Liver Disease Burden and Clinical Follow-Up During a Liver Health Promotion Intervention Integrating Non-Invasive Liver Disease Screening in Drug and Alcohol Settings: The LiveRLife Study

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Partners
Developing the campaign

PHASE I: Message Development

• Targeted focus groups with community peers
• Assess knowledge, attitudes & beliefs about liver disease, testing and treatment

PHASE II: Message Testing

• Focus test the messaging and resources with community peers

OUTCOME

• Target one achievable behavior
LiveRLife resources

- PRINTED RESOURCE
- POSTER CAMPAIGN
- FIBROSCAN REPORT
- STUDY WEBSITE
  LIVERLIFE.ORG.AU
- SHORT FILM
Developing the campaign

PHASE III: Campaign Implementation

To evaluate the impact of a healthy liver campaign on liver disease knowledge, assessment and treatment among people attending drug & alcohol services

Inclusion

☑ ≥18yrs of age
☑ History of injecting drug use

Exclusion

☒ Pregnant women

Recruitment

• Through one community-based primary health care clinic, two opioid substitution treatment clinics, and one medically supervised injecting centre in New South Wales, Australia
Enhanced liver disease assessment – FibroScan®

Post-Assessment Survey
- FibroScan and campaign assessment

Study Enrolment
- Informed consent

Pre-Assessment Survey
- Self-Administered Survey
  - Demographics
  - Injecting history
  - Treatment history
  - General liver knowledge
  - FibroScan willingness

Clinic Waiting Area
- LiveRLife resources
- Food & refreshments
- Peer support discussion

Dried Blood Spot
- HCV antibody and RNA analysis

Nurse Consultation
- Assessment of liver health and review of FibroScan results

FibroScan
- Assessment of liver disease
- Review of FibroScan results

Campaign days

- A team of staff attended each campaign day
- Support from the service was key to building interest and participation
- Clients were keen to participate and have their liver health assessed
- An opportunity to engage individuals with significant disease staging
Participant characteristics

- LiveRLife has been run at 4 clinics (n=253)
- 70% HCV RNA+

- Average age: 43
- Male: 68%
- Aboriginal ethnicity: 21%
- Born in Australia: 90%
- Full or part time employment: 7%
- Completed high school or higher education: 27%
- Rented housing: 51%
- Ever been in prison: 66%
- Ever been in prison in the last 12 months: 33%
Disease staging

- F0/F1: 68%
- F2: 13%
- F3: 10%
- F4: 9%

- No/Mild fibrosis
- Moderate fibrosis
- Severe fibrosis
- Cirrhosis
## Factors associated with F3/4 disease staging

<table>
<thead>
<tr>
<th></th>
<th>Number with F3/4 (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;35 years</td>
<td>3 (5%)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>&gt;=35-&lt;45 years</td>
<td>13 (16%)</td>
<td>3.69 (1.00, 13.58)</td>
<td>0.050</td>
</tr>
<tr>
<td>&gt;=45 years</td>
<td>29 (31%)</td>
<td>8.48 (2.45, 29.31)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>9 (13%)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>Male</td>
<td>34 (21%)</td>
<td>1.82 (0.82, 4.02)</td>
<td>0.142</td>
</tr>
<tr>
<td><strong>HCV RNA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetectable</td>
<td>9 (13%)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>Detectable</td>
<td>35 (23%)</td>
<td>2.09 (0.95, 4.63)</td>
<td>0.068</td>
</tr>
</tbody>
</table>
Clinical follow-up

Kirketon Road Centre
- Enrolled N=65
  - Follow-up N=43, 66%

Newcastle Pharmacotherapy Service
- Enrolled N=74
  - Follow-up N=52, 70%

Sydney Medically Supervised Injecting Centre
- Enrolled N=56
  - Follow-up N=19, 33%

Coffs Harbour Drug & Alcohol Service
- Enrolled N=58
  - Follow-up N=38, 66%

Total follow-up 152 of 253 60%
Xpert® HCV Viral Load point-of-care assay

- Automated, self-contained, single use, random access
- European CE-IVD approved (plasma)
- Single platform for integration (HIV, HPV, TB)
- Minimal training, rapid (60-105min), capillary blood (alpha testing)
- Multiple configurations
Method: Venous blood and finger-prick samples

