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Diagnostics for Hepatitis E in India (2018–2025): Current Gaps and Future Innovations.

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Abstract: Hepatitis E Virus (HEV) is a major contributor to acute hepatitis worldwide, particularly in Asia and Africa. This contribution of hepatitis is from the high- to low-resource regions; as a result, the diagnosis is often delayed, leading to severity, especially in vulnerable populations such as pregnant women. This review mainly focused on the current strategies for HEV diagnosis and recent technological advances, with the goal of identifying the diagnostic gaps in innovation in high-burden countries such as India. This study reviewed the scientific literature (PubMed, PMC) from 2018 to 2025, focusing on diagnostic technologies, global guidelines, and surveillance strategies. Anti-HEV IgM and HEV RNA remain the most prominent and widely used for the diagnosis of HEV. However, there are challenges associated with diagnostic advances, including variability in test sensitivity, lack of standardized algorithms, and limited access to molecular assays. Innovations such as virus-like particle (VLP)-based assays, point-of-care molecular tests, and the integration of HEV diagnostics into the WHO's REASSURED framework offer promising directions. Advances in HEV diagnostics often come from a unified protocol, rapid testing tools, and national policies that are needed to address under-diagnosis and late detection, especially in endemic regions.

I. INTRODUCTION

Viral hepatitis remains a major global health problem around the world, and hepatitis E virus (HEV) has become one of the main causes of sudden viral hepatitis in many developing areas. The World Health Organization estimates approximately 20 million HEV infections annually worldwide, with tens of thousands of associated deaths [1]. This problem is mostly observed in South Asia, Southeast Asia, and parts of Africa below the Sahara Desert. This is due to environmental issues, economic struggles, and problems with healthcare, which lead to repeated health crises [2].

Studies from India indicate that HEV contributes substantially to cases of acute viral hepatitis and is responsible for a majority of waterborne hepatitis outbreaks [3,4]. The infection mostly affects weak groups, especially pregnant women. In these women, HEV infection can lead to severe liver failure and high mortality rates, ranging from 20 to 30% [5]. Individuals with weak immune systems, such as those who have undergone organ transplants, are at risk of developing long-lasting HEV infections, which complicates disease management [6].

Precise and convenient determination of HEV is pivotal for clinical administration, episode discovery, and open health observation. Currently, the symptomatic tool stash incorporates serological tests recognizing anti-HEV IgM, IgG, and antigen, as well as nucleic acid amplification tests for HEV RNA [7,17]. However, despite these alternatives, there are noteworthy challenges. Serological measures regularly endure from inconstancy in execution due to contrasts in antigens and commercial pack plan, whereas atomic diagnostics, in spite of the fact that they are profoundly particular, costly and restricted to reference research facilities [9,10]. In addition, India needs a bound together national symptomatic calculation for HEV, resulting in demonstrative irregularity in healthcare settings [11].

Between 2018 and 2025, a few advancements were made to address these gaps. Virus-like particle (VLP)-based measures have improved test specificity, whereas point-of-care atomic tests have been developed as promising instruments for fast field-level conclusions [12,13]. The World Health Organization (WHO) Consoled framework emphasizes diagnostics that are Real-time, Simple, Reasonable, Delicate, Particular, User-friendly, Fast, Equipment-free, and Deliverable and offers a worldwide standard for directing HEV symptomatic development [14]. However, the integration of such progress into India’s well-being framework remains limited.

This review looks at how HEV (Hepatitis E Virus) is diagnosed in India between 2018 and 2025. This review critically evaluates the ongoing problems and suggests new ideas that could improve the tracking and treatment of the disease. We examine India's

diagnostic problems in the context of global progress and suggest ways to connect new ideas with real use in places where diseases are common. .

II. Review of Literature

In the late 1970s and the early 1980s, India first recognized hepatitis E virus (HEV) as a cause of water-related hepatitis outbreaks. In 1983, Balayan and colleagues analyzed stool samples from ailing patients and identified the virus for the first time using an electron microscope [16]. In a span of ten years, scientists achieved partial cloning and sequencing of the HEV genome, which facilitated the establishment of the first diagnostic tests for detection [13]. Prior to the development of these tools, physicians relied on the symptoms presented by patients and the transmission patterns of illnesses. serological assays have brought greater significance to markers including IgM and IgG. When someone is infected, IgM anti-HEV becomes detectable relatively quickly, aiding in the identification of new infections. Generally, it is present in the body for around 3 to 4 months, but occasionally it can endure for as long as a year. Despite these improvements, India continues to grapple with significant challenges in testing and diagnosis. Although IgM/IgG ELISA tests are the most frequently utilized serological assays, their performance can differ greatly depending on the brand [22]. Studies from hospitals have demonstrated that the percentage of patients with acute hepatitis who test positive for IgM varies from 18% to 78%. This emphasizes the variability and absence of uniform quality assurance in testing procedures [17].

