



**FINDD**

Because diagnosis matters

## Hepatitis C Elimination through Access to Diagnostics (HEAD-Start)

“Testing and diagnosis of hepatitis B and C infection is the gateway for access to both prevention and treatment services, and is a crucial component of an effective response to the hepatitis epidemics. Early identification of persons with chronic HBV or HCV infection enables them to receive the necessary care and treatment to prevent or delay progression of liver disease.”

—WHO<sup>1</sup>

The FIND HEAD-Start project is working to improve diagnosis of HCV by making it more affordable and more widely available to those in need, with a focus on serving people coinfecting with HIV.

HEAD-Start is designed to drive a change in global implementation guidelines and national policies that are conducive to scaling up HCV management in support of the WHO elimination targets for 2030.

### Obstacles to HCV disease elimination

Breakthroughs in drug development mean that hepatitis C can be cured in as little as 3 months with a simple regimen of pills. These treatments are increasingly accessible in LMICs. However, they will only be game-changing when the millions of people with undiagnosed HCV are found and linked to care.

This remains a major challenge – R&D of HCV diagnostics has not kept pace with drug development. Very few tools currently available for HCV screening and diagnosis are affordable or appropriate for use at the point of care in LMICs. Moreover, these tools are of limited utility in certain populations, especially for patients who are coinfecting with HIV.

Most people with HCV are unaware of their infection and tend to seek care only when they have advanced disease, increasing the likelihood of mortality and morbidity, as well as the possibility of transmitting the infection to others. New diagnostic tools, and tailored strategies for making them available to patients in different settings, are urgently needed to ensure patients are found early and linked to care.

WHO 2015–2030 viral hepatitis strategy aims for:

**90%** of patients diagnosed

**80%** receiving treatment

**90%** reduction in incidence

**65%** reduction in mortality

If implemented, this would avert **2.1m HCV-associated deaths**

### HCV at a glance<sup>2</sup>

- **71m** people are infected with chronic HCV
- **80%** of cases are in LMICs
- **20%** know their diagnosis
- **7.4%** started treatment
- **2.3m** people are living with HCV/HIV coinfection
- **5.6m** infected with HCV currently inject drugs
- **400k** deaths per year

HCV is a cancer-causing illness and one of the world's most common infectious diseases, usually contracted through unsafe healthcare and injection drug use. HCV causes liver infections ranging from short, mild illnesses to serious, lifelong disease leading to premature death.

HCV predominantly affects at-risk or marginalized populations in LMICs and is now understood to be a critical public health problem for people living with HIV. HCV/HIV co-infected patients face higher morbidity and mortality due to rapidly progressing liver scarring. Likewise, PWID are at high risk for infection yet are unlikely to be diagnosed. Drug use in many LMICs is stigmatized and/or criminalized, so PWID are far less likely to seek care through traditional medical service providers.

## Major obstacles to diagnosis<sup>3</sup>

### Lack of funding

5/29 countries have a dedicated national HCV budget sufficient to meet or exceed the WHO 2020 targets.

### Limited laboratory networks

Limited laboratory networks negatively impact the scale-up of HCV diagnostics and treatment in many high-burden countries.

### Too few healthcare workers

Few frontline healthcare workers are assessing patients for risk of HCV and referring for appropriate diagnosis.

### Insufficient data

Most countries do not track the volume or yields of screening or viral load tests at a national level, impeding the development of well-informed country strategies, the proper use of diagnostic commodities, and effective price negotiations with suppliers.

### Lack of strategy

Few countries have concrete diagnostic targets or scale-up plans for HCV that operationalize the WHO HCV diagnosis targets.

### Low public awareness of HCV

In-country education and awareness programmes are critical to improving the general public's knowledge and reducing stigma associated with HCV, leading to increased demand for testing and improved case-finding.

## HEAD-Start principles

### Transform disease control by integrating diagnostic tools and services

One of the challenges in managing HCV and HIV coinfections are the siloed approaches to disease management that prevail in many LMICs. Merging HCV and HIV services and diagnostic tools can transform control efforts for coinfection in general, and HCV in particular.

