

Understanding and addressing the challenges to an effective hepatitis C response in Georgia

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Introduction

The World Health Organization (WHO) estimates that 180 million people worldwide have been infected with the hepatitis C virus (HCV), and that perhaps 4 million new infections occur each year. As in nearby nations including Russia and Ukraine, information about hepatitis C in the Republic of Georgia has been limited and unreliable. The results of one of the most comprehensive surveys on hepatitis to date, released in 2008, indicate that hepatitis C is far more widespread in Georgia than many observers and experts had assumed.¹ Adult HCV prevalence was found to be 6.7%, based on a series of initial and confirmatory tests for HCV on blood samples from 2,000 adults.² That is more than double the global rate of about 3% and higher than most other countries in the region for which data are available. In a national population of about 5 million, a 6.7% adult prevalence would mean that some 200,000 people are infected with HCV.

The exact consequences are difficult to predict because the majority of individuals infected with HCV do not experience serious symptoms and disease progression can take years. Even so, the impact is likely to be substantial because between 20% and 40% of people with chronic hepatitis C develop cirrhosis and are then at high risk for liver cancer and liver failure, if no treatment and care are provided. Based on the 2008 survey findings, this would mean perhaps 80,000 people living in Georgia today will eventually develop some form of serious liver disease.

Unfortunately, health authorities and patients have few easy options in the face of this looming public health problem. Of particular importance is the fact that hepatitis C disproportionately affects members of marginalized communities such as injecting drug users. In Georgia and elsewhere, members of that group are less likely to be reached by or connected to health or social systems. As in most other countries in Eastern Europe and Central Asia, effective hepatitis C prevention in Georgia is hampered by limited access to preventive services such as needle and syringe exchange projects for injecting drug users.

Regardless of their drug-use history, those who seek out care for hepatitis C may find it lacking even if they are clearly in need. Despite recent efforts to reform and improve health care, the quality and scope of the Georgian health system have yet to recover from years of economic decline and resource constraints.

Key challenges and constraints: Lack of reliable data and high cost of services

Data collection on hepatitis C in Georgia is problematic. One consistent limitation is the lack of adequate reporting of cases to the National Center for Disease Control and Public Health. Another challenge is that thorough HCV testing, which includes both antibody and PCR tests, is not readily or easily available due to high cost. One recent multi-country review estimates that up to 90% of cases might be undiagnosed even in countries with better-resourced health systems.³

Outside of the government, more reliable hepatitis C estimates are available from surveys and studies of varying breadth and quality over the past decade. They indicate that hepatitis C prevalence in Georgia is especially high among injecting drug users (up to 70%⁴) and people living with HIV (48.6%⁵).

Georgian national guidelines for managing hepatitis C reflect international recommendations. Many doctors in the country are also considered sufficiently qualified as per international standards to monitor and treat hepatitis C patients. However, the guidelines and caregivers' quality alone cannot and do not influence access to and availability of necessary services. Although hepatitis C diagnostic tests are available nationwide, they are not provided free of charge even at government facilities. Recent estimates suggest that out-of-pocket costs can total as much as 1,600 GEL (US\$ 900) for a full suite of diagnostic procedures (antibody tests, qualitative and quantitative PCR tests, genotype tests, liver elastography, etc.).

Access to treatment also remains limited due to high cost. The standard of care treatment regimen—ribavirin plus pegylated interferon—costs as much as 21,500 GEL (US\$ 11,580) for a 48-week course of treatment for HCV genotype 1, which is by far the most common genotype in Georgia (more than 60% of all cases).

As elsewhere in the world, the price of the standard of care regimen reflects the high cost of pegylated interferon, only two versions of which are widely available. Both are branded drugs made and marketed by international pharmaceutical companies: PegIntron (from Schering-Plough Corp., now Merck & Co.) and Pegasys (F. Hoffmann–La Roche Ltd.).

