

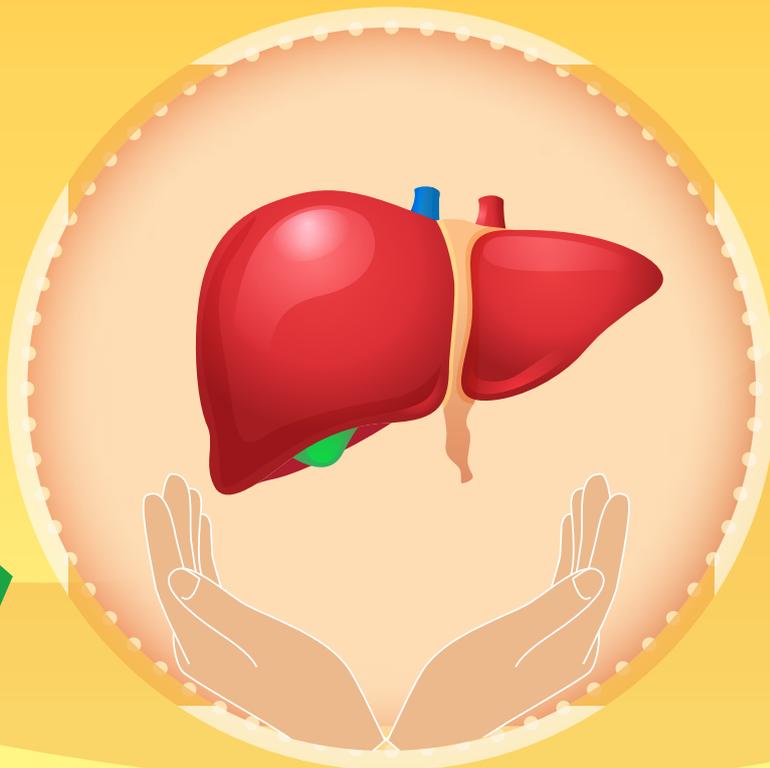


Ministry of Health and Family Welfare
Government of India



National Viral Hepatitis Control Program

Operational Guidelines



2018

National Viral Hepatitis Control Program

Operational Guidelines



जगत प्रकाश नड्डा
Jagat Prakash Nadda



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



MESSAGE

Viral hepatitis is recognized as a public health problem in India. Various etiological agents (Hepatitis A, B, C, D and E viruses) have been implicated that can lead to acute, chronic or sequel of chronic infection. While Hepatitis A and E are often the cause for sporadic outbreaks of hepatitis, hepatitis B and C can either clear spontaneously or can lead to chronic infection and thereafter sequel like Cirrhosis and Hepatocellular Carcinoma (HCC).

India is committed to combating viral hepatitis as a public health threat by 2030 in line with the Sustainable Development Goal (SDG) target. The Government of India has affirmed this commitment at the 69th World Health Assembly. Achieving this goal will require us to adopt an integrated approach towards all types of viral hepatitis. However, it requires sustained commitment and action to address the challenges ahead.

Hepatitis B and C are known to cause significant morbidity and mortality. Ministry of Health and Family Welfare has launched the 'National Viral Hepatitis Control Program' under the umbrella of National Health Mission. Hepatitis C can now be cured with the advent and availability of directly acting antiviral drugs. The program proposes to offer free drugs and diagnostics benefiting an estimated 5 crore patients suffering from chronic Hepatitis B and Hepatitis C infections. The program will provide laboratory testing and management of viral hepatitis which will be decentralized and scaled up to the health and wellness centers in a phased manner. Further, the program will integrate with other Ministries and national programmes and schemes to provide a promotive, preventive and curative package of services.

It is indeed heartening to see that the "Operational Guidelines for the National Viral Hepatitis Control Program" will facilitate and encourage everyone to play their part in achieving the SDG target to combat hepatitis by 2030.

(Jagat Prakash Nadda)

348, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
348, A-Wing, Nirman Bhawan, New Delhi - 110011
Tele.: (O) : +91-11-23061661, 23063513, Telefax : 23062358, 23061648
E-mail : hfwminister@gov.in



अश्विनी कुमार चौबे
Ashwini Kumar Choubey



सत्यमेव जयते
सर्वेषाम् निरामया



स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA



Message

The estimated burden of viral hepatitis is high, necessitating focus on prevention and control measures of hepatitis to mitigate the morbidity and mortality due to hepatitis. There are several components that are already existing in the different programs of Government of India like immunization for hepatitis B, Swachh Bharat Mission, safety of blood and blood products, safe drinking water and sanitation, that are directly or indirectly related to the response to viral hepatitis. These need to be addressed specifically with an integrated approach.

Currently services for diagnosis and treatment of viral hepatitis are limited, there was a felt need for standardized diagnosis and treatment protocols for viral hepatitis. The National Viral hepatitis Control Program will facilitate to bridge this gap. Scale up of services up to the health and wellness centres will play a major role in enhancing access. Integrated efforts have to be made along with the state governments for effective implementation of the program.

I am confident that these guidelines will enable the various stakeholders to effectively implement this initiative and manage patients detected with the disease.

(Ashwini Kumar Choubey)

Dated:-
New Delhi



सत्यमेव जयते



एन.एच.एम.सी.एन.सी.एन.सी.



MESSAGE

1.34 million Deaths were reported globally in 2015, on account of viral hepatitis which is a number comparable to deaths caused by tuberculosis. Viral hepatitis is therefore a major public health challenge and requires an urgent response. It was in this background that the Ministry of Health & FW decided to provide diagnosis and management of viral hepatitis free of cost through a new program for prevention and control of viral hepatitis with an integrated approach.

Whilst Government of India has resolved to take the challenge of combating viral hepatitis, it fully acknowledges the enormity of the task. In a country which is so vast and diverse and where each state, district, block and village have their own needs and challenges which are compounded by inadequate sanitation and hygiene in many parts with huge inter and intra State disparities, the journey may be long, hard and arduous. This will require much greater capacities for decentralized health care planning and management for providing services for viral hepatitis till the grass root level. But I am confident that the strategies formulated under the National Viral Hepatitis Control program shall yield meaningful outcomes.

We are committed to address the challenge of viral hepatitis and I personally request all the stakeholders-the State Government, the developmental partners, the community and the civil society to come forward and join us in our fight against viral hepatitis.


(Anupriya Patel)



प्रीति सूदन

सचिव

PREETI SUDAN

Secretary



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

Dated : 19th July, 2018



MESSAGE

Viral hepatitis is now being recognized as a major public health problem in India. While hepatitis A and E are often the cause for sporadic or outbreaks of hepatitis, hepatitis B and C can either clear spontaneously or can lead to chronic infection and thereafter sequel like Cirrhosis and Hepatocellular Carcinoma (HCC).

The available literature suggests that HAV is responsible for 10-30% and HEV accounts for 10-40% of acute hepatitis. It is estimated that there are 40 million people chronically infected with Hepatitis B and 6-12 million people with Hepatitis C in India.

Considering the magnitude of the problem, Ministry of Health and Family Welfare has launched the 'National Viral Hepatitis Control Program', with the goal of ending viral hepatitis as a public health threat by 2030 in the country. This operational guideline has been developed with the aim to provide an actionable framework at all levels of healthcare for implementing evidence-based interventions at scale. This will ensure that equitable and sustainable efforts are made to reaching out to all in need with the required health services. Standard diagnostic and management tools under this initiative will further enhance in providing quality services to one and all. A major reduction in pricess of newer drugs to potentially cure hepatitis C offers an added opportunity to work towards its control.

I hope that this guideline works out to be an effective tool in realization of the aims and objectives of the program.


(Preeti Sudan)



मनोज झालानी

Manoj Jhalani

अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)

Additional Secretary & Mission Director (NHM)



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011



FOREWORD

Vaccine against Hepatitis B is already part of the universal immunization programme. Thrust is now being given on improving the coverage of birth dose which will aid in an early win for prevention. The nation has also made good progress in keeping blood supply safe and improving injection safety in health-care settings, substantially reducing the risk of both Hepatitis B and C virus infections. However, a large number of people are still affected with the disease/infection. Many of them harbouring Hepatitis B & C remain asymptomatic for decades. These people are at risk of a slow progression to severe liver disease and death, unless they receive timely testing and treatment. The recent development of highly effective direct acting anti-virals has revolutionized the treatment of Hepatitis C infections.

It is with this background that Government of India has launched the 'National Viral Hepatitis Control Program' to provide access to affordable care for the management of viral Hepatitis with focus on treatment of Hepatitis B and C. It is envisaged that the initiative will be scaled up to grass root level in a phased manner.

The Guideline provides the why and how of the program and will help the implementers at different levels. I am sure that this guideline will help achieve the goals under the program of controlling Viral Hepatitis and help in mitigating suffering to millions of patients and their families in leading and lead a disease free life. The program provides cost effective interventions to avert DALYs and will help the country achieve the SDG3 target on Viral Hepatitis.

I compliment the efforts of the technical team from NCDC under the guidance of DGHS, the technical experts in the Technical Working Groups, ILBS in completing this huge task in a short period of time to make this possible.


(Manoj Jhalani)

स्वच्छ भारत—स्वस्थ भारत

Telefax : 23063687, 23063693 E-mail : manoj.jhalani@nic.in



विकास शील
संयुक्त सचिव
VIKAS SHEEL
Joint Secretary



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011
Phones : 23061481, 23063506 (T/F)
E-mail : jsnvbdcp-mohfw@gov.in



Preface

National viral hepatitis control program has been launched by Ministry of Health and Family Welfare with the aim to reduce morbidity and mortality due to viral hepatitis. The key strategies adopted under the program include preventive and promotive interventions with focus on awareness generation, increasing access, promoting diagnosis and providing management of viral hepatitis.

Emphasis will also put on building capacities at all levels of healthcare facility so that there is access to diagnosis and management at the lowest level of health care delivery system. Co-ordination and collaboration with different ministries and departments will be one of the pivotal strategy to address the issue of viral hepatitis. I am confident that this integrated approach of working closely with such national programs/schemes associated directly or indirectly to the response to viral hepatitis will have a synergistic effect in controlling the disease.

I am certain that content of this document will provide a framework of roll out of the program in a simplified manner for its step by step implementation. These guidelines will play an instrumental role in achieving the Program's aim of reducing the morbidity and mortality attributable to viral hepatitis. It will pave the way for the state governments to move towards the path of achieving the Sustainable Development goal of combating viral hepatitis.

