Could you begin by introducing the key objective of FIND (formerly the Foundation for Innovative New Diagnostics)?

CD: FIND was founded in 2003 to bridge development gaps for essential diagnostics by initiating and coordinating R&D projects in collaboration with the international research community, the public sector and the in vitro diagnostics industry. We lead products through the clinical trials pathway to global policy on use and market entry, and accelerate access by supporting the uptake and appropriate use of diagnostics to achieve health impact. We have extensive experience in bringing fit-for-purpose diagnostic solutions to patients suffering from poverty-related diseases.

Why is now the time to act on hepatitis C?

JC: Now more than ever, we are closer to successfully eliminating hepatitis C through a treatment revolution. Novel all-oral, direct-acting antiviral (DAA) therapies are more effective, safer for patients and easier to administer than previous injectable therapies, and have the potential to be much more affordable and allow for decentralisation and task shifting, because they are simpler and safer to use. These new treatments will also transform the hepatitis C diagnostics landscape because fewer tests will be needed – for example, DAAs may allow us to reduce the number of hepatitis C viral load tests from five or six per treatment course to just two or three. Furthermore, the safety profile of DAAs allows us to drop certain monitoring tests entirely. However, if we are to see the incredible potential benefits of new DAAs, significant steps must be taken now to ensure their availability to patients living in low- and middle-income countries (LMICs).

Could you provide a brief overview of FIND’s 2015-20 hepatitis C strategy?

CD: In order to capitalise on the promise offered by new treatments, the diagnostic landscape for hepatitis C has to be dramatically improved. We are aiming to do that by:

1. Facilitating the development and implementation of cost-effective and fit-for-purpose diagnostics
2. Widening access to diagnostics
3. Engaging in efforts to prevent infection
4. Advocating for the necessity of interventions that support scale-up

Specifically, molecular tests adapted for use in low-resource settings are needed to confirm active infection. A core-antigen test at low cost could conceivably be used as a one-step solution for diagnosis (combining detection and confirmation). As we wait for development of these novel tests at appropriate price-points, improvements to serological tests to increase quality and specificity in sub-Saharan Africa are also needed, as are better tools for fibrosis staging that can inform treatment decisions in programmatic settings. Beyond novel tests, there is an acute need to improve the approaches and programmes through which hepatitis C services are delivered. Here,
A drive for diagnostics

Working in collaboration with the international research community, the in vitro diagnostics industry, global and local policy makers and implementing partners, FIND is working to make essential diagnostics for hepatitis C available in low- and middle-income countries.

DISEASES ASSOCIATED WITH poverty are a major cause of mortality, illness and economic stagnation. One poignant example is chronic hepatitis, which has surpassed HIV/AIDS as the leading cause of death in some developing countries. It is estimated that 110-150 million people worldwide are infected with hepatitis C and over 75 per cent are in low- and middle-income countries (LMICs). Approximately 350,000 to 500,000 die every year as a result of this disease. In fact, infectious hepatitis is threatening the success achieved in HIV care, as liver-related deaths already surpass HIV as the most common cause of death from an infectious disease in many parts of the world. Hepatitis C is caused by the hepatitis C virus (HCV), a blood-borne virus that attacks the liver and has no vaccine. The overwhelming majority of hepatitis C patients are initially unaware they carry the virus because the early stages of the infection are usually asymptomatic. It is the long-term effects that are deadly and can progress from cirrhosis to liver cancer and liver failure.

In recent years, major strides have been made in the treatment options for hepatitis C. Developed countries already have access to new and potent all-oral therapeutics with cure rates of over 90 per cent following just 12 weeks of treatment, compared to 24-48 weeks for previous treatments. Encouragingly, the large-scale manufacture of these innovative new regimens could spell a dramatic price drop in the drugs, enabling developing countries to focus on tackling this hitherto unprioritised disease.

