

# National viral hepatitis control program in India: Call for update

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## ABSTRACT

Viral hepatitis is a serious yet manageable and preventable public health menace that infects about 3 million of people and leads to 1.1 million deaths worldwide every year. An acute episode of viral hepatitis usually subsides on its own, however, if not intervened timely, chronic infection puts people at risk of cirrhosis, liver cancer, and eventually death. In 2015, the global community allied to tackle viral hepatitis, as a result of which combating viral hepatitis target was included in the sustainable development goals (SDGs), and the World Health Organisation (WHO) constituted the first-ever global health sector strategy on viral hepatitis for 2016 to 2021 which is also renewed recently. Conforming to the global commitment, India launched the National Viral Hepatitis Control Program in the year 2018 with the aim to eliminate viral hepatitis as a public health threat by the year 2030. In the Subsequent years, WHO and various other international societies have released updated recommendations with respect to vaccination, prevention of mother-to-child transmission, strategies to increase testing uptake including self-testing, newer diagnostics including point of care and reflex testing approaches, simplified treatment algorithms, expanded treatment eligibility criteria, and simplified service delivery models. With the program being in its fifth year of implementation, there is a need to revamp the operational guidelines based on various global evidence-based advancements in order to attain the ambitious elimination goal by 2030.

**Keywords:** NVHCP, Viral Hepatitis, India

Combating viral hepatitis has been highlighted in the Sustainable Development Goals (SDGs) and has risen up in the global agenda of the World Health Organization (WHO) and the national health agenda of many countries in the last few years. In 2018, India put in place the National Viral Hepatitis Control Program (NVHCP) with the ambitious goal of eliminating viral hepatitis as a public health menace by 2030. NVHCP has its administrative units at the national, state, and district levels, besides, the program envisions delivering service in an integrated manner with primary,

secondary, and tertiary care units as per need. The program has also endorsed the training of pre-existing healthcare workers at all levels with respect to the operational guidelines in a phased manner. Thus, NVHCP is being implemented in a decentralized way with an emphasis on task shifting and an integrated service delivery approach as suggested by WHO.<sup>[1,2]</sup>

With the program being in its fifth year of implementation, there is a dire need to revise the operational guidelines in sync with WHO's recent recommendations on disease management and program implementation. This is an overview of several evidence-based international recommendations that NVHCP can accommodate to reinforce the elimination strategy. In its updated recommendation on the treatment of adolescents and children with chronic HCV infection, and HCV simplified service delivery and diagnostics, 2022, WHO has expanded the 2018

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**Table 1: Summary table of current recommendations NVHCP guidelines and scope of an update as per various recommendations**

Cascade of care	NVHCP, 2018	Scope of update
PMTCT	Integration with routine Antenatal care (ANC) which includes- <ul style="list-style-type: none"> <li>• Optional HBV and HCV screening during ANC<sup>[20]</sup></li> <li>• HBIG Administration to the newborn of all hepatitis B status positive mothers<sup>[1]</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Mandatory HBV screening in pregnant females<sup>[22]</sup></li> <li>• Mandatory HCV screening in pregnant females<sup>[13]</sup></li> <li>• HBIG to the new-born of all hepatitis B status positive and unknown mothers<sup>[23]</sup></li> <li>• HBeAg positivity as an alternative to HBV DNA testing to determine eligibility for Tenofovir prophylaxis<sup>[22]</sup></li> <li>• Tenofovir prophylaxis is from the 28<sup>th</sup> week period of gestation until birth in all HBsAg positive females with a viral load <math>\geq 200,000</math> IU/mL<sup>[22]</sup></li> </ul>
Vaccination	Integration with routine immunization as per National Immunization Schedule <sup>[1]</sup>	Catch-up vaccination in children as well as adults <sup>[23]</sup>
Screening and diagnosis	Laboratory-based assays <sup>[1]</sup> No provision of screening for asymptomatic general population <sup>[1]</sup>	<ul style="list-style-type: none"> <li>• Point of Care assays<sup>[2]</sup></li> <li>• Reflex nucleic acid assay<sup>[2]</sup></li> <li>• Dried Blood Spot (DBS) specimens<sup>[2]</sup></li> <li>• HCV self-testing<sup>[14]</sup></li> <li>• Combination fingerstick whole blood or oral-based multi-disease assays<sup>[16]</sup></li> <li>• Polyvalent diagnostic platforms for HIV, Tuberculosis, and HCV<sup>[17]</sup></li> <li>• One-time hepatitis C testing of all adults <math>\geq 18</math> years<sup>[13]</sup></li> </ul>
Treatment	All adults living with chronic HCV infection <sup>[1]</sup>	Age $\geq 3$ years old and living with chronic HCV infection <sup>[2]</sup>

