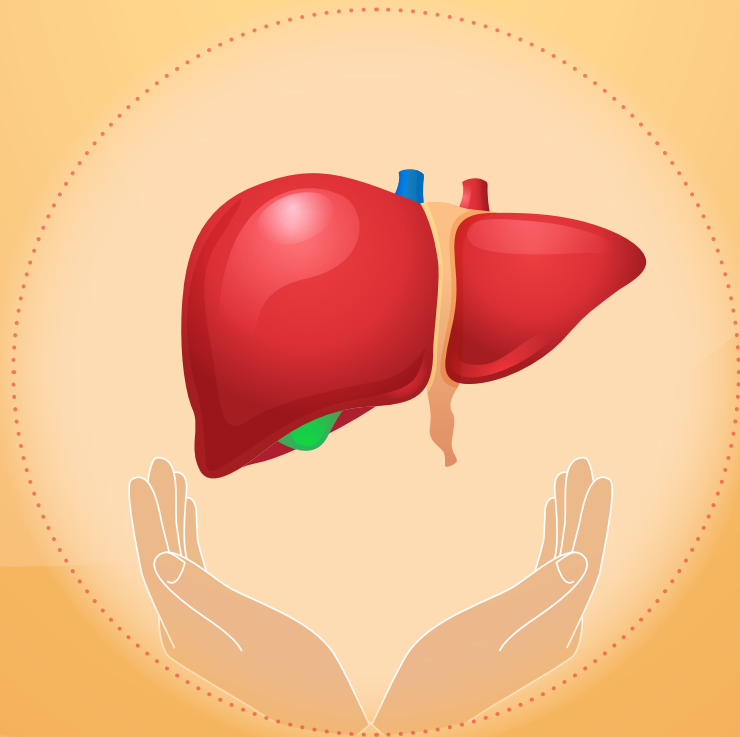




Ministry of Health and Family Welfare  
Government of India



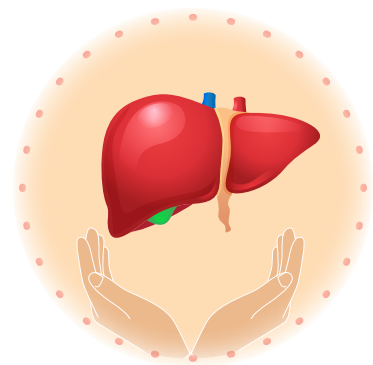
# *National Action Plan* *Combating* **Viral Hepatitis in India**



2019



*National Action Plan*  
*Combating*  
**Viral Hepatitis in India**







**जगत प्रकाश नड्डा**  
**Jagat Prakash Nadda**



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**स्वास्थ्य एवं परिवार कल्याण मंत्री**  
**भारत सरकार**  
**Minister of Health & Family Welfare**  
**Government of India**



**Message**

Viral Hepatitis is recognised as a public health problem worldwide, including India. India is committed to combating the disease in line with the Sustainable Development Goal (SDG) target. The Government of India has affirmed this commitment at the 69<sup>th</sup> World Health Assembly.

2. Achieving this goal will require us to adopt an integrated approach towards all types of viral hepatitis. The time has come for a coherent public health response that prioritises effective interventions and promotes service delivery approaches that ensure quality and equity, to achieve sustained impact at the population level, and establishes clear stakeholder responsibility and accountability.

3. Accordingly, National Action Plan for Viral Hepatitis has been designed to contribute to the attainment of the Sustainable Development Goal. Following the development of the plan, National Viral Hepatitis Control Program (NVHCP) was launched in 2018 under the umbrella of National Health Mission, Union Ministry of Health and Family Welfare. The program proposes to offer free drugs and diagnostics, aiming to benefit an estimated 5 crore patients suffering from chronic Hepatitis B and Hepatitis C infection.

4. It is beyond doubt that this National Action Plan and unstinting guidance and technical support of the experts from across the Country, who have worked very hard towards developing this strategic document, will augment the efforts of National Viral Hepatitis Control Program towards eliminating viral hepatitis from our Country.

(Jagat Prakash Nadda)

New Delhi,  
February , 2019

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भारत सरकार  
MINISTER OF STATE FOR  
HEALTH & FAMILY WELFARE  
GOVERNMENT OF INDIA



### Message

India is proud to come up with National Action Plan for viral hepatitis which provides a holistic approach on various strategies for prevention, diagnosis and treatment of viral hepatitis which the country can imbibe to eliminate viral hepatitis. It discusses the components of prevention related to viral hepatitis already existing under various national health programs/schemes including immunization, injection safety, safety of blood and blood products and harm reduction in key populations. It also illustrates the lacunae prevailing in the system.

As a step further towards combating viral hepatitis, this strategic document has provided as insight to the policy makers towards formulating strategies under National Viral Hepatitis Control Program in alignment with the plan towards significant reduction in morbidity and mortality attributed to viral hepatitis.

I gratefully acknowledge the valuable inputs from the expert group members and other contributors for their collaborative effort to come up with this strategic plan which will enable the nation to move to the path of eliminating viral hepatitis.

  
(Ashwini Kumar Choubey)

New Delhi  
Dated 20 February, 2019

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**अनुप्रिया पटेल**  
**Anupriya Patel**



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भारत सरकार

**Minister of State For  
Health & Family Welfare  
Government of India**



### **MESSAGE**

I am pleased to present the National Action Plan for Viral Hepatitis which highlights the various components related to it including immunization, injection safety, safety of blood and blood products, harm reduction in key populations. It also highlights the need for access to free diagnostics and drugs at point of care based on standardized testing and treatment algorithms which has now been addressed by the rollout of National Viral Hepatitis Control Program.

I congratulate the entire team of experts who have compiled an updated and much required action plan for viral hepatitis for the nation, keeping the experience of other countries into consideration and adapting the plan as per the country's need and situation.

I also take this opportunity to thank all experts who participated in and shaped the development of this landmark strategy for the country. Implementing the robust strategies and detailed roadmap illustrated in this document will enable the nation to walk on the path of reduction in the morbidity and mortality due to viral hepatitis.

We need to make this a reality in every state and district. The success of the plan requires a coordinated, collaborative and sustained approach for viral hepatitis prevention, diagnosis, surveillance, treatment, policy planning and resource mobilization across the country.

  
(Anupriya Patel)





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सचिव

PREETI SUDAN

Secretary



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Department of Health and Family Welfare

Ministry of Health & Family Welfare

Dated: 18<sup>th</sup> February, 2019



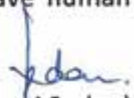
### MESSAGE

Viral hepatitis is a global public health problem of epidemic proportions that caused 1.34 million deaths in 2015 a number comparable to deaths caused by tuberculosis and higher than those caused by HIV. Various etiological agents (hepatitis A,B,C,D and E virus) have been implicated that can lead to acute, chronic or sequel of chronic infection.

In India, the estimated burden of viral hepatitis is very high necessitating focus on prevention and control measures of hepatitis to mitigate the morbidity and mortality due to the infection. There are several components that are existing in the different programs of Government of India like Universal Immunization Program (UIP), Swachh Bharat Mission, safety of blood and blood products, safe drinking water and sanitation, that are directly or indirectly related to the prevention of viral hepatitis.

Antiviral agents active against HBV are available, and have been shown to suppress HBV replication, prevent progression to cirrhosis, and reduce the risk of hepato-cellular carcinoma (HCC) and liver related deaths. The treatment available fails to eradicate the virus in most of those treated, necessitating potentially lifelong treatment. In recent years, there is availability of highly safe, effective oral and pan-genotypic directly acting anti-viral (DAAs) which has revolutionized the treatment and cure of chronic hepatitis C virus infection.

I am confident that the strategies in this national action plan describe priority actions required to be undertaken through National Viral Hepatitis Control Programme conceptualized and launched based on this plan towards combating viral hepatitis such that it can benefit large number of people infected in our country and save them and their families from grave human sufferings.

  
(Preeti Sudan)





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दिनांक/Dated.....

## MESSAGE



Viral Hepatitis B and C can result in chronic infection in a proportion of cases, which can progress to cirrhosis or even liver cancer. Since Viral Hepatitis is a public health challenge in India, the National Action Plan was developed based on the recommendation of the National Steering Committee. The plan includes evidence based strategies that has guided the policy makers to evolve the national Viral Hepatitis Control Programme.

Under the programme effective antiviral drugs available against Hepatitis B and Hepatitis C will be provided free of cost. Although, the treatment duration for Hepatitis C has been defined for duration of 12-24 weeks under the programme, the drugs for Hepatitis B management would be provided lifelong.

There is an effective preventive vaccine against Hepatitis B which is a part of Universal Immunization Programme since almost a decade. The programme proposes providing antenatal screening for Hepatitis B, ensuring prevention of Mother to Child Transmission of Hepatitis B through administration of Hepatitis B immunoglobulin along with birth dose vaccination of Hepatitis B already existing under Universal Immunization Programme. The vaccination for Hepatitis B has been extended to health-care providers and high risk groups against Hepatitis B by virtue of their occupation and behavior. Another important strategy adopted by the programme is propagating the use of re-use prevention (RUP) syringes in the country.

I am confident that the National Action Plan will act as a reference guide to facilitate effective implementation of the National Viral Hepatitis Control Programme.