However, before these new treatments can have maximum impact, the diagnostic landscape for hepatitis C must be improved. Organisations like FIND are required to close the diagnostic gaps and drive fit-for-purpose diagnostics forward at affordable prices. UNITAID is required to help shape markets for hepatitis C products (both diagnostics and drugs), while funders such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the President’s Emergency Plan For AIDS Relief (PEPFAR) must also contribute to the effort. Diagnostic Product Development Partnerships must help bring products such as hepatitis C antigens to market, while originator companies should offer fair, transparent voluntary licenses that have wide geographic scope, including middle-income countries. Finally, the World Health Organization Prequalification of Medicines Programme is required to rapidly assess the bioequivalence of potential generics and quality of diagnostics.

Taking advantage of the delivery structures already in place for co-morbid diseases like HIV and tuberculosis will be hugely beneficial. Moreover, increasing prevention and advocacy efforts would limit the spread of infection and increase prioritisation of hepatitis C care.

What critical partnerships must unite to tackle hepatitis C?

JC: In order to control hepatitis C, cooperation is necessary from all partners in the global healthcare community. National governments must express need and demand action on hepatitis C; design and support programmes; and where necessary use Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to ensure access to generic medicines. Communities and activists are needed to create demand for hepatitis C diagnosis and treatments and push price reductions and programme development. Organisations like FIND are required to close the diagnostic gaps and drive fit-for-purpose diagnostics forward at affordable prices. UNITAID is required to help shape markets for hepatitis C products (both diagnostics and drugs), while funders such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the President’s Emergency Plan For AIDS Relief (PEPFAR) must also contribute to the effort. Diagnostic Product Development Partnerships must help bring products such as hepatitis C antigens to market, while originator companies should offer fair, transparent voluntary licenses that have wide geographic scope, including middle-income countries. Finally, the World Health Organization Prequalification of Medicines Programme is required to rapidly assess the bioequivalence of potential generics and quality of diagnostics.

Hepatitis C virus causes an estimated 350,000-500,000 deaths per year.
The majority of infections and deaths occur in LMICs.
A large proportion of the burden of infections and coinfections (with HIV and TB) occur in vulnerable populations.

All Hepatitis C chronic carriers: 110-150 million
Patients who know their status: 8 per cent
Patients on treatment: Unknown (likely close to zero in LMICs)

Living in LMIC

Actual
Ideal

Actual
Ideal

Hepatitis C virus causes an estimated 350,000-500,000 deaths per year. The majority of infections and deaths occur in LMICs. A large proportion of the burden of infections and coinfections (with HIV and TB) occur in vulnerable populations.

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INTELLIGENCE

HEPATITIS C STRATEGY 2015-2020

OBJECTIVES

To reduce hepatitis C transmission, morbidity, mortality, and socioeconomic impact at individual, community and population levels.

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CLAUDIA DENKINGER completed medical training and doctoral studies in immunology at Julius-Maximilians University, Germany, before training in internal medicine at the Beth Israel Deaconess Medical Center (BIDMC), Harvard Medical School, USA. After obtaining a Master’s in Tropical Medicine and International Public Health as well as a Diploma in Tropical Medicine and Hygiene at the London School of Hygiene and Tropical Medicine, UK, Denkinger worked for NGOs in HIV and TB care in South Africa and South America. After returning to the BIDMC for an infectious disease fellowship, Denkinger completed a postdoctoral fellowship at McGill University, Canada, with a focus on TB epidemiology and impact assessment as well as mathematical modelling of TB diagnostics. Today, in addition to heading the Tuberculosis Programme at FIND, Denkinger continues to hold a faculty appointment in the Division of Infectious Disease at BIDMC.