(Vikas Sheel)

ACRONYMS

ALF	Acute Liver Failure
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
DVHMU	District Viral Hepatitis Control Management 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 Worker
GoI	Government of India
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HBsAg	Hepatitis B surface antigen
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 centre
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
NVHMU	National Viral Hepatitis Control Management Unit
OQ	Operational Qualification
OST	Opioid Substitution Therapy
PHC	Primary Health Centre
PIP	Program Implementation Plan
PQ	Performance Qualification
PT	Proficiency Testing
PWID	People Who Inject Drugs
RNA	Ribonucleic Acid
RUP	Reuse Prevention
SACS	State AIDS Control Society
SDG	Sustainable Development Goal
SGPGI	Sanjay Gandhi Post-graduate Institute
SVHMU	State Viral Hepatitis Control Management Unit
STI	Sexually Transmitted Infection
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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CHAPTER 1

Background

Introduction

The global hepatitis report, 2017 by WHO, provides the baseline statistics on Hepatitis B virus (HBV) and Hepatitis C virus (HCV) infection, including mortality and coverage levels of key interventions. (1) Hepatitis B and C, the two main types of the five different hepatitis infections (A,B,C,D,E), are responsible for 96% of overall viral hepatitis related mortality.

Epidemiology of Viral Hepatitis

Global

Viral hepatitis is now recognized as a major public health challenge that requires an urgent response. Viral Hepatitis caused 1.34 million deaths in 2015, a number comparable to deaths caused by tuberculosis and higher than those caused by HIV. (1)

It is estimated that worldwide, Hepatitis A Virus (HAV) infections caused approximately 11,000 deaths in 2015 (accounting for 0.8% of the mortality from viral hepatitis). (2)

It is estimated that 325 million people worldwide are living with chronic HBV or HCV infection. Approximately, 1.75 million people were estimated to be newly infected with HCV in 2015, increasing the total number of people living with Hepatitis C to 71 million. (1)

Every year, there are an estimated 20 million Hepatitis E Virus (HEV) infections worldwide leading to an estimated 3.3 million symptomatic cases of acute hepatitis E. It is estimated that Hepatitis E caused 44,000 deaths in 2015 (accounting for 3.3% of mortality due to viral hepatitis). (1)

India

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 accounts for 10-40% of acute hepatitis and 15-45% of acute liver failure. (3)

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%. (3) Based on some regional level studies, it is estimated that in India, approximately 40 million people are chronically infected with Hepatitis B and 6-12 million people with Hepatitis C. (4) Chronic HBV infection accounts for 40% of Hepato-cellular Carcinoma (HCC) and 20-30% cases of cirrhosis in India. (3) Chronic HCV infection accounts for 12-32% of HCC and 12-20% of cirrhosis. (3)

Population based syndromic and health facility based surveillance of viral hepatitis is mandated under the Integrated Disease Surveillance Programme (IDSP).

A systematic review of available information from published studies and from large unpublished reliable datasets, to assess the prevalence of chronic HCV infection in the Indian population has recently been done to assess the prevalence of overall HCV infections, and by age, sex, risk factors and place in the country. This meta-analysis data estimated that India (current population approx. 1.3 billion) has 5.2-13 million anti-HCV positive persons. As the data on HCV viremia amongst the anti-HCV positive persons were not available, data from elsewhere was used to estimate that India has about 3 million to 9 million persons with active HCV infections. (5)

All key and bridge population groups under the NACP for HIV infections are specially vulnerable to viral hepatitis infections too. There include groups like recipients of multiple blood/blood products transfusion, patients on hemodialysis, People Who Inject Drugs, MSM, femalesex workers, sexual partners of infected people, prisoners, migrants and truckers etc. Also, high risk population for viral hepatitis include close first degree relatives and family members: mother, siblings, spouse and children, of persons affected with viral hepatitis. 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. Such population groups shall be treated as key populations or high-risk groups (HRGs) under the National Viral Hepatitis Control Program.

Hepatitis B and C infections have long gestation periods before the disease progresses to advanced stages resulting in liver cirrhosis and liver cancer, resulting in mortality if treatment is not provided in time. Intervene to prevent advancement of the disease is particularly more challenging because during the gestation period, the disease does not manifest itself through any specific symptoms.

Recent advances in diagnostics have now made it possible to diagnose people carrying viral hepatitis infections through point-of-care rapid diagnostic kits. Several new technologies and platforms are also now available for conducting confirmatory tests through viral load testing. Reliable treatment of viral hepatitis B & C is now possible with new medicines. Diagnostics and treatment services have so far been available only through the private sector in India. In absence of a public health initiative, such incidence of disease leads to high out of pocket expenditure.

The Government of India has, hence, decided to launch a new National Viral Hepatitis Control Program (NVHCP) for prevention and control of viral hepatitis, with a view to provide free of charge screening, diagnosis, treatment & counselling services to all, and specially to people belonging to high-risk groups.

CHAPTER 2

Introduction to the Program

India is committed to progressively move towards elimination of viral hepatitis B and C and control other virus induced hepatitis. This is in line with our global commitment towards achieving Sustainable development goal (SDG) goal 3; target 3.3 which aims to “By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water borne diseases and other communicable diseases” 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 India, the estimated burden of hepatitis is very high, necessitating focus on prevention and control measures to mitigate morbidity and mortality arising out of hepatitis. (6)

There are several components that exist in the different programs of Government of India, such as Immunization for Hepatitis B; Swachh Bharat Mission; Safety of blood and blood products; Safe drinking water and sanitation, which are directly or indirectly related to the response to viral hepatitis.

The sequel of chronic hepatitis which includes cirrhosis and HCC poses long term burden on the health system. A recent cost benefit analysis of treating hepatitis C infection demonstrated that curing the HCV with 12-24 weeks of directly acting antivirals (DAAs) is substantially more cost effective than managing the sequels and has better health outcomes. (7) Unsafe injection practices during health care or otherwise, remain a risk and have potential to transmit the HBV and HCV infection. Use of Reuse Prevention (RUP) syringes is a critical intervention to interrupt the chain of such transmission. India manufactures RUPs for injection in therapeutic care and mandating its use in public and private sector offers a new opportunity to address unsafe injections. With the view to address the existing gaps in current programs, the program proposes to address management of all types of viral hepatitis. The advent of newer and safe drugs for treatment of Hepatitis C ensuring cure makes it easier to combat it. Similarly, the available drugs for hepatitis B treatment are quite potent and safe and keep the virus suppressed for prolonged periods, reducing the risk of cirrhosis and liver cancer.

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.

Key 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.

Components

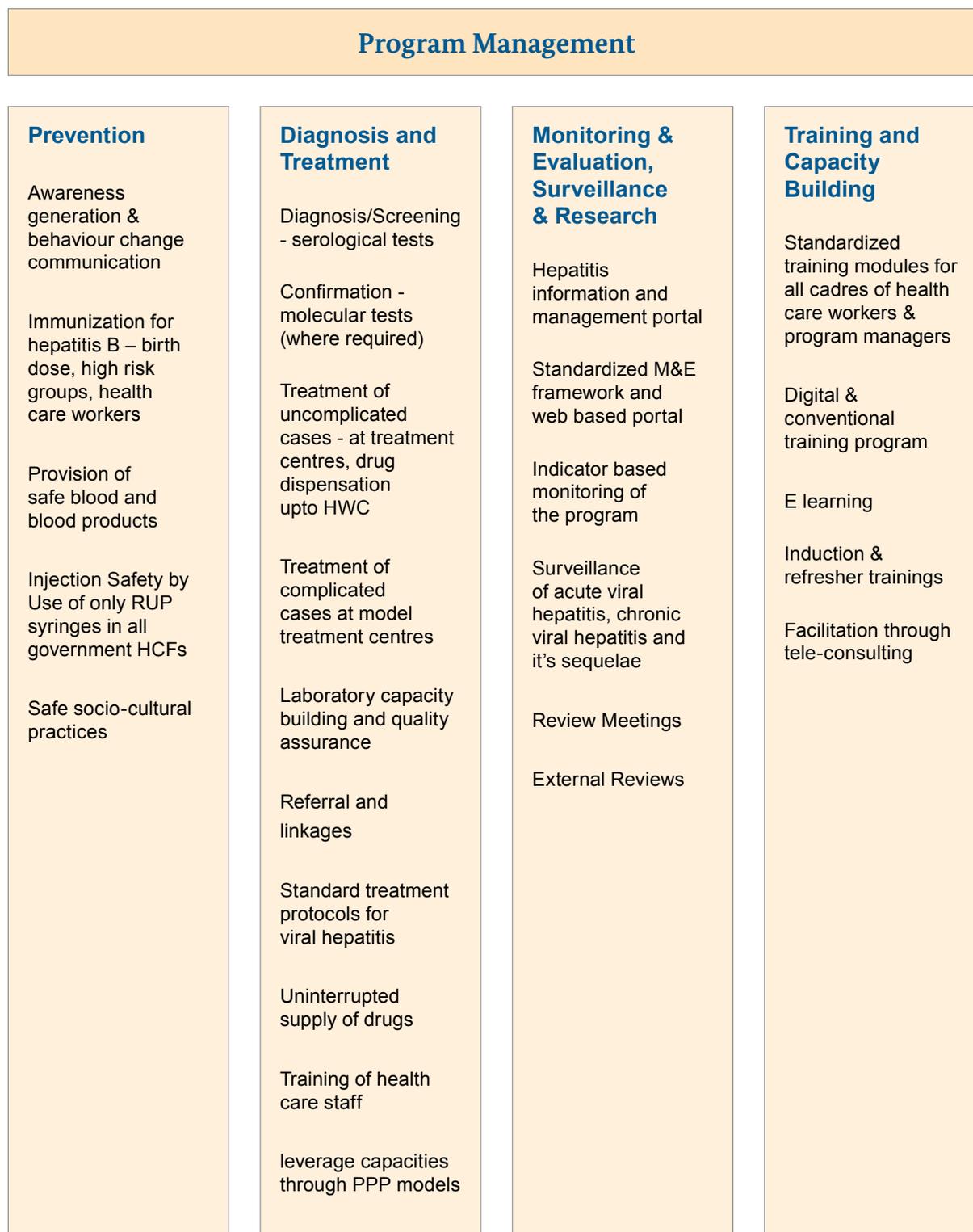
The key components include:

1. Preventive component: This remains the cornerstone of the NVHCP. 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 Department of Health Research (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 electronic, e-learning and e-courses.