The high cost of treatment has long been the reason neither the health system nor insurance schemes in Georgia cover costs of hepatitis C diagnostics or treatment services. As noted earlier, most people with chronic hepatitis C, perhaps about 75% of the total, may experience few or no symptoms. Yet there is little doubt that despite the lack of reliable data, the 320 individuals who reportedly received hepatitis C treatment in Georgia in 2009 constituted only a small minority of people currently in need.

Moreover, nearly all of those individuals had to pay for treatment out of pocket, an option not available to most patients. One current exception is that the Georgian Department of Corrections and Legal Assistance provides standard of care treatment to a limited number (about 10 a year) of prisoners. That relatively recent development stems from a 2009 ruling against the government in *Ghavidze v. Georgia*, at the European Court of Human Rights.

Recommended action steps

Greater access to hepatitis C treatment is expected in 2011 due to a project supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria. In its successful proposal in Round 9 of the Global Fund, the Georgian country team sought funding to provide diagnostics, treatment and care free of charge to an average of 100 patients per year.

Because of its specific limitations, including the fact that eligibility is restricted to individuals co-infected with HIV, the Global Fund project is not necessarily a cornerstone of a sustainable effort to expand access to hepatitis C services. It does highlight the impact of an important trend, however: advocacy by and on behalf of HCV-infected individuals is slowly increasing in Georgia, including among healthcare experts. One of their main goals is reduced prices for pegylated interferon, an effort that will likely require broader international cooperation and coordination.

In the meantime, national advocates can achieve additional important gains in the short- and medium-term by directly addressing several other existing challenges to improved hepatitis C service delivery. One priority objective would be to advocate for the Georgian government to create a dedicated hepatitis C program within the Ministry of Labour, Health and Social Assistance. Key responsibilities of that program would include:

- creating and maintaining a comprehensive hepatitis C registry that provides reliable statistical data at regular intervals;
- developing and implementing strategies to increase hepatitis C awareness, with targeted initiatives aimed at members of vulnerable populations (especially injecting drug users, people living with HIV and prisoners);
- ensuring that all relevant hepatitis C medicines are included on the Model List of Essential Drugs of Georgia;
- increasing access to and uptake of HCV testing services among the general population, an effort that should also focus on highlighting the benefits of knowing one's status even if treatment is not needed or available;
- increasing focus on and resources for evidence-based prevention efforts, including improved access to harm reduction materials (e.g., clean needles and opioid substitution therapy) among injecting drug users outside and inside prisons; and
- supporting at least a share of hepatitis C treatment costs annually.

Advocates also should seek to increase engagement of members of key vulnerable groups in the movement for improved hepatitis C treatment and care. As with HIV, engagement of those directly affected is likely to be crucial to building the foundation for community-driven

awareness and treatment literacy initiatives. Evidence around the world indicates that a strong, knowledgeable civil society sector is a crucial element of effective treatment advocacy.

¹ Sharvadze L, Nelson K, Imnadze P, Karchava M, Tsertsvadze T, “Prevalence of HCV and genotypes distribution in general population of Georgia”. *Georgian Medical News* 12: December 2008, pp. 71-77.

² Confirmatory results were obtained via recombinant immunoblot assay (RIBA). Initial antibody tests were conducted via ELISA (enzyme-linked immunosorbent assay).

³ Merkinaitė S, Lazarus J, and Gore C, “Addressing HCV infection in Europe: reported, estimated and undiagnosed cases”. *Cent Eur J Public Health* 2008; 16 (3): 106–110.

⁴ Shapatava E, Nelson KE, Tsertsvadze T, del Rio C. “Risk behaviors and HIV, hepatitis B, and hepatitis C seroprevalence among injection drug users in Georgia”. *Drug Alcohol Depend.* 2006;82(Suppl 1):S35-8.

⁵ Badridze N, Chkhartishvili N, Abutidze A, Gatserelia L, Sharvadze L, “Prevalence of hepatitis B and C among HIV-positive patients in Georgia and its associated risk factors”. *Georgian Medical News* 12: December 2008, pp. 54-60.