DOI: 10.7860/JCDR/2026/87754.24452

Review Article

Public Health Section

Point of Care Diagnostics for Hepatitis B and C in Low-resource Settings: A Narrative Review

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ABSTRACT

Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) continue to be major public health challenge especially in Low- and Middle-Income Countries (LMICs), with poor laboratory capacity and the ability to detect the disease earlier and contribute to its management. Proper and timely diagnosis is crucial for clinical intervention and global elimination. The present narrative review explores the potential for the use of Point-Of-Care (POC) testing to enhance the testing of HBV and HCV in low-resource settings. Peer-reviewed literature, global health reports, and grey literature were reviewed to assess the state of the art of POC technologies, diagnostic performance, and implementation in resource-limited settings, as well as new developments. Existing challenges and future opportunities for improving access to timely and effective HBV and HCV diagnosis are also pointed out. New technologies and features, such as mobile healthcare integration, Artificial Intelligence (AI)-powered interpretation, and self-testing, enhance their capabilities. There are still areas of challenge, including uneven policy adoption, supply chain issues, and social stigma, that make it difficult to scale. POC diagnostics have the potential to accelerate hepatitis elimination by improving access to rapid testing. Their successful implementation requires strengthened health systems, trained healthcare workers, and integration into existing healthcare services.

Keywords: Health care, Hepatitis B virus infection, Point-of-care testing, Resource-limited settings

INTRODUCTION

The HBV and HCV are important health challenges that are central contributors to chronic liver disease with cirrhosis and Hepatocellular Carcinoma (HCC) worldwide [1]. The World Health Organisation (WHO) estimates that there are about 254 million chronic HBV and 50 million HCV infections, which translates to 304 million people all around the world. New infections per year fell from three million in 2019 to 2.2 million in 2022 (1.2 million HBV, 1 million HCV) but death rates from viral hepatitis have doubled, accounting for approximately 1.3 million deaths per year and now ranking it as one of the top three most lethal infectious diseases after TB and HIV [2].

The burden is borne by LMIC, especially sub-Saharan Africa, South Asia, Eastern Europe, and Latin America. The challenges there include a lack of diagnostic facilities, knowledge of medicine and the skills of doctors and technicians, and poor access to treatment. The diagnosis rate for HBV and HCV is still very low, with 13% of people with HBV diagnosed and 36% with HCV [3] and the rate of treatment is 3% of HBV diagnosed individuals and 20% of HCV diagnosed individuals.

In LMICs, many conventional diagnostics, such as Enzyme-Linked Immunosorbent Assays (ELISA) and Nucleic Acid Testing (NAT), involve procedures that are expensive, require multiple skilled staff members, are time-consuming, and rely on cold chain systems that are absent and inadequately maintained in most settings [4]. By comparison, POC diagnostics will provide a breakthrough alternative. These are tools that can be used to achieve the criteria laid out by the WHO (Affordable, Sensitive, Specific, User-friendly, Rapid/robust, Equipment-free and Deliverable) to be able to do decentralised testing and fill diagnostic gaps [5].

Integrating POC diagnostics with interventions outside of specialised health systems, such as HIV, TB, and antenatal care, in remote areas enables by scaling up these diagnostics for task shifting and enhancing non-loss to follow-up outcomes [6]. Their contribution to better access together with their shortcomings, are essential to the WHO targets on the elimination of viral hepatitis by 2030 [7].

MATERIALS AND METHODS

The present narrative review used a rigorous search strategy using electronic databases Pubmed/MEDLINE, Google Scholar to identify literature published in the past ten years on HBV and HCV POC diagnostics in LMICs. The search strategy included Medical Subject Headings (MeSH) and free-text search terms and terms relevant to resource-limited settings, including “POC testing,” “POC diagnostics,” “diagnostic performance,” and “elimination models”. Studies reporting on diagnostic accuracy, feasibility and/or clinical outcomes of POC modalities in LMICs, published in English only, and those reporting solely on laboratory-based modalities (e.g., ELISA or central NAT) were excluded.