  
(S. Venkatesh)





**मनोज झालानी**  
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## **FOREWORD**

The "silent epidemic" of viral hepatitis that affects a large part of the world's population is increasingly being recognized as a major public health problem. It is not therefore surprising that control of Hepatitis is one of the SDG-3 targets. In India, the estimated burden of hepatitis is high, necessitating focus on prevention and control measures to mitigate morbidity and mortality arising out of hepatitis.

The National Viral Hepatitis Control Program is one of the groundbreaking actions by Ministry of Health and Family Welfare to combat viral hepatitis. Under the program, thrust on prevention strategies, testing and early diagnosis of hepatitis B (HBV) and C (HCV) infection is a crucial component of an effective response to the hepatitis epidemic. Early identification of persons with chronic HBV or HCV infection will enable them to receive the necessary care and treatment to prevent or delay progression of liver disease. The program will also provide an opportunity to link people to interventions to reduce transmission, through spreading awareness on risky behaviors and advocating the use of prevention commodities (such as Re-use prevention syringes) and hepatitis B vaccination.

I am confident that these guidelines will help in seamless and effective roll out of the Program.

  
(Manoj Jhalani)

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### Preface

The national action plan for viral hepatitis has been developed keeping the global perspective and strategic framework into consideration. Based on the recommendations of this strategic framework document, National Viral Hepatitis Control Program has been designed and launched in 2018 under National Health Mission. Access to quality-assured diagnostics and management services for viral hepatitis in addition to thrust on preventive strategies will remain the hallmark of the program. These services will be scaled up to the lowest level of care through this program.

Many countries have achieved outstanding coverage with the hepatitis B vaccine, scoring an early win for prevention. In India, Hepatitis B vaccine was introduced in the Universal Immunization Program a decade ago. Since healthcare workers and high-risk groups by virtue of their occupation and behaviour are more vulnerable to acquiring infection, it is envisaged to extend the beneficiaries for this vaccine to healthcare workers and high risk groups under the NVHCP. In addition, the program has also provisioned for Hepatitis B immunoglobulin to be administered to newborns of Hepatitis B positive mothers to prevent mother to child transmission.

I take this opportunity to commend all experts and officials involved towards developing the plan for the country for viral hepatitis. I am sure that this would be extremely useful for all stakeholders engaged under NVHCP in understanding their roles in making progress and further augmenting the response to viral hepatitis.

(Vikas Sheel)

# Acronyms

|         |   |
|---------|---|
| ALF     | Acute Liver Failure   |
| AntiHCV | antiHepatitis C virus   |
| APRI    | AST to platelet Ratio index                                     |
| ART     | Anti-Retroviral Therapy   |
| B.Sc    | Bachelor of Science   |
| BCC     | Behaviour Change Communication                                  |
| CBO     | Community Based Organization                                    |
| CDSCO   | Central Drugs Standard Control Organization                     |
| CoE     | Centre of Excellence  |
| CST     | Care, Support and Treatment                                     |
| CT      | Computed Tomography   |
| DAA     | Directly acting anti-viral                                      |
| DMLT    | Diploma in Medical Laboratory Technology                        |
| DOEACC  | Department of Electronics and Accreditation of Computer Courses |
| DSU     | District Surveillance Unit                                      |
| EQA     | External Quality Assessment                                     |
| EQC     | External Quality Control  |
| FEFO    | First Expiry First Out  |
| FSSAI   | Food Safety and Standards Authority of India                    |
| FSW     | Female Sex Workers  |
| GoI     | Government of India   |
| HAV     | Hepatitis A Virus   |
| HBV     | Hepatitis B Virus   |
| HCC     | Hepatocellular Carcinoma  |
| HCV     | Hepatitis C Virus   |
| HDV     | Hepatitis D Virus   |
| HEV     | Hepatitis E Virus   |
| HIV     | Human Immunodeficiency Virus                                    |
| HR      | Human Resource  |
| ICMR    | Indian Council of Medical Research                              |
| ICTC    | Integrated Counselling and Testing Centre                       |
| ICU     | Intensive Care Unit   |
| IDSP    | Integrated Disease Surveillance Program                         |
| IEC     | Information, Education and Communication                        |
| IQC     | Internal Quality Control  |
| IQ      | Installation Qualification                                      |

|       |                                       |
|-------|---------------------------------------|
| M&E   | Monitoring and Evaluation             |
| MLT   | Medical Laboratory Technology         |
| MoHFW | Ministry of Health and Family Welfare |
| MO    | Medical Officer                       |
| MRI   | Magnetic Resonance Imaging            |
| MSM   | Men who have sex with men             |
| MTC   | Model Treatment centres               |
| NACO  | National AIDS Control Organization    |
| NACP  | National AIDS Control Program         |
| NAT   | Nucleic Acid Testing                  |
| NCDC  | National Centre for Disease Control   |
| NGO   | Non-governmental Organization         |
| NHM   | National Health Mission               |
| NPMU  | National Program Management Unit      |
| OQ    | Operational Qualification             |
| OST   | Opioid Substitution Therapy           |
| PIP   | Program Implementation Plan           |
| PQ    | Performance Qualification             |
| PT    | Proficiency Testing                   |
| PWID  | People Who Inject Drugs               |
| RNA   | Ribo-nucleic acid                     |
| RUP   | Reuse prevention                      |
| SACS  | state AIDS control society            |
| SDG   | Sustainable Development Goal          |
| SGPGI | Sanjay Gandhi Post-graduate Institute |
| SPMU  | State Program Management Unit         |
| SSU   | State Surveillance Unit               |
| STI   | Sexually Transmitted Infections       |
| SVR   | Sustained Virological Response        |
| TC    | Treatment Centre                      |
| TG    | Transgender                           |
| TTIs  | Transfusion transmitted infections    |
| UIP   | Universal Immunization Program        |
| WHA   | World Health Assembly                 |
| WHO   | World Health Organization             |

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# **Introduction**

Viral hepatitis is a global public health problem of epidemic proportions that caused 1.34 million deaths in 2015 a number comparable to deaths caused by tuberculosis and higher than those caused by HIV. Infection can be caused by the five known hepatitis viruses – A, B, C, D and E (HAV, HBV, HCV, HDV and HEV). Many of these infections are preventable. Hepatitis B and C are responsible for 96% of overall hepatitis mortality

## I. Magnitude of the problem and high risk areas/groups

### Global Scenario

Hepatitis A and E usually cause acute hepatitis. They are transmitted mostly through exposure to contaminated food or water, or through personal contact with an infected person. WHO estimates that worldwide, hepatitis A caused approximately 11 000 deaths in 2015 (accounting for 0.8% of the mortality from viral hepatitis).

There are an estimated 20 million HEV infections worldwide, leading to an estimated 3.3 million symptomatic cases of acute hepatitis E. WHO estimates that hepatitis E caused approximately 44 000 deaths in 2015 (accounting for 3.3% of the mortality due to viral hepatitis)

Hepatitis B and C are transmitted by unsafe injection practices & through contaminated syringes and needles, infected blood and blood products, sexual transmission, from infected mother to child. Globally, in 2015, an estimated 257 million people were living with chronic HBV infection, and 71 million people with chronic HCV infection.

Among the 36.7 million persons living with HIV in 2015, an estimated 2.7 million had chronic HBV infection and 2.3 million had been infected with HCV. Liver diseases are a major cause of morbidity and mortality among those living with HIV and co-infected with viral hepatitis.

### Scenario in South East Asia Region

According to WHO, the South-East Asian region has an estimated 100 million people living with chronic hepatitis B and 30 million people living with chronic hepatitis C. In this region, viral hepatitis is responsible for an annual estimated 350,000 deaths with 81% of total mortality being attributed to liver cancer and cirrhosis due to hepatitis B and C.

Data on Hepatitis A is limited in the region. Infection with HEV is reported worldwide, but it is most common in East and South Asia.

### Indian Scenario

Viral hepatitis is increasingly being recognized as a public health problem in India.

HAV and HEV are important causes of acute viral hepatitis and acute liver failure (ALF). Due to paucity of data, the exact burden of disease for the country is not established. However, available literature indicates a wide range and suggests that HAV is responsible for 10-30% of acute hepatitis and 5-15% of acute liver failure cases in India. It is further reported that HEV 10-40% of acute hepatitis and 15-45% of acute liver failure.

Based on the prevalence of Hepatitis B surface antigen, different areas of the world are classified as high ( $\geq 8\%$ ), intermediate (2-7%) or low HBV endemicity. India falls under the category of intermediate endemicity zone (average of 4%). Hepatitis B surface antigen (HBsAg) positivity in the general population ranges from 1.1% to 12.2%, with an average prevalence of 3-4%. Anti-Hepatitis C virus (HCV) antibody prevalence in the general population is estimated to be between 0.09-15%. Since India has one-fifth of the world's population, it accounts for a large proportion of the worldwide HBV burden. India harbours 10-15% of the entire pool of HBV carriers of the world. It has been estimated that India has around 40 million HBV carriers. About 15-25% of HBsAg carriers are likely to suffer from cirrhosis and liver cancer and may die prematurely.

Anti-Hepatitis C virus (HCV) antibody prevalence in the general population is estimated to be between 0.09-15%. Based on some regional level studies, it is estimated that there are 6-12 million people with Hepatitis C in India.