Venous whole blood

1. Collect venous whole blood by venepuncture
2. Centrifuge
3. Load plasma into Xpert® HCV Viral load (RUO) cartridge
4. Result < 100min

Finger-prick capillary blood (interim)

1. Collect 100µL capillary blood by finger-prick into a Minivette
2. Load blood into Xpert® HCV Viral load (RUO) cartridge
3. Add 1mL dilution buffer
4. Result < 100min

Gold standard comparator: Abbott RealTime HCV assay, v7, m2000
**Results: Sensitivity and specificity (detectable)**

<table>
<thead>
<tr>
<th>Abbott plasma</th>
<th>Xpert® HCV VL plasma</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetected -</td>
<td>114</td>
<td>115</td>
</tr>
<tr>
<td>Detected +</td>
<td>0</td>
<td>51</td>
</tr>
<tr>
<td>Total</td>
<td>114</td>
<td>52</td>
</tr>
<tr>
<td><strong>Sensitivity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>100% (95%CI, 93-100%)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>99.1% (95%CI, 95.3-100%)</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Abbott plasma</th>
<th>Xpert® HCV VL finger-prick</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetected -</td>
<td>111</td>
<td>113</td>
</tr>
<tr>
<td>Detected +</td>
<td>2</td>
<td>49</td>
</tr>
<tr>
<td>Total</td>
<td>113</td>
<td>49</td>
</tr>
<tr>
<td><strong>Sensitivity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>95.9% (95%CI, 86-99.5%)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>98.2% (95%CI, 93.8-99.8%)</strong></td>
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</tr>
</tbody>
</table>

One discrepant result:

1201-61410-018  Abbott = 0  Xpert = 3,380,000

Four discrepant results:

1201-61410-018  Abbott = 0  Xpert = 7,686,000
1201-61249-030  Abbott = 38  Xpert = 0
1201-61249-104  Abbott = 0  Xpert = 5 (<110)
1201-61223-002  Abbott = <12  Xpert = 0

**Grebely J, Lamoury F et al, manuscript in prep (2016)**
### Results: Sensitivity and specificity (quantifiable)

<table>
<thead>
<tr>
<th>Abbott plasma</th>
<th>Xpert® HCV VL plasma</th>
<th>Xpert® HCV VL finger-prick</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unquantifiable</td>
<td>Quantifiable</td>
</tr>
<tr>
<td>Unquantifiable</td>
<td>114</td>
<td>0</td>
</tr>
<tr>
<td>Quantifiable</td>
<td>1</td>
<td>48</td>
</tr>
<tr>
<td>Total</td>
<td>115</td>
<td>48</td>
</tr>
</tbody>
</table>

**Sensitivity**
- Abbott plasma: 98% (95%CI, 89.1-99.9%)
- Xpert® HCV VL plasma: 97% (95%CI, 88.7-99.9%)

**Specificity**
- Abbott plasma: 100% (95%CI, 96.8-100%)
- Xpert® HCV VL plasma: 100% (95%CI, 96.8-100%)

**Note: Outlier excluded**

One discrepant result:
- 1201-61249-030  Abbott = 38,  Xpert = <10

Excluding those on treatment, n=10 (69, 4.8%)

**Sensitivity**
- 97% (95%CI, 88-99.9%)

**Specificity**
- 100% (95%CI, 96.7-100%)

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Grebely J, Lamoury F et al, manuscript in prep (2016)
Conclusions

• Demonstrated considerable liver disease burden in this population

• A high proportion attended post-LiveRLife clinical follow-up

• Provided an opportunity to address other health issues (e.g. HAV/HBV vaccinations)

• Developed key partnerships between services, clinical providers, and researchers

• Demonstrated the feasibility of interventions to enhance health outcomes among people in drug and alcohol settings

"It’s good to know the health of my liver, now I don’t feel anxious about it. FibroScan makes it easier to take that first step!"

SALLY’S STORY
Future directions

• Additional 250 participants have been recruited from homelessness settings, drug and alcohol clinics and NSPs (including POC HCV RNA testing) in Australia

• Planned project to evaluate LiveRLife in Bangkok, Thailand in collaboration with HIV-NAT

• Simplified LiveRLife intervention planned to increase testing, linkage to care and DAA therapy for ETHOS-II study (to begin in March 2017)
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