The Evolving Landscape of Point-of-Care (POC) Diagnostics for Viral Hepatitis

Poor surveillance and limited diagnostic capacity remain major barriers to viral hepatitis control, particularly in LMICs. Rapid Diagnostic Tests (RDTs) are the frontline diagnostic tools that are widely used and include both Hepatitis B Surface Antigen (HBsAg) and anti-HCV antibody RDTs [8]. These assays have high diagnostic performance with specificities usually over 98% and sensitivities depending on the assay, specimen type and population tested. Pooled sensitivity and specificity for HBsAg RDTs were found to be ~90% and ~99.5%, respectively, and for anti-HCV antibody RDTs it was found to be ~97% and ~99% respectively, suggesting the utility of anti-HCV antibody RDTs for decentralised screening strategies [9]. Similar performance has been observed in field settings in countries such as The Gambia and Ghana using both serum and whole blood samples. However, the primary challenges lie not in test performance but in systemic barriers such as limited healthcare access, inadequate infrastructure, and insufficient workforce training [10,11].

Evidence from Vietnam further highlights additional barriers, including low awareness, stigma, complex care pathways, inadequate counselling, poor healthcare access, and high treatment costs, all of which hinder timely diagnosis and linkage to care [12].

Traditionally, hepatitis diagnosis has relied on centralised molecular testing, often leading to delays. Recent advances in near-patient molecular platforms, such as cartridge-based systems enable rapid nucleic acid detection within a single device. These technologies support same-visit diagnosis and clinical decision-making improving linkage to care, treatment initiation, and retention particularly among high-risk and underserved populations, while facilitating integrated "test-and-treat" models [13,14].

Hepatitis B (HBV)

Although initially patient tests should focus on HBsAg levels, the measurement of HBV Deoxyribonucleic Acid (DNA) is very important for disease staging and determining when to start treatment, with viral load criteria (such as >20,000 IU/mL) being the basis for treatment decisions [15]. Real time PCR is still very sensitive but if it is used in decentralised locations, many of the costs of its implementation and the necessary infrastructure prevent its widespread use.

Near patient, viral load platforms based on Electrochemiluminescence (ECL) cartridges provide both qualitative and quantitative results using a minimal amount of technical expertise and turnaround time. Research done in Uganda shows that costs are comparable to other centralised systems and turnaround times are shortened [16], while implementation in Ethiopia has provided the opportunity to carry out clinical decisions on the same day despite some challenges including poor availability of stock and difficulties in logistics [17].

Cost-effectiveness evidence indicates that sustainability of decentralised diagnostics improves when integrated with high-volume programs such as HIV and Tuberculosis (TB), where shared infrastructure and testing demand enhance efficiency [18]. The demonstrated performance of decentralised molecular platforms for HIV viral load testing supports the technical feasibility of extending similar platforms to HBV DNA testing [19]. However, further HBV-specific clinical validation and implementation studies are required before widespread decentralised adoption.

Hepatitis C (HCV)

In the case of HCV, antibody detection is the first, and most important step, in the diagnosis process, which means someone has had or is infected with HCV. RDTs can take 20 to 50 minutes, and are based on lateral flow immunoassays, with samples from oral fluid, whole blood, serum, or plasma. They are widely available, have high sensitivity (97-100%) and specificity (~99%) and are WHO pre-qualified [20]. Utilisation of oral-fluid tests has increased the acceptability of the tests in community environments and amongst high-risk groups (e.g., People Who Inject Drugs (PWID) and individuals in correctional facilities [21].

