Simplifying HCV diagnosis to expand access to testing and treatment towards elimination

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6 - 10 July 2020

VIRTUAL
KEY FINDINGS FROM USE OF PoC HCV VIRAL LOAD IN PROMOTING ACCESS AMONG PWID IN MYANMAR

Presented by: Bridget Draper, Burnet Institute
Presentation on the CT2 Study in Yangon, Myanmar
Implemented by Burnet Institute and Myanmar Liver Foundation, in partnership with FIND

A project funded by:

Unitaid
Innovation in Global Health

HEAD-Start
Hepatitis C Elimination through Access to Diagnostics

FIND
Business diagnostic solutions
Background - Myanmar

Hepatitis C - prevalence

- Population of 53 million
- 2.7% anti-HCV antibody positive
- 56% anti-HCV antibody positive among people who inject drugs
- Most common genotypes: GT3, GT6

Hepatitis C – health care

- National Hepatitis Control Program
- QuickStart Hepatitis C Hospital Treatment Program
- Private GPs, hepatologists
- NGOs / research projects

References:
Study Design

‘one-stop-shop’ model of care

- PoC HCV RNA test using on-site Cepheid GeneXpert
- GPs initiating treatment

- Burnet Institute (BI) Thingangyun Service for PWID
- Myanmar Liver Foundation (MLF) Than Sitt Charity Clinic
Study Recruitment

Recruitment & Eligibility criteria
• Aged 18 years and over
• Not known RNA positive
• Registered for enrolment and called up
  OR Present during study recruitment

Exclusion criteria
• HIV infection
• HBV infection
• eGFR <30
• Active TB/ongoing treatment for TB
• Previous HCV treatment
• Current pregnant/breast-feeding
• Serious drug-drug interaction with sofosbuvir/daclatasvir
Clinical Assessments

Anti-HCV antibody negative

HCV RNA negative

HCV RNA PCR test (GeneXpert®)

Return of HCV RNA result to patient

HIV RDT positive HBsAg positive

External laboratory investigations

Current HBV infection (confirmed with HBV serology / HBV VL test)

Specialist review

Initiate DAA therapy

Visit 1

Visit 2
Specialist Referrals

**Referrals**
Protocol for referral to hepatologist:
- Any physical signs of decompensation
- Liver enzymes (AST, ALT) >200

Referral to other specialist:
- At GP discretion, reasons included:
  - Chest X-rays
  - Cardiologist
  - Uterine fibroid
  - Renal stones

**Outcomes of referrals:**
- 1-3 weeks of liver supportive supplements prescribed; re-check LFTs and initiate DAAs
  - incl: Liver Care, Hepasel, Livolin Forte, LiveUp, Hepacol,
- Referral for hepatobiliary surgery
On-Treatment Monitoring, SVR12 assessment

**On-Treatment**
- Treatment dispensed every four weeks
- 12 week course (APRI < 1.5)
- 24 week course (APRI ≥ 1.5)

**SVR12**
- Test of cure (sustained virological response - SVR) done 12 weeks after completing treatment
## Results – Participant characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total N = 633</th>
<th>BI N = 253</th>
<th>MLF N = 380</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>405 (64%)</td>
<td>239 (94%)</td>
<td>166 (44%)</td>
</tr>
<tr>
<td>Age (median, IQR)</td>
<td>42 (31, 53)</td>
<td>32 (27, 39)</td>
<td>50 (39, 59)</td>
</tr>
<tr>
<td>Ever injected drugs</td>
<td>264 (42%)</td>
<td>252 (99%)</td>
<td>12 (3%)</td>
</tr>
<tr>
<td>Injected drugs in the past six months</td>
<td>236 (37%)</td>
<td>235 (93%)</td>
<td>1 (&lt;1%)</td>
</tr>
<tr>
<td>Currently on methadone</td>
<td>161 (25%)</td>
<td>161 (64%)</td>
<td>0 (0%)</td>
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</table>
**Results - Cascade of Care**

