

## Editorial

### Fast pacing India's fight against viral hepatitis: Targets & action points

Viral hepatitis (VH), particularly hepatitis B (HBV) and hepatitis C (HCV), present significant public health challenges in India, contributing substantially to chronic liver disease (CLD), cirrhosis, and hepatocellular carcinoma (HCC)<sup>1</sup>. In response to Sustainable Development Goal 3.3 of eliminating VH as a public health threat by 2030, the Government of India launched the National Viral Hepatitis Control Program (NVHCP) in 2018 as a comprehensive initiative offering free diagnosis and treatment for HBV and HCV infections<sup>2</sup>. Significant progress has since been made under NVHCP in establishing screening, diagnosis, and treatment centres across the country. However, we are still nowhere near the initial commitment. Achieving this ambitious target necessitates the development of a comprehensive approach unique to the Indian context and implementing effective strategies to overcome inherent challenges. This editorial, on the occasion of the World Liver Day 2025, assesses the burden of these chronic viral infections of the liver, and examines the status of India's VH elimination initiatives, key challenges hindering their progress and strategic recommendations to strengthen the fight against VH, in line with the latest global guidelines.

#### The problem statement in India

Viral Hepatitis (VH) remains a leading cause of liver disease in India, significantly contributing to cirrhosis and liver cancer cases<sup>3</sup>. According to NVHCP data, the overall population prevalence of hepatitis B virus (HBV) in India is 0.95 per cent (confidence range 0.89-1.01%), with certain States reporting prevalence rates above the national average. HBV infection is more prevalent in rural areas. The hepatitis C virus (HCV) prevalence of 0.32 per cent (confidence range 0.28-0.36), has a predilection for urban areas. These estimates are based on samples collected during the 2015-16 National Family Health Survey-4<sup>4</sup>. Given the time elapsed, there is a pressing need for updated

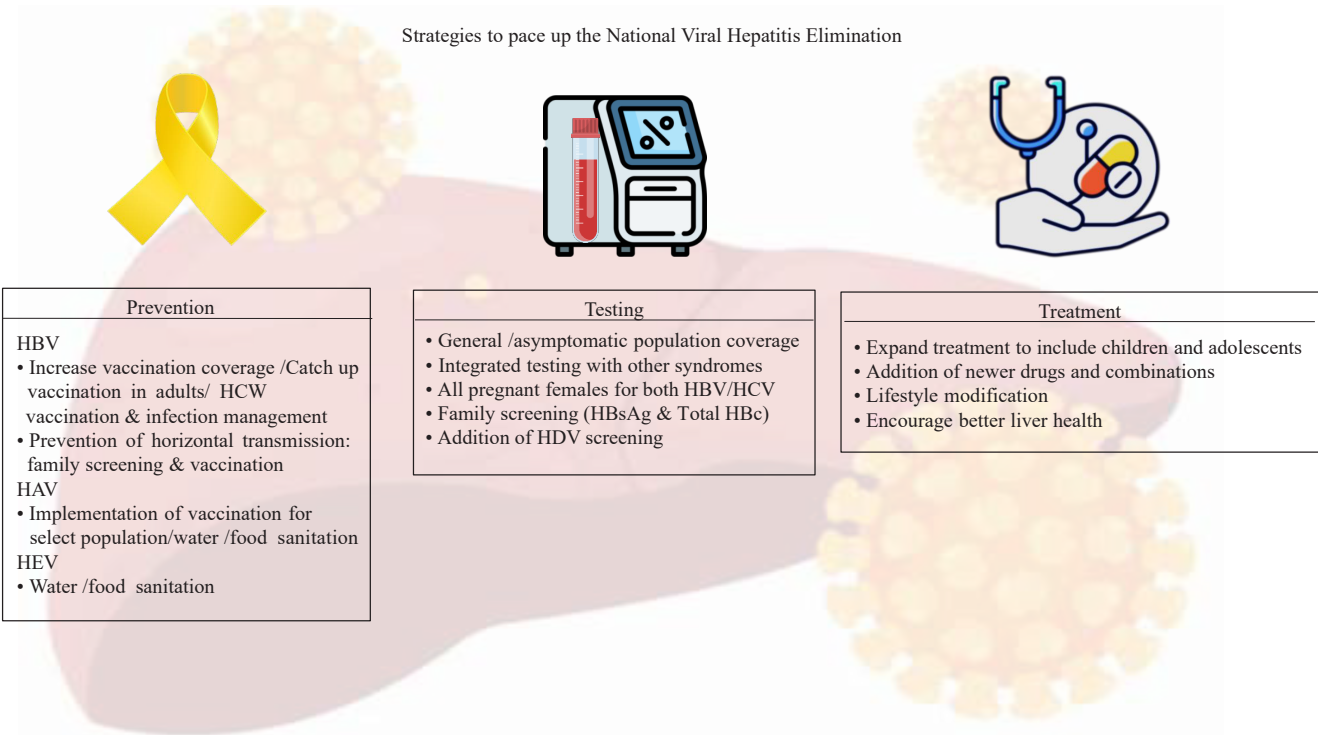
assessments and fresh data collection at a pan-India level.

