



Prequalification of the First Rapid Diagnostic Hepatitis C Virus Test: The World Health Organization

Dear Editor,

Hepatitis C is a viral disease manifesting in both acute and chronic forms, with its severity ranging from mild to serious and long-term illness.¹ The available global estimates indicate that on an average 140 million people are having the chronic infection and close to 0.7 million people die annually from the disease-related complications like liver cirrhosis or malignancy.^{1,2} However, it has been observed that close to 30% of the infected persons clear the virus in a span of 6 months without taking any treatment whereas the remaining develop the chronic infection.¹

Regardless of the severity of the disease and its associated complications, the global response to contain the infection was very much incomplete until the introduction of the direct-acting antivirals.¹ Since then, we have access to drugs which can cure almost 95% of the infections completely within 2–3 months of the treatment, without exposing them to adverse side effects of the previous therapies.¹ Nevertheless, the main challenge is to improve its access to people as the treatment is not affordable, predominantly for those who are from higher- and middle-income nations.^{1,3} Even though various strategies (namely, issuing licenses to generic manufacturers, successful negotiation for cost reduction, etc.) have been tried successfully to reduce the price of drugs in low-income nations, similar gains have not yet been achieved for higher-income nations.³

To improve the response to the infection, the World Health Organization (WHO) formulated a global health sector strategy for the next 5 years starting from 2016, with a prime focus on improving the diagnosis and access to treatment for all.^{1–3} Although progress has been made on the treatment front, with regard to diagnosis of the disease, only few rapid tests were available in the market, which also had the limitation of being too expensive or less reliable.^{1,4} However, for the very first time, the WHO has prequalified a rapid diagnostic test-SD Bioline hepatitis C virus (HCV) for the infection, which will facilitate the process of detection of HCV in low-resource settings and in improving treatment access.⁴

It is a defining step in the global battle against the disease, as we already have extremely effective medicines available for the infection, and only area which required investment was to have an effective, quality-assured, and affordable diagnostics.⁴ The newly prequalified test is a point-of-care diagnostics and is quite useful in low-resource settings with scarcity of testing

laboratories or trained staff.⁴ The test can be performed by health workers with minimal training, and the results are available in <20 min and are expected to enhance the opportunity of getting cured from the infection by promoting early diagnosis and then linkage with appropriate therapy.^{1,4} Moreover, there is no requirement for hospital settings or electricity for performing these tests.⁴ Nevertheless, the limitation of the product is that it has not been validated for infants or children till date and so it cannot be used among them.⁴

To conclude, the act of prequalification of a rapid diagnostic test for hepatitis C will prove to be a crucial milestone in the global mission to eliminate hepatitis and will help program managers immensely in containing the situation in the low-resource settings.

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Conflicts of interest

There are no conflicts of interest.

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