Activities

The main activities of the program would include the following:



Targets for the NVHCP

The National Viral Hepatitis Control program has the following cumulative physical targets for the first three years:

1. Program Management:
 - a. National Viral Hepatitis Management Unit (NVHMU): To establish a NVHMU in the first year.
 - b. State Viral Hepatitis Management Unit (SVHMU) - To establish a State Viral Hepatitis Management Unit in the first year within existing state health governance structure i.e. State Health Society. This would be structured on similar lines as the NVHMU.
2. Prevention:
 - a. Develop and implement the protocol for ante-natal screening of pregnant women for Hepatitis B; and start screening in the first year.
 - b. Develop and implement tracking mechanism to ensure institutional delivery for all Hepatitis B carrier pregnant women.
 - c. Increase Hepatitis B zero dose immunization to over 90%
 - d. Implement safe injection practices in government systems immediately
 - e. Blood safety targets
 - f. To develop institutional mechanism for periodic testing of drinking water sources in coordination with Department of Drinking Water and Sanitation (DoDWS).
 - g. Improved IEC for prevention and checking transmission
3. Diagnosis & Treatment
 - A. Diagnosis:**
 - a. Set up the National Reference Laboratory by the end of first year.
 - b. Establish State level reference laboratories in each state by the end of first year.
 - c. Develop District Diagnostics centres with viral load testing capabilities by the end of first year.
 - d. Start first line diagnosis through Rapid Diagnostic Kits at all levels by the end of first year.
 - e. Test 1.6 lakh individuals in the first year, 10.1 lakh in second year and 30.1 lakh in the third year for Hepatitis C.
 - f. Start screening people belonging to high-risk groups for Hepatitis B in first year.
 - g. Encourage opportunistic screening for HBV and HCV of patients visiting health care facilities
 - B. Treatment:**
 - a. Establish at least one Model Hepatitis Treatment Centre in each state\UT in the first year in an institution identified by the respective state\UT government. Increase the number of such centres if required (on the basis of need assessment) in consultation with the concerned state\UT government, in subsequent years.
 - b. Establish at least one Treatment Centre at district level in the public sector, preferably in a medical college or the District Hospital, by the end of second year to offer access to quality assured management of Viral Hepatitis.
 - c. Number of new hepatitis C cases to be treated across the country: over 3 lakh patients in 3 years
 - d. Start treatment for Hepatitis B for people needing treatment, by the end of first year

4. Training:
 - a. Ensure all trainings to operationalize state reference laboratories and Model Treatment Centres by the end of first year.
 - b. To develop capacities of state\UT teams for training of personnel at the district laboratories and treatment centres.
 - c. To develop IT driven institutional mechanisms for offering online counselling and courses to personnel at all levels. The program will also explore facilitation through tele consulting where required.
 - d. To develop capacities of functionaries in Community Health Centre, Primary Health Centre and Health and Wellness Centre (CHC, PHC and HWCs) to implement diagnostic and treatment support protocol appropriate at that level
5. Monitoring and Evaluation, Surveillance and Research:
 - a. To develop and operationalize the Viral Hepatitis Information Management System (VHIMS) for
 - i. Maintaining a registry of patients
 - ii. Tracking of patients for ensuring treatment adherence and compliance.
 - iii. Developing dashboards and reports for monitoring of the Program.
 - b. Co-ordinate with the National Viral Hepatitis Surveillance Program
 - i. Surveillance of acute viral hepatitis
 - ii. Surveillance of chronic viral hepatitis
 - iii. Surveillance of sequelae of chronic viral hepatitis
 - c. Research: Identify evidence based operational research and implement in collaboration with DHR

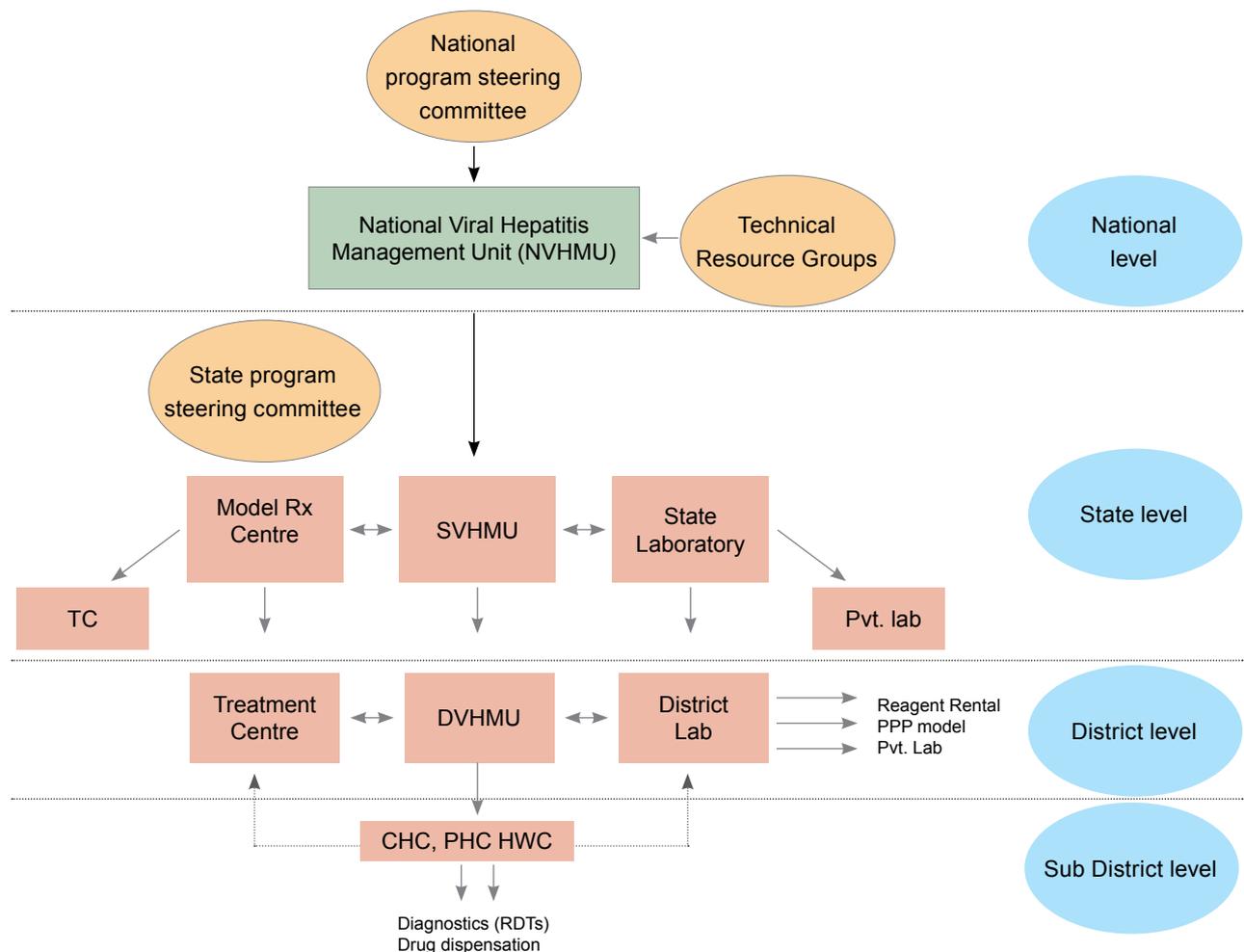
CHAPTER 3

Program Management

The NVHCP 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)

Organizational Structure



The laboratory and treatment site should preferably be co-located. The NVHCP envisages a service delivery mechanism in subsequent years where there will be co-location of district labs and treatment centres with due considerations to capacity in different domains and move towards PHC for screening and drug dispensation.

National Program Steering Committee:

There will be a National Program Steering Committee headed by Secretary Health & Family Welfare. The Committee shall inter alia include

1. Secretary, Department of Health Research (DHR)
2. DGHS,
3. Mission Director, National Health Mission
4. Director General, National AIDS Control Organisation
5. Representative of RCH, Immunization division, IDSP, NHM Policy, and IEC divisions in the Ministry of Health and Family Welfare.
6. NCDC representative
7. Principal Secretaries from 2 states nominated by the Secretary Health & Family Welfare, Government of India
8. Mission directors from 2 states, nominated by the Secretary Health & Family Welfare, Government of India
9. Director, ILBS
10. ED, NHSRC
11. 2-3 eminent persons from academic institution across the country,
12. Representatives of Swachh Bharat Mission for both urban and rural sectors
13. Representative from Ministry of Drinking water and sanitation,
14. Representatives of the community (like PWID, haemophiliacs, PLHIV, FSW, MSM)
15. Development partners like UNICEF and WHO.

The Joint Secretary looking after the NVHCP shall be the convenor of the Committee.

The Steering Committee shall monitor & provide guidance for implementation of the Program and shall meet as often as necessary, but at least once every 6 months..

Key Functions of the Program Steering Committee

1. Monitor the progress of the National Program
2. Advise on the newer interventions over the process of implementation
3. Guide on the external evaluation process

National Viral Hepatitis Control Management Unit

The NVHCU established at the Centre within the NHM and will be responsible for implementation of program and activities of the Program. The NVHCU will be headed by a Joint Secretary who will report to the Mission Director (NHM). It will have following wings, namely –

1. Prevention unit (Will perform the functions of IEC, coordination and linkage with other programs)
2. Diagnosis and Treatment unit
3. Surveillance , monitoring and Evaluation
4. Training and capacity building

Appropriate number of consultants with needed competencies will be engaged to support the NVHMU. The support will be provided through the NVHMU budget under the NHM. The key functions of NVHMU will include procurement and supply chain management, training and capacity building, development of guidelines for the use in the program, collaboration with existing programs and divisions of GoI [like UIP, safety of blood and blood products, IDSP, Indian Council of Medical Research (ICMR) etc] and overall implementation, supervision, monitoring and evaluation.

Roles and Responsibilities of National Viral Hepatitis Control Management Unit (NVHMU) in the Centre

- » Provide technical assistance for facilitating the implementation of the ‘National Viral Hepatitis Control Program’ and achieving the yearly physical and financial targets at various levels.
- » Development of Standard Treatment Protocols and Standard Diagnostic Protocols for Acute and Chronic Hepatitis under the guidance of a “Inter-Ministerial Task Force” and the “Technical Working Group”.
- » Provide normative guidance (technical and operational) and standard operating procedures, biomedical waste management and bio-safety guidelines for the various points of service delivery.
- » Development of standardised Training manuals for all cadres of health care providers including doctors, pharmacist, data managers, peer supporters, ANM, Para-medical professionals etc
- » Collaboration and coordination with the other existing national health programs/schemes at the national level (like Universal Immunization Program; Injection Safety; Safety of Blood and blood products; Integrated Disease Surveillance Programme (IDSP); National AIDS Control Program (NACP); Harm reduction in key population; Surveillance of Viral Hepatitis; Swachh Bharat Mission; Safe drinking water and sanitation Program; Biomedical waste management).
- » Coordinate with IDSP at the Central Surveillance Unit (CSU) for epidemic/outbreak investigation as and when required.
- » Facilitate all work related to External Quality Assessment (EQA) with the designated laboratory periodically
- » Budgeting and financial planning for the NVHCP including maintaining expenditure Control Register, manage records with respect to finance and accounts, reconcile head-wise expenditure for the NVHCP at the national level.
- » Responsible for providing inputs for preparing the Program Implementation Plan for the states with respect to the NVHCP and appraising the PIPs received from the states.
- » Regular monitoring of the functioning of State and District Laboratory network under the NVHCP and with IDSP through Central, State and District Surveillance Unit.

