



Because diagnosis matters

STRATEGY
FOR HEPATITIS C

2015-2020



ABOUT FIND

FIND was founded in 2003 to bridge existing development gaps for essential diagnostics by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector and the in vitro diagnostics industry. Today, FIND is a leading partner across the value chain of diagnostics development and delivery. We have programmes in Tuberculosis and Acute Febrile Respiratory Infections, Malaria and Acute Febrile Syndrome, Hepatitis C and Neglected

Tropical Diseases. We also have mini-portfolios in areas affecting reproductive and child health: HIV; sexually transmitted infections; and infections and nutritional deficiencies in children under five years old. At FIND, we envision a world where diagnostics guide the path to health for all people. We aim to turn complex diagnostic challenges into simple solutions to transform lives and overcome diseases of poverty. To do this we focus on four strategic goals throughout all the disease areas in which we work:

■ Catalyse development

Identify needed diagnostic solutions and remove barriers to their development

■ Guide use & policy

Lead products through the clinical trials pathway to global policy on use and market entry

■ Accelerate access

Support uptake and appropriate use of diagnostics to achieve health impact

■ Shape the agenda

Improve understanding of the value of diagnostics and strengthen commitment to their funding and use

FIND's Vision

A world where diagnosis guides the way to health for all people

FIND's Mission

Turning complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives

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ABOUT HEPATITIS C VIRUS

Today, over 420 million people are chronically infected with hepatitis B and C. Hepatitis C is an infectious disease that primarily affects the liver and is caused by the hepatitis C virus. The infection is often asymptomatic, which means that a large percentage of those infected are unaware of their illness. Scarring of the liver and ultimately cirrhosis can result from untreated chronic infections, and this in turn can develop into more serious conditions, such as liver failure, cancer of the liver or severe oesophageal and gastric varices. Chronic hepatitis-related deaths have surpassed HIV as the leading cause of death in many parts of the world. Given the availability of a vaccine and effective oral therapy for hepatitis B, the major focus on improving diagnostics and treatment has been for hepatitis C, although platform synergies can be leveraged between diagnostic needs for both diseases.

Hepatitis C is transmitted primarily through: unsafe injection practices; transfusion of hepatitis C infected blood; and more rarely through unprotected sexual intercourse. It disproportionately affects vulnerable populations of people co-infected with HIV or tuberculosis and if untreated can progress to liver cirrhosis or cancer and cause significant morbidity and mortality. Today, hepatitis C causes an estimated 350,000 deaths per year, although the actual mortality numbers are likely much higher.

The treatment landscape for hepatitis C is currently undergoing a dramatic transformation. High-income countries already have access to potent, well tolerated, all-oral regimens that achieve cure rates of more than 90% with 12 weeks of treatment. With large-scale manufacturing of new regimens, treatment would

become affordable for use in low-income countries. For example, Sofosbuvir is one drug for hepatitis C and currently costs US\$ 84,000 in the USA and US\$ 900 per course in Egypt; with large-scale production, this price would decrease to US\$ 100-250 per course. This offers a unique opportunity to tackle the hepatitis C epidemic in poorer countries that have thus far not prioritized the fight against this disease. Rapid, inexpensive and accurate diagnosis remains the critical bottleneck that must be addressed to eradicate hepatitis C.

Diagnostics for hepatitis C are available in less than 1% of low- and middle-income countries (LMICs), and less than 1% of infected people in LMICs are aware of their disease. The diagnostics that do exist in LMICs are provided mainly through a small and unregulated private sector market. Public sector programming for hepatitis C is non-existent in most developing countries, with a few exceptions like Egypt. Existing diagnostic algorithms are complex and expensive, and many of the available tests used for hepatitis C detection (primarily serological rapid diagnostic tests) are of poor or unknown quality. Molecular tests that confirm the results of serological tests are unsuitable for low- and middle-income countries and only available in a few centralized settings.

Finally, the global burden of hepatitis C and its impact on morbidity and mortality have not yet been fully understood within the international community. In order to scale up the fight against hepatitis C, we must better understand and communicate the gravity of the disease in low-resource countries, reaffirm the proven socio-economic benefit of improved care and lobby for adequate political and financial commitments.

PAST AND CURRENT ACTIVITIES

Hepatitis C is a new field for FIND that was identified during the development of our 2015 – 2020 organizational strategy. We have prioritized this disease area because FIND is uniquely

