support this project and the Government of Georgia through technical assistance, monitoring and evaluation, and research. In 2015, CDC provided technical assistance and resources to NCDC/Georgia to conduct a national population-based serosurvey to define the burden of HCV in the country. CDC and WHO (Headquarters and the Regional Office for Europe) provide additional technical support to ensure sustainability of various interventions, including development of the Elimination Plan. Other international partners include Global Fund, Global Hepatitis Alliance, European Association for the Study of the Liver (EASL), American Liver Foundation, American Association for the Study of Liver Diseases, and private industry partners (e.g., Abbott and Becton-Dickinson). Academic institutions (e.g., Emory University and Bristol University) and subject matter experts are also supporting the hepatitis C elimination program, participating in national workshops and TAG meetings and sharing their knowledge and expertise with Georgian stakeholders.

GAPS

Despite the strong partnerships in place in Georgia, general understanding of the whole course of the disease, available diagnostic and treatment options, and expected outcomes may be inadequate among the general public and high-risk groups. Broad-based education about HCV will help change HCV-related attitudes and reduce stigma, preventing patients' feelings of isolation and increasing the likelihood that these patients will receive appropriate treatment and achieve cure.

Data are limited regarding the social implications (e.g., stigma) of an individual being diagnosed with HCV infection. However, data are available to suggest that diagnosis with hepatitis C has a profound impact on social functioning [16]. Perceived stigma associated with HCV infection within community and healthcare settings can lead to high levels of anxiety and exaggerated fear of transmission, and it can be a major cause of social isolation and reduced intimacy in relationships. The well-known link between HCV [17] and injecting-drug use further stigmatizes patients diagnosed with HCV.

OBJECTIVE 1.1. EDUCATE THE PUBLIC AND HIGH-RISK GROUPS ABOUT VIRAL HEPATITIS AND THE IMPORTANCE OF TESTING

Implementation of this objective will increase community awareness regarding the benefits of HCV diagnosis, treatment, and prevention. Communication strategies will focus on the importance of the early diagnosis and treatment and most importantly explain how patients can best access diagnostic and treatment services, including antiviral drugs, free of charge. The campaign will address 1) the importance of infection control and the role of both patients and providers in creating public demand for safe infection-control practice and eliminating use of unnecessary therapeutic injections, 2) the need to reduce stigma by emphasizing, when epidemiologically sound, general population-based approaches to testing rather than a primary focus on PWID, and 3) the benefits of HCV testing, care, and treatment. To reduce transmission risk, messages must target populations of PWID and employ harm reduction and other interventions that reduce the risk of HCV transmission. The infection-control awareness campaign will target the general public, encouraging consumers to demand newly opened, sterile equipment for all percutaneous procedures in settings other than healthcare facilities (e.g., tattoo, piercing, and acupuncture establishments).

For the educational campaign, all public and private partners and non-governmental organizations will be actively involved in disseminating informational materials to ensure maximum coverage among the general population and to target large subpopulations with increased risks (e.g., men aged 30-49 years); this effort will also reduce stigma. Non-governmental organizations have key roles in outreach to demographic subpopulations and populations at risk for HCV transmission (e.g., PWID). Effectiveness of the campaign will be evaluated regularly during the implementation of the HCV Elimination Program by measuring changes in knowledge, attitudes, and practice (KAP) as compared with the baseline.

The following activities will be implemented to raise awareness of HCV among the general public and high-risk groups and to monitor the effectiveness of interventions. Activities will be coordinated by the public relations group within the NCDC health promotion division.

Objective 1.1

Educate the public and high-risk groups about viral hepatitis and the importance of testing

ACTIONS

- 1.1.1. Study knowledge, attitudes, and practice (KAP) related to hepatitis C prevention, diagnosis, treatment, and infection control (including injection-drug use and unnecessary therapeutic injections) in the general public, segments of the general population with the highest prevalence of disease, and high-risk groups.
- 1.1.2. Develop communication strategies based on KAP survey results for each risk group that include messages, delivery channels, and timelines for materials regarding HCV prevention, diagnosis, progression of disease, and treatment.
- 1.1.3. Update/develop and deliver educational materials and messages to the general public, demographic sub-populations, and risk groups recommended for HCV testing through effective delivery channels including (but not limited to) peer education/patient classes, face-to-face consultation, social and printed media, public service announcements, observance of World Hepatitis Day, and designation of HCV screening days.
- 1.1.4. Develop public-awareness campaigns to reflect changes in screening recommendations and locations of treatment facilities.
- 1.1.5. Develop educational materials and messages that address liver damage caused by the synergistic effect of alcohol consumption and hepatitis C infection.

OBJECTIVE 1.2: REDUCE STIGMA AND DISCRIMINATION ASSOCIATED WITH HEPATITIS IN HEALTHCARE SETTINGS AND AMONG THE GENERAL PUBLIC

Hepatitis C not only causes serious liver damage, but is also associated with mental, psychological, and social consequences and stigma. Although HCV education campaigns can reduce the stigma associated with an HCV diagnosis, such campaigns must be informed by evidence on the societal factors that drive stigma. Reducing stigma towards and preventing discrimination of HCV-infected persons will help to prevent patients' feelings of isolation and increase the likelihood that at-risk persons will be tested and receive appropriate treatment and achieve cure, if infected.

Activities will be targeted at high-level policy makers, healthcare workers (HCWs), and other relevant groups to measure and address HCV-related stigma. The health promotion and public relations groups within NCDC will lead implementation of activities described herein.

Objective 1.2

Reduce stigma and discrimination associated with HCV infection in the community

ACTIONS

- 1.2.1. Conduct research to assess existing stigma and discrimination related to hepatitis C infection.
- 1.2.2. Develop and disseminate HCV-related anti-stigma messages and materials for policymakers, HCWs, and other relevant groups.
- 1.2.3. Create opportunities for collaboration between patient advocacy groups and government (including law enforcement system and ombudsmen), healthcare entities, and others to identify activities to reduce stigma.
- 1.2.4. Develop and implement interventions empowering people with hepatitis C against stigma and discrimination.
- 1.2.5. Develop testing policies that reduce stigma.

STRATEGY 2: PREVENT HCV TRANSMISSION

HARM REDUCTION

CURRENT ACTIVITIES

Preventing new cases of HCV is a critical strategy towards eliminating hepatitis C infection in Georgia that will require working across several cross-cutting areas. PWID must be provided with effective harm-reduction services and linkages to HCV treatment. Blood banks must improve practices to better protect persons who receive blood products from HCV-contaminated blood. Healthcare facilities must improve infection-control measures to protect patients from nosocomial viral hepatitis infections. Other professionals whose work entails potential patient and/or provider exposure to blood (e.g., acupuncturists, tattoo artists, and persons who provide invasive cosmetic procedures) must implement appropriate infection control according to risk.

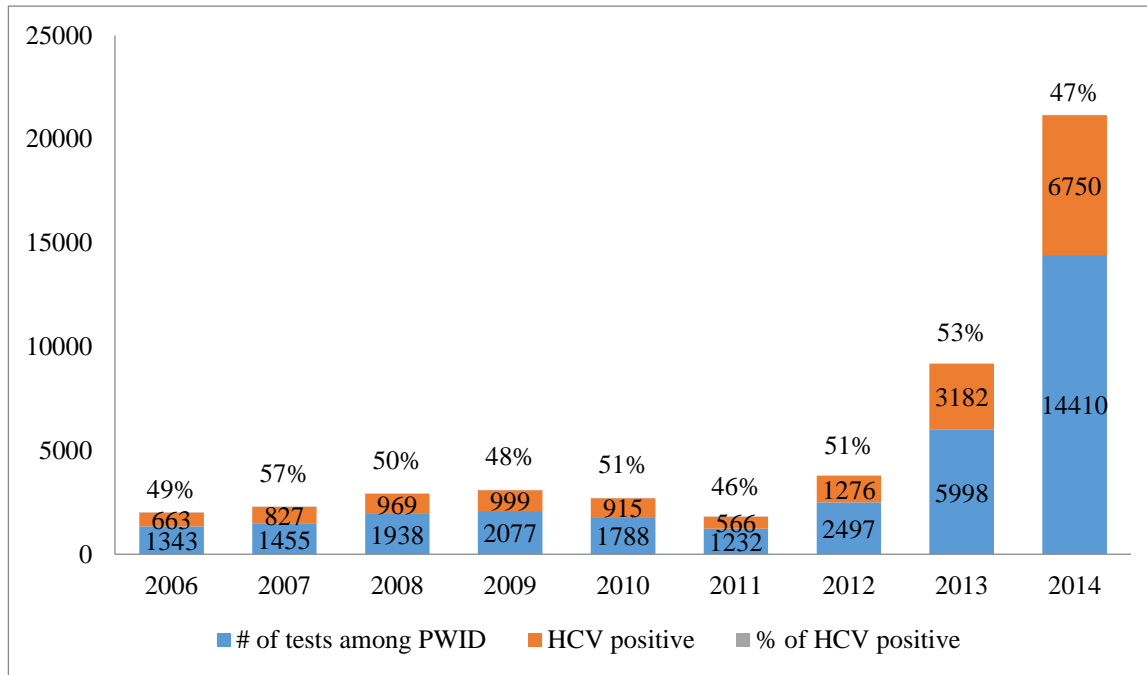
An estimated 50,000 PWID lived in Georgia in 2014, and up to 60% are infected with HCV [14]. Prevalence of risk behavior is high among PWIDs, with only 74% of PWID reporting use of sterile injecting equipment; 8% of PWIDs report sharing injecting equipment during last injection [18].

The types of drugs most commonly used among PWID in Georgia have changed dramatically over the past few years. Limited availability of conventionally used drugs (e.g., opium and heroin) have contributed to increasing use of homemade substances (e.g., Crocodile, Vint, and Jeff) derived from over-the-counter medicines. In response to this trend, Georgia established new regulations that provide for stronger control of pharmacies. However, when coupled with Georgia's lack of treatment/rehabilitation programs and insufficient coverage by needle/syringe programs (NSP) and opioid substitution treatment (OST) services, these new regulations have only served to promote introduction of new, less-studied substances, which potentially cause more harm.

In 2001, with support from the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), Georgia initiated harm reduction services by establishing 14 NSP drop-in centers in 11 major cities. Coordinated by a network of community-based organizations known as the Georgian Harm Reduction Network, these centers provide a basic package of services to PWID, including distribution of sterile injection equipment; voluntary counseling and testing (VCT) for HIV, HCV, HBV, and syphilis; distribution of safe sex information and prophylactics; and overdose prevention (i.e., distribution of naloxone). Services are provided within the drop-in centers as well as through outreach services (e.g., four mobile ambulatories).

Peer Driven Intervention (PDI) methodology [19] was introduced in Georgia in 2010 to increase education and extend the reach of education-focused activities to new PWID clients. Beginning in 2014, PDI was complemented by community-based outreach services. Within the GFATM project, four mobile laboratories were procured to expand the geographic coverage of VCT services. Currently, the outreach program covers 45 cities in 10 regions of the country; in 2016 two more mobile laboratories will be procured, increasing the number of cities with access to VCT to 55. According to NSP program data, HCV testing rates have dramatically increased in the last few years (NCDC, unpublished data, 2016) (Figure 3) likely as a result of such efforts.

FIGURE 3. NUMBER OF HCV TESTS CONDUCTED AMONG PERSONS WHO INJECT DRUGS, GEORGIA



With the support of GFATM, OST programs first started operating in Georgia in 2005 and expanded in 2008 with state funding. A total of 22 OST centers currently operate in Georgia, of which 20 provide OST maintenance services to the community; the remaining two centers represent methadone detoxification services in penitentiary institutions. OST services are supported by both the state and GFATM-funded programs. Although the GFATM program is free of charge, the state program covers cost of the medicines and part of the service costs, with other costs (i.e., co-payment in the amount of 110 GEL) being covered by clients themselves (with the exception of those who are HIV positive and those living below the poverty line). This service is provided on a daily basis through directly observed therapy (DOT).