The key functions of NVHMU will include

- » Awareness generation
- » Procurement and supply chain management,
- » Training and capacity building,
- » Development of guidelines for the use in the program,
- » Collaboration with existing programs and divisions of GoI [like UIP, safety of blood and blood products, IDSP, Indian Council of Medical Research (ICMR) etc] and
- » Discussions with states and guidance to formulate State PIP to meet annual targets
- » Overall implementation, supervision, monitoring and evaluation

State Viral Hepatitis Control Management Unit (SVHMU)

A State Viral Hepatitis management unit for coordination shall be set up in all the states and UTs, within the existing state health governance structure i.e. the State Health Society with dedicated nodal officer and required essential manpower for the program. This will be guided by a state program steering committee and supported by technical experts (in synchronization with the NVHMU structure) involved in the program implementation. The SVHMU shall be responsible for planning, implementation, monitoring and reporting of all the Program activities in the state\UT. This will include supply chain management and distribution within the state, training and capacity building, integration with existing programs and divisions at the state level (like UIP, safety of blood and blood products, ICMR etc.), coordination with the NVHMU and the laboratory and treatment sites at all levels, establishing supervision, monitoring and evaluation framework for viral hepatitis at the state level.

Roles and Responsibilities of the State Viral Hepatitis Management Unit in the State

1. Budgeting and financial planning for the prevention and control of viral hepatitis at the state and district level. Responsible for preparing the Program Implementation Plan (PIP) for the respective state for the NVHCM.
2. To submit evidence based proposal during the state PIP development
3. Provide technical assistance for facilitating the implementation of program for achieving the yearly physical and financial targets at various service delivery components.
4. Ensure that the normative guidance, guidelines and standard operating procedures provided by the centre are followed at the point of service delivery.
5. Ensure implementation of standard operating procedures, diagnosis & treatment guidelines and quality control measures.
6. Collaboration and coordination with the other existing national health programs/schemes at the state level (like UIP; Injection safety; Safety of blood and blood products; Integrated disease surveillance program; State aids control society; Harm reduction in key population and Surveillance of viral hepatitis; Swachh Bharat mission; Safe drinking water and sanitation program; Biomedical waste management).
7. Coordinate with NVHMU and state and district level to help in capacity building under the NVHCP.
8. Collect, collate and analyse the state and district level data on components of the NVHCP on regular basis and send the same to the NVHMU.
9. Coordinate and collaborate with other ministries at the state level for better synergy in implementing the NVHCP
10. Supervise through on site visits and provide technical support for strengthening of state and District Hepatitis units under the program;
11. Regular monitoring of the functioning of State and district level facilities for diagnosis and treatment.
12. Maintain expenditure control register, manage records with respect to finance and accounts, reconcile head-wise expenditure.

Key Functions of the SVHMU

1. Identify a nodal person for Viral Hepatitis related program activities in the state and district
2. Develop State PIP for submission to NVHMU to set targets for the state
3. Identify the service delivery sites and regularly monitor them
4. Conduct state level review meeting and field visits to monitor the program implementation at state level
5. Ensure coordination with other program of GoI
6. Ensure that the data is analysed at state level for better program planning and regularly reported to centre.

District Viral Hepatitis Control Management Unit (DVHMU)

A district Viral Hepatitis management unit for coordination shall be set up in all the districts, within the existing health governance structure.

The state government will designate a program officer at the district level from available manpower as the nodal person to supervise and facilitate the logistics, supply chain, outreach, training etc.

Roles and Responsibilities of the District Viral Hepatitis Management Unit (DVHMU)

1. To ensure that the district labs and treatment centres are functional
2. To identify sites for service delivery
3. To ensure training of the personnel
4. To establish referral networks both for diagnostics and treatment wherever required
5. To ensure linkages with existing program NVHCPs to achieve the set targets.
6. To assist in distribution of IEC material at the facilities
7. To ensure data recording, and reporting from the service delivery units on a real time basis as far as possible

CHAPTER 4

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.

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 NVHMU and SVHMU 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. Provision of vaccination for health care workers should be followed one month later by testing for protective hepatitis B antibody levels (anti HBs>10 IU/ml). 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.

NVHMU, SVHMU and DVHMU will establish linkages with the existing system of NACP at 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 and 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 the 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 population 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.

Country Target

S.No.	Indicator
1.	By 2020, 100% of injection devices are safety engineered devices in India.

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 Pradhan Mantri National Dialysis Program for making special emphasis on the component of injection safety and infection control in their program module. NVHMU and 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 and SVHMU will integrate with the IDSP

- To provide technical support for outbreak investigation and reporting and monitoring of outbreaks of viral hepatitis, specially hepatitis E and A.
- 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 up to 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 co-located 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 NVHCP 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 there prevalence can certainly 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 amongst general population and food business operators.

CHAPTER 5

Service Delivery: New Interventions- 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

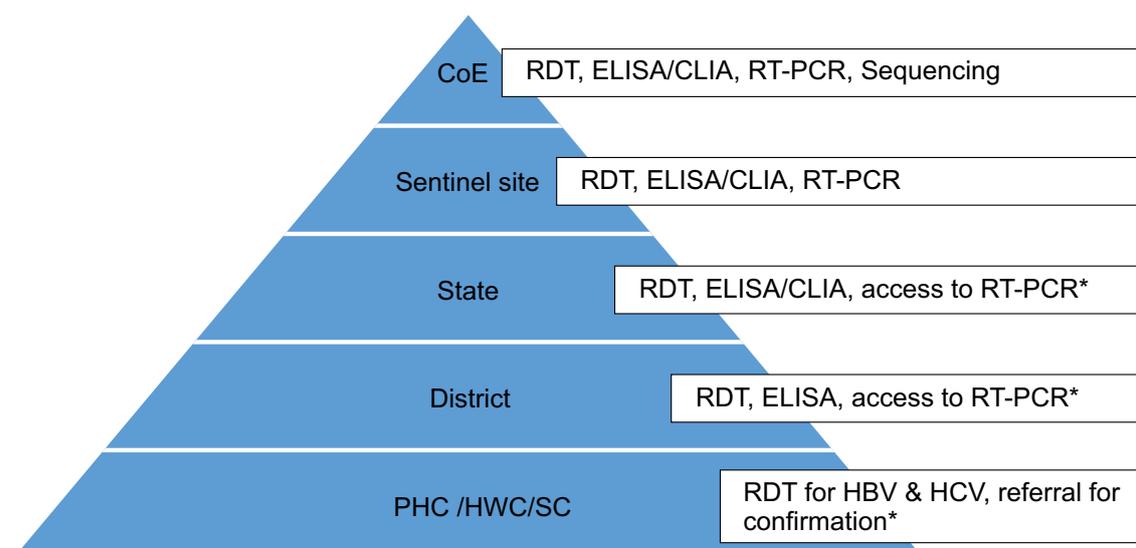
Laboratories Services

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, up to PHC 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.*

Centre of Excellence for laboratory testing

Centre of Excellence (CoE) will be situated at National Centre for Disease Control (NCDC).

Roles and Responsibilities

- All samples will be archived. A subset will be sequenced to determine the genotype and maintain a national database on the virus genotypes circulating in the population.
- Capacity building of the sentinel sites for onward training of the state labs nominated.
- Formulation and dissemination of guidelines as part of the NVHCP
- Supervision of all the laboratory activities under the NVHCP
- Provide technical assistance for implementation of the NVHCP
- Building capacities at national and state level under the NVHCP
- Facilitate all work related to EQA/proficiency testing (PT) with the designated PT provider(s) and the participating labs
- Undertake review of literature and stay up-to-date on current trends in health systems strengthening with regard to the NVHCP for prevention and control of viral hepatitis.

State Laboratories

It is targeted to strengthen state laboratories under the program. State Laboratories under the NVHCP will be selected by the state based on the burden of disease according to available evidence in form of studies, outbreaks, case reports, blood bank data etc.

In the first year, State Laboratories will be co-located in those Microbiology labs which are also the sentinel site labs under the National Program on Surveillance of Viral Hepatitis. State laboratories will build the capacity of the district laboratories in a time bound manner (based on the operational guidelines on the laboratory services for viral hepatitis NVHCP). Some of the state labs will be identified and their capacity built for HBV DNA / HCV RNA testing. It is proposed to adopt a reagent rental model for molecular testing wherever feasible. Sample transportation is envisaged to meet economies of scale. However, looking at the diversity of the country, the NVHCP will explore public private partnership models in hard to reach areas and use of existing infrastructure and equipment to facilitate access to HCV RNA testing in a cost efficient manner.