Chronic HBV infection accounts for 40-50% of hepatocellular carcinoma (HCC) and 20-30% cases of cirrhosis and chronic HCV infection accounts for 12-32% of HCC and 12-20% of cirrhosis in the country.

Recently, a meta-analysis of studies on hepatitis C prevalence was undertaken by SGPGI, Lucknow. The study documented the pooled prevalence of Hepatitis C amongst various sub populations.

Overall, this systematic review and meta-analyses showed pooled anti-HCV sero-prevalence rates for various groups as follows:

| Studygroup*  | Number of studies included                  | Pooled prevalence [% (95% confidence intervals)] |
|--|---|--|
| Community based studies  | 6*  | 0.85 (0.00-3.98)                                 |
| Groups likely to be fairly representative of community with some limitations | Healthy blood donors                        | 211<br>0.44 (0.40-0.49)                          |
|  | Pregnant women                              | 16<br>1.03 (0.36-1.99)                           |
|  | Other groups e.g, hepatitis screening camps | 8<br>0.61 (0.20-1.20)                            |
| Groups at a higher than usual risk of HCV infection                          | PLHIV                                       | 40<br>3.51 (2.43-4.76)                           |
|  | Maintenance hemodialysis (MHD)              | 37<br>19.23 (13.52-25.65)                        |
|  | PWID  | 46<br>44.71 (37.50-52.03)                        |
|  | Recipients of multiple transfusions         | 38<br>24.06 (20.00-28.36)                        |
|  | Patients with sexually-transmitted diseases | 7<br>4.10 (0.98-9.04)                            |
|  | High-risk sex behavior or sex workers       | 6<br>4.06 (1.79-7.10)                            |
| Special groups   | Tribal population                           | 6<br>4.91 (3.10-7.08)                            |
|  | Slum dwellers                               | 1<br>1.15 (0.24-3.34)                            |

\*Two of the studies were overlapping and were considered at high risk of selection bias and were excluded, leaving only 4 studies for analysis.

The data from community-based studies were limited to only 4 studies with limited geographic coverage and extreme heterogeneity. Hence, the pooled rate from these studies is not easily generalizable to the entire country.

A large number of studies providing data from blood donors were available, and these provided a pooled prevalence of anti-HCV antibodies of 0.44% (0.40%-0.49%) with a narrow range. However, these data appear to relate largely to young and middle-aged men, and may have other limitations. In future too, this data source, being readily available at low cost, can continue to provide useful data; however, the utility of these data can be increased if information on age, sex, replacement/voluntary donation status, and first-time/repeat donor status can be recorded for each donor and entered into a database.

The data from pregnant women were available from several individual studies, and yielded a pooled estimate of HCV sero-prevalence of 1.03% (0.36%-1.99%). This rate relates primarily to young women. It however is based on studies from only a few states and hence be confounded by the geographic origin of studies in this group. This interpretation is strengthened by the fact that there were no consistent differences between rates in pregnant women and donors, when data for the two groups from the same state were compared.



There were high anti-HCV antibody prevalence rates found among PWID, PLHIV, patients on maintenance hemodialysis, or those receiving repeated blood and blood transfusion. However, the rates among PLHIV were lower than those in other countries, particularly those where injection drug use is the most common route of HIV transmission.

This meta-analysis concluded that based on the above studies, it can be estimated that India (current population = ~1.3 billion) has 5.2 to 13 million anti-HCV positive persons. The data on HCV viremia rates among anti-HCV antibody positive persons were not available. Hence it is difficult to arrive at a conclusion on this. However, using data from elsewhere that 60%-70% of anti-HCV antibody positive persons have HCV viremia, it can be estimated that India has ~3 million to ~9 million persons with active HCV infection.

## **Injection Safety and risk of Hepatitis B and C:**

According to a global estimate, nearly 16 billion injections are administered every year, and up to 40% of these injections are unsafe. Out of these total number of injections, 85-90% injections are administered for therapeutic purposes, 5-10% for immunization, and remaining for IV drugs, blood transfusion, diagnostic reasons etc.

A study published in 2003 estimated that unsafe injections cause 1.3 million early deaths annually, a loss of 26 million years of life, and direct medical costs of 535 million USD.

According to a national level India study conducted by IPEN in 2003-04, approximately 3 billion injections are administered in India alone, out of which an estimated 1.89 billion (62.9%) are unsafe posing higher risk for transmission of blood-borne viral infections. The study found that frequency of injections in India is 2.9 per person per year.

In India, unsafe injections lead to very high incidence of infections in the magnitude of:

- 260,000 HIV infections (5% of global burden)
- 21 million HBV infections (32% of global burden)
- 2 million HCV infections (40% of global burden)

There are experiences from India where unsafe injections have been known to cause outbreaks of blood-borne infections. In 2009, in Gujarat an outbreak of Hepatitis B was investigated and 40% of all positive cases (n=856) were found to have received therapeutic injections in the past 1.5 to 6 months. In another study conducted among primitive tribes of Andaman and Nicobar Islands found high prevalence (26.3%) of hepatitis B virus infection. Unsafe injections were found to be independent risk factor for acquiring HBV infection in the population.

IPEN study (2003) showed that satisfactory terminal disposal of injection waste was practiced in less than half of the facilities visited (44.8%) in India.

## **II. Review of the existing programs**

At present multiple activities are being carried out for prevention and control of viral hepatitis under various divisions in the Ministry of Health & Family Welfare ( MoHFW), as follows:

- » Swachh Bharat Mission
- » Safe drinking water and sanitation Programme
- » Provision of sanitary toilet to every household
- » Smart city with good sewage system

- » River water pollution control
- » Hygiene and sanitation in the municipal areas
- » Biomedical waste management
- » Immunization
- » Injection Safety & infection control
- » Safety of Blood and blood products
- » Harm reduction in key populations ( through NACP)
- » Surveillance of Viral Hepatitis

## Prevention

### Immunization

**Hepatitis B vaccination for children:** The national immunization schedule recommends hepatitis B birth dose to all infants in first 24 hours, followed by three primary series at 6,10 and 14 weeks to complete the schedule.

- Hepatitis B vaccine was introduced in the Universal Immunization Programme (UIP) of India in 2002 and scaled-up nationwide in 2011. Hepatitis B birth dose was introduced in the national programme in 2008
- The Hepatitis-B birth dose coverage among institutional deliveries was 55% in 2015 and increased to 67% in 2016. Of the total live births, the hepatitis B birth dose coverage was 45% in 2015 and 60% in 2016

### Injection Safety:

Government of India is cognizant of the fact that for the control of the spread of life threatening blood borne infections, promotion of safe injection practices is crucial. Ministry of Health & Family Welfare, Government of India has already constituted a National Technical Expert Group on injection safety to advise ministry on various aspects of injection safety and waste management.

In India, an injection safety project is being implemented in Punjab. The project aims for adoption of Re-Use Prevention (RUP) syringes in therapeutic care, as well as to make injections safe and improve healthcare waste management practices. Since the start of project in July 2016, state government has made policy decision to switch to the use of re-use prevention (RUP) syringes in therapeutic care in government facilities and promote use of these syringes in private sector as well. The procurement process for purchase of RUP syringe is to be started by the state government.

The government of India has already advised the states to progressively shift the procurement in the government sector to RUP syringes in a phased manner, since 2018.

Bio-medical waste management is regulated by law and it is mandatory for every clinical establishment generating bio-medical waste, to follow the standard disposal practices.

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### Safety of blood and blood products:

Availability of safe blood is one of the most important measures to prevent viral hepatitis by HBV and HCV. Blood safety is also ensured by increasing voluntary blood donations (100%). Blood Banks are regulated by

an Act of parliament namely “The Drugs and Cosmetics Act (1940)” and the regulations therein. As per the requirements of the Act, it is mandatory to screen every unit of blood for HBV and HCV before transfusion. In all licensed Blood Banks, screening for Hepatitis C was introduced in 2001 and made mandatory across blood banks in India ([www.naco.gov.in](http://www.naco.gov.in)).

There are 2760 licensed Blood Banks across the country (February, 2015 CDSCO). The collection in the blood banks is 11,094,145 units (2016-17) out of which 66,04,392 units are collected in NACO supported Blood Banks.