GAPS

Several challenges are faced by NSP and OST programs that may impact HCV elimination among PWID. Policies that make injection-drug use a punishable crime serve as a barrier to reaching PWID with prevention services. According to the Georgian legislation, illicit drug use is an administrative offense [20] punishable with a fine of GEL 500 (USD \$200). Illicit drug use becomes a criminal offense for persons who repeatedly test positive for any type of illicit drug use within the 12 months following the initial charge [21] and is punishable with fine up to GEL 2,000 (USD \$800) or up to 1 year of imprisonment. Beyond use of these drugs, possession of illicit drugs is associated with a harsher sentence that can result in 6–14 years of jail time [22]. Current drug legislation in Georgia not only affects PWID, but persons involved in providing services. While it is possible to organize clean needle/syringe distribution in the country, the exchange of used and new equipment is not feasible, because detection of even a trace amount of illicit substance in the used equipment is considered grounds for imprisonment of a client or outreach worker.

This dynamic creates unstable and unsafe working conditions for outreach workers and peers engaged in Georgia's NSP program and is a barrier to providing services.

Stigmatization of PWID poses additional challenges to eliminating HCV infection in Georgia. Although domestic funding provided through GFATM currently supports both OST and NSP programs, the funding is not expected to continue indefinitely, increasing the urgency for domestic funding of these programs. Because OST programs are also covered by the state budget, clients are required to cover part of the service costs, at a price of GEL 110 (USD \$45) per month. Most PWID are considered low income, and therefore out-of-pocket fees associated with OST limit access among the population for which the service is intended.

Other barriers to providing services for PWID exist in Georgia. For instance, current policy does not allow outreach workers to issue take-home doses to their clients, and neither OST nor NSP services are available in prisons. Current services do not cater to the needs of women who inject drugs, and the comprehensive package of healthcare and social rehabilitation services limits uptake and retention rates in the program.

NSP interventions are designed to provide a basic package of services suited for risk reduction and HIV prevention among male PWID in major cities. However, the plan calls for NSPs to provide PWIDs with HCV and HBV testing and referral to care and treatment. To eliminate HCV among PWIDs, programs must be scaled up to increase the number of PWIDs reached and number/amount of syringes and sterile ancillary equipment (e.g., cookers) distributed. Furthermore, the package of services offered by NSPs must be expanded to include distribution of sterile paraphernalia and be redesigned to accommodate the needs of neglected sub-groups (e.g., younger clients and women). There is also a need for development of a counseling guideline for PWIDs who have successfully completed HCV treatment to prevent them from reinfection. Further, NSP personnel need specific training in the delivery of VCT for HCV.

Increasing the coverage of harm-reduction interventions is crucial for increasing the number of PWIDs tested for HCV and for preventing and treating HCV infection. According to the Georgian National HIV/AIDS Strategy for 2016–2018, to contain the HIV epidemic among PWID, targets have been established for the scale-up of NSP and OST services. The strategy envisages increased coverage of PWID by NSP services from 11,700 (26% of the estimated PWID population size) in baseline year 2014 to 30,150 (67%) in 2018; OST coverage will expand from 2,850 to 6,000 during the same period [23]. These strategies also support HCV prevention.

Even with expanded availability of curative HCV therapy, such treatment will have minimal impact on HCV incidence and prevalence among PWID [24] without significant scale-up of NSP and OST interventions in Georgia. Thus, addressing the above-mentioned NSP- and OST-associated challenges is crucial for the HCV elimination among PWID, as well as society at large.

OBJECTIVE 2.1. DECREASE HCV INCIDENCE AMONG PWID BY PROMOTING HARM REDUCTION

The overarching goal of harm-reduction interventions (i.e., NSPs and OST) for PWID is to eliminate HCV incidence, prevalence, morbidity, mortality, stigma, and discrimination among PWID in Georgia. PWID

need unlimited access to high quality harm-reduction services. Harm reduction services (including NSPs and OST) in Georgia will continue operating to serve beneficiaries, with the goal of achieving 80% NSP coverage and potentially providing services to 10,000 OST patients by 2020.

The effectiveness of the ongoing OST and NSPs will be evaluated on a regular basis, and after discussions with the affected community, changes will be made to improve performance (e.g., reduced/eliminated co-payments, the option for clients to obtain take away doses, and inclusion of paraphernalia in the sterile kits for NSPs).

An integrated approach will be employed to improve access to both HIV and HCV testing at OST sites. Hepatitis B testing and vaccination will be added to ensure full coverage with preventive services. Centers of Excellence will be created to bring together OST and HCV care and treatment. Starting with these centers, specific, community-based approaches (e.g., DOT, peer support, and reminder messages) will be developed for PWID to strengthen linkages to care and adherence to HCV treatment. A demonstration project will be implemented at selected OST sites. The implementation of these initiatives will be assessed, and if successful, such integration will be undertaken across the country. This integration will be supported through capacity building of staff at OST sites on management of HCV testing, care, and treatment for PWID.

Regarding injection-drug use laws, policymakers will continue to be engaged in discussions regarding transitioning from a law-enforcement-based approach to one that is health-based to decriminalize this behavior. Updating current legislation is critical to attaining all goals and objectives of Georgia’s strategy for eliminating HCV and to sustain program success after the elimination goals are achieved. Model or pilot projects should be considered.

This objective will be implemented through strong collaborations with law enforcement, government, non-governmental organizations, and the public. MoLHSA, NCDC (as a principle recipient of the GFATM programs), Georgia Harm Reduction Network (GHRN), and other clinical services organizations will share the implementation responsibility.

Objective 2.1

Decrease HCV incidence among PWID by promoting harm reduction

ACTIONS

2.1.1. Intensify HCV detection efforts among PWID.

- a) Introduce guidance for HCV testing and confirmatory testing with RNA (or HCV core antigen) for every person who enters an NSP or OST, beginning with a pilot program to assess feasibility and effectiveness.

- b) Provide voluntary counseling and testing (VCT) and peer-driven interventions (PDI) at NSP and OST service points through community-based outreach testing and mobile ambulances.
- c) Provide antibody and RNA testing results to those PWID who test positive.
- d) Establish effective referral mechanisms to full laboratory diagnostic services and linkage to care through case management and social services.

2.1.2. Intensify HCV prevention efforts among PWID.

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

2.1.3. Improve care and treatment for PWID living with HCV.

- a) Provide HCV treatment of PWID at demonstration NSP and OST service points.
- b) Support treatment through peer support and through individual and group counseling (patient schools).
- c) Link PWID released from prison to community harm-reduction services.
- d) Include harm-reduction sites in the screening and treatment monitoring and evaluation system, to include a unique identifier to evaluate linkage to care.
- e) Develop a target for number of PWID treated and cured per year (e.g., at least 5,000 per year), and track program progress by examining the number of treated patients and assessing rates of reinfection.
- f) Improve coordination between Global Fund and the Hepatitis C Elimination program in areas where there is existing overlap.

2.1.4. Establish an environment free of stigma, discrimination, and human rights violations associated with hepatitis C and drug use.

- a) Reach an agreement with the Ministry of Internal Affairs regarding creating a supportive environment (e.g., favorable legislation) for implementation of NSP and OST programs.
- b) Advocate for PWID rights, humanization of legal environment, and development of harm-reduction programs for PWID with special needs (e.g., women, youth, and persons with disabilities).
- c) Provide healthcare providers and other professionals with training to reduce or eliminate stigma related to drug use and HCV infection.
- d) Encourage the continued collaboration among government agencies towards revising legislation that currently penalizes persons who inject drugs.

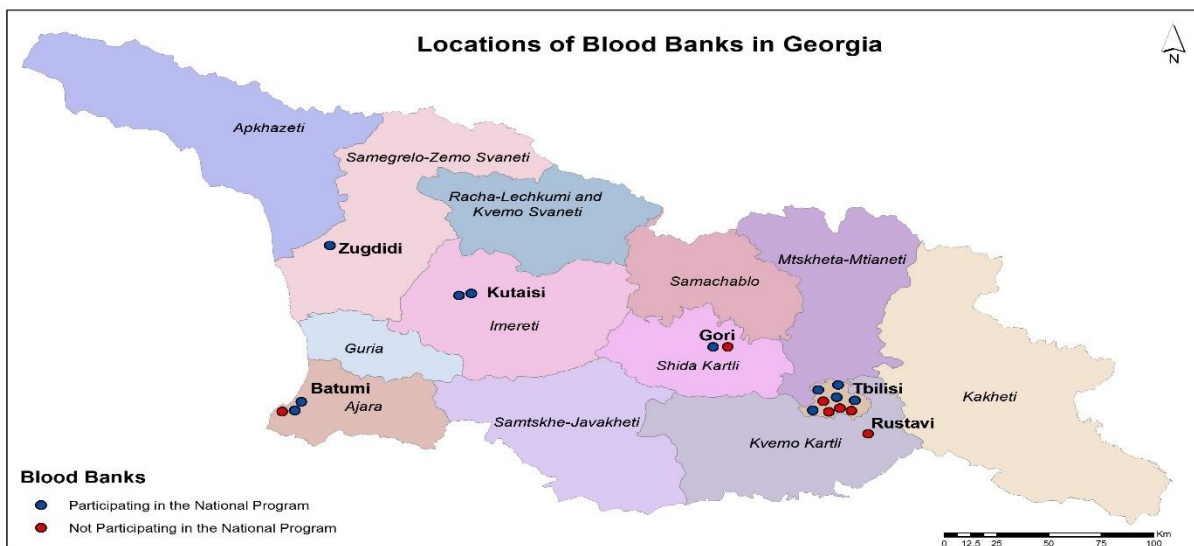
2.1.5. Implement a demonstration project or Center of Excellence that incorporates detection, prevention (e.g., harm reduction including NSP and OST), and HCV anti-viral treatment and expand the model, if successful, to all major cities.

BLOOD SAFETY

CURRENT ACTIVITIES

In 1997, Georgia launched its State Safe Blood Program with the aim of preventing transfusion-transmissible infections (TTIs) and ensuring safety of blood and blood components through high-quality testing of donor blood for HCV, HBV, HIV, and syphilis and increasing the proportion of voluntary, non-remunerated donations. Currently, the blood transfusion service (BTS) in Georgia is fragmented, and the legal status of blood facilities has shifted towards profit-based management. A total of 18 blood banks (eight hospital affiliated) are licensed to collect blood and blood components (Figure 4). Of these, two facilities are nonprofit legal entities (one of them is public nonprofit organization functioning under the authority of the Ministry of Defense of Georgia, and the other a private nonprofit hospital affiliated blood bank); 16 are private, for-profit blood establishments. Six of the 18 blood centers do not participate in the State Safe Blood Program, established to provide external quality control of blood testing in blood establishments.

FIGURE 4. REGIONAL DISTRIBUTION OF BLOOD BANKS, GEORGIA



In Georgia, all blood donations must be tested for the following TTIs regardless of whether a blood bank participates in state blood program: hepatitis B (HBsAg), hepatitis C (anti-HCV), HIV (anti-HIV by ELISA/EIA), and syphilis antibody (by *Treponema pallidum* hemagglutination assay [TPHA]). Because high-quality screening of donated blood is essential to the reduction of TTIs, including HCV, beginning in 2011 blood banks involved in the State Safe Blood Program have been required to undergo routine external

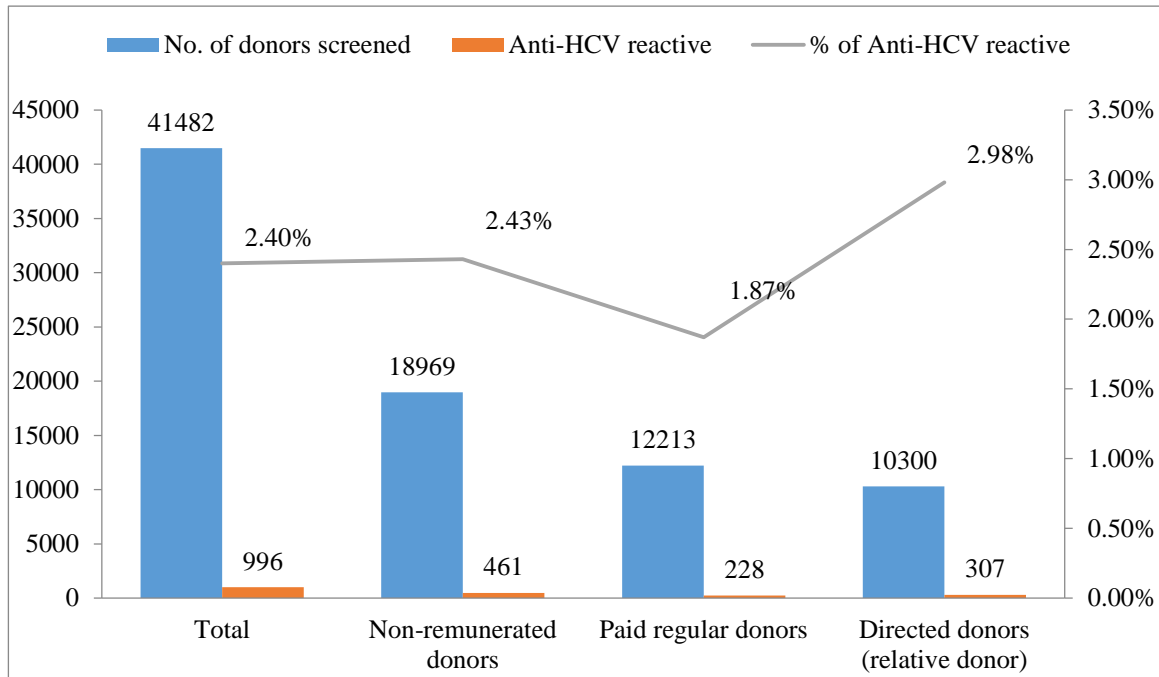
quality control testing, for which randomly selected aliquots from 5% of all donations are rechecked for the TTIs by the NCDC's Lugar Center (a Biosafety Level [BSL] level 3 laboratory established with support from the U.S. government). In addition, since 2015, blood banks participating in the state program are also required to perform quality control through proficiency testing under contracts with international reference laboratories; contracted international reference laboratories distribute panels for testing anti-HCV, anti-HIV, HBsAg, and syphilis antibody to blood banks every 3 months. If discrepancies in proficiency testing results are found, blood banks are required to eliminate existing quality problems before the next round of proficiency testing. If continued discrepancies in results occur at certain blood banks, NCDC retracts the right of these facilities to participate in the state program; however, because no effective mechanisms are in place to enforce suspension or revocation of a state license, these blood banks can continue to produce blood for use in hospitals.