Roles and Responsibilities

1. The laboratory will be required to ensure that the samples are collected from all the HCFs in the geographical area linked to that State lab. These samples should be logged in and stored as per the prescribed guidelines for subsequent testing.
2. Testing of the samples for viral hepatitis as per the prescribed guidelines for testing
3. Some of the state labs will be identified and their capacity strengthened to perform serological and NAT tests. Testing will be done of the samples received from the co-located treatment sites and other state and district laboratories
4. Ensuring a referral mechanism to the treatment centre
5. Storing of the plasma for viral load NAT
6. To develop a repository of panel members to be used for evaluation purpose.
7. Follow a common plan, standard operating procedures (SOPs) and recording/reporting forms for carrying out the activity.
8. The state lab has to ensure that the equipment for the activity are satisfactorily installed by the supplier, facilitate the necessary Installation Qualification (IQ), Operational Qualification (OQ) and the Performance Qualification (PQ) and ensure that the supplier performs the requisite calibration and maintenance of the equipment at specified intervals as per the work order. Ensure on site training by the vendor on the equipment installed before signing of the certificate for satisfactory installation as this is linked to financial obligations of the centre and subject to accountability of all concerned.
9. The state lab needs to ensure that all records pertaining to testing, equipments, manpower, facility etc. are maintained as per the guidelines.
10. Shall ensure quality management systems in pre-analytic, analytic and post-analytic processes of testing.
11. Shall follow the protocols on sample rejection as prescribed by CoE.
12. Shall maintain minimum performance standards for the laboratory to be functional at all times
13. Participate in external quality assessment scheme (EQAS) mandated by CoE.
14. Shall prepare its own IQC panel which will include weakly positive and negative controls.
15. Shall monitor the IQC results regularly and Levy-Jennings charts will be prepared and reviewed every month.
16. Shall ensure that the samples for EQAS are sent to the designated laboratory in proper packaging, and controlled temperature and humidity conditions in cold chain as per the prescribed guidelines.
17. Samples received at the testing laboratories will be stored in adherence to the protocols as specified in this programme Guidelines.
18. Shall follow the standardized testing algorithm
19. Training and Capacity building of the district labs

District Laboratories

These laboratories would be co- located with the Treatment Centres at the district hospitals. The capacities of these labs will be strengthened in a phased manner. The state laboratories will train the district laboratories in carrying out serological testing for viral hepatitis (immuno-assays/rapid Tests). These laboratories will perform the testing and would be linked to other treatment centres in the district, sub-district levels in the region. Each treatment centre would be linked to HBV DNA/HCV RNA estimating laboratories in the Government or private sector. This can be done by using existing machines in the system, reagent rental or PPP model in hard to reach areas as detailed earlier. Cartridge based nucleic acid amplification testing will also be explored.

Roles and Responsibilities

1. Sample collection and serological testing under the NVHCP
2. Molecular testing where feasible
3. Sample transportation for molecular testing, where necessary

Functions at the District Laboratory

1. Undertake testing for screening and diagnosis
2. Undertake molecular testing where feasible and transport the sample for molecular testing where necessary

Laboratories below district level

At all levels below district, provision for screening by using rapid diagnostic tests (RDTs) will be done for screening of HBV/HCV

Roles and Responsibilities

- 1) Sample collection and serological testing under the NVHCP
- 2) Establish referral mechanisms for confirmation and treatment

At all levels below district level, provision for screening by using RDTs will be done for HBV/HCV screening

Sample Transportation for HBV/HCV Quantitative NAT testing

Hub and spoke model will be followed for the collection, storage and transport of the samples for viral load NAT, where required. These samples will travel from the district lab/ state lab to the identified laboratories for DNA/ RNA/NAT testing. (Refer to the National Laboratory Guidelines for Viral Hepatitis Testing) Other options like use of CBNAAT and PPP will also be explored.

The program will endeavor to set up a network of laboratories for drug resistance testing in the future.

Human Resource in Laboratories

To facilitate the diagnosis and laboratory monitoring of treatment, the NVHCP will strengthen the laboratories to deliver services as per the national guidelines. The laboratories so strengthened should have the following manpower.

S No	Manpower at state laboratories
1	Technical officer – 1
2	Data entry operator – 1
3	Laboratory technician – 1

S No	Manpower at district laboratories
1	Laboratory technician -1

The NVHCP will evaluate and provide the same on a need based approach. The staff should be recruited by the institution as per the norms and procedures followed for recruitment of contractual staff as per the guidelines of the National Health Mission (NHM). The terms of reference of the human resource are available in Annexure 3. The remuneration for all these staff shall be in accordance to the state NHM norms. There should be an in-built system of appraisal of such staff from time to time.

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

Approach to Diagnosis of Viral Hepatitis

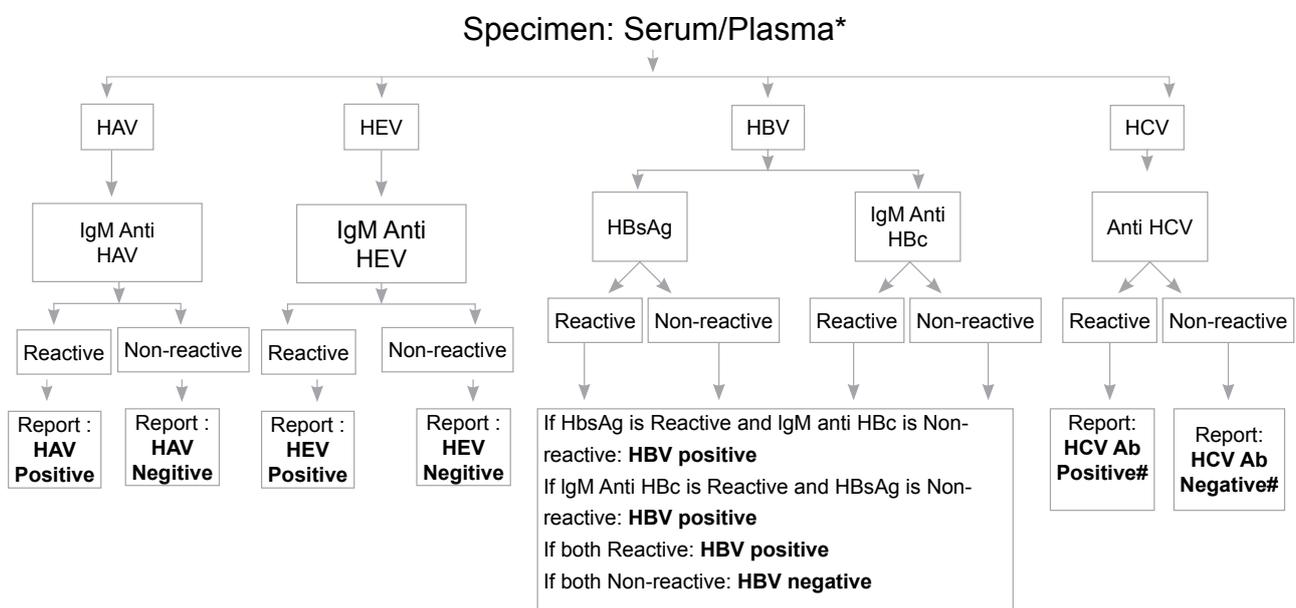
A patient with acute or chronic viral hepatitis infection may present at a healthcare setting with or without jaundice. The patient may be referred by a treating doctor/health worker/mid level provider for investigations after taking a written informed consent with a complete test requisition form.

Testing for HBV in pregnant women- In states where institutional deliveries are less than 80%, screening of all pregnant women should be carried out for HBsAg detection. Institutional delivery of HBsAg positive pregnant women must be mandated to prevent transmission to the child by giving birth dose Hepatitis B vaccine. A birth dose of HBIG as per requirement will be given to the new born at the district level.

Self-presenting asymptomatic individuals at high risk may be provided access to testing by a defined mechanism in the health care facility.

The algorithms to be followed for diagnosis are as under:

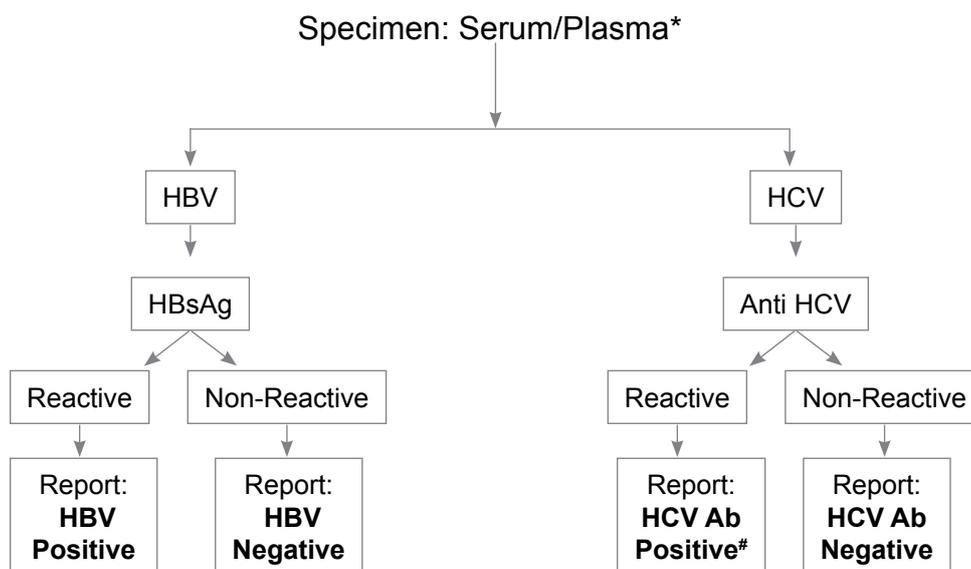
Testing algorithm for Diagnosis of Viral Hepatitis in jaundiced patients



* Serum samples to be used for serological and biochemical testing, to be aliquoted and stored at -20 ° C for retesting for quality purposes, dispute etc.

All HCV antibody (Ab) positive to be referred to treatment centre. Plasma samples to be collected and aliquoted in 3 sterile cryo vials. One vial to be used for quantitative hepatitis C RNA estimation and two archived at -80° C for quality assurance.

Testing algorithm for Diagnosis of Viral Hepatitis in suspected patients (without jaundice)



* Serum samples to be used for serological and biochemical testing, to be aliquoted and stored at -20°C for retesting for quality purposes, dispute etc.

All HCV antibody (Ab) positive to be referred to treatment centre. Plasma samples to be collected and aliquoted in 3 sterile cryo vials. One vial to be used for quantitative hepatitis C RNA estimation and two archived at -80°C for quality assurance

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 Model Hepatitis Treatment centre will 3-4 per state and can be located in the district hospital or co-located with the sentinel sites. All the diagnosis and treatment centres will have the capacity to differentiate whether the patient has advanced liver disease or not. They would deliver the DAA in uncomplicated cases (and few other scenarios as per the national technical guidelines). Selection of the other treatment sites will be based on the concurrence of states after due considerations on existing capacities. They could be situated in any competent health care facility like the medical colleges, district hospitals etc. However, the cases that need more specialized care will be referred to higher centre that have the requisite capacity and experience to manage the complicated cases (e.g. decompensated cirrhosis, thalassemics with HCV infection, and HCV infection in renal impairment etc). These health care facilities with specialized services for diagnosis and management (like availability of Gastro-enterologist /hepatologist, fibroscan, Doppler, CT scan, MRI scan etc) are termed as Model Treatment centre. Hence, the MTC will perform all the functions of a treatment centre, will also receive in-referrals and also be the centres for training, mentoring and conducting operational research under the NVHCP.