In contrast, detection of HEV RNA using tests such as RT-PCR is considered the optimal approach [13,22]. These tests are crucial for patients with weakened immune systems and transplant recipients because of the possibility of insufficient antibody responses. Due to their high cost, the necessity for specialized equipment, and limited availability, these tools are primarily utilized in major urban hospitals. This situation delays the rapid detection of outbreaks and amplifies fears surrounding the safety of transfusions [23]. Globally, advancements in tools for health testing and diagnosis have increased. According to the World Health Organization (WHO), diagnostic tests must meet the **REASSURED criteria**: real-time, affordable, sensitive, specific, user-friendly, rapid, equipment-free, and deliverable [1]. Innovative and captivating breakthroughs consist of tests that incorporate virus-like particles (VLPs) [12]. These evaluations are more reliable and produce fewer false alerts. Likewise, basic tests such as LAMP and RPA can swiftly yield results without the need for complex laboratory equipment [14].

In India, the Integrated Disease Surveillance Programme (IDSP) primarily relies on IgM ELISA tests for monitoring, with nucleic acid tests being utilized infrequently [18]. Emerging techniques, including mobile testing devices and CRISPR applications, are being designed for implementation in settings with limited resources [11]. It is vital to strengthen the Virus Research and Diagnostic Laboratory (VRDL) network to ensure more reliable testing, track disease patterns, and address outbreaks promptly [21]. Overall, serological assays are the key approach for identifying HEV in India; however, their dependability can be questionable.

Molecular methods are much more precise, but they are not widely used. In order to resolve this challenge, India should establish clear national testing guidelines, enhance quality control processes, and integrate new technologies into its public health programs [1,17,18,21,22,23].

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III. Methodology

This review focused on research conducted from 2018 to 2025 to evaluate the approaches used for diagnosing Hepatitis E Virus (HEV) in India. We examined large-scale databases like PubMed and PubMed Central (PMC), together with authoritative reports from the World Health Organization (WHO) and India's National Viral Hepatitis Control Program (NVHCP). The significant phrases searched for were "HEV diagnosis," "IgM ELISA," "RT-PCR," "point-of-care testing," and "India."

Only studies that addressed the precision of tests, their role in the Indian healthcare system, or novel concepts such as virus-like particle tests, accessible molecular testing, and CRISPR detection methods were included. Articles that did not focus on diagnosis or were published before 2018 were omitted.

A detailed examination and comparison of the selected studies were conducted, considering critical factors such as the precision of condition identification (sensitivity), reliability in avoiding false positives (specificity), cost implications, ease of access, and applicability in everyday scenarios. Although not HEV-specific, the WHO REASSURED framework provides a useful benchmark for evaluating diagnostic tools in resource-limited settings [14,15].

Among the various methods evaluated, reverse transcriptase polymerase chain reaction (RT-PCR) has emerged as the optimal option for detecting active infections, as it effectively identifies HEV RNA in blood or stool specimens. However, as shown in previous studies, its use in hospitals in India is limited because it requires advanced laboratory equipment and skilled workers. This suggests that it is predominantly found in major hospitals in urban areas [10,18]. In contrast, rapid diagnostic tests (RDTs) are regarded as effective instruments because of their straightforward and timely nature. However, various studies have emphasized that increased testing is required in India prior to the regular application of these tests for monitoring [14,15].

According to the comprehensive results of this review, there are still significant barriers to obtaining molecular testing, a deficiency in standardized diagnostic methods, and challenges in timely disease detection in rural and low-resource settings. For effective management of HEV in India, experts have proposed improving established testing methods, advancing national quality efforts, and consistently reviewing quick testing systems to ensure accurate tracking and prompt patient assistance. [12,14,17,18,19,21].

A total of studies published between 2018 and 2025 were screened based on title and abstract. After applying inclusion and exclusion criteria, relevant articles focusing on HEV diagnostic performance, accessibility, and innovation were included for qualitative analysis.

