Hepatitis C Self Testing: Preliminary Results and Lessons Learnt for the HIV-HCV Response in Malaysia

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FIND, the global alliance for diagnostics

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Only 21% of estimated 58 million people with chronic hepatitis C virus (HCV) infection were diagnosed in 2019 with variation by regions.

### Hepatitis C

<table>
<thead>
<tr>
<th>Region</th>
<th>Diagnosed (%)</th>
<th>Treated (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>21%</td>
<td>13%</td>
</tr>
<tr>
<td>African Region</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Region of the Americas</td>
<td>22%</td>
<td>18%</td>
</tr>
<tr>
<td>South-East Asia Region</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>European Region</td>
<td>24%</td>
<td>8%</td>
</tr>
<tr>
<td>Eastern Mediterranean Region</td>
<td>37%</td>
<td>33%</td>
</tr>
<tr>
<td>Western Pacific Region</td>
<td>25%</td>
<td>10%</td>
</tr>
</tbody>
</table>

- **Diagnosed**: Percentage of hepatitis C infected persons diagnosed to end 2019
- **Treated**: Percentage of hepatitis C infected persons treated to end 2019

*Source: Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021*
WHAT IS STILL NEEDED?

- WHO launched the 1st HCV self-testing (HCVST) guidelines in July 2021 – important first step to increase awareness and access to HCVST
- Strong recommendation, moderate quality evidence: HCVST should be offered as an additional approach to HCV testing

https://www.who.int/publications/i/item/9789240031128
https://youtu.be/HFyLayeGou4
STATUS OF HCVST KITS IN THE MARKET

Currently no test certified for HCVST

- [Professional use] OraQuick® HCV rapid antibody test kit from OraSure Technologies Inc. (US) – Sensitivity/Specificity 98.1%/99.6% (WHO-PQed and CE-marked)

- [Professional use] First Response® HCV Card Test from Premier Medical Corporation (India) – Sensitivity/Specificity 100%/100% (CE-marked and currently under WHO PQ review)

Both OraSure and PMC have now developed, validated and adapted instructions for use (IFU) for HCVST.

- Research Use Only (RUO) OraQuick® and First Response® HCV Self-Tests were used.
Randomized controlled trial of home-based hepatitis C self-testing (HCVST) for key populations in Malaysia
FIND would like to express our gratitude to all participants, collaborators and partners:

Ministry of Health Malaysia

Research team

Study implementation

Peer support with network of partner organizations

FIND Diagnosis for all

Sponsor

Web development
Data protection

DNDi

In-country supporting partner

Drugs for Neglected Diseases initiative
HCVST STUDY IN MALAYSIA

OVERVIEW

- Nationwide study
- Integration with HIV self-testing
  - Leverage on existing momentum of Jom-Test.com
HCVST STUDY IN MALAYSIA

STUDY METHODOLOGY

Participants are randomized 2:1 to intervention (HCVST) or control arm

ARM 1
1a. Blood-based HCV self-test
1b. Oral fluid-based HCV self-test

ARM 2
Control (Standard of care)

- Total sample size for recruitment = 750
- Intervention arm participants receive HCVST via courier service; control arm participants receive information about standard of care HCV antibody testing available at local testing sites
- Self-reporting of HCVST / standard of care HCV antibody result as well as linkage to care data (confirmation, treatment) in 2 follow-up surveys
- Primary objective: To assess the impact of home-based HCVST on the uptake of HCV antibody testing
PRELIMINARY RESULTS
PRELIMINARY RESULTS FROM SEP 2021 – JUN 2022

RECRUITMENT PROGRESS

- 915 JomTest users completed screening questionnaire
- 124 users were ineligible
- 791/915 (86.4%) were eligible and invited to participate
- 41 users did not proceed to consent / did not consent
- 750/791 (94.8%) consented and were successfully enrolled
PRELIMINARY RESULTS FROM SEP 2021 – JUN 2022

GROUPS PARTICIPANTS IDENTIFY WITH

Transgender women
Sex workers
People who use drugs
People who engage with sex worker
Men who has sex with men

90.4%
## DEMOGRAPHICS

### Preliminary results from Sep 2021 – Jun 2022

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>TOTAL</th>
<th>BLOOD</th>
<th>ORAL</th>
<th>CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (IQR) in years</td>
<td>26 (23-31)</td>
<td>26 (22-30)</td>
<td>26 (23-31)</td>
<td>27 (23-32)</td>
</tr>
<tr>
<td>Male</td>
<td>96.7%</td>
<td>97.2%</td>
<td>95.6%</td>
<td>97.2%</td>
</tr>
<tr>
<td>Highest education level completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>51.5%</td>
<td>48.2%</td>
<td>55.1%</td>
<td>51.2%</td>
</tr>
<tr>
<td>Post-secondary</td>
<td>35.8%</td>
<td>40.2%</td>
<td>35.1%</td>
<td>32.3%</td>
</tr>
<tr>
<td>Secondary</td>
<td>12.3%</td>
<td>11.2%</td>
<td>9.8%</td>
<td>15.7%</td>
</tr>
<tr>
<td>Primary</td>
<td>0.3%</td>
<td>0.4%</td>
<td>0.0%</td>
<td>0.4%</td>
</tr>
<tr>
<td>None</td>
<td>0.1%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>65.6%</td>
<td>66.3%</td>
<td>69.8%</td>
<td>60.9%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>9.3%</td>
<td>8.0%</td>
<td>8.2%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Student</td>
<td>25.1%</td>
<td>25.7%</td>
<td>22.0%</td>
<td>27.4%</td>
</tr>
</tbody>
</table>
### BASELINE HCV TESTING EXPERIENCE AND HCVST ACCEPTABILITY

