

Hepatitis C Diagnostics – the Bottleneck to Unlocking a Global Market

A special Side Meeting at the Occasion of AASLD 2014 and 13th HCV DrAG Meeting
November 11, Sheraton Boston, 1:00-2:30PM

Objective:

- Present and discuss potential of new diagnostic tests to drive access to care and treatment of hepatitis C in limited-resource settings, and beyond
- Bring diverse perspectives together to enable future partnerships and innovation in support of Hep C diagnostics and treatment

Agenda:

Moderated by Veronica Miller, Forum for Collaborative HIV Research

Presentations by Pete Dailey, Cami Graham and Barbara Bulc, FIND

1. FIND – an innovative partner in diagnostics for limited-resource settings
2. Hepatitis C diagnostic tests - strategy and vision to address a global market
3. New opportunities for cross-sector partnerships
4. Q&A and Discussion

Participants:

Experts, researchers and senior leaders from academia, industry (diagnostics, medical devices, pharmaceutical and biotech), regulatory agencies, international organizations and patient advocates.

About the co-hosts:

The HCV Drug Development Advisory Group (DrAG) is a unique initiative organized by the Forum for Collaborative HIV Research that brings together representatives from the U.S. and European regulatory agencies, academia, patient advocates and the pharmaceutical industry to build consensus around drug development-related issues. www.hivforum.org

Foundation for Innovative Diagnostics (FIND) is an innovative international organization and bridge-builder focused on building collaborations that turn complex diagnostic challenges into simple solutions in low resource settings. www.finddiagnostics.org

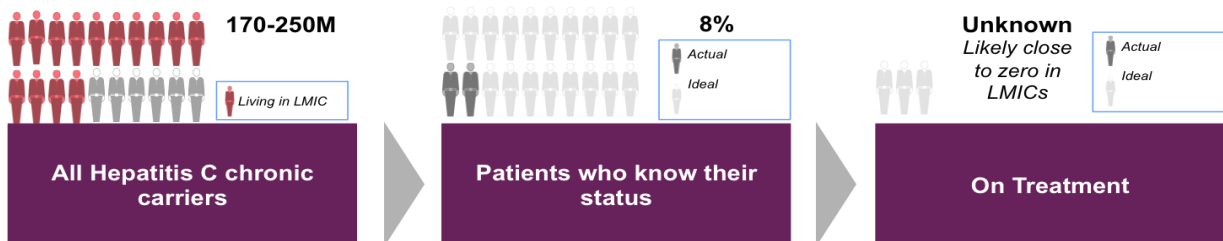
Hepatitis C Diagnostics – the Bottleneck to Unlocking a Global Market

Hepatitis C virus causes an estimated **350,000 deaths/year** with over 75% of infections and deaths occurring in **low/middle-income countries (LMICs)**. Infectious hepatitis-related deaths surpass HIV-related deaths already in many parts of the world. HCV is curable, and cure decreases the risk of severe subsequent liver complications by over 80%.

The treatment landscape for HCV is currently undergoing a **dramatic transformation**, with potent, well-tolerated, all oral regimens increasingly available with cure rates >90% with 12 weeks of treatment. This offers a unique opportunity to address the HCV epidemic in poorer countries, which have thus far not prioritized the fight against this disease.

The bottleneck to appropriate HCV care and treatment, however, is diagnosis: Diagnostic capacity in LMICs is low, with less than 1% of patients in LMICs aware of their infection. Existing diagnostic algorithms are too complex and costly. Tests are not applicable to LMICs as their accuracy is limited due to the different epidemiological settings or HIV co-infection (i.e. serology), or they require substantial expertise currently only feasible in centralized settings (i.e. molecular).