IV. Result And Findings

Findings from studies conducted between **2018 and 2025 indicate the positive and negative aspects of current diagnostic approaches for Hepatitis E Virus (HEV) in India.**

4.1 Diagnostic Accuracy Vs Utilization

An evaluation of several tests demonstrated that molecular techniques, especially reverse transcriptase polymerase chain reaction (RT-PCR), are extremely precise in diagnosing illnesses. RT-PCR is considered the reference standard for HEV diagnosis because of its high analytical sensitivity and specificity [10,17]. These evaluations are essential for verifying whether a person is experiencing an active infection. Individuals with compromised immune systems and expectant mothers are particularly vulnerable and can become very ill, making these measures essential [5,6]. RT-PCR tests tend to be restricted to prominent city hospitals and specialty laboratories because of their significant cost, the need for specific equipment, and the requirement for trained staff [8,18].

In contrast, Serological assays remain the most widely used diagnostic tests for HEV in India, while molecular testing is limited to select centers [18]. Despite their low cost and ease of access, their performance can fluctuate considerably depending on the type of kit used. Hospital studies have revealed that the rate of patients with acute viral hepatitis who have positive results for anti-HEV IgM can differ greatly, with figures spanning from 18% to 78% [19]. This highlights the inconsistencies in testing reliability and the deficiency of standardized quality assessments across laboratories [18,19].

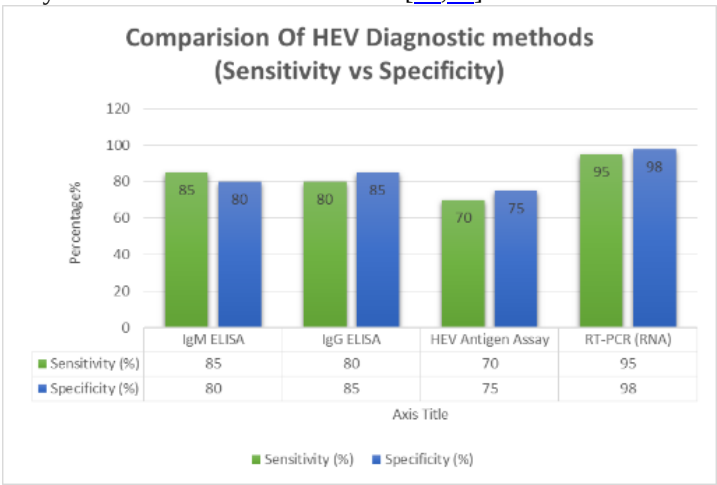

figure 1 comparison of sensitivity and specificity across hev diagnostic methods (rt-pcr, elisa, and rdts).
Source:Compiled by authors based on published literature (WHO 2021; Kamar et al. 2019; Ahmed et al. 2015).

4.2 Current Gaps in Diagnostic Practices

In India, the focus on blood testing contributes to the difference between what can be identified through diagnostics and what is effectively utilized in practice. Although molecular methods are very accurate, Only a minority of suspected HEV cases undergo RT-PCR testing [18]. The absence of a standardized national diagnostic approach exacerbates these discrepancies. This situation has led to several missed cases, postponed outbreak confirmations, and inconsistent surveillance data among various states [19]. Furthermore, since blood banks are not obligated to perform tests for HEV RNA, there are growing concerns about the safety of blood transfusions [8,18].

Despite the availability of blood and genetic tests, their combined utility is limited because there is no uniform method for diagnosis. Figure 4.2 presents a novel diagnostic approach featuring rapid tests, additional assessments, and RNA detection procedures. This systematic approach seeks to decrease the number of overlooked cases and ensure uniformity in diagnoses nationwide [1,4,7,18].