Since 2005, the State Safe Blood Program has ensured operation of an electronic National Blood Registry (Donor Database), representing a significant step towards blood transfusion safety. The Blood Registry, a database of donors and donations from 16 blood banks (including those involved in the state program), enables blood-bank data recording along with reporting within the state-based Safe Blood Program. Specifically, the Blood Registry stores information on blood donors (those that are unpaid, recruited by family members, and paid), donation dates, testing, blood products (e.g., whole blood, red blood cells, washed erythrocytes, platelet concentrate, and plasma), distribution, and storage; however, most participating blood banks fail to enter complete data.

One of the priorities of the national safe blood policy is to increase the proportion of voluntary, non-remunerated donations as well as overall blood donations (Figure 5). Other requirements include

- Holding a state license for the production of blood and blood components;
- Conducting testing of 100% of blood units for hepatitis B, hepatitis C, HIV, and syphilis;
- Having contracts with hospitals on provision of blood and blood products;
- Storing tested blood aliquots 2 years for external quality control by Lugar Center; and
- Conducting proficiency testing with international reference laboratories every 3 months.

FIGURE 5. HCV SCREENING PREVALENCE BY DONOR TYPE — 17 BLOOD BANKS IN GEORGIA, 2014*



*Female=12,546 (30% of the total number of donors); male=28,936 (70% of the total number of donors); first time donors=18,487 (45% of the total number of donors).

Additional activities to facilitate voluntary unpaid donation include the 2010 designation of a World Blood Donor Day (June 14th) aimed at introducing a culture of non-remunerated donation and raising public awareness of the benefits and significance of blood donation. These efforts resulted in an increase in the overall number of donations and the proportion that are voluntary and non-remunerated. In 2014, the average number of donations exceeded 69,000, of which 30% were from unpaid donors, representing a 10% increase from the previous year.

Figure 5 presents the frequency of HCV infection detection by donor type and the frequency of anti-HIV, HBsAg, anti-HCV, and TPHA Syphilis detection among blood donors in 2014.

GAPS

Elimination of transfusion-transmissible infections remains a challenge for the national health system in Georgia for several reasons, including decentralization of blood transfusion services. No management body has been identified at the national level to conduct surveillance of blood transfusion practices, creating obstacles for the development of an effective system of quality blood production and clinical use. Further, although blood and blood components produced by all 18 facilities are used for clinical purposes, only 12 of the 18 licensed blood establishments are currently engaged in the State Safe Blood Program, compromising quality control.

Because profit-based management of blood establishments raises important ethical and safety concerns, transition from profit-based management to nonprofit legal status is essential. Additionally, remunerated donations make up approximately 70% of total donations, presenting a serious challenge in safe blood provision. To improve prevention of TTIs, remunerated donations should be gradually replaced with a non-remunerated donation system, which will require conducting intensive educational campaigns.

Also challenging are the outdated legal provisions for blood collection in Georgia that fail to comply with European Union (EU) regulations and WHO standards. For prevention of TTIs, including HCV, licensing requirements consistent with modern BTS standards should be established and implemented. The National Blood Registry is similarly outdated. It fails to include information on both hospitals and patients who are receiving blood, adverse reactions, applied test-kits and reagents, blood reserves in blood banks and hospitals, blood storing conditions, standardized donor questionnaire and donor assessment interview, and options for electronic order of blood units by hospitals. Further, several blood establishments have yet to join the Registry. Improvement and expansion of the National Blood Registry database will contribute to the prevention of inappropriate transfusions, post-transfusion infections, and complications, as well as ensure vein-to-vein traceability of blood donations.

Introduction of quality-control mechanisms for testing within the State Safe Blood Program has been a step forward; however, establishment of a national quality management system based on the “vein-to-vein” principle remains a major gap. Therefore, all components of a quality-control system are in need of improvement, including organizational, management, low-risk donor identification and selection, blood collection, standardized and valid laboratory testing, and proper use.

The Government of Georgia will continue to implement WHO-recommended procedures to improve blood safety. A key objective will be to implement procedures to decrease the number and proportion of blood donors paid for their donation or recruited by family members. Voluntary blood donation will be promoted through collaborative initiatives with private partners (e.g., designating and promoting blood donation days with the help of a mobile blood donation unit) and creating positive media regarding blood donation. Recruitment of repeat donors who were HCV seronegative and do not belong to a higher risk group for HCV identified on their prior donation will be prioritized.

OBJECTIVE 2.2. PREVENT HEALTHCARE-RELATED TRANSMISSION OF VIRAL HEPATITIS BY IMPROVING BLOOD SAFETY

MoLHSA will develop nationwide, universal standard operating procedures and guidelines for the handling of blood products. Further, MoLHSA will seek partnerships with industry to obtain high quality, affordable HCV tests with the goal of universal nucleic acid testing (NAT) or core antigen testing of all donated blood; the option of testing donated blood using an HCV antigen assay in addition to enzyme immunoassays (EIA) will be considered.

NCDC will consider conducting HCV RNA testing on aliquots from accepted donors received during the past year and stored at the Lugar Center. Such testing would provide information about the numbers of false-negative donors (e.g., persons who donated blood during the window period). Results from such a study would help to further determine the utility of additional NAT testing.

Appropriate use of blood and blood products will be further promoted through incorporating transfusion medicine curricula into existing medical education and training programs.

To address the above-mentioned challenges, the following activities should be undertaken under the leadership of MoLHSA's Department of Health Care, State Regulation Agency for Medical Activities, NCDC.

Objective 2.2

Prevent healthcare-related transmission of viral hepatitis by improving blood safety

ACTIONS

- 2.2.1. Harmonize National Legislative Acts with EU Directives and WHO's Global Strategic Plan (2008–2015) for Universal Access to Safe Blood Transfusion.
- a) Establish a technical workgroup consisting of local and international experts in blood transfusion safety to advise on all elements involved in establishing a modern blood transfusion system in Georgia.
 - b) Establish a lead agency responsible for supervision of all blood-transfusion practice.
 - c) Revise respective legislative acts and harmonize with EU Directives and the WHO Global Strategic Plan.
 - d) Upgrade licensing requirements (including mandatory participation of all blood banks in the National Blood Registry as well as in the state quality control system) consistent with modern standards of blood production practice, and update legislative provision for effective suspension or/and revocation of blood production practice license.
 - e) Establish legislation for blood transfusion service quality assurance and quality control.
 - f) Establish legislative provisions for transition of the existing profit-based management of blood establishments to non-profit legal status.
 - g) Establish legislative provisions for the establishment of centralized TTI testing capacity.

- h) Establish regulations to fully substitute regular paid donations with voluntary non-remunerated donations.

2.2.2. Develop a national blood donor repository based on European standards.

2.2.3. Establish centralized TTI testing capacity.

- a) Establish infrastructure and logistics for centralized TTI testing laboratories at central and regional levels.
- b) Introduce pooled NAT or other sensitive tests (i.e., HCV Ag, HIV combo) for TTI testing.
- c) Conduct nucleic acid testing on all anti-HCV negative donations, and when such testing is not possible, test these donations using Core Antigen testing.

2.2.4. Standardize donor selection and blood testing processes.

- a) Develop national guidelines/standards for donor selection.
- b) Develop national guidelines/standards of blood testing for TTI (including HCV).
- c) Conduct training courses in donor selection for blood banks and blood testing standards for laboratory personnel conducting TTI testing.
- d) Incorporate training in transfusion medicine into the medical education and training curricula.
- e) Introduce developed uniform standards of donor selection in all blood facilities.
- f) Introduce blood-testing standards in centralized TTI testing laboratory.

2.2.5. Develop and implement a quality-control system for blood production and testing.

- a) Develop and implement a quality-control system for blood production practice that covers
 - o donor selection, blood collection, blood testing, processing, storage/transportation (including cold chain procedures) and disposal;
 - o safe handling, storage, and disposal of laboratory reagents/consumables and equipment at blood banks; and
 - o a blood-unit labeling system.
- b) Design and introduce regular inspections and audits for procedures and equipment monitoring.
- c) Develop and implement a quality assurance and management system based on Good Manufacturing Practice (GMP) and International Standards Organization (ISO) principles.

2.2.6. Upgrade the National Blood Registry.

- a) Upgrade and improve database content according to the principle of vein-to-vein traceability by adding new options/fields to the existing base, including
 - o blood receiving hospitals and blood recipients;
 - o adverse reactions;
 - o applied test-kits and reagents;
 - o blood reserves in blood banks and hospitals;
 - o blood storing conditions;
 - o standardized donor questionnaire; and
 - o options for electronic order of blood units by hospitals.

- b) Develop a manual for data entry and operation for all staff working with the Registry (i.e., blood banks, hospitals, and program administrators at NCDC).
- c) Create regulations for mandatory participation of all blood establishments and respective hospitals in National Blood Registry.
- d) Provide administrative and technical support for the database as part of State Safe Blood Program.

2.2.7. Support transition from paid donations to a voluntary, non-remunerated donation system.

- a) Conduct survey of KAP among prospective and registered blood donors as well as medical personnel of blood establishments across the country to understand motivation factors for blood donation in Georgia.
- b) Develop a strategy for attracting, recruiting, and retaining voluntary, non-remunerated donors.
- c) Develop and implement an informational and educational strategy establishing a positive social image of blood donation through
 - o intensive informational and educational campaigns;
 - o integration of thematic courses into educational curricula to create a culture of voluntary unpaid donation; and
 - o collaboration with the Ministry of Education to include information about societal benefits of blood donation in the study curricula of secondary schools and higher educational institutions.
- d) Develop a system of mobile units in blood establishments (i.e., a mobile blood service).
- e) Establish legal obligation for blood establishments to create and maintain voluntary donor recruitment service for regular volunteer donor recruitment and retention through
 - o collaboration between donor recruitment services and educational and other public and private institutions for attracting and retaining voluntary first-time donors from low-risk populations and creating a consistent donor population;
 - o coordination between blood-bank donor recruitment and mobile blood services to conduct “blood donation” days with private partners and to organize community mobile blood drives; and
 - o development of blood-donor recruitment and retention guidelines.

2.2.8. Support blood safety research.

- a) Determine more accurate prevalence of current infection among blood donors in previous years through testing of aliquots sent to Lugar for external quality with a sensitive test (e.g., NAT, HCV Ag test).
- b) Conduct feasibility studies for HCV Ag and HIV combination tests as highly sensitive and cost-effective alternatives to NAT testing of blood donations.

INFECTION CONTROL IN HEALTHCARE SETTINGS

CURRENT ACTIVITIES

Georgia has regulations mandating infection control and prevention in healthcare facilities. Compliance is monitored and regulations enforced by the Agency for State Regulation of Medical Activities. Despite these regulations, HCV transmission likely continues to occur in healthcare settings, although data regarding such transmission are lacking.