The data from NACO supported blood banks shows a declining trend in sero-positivity for HIV, HBV and HCV:

| Financial Year               | Total Collection (in millions) | Collection in NACO supported BB (in millions) | Voluntary Blood Donation in NACO supported BB (%) | HIV (%) | HBsAg (%) | HCV (%) | MP (%) | VDRL (%) | Component Separation in NACO supported BCSU |
|------------------------------|--------------------------------|---|---|---------|-----------|---------|--------|----------|---|
| 2012-13                      | 9.8                            | 5.48  | 84  | 0.2     | 1.1       | 0.4     | 0.1    | 0.2      |   |
| 2013-14                      | 9.95                           | 5.76  | 84  | 0.2     | 1         | 0.4     | 0.1    | 0.2      | 58.7%                                       |
| 2014-15                      | 10.83                          | 6.64  | 84  | 0.14    | 0.85      | 0.33    | 0.08   | 0.18     | 61.6%                                       |
| 2015-16                      | 10.8                           | 6.3   | 79  | 0.14    | 0.86      | 0.34    | 0.07   | 0.15     | 69%   |
| 2016-17 (upto November 2017) | 7.05                           | 4.4   | 77  | 0.12    | 0.92      | 0.30    | 0.05   | 0.21     |   |

Ref: <http://naco.gov.in/blood-transfusion-services> accessed 4 February 2019

## Harm reduction in key populations ( through NACP)

India’s response has always been prevention-focused. With a low level concentrated epidemic where over 99.5% population is uninfected and the vulnerable groups are large in numbers, it was imperative that the programmatic resources and efforts were directed towards prevention of HIV transmission. This was taken as an essential core principle in drafting strategies in all the phases of NACP. Targeted Interventions (TI) for key and bridge populations has been the core prevention strategy under National AIDS Control Program in India. Key population includes Female Sex Workers, Men who have Sex with Men, Transgender & Injecting Drug Users (IDU’s), while bridge population includes migrants and truckers. TIs are implemented as NGO/CBO-led peer outreach model to provide a package of prevention services including behavioral change communication, condom promotion, prevention and management of Sexually Transmitted Infections (STIs), community mobilization and enabling environment, and linkages to HIV testing, care, support & treatment. Needle syringe exchange program and Opioid Substitution Therapy (OST) are provided for prevention of HIV among people who inject drugs (PWID)

### Coverage of key populations by TIs under NACP

| Thematic Group                    | Mapping Estimates (2009) | Program Targets (NACP IV) | Covered under Tis (2015-16) | Percentage Coverage |
|-----------------------------------|--------------------------|---------------------------|-----------------------------|---------------------|
| FSW                               | 8,68,000                 | 9,00,000                  | 6,78,423                    | 75.38               |
| MSM+TG/Hijras                     | 4,27,000                 | 4,40,000                  | 2,72,322                    | 61.89               |
| IDUs                              | 1,77,000                 | 1,62,000                  | 1,30,800                    | 80.74               |
| Migrants                          | 72,00,000                | 56,00,000                 | 32,97,748                   | 58.88               |
| Truckers                          | 20,00,000                | 16,00,000                 | 10,95,400                   | 68.46               |
| TG + Hijra ( separate since 2013) | 75000                    |                           | 25486                       | 33                  |

Source: Report of the Mid-term Appraisal of NACP-IV, NACP August 2016

Beyond the basic package of services outlined above, services being offered in IDU TIs would include

- Hepatitis B and C prevention materials, awareness and behavior change communication (BCC) on Hepatitis B and C, and referrals for Hepatitis C testing and HBV vaccination on a voluntary basis
- Increased emphasis on proper waste disposal as per prevailing norms

A core component of key population specific prevention efforts, is creating an enabling environment with community participation and mobilization.

## Surveillance of Hepatitis

Hepatitis A and E are outbreak prone diseases which are reported through IDSP in the country. The reporting mechanism at the central level is through the central surveillance unit located at National Centre for Disease Control (NCDC), at the state level through the State Surveillance Unit (SSU) and at the district level through the District Surveillance Unit (DSU) which interact with the peripheral reporting unit. At present one SSU exists in each state and one DSU in each district. The reporting formats in the system are the syndromic (S form) which is a reporting mechanism through the health care workers at the periphery, the presumptive/probable (P form) based on the standardized clinical case definition and the L form based on the laboratory confirmed reports.

The surveillance of all acute and chronic hepatitis is being done through a few institutions which can play a role of sentinel centre for surveillance of Hepatitis B and C. It has also recommended undertaking surveillance of sequel as the former two gets established. Meanwhile, the ILBS has initiated the sequel surveillance in coordination with 13 more centers. The spectrum of surveillance should result in generation of good data that can be used to understand the disease burden better in coming years.

## Diagnosis and Treatment of Hepatitis

Laboratory services should be a critical and core component of any response to viral hepatitis. Increasingly, it is being recognized that work related to laboratory services is not confined to testing alone, but is overarching and impacts on other programmatic interventions such as prevention, care, support and treatment, safety of blood and blood products, etc.

There is no reporting for the number of cases treated for hepatitis B and C in the country as there was no national program for the same till 2018. The majority of cases incur out of pocket expenditure for treatment of Hepatitis B and C. However, some states have taken an initiative to provide treatment for hepatitis C.

### Hepatitis C Treatment program in Punjab and other states

Punjab has started free treatment of HCV infected individuals through state government funds since July 2016. Sustained Virological Response (SVR) has been around 93% amongst the patients who underwent the HCV Viral load after 12 weeks of completing the treatment. The Punjab model is a recognized example of decentralized service delivery through public health system and can be considered as one of the best models globally. The program offers a cure certificate to all patients who complete the treatment and have a SVR at scheduled time.

There are a few states (Assam, Manipur, Tripura, Haryana) that have also started some subsidized treatment to HIV-HCV co-infected or to any HCV infected needing treatment. However, the coverage and expected number of beneficiaries is very limited with these schemes.

### III. Gap Analysis in the existing Response

#### Immunization:

The Hepatitis -B birth dose coverage is sub optimal. Of the total live births, the Hepatitis -B birth dose coverage was 45% in 2015 and 60% in 2016. Missed opportunity is about 40% which need to be addressed. The Hepatitis -B birth dose coverage among institutional deliveries was 55% in 2015 and increased to 67% in 2016. The coverage amongst institutional deliveries for Hepatitis -B birth dose was reported to be 71% as of March 2017. (source: MoHFW, July 2017.)

The Immunization for hepatitis B is not routinely available for health care workers. Wherever it is available, the data is not being captured. Immunization of hepatitis B in key population is also not well implemented or documented. There are certain population groups like recipients of multiple blood / blood products transfusion, patients on hemodialysis, PWID, MSM, sex workers, sexual partners of infected people, etc which are at a higher vulnerability to get infection with hepatitis B.

Linkages have to be established with universal immunization program and national AIDS Control program for vaccinating the healthcare workers and key populations respectively against hepatitis B, wherever possible.

About 70-90% newborns infected through perinatal transmission become chronic carriers of HBV. Screening of pregnant women and use of Hepatitis B immunoglobulin in infants born to mothers with active infection is one the vital measures to prevent mother to child transmission. Currently there is no provision of passive immunity to the infant born to HBV positive mothers. It is proposed to provide Hepatitis B immunoglobulin (HBIG) to newborns of hepatitis B positive mothers to prevent the risk of acquiring the infection. HBIG prophylaxis, in conjunction with HBV vaccination is of additional benefit in preventing vertical transmission

#### Injection Safety and Prevention of Hepatitis B and C

Unsafe health care practices by health care providers / traditional healers /quacks pose a major challenge and risk for transmission of HBV and HCV. There is need for developing training material and capacity building for effective roll-out of RUP syringes addressing prescriber practices and community preference for injections. At the same time, it is important to generate evidence / monitor the trends over time through baselines assessments and cost effectiveness studies.

Prevention of infection has to be addressed while respecting the socio-cultural practices like tattooing, religious ceremonies(eg.Mundans), ear/body piercing etc. There are gaps in implementation of bio-medical waste management rules, leading to sharps injuries and increased risk of infections.

#### Safety of Blood and Blood Products

There is a lack of a mechanism for follow up of individuals detected positive on screening, their counseling, confirmatory testing and linkages to care and support services. Lack of optimal quality control measures in TTI testing and strengthening of monitoring small blood banks is required. Currently, there is less than 100% true voluntary blood donation.

Referral & follow up of HBsAg and anti HCV reactive blood component donors is a long felt need by hepatologistsand those in blood transfusion and public health services for following reasons:

**1**

To confirm the presence of infection by confirmatory tests & provide treatment & care to those confirmed infected.

**3**

To counsel and defer confirmed positive donors from future donations & to decide whether and when they can donate again.

**2**

To prevent further spread of infections to close contacts

**4**

To allow future donations by those found to be false positive by confirmatory tests.

## Surveillance of Viral hepatitis

There is lack of nationally representative population based study for assessing the prevalence of hepatitis B and C infection in general population. The primary focus has been on outbreak surveillance which is often not lab confirmed due to lack of facilities at the peripheral level. There has been no structured surveillance of acute (case reporting), chronic hepatitis or sequel to chronic hepatitis.

## Diagnosis and Treatment:

Antiviral agents active against HBV are available, and have been shown to suppress HBV replication, prevent progression to cirrhosis, and reduce the risk of Hepatocellular Carcinoma (HCC) and liver-related deaths. The treatment available fails to eradicate the virus in most of those treated, necessitating potentially lifelong treatment.

In recent years, there is availability of safe, oral and pangenotypic DAAs which has made treatment and cure of hepatitis C possible.

Early diagnosis is critical to timely initiation and scale up of treatment for viral hepatitis. However, there are inadequate services for diagnosis and treatment of hepatitis B and Hepatitis C and consequently, standardized diagnostic and treatment protocols for management of Hepatitis B & C in the country. In addition, there is lack of optimal facilities for screening, diagnosis and treatment of viral hepatitis. There is no standardized intervention for treatment of hepatitis including testing algorithms and treatment guidelines etc.

Recently, as the NVHCP was launched in July 2018, the national guidance on laboratory services as well as on treatment services were developed and released in 2018. These guidelines bring standardization of protocols and algorithms that should be followed in India, and form the basis for roll out of these interventions. These guidance documents shall be updated periodically with evolving experience and scientific evidence.