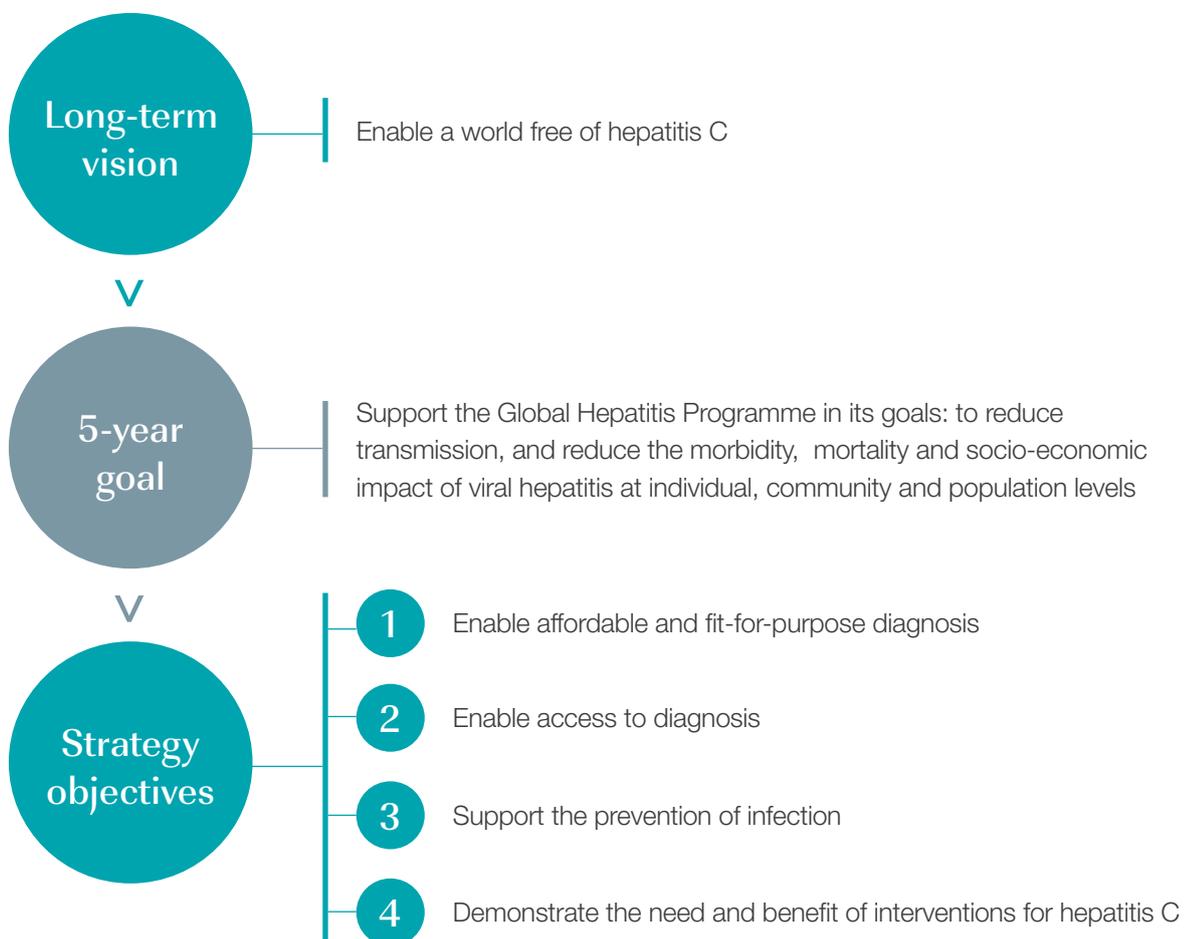
positioned to accelerate access to improved and innovative diagnostic solutions as treatment becomes more feasible and affordable in low-resource settings.

GOALS AND OBJECTIVES OF THE FIND HEPATITIS C PROGRAMME

The FIND 2015-2020 hepatitis C strategy will support the WHO Global Hepatitis Programme to achieve the following goals:

- 1 Reducing the transmission of agents that cause viral hepatitis
- 2 Decreasing morbidity and mortality due to viral hepatitis through improving the care of patients with the disease
- 3 Diminishing the socio-economic impact of viral hepatitis at individual, community and population levels

