Title: Barriers of linkage to hepatitis C care and treatment among people who inject drugs in Georgia

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Funding: This work was supported by CDC Foundation [grant number 807] and Medecins Du Monde France Representation in Georgia.
Title: Barriers of linkage to hepatitis C care and treatment among people who inject drugs in Georgia

Background

People who inject drugs (PWID) in Georgia have a high prevalence of hepatitis C virus antibody (anti-HCV). Access to care among PWID could be prioritized to meet the country’s hepatitis C elimination goals. This study assesses barriers of linkage to hepatitis C care among PWID in Georgia.

Methods

Study participants were enrolled from 13 harm reduction centers throughout Georgia. Anti-HCV positive PWID who were tested for viremia (linked to care [LC]), were compared to those not tested for viremia within 90 days of screening anti-HCV positive (not linked to care [NLC]). Participants were interviewed about potential barriers to seeking care.

Results

A total of 500 PWID were enrolled, 245 LC and 255 NLC. LC and NLC were similar with respect to gender, age, employment status, education, knowledge of anti-HCV status, and confidence/trust in the elimination program (p>0.05). More NLC (13.0%) than LC (7.4%) stated they were not sufficiently informed what to do after screening anti-HCV positive (p<0.05). In multivariate analysis, linkage to care was associated with perceived affordability of the elimination program (adjusted prevalence ratio=8.53; 95% confidence interval: 4.14-17.62).

Conclusion

Post testing counselling and making hepatitis C services affordable could help increase linkage to care among PWID in Georgia.

Key words: PWID, Linkage to care, HCV, Elimination, Barriers
Background

Georgia, with a high burden of hepatitis C (1), embarked on a national program in 2015 to eliminate hepatitis C, with an overall goal of 90% reduction in hepatitis C virus (HCV) prevalence by 2020 (2). The country has one of the highest rates of injection drug use in the world (3), and 66.2%–92.0% HCV antibody (anti-HCV) prevalence among people who inject drugs (PWID) (4) representing 25% of all HCV cases in the country (5-6). Increasing access to hepatitis C screening, care and treatment among PWID is important if Georgia is to be successful in eliminating hepatitis C from the country.

As of April 30, 2019, 56,294 patients had initiated hepatitis C treatment within the program, though there has been a gradual decline in the number of people initiating treatment since late 2016. Despite extensive national screening activities, including among PWID at harm reduction (HR) centers, nearly half of Georgians with HCV infection are not aware of their HCV status. In addition, among those who have screened positive, a significant proportion have not received viremia testing to confirm active HCV infection, and among those with confirmed viremia, a significant proportion have not initiated antiviral treatment (7). PWID bear a disproportionate share of the HCV burden in the country (8) and ensuring access to treatment for this marginalized population is critical for achieving elimination in the country. However, barriers to accessing care in the national hepatitis C elimination program among anti-HCV-positive PWID are not well understood. The objective of this study was to assess barriers of linkage to HCV care among PWID in Georgia.

Methods

All screening, viremia testing and treatment monitoring data are entered into the national elimination program database (7). Access to the database through a unique 11-digit national identification number (NIN) allows for tracking individuals across the whole continuum of care, from screening through
treatment and testing for sustained viral response (SVR), i.e. cure.

Study population
There is a total of 13 HR centers in the country (9). Since 2017, anti-HCV test results among PWIDs who agree to disclose their NIN are recorded in the elimination program database. During 2017-2018, a total of 2780 HR center clients with positive test results for HCV antibody were identified in the program database by their NIN (10).

We compared PWIDs who were linked to HCV care (LC) with those who were not linked to care (NLC). Linkage to care was defined as receipt of HCV viremia testing within 90 days from the date of a positive anti-HCV result recorded in the hepatitis C elimination program database. Convenience samples of LC (n=263) and NLC (n=275) individuals were drawn from the elimination program database by having hepatitis C screening performed and recorded by an HR center using beneficiaries’ NIN. LC were selected for having a positive anti-HCV result dated between August 1, 2017 and January 31, 2018, while inclusion dates for NLC were between January 1, 2017 and January 31, 2018. The selection period for NLC had to be extended for 7 months to allow for more study participants with available and valid contact information.