GAPS

Inadequate infection prevention and control (IPC) measures remains a substantial risk for HCV transmission in Georgia. While Georgia has developed regulations over the past 6 years mandating that IPC be implemented in healthcare facilities, these regulations are not consistently enforced. Further, many hospitals have not established IPC programs and are therefore unable to implement effective surveillance for nosocomial infections.

Many medical staff remain unfamiliar with existing national IPC regulations, standards, and guidelines. A survey conducted by NCDC in 2014 demonstrated that many medical personnel also do not follow safe-injection procedures due to lack of knowledge and practice.

Equipment is not properly sterilized in many hospitals in Georgia. Several factors likely contribute to inadequate sterilization, including lack of perceived importance; old equipment; inappropriate pre-sterilization and monitoring of sterilization procedures; poor recordkeeping on the sterilization process; and mismanagement of medical wastes. In addition, no standard operating procedures (SOPs) are in place regarding management of HCWs exposed to infectious material.

To prevent healthcare-related transmission of hepatitis C (and also hepatitis B), effective infection-control measures must be implemented in healthcare settings. Infection-control practices in both inpatient and outpatient facilities can be improved through implementation of complex systemic and facility-level interventions.

OBJECTIVE 2.3. PREVENT HEALTHCARE-ASSOCIATED TRANSMISSION OF VIRAL HEPATITIS BY IMPROVING INFECTION CONTROL

MoLHSA will update policies to promote patient and healthcare worker safety (e.g. needle-stick injury programs, post-exposure prophylaxis, and HBV vaccination for HCWs). This will include revising national IPC guidelines based on WHO IPC guidelines and expanding IPC committees. Institutional incentives will be identified and implemented to enhance compliance to IPC.

A successful HCV elimination strategy hinges on improving infection control in healthcare settings and eliminating nosocomial transmission. To address the abovementioned challenges, Georgia should

implement the following activities under the leadership of MoLHSA's Department of Health Care, State Regulation Agency for Medical Activities, NCDC.

Objective 2.3

Prevent healthcare-related transmission of viral hepatitis by improving infection control in healthcare facilities

ACTIONS

- 2.3.1. Revise and distribute National IPC guidelines based on WHO core components for infection prevention and control programs and CDC IPC guidelines.
- 2.3.2. Create and enforce national policies and regulation to include patient and HCW safety (e.g. needle-stick injury programs, post-exposure prophylaxis, and hepatitis B and influenza vaccination for HCWs).
- 2.3.3. Expand existing IPC committees in hospitals (currently active in only 2-3 hospitals), develop and activate IPC committees in all other hospitals, and ensure that all committees follow updated national IPC guidelines and policies.
- 2.3.4. Appoint an IPC focal person in all medical facilities responsible for monitoring IPC practices (e.g., adherence to safe injection practices, hand hygiene, and standard precautions); ensuring that appropriate waste management policies are followed, and ensuring that staff follow appropriate sterilization and disinfection procedures.
- 2.3.5. Expand the IPC education program to include all cadres of health staff (e.g., physicians, nurses, and ancillary healthcare providers of therapeutic injections, including pharmacists, dentists, acupuncturists, and traditional healers), to include exploring opportunities for IPC training (e.g., pre-service, in service, and graduate studies) and the development or revision of IPC curricula based on National IPC Guidelines.
 - Create or revise existing IPC training materials, make them available for use in healthcare facilities, and conduct trainings for medical personnel.
 - Develop and implement IPC curricula in all healthcare training sites (e.g., medical universities and nursing colleges), and require every healthcare worker to take a web-based course with a written test on infection-control practices.
 - Establish Centers of Excellence to implement comprehensive infection control training of healthcare workers in collaboration with Becton-Dickenson (BD) and CDC.
 - Develop a plan for investigating risk for HCV exposure in ancillary healthcare settings and establish training programs if indicated.

- 2.3.6. Provide appropriate personal protective equipment (PPE) to HCWs and provide training on PPE use.
- 2.3.7. Assess overuse of injections nationally.
- 2.3.8. Conduct a nationally representative assessment of injection-safety practices in Georgia using WHO methodology.
- 2.3.9. Conduct a baseline assessment of infection-control practices and determine those settings with the highest rates of ongoing HCV transmission.
- 2.3.10. Introduce/expand use of auto-disable syringes universally.
- 2.3.11. Develop and implement national guidelines on injection safety based on WHO best practices and information from the baseline assessment (see 2.3.8).
- 2.3.12. Develop resources for safe-injection practices (e.g., IEC posters, flyers, stickers, SOPs, and observation checklists).
- 2.3.13. Develop and implement National Sterilization and Disinfection Guidelines and observation checklists.
- 2.3.14. Educate all appropriate staff in hospitals and dental clinics on sterilization and disinfection guidelines and SOPs during pre-service and in-service training; disseminate observation checklists.
- 2.3.15. Implement EU regulations on waste management in medical institutions.
 - a) Review available policies addressing waste management; revise/develop policies, as needed.
 - b) Develop guidelines and SOPs for waste management in medical institutions based on EU regulation standards.
 - c) Conduct medical waste management trainings for all appropriate cadres of HCWs, to include hospital personnel (e.g., physicians, nurses, cleaners, and laundry workers); primary healthcare institutions personnel; and medical personal of dental clinics.

INFECTION CONTROL IN NON-TRADITIONAL HEALTHCARE AND OTHER COMMUNITY SETTINGS

CURRENT ACTIVITIES

HCV transmission is suspected to be occurring in community settings. A survey of beauty, tattoo, and piercing salons and acupuncture clinics conducted by NCDC in 2015 revealed substandard infection-control practices, indicating that the risk of HCV transmission posed in non-traditional and community settings could be significant; however, legislation on infection-control procedures in these settings has yet to be

implemented. A wide-reaching informational campaign is needed to promote and created public demand for safe practices during aesthetic and cosmetic procedures, regardless of setting.

GAPS

Although anecdotal and limited research suggest that non-traditional and community settings may pose a risk for HCV transmission, the extent of this risk remains unknown. Additional data are needed. Further, many of these professions are unregulated and do not require rigorous training in infection control.

Objective 2.4

Prevent HCV transmission in non-traditional healthcare and other community settings

ACTIONS

- 2.4.1. Develop and enforce state regulations/policies for IPC during aesthetic and cosmetic procedures (this may entail certification or licensure program for these facilities) and for other procedures performed in non-traditional healthcare and other community settings that may pose risk for HCV transmission.
- 2.4.2. Develop and implement SOPs on sterilization, disinfection, safe injections, and waste management in non-traditional healthcare and other community facilities. SOPs should describe clear procedures for internal and external quality assurance.
- 2.4.3. Implement monitoring of IPC measures in beauty, tattoo, and piercing salons and in acupuncture clinics.
- 2.4.4. Conduct IPC basic training for service staff.
- 2.4.5. Conduct research/assessment regarding current practices and risk for HCV transmission in non-traditional healthcare and community settings.

STRATEGY 3: IDENTIFY PERSONS INFECTED WITH HCV*

CURRENT ACTIVITIES

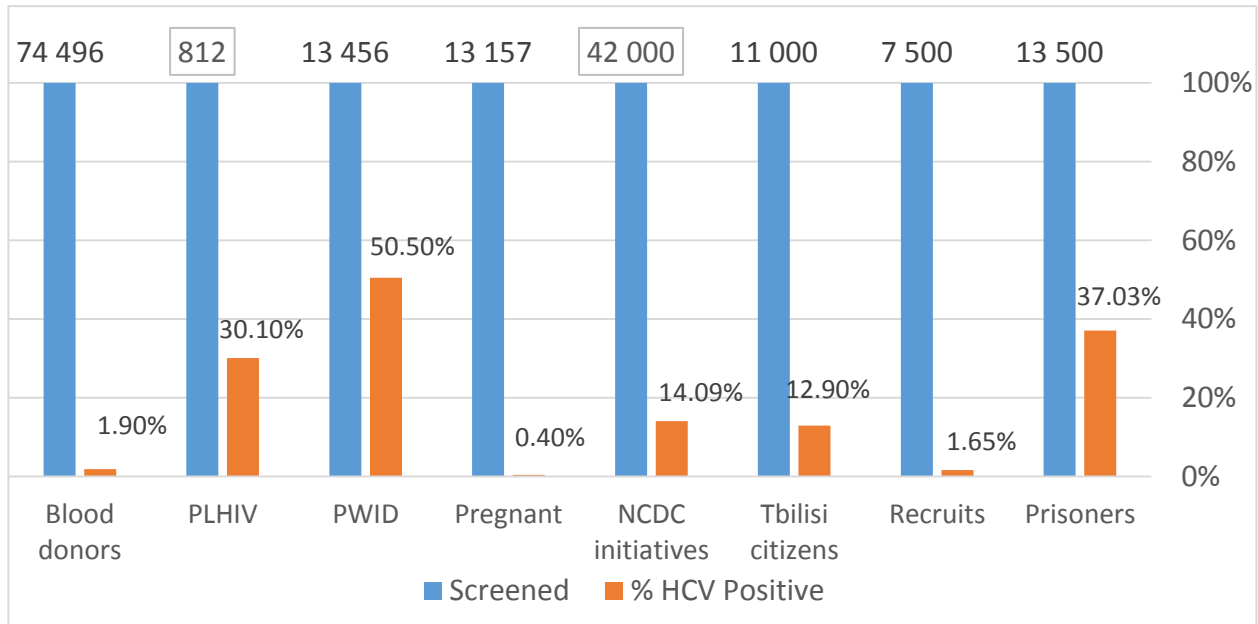
Coordinated by different state programs depending on the target population, HCV testing was conducted in Georgia before the start of the HCV Elimination Program in April 2015. Since 1997, the state HIV program has supported HCV testing among people living with HIV, and the state program for blood safety covers HCV testing among blood donors. HCV testing for PWID has been implemented with the support of GFATM since 2011, and Médecins du Monde France (MDM), a local non-governmental organization, also provides testing for this population. Ministry of Corrections and Legal Assistance (MCLA) of Georgia has provided HCV testing to prisoners since 2014. In May 2015, the Tbilisi Municipality launched an HCV testing program for all persons wanting to know their status regardless of their risk, and by December 2015, HCV testing for pregnant women had been introduced into the Maternal and Child Care program.

NCDC held two free HCV screening events for all Georgian citizens willing to be tested. The first was a 2-day event on May 26 and June 2, 2015, and the second was a 1-week event starting on World Hepatitis Day 2015. As a result, 10,034 persons were screened for HCV, of which 1,991 (20%) were HCV positive. By November 2015, the Government of Georgia had mandated free HCV testing for all citizens. Complying with this mandate, NCDC implemented a routine HCV screening program for the general population in November 2015 with a goal of targeting 50,000 persons, irrespective of risk.

From January 2015 through April 2016, approximately 175,000 people were tested for HCV in Georgia, and about 18.6% had a positive anti-HCV result. All HCV testing was performed using rapid tests. The percentage of persons testing positive for anti-HCV upon testing has varied substantially in Georgia, from 1.9% in blood donors to 50.6% among PWIDs (Figure 6). Data are not yet available from persons who have paid for HCV screening out-of-pocket who did not participate in the abovementioned free testing programs and initiatives. Although free HCV testing programs are expected to be continued into the coming years, further expansion is warranted to accelerate detection of HCV cases.

* Identification of HCV infected-persons involves both screening (i.e., determining risk for infection) and testing (i.e., assessing presence of infection using serologic and other diagnostics).

FIGURE 6. DIAGNOSTIC YIELD WITHIN HCV SCREENING PROGRAM BY TARGET GROUP, GEORGIA, JANUARY 2015- MARCH 2016



Abbreviations: PLHIV=people living with HIV; PWID=persons who inject drugs

GAPS

Experts estimate that only a small proportion of persons infected with HCV in Georgia are aware of their infection. This low proportion is likely because of the limited number of HCV screening and testing programs available in the country. A substantial concern regarding the successful implementation of the National Hepatitis C Elimination Program is identification of people living with HCV. Several gaps exist regarding HCV screening and testing. The following bullets summarize areas in need of improvement to achieve national elimination goals.