Addressing challenges to meet the goals of the Global Hepatitis C Programme



GLOBAL DIAGNOSTIC NEEDS IN HEPATITIS C: THE CURRENT LANDSCAPE

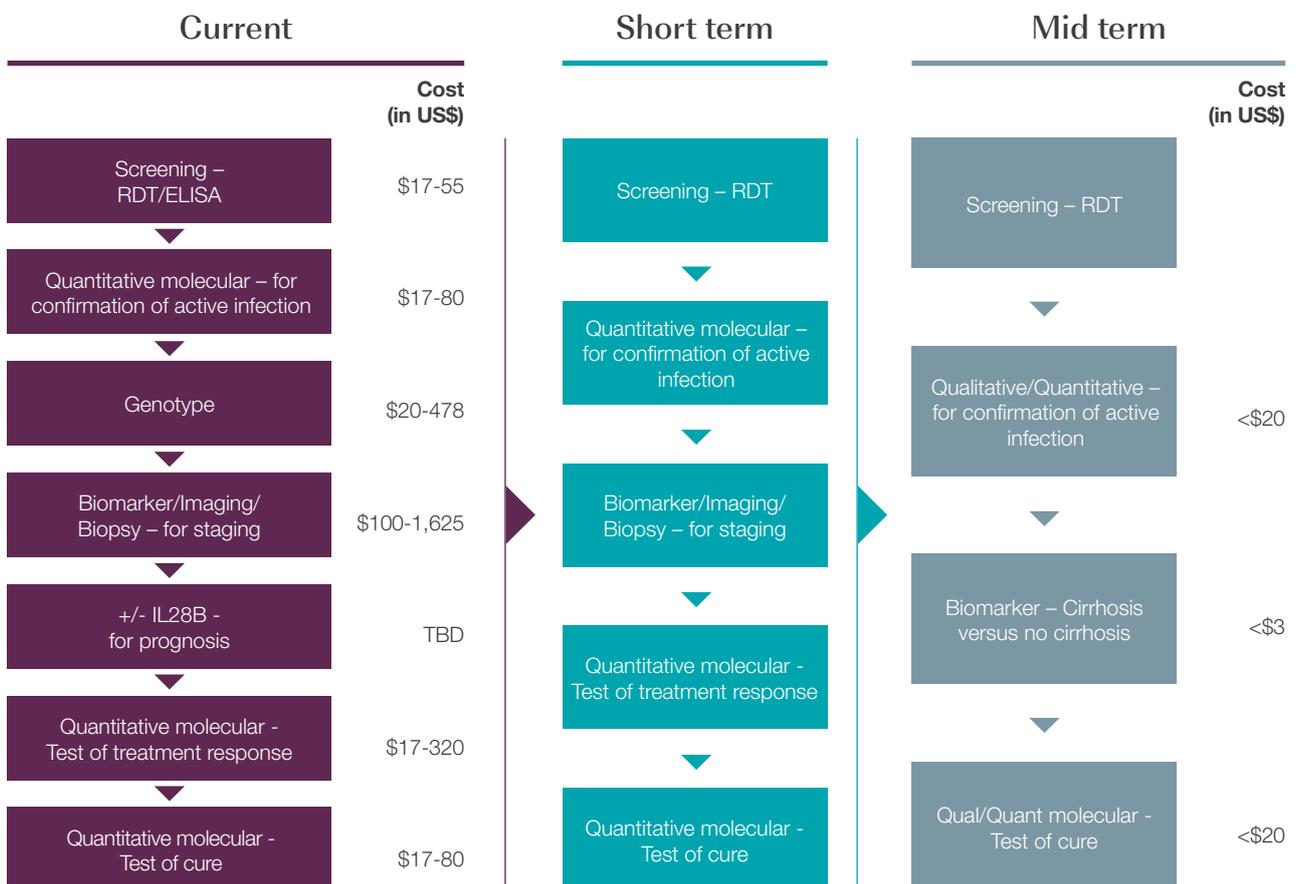
Diagnosis is an important first step in providing effective hepatitis C care in low- and middle-income countries (LMICs). Diagnostic capacity in LMICs is insufficiently developed, with diagnostics available mostly in the private sector and algorithms that are complex and costly. Moreover, currently available tests are of little use in LMICs due to limited accuracy in different epidemiological settings, for example with HIV co-infection (e.g. serology). Others also require substantial expertise and are only feasible in centralized settings (e.g. molecular testing).

With the implementation of new treatment regimens, the current pathway to treatment initiation can conceivably be simplified from four tests, costing between US\$ 250-1000 per diagnosis (i.e. serology

in rapid test format, molecular confirmation, fibrosis staging and genotyping) to two to three tests (i.e. rapid tests with molecular tests and/or fibrosis staging); however, even with this simplified algorithm, the cost for diagnosis would remain high at US\$ 25-80 (see figure below). If the confirmation test becomes affordable or prevalence in the population is high, then a screening test might not be necessary. If the treatment becomes very affordable, then a staging test could be omitted and all patients could be treated independent of fibrosis stage.

It is possible to further simplify algorithms to only one test for diagnosis and test-of-cure with a hepatitis C core antigen assay or inexpensive qualitative molecular assay. In this scenario, staging would only be necessary if there were cost constraints.

Potential for dramatic simplification of hepatitis C diagnosis in the mid to long term



Enabling affordable and fit-for-purpose diagnosis

Most LMICs that currently do hepatitis C testing rely on serological tests to establish a diagnosis. Over 50 serological RDTs of variable quality are available on the market. Twelve are undergoing evaluation in the WHO's prequalification process, but none have been approved to date. There is little to no post-market surveillance for these tests, and they are mostly used in the private sector. However, **serological tests have limited sensitivity** in an HIV co-infected population, limited specificity in sub-Saharan Africa due to cross-reactivity (estimated 30-100% false positives) and are expensive (more than US\$ 7 per test). Performance issues are further aggravated by the unfavourable storage and testing conditions that prevail in LMICs. By definition, serological tests also diagnose prior exposure to hepatitis C and do not differentiate active disease from exposure that resulted in natural cure.

Molecular tests are necessary to confirm active infection, as up to 25% of people will spontaneously clear the infection but remain serologically positive. There are several qualitative and quantitative molecular tests on the market (Genprobe, Novartis, Roche and Siemens; and Roche, Abbott, Qiagen, Sacace and Siemens, respectively), but all operate on costly platforms for centralized, high-resource settings. Three qualitative and six quantitative molecular tests (Wave 80, Mbio and Daktari; and Alere, Cepheid, Daktari, Epistem, Iquum, and Molbio, respectively) that target low-resource, decentralized settings are in

the late stages of development. However, all existing hepatitis C molecular tests are cost-prohibitive, including those in development (US\$ 18-80 per test), and they are largely unavailable in LMICs.