Model Hepatitis Treatment Centre

1. To ensure screening/ diagnosis in suspected cases of hepatitis B and hepatitis C infection
2. Treatment & management of viral hepatitis

3. In referrals for cases screened / diagnosed elsewhere, for the management of hepatitis
4. Management of complicated cases referred from other treatment centres. Prescription and dispensation for the first month shall be done at the MTC and if the patient is stable, he can be transferred out to the nearest dispensing site for regular follow up. In case of any adverse event, s/he may come back to MTC.
5. Management of cases under special categories as per national guidelines(e.g.: paediatric patients, thalasseemics, patient with treatment failure etc.)
6. Ensure compliance and completion of treatment
7. Training and mentoring of other treatment sites
8. Operational research

Key Functions of MTC

1. Screening / Diagnosis of Suspected cases
2. Management of uncomplicated cases
3. Ensure that national guidelines and protocols are adhered to
4. Manage the complicated cases referred from Treatment centres
5. Maintain the data base and ensure timely reporting
6. Undertake training and mentoring of the Treatment centres in their region (as defined by NVHMU and SVHPU)
7. Participate in operational research as per the program needs

Hepatitis Treatment Centre

1. To ensure Screening/ Diagnosis in suspected cases of Hepatitis B/C Infection
2. Treatment and Management of uncomplicated Hepatitis B/C infection
3. In referrals for cases screened / diagnosed elsewhere, for the management of hepatitis and prescription with drugs to be dispensed after first month from site nearest to patient convenience
4. Out referrals to MTC for clinical management as per national treatment guidelines.
5. Ensure compliance and completion of treatment

Key Functions of a Treatment Centre

1. Screening / Diagnosis of Suspected cases
2. Management of uncomplicated cases
3. Ensure that national guidelines and protocols are adhered to
4. Referrals for complicated cases to MTC
5. Maintain the data base and ensure timely reporting

Selection criteria and steps for setting up a centre

Each site will be selected by the state, based on the burden of disease according to available evidence in form of studies, outbreaks, case reports, blood bank data and existing capacities. Once the sites are identified and proposed, a joint team will visit the facility and assess its feasibility for delivery of services, adequacy of needed space and man power and willingness of the institute to set up such centre. The team that will undertake the feasibility visit should ideally comprise of the state and district officials of the NVHCP, central unit officials and other invited partners. The report of feasibility visit should be prepared, signed and kept with the state officials. The format for feasibility visit is attached as annexure 1. Attempts will be made to provide services till PHC.

Inclusion criteria for consideration as a potential treatment site include:

1. Established evidence of case load for viral hepatitis infection or its sequel
2. Evidence of high hepatitis burden in catchment area
3. Commitment and willingness of the state government to have a treatment site and consequent agreement to follow the SOP and protocols under the NVHCP
4. Availability of required infrastructure and existing capacities.
5. Availability of appropriate and optimum human resource for clinical and laboratory management, as well as other services routinely.

Human Resource for the Treatment Sites

The services will be delivered through the existing health system and the institution will have to nominate a nodal officer who would be responsible for the day to day functioning of the centres. Ideally, this could be the Head of department of Internal Medicine/Gastro-enterology/Hepatology (or a person deputed /nominated by head of the institution) in tertiary centres and the physician in district hospitals and elsewhere. The patients should be seen by the attending physician from the system and the documentation of the patient data and management should be recorded in the formats that are made available under the program.

To assist the delivery of services in a uni-flow system and to ensure efficacy, the treatment centres will be provided the following staff under the program in a phased manner:

Staffing provided by the program (contractual staff)

The treatment centres so established should have the following manpower

S No	Model Treatment centres
1	Medical officer – 1
2	Pharmacist -1
3	Data entry operator – 1
4	Peer support -1

S No	Treatment centres
1	Pharmacist -1
2	Data entry operator – 1
3	Peer support -1

The NVHCP will evaluate and provide the same on a need based approach. Since the Model treatment centres will also undertake additional tasks like training, mentoring, operational research and conducting review meetings with state and NVHMU, they will be provided one contractual position of level of medical officer (MO).

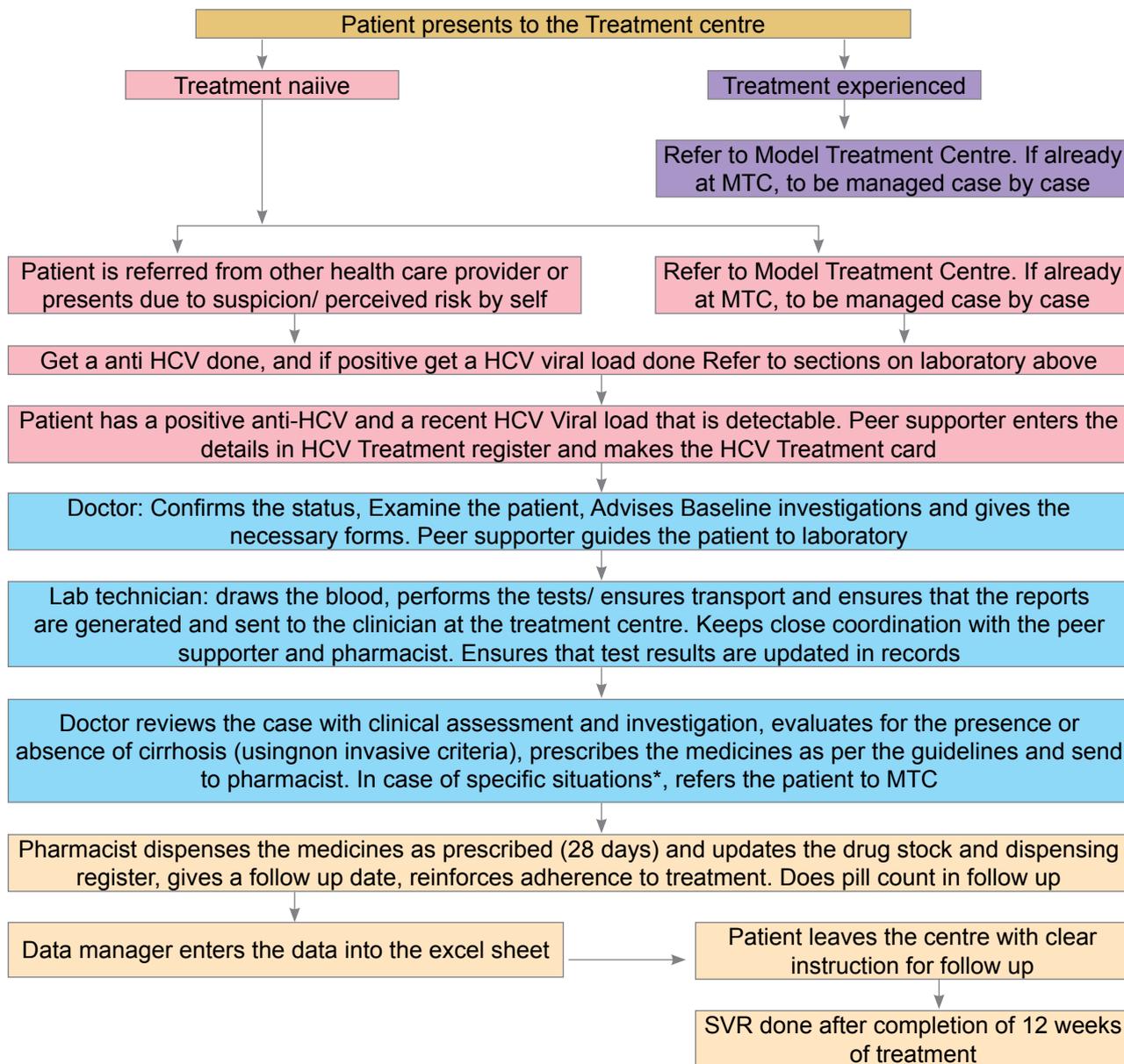
Approach to providing Treatment

The following sections and figure below elaborate on the flow of patient at the treatment centre and also can be used to guide the smooth functioning of the staff.

There are two components:

1. Enrolment of the patient into care
2. Follow up visits of the patient

Enrolment of the patient: The patients who present to the centre could either have a definite diagnosis or might have suspected infection. In case the person is found to have hepatitis C infection by the anti-HCV test (from a government facility), they should be confirmed with HCV RNA as per the diagnosis algorithm in the national guidelines. Every person who has a detectable HCV RNA is eligible to receive treatment after taking consent.



** These specific situations are described in the treatment guidelines and include retreatment cases/ pregnant women/patients with decompensated cirrhosis, malignancy, renal insufficiency etc.*

Every patient found anti HCV positive is registered in care for onward enrolment and has to be confirmed with a detectable HCV viral load for being eligible for treatment. Cases where anti-HCV is positive but no HCV viral RNA is detected do not have an active HCV infection and do not need treatment. Sequential entries for all the registration are to be maintained in the hepatitis C Treatment Register. Once confirmed, the testing and treatment card for the patient is made. It is made in two sets: one to be kept at the centre and other given to the patient. The centre should take an address proof (Aadhaar card as UID is mandatory) from the patient. The confidentiality of the information provided by the patient is to be protected at all cost. Any divulgence of such information will have penal implication as per law for anyone responsible for such divulgence. The testing and treatment card will capture patient demographic information diagnosis and treatment details.

The sections on name and demographic details are filled by the peer supporter while enrolling. The section on the clinical parameters and the laboratory investigations are filled by the treating doctor. The service provider signs the card at the respective places mentioned.

The data entry operator maintains the digitize format of the same.

The details are also entered at each visit as and when they are advised. The follow up entries help in monitoring the disease progress, counselling of the patient for regular treatment, review of adherence of the patient to therapy. The drugs will be dispensed for 28 days. However, the pharmacist should ensure that the patient is given a follow-up day after 25 days. This will ensure that the patient does not land in a situation where s/he is out of drug stock. At every visit, the pharmacist should also count the remaining drugs (pill count) to have an idea if any doses have been missed. The patient should be instructed to bring the bottle of DAA with her/him at every visit so that the pharmacist can perform pill count, collect the old bottle and issue a new one.

The complicated cases, as defined in the technical guidelines, should be referred to the MTC. At the MTC, the drugs should be dispensed and once the patient is stable and the treating doctor is confident that the patient can be managed at the nearest treatment site, then the drug dispensation can be done at the nearest site. However, the patient should be referred back to MTC in case it is deemed necessary for appropriate management.

The uncomplicated cases, as defined in the technical guidelines, should be initiated treatment at the treatment centre. Once the patient is stable and the treating doctor is confident that the patient can be managed at the nearest treatment site, then the drug dispensation can be done at the nearest site. However, the patient should be referred back in case it is deemed necessary for appropriate management.

Summary of the key actions to be undertaken for patient management and record maintenance and the responsible person.