“treat all” policy for all adults to now include all adolescents and children of ages three years or older living with chronic HCV infection. The management is advised with the use of the same pan genotypic Direct Acting Antiviral (DAA) regimen as in adults.<sup>[3-7]</sup> To accelerate screening and diagnosis, WHO has recommended strategies such as Point-of-care HCV RNA assay, dried blood spot testing, and reflex testing. The use of HCV Point of Care (POC) viral load Nucleic Acid Testing (NAT) can be a good alternative to laboratory-based HCV viral load assays, more so in the marginalized population.<sup>[8,9]</sup> Reflex HCV RNA assay in people with a positive HCV antibody is now recommended as an additional strategy to promote linkage to treatment. Two possible approaches for reflex testing can be either a laboratory-based reflex HCV RNA testing using a specimen already stored in a laboratory setting or a clinic-based reflex testing in a healthcare facility through immediate specimen collection for HCV RNA assay following a positive rapid HCV antibody test result, thus avoiding the need for a second visit for blood sample collection.<sup>[10]</sup> Use of Dried Blood Spot (DBS) specimens for serological and virological testing is suggested to be considered in settings where there are no means to collect venous whole blood specimens, poor venous access, non-availability of Rapid Diagnostic Tests (RDTs), or there is a lack of access to nearby laboratory facilities for viral load assays.<sup>[9]</sup>

As per the recent WHO recommendation on HCV testing and treatment for people at ongoing risk of infection issued in 2023, HCV retesting can be offered at an interval of 3-6 months to assess viremia after resolved HCV infection among people at an ongoing risk and with a history of treatment-induced or spontaneous resolution of HCV Infection. However, such investigations should be voluntary and offered as an adjunct to primary prevention, diagnostic, and treatment services.<sup>[10-12]</sup> In addition to the recommendation of regular testing offered to people with risk factors, the Centers for Disease Control and

Prevention (CDC) now recommend one-time hepatitis C testing of all adults aged 18 years or older and all pregnant women during every pregnancy.<sup>[13]</sup>

Another proposed plan of action to encourage HCV diagnosis is HCV self-testing (HCVST). According to WHO, HCV self-testing is considered an additional approach to pre-existing HCV testing services, and linkage to care must be ensured. Several feasible HCVST service delivery models are Facility-based, Community-based, and Secondary distribution which includes distribution to partners, social contacts or peers, digital distribution, Retail outlets, pharmacies, vending machines, distribution from faith-based settings, distribution to workers for testing themselves, and their partners as well.<sup>[14]</sup>

WHO has recently brought out a multi-pronged package of interventions with regard to HIV, viral hepatitis, and STI to enable prevention, diagnosis, treatment, and care for the key population. Viral hepatitis-specific strategies in this package include prevention of vertical transmission, hepatitis B vaccination, HBV, as well as HCV diagnosis and treatment.<sup>[15]</sup> The use of a combination fingerstick whole blood or oral-based multi-disease assays facilitates integrated testing of HIV, HBV, and HCV using a single specimen which enhances the efficiency of testing programs, especially in communities with a high prevalence of HIV/HCV or HBV/HCV coinfection.<sup>[16]</sup> In addition, polyvalent diagnostic platforms for HIV, tuberculosis, and HCV bring new opportunities for collaboration, can increase access, and also provide significant system efficiencies, with cost-savings.<sup>[17]</sup> National Program for Surveillance of Viral Hepatitis in association with National Family Health Survey-4 (NFHS 4) has estimated the state-level seroprevalence of Hepatitis B and Hepatitis C; this can be further expanded to estimate district-level seroprevalence for judicious resource mobilization.<sup>[18]</sup>

Unlike HCV, HBV does not have a cure yet. The mainstay of tackling HBV is vaccination, prevention of mother-to-child transmission, and harm reduction in addition to screening accompanied with linkage to care. The Centers for Disease Control and Prevention (CDC) now recommends the use of the triple panel test which comprises of hepatitis B surface antigen (HBsAg), antibody to hepatitis B surface antigen (anti-HBs), and total antibody to hepatitis B core antigen (total anti-HBc) instead of a single test for hepatitis B surface antigen (HBsAg) in the previous guidelines.<sup>[19]</sup> NVHCP has integrated with the pre-established mother and child health services for antenatal screening and child vaccination, as per these services hepatitis B screening is optional during the antenatal period, and in order to reduce the burden of vertical transmission of HBV, it is advised to opt for mandatory antenatal screening for HBV and HCV.<sup>[20,21]</sup> According to the recent WHO Guidelines on antiviral prophylaxis in pregnancy, Tenofovir prophylaxis is suggested from the 28<sup>th</sup>-week period of gestation until birth in all HBsAg positive females with a viral load  $\geq 200,000$  IU/mL to prevent vertical transmission of HBV. Additionally, any pregnant female who meets the standard criteria for HBV treatment should be treated irrespective of the period of gestation. Furthermore, three doses of HBV vaccination must be ensured along with a timely birth dose. In settings where HBV viral load estimation is not possible, HBeAg positivity can be used as an alternative to HBV DNA testing in order to determine eligibility for Tenofovir prophylaxis.<sup>[22]</sup> As per the recommendations on the management of viral hepatitis in China, it is advised to administer HBIG to the newborns of all hepatitis B status-positive and unknown mothers. Catch-up vaccination in children as well as adults along with screening for the general population in settings where health examination does not include scrutiny of Hepatitis B vaccination status before joining school or workplace are several other evidence-based strategies recommended to reinforce viral hepatitis elimination plan.<sup>[23]</sup>

As a means to optimum care, NVHCP may incorporate the aforementioned recommendations and broaden its operational guidelines to actively detect and link high-risk populations to the cascade of care [Table 1]. Such innovative strategies can aid in delivering care to hard-to-reach communities with constrained access to health care and those with high rates of attrition.

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