A hepatitis C core **antigen assay** can also serve as a test for confirmation of disease. Such a test is available on the Abbott Architect platform for centralized use, with a detection sensitivity of about >1,000 IU/mL hepatitis C (HCV) RNA (misses about 5% of patients). Several groups are exploring the feasibility of a decentralized antigen assay; however, none are in advanced stages of development.

The majority of patients with hepatitis C/HIV co-infection will require treatment for hepatitis C irrespective of the stage of fibrosis, as the disease progresses rapidly. For mono-infected patients, hepatitis C treatment should be prioritized for those with advanced fibrosis, as defined by the Metavir fibrosis scale, to limit cost. **Staging of fibrosis** will therefore be important and can be performed through serum biomarker testing, transient elastography or invasive biopsy. These tests currently have not been evaluated sufficiently to prove sensitivity in certain subgroups (e.g. HIV infected) or to assess whether they are fit for purpose under difficult environmental conditions (i.e. Fibroscan elastography). Furthermore, no multiplexed biomarker test exists. Médecins sans Frontières (MSF) is planning to evaluate the Fibroscan in its demonstration studies starting in 2015.

To ensure appropriate diagnosis of hepatitis C, we will use innovative implementation strategies for existing technologies in the short term, and lay the groundwork for transformational technologies to be developed in the middle to longer term.

Increasing access to diagnosis

In large parts of Asia and Eastern Europe, hepatitis C infection is concentrated in patients with HIV and tuberculosis (TB) due to common risk factors, e.g. unsafe injection practices in intravenous drug use. The use of established HIV and TB programmes to deliver hepatitis C diagnosis and treatment will minimize costs to countries by leveraging programmatic and technology platform synergies. However, hepatitis C mono-infection is of concern in most parts of Africa where transmission may occur through an unsafe blood supply or unsafe nosocomial injection practices. By initially targeting roll-out in HIV/TB treatment programmes, the volume of tests used will increase, enabling demand aggregation and price

decreases. This in turn should allow for expansion to larger programmes to address mono-infection.

Optimized care algorithms within programmatic settings under the auspices of ministries of health will need to be established and their cost-effectiveness demonstrated in order to create sustainable models for care. Given the limited amount of public sector funding for hepatitis C care, the private sector will likely continue to play an important role, and we must engage it with targeted interventions. MSF is planning to evaluate care algorithms within its UNITAID-funded programmes; however, evaluation in the context of public health programmes is also needed.

Supporting the prevention of infection

Detection of hepatitis C is only successful when coupled with a prevention strategy. For example, despite substantial efforts to address the hepatitis C epidemic and facilitate access to care in Egypt, for every patient who is treated, three more individuals become newly infected. Ongoing transmission in many parts of the world is due to unsafe injection practices in nosocomial settings or intravenous drug use. Blood transfusion screening for hepatitis C continues to be

neglected in 38 countries around the world. Efforts are under way to address centralized blood screening with highly sensitive, high throughput platforms; however, ad hoc blood transfusions from family and friends often remain unscreened. Affordable and fit-for-purpose diagnostic tests used for patient care could be potentially used for screening of ad hoc blood transfusions where recommended blood screening methods are not available.

Demonstrating the need for and benefit of interventions to support scale-up

To overcome these challenges, it is critical to obtain an expanded commitment to addressing hepatitis C in general and to developing and using diagnostics more specifically. To achieve this, the world must first have a better understanding of the true burden of this disease. In addition, increased