Data collection
We conducted a telephone survey of LC and NLC PWID inquiring about potential barriers to obtaining viremia testing, and/or enrolling in the national hepatitis C elimination program. Interviews were conducted from September 1, 2018 to December 20, 2018. Interviewers were recruited from HR center staff (HIV voluntary counseling and testing counselors) and trained prior to the study. Five
attempts were made to reach each study participant. We calculated the proportion of individuals that were not reached via phone and those who refused to participate in the survey. The study protocol was approved by the Institutional Review Board of the Health Research Union (IRB00009520; IORG0005619).

Survey tool

The telephone questionnaire was developed and pilot tested among five respondents and adapted based on user feedback prior to administration. The questionnaire collected information about demographics and barriers to HCV care linkage. The social demographic characteristics included age, residence (capital city vs other regions), education, employment, family and personal income. Data collected on HCV included diagnostic test types available in the country, participant’s HCV status and reasons for not being tested. The questionnaire also included questions about current use of HR services (some respondents who were HR center beneficiaries at the time of their anti-HCV test may no longer be receiving HR services at the time of interview), availability of medications, and procedure for enrollment in the program. Participants were also asked about affordability of the program; during the first three years (May 2015 – August 2018) when patients had a co-payment for diagnostic evaluations which was approximately 300 USD at the beginning of the program and later decreased to approximately 100 USD. We also gathered information on respondent preferences for type and source of information about HCV infection.

Data analysis

Following removal of identifying information, data were entered in Microsoft® Excel at study sites and imported in SPSS v.23 statistical software by the study statistician. Descriptive and bivariate
analyses of factors associated with linkage to care were conducted. We calculated unadjusted and adjusted prevalence ratios (PR) with 95% confidence intervals (CI) to assess the associations between LC and NLC using logistic regression models.

Results

Participation

Out of the 538 participants drawn from the elimination program database that were approached, a total of 500 PWID participated in the study (refusal rate of 7.1%); 245 were linked to care and 255 were not linked to care. The participation rates were similar when we compared LC and NLC.

Demographic characteristics of study participants

Overall, 91.2% of study subjects were males, 81.4% were older than 35 years, 63.8% were unemployed, and 34.9% had a university/college degree. No significant differences were found between the two groups (LC and NLC) by age, gender, residence, family income, employment status, education level, and confidence/trust in the hepatitis C elimination program (Table 1).

Knowledge of HCV and elimination program

Most of the study participants (98.2%) were aware of their HCV infection. Of the surveyed individuals, 391 (78.2%) reported that they had been informed about HCV test results from a health care worker (HCW).
When we looked at reasons why the NLC group did not receive viremia testing, 21.7% stated that the reason was cost of the testing, and 42.9% of the NLC group stated that a free laboratory test would improve enrollment in the program. A quarter (24.5%) of NLC participants expressed willingness to receive more information about HCV infection and the hepatitis C elimination program, preferring television and the internet as sources of information.

**Association of linkage to care with different factors**

In bivariate analysis, when comparing those linked and not linked to HCV care, 13.0% of NLC compared to 7.4% of LC stated they did not receive sufficient information to know what to do next after their positive screening test (PR=1.07; 95% CI: 1.01-1.13). More NLC (58.2%) than LC (24.5%) reported that enrollment was not affordable (PR=1.81; 95% CI: 1.53-2.12). Ongoing engagement in HR services was associated with linkage to care (PR=1.31; 95% CI: 1.07-1.61). Nearly 85% of LC and 86.4% of NLC think that it would be more comfortable if HCV treatment were available at HR centers (PR=0.98; 95% CI: 0.91-1.06). However, in multivariate analysis, the only independent predictor of linkage to care was affordability of the program (adjusted PR=8.53; 95% CI: 4.14-17.62) (Table 1).