Figure 1: State of the Hep C epidemic in low/middle-income countries

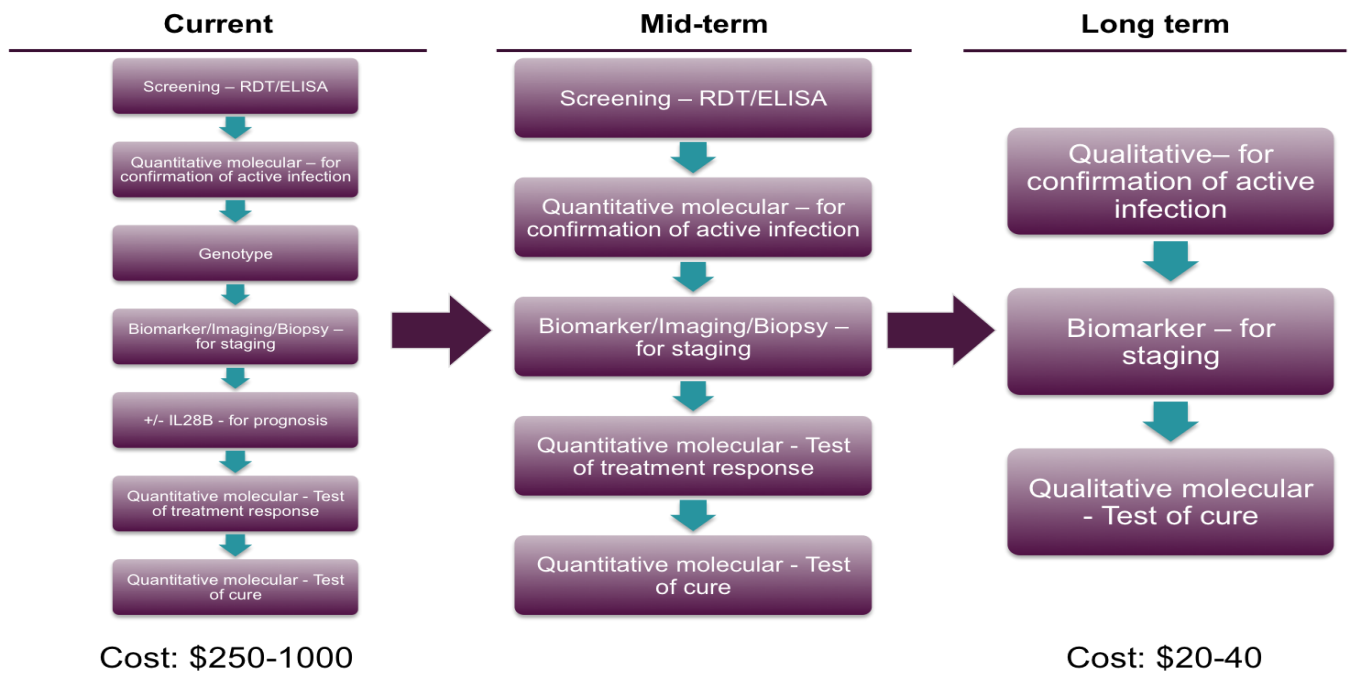


Diagnostic solutions available to address the gap

Investment in the development of fit-for-purpose diagnostic tests for limited resource settings is paramount to uncover the epidemic of HCV. This will help drive models for care and treatment on a large, programmatic scale, potentially impacting all markets.

With the implementation of new regimens **the pathway to treatment initiation can be simplified** to 4 tests to only 2-3 tests at lower cost (from 4 test: 1. Serology in rapid test format (RDT); 2. Molecular confirmation; 3. Fibrosis staging; 4. Genotyping; to 2-3 tests: 1. Rapid test + 2. Molecular +/- 3. Fibrosis staging).

Figure 2: Diagnostic algorithm - current and future



Opportunities for cross-sector collaboration going forward

Although historical focus on hepatitis C has been minimal, some of the leading global health stakeholders, including the World Health Organization, The Global Fund, UNITAID, governments, regulatory agencies and advocates are beginning to address these needs.

Building on success in other disease areas, FIND is committed to exploring and catalyzing cross-sector partnerships necessary to effectively transform diagnostic pathways for hepatitis C and turn into an understood and manageable health issue that can be addressed in low/middle-income countries.

As a first step, **FIND aims to identify key areas of promise for further collaboration across the global health stakeholders, industry partners and academic/research organizations.** FIND will enable and facilitate:

1. Development of affordable fit -for- purpose diagnostics
2. Access to diagnosis by guiding use and policy
3. Development of evidence for the need and benefit of interventions for HCV
4. New collaborations to improve access to diagnosis, to impact care and treatment of HCV.