#### Preliminary Results from Sep 2021 – Jun 2022

<table>
<thead>
<tr>
<th>PARAMETERS</th>
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<th>BLOOD</th>
<th>ORAL</th>
<th>CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCV testing experience prior to the study:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never tested before</td>
<td>58.0%</td>
<td>58.2%</td>
<td>58.0%</td>
<td>57.7%</td>
</tr>
<tr>
<td>Tested in the past 6 to 12 months</td>
<td>12.1%</td>
<td>10.0%</td>
<td>13.1%</td>
<td>13.3%</td>
</tr>
<tr>
<td>Tested more than 1 year ago</td>
<td>14.4%</td>
<td>16.1%</td>
<td>12.2%</td>
<td>14.9%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>15.5%</td>
<td>15.7%</td>
<td>16.7%</td>
<td>14.1%</td>
</tr>
<tr>
<td><strong>Would you test yourself at home for hepatitis C if you have a testing kit and instructions?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>97.0%</td>
<td>97.2%</td>
<td>96.3%</td>
<td>97.6%</td>
</tr>
<tr>
<td>No</td>
<td>0.9%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
### Preliminary Results from Sep 2021 – Jun 2022

**Baseline Risk Behaviours**

#### Parameters

<table>
<thead>
<tr>
<th>_PARAMETERS</th>
<th>TOTAL</th>
<th>BLOOD</th>
<th>ORAL</th>
<th>CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the last 6 months, have you taken any substance by snorting it?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5.1%</td>
<td>2.8%</td>
<td>7.3%</td>
<td>5.2%</td>
</tr>
<tr>
<td>No</td>
<td>94.9%</td>
<td>97.2%</td>
<td>92.7%</td>
<td>94.8%</td>
</tr>
<tr>
<td>In the last 6 months, have you engaged in chemsex or high-fun/hi fun?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7.7%</td>
<td>6.8%</td>
<td>8.2%</td>
<td>8.1%</td>
</tr>
<tr>
<td>No</td>
<td>92.3%</td>
<td>93.2%</td>
<td>91.8%</td>
<td>91.9%</td>
</tr>
<tr>
<td>In the last 6 months, have you injected unprescribed drugs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once</td>
<td>0.8%</td>
<td>0.8%</td>
<td>1.2%</td>
<td>0.4%</td>
</tr>
<tr>
<td>More than once</td>
<td>0.9%</td>
<td>2.0%</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Never</td>
<td>98.2%</td>
<td>97.2%</td>
<td>98.8%</td>
<td>98.8%</td>
</tr>
</tbody>
</table>
Preliminary Results from Sep 2021 – Jun 2022
Impact of Self-Testing on Uptake of HCV Antibody Testing

- Overall LTFU 23.3% - 15.7% blood, 17.7% oral and 37.4% control

- Based on responses from follow-up surveys:

  - Completed testing
    - HCVST (Blood): 98.1% (206/210)
    - HCVST (Oral): 98.7% (152/154)
    - Control (standard of care): 51.4% (55/107)

- Did not complete testing
PRELIMINARY RESULTS FROM SEP 2021 – JUN 2022
HCVST AND STANDARD OF CARE RESULTS

**HCVST**
- Negative: 96.9%
- Invalid: 1.7%
- Did not want to disclose: 0.6%
- Positive: 0.8%

**CONTROL**
- Negative: 87.3%
- Have not been told the results yet: 7.3%
- Did not want to disclose: 3.6%
- Have forgotten: 1.8%
3
RECRUITMENT STRATEGIES
RECRUITMENT STRATEGIES

(1) PROMOTION ON SOCIAL MEDIA AND BY CBOS

- Intervention (blood-based)
- Intervention (oral-based)
- Control (standard of care)
RECRUITMENT STRATEGIES

(2) PROMOTION ON DATING APPS, AT PHCS & VIA DIRECT MARKETING

Dear JOM TEST users,
Thank you for using jom-test.com platform to participate in the HIV Self-Testing Study.

DID YOU KNOW and besides HIV, hepatitis C can also be transmitted through unsafe sex, sharing needles and receiving blood? FIND in collaboration with the Malaysian AIDS Council currently running a pilot project for hepatitis C self-testing. You can get the Hepatitis C self-test kit* for FREE from jom-test.com. Not only that, you will be rewarded if you complete the questionnaires.

Jom test your hepatitis C status. Sign up now!
I got my Hepatitis C self-test kit from jom-test.com/join-study-hcv. You can also get yours for FREE. If you’re sexually active, continuous testing is important to monitor your health.

Jom test your hepatitis C status! Sign up now by using the link above.
Preliminary results show that:

- HCV self-testing via an online distribution model, compared with standard testing services, significantly increased the uptake of HCV testing among key populations in Malaysia.

- HCV self-testing can provide an additional way for people from key populations to test for HCV, including many who have been hesitant or unable to access existing services.

- Increase in targeted testing can accelerate progress towards HCV elimination.

- Important to evaluate resource use with governments.

- Further studies can understand how HCV self-testing can also be distributed via community-based organizations or health facilities.