- Although testing services are easily accessible in some areas (e.g., Tbilisi), some cities and regions with high HCV prevalence remain under-served by HCV screening and testing programs.
- The current treatment data system (STOP-C) is focused on care and treatment-related data and does not collect information on screening and testing outcomes.
- Persons testing positive for HCV antibody through the Elimination Program to date have not had their infection confirmed, and those found positive have not been linked to care and treatment.
- To date, the cost of anti-HCV testing has not been covered by the Elimination Program.
- No system has been established for tracking persons tested for HCV, the results of their tests, and, for those testing positive, linkage to care and treatment (e.g., an HCV registry).

OBJECTIVE 3.1. INCREASE THE NUMBER OF PEOPLE DIAGNOSED WITH HCV INFECTION THROUGH EXPANDED SCREENING AND TESTING[†]

To increase the proportion of persons who know their HCV infection status, access to quality HCV diagnostic services must be ensured through well organized and targeted screening programs. Successful implementation of screening will require multi-sectoral engagement, including the private health sector, governmental entities, and non-governmental organizations. Involvement of the latter will be especially important for supporting the identification of patients and their linkage to clinical services. Related programs (e.g., HIV/AIDS screening programs) should be integrated to improve the efficiency of screening.

MoLHSA and NCDC will implement strategies and new validated technologies to simplify the testing process for current HCV infection (e.g., point-of-care tests in safe-injection programs and laboratory-based reflex virologic testing of anti-HCV-positive specimens collected in clinical centers). Partnerships will be established with corporations providing diagnostic tests to decrease the per-test cost of HCV antibody, virologic, and genotype testing. Routine HCV testing will be integrated (i.e., standing orders for opt-out testing) with other laboratory testing ordered for persons receiving care in inpatient and outpatient settings. A web-accessible HCV testing database will be established linked to HCV treatment data.

Objective 3.1 will be achieved through implementation of the following activities with MoLHSA, NCDC Lugar center, and a designated lead agency serving to guide the implementation steps and processes. Efforts should be based on evidence targeting those most at risk for infection and advance disease.

Objective 3.1

Increase the number of people diagnosed with HCV infection through expanded screening and testing

ACTIONS

3.1.1. Develop and implement evidence-based national HCV guidelines for screening, testing, and linkage to care and treatment, to include a testing algorithm to be used by providers to diagnose current HCV infection.

a) Designate a lead agency to be responsible for HCV screening activities.

[†]Identification of HCV infected-persons involves both screening (i.e., determining risk for infection) and testing (i.e., assessing presence of infection using serologic and other diagnostics).

- b) Develop and convene a national technical workgroup that will work with international experts in HCV screening to develop standard screening and testing guidelines.
- c) Select standardized tests to diagnose current infection after considering cost and sensitivity/specificity.
- d) Establish a testing algorithm to be used by providers to diagnose current HCV infection.
- e) Implement national screening and testing guidelines, to include recommendations addressing pregnant women.
- f) Monitor all screening sites to ensure quality testing.
- g) Use serosurvey data and other sources to develop evidence-based screening and testing guidelines to ensure high-risk populations (e.g., those with advanced liver disease and populations with high prevalence) are prioritized.
- h) Consider demonstration projects to identify best practices for linking HCV infected persons to care and treatment and then expand best practices universally to achieve elimination goals. Examples include projects developed and tested in
 - harm reduction settings;
 - rural areas with limited access to healthcare; and
 - primary-care settings.

3.1.2. Develop and implement a provider-education program to improve coverage with and quality of HCV screening,

3.1.3. Improve information systems to promote linkage to care and treatment for persons testing positive for HCV.

- a) Develop, implement, and maintain a testing registry and integrate with STOP-C to facilitate linkage to care among persons with positive HCV test results.

3.1.4. Eliminate cost-related barriers to HCV diagnosis, including anti-HCV antibody testing.

OBJECTIVE 3.2. EXPAND HCV TESTING TO BETTER REACH HIGH-RISK POPULATIONS

This objective aims to improve HCV case finding through screening persons in high-risk populations. Data from the national serologic survey will help determine the size of the target population needed to meet elimination goals for HCV diagnosis. Priority will be given to target populations with an estimated HCV prevalence greater than the national average as demonstrated by the national serosurvey. Target populations will be selected on the basis of demographics, geographic locations, risks of transmission, and other characteristics associated with increased prevalence of HCV infection (e.g. PWID, persons who are

incarcerated, and recipients of blood and blood products). HCV testing will increasingly be introduced for pregnant women.

The screening program will serve those populations with a high HCV prevalence and those with high-risk exposures or behaviors. HCV testing will be integrated into the established community-based programs that serve PWID, persons who are currently incarcerated or have a history of incarceration, and recipients of blood and blood products. Screening will be provided at relevant venues (e.g., OST clinics, needle/syringe exchange sites, and prisons) and through outreach utilizing mobile units and peer-driven interventions. Because HIV/AIDS programs already cover these key populations, HCV screening will be integrated into existing HIV/AIDS programs. In addition, health-facility-based testing and linkage to care will be implemented and expanded nationally.

MoLHSA will designate a centralized lead agency responsible for HCV screening activities. A national technical workgroup will be convened that will collaborate with international experts in HCV screening to develop standard screening guidelines and advise on other HCV screening-related issues (e.g., defining additional target groups for screening). A web-based registry will be developed to track screening outcomes among all persons tested for HCV infection. The system will collect demographic and risk-factor information and will be interoperable with the STOP-C platform, facilitating linkage to care for those with positive results. Such a system will allow for efficient program planning and implementation, as well as enable monitoring and evaluation.

Objective 3.2 will be achieved through implementation of the following activities, with MoLHSA and NCDC serving to guide the implementation steps and processes; CDC will provide technical assistance regarding the testing activities.

Objective 3.2

Expand HCV testing to better reach high-risk populations

ACTIONS

3.2.1. Implement HCV screening in clinical and public health settings to improve access to testing for high-risk populations and ensure linkage to care.

a) Implement voluntary HCV counseling, testing, and linkage to care for relevant groups based on 2015 serosurvey results and other data sources. Groups for which evidence is available indicating elevated prevalence of HCV include:

- PWID
- HIV/AIDS patients;

- TB patients;
 - persons who have received blood transfusions;
 - patients receiving hemodialysis;
 - prisoners and previously incarcerated persons; and
 - children born to mothers infected with HCV.
- b) Implement routine HCV testing for all males aged ≥ 30 years (or all persons aged ≥ 30 years or older), a strategy that can identify more than 70% of persons living with HCV in Georgia.
- c) Implement voluntary HCV counseling, testing, and linkage to care in high-prevalence geographic areas as identified by the 2015 serosurvey.
- d) Integrate HCV screening into established community-based programs that serve high-risk populations (e.g., OST, NSPs, and hemodialysis units).
- e) Assess HCV prevalence and effectiveness/cost-effectiveness of voluntary HCV counseling, testing, and linkage to care prior to implementation of programs for the following populations:
- HCWs;
 - all persons referred to healthcare facilities;
 - law enforcement;
 - students;
 - persons with sexually transmitted infections;
 - MSM;
 - sex workers; and
 - persons who have received medical or dental procedures.

STRATEGY 4: IMPROVE HCV LABORATORY DIAGNOSTICS

CURRENT ACTIVITIES

Quality assurance of HCV laboratory diagnostics is a major challenge. Because NCDC's public health laboratory network has a significant country presence, implementing screening in those laboratories will likely improve testing accessibility and reduce wait times for patients. Ensuring that standardized procedures for test validation are in place will standardize test results and improve quality assurance. Expansion of testing hinges on reducing prices and creating sustainable access to diagnostics through centralized procurement of reagents at a fixed rate.

Access to high-quality diagnostic services is crucial for timely detection of HCV and follow-up care for those infected with the virus. As the public health agency responsible for HCV surveillance in Georgia, NCDC has established the extensive laboratory infrastructure needed to support quality hepatitis C diagnostics (e.g., serology, polymerase chain reaction [PCR] viral load, and genotyping). NCDC manages a laboratory network comprised of two Zonal Diagnostic Laboratories (located in Kutaisi and Batumi),

seven Laboratory Surveillance Stations (LSS), and the Lugar Public Health Research Centre (a Biosafety Level [BSL] level 3 laboratory established with support from the U.S. government). Laboratory staff at each of these facilities are trained to test clinical specimens for anti-HCV and HBsAg using ELISA.

With technical assistance from CDC, the Lugar Center has developed three panels for verification of the HCV ELISA and HCV RNA kits (EQA-aHCV-60, LEQA-aHCVrep-32, and EQA-HCV-56PCR) using well-characterized, de-identified plasma donor specimens. These panels were used to verify samples received through Georgia’s seroprevalence survey in 2015; sensitivity and specificity of anti-HCV DiaPro ELISA kit (Lugar Center, unpublished data, 2015) was 97%, and intra- and inter-laboratory reproducibility at these sites was 100%. Sensitivity and specificity of the HCV Sacace RT PCR was 90% (lower limit of detection=1,000 IU/mL) (Lugar Center, unpublished data, 2015).

During the initial phase of Georgia’s HCV Elimination Program, diagnostic services were provided by four clinical laboratories and the NCDC laboratory network. All laboratories involved in the program met high laboratory quality standards (Box 1) as demonstrated by high scores on a standard WHO-adapted tool [Hep-LAT]; the Lugar Center is a Center of Excellence for laboratory diagnostic quality management.

BOX 1. LABORATORY REQUIREMENTS ASSOCIATED WITH GEORGIA’S HCV ELIMINATION PROGRAM

Minimum quality management requirements for participating laboratory providers

- Availability of an internal quality control system
- Availability of approved standard operating procedures for each laboratory test
- Availability of technical resources for conducting necessary laboratory tests
- Availability of personnel certified according to the rules established by current legislation
- Ability to provide the tests results within 5 working days of sample collection
- Ability to maintain patient records with test results for at least 2 years
- Capacity and experience to conduct all tests determined by the Program

Mandatory laboratory tests

- Anti-HCV detected by Rapid Point of Care Test (RT) or laboratory-based test (i.e., ELISA or CIA; Quantitative HCV NAT)
- HCV Genotyping by line hybridization assay and/or real-time PCR
- Hematological, biochemical, and serological tests as specified in the Table 1

All laboratories scored higher than 90% in quality of building facilities and services; biosafety, hygiene and security; specimen collection and recording; equipment; reagents and supply; laboratory staff; reporting analysis and communication; and participation in outbreak investigations. However, the laboratories scored 78%–90% in “total quality” due to lack of a specific external quality control (EQC) program for viral hepatitis tests. A detailed description of laboratory testing process currently practiced in Georgia is presented (Box 2, Table 2, Table 3, Table 4).

BOX 2. THREE STAGES OF LABORATORY TESTING FOR HCV INFECTION IN GEORGIA

Stage 1

- Patients with unknown or no documented HCV serological status first undergo anti-HCV antibody testing by rapid or laboratory-based methods (i.e., enzyme-linked immunosorbent assay [ELISA] or chemiluminescent immunoassay [CIA]).
- Patients with documented HCV serological status and positive anti-HCV antibodies tested by rapid or laboratory-based method (i.e., ELISA or CIA) undergo testing to determine active HCV infection by quantitative HCV nucleic acid test (NAT).
- Patients with undetectable HCV RNA in blood do not need antiviral treatment.

Stage 2

- Patients positive for HCV RNA undergo the following laboratory tests: alanine transaminase (ALT) and aspartate transaminase (AST) blood levels, and complete blood count (CBC).
- Patient's age, ALT and AST blood levels, and platelet count (determined from CBC) are used to calculate FIB4 Index.
- Patients with FIB4 Index <1.45 are considered to have a low degree of liver fibrosis and will start treatment during later stages of the elimination program.
- Patients with FIB4 Index >3.25 are considered to have a high degree of liver fibrosis; these patients undergo Stage 3 laboratory testing.
- Patients with intermediate FIB4 Index (1.45--3.25) undergo liver elastography examination for the final determination of the degree of liver fibrosis.

Stage 3

- Patients with liver fibrosis F3 and higher undergo Stage 3 laboratory testing (Table 2).
- Patients with liver fibrosis less than F3 will start treatment during later stages of the elimination program.
- Laboratory testing is co-financed by beneficiaries. Table 2 includes total standard costs, as well as prices after 30% and 70% state funding coverage is applied; the cost for anti-HCV screening is not reimbursed.
- Monitoring of the patient's condition during the treatment is conducted every 4 weeks by measuring CBC, ALT, AST, bilirubin, and creatinine; the HCV RNA monitoring schedule is shown in Table 3 and Table 4.