FINDING A SOLUTION

Founded in 2003, FIND (formerly the Foundation for Innovative New Diagnostics) is dedicated to turning complex diagnostic challenges into simple solutions that combat diseases of poverty and save lives. As a leading partner in the value chain of diagnostics development and implementation, FIND has identified hepatitis C as a key focus area in its 2015-20 organisational strategy, and it is striving to support the World Health Organization (WHO) Global Hepatitis Programme. “FIND is uniquely positioned to address the diagnostic needs of hepatitis C as it has extensive experience in bringing fit-for-purpose diagnostic solutions to patients suffering from poverty-related diseases,” points out Dr Claudia Denkinger, an infectious disease and tropical medicine specialist with FIND. “Through our programmes in tuberculosis (TB), sleeping sickness and malaria, we have led the delivery of 11 tests and have helped transform the diagnostics landscape for each of these disease areas.”

DIAGNOSIS AND IMPLEMENTATION

By 2020, Denkinger and her colleagues hope there will be just one or two diagnostic tests for hepatitis C, with at least one affordable test – a molecular test or an antigen core assay – for active infection that can be performed on all patients. In addition to driving the development of more simple, accurate and affordable diagnostics for use in developing countries, FIND is also aiming to widen access to diagnosis. For instance, in parts of Asia and Eastern Europe, where hepatitis C is mainly concentrated in patients co-infected with HIV and TB, there is significant scope for using the delivery structures already in place for these diseases and minimising costs by allowing for platform synergies. Scaled-up testing through roll-out in HIV and TB intervention programmes could also increase the volume of test production and therefore reduce the cost for everyone, consequently enabling the delivery of HCV programmes in sub-Saharan Africa that address mono-infection.

In view of this, FIND and other implementing partners, such as Médecins Sans Frontières (MSF), are planning to evaluate tests in different diagnostic algorithms in several countries. In turn, they will develop strategies that enable optimised, simple and integrated HCV care and further reduce the cost of implementing diagnostics. Activities in this area will prepare the groundwork for robust global policies and the translation of WHO guidance into the dramatic scale-up of testing in public programmes.

TOWARDS SAVING LIVES AND CURBING THE HCV EPIDEMIC

It is likely that the full extent of the hepatitis C global health burden has been underestimated. Moving forwards, FIND and other organisations, including WHO’s Global Hepatitis Programme, MSF, UNITAID and the Clinton Health Access Initiative, are determined to raise the profile of this devastating disease. They will do so by mobilising civil society, governments and international organisations to tackle it by investing in HCV diagnostics R&D and improving access to care and treatment. The development of cutting-edge diagnostic solutions and access to affordable tests and novel treatments will save lives and lead to significant cost savings in the healthcare system.

Challenges ahead

Dr Jennifer Cohn of Médecins Sans Frontières outlines some of the major challenges limiting the implementation and scale-up of hepatitis C diagnostic and treatment programmes in many LMICs.

Price of direct-acting antivirals (DAAs) and diagnostics – studies have demonstrated that full courses of DAA-based treatment could cost as little as US $120, and yet current prices are often between nine and 750 times higher than this. While there are accessible prices being offered by some companies, these prices are still far above the potential cost of production. In addition, prices for many high-burden middle-income countries such as those in Eastern Europe are much higher, putting treatment programmes out of reach for these key populations. Furthermore, we need more affordable ways to diagnose hepatitis C and prove cure. HCV viral load measurement is currently quite expensive – much more expensive than for HIV.

Lack of information on prevalence at country level – better understanding of the epidemiology of hepatitis C in LMICs is needed if countries and donors are to prioritise hepatitis C programming. Better serostudies are needed, as well as sub-samples that measure definitive diagnosis with HCV viral load or antigen to define the prevalence of chronic infection.

Lack of adapted guidelines and programmes at country level, including for screening – adapting WHO hepatitis C guidance to country guidelines for diagnosis and treatment of hepatitis C will help not only prove the feasibility of hepatitis C care in LMICs, but also demonstrate demand to manufacturers. This will help bring down prices and incentivise generic entry into the market, leading to a virtuous cycle of enlarging programmes and falling drug and diagnostic prices.

Lack of funding – both national and international funding will be needed to implement hepatitis C diagnosis and care, and donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (who support programmes with large numbers of HIV-hepatitis C co-infected patients) will need to step forward.