As per the recent World Health Organisation (WHO) Global Hepatitis Report 2024, India has around 29 million individuals with HBV and 5.5 million with HCV infection, placing it second among the top 10 countries with the highest burden of infections. The report also notes that half of these chronic HBV and HCV infections are in the adult (30-54 age group) and about 12 per cent occurring in children<sup>5</sup>. Thus, there is an urgent need to prioritise the diagnosis and management of HBV/HCV infections in children.

WHO guidelines (2022) for HCV include new recommendations regarding treatment expansion to all children aged three years and older with pan-genotypic direct-acting antivirals (DAAs). This update acknowledges the safety and efficacy of DAAs in younger populations, facilitating earlier intervention to prevent long-term health complications<sup>6</sup>. The new updated WHO Guidelines for HBV (2024) have expanded treatment eligibility to include adolescents aged 12 and over. The guidelines also recommend reflex HBV DNA testing and the use of point-of-care HBV DNA tests, wherever available. Recognising limited access to HBV DNA testing in certain settings, the guidelines provide options for initiating treatment based on alternative criteria without the need for HBV DNA testing<sup>7</sup>. Adapting these new guidelines in the National Program will surely enhance testing and treatment coverage.

Both HBV and HCV infections are well-established risk factors for the development of a hepatocellular carcinoma (HCC) and add significantly to the aetiological fraction for HCC cases in India<sup>8</sup>. HBV infection can lead to liver cancer even in the absence of cirrhosis<sup>9</sup>. For other causes of HCC, the presence of cirrhosis is usually a prerequisite for cancer development. Liver cirrhosis has a multi-factorial aetiology, including alcohol associated and/or non-

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**Figure.** Strategies to pace up the National Viral Hepatitis Elimination. HBV, hepatitis B virus; HAV, hepatitis A virus; HEV, hepatitis E virus; HDV, hepatitis D virus; HCW, healthcare workers; HBsAg, hepatitis B surface antigen; HBc, hepatitis B core. [Source: Internet, copyright free images as declared by the authors].

alcoholic fatty liver disease/cryptogenic chronic liver disease (CLD)<sup>10</sup>. A fair number of the latter are due to occult HBV, a rather underdiagnosed condition in India<sup>11</sup>. Therefore, VH-screening should be broadened to the general population as well as inpatients with liver cirrhosis by other causes.

Hepatitis A virus (HAV) and Hepatitis E virus (HEV) infections remain significant public health concerns in India, with changing epidemiology for both the infections. HEV infection mostly appears as outbreaks and sporadic cases and has recently shown a declining trend. However, HAV infections in the last decade have shown a more severe and fulminant trend, especially in adolescents and young adults<sup>12</sup>. Therefore, the diagnosis of HAV and HEV infections, epidemiological trends, and vaccination strategies all need to be addressed.

**Strengthening India's efforts to eliminate viral hepatitis**

Since its launch, NVHCP has made commendable progress in establishing diagnosis and treatment centres nationwide. However, India's vast population with its widespread distribution across remote and distant locations further complicate the situation,

making achieving stated goals highly challenging. In order to accelerate our progress towards achieving the 2030 goals, we must identify the gaps and adopt recent care strategies. We must consolidate our efforts and advance with a multi-sectoral approach (Figure), especially for the elimination of HBV against which vaccines are available.