TABLE 2. LABORATORY TESTS PERFORMED, BY COST AND STATE PROGRAM CO-FUNDING OPTIONS — HCV ELIMINATION PROGRAM, GEORGIA

| Stage | Laboratory test | Price (GEL) | | | |
|----------|--|----------------------|-----------|-----------|-------|
| | | Total | Minus 30% | Minus 70% | |
| 1 | HCV RNA detection | Quantitative HCV NAT | 110.00 | 77.00 | 33.00 |
| 2 | Determination of liver fibrosis status | Complete blood count | 9.00 | 6.30 | 2.70 |
| | | ALT | 5.00 | 3.50 | 1.50 |
| | | AST | 5.00 | 3.50 | 1.50 |
| | | FIB4 | | - | - |

| | | | | | |
|----------|---|------------------------------|--------|-------|-------|
| 3 | Further examination of patients with F3-F4 and F4 | HCV Genotyping | 140.00 | 98.00 | 42.00 |
| | | HBsAg | 8.00 | 5.60 | 2.40 |
| | | Anti-HBs | 9.00 | 6.30 | 2.70 |
| | | Bilirubin (total and direct) | 5.00 | 3.50 | 1.50 |
| | | G-GT | 5.00 | 3.50 | 1.50 |
| | | Alkaline phosphatase | 5.00 | 3.50 | 1.50 |
| | | Creatinine | 5.00 | 3.50 | 1.50 |
| | | Glucose | 5.00 | 3.50 | 1.50 |
| | | Albumin | 5.00 | 3.50 | 1.50 |
| | | INR | 8.00 | 5.60 | 2.40 |
| | | ANA | 12.00 | 8.40 | 3.60 |
| | | TSH | 9.00 | 6.30 | 2.70 |

TABLE 3. LABORATORY TESTS PERFORMED DURING TREATMENT MONITORING — HCV ELIMINATION PROGRAM, GEORGIA

| Tests | Treatment period (weeks) | | | | | | | After treatment |
|---|--------------------------|---|---|-----|----|----|----|-----------------|
| | 2 | 4 | 8 | 12 | 16 | 20 | 24 | 12 |
| CBC | X | X | X | X | X | X | X | X |
| ALT, AST, Bilirubin (total, direct), Creatinine | | X | X | X | X | X | X | X |
| Quantitative HCV NAT | | X | | X* | | X* | X* | X |
| TSH | | | | X** | | | | |

*HCV RNA is determined at the end of the treatment (week 12, 20, or 24).

**In the case of interferon-containing treatment regimen.

TABLE 4. LAB TESTS PERFORMED DURING TREATMENT MONITORING FOR PATIENTS WITH DECOMPENSATED CIRRHOSIS

| Tests | Treatment period (weeks) | | | | | | | | | | | | | After treatment |
|--|-----------------------------|---|---|----|----|----|----|----|----|----|----|----|----|--------------------|
| | 2 | 4 | 8 | 12 | 16 | 20 | 24 | 28 | 32 | 36 | 40 | 44 | 48 | 24 |
| CBC | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| ALT, AST, Bilirubin (total, direct), Creatinine | | X | X | X | X | X | X | X | X | X | X | X | X | X |
| HCV RNA quantitative PCR | | X | | | | | | | | | | | X | X |

GAPS

Several gaps exist regarding laboratory screening for HCV. The following bullets summarize areas in need of improvement to achieve national elimination goals.

- Laboratory quality control is limited; no national external quality control system has been established.
- Test kits vary by time and availability from the suppliers; most test kits have not been validated. Procurement of small batches of essential diagnostic reagents from third-party distributors can result in non-verified reagents that are subject to variation in quality, potentially compromising testing by laboratory providers.
- No unified standard procedures have been identified for participating laboratories.
- No national certification systems for clinical laboratories exist.
- Laboratory personnel are not provided systematic training in biosafety procedures and standards.
- Testing reagents are expensive and can be cost-prohibitive for laboratories.

To improve the quality of laboratory testing for HCV infection, MoLHSA and NCDC will establish a National Laboratory Reference Center (NLRC) and designate a National Laboratory Quality Manager (NLQM) with responsibility for conducting verification of viral hepatitis diagnostic reagents and developing a quality assurance/quality control (QA/QC) program for hepatitis C elimination. NCDC’s Lugar center, a Center of Excellence in laboratory quality management in Georgia, will be considered to serve in this role. The following activities should be undertaken by MoLHSA (through the State Regulation Agency for Medical Activities).

Objective 4.1

Improve laboratory detection of HCV infection

ACTIONS

- 4.1.1. Develop and implement detailed guidelines for uniform clinical interpretation of laboratory test results.
- 4.1.2. Update and disseminate the diagnostic algorithm according to new developments in the field of HCV laboratory diagnostics (2017 EASL/AASLD recommendations).
- 4.1.3. Conduct all HCV testing using HCV PCR or HCV core-antigen assays.
- 4.1.4. Consider inclusion of HCV Core Antigen for screening and/or confirmatory testing in the Elimination Program, when feasible and cost-effective.
- 4.1.5. Establish a unified system of laboratory quality assurance.
 - a) Establish a registry of laboratories to participate in the hepatitis C elimination program.
 - b) Establish a national reference center with identified expertise for serologic and nucleic acid testing to conduct confirmatory testing as required and execute the national EQA program for hepatitis C diagnostics.
 - c) Establish a national reference center with identified expertise and clinical chemistry and hematology testing to conduct the confirmatory testing as required and execute the national EQA program for hepatitis C treatment monitoring.
 - d) Develop guidelines and reference materials for standardization and validation of serologic and nucleic acid tests, clinical hematology, and biochemical tests.
 - e) Ensure that all assays used for testing, diagnosis, and treatment monitoring are approved by a stringent regulatory authority (e.g., WHO, U.S. Food and Drug Administration [FDA], or European CE marked) or validated by an evaluation protocol, with results reviewed and approved appropriate experts in the field [TAG 6.1].

- f) Prepare and disseminate SOPs and provide regular training in accordance with the requirement of ISO-15189 for the Elimination Program to include the following processes and procedures:
- sample collection, processing, storage, and transportation;
 - handling infectious materials, biosafety, and biological waste management;
 - laboratory tests provided within the HCV Elimination Program;
 - uniform reporting of the results.

4.1.6. Develop and implement the National Program of Competency Assessment (CA) in Laboratory Medicine.

4.1.7. Develop a National Laboratory Certification System.

4.1.8. Conduct research activities.

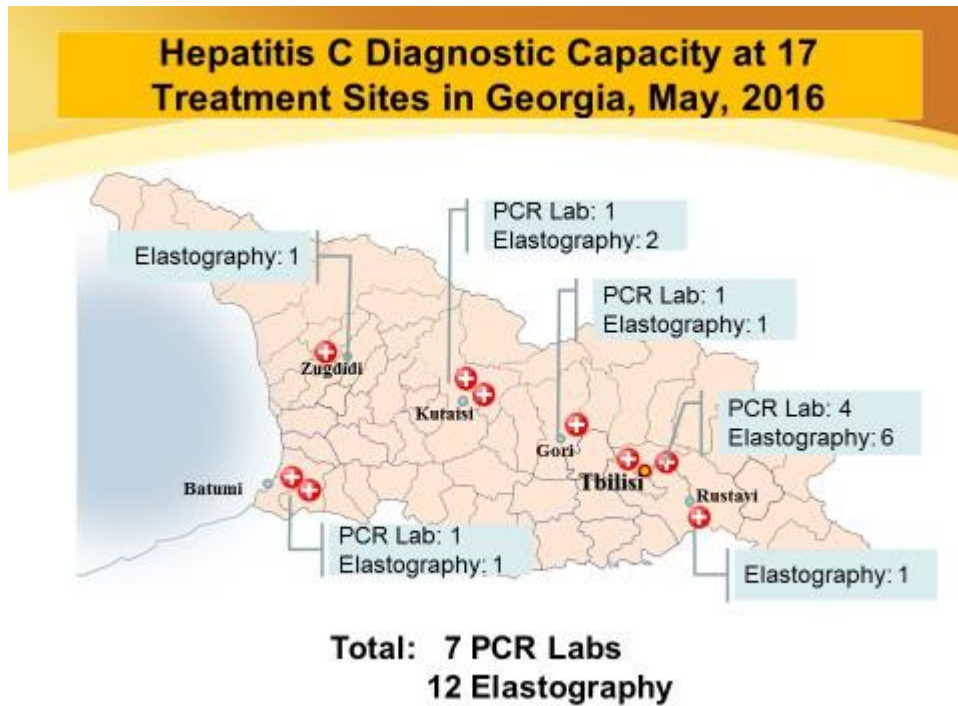
- a) Evaluate feasibility and cost-effectiveness of screening and monitoring the testing algorithm, including HCV-Ag serologic test and HCV NAT.
- b) Evaluate cost-effectiveness of laboratory monitoring and further need for IFN/RBV treatment regimens in the National Program for Hepatitis C Elimination.
- c) Conduct an advanced molecular study of HCV genotype-2 to determine the proportion of recombinant 2k/1b strains and treatment implications.
- d) Conduct multivariate analyses of the factors affecting HCV antiviral treatment outcome in HCV mono-, mixed, and recombinant infections.
- e) Establish a system for archiving samples for HCV-infected persons for future studies.

STRATEGY 5: PROVIDE HCV CARE AND TREATMENT

CURRENT ACTIVITIES

Georgia has well-developed technical and human capacity for the management of persons living with hepatitis C. The country has implemented modern treatment and diagnostic methods, including high-technology molecular diagnostic methods (e.g., qualitative and quantitative polymerase chain reaction [PCR], including real-time PCR) and HCV genotyping. Non-invasive methods for assessing liver fibrosis/cirrhosis, including liver elastography, are also available (Figure 7).

FIGURE 7. HEPATITIS C DIAGNOSTIC CAPACITY AT 17 TREATMENT SITES, — GEORGIA, APRIL 1, 2016



According to Georgian regulations, hepatitis C can be treated by physicians licensed either in infectious diseases or gastroenterology. Highly qualified personnel with strong clinical experience are employed in the field of infectious diseases, and in particular in the field of viral hepatitis. Many have completed cutting-edge short or long-term training in leading European and American Centers, regularly participate in international conferences on HCV, and are involved in research, the results of which are published in international peer-reviewed journals. Of 492 infectious disease physicians and 124 gastroenterologists practicing medicine in Georgia, 95 are experienced in treating hepatitis C and, as of April 1, 2016, have provided HCV care and treatment through the HCV elimination program (Figure 8). HCV diagnostic and provider expertise is mostly concentrated in Tbilisi (Figure 9). Involvement of specialists practicing in outlying areas is needed and highly encouraged. As more persons seek HCV testing and the treatment of hepatitis C in Georgia evolves, primary-care physicians will become increasingly called upon to diagnose and treat persons living with hepatitis C.