Antibody-based tests are not able to differentiate past infection and current illness, however, so there is the need for confirmatory testing. HCV core antigen (HCVcAg) testing has been evaluated as a simplified alternative to HCV Ribonucleic Acid (RNA) testing for the diagnosis and monitoring of active HCV infection. In a retrospective cohort study by Lamoury FMJ et al., (2017), out of 92 participants, the assay demonstrated high concordance with HCV RNA detection, with a baseline sensitivity of 94% (95% Confidence Interval (CI): 88-98%) and specificity ranging from 98% to 100%. HCVcAg levels showed a strong correlation with HCV RNA concentrations and accurately identified post-treatment virological recurrence. These findings support HCV core antigen testing as a reliable, cost-effective, and scalable approach for HCV diagnosis and monitoring, particularly in settings where access to molecular testing is limited [22].

The ability to perform testing at far-flung locations, especially with portable platforms, has increased access of molecular diagnostic approaches and allowed for testing of plasma and serum, as well as Dried Blood Spots (DBS). Newer assays based on capillary blood are easier to perform and make venous blood samples unnecessary. But scalability and cost optimisation is still a challenge [23].

Rapid antibody-based testing, complemented by near-patient molecular confirmation, enables same-day diagnosis and contributes towards a rapid linkage to care and treatment initiation, an important step to advancing towards hepatitis elimination targets. There has been some success in expanding numbers of people that can be tested, but some loss of sensitivity has been reported with alternative testing methods such as capillary blood and oral fluid testing. Improved performance of the assays and new detection platforms are thus needed to improve diagnostics and preserve the benefits of decentralised testing [24].

Field Performance Challenges in LMICs

Although validation studies have been performed well, there are several variables that could affect the reliability of the test in field conditions. These include:

Temperature and Humidity: Lateral Flow Assays (LFAs) are extensively employed in POC Testing (POCT) in which performance is strongly affected by environmental factors such as temperature and relative humidity. Research has demonstrated that for nucleic acid assays, maintaining controlled conditions of 55-65°C and 70-90% relative humidity is much more sensitive than ambient conditions, while for antigen assays, controlled conditions of 37-40°C and similar humidity levels are much more sensitive than ambient conditions. Portable temperature–humidity control devices can then enhance the reliability and quantitative performance of the LFAs in POCT [25].

Specimen Quality: The quality and quantity of the specimen collected may influence the accuracy of RDTs. When people are dehydrated, have advanced immunosuppression, or low viral antigen or antibody levels, there may be lower amounts of analytes detected in oral fluids and in samples taken from their finger prick. This may result in less sensitivity testing.

However, research in Sub-Saharan Africa, India and Southeast Asia indicates that, if used in a well supervised setting with appropriately trained personnel, RDTs can be sensitive and specific with a value of more than 90%. High quality of RDTs is essential to ensure good performance in field. Proper storage methods, such as using dry boxes and moisture-proof packaging, help avoid damage to test components from humidity, dust, and environmental factors. External Quality Assessment Schemes (EQA), Proficiency Testing Programs (PT) and routine operator training are also important for minimising operator error and the accuracy and consistency of diagnostic testing in healthcare facilities and reference laboratories [26].

Models of Implementation in Low-Resource Settings

Low-resource settings are characterised by limited provisions for health services, limited capacity to conduct laboratory testing, limited health workers, and insufficient funds, which all limit the ability to access tests and treatments in a timely fashion [27]. To overcome these obstacles, flexible and community-based strategies for POC diagnostics are required for HBV and HCV. Mobile health technologies, task shifting and health systems integration have shown to increase screening rates, lower attrition rates, and improve linkage to services [28]. Results from various environments illustrate the extent to which these strategies are effective and challenging. Service integration and case detection of HCV in India were related to high-risk groups in which case detection rose, but there were gaps in linkage to the confirmatory RNA test and treatment [29]. Egypt's hepatitis C elimination program demonstrated that strong political commitment, nationwide screening, decentralised healthcare services, and affordable direct-acting antiviral treatment can effectively achieve high treatment coverage and cure rates. However, the program required substantial financial resources, robust healthcare infrastructure, and sustained surveillance to maintain elimination gains, which may limit its scalability and long-term

sustainability in resource-constrained settings [30]. Decentralised POC strategies also worked well in sub-Saharan Africa to increase access to rural populations, but had been hindered by a number of problems such as low molecular testing capacity, limited funding, and disruptions in supply chains. Overall, these results suggest that the performance of POC diagnostics is not solely dependent on the quality of the analytical test; health systems need to have solid performance in terms of affordability, continuity of services and in quickening diagnostic-to-treatment pathways [31].