**Gaps in screening and diagnosis**

Currently, the VH screening is offered at the limited sites defined under the programme; mostly symptomatic patients approach these sites. General population-based screening approaches should be adopted. Screening should be expanded to more decentralised sites and rural areas utilising point-of-care (POC) tests for serological and molecular testing. Recently, the WHO has recommended several new strategies to increase the diagnostic reach, including POC molecular assays, dried blood spot (DBS) testing, and reflex testing. HCV POC viral load Nucleic Acid Testing (NAT) presents a viable alternative to laboratory-based HCV viral load assays, particularly for marginalised populations<sup>13</sup>. Promoting the development and usage of self-testing kits and POC diagnostic devices will add momentum to this direction. In July 2024, WHO prequalified

**Table.** A structured approach to address key challenges in India's viral hepatitis control efforts

Limitations	Gap	Suggested methods to fill the gaps
Limited treatment coverage	In both HBV & HCV infection the treatment is being offered to adult patients	Expand coverage to children & adolescent age groups Introduce newer drugs & combination therapies to improve treatment outcomes Treat all concept in HBV
Lack of universal testing	Testing is offered to patients coming to healthcare facility	Implement nationwide screening programmes with free or subsidised tests Integrate hepatitis testing into routine healthcare check-ups General population-based screening Universal screening in adults $\geq 18$ yr All pregnant females should be screened for both HBV as well as HCV
Absence of point-of-care molecular testing	Delay in patients' enrolment into the programme & being initiated on treatment	Reflex viral load testing should be implemented (lab/clinic based) without the need to have more patient's visit Treatment & testing sites should be nearby One stop-shop for all the tests Point-of-care molecular testing devices should be provided
Gaps in viral hepatitis prevention	Prevention for HBV is by vaccination but integrated with the national immunisation programme	HBV vaccination should be a part of the NVHCP Catch vaccination drive in children should be done Adult vaccination drive should start especially in healthcare workers Counselling services in high risk group patients to prevent re-infection & horizontal spread of infection
Shortage of specialist workforce	Treatment is offered by trained doctors, lack of doctors in remote areas	Train non-specialist healthcare workers to provide care in un-complicated cases Referral of complicated cases to specialised centres should be faster Develop task-sharing models to optimise healthcare delivery

HBV, hepatitis B virus; HCV, hepatitis C virus; NVHCP, National Viral Hepatitis Control Program

the first HCV self-test, the OraQuick HCV self-test, aiming to improve the test-access and support global efforts to eliminate HCV-disease<sup>14</sup>. DBS collection for remote sample processing is also an economical option to decentralise testing to increase patient enrolment in care, encourage reflex viral load testing (lab- or clinic-based), to reduce multiple visits to health care settings, ensure timely treatment, and prevent loss to follow-up. Newer innovations in testing, along with integrated approaches, should be evaluated in our national context and then used to increase their uptake (Table)<sup>15</sup>.

Screening for HBV and HCV should be expanded. New recommendations in the United States (US) include HBV screening using three laboratory tests at least once during a lifetime for adults aged  $\geq 18$  yr: hepatitis B surface antigen (HBsAg), antibody to HBsAg (anti-HBs), and total antibody to HBcAg (total anti-HBc)<sup>16</sup>. This will increase the detection of HBV cases in asymptomatic populations.

Vertical transmission of both HBV and HCV to foetuses and newborns during pregnancy and parturition results in chronic infection. HBV is universally screened during pregnancy, whereas routine screening for HCV during pregnancy is not mandatory in India. A systematic review has reported a global median anti-HCV prevalence of 1.2 per cent

(range:0.1-70.8%) among pregnant females, with 66.1 per cent (range: 61.3-77.2%) of them with active Viremia<sup>17</sup>. Internationally, many professional bodies have recommended universal screening for HCV in all pregnant females<sup>18</sup>; hence, extension of screening for HCV in pregnant females should be started in the country.

At present, the programme runs only in government-run sites, whereas large patient populations are in the private sector. Therefore, involvement of the private sector in intensifying the screening should be encouraged, or at least a common portal for data collection should be initiated.

### Challenges in management

Current treatment guidelines primarily focus on adults, with limited attention to the paediatric population. This oversight delays the diagnosis and treatment of hepatitis in children and adolescents. The latest WHO guidelines expand HCV and HBV treatment to children and recommend simplified treatment protocols with the use of innovative methods<sup>7,8</sup>. There is a need to update country-specific treatment guidelines, make simplified treatment protocols, and train healthcare providers on simplified treatment protocols. Treatment accessibility remains a challenge in India, particularly in rural areas.

Limited participation from private sector hospitals further hampers these efforts. Many individuals with HBV or HCV remain undiagnosed for years, leading to advanced liver disease before seeking medical attention. Empowering the non-specialist workforce in dispensing medicines, monitoring treatment adherence, and using telemedicine services to provide remote consultations, especially in underserved areas, can help address these problems.

In our primary study in the State of Delhi, on decentralised testing for HCV infection done across five hospitals and 15 primary health centres, we demonstrated that a one-stop shop for all the modalities has a better potential to retain maximum patients in the cascade of care<sup>19</sup>. Establishing one-stop hepatitis care centres at the primary healthcare level could help attain NVHCP targets.