FIGURE 8. PROVIDER CAPACITY AT 17 TREATMENT SITES — GEORGIA, APRIL 1, 2016

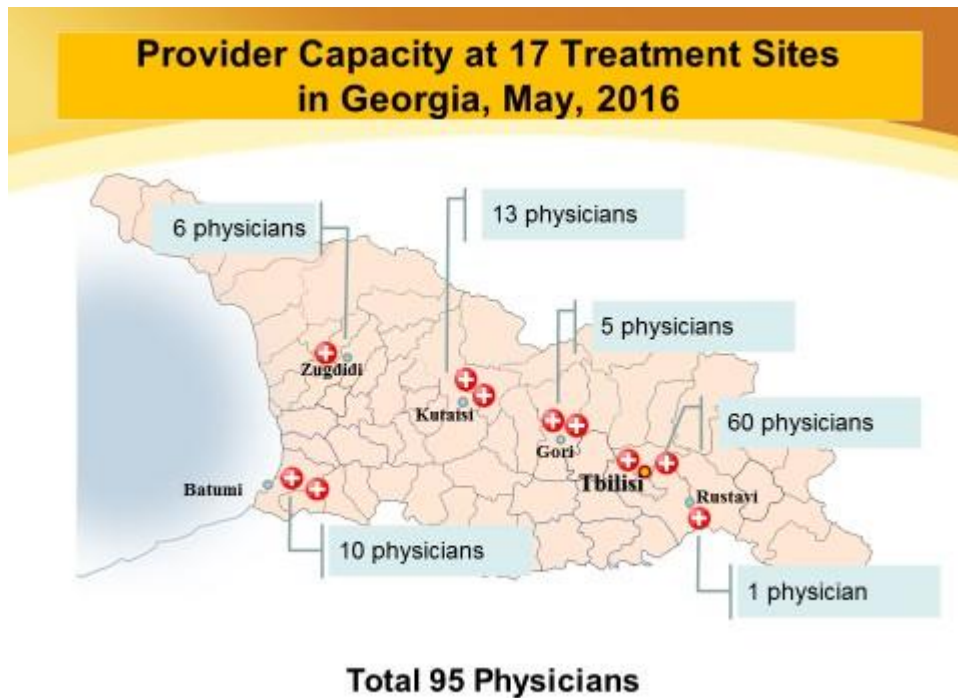
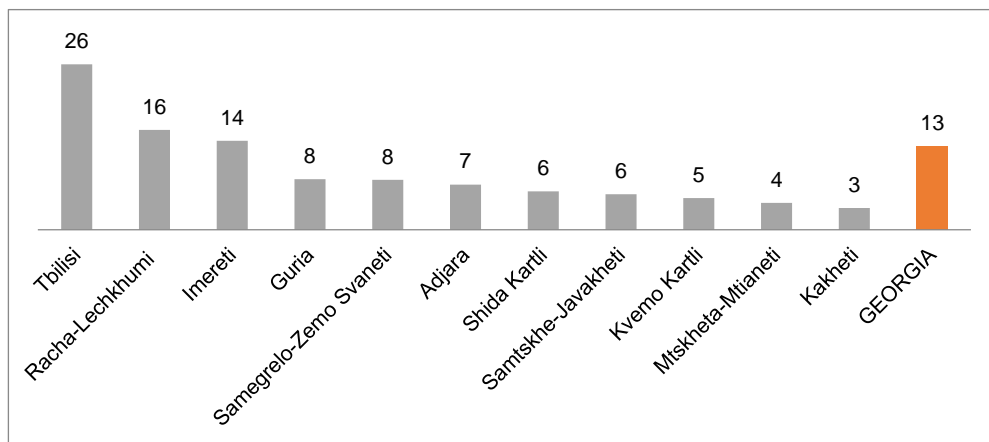


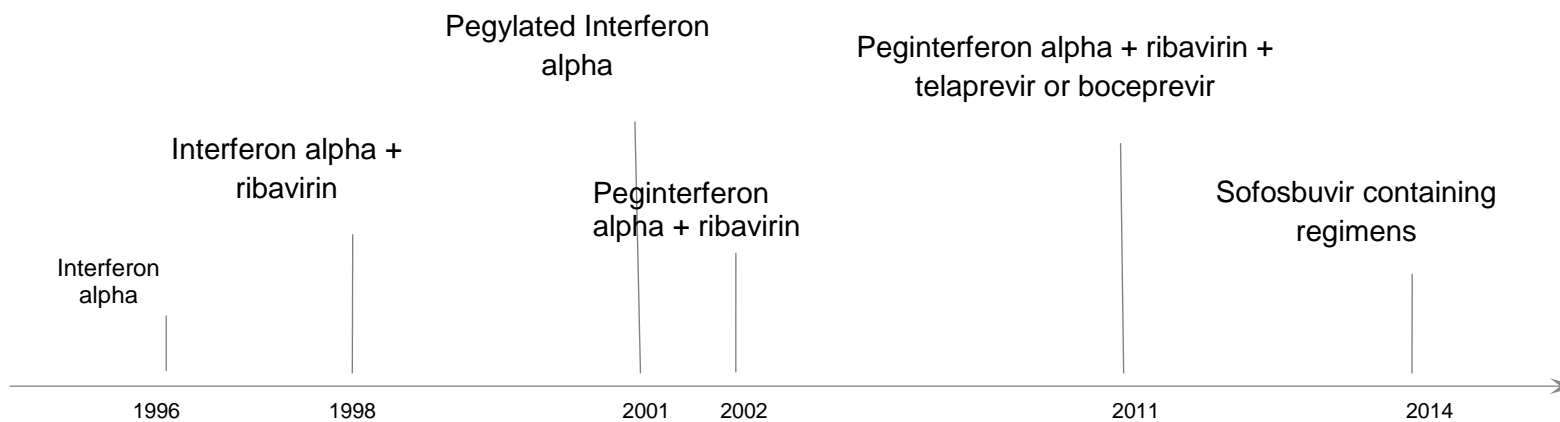
FIGURE 9. GEOGRAPHIC DISTRIBUTION OF INFECTIOUS DISEASE SPECIALISTS PER 100,000 POPULATION, GEORGIA



As of April 2016, HCV treatment has been provided by 17 health facilities, including eight sites in the capital city of Tbilisi, three sites in Kutaisi, two sites in Gori, and one each in Batumi, Zugdidi, and Rustavi. Overall, seven PCR labs (four in Tbilisi) operate and 12 elastography machines are available countrywide (Figure 7). From April 28, 2015 (the launch of the HCV Elimination Program) through April 28, 2016, a total of 27,392 HCV RNA positive persons were registered with the program. Of these, 8,448 eligible patients had started therapy; 325 patients prematurely discontinued therapy, largely due to death during treatment (n=173; 53.2%) and adverse events (n=80; 24.6%) [8].

The unified treatment protocols and simplified diagnostic and monitoring algorithms implemented in Georgia were developed based on Infectious Diseases Society of America (IDSA)/American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL) guidelines and are being used by providers to ensure delivery of quality care. The treatment regimens used in Georgia during program implementation were selected based on availability of only one second generation DAA (i.e., sofosbuvir) along with pegylated interferon and ribavirin. A total of seven interferon-based and interferon-free regimens with sofosbuvir were recommended depending on HCV genotype, presence of liver cirrhosis, and previous treatment history (Figure 10). In February 2016, pharmaceutical manufacturer Gilead Sciences committed to providing treatment regimens consisting of sofosbuvir/ledipasvir (Harvoni); it is anticipated that sofosbuvir/velpatasvir (Epclusa) will be introduced for use in the elimination program during early-to-mid 2017.

FIGURE 10. TIMELINE OF IMPLEMENTATION OF TREATMENT APPROACHES IN GEORGIA



To identify patients with advanced-stage disease to be prioritized for treatment, Georgia’s treatment protocols for the first year of the program required all HCV RNA-positive patients to be screened for liver fibrosis using the FIB-4 test (Table 5). Beginning June 2016, all HCV-infected patients received treatment regardless of liver-disease stage.

Details regarding the timelines and costs associated with laboratory monitoring to assess treatment efficacy and safety for patients receiving HCV treatment are provided in Table 6 and Table 7.

TABLE 5. PRE-TREATMENT EVALUATION

| | | Price in GEL |
|----------------|------------------------|--------------|
| Stage 1 | Physician consultation | 30.0 |
| | HCV RNA quantification | 110.0 |
| Stage 2 | Physician consultation | 30.0 |
| | ALT | 9.0 |
| | AST | 5.0 |
| | Complete blood count | 5.0 |
| | Liver elastography | 80.0 |
| Stage 3 | Physician consultation | 30.0 |
| | HCV genotyping | 140.0 |
| | HBs Ag | 8.0 |
| | Anti-HBs | 9.0 |
| | G-GT | 5.0 |
| | ALP (alkaline) | 5.0 |
| | Bilirubin, direct | 5.0 |
| | Bilirubin, total | 5.0 |
| | Creatinine | 5.0 |
| | Glucose | 5.0 |

| | |
|------------------------|---------------|
| Albumin | 5.0 |
| Prothrombin (INR) | 8.0 |
| ANA | 12.0 |
| TSH | 9.0 |
| Ultrasound examination | 30.0 |
| Total cost | 550.00 |

TABLE 6. TIMELINE AND COSTS OF CLINICAL MONITORING FOR 12-WEEK TREATMENT COURSE

| | Time period in weeks | | | | 12 weeks after end of treatment | Total cost in GEL |
|--|-------------------------|--------------|-------------|--------------|------------------------------------|-------------------|
| | 2 | 4 | 8 | 12 | | |
| Clinical assessment (physician consultation) | 30 | 30 | 30 | 30 | 30 | 150 |
| Complete blood count | 9 | 9 | 9 | 9 | 9 | 45 |
| ALT, AST, bilirubin (direct, total) creatinine | | 25 | 25 | 25 | 25 | 100 |
| HCV RNA quantification | | 110 | | 110 | 110 | 330 |
| TSH | | | | 9 | | 9 |
| Patient service standard | 50 | | | | | 50 |
| Total cost in GEL | 89.0 | 174.0 | 64.0 | 183.0 | 174.0 | 684.0 |

TABLE 7. TIMELINE AND COSTS OF CLINICAL MONITORING FOR 24-WEEK TREATMENT COURSE

| | Time period (weeks) | | | | | | | 12 weeks post-treatment | Total cost in GEL |
|--|---------------------|--------------|-------------|-------------|-------------|-------------|--------------|-------------------------|-------------------|
| | 2 | 4 | 8 | 12 | 16 | 20 | 24 | | |
| Clinical assessment (physician consultation) | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 240 |
| Complete blood count | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 72 |
| ALT, AST, bilirubin (direct, total) creatinine | | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 175 |
| HCV RNA quantification | | 110 | | | | | 110 | 110 | 330 |
| Patient service standard | 80 | | | | | | | | 80 |
| Total cost in GEL | 119.0 | 174.0 | 64.0 | 64.0 | 64.0 | 64.0 | 174.0 | 174.0 | 897.0 |

GAPS

Important challenges need to be addressed for effective program implementation and expansion. Limited provider capacity and a paucity of treatment centers serve as hurdles to provision of HCV treatment. Although capacity was sufficient to serve the patients involved in the beginning stages of the program, only a small proportion of infectious-disease physicians and gastroenterologists in Georgia have extensive experience in managing HCV-infected patients. Provider capacity must be expanded to meet the country's target of treating at least 20,000 persons regardless of disease stage annually.

The health information system also must be expanded to ensure adequate provision of HCV care and treatment. The current health information system (STOP-C) needs improvements to enable effective monitoring of the continuum of HCV care and the collection of other data to assess program effectiveness.

The HCV epidemic in Georgia is characterized by a prevalence of recombinant strain 2k/1b^{vii}. NS5B and 5'UTR/Core sequencing studies indicate that more than half of HCV genotype 2 patients in Georgia are actually infected with the 2k/1b recombinant strain [25, 26]. Studies suggest that persons infected with this strain of HCV who are treated for genotype 2 infection have suboptimal response rates; regimens used for genotype 1 are shown to be more effective in these patients [25, 26]. To achieve HCV elimination in Georgia, optimal treatment options for persons infected with the HCV recombinant form 2k/1b should be identified and offered as part of the elimination effort.

All activities under this objective will be implemented with involvement of national and international partners. A working group will be established to develop strategies and protocols for ensuring that persons diagnosed with HCV progress through the HCV care continuum in a timely manner. Active collaboration between governmental and non-governmental partners will be encouraged for effective HCV case management.

OBJECTIVE 5.1. PROMOTE UNIVERSAL ACCESS TO HCV CARE AND TREATMENT

The overarching goals for HCV care and treatment under the elimination program are to ensure universal access to hepatitis C treatment and achieve high cure rates. Attaining these goals is an essential step on the road to hepatitis C elimination in Georgia. Effective treatment combined with implementation of effective preventive interventions will minimize the infection reservoir and reduce the number of new cases. Achievement of these goals requires high patient engagement in the HCV care continuum, starting from identification of cases through achievement of sustained virologic suppression. Activities proposed under this objective involve developing strategies for targeting populations with ongoing risk for HCV transmission, particularly PWID and other at-risk populations, to optimize adherence and completion of HCV therapy. Treatment will be based on best available evidence and take into account costs to ensure sustainability of the program. Treatment guidelines will be optimized to streamline patient management and minimize blood draws and unnecessary laboratory tests, reducing costs incurred by patients and increasing the number of persons receiving treatment. Use of interferon-free regimens (i.e., all-oral DAAs) will be encouraged for most patients. Cost savings associated with use of less expensive but effective

treatment will be directed towards expanding testing initiatives. Health personnel at HCV screening sites will provide education and counseling to all HCV-positive patients about HCV treatment options and will refer patients to care and treatment.

