Strategies to increase access and linkage to care for Hepatitis C
HEAD-Start project (Hepatitis C Elimination through Access to Diagnostics)

Sonjelle Shilton, Deputy Head HCV Access
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FIND is a global non-profit, driving diagnostic innovation to combat major diseases affecting the world’s poorest populations

- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member
- ISO-certified quality management system for IVD clinical trials

We address market failure by partnering to develop and deliver diagnostic solutions to LMICs

<table>
<thead>
<tr>
<th>ANTIMICROBIAL RESISTANCE</th>
<th>HEPATITIS &amp; HIV</th>
<th>MALARIA &amp; FEVER</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEGLECTED TROPICAL DISEASES</td>
<td>PANDEMIC PREPAREDNESS</td>
<td>TUBERCULOSIS</td>
</tr>
</tbody>
</table>

Geneva
South Africa
Viet Nam
India
Kenya
Available information on strategies to increase access and linkage to care
Available information on strategies to increase access and linkage to care

- World Health Organization (WHO) Guidelines on Hepatitis B and C Testing
  - Chapter 17; Service delivery approached for viral hepatitis testing – examples from the field, can be found [here](#).

- Available published systematic reviews of HCV interventions include interventions from high income countries
  - Interventions to enhance testing, linkage to care and treatment uptake for hepatitis C virus infection among people who inject drugs: A systematic review, Bajis et al., *International Journal of Drug Policy Volume 47, September 2017*
  - A systematic review and meta-analysis of community and primary-care-based hepatitis C testing and treatment services that employ direct acting antiviral drug treatments, Radley et al., *BMC Health Services Research 28 October 2019* ([open access](#)).

- Forthcoming systematic review ‘Service Delivery for Hepatitis C Care: A systematic review and Meta-analysis’ by Oru et al., Includes 85 studies, 19 from LMIC
  - Poster presented at the International Liver Conference 2019 can be found [here](#).
HEAD-Start Country studies and projects

**Georgia:**
**Settings:**
- Harm Reduction Sites
- National Reference Laboratory

**Activities:**
- Decentralization of testing
- Comparison study cAg as test of cure
- Simplification of testing algorithm
- Integration of HCV VL in existing decentralized testing platforms

**India, Manipur:**
**Settings:**
- NGOs that serve PWID

**Activities:**
- Decentralization of HCV care at community level

**India, Punjab:**
**Settings:**
- Secondary and primary facilities

**Activities:**
- Decentralization of HCV diagnosis at ART clinics

**India, Delhi:**
**Settings:**
- Primary facilities and district hospitals

**Activities:**
- Hub-spoke model with decentralized screening and centralized confirmation

**Malaysia:**
**Settings:**
- Drug Treatment Center and community-based clinic
- National Reference Laboratories

**Activities:**
- Integration of testing (RDTs and POC) in decentralized settings
- Optimization of existing polyvalent central platforms

**Myanmar:**
**Settings:**
- Drug Treatment Center and community-based clinic
- National Reference Laboratories

**Activities:**
- Integration of testing (RDTs and POC) in decentralized settings
- Optimization of existing polyvalent central platforms

**Acronyms**
- cAg: Core Antigen
- DNDi: Drugs for Neglected Diseases initiative
- HCV: Hepatitis C virus
- MOH: Ministry of Health
- NGOs: Non-governmental organizations
- POC(T): Point of care (test)
- PWID: People who inject drugs
- RDT: Rapid diagnostic test
- VL: Viral Load

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Hepatitis C Elimination through Access to Diagnostics

5
Emerging lessons

1. Decentralization

2. Simplification

3. Integration
1. Decentralization

Level 3; tertiary health care

Level 2; Secondary health care

Level 1; primary health care
Patient journey

- Increases availability of HCV testing
  - Malaysia: bringing screening from centralized to primary health care in public sector using risk-based screening
  - Georgia: bringing point of confirmation to Harm Reduction Sites from centralized level
- In both countries, catalytic effect of decentralizing diagnosis → decentralized treatment
Malaysia; decentralization of the screening test
Malaysia study sites and design: Introducing HCV RDTs into the Malaysian public health system in a decentralized screening model