Visit Number	Key activity (but not limited to)	Responsible person
First visit and baseline, after confirmation of active hepatitis C infection	Ascertain Diagnosis of active Hepatitis C (anti HCV as well as HCV RNA)	Attending doctor
	Enter patient details in Hepatitis C Treatment Register and demographic details in treatment card	Peer Supporter
	Take a detailed history and examination	Attending Doctor
	Categorize presence/Absence of Cirrhosis and fill relevant section in Treatment card	Attending Doctor
	Select Regimen and start treatment	Attending Doctor
	Explain patient on adherence and follow up date	Peer supporter and pharmacist
	Dispense prescribed medicines	Pharmacist
	Get the baseline investigations done and furnish report to centre	Doctor, Lab technician
Follow up visit	Educate on adherence and regular follow up	Doctor ,Peer supporter and pharmacist
	Dispense prescribed medicines	Pharmacist
	Check for any side effects	Attending Doctor
	Get any investigations needed as per technical guidelines, prescribe the medicines	Attending Doctor
	Update investigations in treatment card	Lab technician, Doctor
End of Treatment	Counsel on Treatment completion and need for weeks of completing treatment 12 SVR after	Doctor, peer supporter
	Recheck the contact details including phone	Peer supporter
For all visits	Update the record from the register and card to the excel based sheet	Data entry operator

Ideally, there should be no expiry at any centre. However, in the event there is expiry of some medicines under the program, they should be discarded as per the hospital policy. The process should be documented with details on the quantity of drug, batch number and should be signed by three regular government employees including the nodal officer of the centre. In case there is no institutional policy for discarding the medicines, from the central and state unit for viral hepatitis under NHM must be sought through a written communication clearly mentioning the absence of such institutional policy. Justifications and reasons for the same must be recorded in writing and kept for review by supervising authorities

Monitoring and Evaluation of the Treatment sites

The treatment sites and the laboratory will be reviewed regularly by the nodal officers for the site level day to day functioning. In addition, the district/state and National officials will also undertake supervisory site visits for supportive supervision and mentoring. The suggested frequency of the monitoring and mentoring visits are:

Level	Frequency of visit
National	Annual
State	Quarterly
District	Once monthly

During the visits, the officials should try and provide on spot trouble shooting wherever needed, should provide clarification, assess the HR availability and required infrastructure, check the completeness and quality of records and reports submitted and randomly check the drug stocks (physical stocks versus the reported stocks)

Additionally, review meetings will be conducted that will provide a platform for experience sharing and review the progress.

Recording tools

The following recording tools are to be used under the program:

1. Site Feasibility Form:
2. Patient Treatment card :
 - a. To be maintained at centre
 - b. Patient Treatment card (for the patient to retain)
3. Hepatitis C Treatment register:
4. Drug stock and dispensing register:
5. Excel based tool for comprehensive record in the documents above.

(Detailed operational guidelines on the care, support and Treatment services for hepatitis C services have been developed and should be referred to for details on site selection, manpower, pattern of assistance, patient management and M & E etc. A detailed guidance on operational issues for management of hepatitis B will be issued subsequently.)

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

The treatment centres so established should have the following manpower

S No	Model Treatment centres
1	Medical officer – 1
2	Pharmacist -1
3	Data entry operator – 1
4	Peer support -1

CHAPTER 6

Supply Chain Management

There will be central procurement of diagnostic equipment, kits and drugs at the national level so as to ensure quality and advantage of economies of scale. These would be provided directly under intimation of the state programme management unit. Each centre will have to generate demand based in the consumption as per the given targets annually.

Once the kits/drugs are provided, a lead time of at least 12 weeks to raise the demand to the central agency will be required to ensure no disruption to supply chain.

The nodal officer in the SVHMU/DVHMU will monitor the same monthly with the facility.

10% buffer to account for quality control/wastage. Supply will be monitored by the centre/state. Supply to the point of consignee periodically in atleast 2 lots per year.

At the time of receipt of the consignment, the nodal officer will keep the receipt in original; will get the stock verified after that sign on the receipt of the consignment. The receipt in original will be sent to the state coordination unit for onward transmission to the NVHMU after keeping due record at all level. For serological tests, equipment will be available in the designated labs. Consumables will be procured locally/through state depending upon the state policy

CHAPTER 7

Trainings

Trainings are important for any new initiative as well as for building capacity of the service delivery points for effective implementation. To ensure standardized and uniform quality of service delivery, there will be capacity building of different cadres of staff in the NVHCP, using standardized training modules and facilitator guides.

The trainings for building capacities of the human resource under the NVHCP will be planned by NVHMU and conducted by identified institutions like model treatment centres and state laboratories using both conventional and digital technology. An ongoing mentoring through digital platform for case discussion and to address various technical issues will be undertaken by Centre of Excellence and the Institute of Liver and Biliary Sciences (ILBS) to maintain and improve quality of care. The training approach will be in hub and spoke model where National Institutes will impart training to trainers and develop Training modules. There should be special trainings conducted for sensitization on confidentiality and respecting the status of a positive patient.

1 st Year	
0-3 months	<ul style="list-style-type: none"> • Identification of the sentinel site labs and Model Treatment Centres • Identification of the regular officers for carrying out the NVHCP • Recruitment of Human Resource • Capacity building of the 15 sentinel site labs and Model Treatment Centre by CoE
3-6 months	<ul style="list-style-type: none"> • Capacity Building of the 50 state labs. (Minimum of 4 persons/lab to be trained) • Training of 15 Model Treatment Centres (All cadre of staff) (15X5=75-minimum persons trained)
6-12 months	<ul style="list-style-type: none"> • Cascade training of identified district/sub-district upto level of PHC labs for viral hepatitis testing. The training of trainers will be in a tiered cascade mechanism. Standardized training modules will be shared • Training of the treatment centres (All cadre of staff) (Minimum of 4 persons/centre to be trained)
2 st Year	
>12months-24months	<ul style="list-style-type: none"> • Capacity Building of the Treatment Centres (other than the MTC) and other districts/ CHC/PHC labs for viral hepatitis testing • (Minimum of 2 persons/lab to be trained at district level) • (Minimum of 2 persons/treatment site to be trained)

CHAPTER 8

Monitoring and Evaluation

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 NVHCP and identify solutions to key barriers and bottle necks. Key gaps identified during the implementation of the NVHCP 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 NVHCP 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

Proper record keeping 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 NVHCP 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 3.

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

CHAPTER 9

Pattern of Assistance and Flow of Funds

Data management

The states will need to factor in their budget proposal in the Programme implementation plan based on the annexure 4.

The flow of funds will be in the mechanisms prescribed under NHM

CHAPTER 10

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Annexure 1: Feasibility Visit for Setting Hepatitis Treatment Centre

Checklist for Feasibility of Hepatitis Treatment Center			
1	Name of the town / District/ City:		
2	Type of Hospital: (Medical College/ District Hospital / Other tertiary care)		
3	Name of the Medical Superintendent or IC of the institution		
4	Names of the identified Nodal officer by Institute		
5	Date of Feasibility Visit		
6	Members of the Visiting Team		
a			
b			
c			
d			
7	Complete postal address of the Hospital with Pin Code		
8	Contact details of the Nodal person (mobile and email)		
BACKGROUND INFORMATION			
1	Is the Institution willing to set up a center for hepatitis treatment	Yes	No
2	Is the In-charge keen on establishing services?	Yes	No
a	Willing to allocate necessary space	Yes	No
b	Willing to have nodal person for treatment and lab services	Yes	No
c	Integrate the functioning and follow the National guidelines and protocols , including recording and reporting	Yes	No
3	What is the annual OPD of the hospital		
4	Is there super-speciality(Gastroenterology/ Hepatology)	Yes	No
5	How many cases of acute hepatitis are seen annually (explore last years report)		
6	How many cases of hepatitis B and C are seeking care (explore previous reports)		
7	Is there a blood bank in institute? What is sero-positivity for hepatitis B and hepatitis C in last three years (record year wise)	Yes	No
8	If this is a district hospital, where are patients referred or usually go for complicated cases?		
9	Do you have a HIV related service?		
a	ICTC	Yes	No
b	ART center	Yes	No
c	Opioid Substitution Center	Yes	No
d	Involvement with Prison	Yes	No
8	Is the institution implementing any other program under NHM? Please mention name(s)	Yes	No
INFRASTRUCTURE			
1	Location of the proposed centre (is it in vicinity to OPD services)	Yes	No
	Is there an ICU	Yes	No
2	Number of rooms		
a	Doctors	Yes	No
b	Pharmacist	Yes	No
c	Data Entry Operators	Yes	No
d	Drug Storage & Pharmacist	Yes	No
e	Lab Technician	Yes	No
f	Peer supporter	Yes	No
3	Is institution willing to provide necessary furniture (chairs, tables, Almirah etc)	Yes	No
4	Will the center have access to internet	Yes	No

HUMAN RESOURCES			
1	Does the institution have the required capacity to manage chronic hepatitis Cases?	Yes	No
a	Gastroenterologist/Hepatologist	Yes	No
c	Physician (Internal Medicine)	Yes	No
d	Pediatrician	Yes	No
e	Microbiologist	Yes	No
f	Pathologist	Yes	No
g	Obstetrician	Yes	No
h	Others (Mention)		
LABORATORY CAPACITY / INVESTIGATIONS FACILITY			
1	Does the institute have a capacity to do HCV RNA	Yes	No
2	Does the Institution have facility to do HCV Screening test (immunoassay - please specify)	Yes	No
3	Are the following investigation routinely available	Yes	No
a	Complete Blood Count / Hemogram	Yes	No
b	Renal Function test	Yes	No
c	Liver Function Test (please ask for each test)	Yes	No
d	Blood Sugar	Yes	No
e	INR	Yes	No
f	Platelet count	Yes	No
g	Pregnancy Test	Yes	No
h	X Ray	Yes	No
l	Ultra Sound abdomen with Doppler	Yes	No
J	Fibroscan	Yes	No
k	CT scan		
l	MRI		
m	Endoscopy		
n	Liver Biopsy	Yes	No
o	Others		

S No	Key Issues Identified	Follow-up Actions suggested

FINAL RECOMMENDATION OF THE TEAM (Please tick)	
Recommended to Select Site for Opening Hepatitis Treatment Site	
Not Recommended to Select Site for Opening Hepatitis Treatment Site	

Signature of the Feasibility Visit Team: 1.....
 2.....
 3.....
 4.....