Mobile Clinics and Outreach Testing

The Mobile Health Clinic (MHC) model is one approach that is an effective way to expand hepatitis C services to underserved and high-risk populations. It helps to address barriers of care access, transportation, lack of health insurance, and stigma, while ensuring linkage to care and treatment completion, through community-based screening, diagnosis, treatment and follow-up. This patient-focused, decentralised strategy provides a scalable framework in the context of promoting equitable elimination of hepatitis C, especially in hard-to-reach and resource-limited communities [32]. Structural evidence emerged on Egypt's "educate-test-treat" approach that showed that screening more than 200,000 people with strong linkage to care was possible, thus providing proof of the potential of integrated outreach models. Nevertheless, this approach requires effective governance, central purchasing and financial commitment, along with support from the health system to be sustainable, making health system support important to long-term sustainability [33].

Task Shifting to Community Health Workers (CHWs)

Shifting tasks to trained non-specialist workers is a primary approach to reach more people with HBV and HCV testing in resource-limited areas. With appropriate training and supervision, Community Health Workers (CHWs) can effectively perform RDT-based screening in both rural and urban areas. CHWs can also enhance community engagement, test uptake, and post-test services because of their presence and credibility in communities, which can have additional benefits for improving diagnostic accuracy. Task-shifting has been successfully applied in several hepatitis C integrated care models to expand service delivery beyond specialist-based care. In Rwanda and Cambodia, trained nurses and non-specialist healthcare workers delivered simplified HCV screening and treatment services through HIV centres and rural health facilities, improving access in decentralised settings. Malaysia further demonstrated the effectiveness of task-shifting by enabling healthcare workers to provide same-day test-and-treat services for people who inject drugs. These models highlight that empowering trained non-specialist providers can increase treatment coverage, reduce healthcare burden, and support hepatitis C elimination, particularly in underserved communities [34]. According to WHO, task shifting, supported by structured training, job aids and external quality assurance systems, will keep diagnostic standards and will ensure the effectiveness of programs. 95% of the 30 programs reviewed focused on non-specialist providers and 70% of the programs reviewed covered the entire continuum of hepatitis services, supporting the capacity of the workforce to provide services at the community level. 20% of the trainings conducted online were developed for LMICs, thus highlighting the need for more context-specific trainings to support viral hepatitis elimination [35].

Incorporation of Modern and Existing Disease Control Programs

Incorporation of diagnostic services for diseases, such as HBV, HCV, HIV, TB, maternal health, into existing (or new) programs currently in place to improve efficiency and scalability in resource constrained environments is well understood. During periods of disruption, integration of diagnostic services with existing healthcare programs enables the shared utilisation of critical infrastructure components, including sample transportation systems, data management platforms, and outreach networks. This integrated approach contributes to cost reduction, enhances operational efficiency, and minimises interruptions in diagnostic service delivery [36].

The consolidated guidelines for HIV, viral hepatitis and STIs WHO 2022 call for an integrated public health response for people with HIV, viral hepatitis and STIs particularly with key populations such as people who inject drugs, sex workers and people in prison. The value of decentralised diagnosis is underscored, as is the role of connecting patients to services for the quality of their care, in communities with gaps [37] where early detection of disease can be achieved through decentralised diagnostic tools like POC diagnostics.

In recent years, maternal uptake of rapid HIV, syphilis and HBsAg testing in the form of multiplex or "three in one" RDTs have been found to have a positive impact on maternal RDT uptake and detection of viral infections that can be transmitted vertically, particularly in Southeast Asia and sub-Saharan Africa [38]. The synergies increase the efficacy of using resources and improve the ability to deliver coordinated comprehensive care pathways, however, the implementation of these synergies needs to be supported by training the workforce, coordination and ongoing support in a programmatic context.