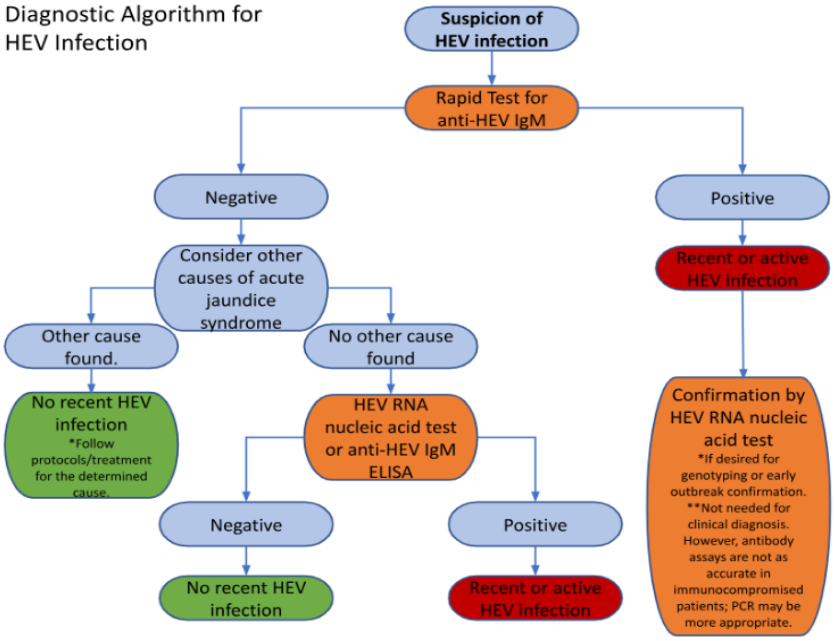

figure 2 Proposed diagnostic algorithm for HEV infection.
adapted by authors based on who and nvhcp diagnostic guidance (1,4,18)

Rapid tests that detect anti-HEV IgM can aid in the early identification of potential cases. Confirmatory tests using HEV RNA tests or ELISA are beneficial, particularly in outbreak situations, to pinpoint virus types and aid patients with weakened immune responses. Based on the recommendations provided by the WHO and national health organizations for the diagnosis of HEV [1,4,7,18].

In addition to the absence of a standardized approach, resource sharing is challenging. Figure 3 illustrates the testing methods employed in India, showing that serological tests are more prevalent than molecular diagnostic methods [18,19].This lack of balance illustrates the need for strategic policies to provide equitable access to advanced testing in a range of healthcare environments.

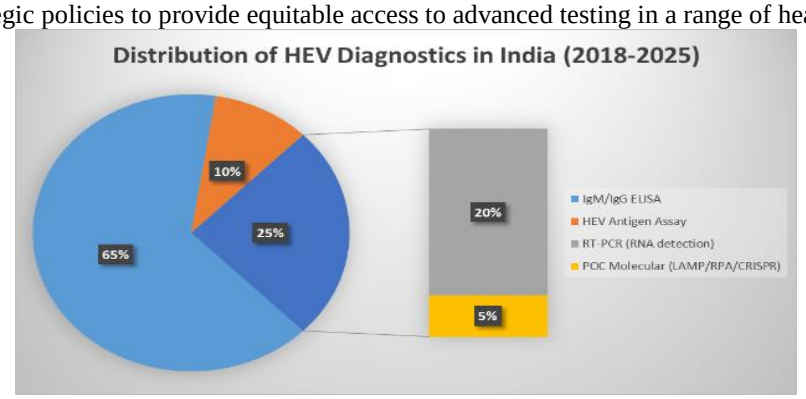

figure 3 Diagnostic usage trends in India (2018–2025): proportion of testing using ELISA, RT-PCR, and other methods.
Source: Compiled by authors based on published literature (NVHCP; Aggarwal & Goel 2021; Indian Surveillance Data (2014–2017))

Without timely and significant reforms, India risks overlooking instances of HEV, discovering outbreaks too late, and experiencing preventable fatalities among vulnerable populations, such as pregnant women and those with compromised immune systems.

4.3 Emerging Diagnostic Innovations (2018–2025)

From 2018 to 2025, a variety of cutting-edge technologies were developed to help resolve these problems. ELISA kits that utilize virus-like particles (VLPs) are more effective because of their resemblance to actual viruses. This approach allows for the targeted detection of the appropriate virus while lowering the chances of errors, such as false positives, which can occur with outdated tests [20]. Likewise, molecular tools for point-of-care (POC) testing, including LAMP and RPA, facilitate swift detection in clinical settings without the need for complex laboratory apparatus [21]. This significantly helps satisfy the diagnostic needs of rural communities in India. Researchers are developing novel CRISPR testing methods. Due to their affordability, ease of transport, and high sensitivity, they are well suited for community health assessments [22]. Recent proposals are in accordance with the WHO REASSURED standards for tests. In other words, the tests are designed to be available in Real-time, Easy, Affordable, Sensitive, Specific, User-friendly, Rapid, Equipment-free, Deliverable [1,14]. Nevertheless, their integration into India's public health system remains minimal, with slow and inconsistent advancement.