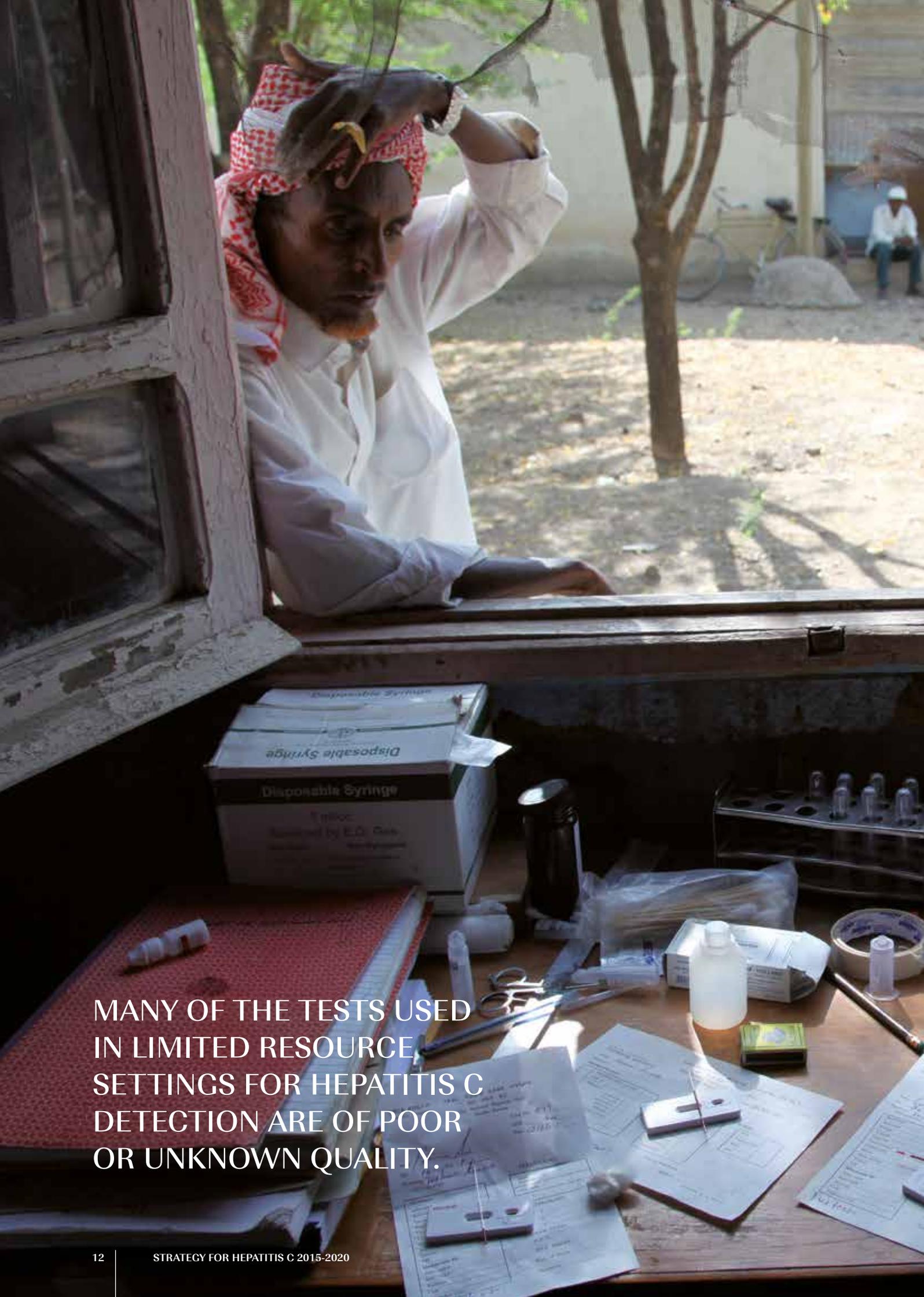
efforts should be made to demonstrate the value of diagnostics through data collection, modelling and impact measurement. This information will provide a foundation for expanded advocacy efforts to increase knowledge and commitment to diagnostics for hepatitis C.

The diagnostic needs for hepatitis C in the context of the strategic pillars of FIND

Strategic pillar	Need	Explanation
Catalyse development	An improved serological test	A rapid, accurate serological test with increased sensitivity in HIV patients on an easy to access sample (e.g. whole blood or saliva) with improved performance characteristics under difficult environmental conditions. Ideally multi-analyte test for HIV/ hepatitis B & syphilis.
	A molecular test for use in decentralized settings	A rapid, accurate molecular test (quantitative or qualitative) that can be implemented in a decentralized setting for confirmation after an immunoassay. Ideally able to do multi-analyte testing for HIV/hepatitis B and possibly TB. This test could also be used as a test-of-cure.
	A “1-test solution” molecular test for use in decentralized settings	A rapid, accurate qualitative molecular test that can be implemented in a decentralized setting as a 1-test solution. Ideally able to do multi-analyte testing for HIV/hepatitis B and possibly TB. This would be a disruptive innovation that would obviate the first two interventions. This test could also be used as a test-of-cure. The primary difference to the molecular test suggested above is cost. A 1-step solution is only feasible if the test is affordable enough not to require up-front triaging with an immunoassay.
	An antigen test for use in decentralized settings	Technically it would also be feasible to reduce the 2-step approach for diagnosis (RDT+molecular) to a 1-step approach through a rapid diagnostic test for hepatitis C core protein. This is already commercially available on the Abbott Architect platform for centralized use. While such a test may miss 5% of patients (assuming a limit of detection of 1,000 IU/mL HCV RNA), it has tremendous potential to revolutionize the testing algorithm at a low cost (<US\$ 3) in a decentralized setting. This also would be a disruptive innovation that would obviate the first two and if sufficiently sensitive also the third intervention above. It could also be used as a test-of-cure.
	An improved biomarker staging test	A staging test that will allow the targeting of patients most in need for immediate therapy. If cost permits, all patients should be treated without staging. Biomarkers are available for staging (e.g. APRI, Fib-4) with reasonable performance at the extremes of the fibrosis scale (i.e. no fibrosis, advanced fibrosis). Multiplexing of tests on only one platform would be ideal.
	Improved imaging tests for staging and monitoring (incl. for hepatocellular carcinoma)	Imaging tests are also available for staging (i.e. elastography) with possibly improved performance over biomarkers in HIV patients. Portable tests are available but have not been evaluated in low-resource settings.