## Awareness generation

Hepatitis A and E are preventable by use of safe drinking water and proper sanitation. There is a need to create awareness among general population to achieve elimination of the same. Education and awareness on safe injection practices, socio cultural practices and their risk in spread of infection of hepatitis B and C is the mainstay for the larger objective of elimination of hepatitis B and C. Further there is a need to integrate campaigns on immunization of new born for hepatitis B which can prevent infection and also serve the long term objective of elimination

There is lack of awareness amongst general population and Health Care Workers about hepatitis and inadequate or lack of comprehensive focus on the entity of hepatitis in the awareness and communications campaigns to raise the awareness of hepatitis in the community. It is important to create awareness amongst municipalities, district administration, Panchayati Raj Institutions (PRIs), sanitation workers and people at large to understand their role in these preventable infections specially hepatitis A and E. There is a need for integration with the Ministry of Urban Development and Ministry of Drinking Water and Sanitation, to eliminate these water borne infections.

## IV. National Viral Hepatitis Control Program

In India, the estimated burden of viral hepatitis is very high as mentioned in the section on the magnitude of the problem, necessitating focus on prevention and control measures of hepatitis to mitigate the morbidity and mortality due to hepatitis.

There are several components that are existing in the different programs of Government of India like UIP, Swachh Bharat Mission, safety of blood and blood products, safe drinking water and sanitation, that are directly or indirectly related to the prevention of viral hepatitis.

Currently, some states are providing treatment and care for patients with hepatitis C with the newer class of directly acting anti-viral drugs that are safe, effective and easy to administer with high cure rates. Some healthcare facilities are also providing antiviral treatment for chronic Hepatitis B infection/disease. However, as the NVHCP is rolled out under NHM, all the state programs shall be transitioned to the National Program and will align with the National protocols and guidance on testing as well as management of the all the different types of viral hepatitis (namely A, B, C, D and E viruses).

Unsafe injection practices during health care remain a risk and have potential to transmit the HBV and HCV infection. RUP/AD syringes offer a critical intervention that India has agreed to. It is to be noted that India manufactures RUPs/ADs for injection in therapeutic care and this offers new opportunity to address unsafe injection.

India is also committed to achieve the SDGs. The SDG 3.3 aims to “...Combat viral hepatitis”. The government of India is a signatory to the resolution 69.22 endorsed in the WHO Global Health Sector Strategy on Viral Hepatitis 2016-2021 at 69th WHA towards ending Viral hepatitis by 2030.

In view of the above and existing gaps in current programs, it is pertinent to address all aspects

### Aim -

- 1 Combat hepatitis and achieve country wide elimination of Hepatitis C by 2030
- 2 Achieve significant reduction in the infected population, morbidity and mortality associated with Hepatitis B and C viz. Cirrhosis and Hepato-cellular carcinoma (liver cancer)
- 3 Reduce the risk, morbidity and mortality due to Hepatitis A and E.

### Objectives: -

- 1 Enhance community awareness on hepatitis and lay stress on preventive measures among general population especially high-risk groups and in hotspots.
- 2 Provide early diagnosis and management of viral hepatitis at all levels of healthcare
- 3 Develop standard diagnostic and treatment protocols for management of viral hepatitis and its complications.
- 4 Strengthen the existing infrastructure facilities, build capacities of existing human resource and raise additional human resources, where required, for providing comprehensive services for management of viral hepatitis and its complications in all districts of the country.



**5** Develop linkages with the existing National programmes towards awareness, prevention, diagnosis and treatment for viral hepatitis.

**6** Develop a web-based “Viral Hepatitis Information and Management System” to maintain a registry of persons affected with viral hepatitis and its sequelae.

## Programme Strategies

### Strategy 1

Preventive and promotive interventions with focus on awareness generation, safe injection and socio cultural practices, sanitation and hygiene, safe drinking water supply, infection control and immunization.

### Strategy 2

Co-ordination and collaboration with different Ministries and departments, NACP for safety of blood and blood products and with IDSP and NACP for surveillance

### Strategy 3

Increasing access and promoting diagnosis and providing treatment support for patients of viral hepatitis.

### Strategy 4

Building capacities at national, state, district and sub district levels upto PHC and Health and Wellness center in a phased manner

## Programme components

The key program components include:

The key components include:

**1** Preventive component: This remains the cornerstone of the initiative. It will include

- a. Awareness generation
- b. Immunization of Hepatitis B (birth dose, high risk groups, health care workers)
- c. Safety of blood and blood products
- d. Injection Safety, safe socio-cultural practices
- e. Safe drinking water, hygiene and sanitary toilets

**2** Diagnosis and Treatment:

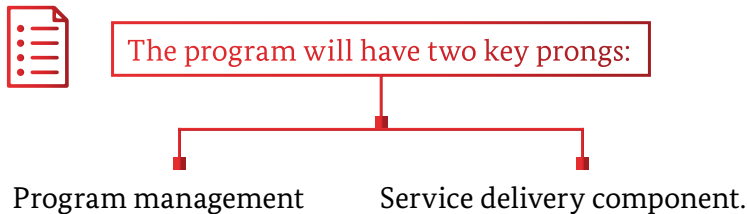
- a. Screening of pregnant women for HBsAg to be done in areas where institutional deliveries are < 80% to ensure their referral for institutional delivery for birth dose Hepatitis B vaccination.
- b. Free screening, diagnosis and treatment for both hepatitis B and C would be made available at all levels of health care in a phased manner.
- c. Provision of linkages, including with private sector and not for profit institutions, for diagnosis and treatment.
- d. Engagement with community/peer support to enhance and ensure adherence to treatment and demand generation.

**3** Monitoring and Evaluation, Surveillance and Research effective linkages to the surveillance system would be established and operational research would be undertaken through DHR. Standardised M&E framework would be developed and an online web based system established.



- 4** Training and capacity Building: This would be a continuous process and will be supported by NCDC, ILBS and state tertiary care institutes and coordinated by NVHCP. The hepatitis induction and update programs for all level of health care workers would be made available using both, the traditional cascade model of training through master trainers and various platforms available for enabling e-learning and e-courses.

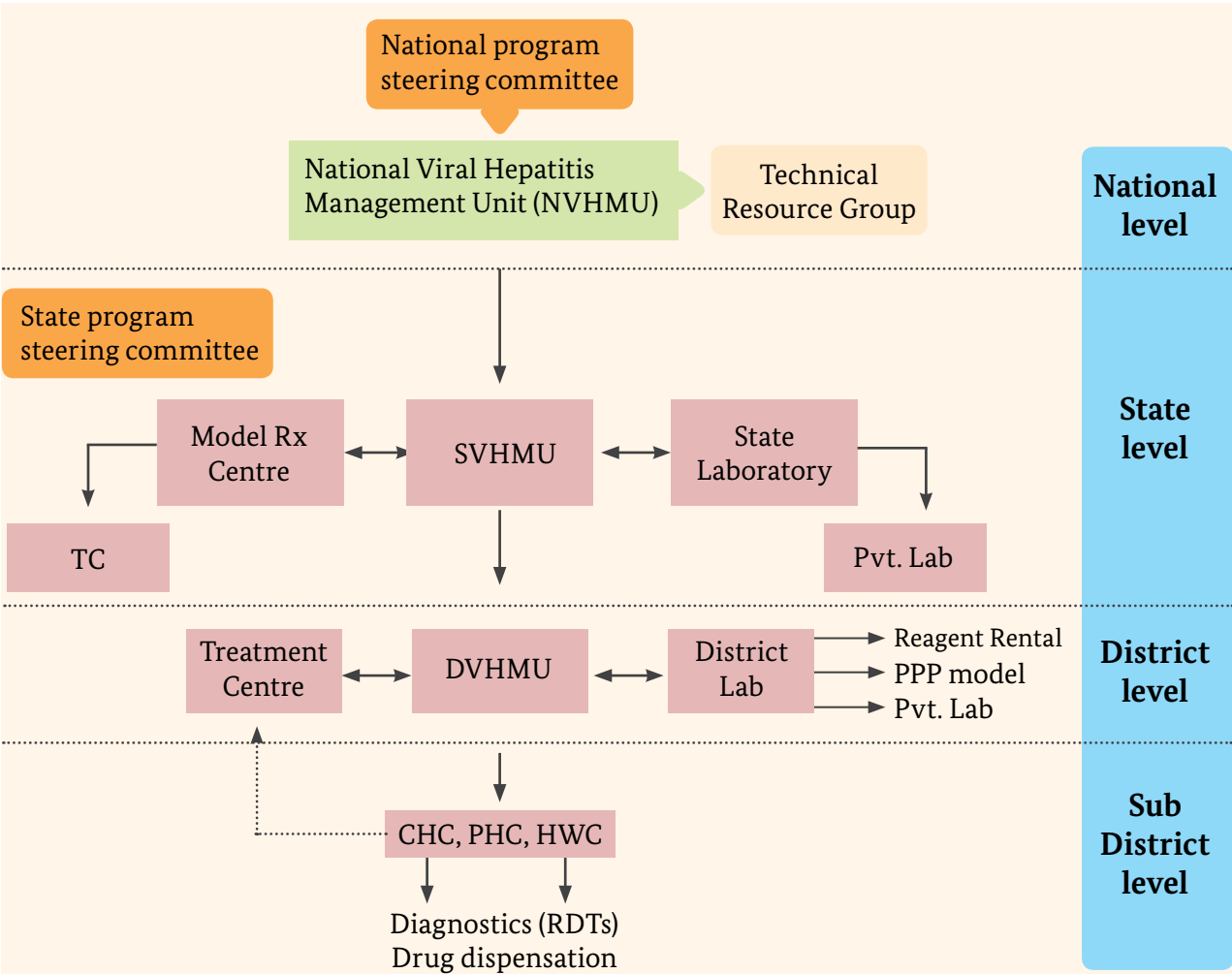
**Implementation structure at National, State and District Level**



**Program Management**

The initiative will be coordinated by the units at the centre and the states.