Selected hospital 1

- IMR
- PHC 1
- PHC 2
- PHC 3
- PHC 4
- PHC 5

Key

- Dashed line: Patients referred to selected treatment site
- Solid line: Samples referred to IMR for HCV RNA testing
- Light blue circle: Community-level screening site, using rapid diagnostic tests (RDTs)
- Purple circle: HCV treatment site referring samples for RNA testing
- Orange square: Site with existing RNA capacity (National Reference Lab)

National epidemiology
Population: 32 million
HCV % Gen Pop: 0.3%–2.5%
HCV % PWID: ~89.9%
Malaysia, targeted screening results in high yields

27 December 2018 – 31 December 2019 (preliminary data)

Total number screened: 15,323

- RDT- (2,011, 13%)
- RDT+ (13,312, 87%)

Risk factors all participants:

- 0% Sex Worker
- 1% Needle stick Injury
- 1% Transgender
- 0% HCV + mother
- 0% Dialysis
- 2% Blood transfusion
- 5% Chronic Liver Disease
- 4% Tatoos
- 1% HCV + partner
- 1% Other/undisclosed
- 17% Surgery
- 10% Intranasal Drugs
- 20% Piercing
- 8% Prisoner (past)
- 5% MSM
- 13% PWID
- 7% HIV

Cost per patient identified $6.23

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Georgia; decentralization of the confirmatory test
**HEAD-Start: Georgia study design**

**National epidemiology**
Population: 3.7 million
HCV seroprevalence in Gen Pop: 7.7%
Est. number of PWID: 49,700 (2015)
HCV seroprevalence PWID: 50-91.9%

**Harm Reduction Sites**
(8 HRS)

**Nonrandomized 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

1. Tbilisi Akeso
2. Rustavi New Vector
The proportion of study participants who completed HCV viremia test, as of 1 Nov 2019, by arms

<table>
<thead>
<tr>
<th>Arm</th>
<th>Completed HCV Confirmatory Tests</th>
<th>Total enrolled</th>
</tr>
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<tbody>
<tr>
<td>Arm 1</td>
<td>621</td>
<td>1672</td>
</tr>
<tr>
<td>Arm 2</td>
<td>483</td>
<td></td>
</tr>
<tr>
<td>Arm 3</td>
<td>438</td>
<td></td>
</tr>
</tbody>
</table>

- Positive HCV Confirmatory results: 1255 (81.4%)
- Negative HCV Confirmatory results: 262 (18.6%)
Key considerations

Decentralizing screening and confirmatory services can increase access to testing

Screening approaches that are targeted cost less per patient identified than a ‘screen all who attend for care’ approach

On-site blood draw and on-site point of care testing for confirmatory tests results in very high completion of confirmatory testing
2. Simplification
Simplification: why it’s better

Easier for patient: fewer visits, reducing number of tests
- 1 visit for both screening and blood draw (for confirmation and liver staging results) for high retention patients in the HCV care cascade, as seen in HEAD-Start Delhi

Easier for system: fewer tests = less monetary outlay from government budgets
- Reducing tests to bring algorithms in line with WHO recommendations
- Quickest treatment initiation is seen when genotyping and ultrasound (as standard for all patients) are removed
HEAD-Start Delhi study design

- Introducing HCV care into 5 district hospitals, and screening at 15 polyclinics and screening camps

**Delhi State epidemiology**
Population: 18 million
HCV % (Gen Pop): estimated 1%
# HCV Diagnosis and Treatment Management

<table>
<thead>
<tr>
<th>Visit No</th>
<th>Project Activities</th>
<th>Outcome</th>
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</table>
| **Visit 1** | HCV screening using RDTs and WBFPT & results shared within 20 mins. Blood collected from HCV+ve patients for HCV RNA confirmatory test and baseline investigations | • HCV screening result (Ab-ve or +ve) known to patient 20 minutes  
• Blood sample provided for confirmatory and baseline tests |
| **Visit 2** | HCV RNA and baseline investigations reports shared with patient | • HCV RNA: Detected / Not Detected; patient knows if they are viremic and thus needing treatment  
• Non-complicated cases initiated on HCV treatment |
| **Visit 3** | Follow up visits of HCV Patients on Treatment  
HCV treatment initiation for non-complicated cases | Patient management and HCV DAA refill  
Complicated cases referred to ILBS for medical advice |
| **Visit 4, 5** | Review on DAA treatment | HCV – DAA Refill |
| **Visit 6** | Test for sustained viral response (SVR) | Sample collection for SVR |
| **Visit 7** | SVR Report | SVR Test result collection |

preliminary data

Number screened: 22,756
3.1% RDT+

Cost per patient identified $26.08

hospital care cascade

Number screened RDT+ 699
HCV RNA test done 648
HCV+ result 520
Started HCV treatment 458