- Total number of RDT screened: 633
- Number of RDT positive (HCV Ab+ detected): 606
- Number of HCV RNA tested among Ab positive: 606
- Number of HCV RNA detected among RNA tested: 535
- Number of patients eligible to start treatment: 489
- Number of patients initiated treatment: 488
- Number of patients completed treatment: 477
- Eligible for SVR testing: 474
- SVR test completed: 433
- SVR Achieved: 402

- Eligible for SVR testing: 91%
- SVR test completed: 93%
- SVR Achieved: 96%
- Total number of RDT screened: 100%
- Number of RDT positive (HCV Ab+ detected): 96%
- Number of HCV RNA tested among Ab positive: 98%
- Number of HCV RNA detected among RNA tested: 88%
- Number of patients eligible to start treatment: 91%
- Number of patients initiated treatment: 99%
- Number of patients completed treatment: 97%
- Eligible for SVR testing: 88%
- SVR test completed: 91%
Results - Turn-Around-Time

TAT from Antibody test to DAA prescription, including specialist reviews

- Median of 4 days (IQR: 2, 6) for BI Clinic (range: 2 – 120)
- Median of 1 day (IQR: 1, 2) for MLF Clinic (range: 1 – 86)
Results - Cascade of Care, by site

<table>
<thead>
<tr>
<th>Category</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
<th>Site 7</th>
<th>Site 8</th>
<th>Site 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of RDT screened</td>
<td>380</td>
<td>368</td>
<td>368</td>
<td>331</td>
<td>312</td>
<td>312</td>
<td>303</td>
<td>301</td>
<td>277</td>
</tr>
<tr>
<td>Number RDT positive (HCV Ab+ detected)</td>
<td>253</td>
<td>238</td>
<td>238</td>
<td>204</td>
<td>177</td>
<td>176</td>
<td>174</td>
<td>173</td>
<td>156</td>
</tr>
<tr>
<td>Number of HCV RNA Test performed among HCV Ab+</td>
<td>97%</td>
<td>100%</td>
<td>100%</td>
<td>86%</td>
<td>87%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>90%</td>
</tr>
<tr>
<td>Number of HCV RNA detected among HCV Ab+</td>
<td>238</td>
<td>238</td>
<td>204</td>
<td>177</td>
<td>176</td>
<td>174</td>
<td>173</td>
<td>156</td>
<td>142</td>
</tr>
<tr>
<td>Number of patients eligible for treatment</td>
<td>100%</td>
<td>90%</td>
<td>94%</td>
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<tr>
<td>Number of patients initiated on Treatment</td>
<td>90%</td>
<td>94%</td>
<td>94%</td>
<td>86%</td>
<td>87%</td>
<td>99%</td>
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<td>91%</td>
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<tr>
<td>Number of patients completed treatment</td>
<td>97%</td>
<td>92%</td>
<td>86%</td>
<td>94%</td>
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<td>99%</td>
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<tr>
<td>Eligible for SVR testing</td>
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<tr>
<td>SVR test completed</td>
<td>92%</td>
<td>92%</td>
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<tr>
<td>SVR Achieved</td>
<td>94%</td>
<td>94%</td>
<td>94%</td>
<td>94%</td>
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<td>94%</td>
<td>94%</td>
<td>94%</td>
<td>91%</td>
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Conclusions

• Model of care is feasible, safe and effective
  – Possible to implement at NSP site; clinic site renovated to fit clinical requirements

• Retention in care is exceptional
  – In particular, through diagnostic pathway and then onto treatment
  – Similar among PWID and general population

• SVR12 rates are very good
  – Similar across both sites

• Evidence for model of care implementation in Myanmar, planning for expansion of services
ACKNOWLEDGEMENTS

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PhD Scholarship
NHMRC Postgraduate Scholarship

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