- 1** National Viral Hepatitis management unit(NVHMU)
- 2** State Viral Hepatitis management unit(SVHMU)
- 3** District Viral Hepatitis management unit (DVHMU)



The details on the constitution, function and roles and responsibilities of the steering committee, and the program management units at national, state and district level are elaborated in the operational guidelines for the NVHCP, 2018

## Service Delivery : Synergies with the existing programs and relevant ministries

Service Delivery Component will include the following two aspects:

- 1** Synergies with the existing programs and relevant ministries of Government of India
- 2** New Interventions- Diagnosis and Management of Viral Hepatitis with focus on treatment of Hepatitis B&C

The delivery of services for the components already existing shall be done through the currently established channels like the UIP; Injection safety; Safety of blood and blood products; IDSP; State AIDS control society(SACS); Harm reduction in key population; Surveillance of viral hepatitis; Swachh Bharat Mission; Safe drinking water and sanitation program; Biomedical waste management). These synergies will be established to ensure that there is no duplication of resources and efforts and the plan under the Viral Hepatitis is aligned with the respective, existing components. This will largely be done by NVHMU and SVHMU at their respective levels of administrative control.

## Prevention of Viral Hepatitis

### Universal Immunization Program

Hepatitis B vaccine was universalised nationwide in 2011. The UIP schedule recommends hepatitis B birth dose to all infants within 24 hours, followed by three doses at 6, 10 and 14 weeks to complete the schedule.

The hepatitis-B birth dose coverage among the total live births was 45% in 2015 and 60% in 2016. Missed opportunity is about 40% which need to be addressed. The coverage amongst institutional deliveries for Hepatitis -B birth dose was reported to be 76.36% as of December 2017.

### India's target for Hepatitis B immunization

| S.No. | Country Targets (to be provided by UIP)                           | Baseline (2016-17) | 2019-20                |
|-------|---|--------------------|------------------------|
| 1.    | Coverage of Birth Dose of Hepatitis B ( All deliveries)           |                    | 90%                    |
| 2.    | Coverage with three doses of Hepatitis B vaccine in infants (B3). |                    | 95%                    |
| 3.    | Routine Hepatitis B vaccination among health-care workers.        | N/A                | Will be made Available |

The NVHCP will therefore integrate with the UIP for the following:

- a. Strengthen routine immunization services to achieve and sustain the desired coverage of the timely birth dose followed by three doses of hepatitis B vaccine
- b. Coordinate with the Universal immunization programme for mandatory immunization of all healthcare workers. This approach will not only provide protection to the healthcare workers against contracting hepatitis B accidentally, but will also help detect and support the positive HCWs.

### National AIDS Control Program (NACP)

There are certain population groups like recipients of multiple blood / blood products transfusion, patients on hemodialysis, PWID, MSM, female sex workers, sexual partners of infected people, prisoners etc which are at a higher vulnerability to get infection with hepatitis B and hepatitis C.

The NVHMU will coordinate with NACP for surveillance of hepatitis in key populations, establishing linkages for testing and care for hepatitis C infected PLHIV and vaccination of the vulnerable population. The SVHMU will coordinate in a similar manner with the state machinery for executing the same.

## Safety of blood and blood products

HBV and HCV can be transmitted through contaminated blood and blood products and hence the need for strengthening blood safety. Ensuring availability of safe blood and blood products is one of the critical interventions for reducing transmission. One of the ways to ensure safety of blood & blood products is by increasing voluntary blood donations (100%). Blood Banks are regulated by an Act of parliament namely “The Drugs and Cosmetics Act (1940)” and the regulations therein. As per the requirements of the Act, it is mandatory to screen every unit of blood for HBV and HCV along with other transfusion transmitted infections (TTIs) before transfusion, in all licensed blood banks. Screening for HCV was made mandatory and introduced in 2001 across blood banks in India.

NVHCP will establish linkages with the existing system of NACPat the central and state level, for the following

- 1 To review and strengthen national policies and practices on blood safety those promote rational use of blood and blood products, and move towards 100% voluntary blood donation.
- 2 Setting up a mechanism for follow up of individuals detected positive on screening, their counselling, confirmatory testing and linkages to care and support services for viral hepatitis.
- 3 Strengthen systems for surveillance, hemo-vigilance and monitoring of the incidence and prevalence of viral hepatitis infections in blood donors, and monitor the risk of post-transfusion hepatitis.
- 4 Establish mechanisms for counselling of HBsAg & anti-HCV reactive blood donors for referral and follow-up to confirm the presence of infection by confirmatory tests & provide treatment for Hepatitis B and C where necessary.
- 5 Developing/updating training modules with SACS, State Blood Transfusion Council and blood cells on safety of blood and blood products with special focus on prevention of Viral Hepatitis through transfusion of blood and blood products and linkages for those screened positive.

### Country Target

| S No | Indicator ( from NACP and NHM)*                         | Target       |
|------|---|--------------|
| 1    | % of blood donations that are voluntary                 | 80% by 2020  |
| 2    | % of donated blood units screened for Hepatitis B and C | 100% by 2018 |

\* To be monitored and submitted to NVHCP twice every year (as absolute numbers as well as percentage)

## Harm reduction in key populations

Targeted Interventions (TI) for key and bridge populations has been the core prevention strategy under NACP in India. Key population include female sex workers (FSW), men who have sex with men (MSM), transgender (TG) & people who inject drugs (PWID), while bridge populations include migrants & truckers.

TIs are implemented as NGO/CBO-led peer outreach model to provide a package of prevention services including behavioural change communication, condom promotion, prevention and management of sexually transmitted infections (STI), community mobilization and enabling environment, and linkages to HIV testing, care, support & treatment. Needle syringe exchange program and opioid substitution therapy are provided for prevention of HIV among PWID. Since the mode of transmission of Hepatitis B and Hepatitis C are largely similar to HIV/AIDS, NVHMU and SVHMU will coordinate with NACP for including prevention/management of hepatitis B and C in the package of prevention services for the key and bridge population.

In addition to the key populations under NACP, there are other focus groups that need to be attended to under the NVHCP. These focus groups include close first degree relatives and family members of infected person: mother, siblings, spouse and children. The other populations for both hepatitis B and C include those who have received blood or blood products specially before implementation of hepatitis C testing at a large scale in India; i.e. before 2001, recipients of multiple blood transfusion, person exposed to unsafe injection practices by informal health care providers, etc. Identification of hot spots of hepatitis B and C should also be one of the priorities of the NVHCU.

## Injection safety and infection control

| S.No. | Targets WHO Regional Action Plan for Viral Hepatitis in South-East Asia: 2016–2021 |
|-------|--|
| 1     | By 2020, 50% of all injections are administered with safety engineered devices.    |

Unsafe health care practices by health care providers/ traditional healers/ quacks pose a major challenge and risk for transmission of HBV and HCV. There are gaps in implementation of bio-medical waste management rules, leading to sharps injuries and increased risk of infections.

NVHMU and SVHMU will integrate with the national and state regulatory bodies to strengthen the infection prevention and control practices in healthcare settings (public and private), including in laboratories, dental clinics, endoscopy clinics and haemodialysis units etc. Coordinate with the PradhanMantri National Dialysis Program for making special emphasis on the component of injection safety and infection control in their program module. NVHMU & SVHMU will also coordinate with the regulatory body towards effective roll-out of re-use prevention (RUP) syringes, addressing prescriber practices and community preference for injections while respecting the socio-cultural practices like tattooing, religious ceremonies (e.g. mundans), ear/body piercing etc. States need to identify CBOs/NGOs and incentivise them for training on prevention of HAV and HEV during mass religious activities; and mundan ceremonies and community barbers for HBV and HCV. NVHMU and SVHMU will coordinate with the Ministry of Environment & Forestry and pollution control board (at national and state level) for capacity building for effective implementation of the bio-medical waste management rules.

## Integrated Disease Surveillance Programme

The NVHMU, SVHMU and DVHMU will integrate with the IDSP

- To provide technical support for outbreak investigation and reporting and monitoring of outbreaks of viral hepatitis, specially hepatitis A and E.
- Assisting in rapid response team activities during outbreaks.
- Ensure linkages with the laboratory and treatment facilities of those affected in the outbreak with the disease.
- To involve all structures upto PHC level

## National program for Surveillance of Viral Hepatitis

The initiative will integrate with the National Program for Surveillance of Viral Hepatitis such that the sentinel sites for surveillance are colocated and function with MTC. This will ensure that all those found positive in surveillance can be linked for further testing and treatment.

| S.No. | Targets WHO Regional Action Plan for Viral Hepatitis in South-East Asia: 2016–2021                                       |
|-------|--|
| 1     | Have effective outbreak response and surveillance systems in place to monitor HAV and HEV outbreaks and outcomes by 2020 |

The initiative will undertake surveillance of acute, chronic hepatitis as well as their sequel over the next three years. It will also have estimates for the disease burden for Hepatitis B and C in the country.

