HEAD-Start

Hepatitis C Elimination through Access to Diagnostics

World Hepatitis Summit

Francesco Marinucci
Head of HIV/HCV Programme, FIND
1 November 2017
WHO’s elimination goal requires access to HCV diagnosis & treatment

~ 70M

1%

Unknown
Likely close to zero in LMICs

- All Hepatitis C chronic carriers
- Patients who know their status
- On Treatment

Meeting WHO targets in Test and treat dramatically reduces total infected

Annually Screened - Status Quo vs. WHO targets
HEAD-Start addresses major barriers to scaling up HCV diagnostics in LMICs

- Lack of interest in new & emerging markets
- Lack of awareness
- Low evidence of WHO guidelines
- Technological barriers
- Diagnostic tool or service
- Price barriers
- Reluctance in changing national policy
- Silo approach

Achieving the global targets towards elimination will require adoption of simplified and accessible service delivery approaches to promote access to testing (prevention and treatment) of hepatitis C
HEAD-Start covers all activities to accelerate product development, in-country adoption & policy change.

**Product development**
- Needs assessment (Global)
- Technology scouting
- Target Product Profile
- Feasibility studies
- Assays development
- Product validation

**Clinical & regulatory**
- Preparation for introduction (Global to national)
- Evidence package for SRA/WHO PQ
- In-country training/capacity building
- Data management & connectivity
- Quality assurance
- Support and supply chain
- Impact measurement

**Global & national policy**
- Transition to access (National to global)
- Stakeholder engagement
- Pilot projects
  - Simplification
  - Differentiation
  - Integration
  - Decentralization
- Evidence dissemination
- Implementation plans

FIND's ability to bridge development, global policy and access is a key competitive advantage to unlocking the HCV diagnostics market.
<table>
<thead>
<tr>
<th>Platform polyvalence and integration through DBS protocol</th>
<th>Expand use of HCV core antigen assays</th>
<th>Increase access to quality-assured HCV RDTs</th>
<th>Decentralization of HCV diagnosis through POC molecular</th>
</tr>
</thead>
</table>
| • Validate DBS sampling for NAT assays  
  • Validate DBS sampling for EIA assays  
  • Support manufacturer in compiling the dossier for regulatory approval | • Feasibility of cAg assay in RDT format  
  • Development of cAg antibodies  
  • Supporting development of new technology for HCV POC immunoassay | • Identify RDTs that meet WHO PQ criteria  
  • Markedly increase RDTs performance  
  • Development/ Optimization of combo HIV/HCV test  
  • Modification of RDTs to HCV ST/ combo ST | • Catalyzing the development of HCV RNA tests in the pipeline  
  • Validate design-locked POC molecular tests  
  • Development of an innovative polyvalent POC platform for diagnosis of infectious diseases |
HEAD-Start country projects

Georgia:
Settings:
• Harm Reduction Sites
• National Reference Laboratory
Activities:
• Innovative screening approaches
• Decentralization of testing and treatment (pan-genotypic DAA)
• Comparison study cAg as test of cure
• Integration in existing polyvalent central platform
• Simplification of testing algorithm

India, Punjab:
Settings:
• Secondary and primary ARV facilities
• Decentralization of HCV screening at community level
• Integration of testing (RDTs and POC) in decentralized settings in hepatitis C state program with focus on hard-to-reach groups

India, Manipur:
Settings:
• Integrated Care Centers for ARV services in PWIDs
• Decentralization of HCV screening at community level
• Integration of testing (RDTs and POC) in decentralized settings in AIDS state program with focus on HIV/HCV co-infected

Vietnam
Settings:
• OST and ARV facilities at district level

Activities:
• Integration of testing (POC) in decentralized TB platform
• Integration of DBS in existing polyvalent central platform

Cameroon:
Settings:
• Rural & Urban District hospitals
• Tertiary hospitals
Activities:
• Integration of testing (POC) in decentralized EID platform
• Hub-spoke model with decentralized screening (RDT) and centralized confirmation
• Integration of DBS in existing polyvalent central platform
• Simplification of testing algorithm

Myanmar:
Settings:
• Drug Treatment Center, ARV clinic and community-based clinic
• National Reference Laboratories
Activities:
• Integration of testing (RDTs and POC) in decentralized ARV clinic
• Integration of DBS in existing polyvalent central platform
• Pilot ST & combo HCV/HIV testing to improve HCV screening with innovative technologies

India, Delhi:
Settings:
• Primary and community-based facilities
Activities:
• Hub-spoke model with decentralize screening and centralized confirmation
• Pilot combo HCV/HIV testing to improve HCV screening with innovative technologies

Malaysia
Settings:
• Secondary and primary facilities
• National Reference Laboratory
Activities:
• Hub-spoke model with decentralize screening and centralized confirmation
• Integration in existing polyvalent central platforms

Map and 2015 prevalence figures from WHO World Hepatitis Report 2017
Impact of HEAD-Start on decentralization, differentiation, integration & simplification

Standard of care

Two-step Decentralized/integrated

One-step Decentralized/integrated

One-testing Decentralized
Getting to adopt HCV simplified diagnostic solutions: What will it take?

<table>
<thead>
<tr>
<th>Ingredients for elimination</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to cure, to diagnose</td>
<td>✔️</td>
</tr>
<tr>
<td>Integration of HCV with other interventions (HIV + TB + HR)</td>
<td></td>
</tr>
<tr>
<td>Feasibility of testing &amp; service delivery models to meet different needs</td>
<td>✔️</td>
</tr>
<tr>
<td>Broad portfolio of quality-assured Dx for decentralization of testing</td>
<td></td>
</tr>
<tr>
<td>Unlock domestic funding and global support to achieve near-term scale-up</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Thank you!

www.finddx.org