**Discussion**

This is the first quantitative study in Georgia to examine barriers to HCV treatment among PWID, which represents a priority for the program. Mathematical modeling suggests that for countries with a large burden of injection drug use, HCV treatment for PWID is critical to achieving HCV elimination (11). We found that barriers to linkage to care among anti-HCV positive PWID include perceived high
cost of care and a lack of information on what to do after a positive screening.

The eligibility criteria for HCV-infected individuals to enroll in the hepatitis C elimination program in Georgia are simple i.e., a person must be a citizen of Georgia aged ≥18 years. At the beginning of the program (April 28, 2015 to June 9, 2016) only patients with advanced liver fibrosis level were eligible for treatment (12). However, since June, 2016, the program has been expanded to all HCV-viremic individuals regardless of disease severity (13). This expansion resulted in an increase in the number of enrolled individuals, but enrollment gradually declined after its peak in September 2016. Exact reasons for this decline are not known but high cost of diagnostics earlier in the program may be attributed to this decline. In our analysis, affordability of the program was the only independent predictor of linkage to care.

Although all PWID interviewed were utilizing HR services at the time they were screened, more than half of study participants were no longer receiving HR services at the time of interview. Disengagement with HR services was one of the factors associated with poor linkage to care. Research suggests engagement in opioid substitution therapy and other HR services increases linkage to care among PWID (14). Our data seem to correlate with this finding.

One important finding of this study was that more than 20% of respondents did not indicate they were informed of their test results by a HCW. Ensuring counseling to communicate screening test results and the need and procedure for follow-up viremia testing among those with positive screening results may result in increased linkage to care. Further, standardized counseling procedures need to be developed and implemented at all HR facilities to inform anti-HCV-positive patients about the need
for HCV viremia testing to improve linkage to care.

This study is subject to limitations. Firstly, our findings are not representative of all PWID in the country. We were unable to include those PWID in our study who were not enrolled in HR service at the time of anti-HCV testing and who did not agree to provide NIN to be registered in the elimination program database. Individuals not enrolled in HR services are likely among the hardest to reach, and we were not able to survey this population. Secondly, these findings are self-reported and are subject to recall and social desirability biases. Another limitation of the study is different selection period for NLC and LC groups (longer selection period for NLC), which could lead to information bias, as awareness of the study participants could change over time.

Interventions to improve linkage to hepatitis C care among PWID have been identified by different studies. One study found increased enrollment rates and adherence to treatment among PWID with advanced liver fibrosis level when hepatitis C screening is done on-site (at the HR center) and when peer navigation services are available (6).

Because of technical advisory group (TAG) recommendations in Georgia and our study findings, the government has made all diagnostics free of charge since September, 2018. Other services, such as on-site viremia testing and treatment have also been shown to be effective (15), and could help the country to reach elimination. Reducing barriers for PWID is critical, and data from this study may be useful for other countries with a high HCV prevalence and where injection drug use is a major route of HCV transmission.
Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.
Table 1. Comparison of linked to care (LC) and not linked to care (NLC) among people who inject drugs by different characteristics, Georgia