## **Swachh Bharat Mission- Urban & Rural**

Swachh Bharat Mission, an initiative of Ministry of Housing and Urban Affairs, Government of India in urban areas has the objective of improving the sanitation by eliminating open defecation, eradicating manual scavenging, managing municipal solid waste through modern and scientific techniques, generating awareness about sanitation especially in context of viral hepatitis A and E (relating to contamination of water and food), and effecting behaviour change regarding healthy sanitation practices will play a vital role in achieving the objective of preventing and controlling viral hepatitis especially in context of hepatitis A and hepatitis E which are largely spread through faecal oral route and their prevalence can certainly be reduced significantly by efforts towards improved sanitation. NVHMU and SVHMU will therefore establish linkages with Swachh Bharat Mission through meetings and consultations with the officials of Ministry of Housing and Urban Affairs at the national and state level so as to achieve the objectives of the mission and indirectly help reduce the burden of hepatitis A and E. NVHMU and SVHMU will also work towards ensuring training of each facility towards cleanliness and environmental hygiene.

The Swachh Bharat Mission in rural areas implemented through Ministry of Drinking Water and Sanitation will also be involved in a similar manner.

## **Ministry of Drinking Water and Sanitation**

NVHMU and SVHMU will also establish linkages with the Ministry of Drinking Water and Sanitation for strategizing towards provision of clean drinking water and sanitation. This will further help in reducing the burden of Hepatitis A and E. Advocate for and communicate the importance of safe water, hygiene and sanitation and improve access to safe sanitation facilities. Educate the public on safe disposal of human faeces.

## **Food Safety and Standards Authority of India (FSSAI)**

Ensure inter-sectoral collaboration with FSSAI for access to safe food through enforcement mechanisms at national, state and district levels. To promote and advocate for safe food to reduce the burden of hepatitis A & E amongst general population and food business operators.

## **Diagnosis and Management of Viral Hepatitis with focus on treatment of Hepatitis B&C**

There will be need to establish implementation mechanism and service delivery points for interventions like diagnosis and treatment, surveillance and awareness generation. The service delivery for these will happen at facilities identified for each type of services, based on evidence and existing capacities. Additional staff wherever required for each service delivery type is proposed. The various components of service delivery under this head will include:

a. Laboratory services

b. Treatment services

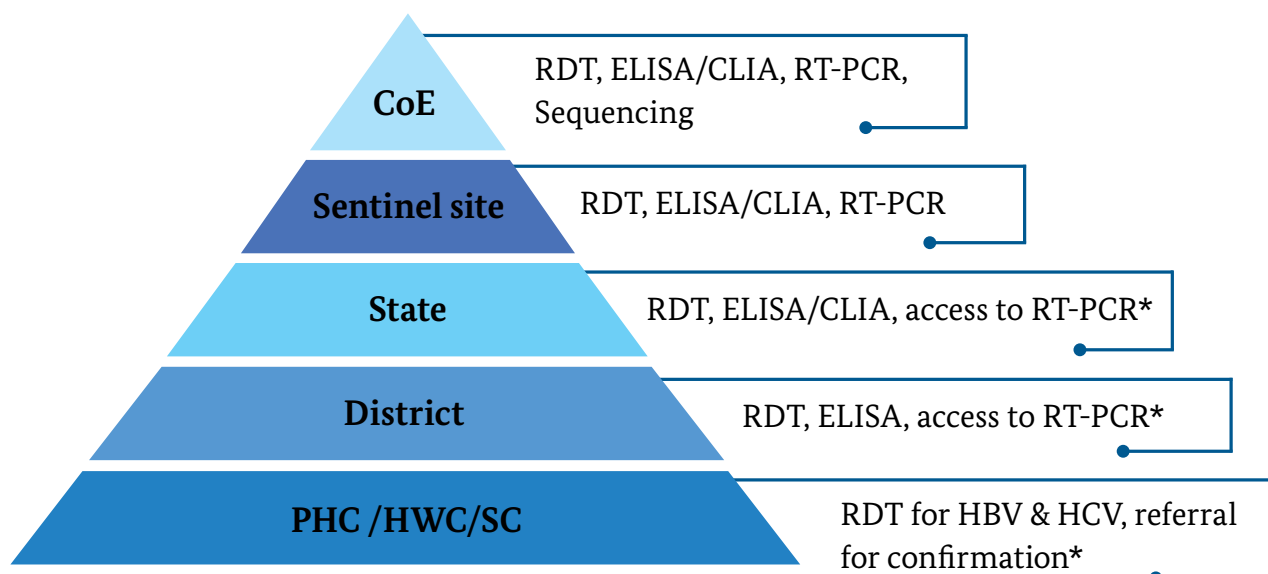
### **Laboratories Services**

Laboratory services are necessary for screening, confirmation and monitoring the response and outcomes of treatment. A tiered mechanism as shown in figure below reflects on the facilities being offered at various levels.

To facilitate the same, the program will strengthen the state, district, and sub district level laboratories in a phased manner. In the first year, the focus will be on laboratory which will be designated as sentinel sites to be used for both testing and training. Some of the state medical college laboratories will also be engaged for the same. All efforts will be made to cascade these trainings and capacities to below district level labs (for screening) in a time bound manner, to strengthen them to provide quality assured testing for viral hepatitis.

Procurement of services using the reagent rental model, existing facilities and PPP models for molecular testing will be explored to enhance access to them in a quality assured manner.

## Network of Laboratories under the National Viral Hepatitis Control Program



*\*If samples are to be transported, they need to be collected, packaged and transported within six hours of collection under suitable environmental conditions.*



(Detailed operational guidelines on the laboratory services for viral hepatitis have been developed and should be referred to for manpower, pattern of assistance, etc).

## Treatment Sites

The services under the hepatitis treatment initiative will be delivered through the designated treatment sites that are located within an existing health facility, such as district hospitals and state medical colleges. It will utilize the current health care system. However, the extent of services can be graded upon the availability of the expertise in the selected sites. There will be a few sites that will be labelled as Model Hepatitis Treatment centres (MTC). These will also act as places for referral and mentoring of the other treatment centres (TC). The Hepatitis Treatment centre can be located in the district hospital or co-located with the sentinel sites. All the diagnosis and treatment centers will have the capacity to differentiate whether the patient has advanced liver disease or not. They would deliver the treatment for hepatitis C and B whenever indicated according to the technical and operational guidelines for management of hepatitis B and C infections. These guidelines have been developed under the NVHCP and are periodically updated.

## Services Available to Patients at Different levels of Health Care Facility

| Level   | Screening                   | Confirmation | Treatment of uncomplicated cases          | Treatment of Complicated case |
|---|-----------------------------|--------------|---|-------------------------------|
| Health and Wellness centers                     | Introduced in phased manner |              |   |                               |
| PHC   | Y                           |              |   |                               |
| CHC   | Y                           | Y            | In phased manner after assessing capacity |                               |
| District Hospital                               | Y                           | Y            | Y   |                               |
| Medical Colleges and specialised centers ( MTC) | Y                           | Y            | Y   | Y                             |



States will select the number and locations of sites based on capacity assessment and feasibility visits and propose in the State PIP. The services shall be scaled up till PHC



## Training

Training and capacity building are crucial in delivery of quality health care. It is proposed to develop standardized training manuals and online training modules for health care providers and undertake their capacity building using conventional and other platforms. It is proposed to identify centers over 3 years who could take the task of mentoring the human resource from the centers that are linked to them. These centers could also support the program in undertaking research and secondary data analysis to inform policy.



## Awareness Generation

Awareness generation will be an important component of the viral hepatitis program. The demand generation campaigns will be the focus. The IEC and BCC will remain an important component of all prevention efforts and will have continued focus on:

- 1 Increasing awareness among general population. Various communication channels will be used (like mass media, advertisements, radio jingles, posters, TV spots etc)
- 2 Behavior change communication strategies for vulnerable groups
- 3 Continued focus on demand generation of services including hepatitis B birth dose and safe injections and testing for hepatitis.
- 4 Increasing treatment literacy and adherence to treatment

## Collaboration & co-ordination (intra and inter Ministry)

Since some of the components that are part of a plan for hepatitis prevention and control are already being implemented by Government of India under different programs / Ministry, it is of utmost importance to ensure that there are no duplication of efforts and resources. It is desirable that optimal coordination and synergies between the existing program components and the information flow is maintained. These existing components include immunization program (specifically, hepatitis B vaccination), blood safety program under the NHM and NACO, and Drinking Water and Sanitation, Swachh Bharat Mission.

It is proposed to have a defined unit for program management of viral hepatitis headed by senior level regular government staff (both at National and State level) who will coordinate the process / implementation and reporting from the other ministries as well as from within the MoH.