Strategic pillar	Need	Explanation
Guide use & policy	Clinical trials of novel tests	Demonstration studies of tests in different contexts (HIV/TB co-infection, injecting drug users) and different endemic settings to assess best algorithms for hepatitis C care and evaluate their impact to inform WHO policy and in-country use.
	Clinical and operational studies	Studies to enhance understanding of current diagnostic ecosystem to improve use of existing tests & optimize placement of new tests
	Improved market/regulatory understanding	Improved understanding of regulatory and market aspects in target countries to accelerate market entry
Accelerate access	Implementation of comprehensive hepatitis C care	Countries need support to develop national policies and roll out plans for hepatitis C care programmes
	Better integration into existing health care systems	Given the limited availability of funding and the overlap of populations affected and platforms used for testing, integration into existing HIV and TB programmes would be a useful first step to establish hepatitis C care programmes i) Focusing on HIV programmes in countries where HIV treatment programmes provide an opportunity to integrate hepatitis C care in a cost-effective and synergistic way. ii) Focusing on TB programmes in countries with a large TB and smaller HIV burden, or where there is major HIV-related stigmatization. Multi-analyte testing on one platform will facilitate the integration of testing. This path would aid the scale-up of diagnostic testing and assure linkage to care.
	Structured mentoring for quality management systems strengthening	A structured training and mentoring programme focused on laboratory quality management systems (including, quality assurance, safety, supply chain management), which provides a platform for systems' strengthening to be implemented in parallel with new diagnostics roll-out.
	Better engagement of the private sector	To penetrate the private sector with quality products, a campaign is needed to raise awareness of quality tests, provide training in the appropriate algorithms and quality aspects and negotiate price reductions for the private sector. As shown for TB in India (i.e. IPAQT), preferential pricing for the private sector has an impact on product selection. This is expected to shift market shares towards good quality products and reduce the use of available low quality tests.

Strategic pillar	Need	Explanation
	Improved availability of tests for screening of ad hoc blood transfusion to prevent infection	Leverage the overlap of needs for testing for detection of disease in patients to support the screening of ad hoc blood transfusions. Focus on diagnostic tests that are capable of multi-analyte testing for hepatitis C and HIV/hepatitis B and syphilis.
Shape the agenda	Better understanding of the impact of different diagnostic solutions through modelling and/or operational research	<p>Once novel tools are available, impact assessment of these tests and care pathways can demonstrate:</p> <ul style="list-style-type: none"> • Access to diagnostics • Effect of interventions to maximize impact and improve quality of diagnostics • Patient important outcomes (e.g. time to diagnosis and treatment, mortality) • Population-level impact and cost-effectiveness • Market served, market projections
	Advocacy efforts and patient mobilization	Campaigns to raise awareness of the burden of disease to mobilize patients and generate donor support and government commitment.



MANY OF THE TESTS USED
IN LIMITED RESOURCE
SETTINGS FOR HEPATITIS C
DETECTION ARE OF POOR
OR UNKNOWN QUALITY.

FIND'S HEPATITIS C MANDATE FOR 2015-2020

Priorities in development

Given the broad range of potential interventions for FIND in the field of hepatitis C, we have prioritized our development activities based on two measures: the expected impact of the new solutions both for individuals and overall public health; and the likelihood of success given technical feasibility, FIND's capabilities and availability of funding.

Our prioritization reflects a two-pronged approach. We will capitalize on existing technologies and use **innovative implementation strategies** to facilitate incremental improvements that can be delivered in the short term, while laying the groundwork for transformational technologies to be developed in the middle to longer term.

Prioritization of tests for development

Impact

- Public health impact
- Individual impact



Likelihood of success

- Technical feasibility
- Availability of funding
- Fit with FIND's capabilities/strategy

Key

- Core FIND focus
- FIND supporting/coordinating role

In the area of development, our top two priorities are the development of both a core antigen test and a molecular test for use in decentralized settings.

To support the development of these tests we will perform a range of activities, including: defining target product profiles (TPPs); identifying and bringing together relevant partners (product developers, funders, etc.); collecting and providing specimens; conducting early validation of technology; and supporting clinical evaluation.

Despite the potentially transformational nature of these technologies, there are significant associated risks.

While an antigen-based test would be ideal (yet also a disruptive intervention), the feasibility of the assay on a point-of-care platform is unclear. Similarly it is

unclear whether a molecular test in a decentralized setting can ever achieve a price point cheap enough to be used as an up-front assay. Given these risks, **we will partner with manufacturers to support improvements to existing serological assays.**

In addition, although the ideal future algorithm would be one in which all patients with hepatitis C receive treatment after qualitative molecular confirmation of active infection, it is likely that cost constraints will limit treatment to patients at certain stages of disease progression. For this reason, we still plan to play a supporting and coordinating role for the development of **improved staging tests**. To do this, we will engage manufacturers to support the development of multiplex platforms with existing biomarkers. We will also support the evaluation and improvement of the speed of existing imaging tools for staging.

