Decentralizing HCV Testing to Harm Reduction Sites; HEAD-Start Georgia

Maia Japaridze, Country Project Manager, FIND; Georgia
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The need in Georgia

Population of 3.7 million people. Started a national HCV elimination program in 2015

• 2015 HCV seroprevalence survey:
  • HCV seroprevalence - 7.7%, HCV chronic infection - 5.4% ¹
  • HCV Prevalence among PWID is highest affected group
  • PWIDs: ~66% ² (~50,000 PWID in the country) ²

National program is making good progress however need to strengthen reach among key populations. Estimated that from 2015 to 2018 55% PWID who screened anti-HCV antibody positive did not receive a confirmatory test

To reach national elimination goals this gap needs to be addressed with considerations on

• Effective service provision for PWID that will decrease this loss to follow up (LTFU)
• Cost considerations of the service provision modalities as the Georgian government is financing the diagnostic components of the HCV Elimination program

¹ NCDC, National Survey, 2015
² Addiction Research Development in Georgia Project, Drug situation in Georgia 2015, report
Purpose of HEAD-Start Georgia study is to identify effective modalities of service provision that decrease loss to follow up (LTFU) between HCV screening and confirmatory testing among PWID

Objectives of the study:
- To determine whether the proportion of participants who receive results of HCV viremia testing differs between the Arms.
- To characterize the HCV care cascade for PWID identified through HRSs in Georgia, and quantify the proportion that go through each step in the cascade.
- To assess the cost of the different testing strategies per Arm

Partners:
- Georgia MoH,
- Georgia NCDC,
- Georgian Harm Reduction Network,
- Harm Reduction Sites
**HEAD-Start Georgia study design**

**Harm Reduction Sites**
(8 HRS)

**Non randomized assignment**

### Arm 1:
(on-site POC molecular)
4 HRS
- Blood draw at point-of-care service (HRS)
- HCV confirmatory testing
- HCV viremia results given at HRS on same day

1. Tbilisi New Vector
2. Zugdidi Xenon
3. Kutaisi New Way
4. Batumi Imedi

### Arm 2:
(on-site blood draw for centralized cAg)
2 HRS
- Blood draw at point-of-care service
- Plasma shipped to central lab for HCV confirmatory testing

### Arm 3:
(patient who screens RDT+ referred to HCV treatment site SOC)
2 HRS
- Standard of care: patients referred to treatment center for blood draw and confirmatory testing

1. Gori Step to Future
2. Tbilisi New Way

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A project funded by **Unitaid**
Innovation in Global Health
# Georgia

## City Population # of PWID HCV prevalence in city among PWID (2015)

<table>
<thead>
<tr>
<th>City</th>
<th>Population of city</th>
<th># of PWID in city</th>
<th>HCV prevalence in city among PWID (2015)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tbilisi</td>
<td>1,113,000</td>
<td>38,463</td>
<td>73.7%</td>
</tr>
<tr>
<td>Batumi</td>
<td>154,600</td>
<td>5,294</td>
<td>79.8%</td>
</tr>
<tr>
<td>Kutaisi</td>
<td>147,900</td>
<td>7,061</td>
<td>74.6%</td>
</tr>
<tr>
<td>Zugdidi</td>
<td>105,200</td>
<td>5,892</td>
<td>73.3%</td>
</tr>
<tr>
<td>Rustavi</td>
<td>126,000</td>
<td>10,443</td>
<td>50%</td>
</tr>
<tr>
<td>Gori</td>
<td>126,100</td>
<td>2,706</td>
<td>57.1%</td>
</tr>
</tbody>
</table>

**City Notes:**
- TBILISI AKESO HRS
- TBILISI NEW WAY HRS

**Map Notes:**
- Point of Care RNA at HRS
- cAg, blood draw at HRS
- Standard of Care, referral
HEAD-Start Georgia study care cascade; preliminary data: May 2018 to 15 May 2020

1958 were evaluated for study eligibility

Patient Demographics
95.4% male, median age: 43 [19-88] yrs, 77.0% current PWID

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Arm 1</th>
<th>Arm 2</th>
<th>Arm 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>619</td>
<td>619</td>
<td>512</td>
</tr>
<tr>
<td>HCV RNA test done</td>
<td>484</td>
<td>483</td>
<td>398</td>
</tr>
<tr>
<td>HCV+ result</td>
<td>512</td>
<td>504</td>
<td>411</td>
</tr>
<tr>
<td>Started HCV treatment</td>
<td>429</td>
<td>312</td>
<td>411</td>
</tr>
<tr>
<td>Completed tx</td>
<td>403</td>
<td>364</td>
<td>355</td>
</tr>
<tr>
<td>Eligible for SVR 12</td>
<td>401</td>
<td>292</td>
<td>289</td>
</tr>
<tr>
<td>SVR 12 completed</td>
<td>300</td>
<td>221</td>
<td>292</td>
</tr>
<tr>
<td>Acheived SVR</td>
<td>219</td>
<td>243</td>
<td>242</td>
</tr>
</tbody>
</table>

Arm 1 v 2 p=0.942 Arm 1 v 3 p=0.171 Arm 2 v 3 p=0.223
## Turn around time by arms, preliminary data

<table>
<thead>
<tr>
<th>Time between HCV screening and sample collection for confirmation test</th>
<th>Sample collection and completion of sample testing</th>
<th>Completion of sample testing and result entered into National Database</th>
<th>Result entered into database and result delivered back to patient</th>
<th>Result to patient and patient started treatment</th>
<th>Total Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm 1</td>
<td>Same day (0 - 0) n=619</td>
<td>1 hr 53 min (1 hr 27 min – 23 hr 41 min) n=619</td>
<td>16 hr 24 min (0 - 61 days) n=619</td>
<td>24 minutes* (0 – 3hr 13 min) n=619</td>
<td>84.7 days (9-638 days) median=57 n=431</td>
</tr>
<tr>
<td>Arm 2</td>
<td>Same day (0 - 63 days) n=477</td>
<td>6.3 days ** (1 - 65 days) n=476</td>
<td>4.0 days (0 - 43 days) n=471</td>
<td>10.0 days (0 - 118 days) n=476</td>
<td>65.9 days (11-586 days) median=30 n=307</td>
</tr>
<tr>
<td>Arm 3</td>
<td>8.9 days (0 - 450 days) n=469</td>
<td>5.6 days (0 - 93 days) n=468</td>
<td>4.5 days (0 – 388 days) n=461</td>
<td>6.9 days (0 – 97 days) n=411</td>
<td>64.0 days Median=43 (9-579 days) n=301</td>
</tr>
</tbody>
</table>

* time between completion of sample testing and result delivered back to patient

** includes the time spent for repeated test of PCR if cAg test result is negative or in grey zone.
Preliminary conclusions and lessons learned

- The introduction of decentralized HCV confirmatory testing catalyzed the decentralization of HCV treatment in the HRS.

- On location based approaches to blood sample collection resulted in a larger proportion of participants receiving their confirmatory test results;

- The turnaround time for confirmatory testing was shortest where POC service was performed.
We are grateful for the input and feedback of many of the organizations also doing great work in the area of HCV elimination in Georgia.