Diagnostics for hepatitis C: an urgent need for action

Hepatitis C virus (HCV) is a global health problem with an estimated 130–150 million people infected and 350 000–500 000 deaths annually; most of which occur in low-income or middle-income countries. As drug prices decrease and new treatments become more affordable, as outlined by Mohga Kamal-Yanni (February issue), there is an opportunity for high-burden countries to prioritise their activities against this disease.

One of the lessons the global health community learned from its experience with HIV was the need for action (due to cross-reactivity). Diagnostic tests are complex and expensive, and can only be performed at centralised laboratories, which are few and far between in low-resource settings; some of the available tests (eg, rapid tests) for HCV detection are of poor or unknown quality.

Simple algorithms for diagnosis need to be integrated into the established workflow and fit-for-purpose tests for decentralised use (eg, a novel core-antigen test at low cost to provide a one-step solution for diagnosis) must be developed. Meanwhile, there is a need to improve both quality and specificity of serological tests sub-Saharan Africa (due to cross-reactivity).

Major donors must be better informed of the importance of diagnostics in the fight against HCV. An understanding of the economic value of HCV diagnostics will foster investments in diagnostic development. Although there is an appreciation of the effect of reliable diagnostics on treatment, the value in the reduction of the overall cost to health systems in low-resource settings is unfortunately underappreciated. To date, most funding for general diagnostic development in low-resource countries comes from the public sector and from the Bill and Melinda Gates Foundation. The global health community needs to come together to devise strategies that will attract more funding into HCV diagnostics. For example, industries with a high incidence of HCV among its employees have an economic incentive to promote the health of their employees and should be encouraged to contribute funding. Governments in endemic countries need to be convinced to contribute to diagnostic development, either by providing funding or donation of resources, such as clinical trial support in governmental facilities.

For a diagnostic to be appropriate in low-resource countries, it needs to be affordable, accurate, user-friendly, robust, and ideally also rapid (particularly at the point-of-care). Manufacturers can be incentivised via access to scientific and regulatory expertise through organisations such as the Foundation for Innovative New Diagnostics, which help to reduce the cost and development time. This strategy has been effective for tuberculosis diagnostics, exemplified by the successes of the Xpert MTB/RIF assay (Cepheid). Organisations involved in diagnostics for low-resource settings have developed close ties with Ministries of Health and can provide substantial support in the implementation of novel HCV diagnostics in the public and private sectors. This assistance is of paramount importance to the less well capitalised or nascent manufacturers in high-resource settings as well as in low-income countries. Financial incentives can be created to guarantee appropriate returns on manufacturers’ investments. Knowledge transfer can also be considered to ensure affordable prices.

Organisations that have been successful in fostering development of diagnostics for global health should collaborate to leverage their respective resources and expertise, thereby enhancing the likelihood of development of HCV diagnostics. A broad coalition of stakeholders such as diagnostic-focused product-development partnerships, donors, governments, WHO, and Ministries of Health, among others, will be needed. This approach was taken in the Ebola outbreak and should shorten the development timeline for a successful test. Product-development partners have already embarked on this path in other settings and should be encouraged to do so for HCV.

Unfortunately, in the absence of a concerted effort to fund HCV diagnostics, the global health community will find itself faced with little effect of the development in treatment options and an ever-increasing morbidity and mortality from HCV that will drain the scarce resources that low-resource countries have for the health of its citizens. CMD is employed by the Foundation for Innovative New Diagnostics (FIND), a non-profit organisation that collaborates with industry partners for the development, assessment, and demonstration of new diagnostic tests for poverty-related diseases. MK is the chairman of FIND.

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