Welcoming remarks
Sonjelle Shilton, Deputy Head HCV Access
World Hepatitis Day Webinar

30th July 2020
<table>
<thead>
<tr>
<th>Event</th>
<th>Duration</th>
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<tr>
<td><strong>Opening remarks and welcome</strong></td>
<td>10 MINS</td>
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<tr>
<td><strong>Sonjelle Shilton</strong> – Deputy Head HCV Access, FIND</td>
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<td><strong>Keynote address</strong></td>
<td>10 MINS</td>
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<td><strong>Prof. R.P. Shanmugam</strong> – Executive Board Member South-East Asia, WHA</td>
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<td><strong>FIND-DNDi partnership model to enhance HCV Tx access by leveraging Dx</strong></td>
<td>10 MINS</td>
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<td><strong>Jean-Michel Piedagnel</strong> – Director of Regional Office, DNDi South-East Asia</td>
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Today’s agenda

Unitaid-supported HEAD-Start multi-country project: preliminary outcomes

**HCV diagnosis: Impact of decentralized, simplified, and early testing**

Moderator: Dr Philippa Easterbrook – Global Hepatitis Program, WHO

**Datuk Dr Muhammad Radzi Abu Hassan** – National Head, Gastroenterology and Hepatology Services, MoH (Malaysia)

**Professor Win Naing** – Head, Hepatology Unit, Yangon Specialty Hospital (Myanmar)

**Dr Amiran Gamkrelidze** – Director General, National Center for Disease Control and Public Health (NCDC)* (Georgia)

**Dr Ekta Gupta** – Professor, Virology, ILBS (Delhi, India)

**Dr Gagandeep Grover** – State Nodal Officer, NVHCP (Punjab, India)

**Additional resources to facilitate HCV Dx access: HEAD-Start**

**Sonjelle Shilton** – Deputy Head HCV Access, FIND

**Q & A and Wrap-up**

**Dr Philippa Easterbrook** – Global Hepatitis Program, WHO

5 MINS

5 MINS

5 MINS

5 MINS

5 MINS

5 MINS

5 MINS

15 MINS
Today’s agenda

**Community awareness and mobilization: importance and approaches**

**Empowering communities: HCV Dx literacy toolkit & MapCrowd**
Bryn Gay – HCV Project Director, Treatment Action Group

**Community mobilization – then and now: importance of community workers**
Maria Donatelli – Senior Partnerships Manager, Coalition PLUS
Anushiya Karunanithy – Manager, HCV Project, Malaysian AIDS Council

**Q & A and Wrap-up**
Dr Philippa Easterbrook – Global Hepatitis Program, WHO

**Vote of thanks**
FIND and WHA
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
What is the need?

Major gaps in HCV testing: screening and diagnosis
80% undiagnosed in 2016

Source: Progress Report on Access to Hepatitis C Treatment Focus on Overcoming Barriers in Low- and Middle-Income Countries March 2018, WHO
Find the missing millions

Link them to care

In a cost efficient manner
How can we do it?

- Decentralized risk based screening
- At places people already go for care
- With reflex testing for RNA and liver staging
- And decentralized treatment
1. Accelerate diagnostic pipeline to increase diagnostic tools available for use in decentralized, simplified, integrated HCV diagnostic algorithms

2. In-country work preparing the market for use of decentralized, simplified, integrated HCV diagnostics

3. Market forecasting on HCV diagnostics

4. Evidence sharing to inform global, regional, and country policies to support use of decentralized, simplified, integrated HCV diagnostics
HEAD-Start R&D

HEAD-Start research and development projects and studies

HCV molecular POC technologies
HEAD- Start R&D pipeline

Simplification

- HCV self-test (pilot feasibility studies and diagnostic accuracy studies)

Decentralization

- cAg RDT; in development
- GeneDrive; evaluation in intended setting of use completed in Cameroon and Georgia
- Xpert FS assay Cepheid; CE marked
- Molbio; evaluation in intended setting of use ongoing in Denmark, Ethiopia, Georgia, Thailand, Ukraine
- Validating manufacturer DBS protocols; RNA completed in Cameroon, Georgia, Greece, ongoing in Rwanda & EIA completed in Ukraine

