American Association for the Study of Liver Diseases (AASLD) 2009 Practice Guidelines [12]. Treatment medications during the evaluation period included pegylated interferon and ribavirin for 24 or 48 weeks depending on the HCV genotype. The program had resources to provide treatment to 500 prisoners free of charge each year. Interferon-free regimens were not available in Georgia prior to April 2015.

Statistical analysis

We described the HCV care cascade among prisoners by calculating the number of prisoners who: a) received anti-HCV testing; b) received confirmatory HCV-RNA and HCV genotype testing, and liver elastography score; c) were deemed eligible for treatment; d) enrolled in HCV treatment; e) began and completed their prescribed treatment course; and f) achieved a sustained virologic response (undetectable HCV RNA) at least 12 weeks post therapy (SVR12). The proportion achieved for each step was calculated using the preceding value as the denominator. We described the demographic characteristics, HCV genotype, and non-invasive liver fibrosis assessments for chronically infected prisoners who were treatment eligible. We calculated other non-invasive fibrosis assessments using the fibrosis-4 (FIB-4) score and AST to Platelet Ratio Index (APRI) for those who had laboratory data available. The FIB-4 score was calculated using the formula: (age [years] x AST [U/L]) / (platelets [10^9/L] x square root ALT [U/L]) in which the age of the patient was the age at the time of the blood draw. FIB-4 scores < 1.45 have a negative predictive value of 90% for advanced fibrosis and scores > 3.25 have a 65% positive predictive value for F3/4 [13]. APRI was calculated using the formula: (AST [IU/L] / AST upper limit of normal [37 IU/L] / platelet count [10^9/L]) $\times$ 100. The lower the APRI score (< 1.0) the greater the negative predictive value, and scores > 2.0 have a specificity of 91% for identifying cirrhosis [14]. Analyses were conducted using SAS Institute Inc. version 9.3 (Cary, NC, USA).

Results

This assessment included data from the program's inception in December 2013 through April 2015. The total number of prisoners housed by MOC during the evaluation period was difficult to ascertain, but the MOC estimates 30,000 persons were in the prison system at some time during the evaluation period. Figure 1 illustrates the HCV care cascade. An estimated 13,500 (45%) prisoners received anti-HCV testing, and 5175 (38%) tested positive. Of those who tested positive, 3840 (74%) had confirmatory HCV RNA testing performed, and of those who had RNA testing, 2730 (71%) tested positive and were diagnosed with chronic HCV infection. Of 2730 prisoners diagnosed with chronic HCV infection, 880 (32%) met the eligibility criteria for treatment. Of these, 858 (98%) were male, 155 (18%) had elastography ≥ 12.5 consistent with Metavir F4, and most were infected with HCV genotype 3 (48%). Other characteristics are listed in the Table 1. FIB-4 and APRI identified 52

and 62 prisoners with advanced fibrosis or cirrhosis, respectively (Table 1). The strength of the agreement for liver elastography was moderate for FIB-4 (kappa = 0.568; 95% CI 0.456 to 0.679) and APRI (kappa = 0.545; 95% CI 0.437 to 0.653).

Of treatment eligible prisoners, 585 (66%) enrolled in treatment (Fig. 1). Of these, 405 (69%) had completed

Georgian MOC has the potential to reduce the burden of HCV infection within prisons, as well as contribute substantial public health impact by slowing the country's overall HCV epidemic.

Early results from Georgia's HCV prison program also demonstrate its ability to support successful completion of HCV treatment, as more than 70% of prisoners who initiated treatment completed their treatment course. Of the prisoners unable to complete their prescribed regimen, the majority discontinued due to tolerability issues at a rate lower or comparable to non-institutionalized populations [20, 21]. Drop-out rates are likely to decrease with the introduction of newer, all-oral interferon-free DAA regimens. In addition, some prisoners decided to defer interferon-based treatment and wait until the interferon-free regimens were available. We hypothesize that integrating these new regimens would lead to an even higher impact on reducing HCV infection prevalence in Georgia's prison system.

Despite these early successes, there are areas for improvement in Georgia's current HCV prison program. First, due to the opt-in structure of the screening component, less than half of prisoners received anti-HCV testing during the evaluation period. To overcome this challenge, the MOC could adopt an opt-out structure. Second, there were 1335 (26%) anti-HCV positive prisoners who did not receive confirmatory HCV-RNA PCR testing, which may have resulted in an underestimated burden of chronic HCV infection in Georgian prisons. A second blood draw is required to perform HCV RNA testing which may have been a contributory factor. Reflex HCV RNA testing could overcome this barrier. Third, more than half of prisoners with chronic infection did not receive full diagnostic evaluation including non-invasive fibrosis staging. This gap may have led to under treatment of eligible prisoners with chronic HCV

Fourth, costs for the program were not assessed, and could inform future policy. Finally, since this was a retrospective analysis, we were not able to perform quality assurance and quality control on the data collected.

Conclusions

In conclusion, this evaluation demonstrates that a HCV treatment program within the Georgian prison system is feasible, as the majority of prisoners enrolled in treatment in the first 2 years of this program's operation were able to complete their prescribed treatment course. This evaluation also provided an important opportunity to strengthen the public health capacity of Georgia, and thereby enhance global health security. There are several opportunities to enhance the success of the HCV treatment program in the Georgian prison system in the future. Specifically, an opt-out anti-HCV screening structure would further increase identification of infection, and use of newly introduced interferon-free regimens could improve treatment enrollment, adherence, efficacy, and completion. Offering linkage to community-based care to prisoners with short sentences could improve enrollment and completion rates as well. In addition, improved health information data systems would allow for optimal evaluation of future programs. Because most prisoners are eventually released and reintegrated into the community, HCV treatment and prevention in prisons can reduce the HCV infection burden in the general population, contributing to Georgia's overall goal of HCV elimination and serving as a model for other countries pursuing similar targets.

Abbreviations

ALT: Alanine aminotransferase; Anti-HCV: Antibody to hepatitis C virus; APRI: Aspartate aminotransferase to platelet ratio index; AST: Aspartate aminotransferase; DAA: Direct acting antiviral; FIB-4: Fibrosis-4 score; Fx: Liver fibrosis stage; HCV Genotype: Hepatitis C virus genotype; HCV RNA: Hepatitis C virus ribonucleic acid; HCV: Hepatitis C virus; IDACIR: Infectious Diseases, AIDS and Clinical Immunology Research Center; IDU: Injection drug use; IU/L: International units per liter; MOC: Ministry of corrections; PCR: Polymerase chain reaction; PWID: People who inject drugs; SVR12: Sustained virologic response 12 weeks after completion of treatment

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