FIND 2015 – 2020 hepatitis C Priorities

Development priorities:

- 1 Decentralized antigen test
- 2 Decentralized molecular test
- 3 *Improved serological test*
- 4 *Improved staging tests*

Enabling interventions:

- Establish a public specimen bank
- Conduct demonstration trials to determine optimal diagnostic algorithms and support guidance on use (including for blood screening)
- Support country implementation of new tools in public and private sector
- Advocate for increased prioritization of hepatitis C diagnosis using impact and cost-effectiveness data and modelling

Note: for items in italics we will only play a supporting and coordinating role

Enabling interventions

In addition to focusing on these two development priorities, FIND will also support its objectives for hepatitis C through a set of enabling activities. A key component of supporting test development is improving the availability of samples and strains for early proof-of-principle studies. To support test development, we will establish a **publicly accessible specimen bank for manufacturers** with geographically and genotypically diverse specimens.

We will **facilitate access to care through simplified and optimized diagnostic algorithms** for both new and existing tools. To do this, we will evaluate tests in different diagnostic algorithms in countries and explore innovative approaches to reduce the cost of implementation through large-scale demonstration projects in different contexts (HIV/TB co-infection, injecting drug users).

These demonstration projects will generate the evidence base needed for global policy and guidance of use and provide a mechanism to drive up the volume of tests used, thereby helping to lower market prices. This will support development of diagnostics for hepatitis C mono-infection as well. Moreover, the projects will build the capacity to translate WHO guidance into rapid scale-up of testing within public programmes. Our immediate priorities in this area are to select the best existing serology test and evaluate the optimal algorithms for existing serology plus

centralized molecular tests. We will shift our focus to evaluating and supporting policy guidance for new and improved tests as they emerge.

To **prevent disease transmission**, we will evaluate the impact of using novel hepatitis C detection tests for screening of decentralized ad hoc blood donations in low- and middle-income countries.

FIND is also accelerating access to diagnostics by ensuring that all tests are part of a “packaged solution” that includes clear guidance on use, training materials, maintenance and support, quality assurance, impact measurement and linkage to care and surveillance. By supporting country programmes, national policy and roll-out plans of hepatitis C care programmes can be more easily integrated into the public health care system. We will help design awareness campaigns, trainings and incentive strategies to penetrate the private sector with quality products.

All our work is guided by data, cost effectiveness and impact modelling to **demonstrate the need for and benefit of intervention and to support the scale-up of solutions**. Through the evidence from our projects, the true burden of the disease and the impact of high-quality diagnostics become apparent. We will also advocate for universal, centralized screening of blood transfusions with appropriate tools to prevent transmission.

To support test development, we will establish a publicly accessible specimen bank to improve the availability of samples and strains for early proof-of-principle studies.

WE WILL FACILITATE
ACCESS TO CARE
THROUGH SIMPLIFIED
AND OPTIMIZED
DIAGNOSTIC
ALGORITHMS.



FIND'S HEPATITIS C MANDATE FOR 2015-2020

The diagnostic needs for hepatitis C in the context of the strategic pillars of FIND

Intervention	Direct impact indicators by 2020	Patient/Programme level indicators by 2020
Support development and evaluation of molecular test for use in decentralized settings	<ul style="list-style-type: none"> • TPP developed • >3 feasibility studies done for hepatitis C core antigen • >3 clinical studies undertaken for novel molecular tests and hepatitis C core antigen 	<p><u>Programme level indications</u></p> <ul style="list-style-type: none"> • Increase in cases diagnosed • Incidence reduction
Support development and evaluation of an antigen test for use in decentralized settings	<ul style="list-style-type: none"> • 2 decentralized molecular tests that are WHO-recommended and introduced in >7 countries • 1-2 core antigen tests that are WHO-recommended and introduced in >7 countries 	<p><u>Patient important outcomes</u></p> <ul style="list-style-type: none"> • Increase in number of patients diagnosed and treated • Reduction in hepatitis C-associated mortality
Support development and evaluation of an improved serological test	<ul style="list-style-type: none"> • Sample bank established • Validation and EQA panels developed; knowledge transfer achieved to in-country/regional reference laboratories • Comparative studies of serological tests undertaken to inform country policy • 5 highly accurate serological tests identified and introduced 	
Support improvement of biomarker staging test (incl. evaluation)	<ul style="list-style-type: none"> • Roll-out of >2 highly accurate, multiplexed biomarker staging tests that are WHO-recommended 	<p><u>Patient important outcomes</u></p> <ul style="list-style-type: none"> • Reduction in time to treatment initiation for Metavir fibrosis scale >2 • Reduction in hepatitis C-associated mortality
Support improvement of imaging tests for staging and monitoring tests (incl. evaluation for hepatocellular carcinoma)	<ul style="list-style-type: none"> • >1 accurate and rugged imaging staging test evaluated and WHO-recommended 	<ul style="list-style-type: none"> • Reduction in advanced hepatocellular carcinoma <p><u>Programme level indications</u></p> <p>Decreased cost from hepatitis C morbidity and mortality</p>

In addition to the development targets listed, we will also have impact through our enabling work in-country. The specific targets for this work will be project dependent, but our overall goal will be to support

improved country implementation of both new and existing tools. We will fight hepatitis C by enabling access to diagnosis and ensuring linkage to treatment to reduce the burden of disease.