### Diagnostic platforms

Tools that are capable of testing for multiple infectious agents—diagnostic platforms—streamline and simplify infectious disease diagnosis and management. A number of such technologies are already available, and the field is rapidly expanding, particularly for POC tests. Using HCV on these platforms would mean that the existing diagnostic infrastructure, which is in place for other diseases and often not used at full capacity, could be leveraged to increase the cost-effectiveness of scaling up HCV diagnosis.

### Service integration and decentralization of HCV testing to reach key populations, including PWID

Integration of HCV and HIV services would give potential patients the opportunity to be tested and treated for both infections in one place. This would increase the likelihood of identifying coinfection and ease the time and cost burdens that patients face when services are not offered in the same places.

At present, HCV testing and confirmation is almost exclusively available at centralized laboratories. Decentralizing and integrating HCV testing at HIV testing sites, which offer some of the most accessible testing services in LMICs, is paramount for reaching both HIV/HCV coinfecting populations and PWID.



## The HEAD-Start solution

The FIND HEAD-Start project has four components that are designed to overcome the major obstacles to scaling up of HCV testing in support of WHO targets.

### 1. R&D

Expand the number of tools available for HCV screening and confirmation and for sample collection and transport that are ready for purchase or use in countries by catalysing R&D of diagnostic solutions, with a focus on POC tools and platform technologies that can facilitate an integrated approach to diagnosis of HCV.

### 2. Pilot projects

Prepare the market for the introduction, use and placement of the new tools through seven projects in four countries by introducing HCV testing, integrated into HIV programmes, with a focus on bringing testing closer to where patients first seek care (decentralization) and better addressing coinfection.

### 3. Ensuring affordability

Increase affordability of HCV diagnosis by negotiating prices with diagnostics manufacturers, developing a global market analysis on HCV diagnostics, and investigating the cost-effectiveness of different testing pathways.

### 4. Evidence sharing

Deliver evidence to support global, regional and national policy change, as well as the development of WHO guidelines for implementation and scale-up of HCV testing.