Barriers to Effective Deployment

While POC diagnostics have the potential to increase access to HBV/HCV testing in LMICs, many challenges exist that can hinder scalability and sustainability. The five defined barriers occupy policy, regulatory, logistic, social, and economic sections [39].

Policy and Regulatory Gaps

Policy and regulatory barriers are one of the major barriers to the POC diagnostic use in LMICs. In many countries, viral hepatitis is not adequately prioritised in national health strategies, and hepatitis diagnostics is not sufficiently included in national biosecurity or essential diagnostic lists, or procurement processes.

Valuation requirements, import barriers and procurement delays present regulatory obstacles to access of WHO prequalified diagnostic technologies. Furthermore, there are no standardised guidelines for confirmatory testing, QA, or post market surveillance, which results in variations in how diagnostics are being applied to situations. Alignment of national policies and international efforts must be strengthened, and the regulatory process must be made easier to ensure better access to hepatitis diagnostics equally [40].

Problems with the Supply Chain

Trustworthy systems in the supply chain are key to sustainable use of POC diagnostics. LMICs have reported stock-outs, poor forecasting and procurement systems, and challenges to transporting supplies to decentralised and remote communities are common.

Countries like South Africa, Uganda, Ethiopia, Mozambique and Zambia have found inefficiencies, including the lack of effective diagnostic services, such as fragmentation in procurement, competition for limited resources, and poor diagnostic distribution systems. Poor inventory management at primary health care leads to low availability of tests and wastage due to test expiry, loss of program effectiveness [41]. The findings indicate that the same types of supply chain issues may constrain opportunities to access hepatitis diagnostics in other health systems with similar structures. Building coordinated supply chains and linking procurement activities across disease programmes are key to access security.

Acceptance and Awareness of Community

Lack of uptake of HBV and HCV testing at community level is hampered by stigma, misconceptions and fear. These are the issues that are associated with the perceived connection to injection

drug use or sexual transmission. Research conducted among immigrants from Southeast Asian, Pacific Islands, sub-Saharan Africa and the Caribbean communities found low levels of hepatitis B and liver cancer awareness, which may have been a factor in low rates of diagnostic screening. Stigma and misunderstanding about the disease were important factors in delaying testing and early detection of disease, which underscored the need to create culturally responsive education to increase uptake in hepatitis screening programmes. Culturally targeted education, community leader involvement and awareness building activities to address misinformation and stigma are important to help facilitate community acceptance [42].

Cost Sustainability

RDTs are typically less expensive than traditional ELISA and PCR tests, but the cost of initiating POC hepatitis programs also involves the cost of training the workforce, quality assurance, sample transport, and confirmatory Nucleic Acid Amplification Testing (NAAT). There have been a number of cost-effectiveness studies which demonstrate that decentralised POC testing models can improve the healthcare for the patient, reduce loss to follow-up and result in earlier POC diagnosis and treatment. This can lead to savings over time in terms of health care costs, particularly for HCV infection. Confirmatory NAAT is, however, very expensive and not widely available in many LMIC countries. Likewise, dependence on outside donor funding will be associated with concerns about the sustainability of hepatitis testing programs. This highlights the importance of negotiated pricing, government support, and the incorporation of hepatitis services into existing healthcare systems [43].

New Technologies in Point of Care (POC) Diagnostics for HBV and HCV

New technologies in diagnosis are quickly moving from centralised laboratory services to community-based testing for hepatitis. Current innovations have largely concentrated on improving diagnostic accuracy and reducing infrastructure needs, as well as embedding diagnostics into existing health systems and, especially in LMIC countries.