Integration

Simplification

Decentralization

Integration
Exploring feasibility of HCV self-testing

FIND has conducted prospective observational studies in 5 countries

To determine **acceptability** of and **preferences** for HCV self-testing among different population groups in high HCV prevalence settings

To determine **usability** (the ability to correctly perform test and interpret results) of an HCV self-test using observed testing model
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, 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

India, Manipur:
Settings:
- Integrated Care Centers for ARV services in PWIDs
Activities:
- Decentralization of HCV care at community level

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

Malaysia:
Settings:
- Secondary and primary facilities to support DNDi phase 3 trial and MOH NHP
- National Reference Laboratory
Activities:
- Hub-spoke model with decentralized screening and centralized confirmation
## Summary of project designs

<table>
<thead>
<tr>
<th>Project</th>
<th>Partners</th>
<th>Population</th>
<th>Number screened</th>
<th>Screening sites</th>
<th># of persons undergoing confirmatory testing</th>
<th>Confirmation assay</th>
<th>Confirmation sites</th>
<th>Confirmation model</th>
<th>Treatment location</th>
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<tr>
<td>Malaysia</td>
<td>DNDI, MOH</td>
<td>High risk groups</td>
<td>15,413</td>
<td>25 PHC</td>
<td>1,553</td>
<td>Roche HCV VL assay</td>
<td>1 x IMR</td>
<td>Referral of patient from PHC to tertiary hospitals for blood collection, plasma sent to IMR</td>
<td>Tertiary hospitals</td>
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<td>Punjab, India</td>
<td>NVHCP, PMOH</td>
<td>PLHIV</td>
<td>26,781</td>
<td>13 ART clinics</td>
<td>5,403</td>
<td>Xpert HCV VL</td>
<td>4 Xpert lab hubs</td>
<td>Referral of whole blood sample to Xpert lab hub</td>
<td>Start of project: CV treatment clinic/By project end: ART clinics</td>
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<tr>
<td>Georgia</td>
<td>NCDC, HRU</td>
<td>PWID</td>
<td>N/A</td>
<td>8 Harm Reduction Sites</td>
<td>1,606</td>
<td>Arm 1: Xpert HCV VL&lt;br&gt;Arm 2: HCV cAg&lt;br&gt;Arm 3: HCV RT PCR assay</td>
<td>Arm 1: 4 HRS&lt;br&gt;Arm 2: 1 x lab (Lugar Centre)&lt;br&gt;Arm 3: 1 x lab (Lugar Centre)&lt;br&gt;Arm 1: Xpert on site (same day)&lt;br&gt;Arm 2: Refer plasma to lab&lt;br&gt;Arm 3: Refer patient to hospital for blood draw</td>
<td>Arm 1: Treatment center/HRS&lt;br&gt;Arm 2: Treatment centre&lt;br&gt;Arm 3: Treatment centre</td>
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<td>Delhi, India</td>
<td>ILBS, DGHS</td>
<td>Gen Pop</td>
<td>38,768</td>
<td>15 Polyclinics&lt;br&gt;5 District Hospitals Screening camps</td>
<td>704</td>
<td>Abbott HCV VL assay</td>
<td>1 x ILBS</td>
<td>Referral of plasma from PHC/DH to ILBS</td>
<td>District Hospitals or Primary Health Clinics, complicated cases ILBS</td>
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<tr>
<td>Manipur, India</td>
<td>YRG Care</td>
<td>PWID</td>
<td>7,909</td>
<td>4 Opioid Substitution Therapy Sites</td>
<td>2,888</td>
<td>Xpert HCV VL</td>
<td>2 study sites (YRG)</td>
<td>Referral of patient to YRG clinic</td>
<td>DOTS at YRG clinics or OST</td>
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<td>Myanmar</td>
<td>Burnet, MLF</td>
<td>PWID and liver patients</td>
<td>633</td>
<td>1 study clinic and 1 liver clinic</td>
<td>606</td>
<td>Xpert HCV VL</td>
<td>1 study clinic and 1 liver clinic</td>
<td>One-stop shop at each clinic</td>
<td>At study and liver clinic</td>
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Thank you to all of our partners and participants who have made HEAD-Start a success!