Access to HCV treatment will be expanded by increasing the number of gastroenterology and infectious-disease specialists providing HCV therapies. With support from the Extension for Community Healthcare Outcomes (ECHO) Project, MoLHSA will integrate HCV treatment into primary-care services.

The following objectives and actions are proposed to overcome challenges in HCV care and treatment. Implementation will be coordinated by the HCV Multisectoral Commission at MoLHSA.

Objective 5.1

Promote universal access to HCV care and treatment

ACTIONS

5.1.1. Develop and implement mechanisms for rapid and effective linkage of identified HCV patients to clinical-care services dedicated to HCV care.

- a) Develop professional education and consultative services to scale up the number of clinicians prepared to test and treat HCV without the need for patient referral.
- b) Establish a centralized system at the National Hepatitis C Elimination Program management unit of MoLHSA to support timely delivery of patient navigation services. This effort includes
 - operating an online patient registration system;
 - operating a registry of HCV screening and care providers and integrating this registry into STOP-C to facilitate linkage of diagnosed patients;
 - maintaining direct contact with service providers; and
 - operating a dedicated hot-line.

5.1.2. Ensure provision of pre-treatment evaluation. A basic package of diagnostic and clinical services will be available for all patients linked to care. The package, which will help to define disease status and promote selection of optimal treatment regimen, can include:

- physician consultation;
- HCV RNA quantification;
- HCV genotyping;
- resistance testing if indicated;
- assessment of liver fibrosis; and
- other diagnostic and clinical services (e.g., HAV and HBV vaccination and alcohol/drug counseling) specified in the approved care and treatment protocols.

- 5.1.3. Ensure provision of free antiviral therapy for all patients linked to care, ideally at the same site where testing is provided.
- 5.1.4. Ensure access to treatment regimens for special populations (e.g., persons with renal failure) and ensure that these regimens are included in national treatment guidelines and available to patients free-of-charge.
- 5.1.5. Ensure HCV screening, care, and treatment for incarcerated persons and transition of care for prisoners released into the community.
- 5.1.6. Revise treatment guidelines as new treatments become available and increase provider awareness of new treatment options, with the goal of using all-oral DAAs and eliminating use of pegylated interferon/ribavirin-containing regimens in the national program.
- 5.1.7. Provide all patients receiving antiviral treatment with the proper diagnostic and other medical services foreseen by the national protocols and program, including:
 - monitoring treatment effectiveness (via sustained virologic response);
 - monitoring adverse events and deaths;
 - monitoring treatment adherence and complications; and
 - assessing clinical management.
- 5.1.8. Regularly update guidelines to incorporate evidence that can simplify delivery of HCV testing services, pre-treatment evaluation, HCV treatment schedules, and treatment monitoring, increasing accessibility for providers.
- 5.1.9. Strengthen technical capacity of providers to treat HCV.
 - a) Implement a provider-education program and assess its effectiveness regularly.
 - b) Identify a core group of technical clinical experts (i.e., a sub-set of the working group that is established to develop guidelines on care and treatment) to routinely assist with the provider education program, including case-based learning.
 - c) Develop and implement onsite, hands-on training on use of the STOP-C health information system that includes demonstration of the program and addresses ways to overcome common challenges.
- 5.1.10. Build capacity to effectively monitor the cascade of HCV care.
 - a) Establish a comprehensive data system to capture key elements of care cascade and ensure complete data entry and quality.
 - b) Enter HCV case-management data at each treatment site as appropriate; a staff member should be designated for data entry to ensure completeness and quality of data, which will be analyzed on an ongoing basis to assess program outcomes.
 - c) Establish a core group of technical staff at a central level to ensure data analyses.
- 5.1.11. Conduct research to generate evidence on various aspects of the HCV care and treatment program.
 - a) Conduct a pilot project to determine feasibility of and costs associated with simplified care and treatment regimens (i.e., sofosbuvir/velpatasvir), to include assessment of

- antigen testing (instead of RNA) to determine infection;
 - costs savings associated with reduced laboratory monitoring (e.g., limited RNA testing);
 - cost savings associated with use of regimens with fewer adverse effects (i.e., regimens free of pegylated interferon/ribavirin); and
 - use of ancillary healthcare providers (i.e., patient navigators, counselors, and nursing assistants) for HCV testing, assessing liver disease stage, and monitoring during treatment.
- b) Conduct an assessment of patient engagement in HCV care, treatment outcomes, and associated factors (including issues related to possible delays and barriers in accessing care, adhering to treatment, receiving follow-up services, and other outcomes).
 - c) Assess the need for and usefulness of clinical decision tools/reminders in the medical record system.
 - d) Conduct pilot/demonstration projects in harm-reduction centers and rural areas to expand treatment access.
 - e) Conduct a demonstration project to examine the feasibility of co-locating HCV testing, diagnosis, and treatment in settings providing addiction treatment (e.g., OSTs).

STRATEGY 6: IMPROVE HCV SURVEILLANCE

CURRENT ACTIVITIES

Public health surveillance is an important tool for assessing burden of disease and risk factors for transmission of HCV and monitoring program effectiveness. Surveillance helps direct public health response through the collection of information on acute and chronic forms of the disease and detection of possible healthcare-associated and other outbreaks. The existing hepatitis C surveillance system in Georgia is limited to monthly collection of aggregated data on acute and chronic forms of HCV based on laboratory results. The system does not include surveillance for HCV transmission risks or HCV-associated complications (e.g., hepatic cirrhosis and hepatocellular carcinoma [HCC]), nor does it provide data on disease distribution in the general population.

The communicable diseases surveillance system in Georgia and the Electronic Integrated Disease Surveillance System (EIDSS) are tailored for registration, research, and classification of acute disease cases (i.e., those that are suspect, probable, and confirmed). EIDSS manages case data, aggregate data with corresponding samples, and laboratory data linked to cases. Overseen by the Communicable Diseases Department of NCDC, this system collects and distributes data entered by epidemiologists in public health centers; creates notifications on disease events in near real-time; and provides access from desktop, web, and mobile devices, allowing secure linkage for diverse users. EIDSS provides data to WHO's Computerized Information System on Infectious Diseases (CISID) via a transfer module and uses an open architecture approach to establish authorized data exchanges with other electronic systems, including the hospital-level MoLHSA Health Management Information System (HMIS). The EIDSS network covers Georgia's regional and district public health centers.

Population surveys provide critical data to supplement the existing surveillance system. Before 2015, only one population-based survey of hepatitis C existed; this 2002 survey was limited to the city of Tbilisi. A comprehensive, national population-based survey of hepatitis B and hepatitis C prevalence in Georgia was conducted in 2015 to provide a clearer picture of countrywide and regional prevalence and risk factors associated with HCV infections.

GAPS

The current hepatitis C surveillance system is not sufficient for assessing the heavy burden of HCV in Georgia. The following factors hinder the existing system.

- Case definitions for acute and chronic HCV are not aligned with WHO recommendations.
- HCV cases are underreported by laboratories and treating facilities.
- Aggregate reporting does not provide sufficient information to inform prevention, control, and planning.
- EIDSS is designed for surveillance of acute infectious diseases (especially dangerous pathogens and vaccine-preventable diseases) rather than for chronic diseases like hepatitis C.
- No data are available regarding HCV-related morbidity and mortality (i.e., cause of death is frequently unspecified on vital records).

To be useful in informing prevention and intervention strategies, surveillance systems must enable analysis of individual-level (rather than aggregate) data about HCV cases.

OBJECTIVE 6.1. ESTIMATE THE NATIONAL BURDEN OF CHRONIC VIRAL HEPATITIS

This objective will be implemented through building the national HCV surveillance system, promoting the collection and analysis of data to 1) detect new or recent HCV infections (including outbreaks) and 2) monitor performance of prevention, testing, and treatment programs. The surveillance system will focus on patient outcome and receipt of services within the HCV care cascade. Data will be collected from all viral-hepatitis testing laboratories and treatment sites serving the general population. Sentinel surveillance[‡] will be introduced for key populations targeted for prevention, testing, and treatment interventions (e.g., PWID and persons in correctional facilities). Amount of data to be collected will be determined based on an assessment of available resources and feasibility.

MoLHSA and NCDC will coordinate implementation of the following activities to establish a system for estimating burden due to hepatitis C.

[‡] Reporting system based on selected institutions or people who provide regular, complete reports on one or more diseases occurring ideally in a defined attachment.

Objective 6.1

Estimate the national burden of chronic viral hepatitis

ACTIONS

- 6.1.1. Revise and modify current case definitions for acute and chronic hepatitis C.
- a) Implement unified case definitions as proposed by WHO or as published by CSTE/CDC (United States) to ensure consistency in classification of cases and a higher quality of data for analysis.
 - b) Implement case reporting using new case definitions at clinical facilities.
- 6.1.2. Collect HCV risk-factor data by selecting medical facilities participating in the HCV treatment program as sentinel sites; these sites will routinely collect clinical data and data on HCV risk factors.
- 6.1.3. Enhance public health centers' capacity and infrastructure for participation in HCV surveillance.
- a) Elaborate and introduce standard procedures and forms on registration, notification, and reporting of HCV cases.
 - b) Conduct training for all public-health-center and health-facility staff on new HCV reporting requirements.
- 6.1.4. Implement sentinel acute viral hepatitis and HCV surveillance to monitor trends, detect new cases, identify outbreaks, and monitor risk factors for HCV infection.
- a) Use acute HCV surveillance data to detect HCV outbreaks (e.g., those that are healthcare-associated).
 - b) Implement an outbreak investigation system for selected cases or clusters of acute HCV.
 - c) Record seroconversions among highly exposed population groups (e.g., dialysis patients, oncology patients, and PWID).
- 6.1.5. Use data from epidemiologic studies to better define hepatitis C incidence in subpopulations.
- a) Use 2015 HCV population survey data to plan surveillance and treatment interventions.
 - b) Plan and implement additional surveys to assess hepatitis C incidence in various population groups after implementation of HCV Elimination Plan activities (e.g., among PWID and patients undergoing invasive medical procedures, like dialysis).

- 6.1.6. Use the HCV Registry as a surveillance tool to enhance epidemiologic analyses that will inform the HCV elimination campaign; data sources will include laboratory test results with markers for HCV infection from laboratory tests and screening programs.
- 6.1.7. Conduct epidemiologic analyses using data from the HCV registry to improve ascertainment of prevalent HCV infections and to better characterize the burden of the HCV epidemic in Georgia.
- 6.1.8. Conduct research to generate evidence on various aspects of HCV surveillance.
- a) Repeat the national population seroprevalence survey in 2020.
 - b) Survey PWID using various methods (e.g., response-driven, snowball, and baseline/repeat at year 5 of elimination program) to determine the proportion of the population not utilizing harm-reduction centers, and identify approaches to improve PWID services.
 - c) Collect data from HCV-infected persons regarding alcohol use and other behavioral factors.
 - d) Collaborate with CDC laboratory to utilize advanced molecular diagnostics to assess transmission networks.
 - e) Conduct a seroprevalence survey among dentists.
 - f) Conduct a seroprevalence survey among frequent users of healthcare services (e.g., persons with chronic medical conditions) to assess potential for increased HCV risk resulting from increased opportunities for exposure.
 - g) Consider conducting study to assess association of HCV with receipt of endoscopy or other invasive procedures
- 6.1.9. Develop a system to enable de-duplication of cases through the use of National ID number or other unique identifiers.
- 6.1.10. Conduct surveillance of morbidity and mortality caused by chronic hepatitis C-related complications.
- a) Conduct a rapid situational assessment of 1) current practices in diagnosis, referral, and care of persons with HCC and cirrhosis in Georgia and 2) death certificates for 2010-2015 to enumerate and characterize deaths in which HCC or cirrhosis is listed as an underlying or contributing cause of death.
 - b) Evaluate the quality of reports of HCV-associated deaths in national registries to determine if the data can be used for baseline mortality assessment and for periodic monitoring to assess the impact of the Elimination Program on trends in HCV mortality. If deficits in quality are found but are feasible to correct, develop a plan to improve data quality or develop an analysis plan that takes into account the limitations of the data.

- c) Implement a program to ensure systematic testing for markers of HCV infection among persons diagnosed with HCC and cirrhosis.
- d) Conduct surveillance of hepatitis C-related liver cirrhosis and HCC in gastroenterology/hepatology and oncology clinics by implementing a reporting system for each diagnosed case of liver cirrhosis and HCC among patients with HCV infection.
- e) Conduct a study to assess the re-infection rate among PWID.

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