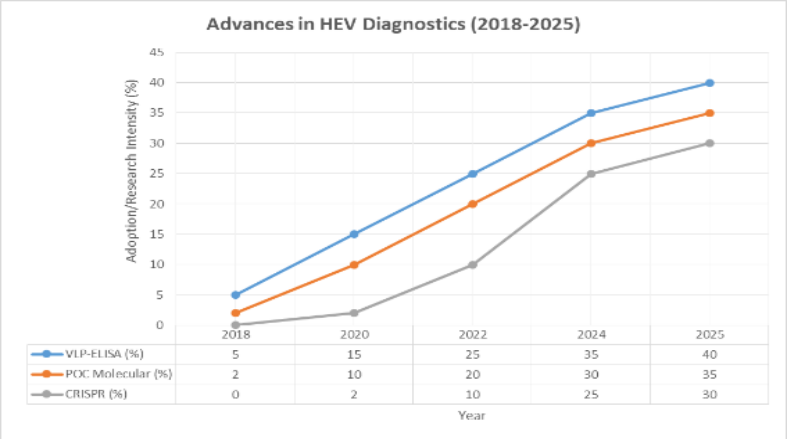

figure 4 Emerging diagnostic innovations for HEV (VLP-based ELISA, POC assays, and CRISPR platforms) and their alignment with the WHO REASSURED criteria.
Source: Compiled by authors based on published literature(WHO 2018–2022; Kanda et al. 2024; POC & VLP studies 2020–2021)

Diagnostic Method	Sensitivity	Specificity	Cost	Infrastructure Requirement	Field Applicability
ELISA (IgM/IgG)	Moderate	Low Moderate	Low	Basic lab (widely available)	High (but variable accuracy)
RT-PCR	High	High	High	Advanced molecular labs, trained personnel	Low (urban tertiary centers only)
VLP-based ELISA	High	High	Moderate	Moderate lab setup (under validation)	Moderate (not yet scaled)
POC/CRISPR assays	High	High	Low–Moderate	Minimal; portable kits possible	High (suitable for rural & low-resource settings)

Table 1. Comparison of HEV diagnostic methods (ELISA, RT-PCR, VLP-based ELISA, and POC/CRISPR assays) in terms of sensitivity, specificity, cost, infrastructure, and field-applicability.
Source: Compiled by authors based on published literature (WHO 2021; Aggarwal & Goel 2021; NVHCP data; Kanda et al. 2024; POC & VLP studies, 2020–2021).

4.4 Conclusive Evidences from Literature

This Review has demonstrated that although diagnostic technology has improved worldwide, India still grapples with various issues. There is an over-reliance on serological assays in the country, coupled with a lack of adequate quality control and a deficiency in conducting advanced molecular testing [18,19,20]. This review highlights the necessity of promptly establishing a national framework for HEV diagnosis, boosting the capacity to perform molecular tests in areas that are not within city limits, evaluating and enhancing rapid diagnostic tests (RDTs) and point-of-care (POC) instruments used for health monitoring in rural regions, and integrating innovative technologies such as VLP and CRISPR into the NVHCP framework [19,20,21]. Failure to implement these actions will make early disease detection and rapid outbreak identification difficult. Those at risk, especially expectant mothers and individuals with weakened immune systems, remain exposed to the danger of severe illness or even death as a result of this [5,6,18].

V. Discussion

Hepatitis E Virus (HEV) presents a major health challenge worldwide, especially in developing countries like India, which still faces ongoing cases and outbreaks. The occurrence of Hepatitis E Virus (HEV) varies significantly across different locations worldwide. In regions such as South Asia, Africa, and parts of the Middle East, significant outbreaks often arise from polluted drinking water [1, 3]. India's experiences with substantial outbreaks, such as the Kanpur epidemic, reveal the urgent need to improve sanitation and ensure the availability of clean drinking water to mitigate these risks [3].

Globally, HEV genotypes 1 and 2 exclusively affect humans and frequently lead to outbreaks in low- and middle-income countries. In comparison, genotypes 3 and 4 can infect humans from animals, predominantly through the consumption of improperly cooked pork and other animal sources [2]. The dual pattern of disease spread introduces varied management challenges because of the differing reasons for transmission in wealthier versus poorer communities.