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Linked to care (LC)</th>
<th>Not linked to care (NLC)</th>
<th>Prevalence Ratio (PR) and 95% CI</th>
<th>Adjusted Prevalence Ratio (aPR) and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>224</td>
<td>91.4</td>
<td>232</td>
<td>91.0</td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>8.6</td>
<td>23</td>
<td>9.0</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤35</td>
<td>38</td>
<td>15.5</td>
<td>55</td>
<td>21.6</td>
</tr>
<tr>
<td>&gt;35</td>
<td>207</td>
<td>84.5</td>
<td>200</td>
<td>78.4</td>
</tr>
<tr>
<td>Residence (district)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tbilisi</td>
<td>105</td>
<td>42.9</td>
<td>127</td>
<td>49.8</td>
</tr>
<tr>
<td>Regions</td>
<td>140</td>
<td>57.1</td>
<td>128</td>
<td>50.2</td>
</tr>
<tr>
<td>Level of education*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University/Post-graduate</td>
<td>80</td>
<td>33.3</td>
<td>91</td>
<td>36.4</td>
</tr>
<tr>
<td>Other</td>
<td>160</td>
<td>66.7</td>
<td>159</td>
<td>63.6</td>
</tr>
<tr>
<td>Employment*</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Employed</td>
<td>92</td>
<td>38.0</td>
<td>87</td>
<td>34.4</td>
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<td>Unemployed</td>
<td>150</td>
<td>62.0</td>
<td>166</td>
<td>65.6</td>
</tr>
<tr>
<td>Family income (per month)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1000 GEL</td>
<td>122</td>
<td>87.8</td>
<td>133</td>
<td>90.5</td>
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<tr>
<td>&gt;1000 GEL</td>
<td>17</td>
<td>12.2</td>
<td>14</td>
<td>9.5</td>
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<tr>
<td>Affordability of HCV Elimination Program*</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>182</td>
<td>75.5</td>
<td>105</td>
<td>41.8</td>
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<tr>
<td>No</td>
<td>59</td>
<td>24.5</td>
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<td>58.2</td>
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<td>Question</td>
<td>Option 1</td>
<td>Percentage 1</td>
<td>Option 2</td>
<td>Percentage 2</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------</td>
<td>--------------</td>
<td>----------</td>
<td>--------------</td>
</tr>
<tr>
<td>Who notified you about the screening test result?*</td>
<td>Person who conducted the test</td>
<td>64</td>
<td>33.2</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>Physician/Consultant</td>
<td>129</td>
<td>66.8</td>
<td>142</td>
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<tr>
<td>Do you feel that you received sufficient information to know what to do next after screening test?*</td>
<td>Yes</td>
<td>226</td>
<td>92.6</td>
<td>220</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>18</td>
<td>7.4</td>
<td>33</td>
</tr>
<tr>
<td>Trusting HCV elimination program*</td>
<td>Yes</td>
<td>231</td>
<td>95.1</td>
<td>236</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>12</td>
<td>4.9</td>
<td>19</td>
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<td>Do you currently use the services in HR centers?*</td>
<td>Yes</td>
<td>111</td>
<td>48.7</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>117</td>
<td>51.3</td>
<td>151</td>
</tr>
<tr>
<td>Would it be more comfortable if HCV treatment were available in HR centers?*</td>
<td>Yes</td>
<td>169</td>
<td>84.9</td>
<td>190</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>30</td>
<td>15.1</td>
<td>30</td>
</tr>
</tbody>
</table>

*Missing values not shown

Abbreviations: CI=confidence interval, HCV=hepatitis C virus, GEL=Georgian lari, HR=harm reduction


Acknowledgements

This work was supported by CDC Foundation [grant number 807] and Medecins Du Monde France Representation in Georgia.
List of abbreviations

PWID - People who inject drugs
LC - linked to care
NLC - not linked to care
HCV - hepatitis C virus
HR - harm reduction center
NIN - national identification number
SVR - sustained viral response
PR - prevalence ratio
CI - confidence interval
TAG - technical advisory group
Declarations

Ethics approval and consent to participate

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The study was approved by institutional review board of Health Research Union (IRB#00009520).

Consent for publication: Not applicable.

Availability of data and materials: All data generated or analysed during this study are included in this published article.

Competing interests: The authors declare that they have no competing interests.

Funding: This work was supported by CDC Foundation [grant number 807] and Medecins Du Monde France Representation in Georgia.

Authors' contributions: MB developed the study design and supervised data collection, analysis and manuscript preparation activities; TA and LG participated in data collection, entry and analysis and manuscript writing; TK developed study instrument; MG supervised pilot testing among study respondents; GK verified the analytical methods and performed statistical analysis; The concept for the study was developed with LG, TK, IT and MT; All authors contributed to interpretation of results, writing report, edited and approved the final manuscript.

Acknowledgements: This work was supported by CDC Foundation [grant number 807] and Medecins Du Monde France Representation in Georgia.