EXPANDING OUR PARTNERSHIPS

Possible partners across the pillars of the FIND strategy



**Catalyse
development**



**Guide use
& policy**



**Accelerate
access**



**Shape
agenda**

Academia

Industry

PATH

Centers for Disease Control and Prevention

Country governments/ministries of health

WHO/Global Hepatitis Programme

Clinton Health Access Initiative

Médecins Sans Frontières

Partners in Health

ASLM

Civil society organizations

Treatment Action Group

FIND will catalyse the development of new innovative tests through our partnerships in academia and industry. As previously outlined, there are a number of manufacturers with tests already in development, and we will work with them to communicate the diagnostic needs for hepatitis C, e.g. with target product profiles. As demonstrated in other disease areas, many of these developers have limited resources to support the various phases of product development through to product realization. We will provide mentorship and support to help product developers address these gaps and ensure the development of fit-for-purpose products for low- and middle-income countries.

We will establish a biorepository to enable early proof-of-principle and validation studies. To build a sample collection that will support diagnostic development, we will partner with groups that perform clinical studies in countries such as MSF or

Partners in Health (PIH) and reference laboratories. With our biobanking partner, Zeptomatrix and other partners, we will work on the development of validation panels and quality assurance programmes. We will then support the transfer of knowledge to national and regional reference laboratories to enable national health programmes to scale-up their own validation and external quality assurance. For demonstration projects, we will seek partnerships with ministries of health (MoHs) to ensure the applicability of findings within the public sector. We will also engage with other implementation groups such as PIH or MSF that work more in their own programmatic settings. For in-country implementation, we will engage with MoHs through our long-standing partnerships. We will also foster our partnership with the WHO's Global Hepatitis Programme to support policy development and advocacy and enable data collection for surveillance.

The next steps

With new treatments on the horizon, the world is coming to a crossroads with respect to hepatitis C. Scientific advances offer the chance to dramatically reduce the burden of a disease that is known to kill many and likely takes a much larger human and economic toll than is currently known. As treatments come to market and partners work to make them affordable and accessible, diagnosis remains the biggest bottleneck to appropriate treatment. A surge in financial and political commitment to diagnosing, treating and preventing

hepatitis C is urgently needed worldwide. We estimate that the execution of the strategy described in this document alone will cost more than US\$ 20 million over 5 years. This investment, though significant, will enable us to capture the promise of novel treatments through innovative diagnostic solutions. We must act now to make sure that we have the strategies and tools in place to maximize the impact of hepatitis C control efforts over the coming decade and potentially enable the elimination of this devastating disease.

As treatments come to market and partners work to make them affordable and accessible, a surge in financial and political commitment to diagnosing, treating and preventing hepatitis C is urgently needed.



ENSURING RAPID, INEXPENSIVE
AND ACCURATE DIAGNOSIS IS
CRITICAL FOR CONTROLLING
HEPATITIS C.

APPENDIX A: ADDITIONAL TABLES

Detail on FIND’s role and preconditions for select activities

Intervention	FIND’s role	Preconditions
Support development and evaluation of an improved serological test	<ul style="list-style-type: none"> Scout technology Proof-of-principle evaluations on samples TPP development Match-make on TPPs 	<ul style="list-style-type: none"> Improved limit of detection (LOD) can be achieved on simple, low-cost devices LOD can be achieved on saliva-based assays similar to LOD on blood-based assays
Support development and evaluation of molecular test for use in decentralized settings	<ul style="list-style-type: none"> Support development Build sample bank; provide specimens for early feasibility studies Develop panels for validation and QA 	<ul style="list-style-type: none"> Platforms can be developed for use at lower levels of the health care system Cost can be sufficiently decreased
Support development and evaluation of an antigen test for use in decentralized settings	<ul style="list-style-type: none"> Provide platform for clinical evaluation Support development of WHO guidelines 	<ul style="list-style-type: none"> Antibodies targeting hepatitis C core antigen will be available for development (exclusive license owned by Ortho diagnostics) LOD can be achieved on decentralized platforms similar to that on centralized platforms
Support improvement of biomarker staging test (incl. evaluation)		<ul style="list-style-type: none"> Improved biomarkers for staging are identified
Support improvement of imaging tests for staging and monitoring tests (incl. evaluation for hepatocellular carcinoma)		<ul style="list-style-type: none"> Cost of imaging platform can be sufficiently decreased
Integration into existing health care system	<ul style="list-style-type: none"> Facilitate national policy decisions Support development of roll-out plans Help MoHs identify gaps (e.g., link to care, connectivity), coordinate solutions, and deploy experts Develop QA tools & strategies 	<ul style="list-style-type: none"> Appropriate partnerships with donors, agencies, MoHs, academia and industry Country commitment will be achieved Implementation of tests will not be delayed due to local regulatory approval of tests
Engage the private sector	<ul style="list-style-type: none"> Develop public–private mix initiatives and engage stakeholders Negotiations on price reductions for the private sector 	<ul style="list-style-type: none"> Commitment of private providers will be achieved

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