Pregnant women are vulnerable to serious health risks, as HEV infection can lead to acute liver failure and increased mortality rates for both the mother and her baby [5,20]. While the factors that lead to heightened risks during pregnancy remain somewhat ambiguous, it is generally believed that hormonal fluctuations and immune system alterations have an impact [20].

The difficulty in diagnosing HEV stems from the inconsistent effectiveness of the currently available tests. Although serological tests, such as anti-HEV IgM, serve as valuable screening tools, they can produce ambiguous outcomes due to the lack of standardization between different testing kits [7,8,9]. Reverse transcriptase PCR is the optimal choice for virus testing, especially for identifying recent infection [7,10]. However, the elevated price and scarcity of this resource hinder its application in locations with limited resources [10,14]. Recent advancements in immediate hepatitis virus testing have enabled a greater number of individuals to undergo testing. However, issues persist, such as elevated costs, a lack of available resources, and the difficulty of incorporating these tests into healthcare systems [14,15].

The World Health Organization has indicated the importance of strengthening testing capacities and has added HEV testing to its list of vital tests [15]. This highlights the need for trustworthy, economical, and flexible testing tools that can be applied in a range of situations. The Indian Ministry of Health and Family Welfare has initiated programs such as the National Viral Hepatitis Control Program (NVHCP) to enhance disease monitoring and facilitate diagnosis and treatment in individuals [4]. Additional aid is being offered through the network of Virus Research and Diagnostic Laboratories established by the Indian Council of Medical Research [21].

Although India primarily relies on serological assays and has a small supply of RT-PCR tests, numerous other nations have established structured strategies for the diagnosis and management of HEV. New health protocols have just been introduced in Japan. These recommendations emphasize the importance of conducting early disease screenings, utilizing ribavirin for prolonged cases, and establishing a defined protocol for diagnosing patients of various demographics [20]. This systematic process guarantees equal detection and treatment of cases for everyone, especially for individuals with vulnerable immune systems. Countries within the European Union, including the United Kingdom, France, and Germany, have initiated testing of blood donations for HEV

RNA.As a result, the risk of spreading HEV through blood transfusions has been greatly diminished [13,19]. These initiatives address a significant issue within India's system, as blood banks are not mandated to conduct HEV RNA testing, despite evidence indicating potential risks associated with blood transfusions [18]. Concurrently, China has enhanced its capabilities not only in disease diagnosis but also in prevention, as evidenced by its approval of the world's first HEV vaccine (HEV 239, Hecolin). Large-scale trials showed the vaccine works really well, and it is now being used for people who are at higher risk [12]. India has faced several outbreaks of HEV but still doesn't possess a vaccine for it. These international insights emphasize the importance of India developing a comprehensive national strategy that incorporates accurate testing, safe blood practices, and sustainable prevention measures. Failing to take these steps will result in us overlooking critical issues, particularly affecting vulnerable populations such as pregnant women and those with weakened immune systems [5,6].

Treatment options for HEV are scarce because the infection often clears up naturally [2,8]. In treating chronic conditions, ribavirin has proven somewhat effective, especially among patients with weakened immunity and those who have undergone transplants [6]. However, the treatment guidelines continue to undergo revisions. Recent medical guidelines in Japan have begun to include the use of ribavirin treatment and propose testing protocols for different patient populations [20].

The most effective course of action continues to be implementing preventive strategies. Ensuring clean water, proper sanitation, and good hygiene is essential for minimizing the spread of HEV in areas where it frequently occurs [1,13]. Scientists are exploring the use of virus-like particles (VLPs) in vaccine development, with preliminary results indicating promising efficacy [12]. While the HEV vaccine known as HEV 239 is authorized and utilized in China, it is not readily available in many parts of the world [13]. This indicates that we must enhance the processes of vaccine development and distribution [12,13]

In conclusion, we have acquired extensive knowledge regarding HEV infection trends, their health ramifications, how to identify the virus, and preventive measures, yet there remain crucial areas that warrant additional research.There is a need to make medical tests uniform, improve access to healthcare in low-resource settings, protect mothers' health, and enhance the adoption of vaccines.It is essential to prioritize these objectives without delay.It is essential to partner with governmental health programs, global agencies, and research institutions to effectively control HEV worldwide.

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