93% 80% 88%

Cost per patient identified $26.08
Study conducted in partnership with Y.R.G. Care

Demonstration study to provide model of care for PWID through offering decentralized HCV care

- Simplified diagnostic algorithm which starts with HCV RDT screening in OST* centers
- HCV point-of-care confirmation and treatment in primary health care centers

**Epidemiology**
Population: 2.7 million
HCV PWID: 64.9%

*Opioid substitution therapy
Screening at NGOs. Those screen positive referred to YRG sites

Confirmatory testing, treatment and SVR 12 at same site for non-complicated cases.

Confirmatory testing and SVR 12 at YRG clinics with linkage to RIMS for treatment for complicated cases.

**Key**

- **SASO**
- **MPPN**
- **CARE**
- **SALOM**
- **YRG Imphal**
- **YRG Churachandpur**
- **RIMS**

- Represents care pathway which beneficiary will be assisted by ‘navigator’ to minimize LTFU
- NGO operated multi service center for PWIDs which includes OST, ART, and needle exchange
- HCV RNA testing and treatment site
- Tertiary hospital with Hepatologist
HEAD-Start Manipur: care cascade

preliminary data

Number screened: 6958
49.7% RDT+

Cost per patient identified $1.72

Care cascade

Number screened RDT+: 3461
HCV RNA test done: 2891
HCV+ result: 2476
Started HCV treatment: 2027

84% 86% 82%

Study care cascade
Key considerations

Bringing HCV testing algorithms in line with WHO recommendations is a good place to start simplification.

Reducing the number of visits a patient has to make to start treatment can decrease loss to follow up.

Need to find balance between simplifying as much as prudent while still maintaining high quality care.
3. Integration
Integration of HCV services and diagnostic testing

Integration of services: must be tailored to patient population, infrastructure
- Diagnostic algorithm adjusted to serve patients who are likely to return for other services
- Malaysia and Delhi integrating services in primary health care clinics; adjust diagnostic algorithm to reduce LTFU

Integration of diagnostic testing
- Many testing machines can perform tests for many different diseases depending on the assays and set up of the machine
- Integration of diagnostic testing looks at what happens when you introduce HCV testing onto a machine that is being used already for a different disease, such as TB or HIV
Integration of services
Introducing HCV care into 13 existing ART centres / Hub and spoke model

- Simplifying the HCV algorithm by introducing RDTs
- Reflex RNA testing of those who screen HCV positive by sample referral from ART centers to 4 Xpert testing hubs

Cost per patient identified $4.29

Punjab State epidemiology
Population: 29.9 million
HCV % Gen Pop: 3.29%
HCV % PLWHIV: 20% (from HEAD-Start study)
HEAD-Start Punjab: care cascade; ART
(22 Oct 2018 to 30 Sept 2019) preliminary data

Care cascade

No. screened | No. screened RDT+ | HCV RNA test done | HCV+ result
---|---|---|---
20% | 98% | 81%
Key considerations

HEAD-Start Punjab project resulted in the screening of over 80% of all patients attending ART care who were eligible for HCV screening (32,000+ ART patients)

Cooperation between various departments and clear agreement on responsibilities is key for ensuring linkage of HCV positive PLHIV to care

Considerations of additional workload important with integrating a new service into an existing one; more work for same pay?
Key takeaways
Key takeaways

The easier it is for the patient, the stronger (more effective and cost-efficient) the care cascade will be!

1. **Decentralization** of diagnostics to primary healthcare level can be done through RDTs, POC, or onsite blood draw with sample sent away for confirmation.

2. **Simplification** is key to keeping patients engaged in the care pathway. It is possible to complete all needed blood draws on first visit after RDT+ result.

3. **Integration** of HCV diagnostics into existing services results in high case finding, can be cost effective, and requires continuous coordination between departments and branches of the health system.
Thank you!

Our HEAD-Start partners and collaborators

Technical collaborators and guidance

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