## Targeting coinfection is essential<sup>2</sup>

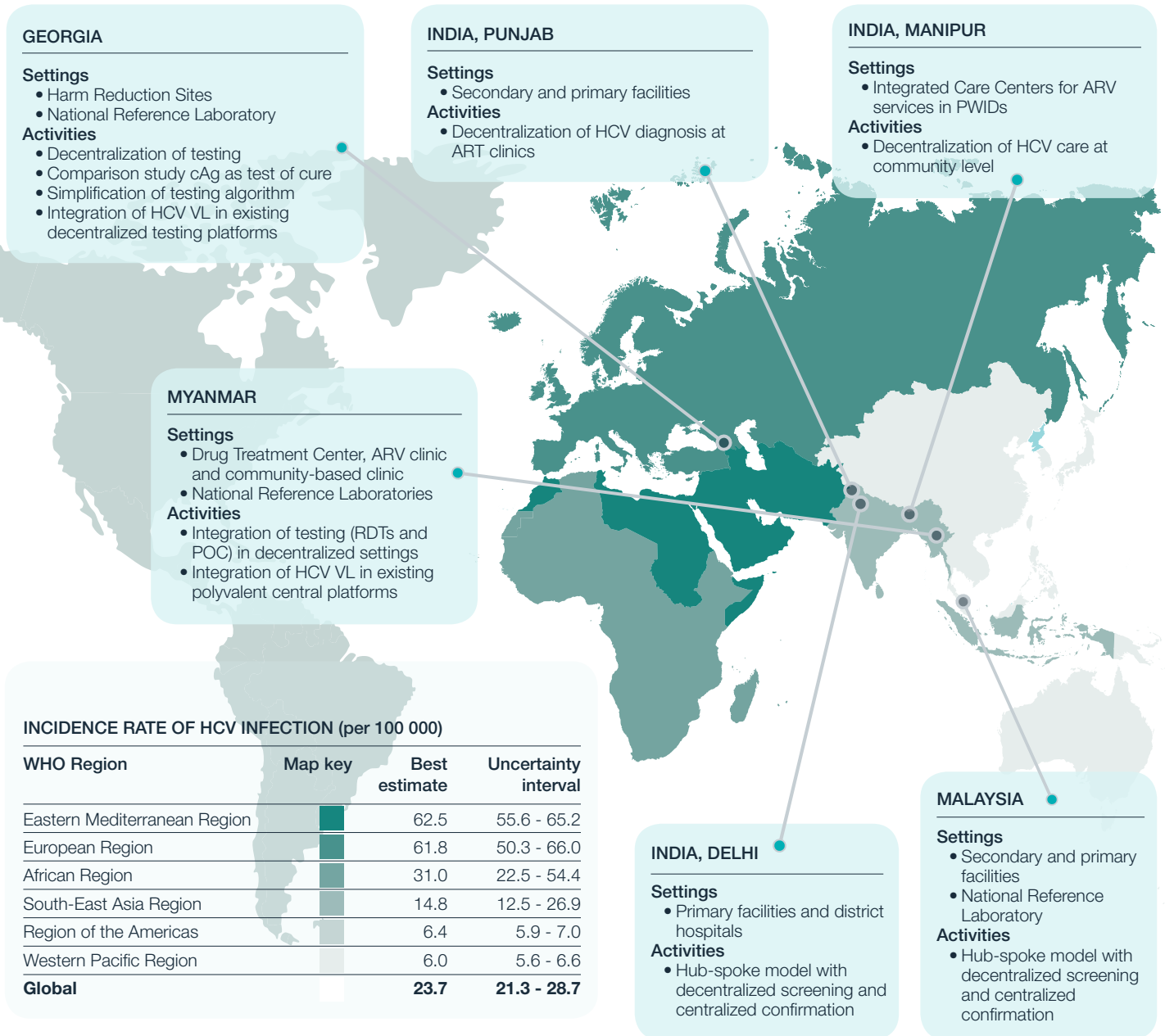
Coinfections are undermining the gains that have been made in curbing deadly pandemics. They are rampant and dramatically increase rates of mortality and morbidity associated with major infectious diseases.

According to WHO, people living with HIV are an average of six times more likely to have HCV infection, and face increased risk of morbidity and mortality as a result. HIV/TB coinfection is equally sinister: TB causes one in three HIV-related deaths.

Even though coinfections are common, only a small percentage of people are aware of their infection status. Failing to rapidly detect infections and link people to care puts patients' lives at risk, amplifies opportunities for transmission and considerably increases both personal and public health costs.



# In-country pilot projects generate evidence for accelerating access



2015 PREVALENCE FIGURES FROM WHO WORLD HEPATITIS REPORT 2017

**Abbreviations:**

AIDS Acquired Immunodeficiency Syndrome	HIV Human immunodeficiency virus
ARV Antiretroviral	LMIC Low- and middle-income country
cAg Core antigen	POC Point of care
DAA Direct-acting antiviral	PWID People who inject drugs
DBS Dried blood spot	R&D Research and development
EID Early infant diagnosis	RDTs Rapid diagnostic tests
FIND Foundation for Innovative New Diagnostics	TB Tuberculosis
HBV Hepatitis B virus	WHO World Health Organization
HCV Hepatitis C virus	

**References:**

1. Guidelines on hepatitis B and C testing, World Health Organization, 2017 <http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1>
2. Global hepatitis report, 2017. World Health Organization <http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/>
3. HCV Diagnostics Market Intelligence Report 2017. FIND and CHAI [https://www.finddx.org/wp-content/uploads/2018/04/HCV-Diagnostics-Market-Intelligence-Report\\_18APR2018.pdf](https://www.finddx.org/wp-content/uploads/2018/04/HCV-Diagnostics-Market-Intelligence-Report_18APR2018.pdf)

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Campus Biotech, Chemin des Mines 9  
1202 Geneva, Switzerland  
T +41 (0)22 710 05 90  
info@finddx.org  
www.finddx.org