*Treat all strategy:* Present guidelines recommend treatment for non-cirrhotic HBV infected individuals based on the level of ALT elevation, high HBV DNA, and/or significant liver fibrosis. Unfortunately, these guidelines presume ALT elevation as a marker for inflammation and persistently undetectable HBV DNA as a marker of viral inactivity. Therefore, many asymptomatic patients with HBsAg positivity remain untreated, and remain at the risk of developing advanced liver disease, HCC, and also contribute to the horizontal transmission of infection. Enough evidence is available to support ‘treat all’ approach<sup>20</sup>. This will decentralise the treatment implementation from the hands of specialists to the hands of general practitioners and even healthcare workers (HCWs). Furthermore, it will help reduce the pool of HBV sources by continuously suppressing HBV DNA, reducing the emergence of new cases, and eliminating HBV from India. When we have adopted the policy of treating all cases of HIV, HCV, and TB, why not treat all cases of chronic HBV? India needs to make this its far-reaching new policy for HBV elimination. Research into curative therapies for HBV must also be prioritised, as current treatments do not provide a definitive cure<sup>21</sup>. Evaluation and provision of newer drugs for both HBV and HCV infection should be added to the programme.

### Challenges in prevention

Preventive measures, including vaccination and harm reduction strategies, remain underutilised in India. Although a universal HBV vaccination programme exists, birth-dose coverage is inconsistent,

particularly for home births. Needle-sharing among people who inject drugs (PWID) and unsafe medical practices continue to drive new infections. Mother-to-child transmission remains a major concern, yet antenatal screening and preventive antiviral therapy for expectant mothers are not universally implemented. Despite India's Universal Immunization Programme (UIP), HBV vaccine coverage remains inadequate – between 2015 and 2016, approximately 45 per cent of children aged 12 to 59 months had not received the vaccine, leaving them vulnerable to infection<sup>22</sup>. There are no uniform practice guidelines available in India for the management and prevention of HBV and HCV in pregnant women<sup>23</sup>. Recently, WHO has recommended tenofovir prophylaxis from the 28<sup>th</sup> wk of gestation until delivery for all HBsAg-positive women with a viral load  $\geq 200,000$  IU/ml to prevent vertical transmission of HBV<sup>24</sup>.

HCWs face a continuous risk of acquiring infections from bloodborne viruses (BBVs) due to occupational exposure. To mitigate this risk, HBV vaccination should be mandatory for all HCWs, with post-vaccination serologic testing to confirm immunity and ensure adequate protection. The anti-HBs levels should be monitored in HCWs every five yr. It is unfortunate that a fair number of HCWs have not taken the booster dose or got their anti-HBs levels tested<sup>25</sup>. This is unacceptable and should be mandated. Under the national programme, HBV vaccination, anti-HBs estimation, and hepatitis B immunoglobulin (HBIG) should be made available in all healthcare settings. Additional strategies, including catch-up vaccination for children and adult immunisation, should be encouraged. Moreover, the national guidelines should incorporate screening for HBV/HCV infections at workplace entry and provide clear protocols regarding exposure-prone procedures and ethical work practices. Currently, these measures are lacking, and pre-employment testing for HBV/HCV is often misused as a discriminatory employment practice rather than a means of ensuring workplace safety.

Along with HBV, prevention of other VH like HAV and HEV should also be incorporated under the programme. Given the severity of HAV infection in adults, implementing adult vaccination strategies for HAV should be prioritised wherever feasible.

### Enhancing public awareness

Increased awareness is crucial for improving prevention, testing, and treatment uptake. Stigma, lack of knowledge, and limited healthcare-seeking



behaviour hinder early diagnosis. Expanding educational campaigns and community outreach can encourage timely testing and treatment. Programmes like EMPATHY (Empowering People Against Viral Hepatitis), an initiative of the Institute of Liver and Biliary Sciences (ILBS) has provided a voice to the people living with hepatitis, supporting their cause for equal rights and status in the society. Community engagement remains crucial in such and other similar initiatives.

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**Ekta Gupta<sup>1</sup> & Shiv Kumar Sarin<sup>2,\*</sup>**

Departments of <sup>1</sup>Clinical Virology, & <sup>2</sup>Hepatology,  
Institute of Liver and Biliary Sciences,  
New Delhi 110 070, India

*\*For correspondence:*  
e-mail: shivsarin@gmail.com

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