Integration with existing healthcare delivery systems (such as NACP, IDSP, other public and private sector establishments) will be undertaken.

## Research

It is proposed to enhance knowledge and skills required for evidence base on various aspects of the epidemic, up-scaled operational research, cross-cutting, multi-disciplinary themes, improved research quality, better research capabilities and expanded partnerships, utilization and management of research based knowledge on viral hepatitis, relevant measurable and context specific indicators for tracking the epidemic and assessing



impact. It is proposed that the program will coordinate and collaborate with ICMR and other research institutions for research. The basic research and validations will be done in the agencies already mandated to do so under the MoHFW. The program will focus more on operational research that could feed into planning and policy decision.

## **Monitoring, surveillance, supervision and evaluation**

### **Surveillance :**

Surveillance denotes ongoing systematic collection, collation, analysis, and interpretation of output and outcome-specific data for the planning, implementation, evaluation, and improvement of programme for Viral Hepatitis.

The objective is to develop and implement evidence-based effective interventions. Such Surveillance systems can provide information on time, place, and person distribution of, either all cases of disease diagnosed in 'any' setting (known as universal surveillance), or a sample of population considered at high risk of acquiring that disease (known as sentinel surveillance).

The burden of viral hepatitis has already been detailed earlier in this document. As most of the newly infected persons with viral hepatitis are asymptomatic, and even symptomatic persons are underreported, reported hepatitis cases tend to markedly underestimate their true incidence and prevalence. Hence, an efficient program management for viral hepatitis requires reliable and consistent information on acute and chronic viral hepatitis.

The requirement of such surveillance programme will be to assess the levels and trend of recently acquired viral hepatitis (acute infections), and prevalence of viral hepatitis in general as well as different population (sub-)groups that are at a higher risk of acquiring such infections (chronic infections). Surveillance to detect the levels and trend of recently acquired viral hepatitis (acute infections) can detect outbreaks, monitor trends in incidence and identify risk factors for incident infections. Identifying individuals with acute infections serves to describe modes of transmission and to detect and control outbreaks.

The surveillance system will also estimate the prevalence of chronic infections, and monitor trends in the general population or in high-risk groups (different population groups that are at a higher risk of acquiring such infections).

Implementing surveillance systems for acute viral hepatitis complies with the International Health Regulations to strengthen disease detection. Surveillance is also required to provide a good quality reliable estimate for the burden of sequelae due to chronic hepatitis that would include cirrhosis and hepatocellular carcinoma (HCC).

### **M&E Framework:**

Monitoring of programme of all interventions at all levels will be the key to ensure the quality of services in the stipulated timeframe, with active involvement of programme management structure.

Impact evaluation of the programmatic component of the viral hepatitis provides important feedback to the programme. Information that is obtained from such a viral hepatitis programme becomes one of the important sources for monitoring and evaluating programmatic interventions. Consequently, an efficient evaluation mechanism can potentially identify key gaps and guide the programme to improve overall performance in synergistic areas, including water and sanitation, safety of blood and blood products and injection safety etc.

### **Data management**

Timeliness is a key feature of an efficient delivery system. A computerized data management system under the 'Integrated Initiative for Prevention and Control of Viral Hepatitis' would facilitate automated data transfer, data validation, monitoring and evaluation. Data should therefore, be entered in standard data formats at the



source, in software capable of handling multilevel entries and validation. Standard formats for recording and reporting will be prescribed by the NVHMU. The data needs to be shared by all the service delivery points, maintaining confidentiality.

Review meetings of the SVHMU officials will be organized on a quarterly basis to assess physical and financial progress, discuss constraints in implementation of the initiative and identify solutions to key barriers and bottlenecks. Key gaps identified during the implementation of the initiative will also be addressed through planned operational research.

In addition to the data collected from the service delivery points in the newer activities (diagnosis and management of viral hepatitis, etc), the integrated initiative will also coordinate with the existing programs and schemes that contribute towards the response to viral hepatitis and this would be compiled for monitoring a comprehensive program update at national level as well as for fulfilling the international commitments and reporting.

## **Record keeping**

A technical group will advise on development of the flow charts and mechanisms to address the collection and flow of information from ground level to national level in pre designed formats at a frequency, as decided. Monitoring of the progress for the existing components for Immunization, Blood Safety and Drinking Water and Sanitation shall be done through the existing program and their recording and reporting system, while formats for reporting shall be developed for the newer components.

Proper recordkeeping of client results is vital for providing quality service, tackling the medico-legal issues, and operational research. As per the guidelines, all documents must be stored for at least 5 years or as per state/ institutional guidelines whichever is longer.

## **Indicators**

The initiative has some components that involve coordination with other existing programs and schemes, and there are few interventions that are new and will be directly implemented under the aegis of NHM. These have been discussed in the respective sections and the relevant targets have been enlisted there. A compiled table for the indicators is attached in Annexure 1.

Independent evaluation of the initiative will also be planned and organized by National Program Management Unit. Key gaps identified during implementation of the initiative and innovative interventions would also be planned through operational research and will follow the established procedures under the guidance from the NVHMU.

## **Budget requirement for implementation**

The estimated requirement for the budget for various components has been estimated at Rs 907 crore over three years. These have been approved under the domestic funds from Government of India, under the National Health Mission (NHM). The budget for carrying out activities through the existing programs and schemes (including UIP, IEC, NACP, Swachh Bharat etc) that contribute to response towards viral hepatitis as well, are mandated under the respective programs and schemes.

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# Annexure 1

## Indicators for Monitoring and Evaluation under NVHCP

**Table 1: Monitoring Indicators for Diagnosis and Management of Viral Hepatitis**

| S No             | Indicator   | Base-line | Achievement    |  |  | Source of reporting/data/ verification and level |
|------------------|---|-----------|----------------|--|--|--|
|                  |   |           | Target- Year 1 | Target Year 2                                  | Target Year 3                                  |  |
| Input indicators |   |           |                |  |  |  |
| 1                | Number of states in which State Program Management Unit has been established              | N/A       | 36             | 36   | 36   | NHM/ State Health Machinery                      |
| 3                | Cumulative number of state labs strengthened to carry out testing under the initiative    |           | 36             | As per assessed need & demand from States/ UTs | As per assessed need & demand from States/ UTs | NVHMU/State Health Machinery                     |
| 4                | Cumulative number of district labs strengthened to carry out testing under the initiative |           | 250            | 500  | All districts                                  | NVHMU/State Health Machinery                     |
| 5                | Cumulative number of treatment sites strengthened under the initiative                    | N/A       | 100            | 300  | All districts                                  | NVHMU/State Health Machinery                     |

| Process Indicators |  |     |          |           |           |                                  |
|--------------------|--|-----|----------|-----------|-----------|----------------------------------|
| 1                  | % of State laboratory sites which have been trained on the SOPs for labs with respect to diagnosis of Viral Hepatitis under the initiative | 0   | 100%     | 100%      | 100%      | Training report; NVHMu and SVHMu |
| 2                  | % of Treatment sites which have been trained on the SOPs on Management of Viral Hepatitis with focus on Hepatitis C under the initiative   | N/A | 100%     | 100%      | 100%      | Training report; NVHMu/SVHMu     |
| Output Indicators  |  |     |          |           |           |                                  |
| 1                  | Number of new serological tests done for diagnosing viral hepatitis  | N/A | 1.6 lakh | 11.7 lakh | 41.8 lakh | Compiled facility report         |
| 2                  | Number of new patients initiated on treatment of hepatitis C   | N/A | 1 lakh   | 2 lakh    | 3 lakh    | Compiled facility report         |



\*Numerical targets are cumulative and as on end of the target period

**Table 2: Monitoring Indicators - Integration with other programs and Ministries/Departments**

| S.NO. | Indicator   | Targets to be advocated for           |        |                                 | Programs/ Institutions responsible for implementation | Frequency of reporting to NVHMU |
|-------|---|---------------------------------------|--------|---------------------------------|---|---------------------------------|
|       |   | Year 1                                | Year 2 | Year 3                          |   |                                 |
| 1     | Proportion (%) of newborns who have benefited from timely birth dose of hepatitis vaccine (within 24 hours) | 65%                                   | 70%    | 90%                             | Universal Immunization Program + States               | Bi annually                     |
| 1     | Proportion(%) of infants (<12 months of age) who received the third dose of hepatitis B vaccine (HepB3)     | 95%                                   | 95%    | >95%                            | Universal Immunization Program                        | Bi annually                     |
| 3     | Routine Hepatitis B vaccination among health-care workers.  | N/A                                   |        | Available (for all who need it) |   |                                 |
| 4     | Number of needles–syringes distributed per person who injects drugs   | As per NACO                           |        |                                 | NACO  | Annually                        |
| 5     | Is Vaccination for Hepatitis B available to key populations   | Currently No; Policy decision by NACO |        |                                 | NACO  | Bi annually                     |
| 6     | Proportion of blood units screened for TTIs (HBV and HCV)   |                                       | 100%   | 100%                            | NACO  | Bi annually                     |
| 7     | Proportion of all blood donations that are voluntary  |                                       |        | 80%                             | NACO  | Bi annually                     |
| 8     | Proportion of health-care facilities (sampled) where all injections are safe ( RUP)                         |                                       |        | 50%                             |   | Year 3                          |