Smartphone-enabled Diagnostic Platforms

The use of smartphones to read the results of RDTs decreases the variability of the tests among operators and enhances the quality of LFA results. Early research demonstrated the automation of test interpretation, the provision of ease to digital reporting and the possibility of real-time disease tracking with mobile phone readers [44]. Meanwhile, self-testing approaches are starting to emerge as valuable tools to drive up hepatitis screening uptake. In Vietnam a study showed that OFS was highly accepted and had high agreement with health workers' test results [21]. However, issues like regulatory approval, quality assurance, and connecting patients to care remain critical factors for widespread use.

Home-based Diagnostics, Self-Testing

In recent years, HIV self-testing has proven to be effective in advancing the distribution of HIV testing and, following this, other self-testing programs have been developed and are currently in use for HBV and HCV. While the regulatory pathways and quality assurance systems are still being developed, hepatitis self-testing has significant potential to increase uptake of testing, earlier diagnosis and linkage to care among vulnerable and hard-to-reach populations. The WHO recommends HCV Self-Testing (HCVST) as a complementary approach to existing facility- and community-based testing services, enabling individuals to test themselves conveniently and confidentially. HCVST has the potential to improve testing coverage. among key populations, underserved communities, and individuals reluctant to access conventional healthcare services. Nevertheless, self-testing is only the first step, and individuals with reactive results should undergo confirmatory testing for active infection followed by timely linkage to treatment and care. Effective implementation of HCVST requires supportive national policies, quality-assured and affordable test kits, community participation, appropriate user education, and flexible service delivery models that reflect local healthcare needs [45]. By addressing existing diagnostic barriers, HCVST can strengthen hepatitis C screening programmes and contribute significantly to global elimination efforts.

Artificial Intelligence (AI)-assisted Diagnostics

The use of Artificial Intelligence (AI) is underway to improve the performance of POC diagnostics in terms of its ability to be more scalable and accurate. The image of the LFA can be captured by using a smartphone; in such cases, machine learning algorithms can be used to enhance the detection of faint test lines and improve overall sensitivity. AI can also aid in clinical decision-making, by identifying high-risk patients and optimising testing protocols [46]. Although promising, broad validation and implementation assessments, especially in resource-poor settings, with regulatory approval and cost-effectiveness, both of which have yet to be completed, are needed.

CONCLUSION(S)

The POC diagnostic tools represent a paradigm shift for diagnosis and management of HBV and HCV in LMICs, where access to conventional lab services is still lacking. The data presented in this review suggest that RDTs and decentralised molecular platforms offer high levels of diagnostic accuracy and benefit in earlier diagnosis, same-day clinical decision making and faster linkage to care. They are also integrated into existing HIV, TB, antenatal and primary healthcare programs, thus increasing their feasibility, cost-effectiveness and service delivery. Smartphone-assisted interpretation, AI, multiplex assays and self-testing have the promise of increasing access to hepatitis screening and monitoring even more in recent advancements. While the effectiveness of diagnosis is important, it is not enough; building the capacity of health systems, ensuring sustainable financing, maintaining viable supply chains, and training health personnel as well as engaging in supportive national policy and community engagement are essential to address issues of availability, accessibility, affordability and stigma.

The POC diagnostics should be viewed not merely as diagnostic tools but as a key component of integrated, patient-centred hepatitis care. Building up health systems and implementing innovative, affordable and decentralised diagnostic approaches will play a key role in ensuring equitable access to hepatitis services and help catalyse action toward WHO 2030 hepatitis elimination targets.

Authors' contribution: RA was responsible for the conceptualisation and design of the narrative review, literature collection, screening of relevant articles, and drafting of the manuscript. SG contributed to the screening of literature, manuscript drafting, and critical review of the content. AS was involved in reviewing the manuscript, proofreading and improving clarity and coherence. All authors read and approved the final manuscript.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Feb 15, 2026
- Manual Googling: Jul 23, 2026
- iThenticate Software: Jul 25, 2026 (2%)

ETYMOLOGY: Author Origin

EMENDATIONS: 8

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? No
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jan 28, 2026**
Date of Peer Review: **Feb 26, 2026**
Date of Acceptance: **Jul 28, 2026**
Date of Publishing: **Oct 01, 2026**