Annexure 2: Monitoring and Evaluation Indicators

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

Sl. No.	Indicator	Base line	Achievement			Source of reporting/data/ verification and level
			Target Year 1	Target Year 2	Target Year 3	
Input indicators						
1.	National Program Management Unit established	N/A	Yes	Yes	Yes	NHM
2.	Number of states in which State Program Management Unit has been established	N/A	30	30	30	NHM/ State Health Machinery
3.	Cumulative number of state labs strengthened to carry out testing under the initiative		10	60	65	NVHMU/ State Health Machinery
4.	Cumulative number of district labs strengthened to carry out testing under the initiative		0	300	600	
5.	Cumulative number of treatment sites strengthened under the initiative	N/A	15	60	100	NVHMU/ State Health Machinery
6.	Are operational guidelines for the initiative developed?	N/A	Yes			Program Documents at NHM
7.	Are standard laboratory guidelines for diagnosing of Viral Hepatitis developed under the initiative?	N/A	Yes			Program Documents at NHM
8.	Are standard treatment guidelines for Viral Hepatitis developed under the initiative?	N/A	Yes	√	√	Program documents at NHM
9.	Is there a standard Training curriculum developed for the initiative?	N/A	yes	√	√	Program Documents at NPMU
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; NPMU and SPMU
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; NPMU/ SPMU
Output Indicators						
1	Number of new serological tests done for diagnosing viral hepatitis	N/A	1.6 lakh	10.1lakh	30.1 lakh	Compiled facility report
2	Number of new patients initiated on treatment of hepatitis C	N/A	1 lakh	1lakh	1 lakh	Compiled facility report

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

S.NO.	Indicator	Target			Source (Information to be collected by NPMU-VH)	Frequency of reporting to NPMU
		Year 1	Year 2	Year 3 (2020)		
1.	Proportion(%) of infants (<12 months of age) who received the third dose of hepatitis B	95%	95%	>95%	Immunization Program	Bi annually
2.	Proportion (%) of newborns who have benefited from timely birth dose of hepatitis vaccine	95%	95%	>95%	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 and NHM (to report as % and numbers to NPMU –VH)	Bi annually
	Proportion of all blood donations that are voluntary			80%		Bi annually
7.	Proportion of health-care facilities (sampled) where all injections are safe (RUP)			50%	Survey	Year 3

Annexure 3: Terms of Reference of Human Resource

Laboratory In-charge (State Lab)

Designated Microbiologist of the Institution, or Pathologist in the absence of Microbiologist

Job Responsibilities

1. Supervises the work of laboratory personnel
2. Verification and signing of reports generated in the laboratory
3. Ensuring that all job responsibilities are adhered to, by all laboratory personnel
4. Management of funds with relation to laboratory
5. Ensure participation in and review of EQA
6. Ensure training and competence of all the laboratory personnel
7. Ensuring timely reporting of data.

Technical officer (State Lab)

Qualification: MSc Medical Microbiology with 1 year experience in clinical laboratory services. Candidates with PhD Medical Microbiology from recognized university with 3 months experience in clinical laboratory services will be preferred.

Job Responsibilities

1. Supervises the work of Laboratory technician under the guidance of the Laboratory In-charge.
2. Molecular testing where available
3. Preparation of SOPs and work instructions.
4. Verification of reports generated in testing laboratory
5. Preparation of quality control (QC) samples
6. Preparation & distribution of proficiency panels (PT) panels
7. Inventory and financial document management in lab.
8. Maintaining and monitoring timely calibration / verification of all devices and ensuring that all monitoring and measurements are done with devices having valid verification / calibration status.
9. Adherence to Bio-safety guidelines.
10. Maintenance of records and logs in laboratory.
11. Disposition of nonconforming products in her area of operation.
12. Help in the conduct of teaching and training programs.
13. Participate in surveillance activities of programme, through NCDC
14. Onsite field visit to district lab for mentoring and quality assurance.
15. Reporting to laboratory In-charge
16. Any other duty assigned by laboratory In-charge

Laboratory Technician (State/District Laboratory):

Qualification: DMLT two year course or certificate in MLT for one year or B.Sc in MLT from recognized university.

Job Responsibilities

1. Collect / receive specimens in the laboratory.
2. Assist in sample transportation to referral laboratory as and when required.
3. Performs tests for hepatitis markers and preparation of reports.
4. Storage and maintenance of serum samples as per guidance.
5. Confirmation of reference samples from state medical college labs and compilation of reports.
6. Perform regular internal quality control testing, EQA and their documentation
7. To maintain essential records in the laboratory
8. Inventory preparation for equipment and reagents.
9. Indent for supplies to the Laboratory through Lab In charge and ensure sufficient stock of Laboratory consumables is available.
10. Participate in trainings and workshops conducted.
11. Assist in molecular testing of samples where required.
12. To maintain cleanliness in and safety and follow proper biomedical waste disposals.
13. Any other work/ activity assigned from time to time.

Data Entry Operator (State laboratory):

Qualification: The Data Entry Operator should be a graduate with Diploma in Computer Applications (from a recognized institute or university) or 'O' Level course from DOEACC. S/he has to undergo training under the initiative in monitoring and evaluation tools (M & E) of the initiative aimed to build the capacity of the person in recording data, preparing and sending reports and maintaining records properly.

Job responsibilities of Data Entry Operator:

1. S/he has to work under the guidance and supervision of nodal officer (Microbiologist)
2. Ensure that all data recording and reporting is updated for all activities under the initiative, including surveillance of viral hepatitis, if the lab is also participating in the surveillance program for viral hepatitis
3. Print and share all circulars/information sent by NHM/States to the Nodal Officer and maintain a file for orders/communication
4. Maintain the attendance register for the staff and get it verified by the nodal officer (daily/ end of the month)
5. Maintain the personnel file/s including the bio-data of the staff, copies of certificates, appointment letters, contractual service agreement, performance appraisal report, training details, remuneration etc
6. Prepare and send all the monthly reports prescribed by the initiative after approval of Nodal Officer
7. Assist in analysis of data under the supervision of the Nodal Officer
8. Any other duty assigned by nodal officer.

Terms of Reference for various staff at Treatment site

1. Nodal Officer

1. Overall responsibility of the functioning of the centre, reporting to state / central unit, participation in review meeting, coordinate and develop referral system and linkages with other departments of the hospital
2. Ensure that patient are not discriminated in the hospital and are not denied admission/ care.
3. Ensure that all ethical practices including confidentiality are maintained.
4. Ensure availability of adequate stock of quality drugs as per defined targets at all times
5. Ensure reporting of any short expiry drug in a timely manner to allow timely relocation and avoid financial loss
6. All administrative matters relating to the centre including sanctioning of leave of contractual staff, annual performance appraisal of the staff etc as per guidelines
7. Ensure adherence to the highest standards of quality and excellence in patient care
8. Ensure that all staff should be entering data electronically
9. Review and monitor the functioning of the centre periodically and in depth and ensure submission of reports as required.
10. Act as Focal point for interaction with central unit/ State program management officials etc

2. Medical officer (MO) of Model Treatment Centre (MTC)

Qualification: The MO should be a Medical graduate (MBBS) with 5 years of experience in clinical care preferably related to infectious diseases. S/he must be registered in the concerned state Medical Council.

Job Responsibilities

1. S/he is the functional team leader of the centre under the overall guidance of the Nodal officer. The MO has to supervise the administrative and medical functions of the centre on a day- to- day basis and provide leadership to staff to work as a cohesive team and deliver the services effectively
2. S/he should examine the patients, advise required investigations, review the investigations and prescribe the treatment.
3. Refer difficult/ complicated cases to the Nodal Officer or other specialist for further expert opinion and interventions including admission and inpatient care, if required
4. Monitor the consumption and availability of drugs, and alert the concerned authorities in case of impending shortage well in advance so as to enable adequate replenishment without disruption of services
5. S/he must ensure that all records, registers, cards are updated on a daily basis and reports are sent to the concerned authorities on time. All reports should be checked by the MO before taking approval from the Nodal Officer for sending them to the concerned authorities
6. S/he has to ensure that the guidelines for running and maintaining the centre are abided by.
7. Facilitate and coordinate trainings in the centre.
8. Ensure that a daily due list is prepared for the patients expected to visit and a follow up action is taken to contact the defaulting patients.
9. Any other duty assigned by Nodal Officer/ Programme.

3. Pharmacist

Qualification: The pharmacist should hold a Degree in Pharmacy from a recognized institute. If candidate with degree is not available, diploma holder in pharmacy with 3 years of experience in health care institution can be considered. S/he must be registered in the concerned state pharmacy council.

Job responsibilities of Pharmacist:

1. S/he has to work under the guidance and supervision of nodal officer/MO
2. Dispense drugs with proper counselling / interaction with patient
3. Advise the patients and family about the importance of adherence during each visit
4. Counsel the patient on possible drug toxicities and report the same, if significant
5. Do pill count and report any adverse effects of drugs Also, confirm the next visit date and inform the patient
6. Maintenance of the drug stores
7. Maintain and update drug stock and drug dispensing registers regularly every day. Inform the concerned medical and nodal officer in case of any discrepancy. Duly take signature of nodal officer every fortnightly in the stock register
8. Ensure that the centre has enough stock of drugs for at least 3 months and inform the concerned authority about any near expiry or excess stocks well in time for relocation to other sites and ensure FEFO protocol is followed
9. Physical verification of the drugs under the supervision of the nodal officer and/or the MO
10. Besides all the above, any other duty assigned by nodal officer.

In case pharmacist is not available/on leave, the nodal officer in consultation with the head of institute will make any alternative arrangement so that the functioning does not suffer and regular staff of the facility must also be integrated for service delivery.

4. Data entry operator

Qualification: The Data entry operator should be a graduate with Diploma in Computer Applications (from a recognized institute or university) or 'O' Level course from DOEACC. S/he has to undergo training under the initiative in monitoring and evaluation tools (M & E) of the programme aimed to build the capacity of the person in recording data, preparing and sending reports and maintaining records properly.

Job responsibilities of Data Entry Operator:

1. S/he has to work under the guidance and supervision of MO and/or nodal officer
2. Ensure that all data recording and reporting is updated
3. Print and share all circulars/information sent by central unit/States to the Nodal Officer/MO and maintain a file for the important orders/communication
4. Maintain the attendance register for the centre staff and get it verified by the nodal officer everyday and by the Nodal Officer at the end of the month
5. Maintain the HR file including the bio-data of the staff, copies of certificates, appointment letters, contractual service agreement, performance appraisal report, training details, remuneration etc
6. Prepare and send all the monthly reports prescribed by central unit after approval of Nodal Officer
7. Assist in analysis of data under the supervision of the Nodal Officer
8. Any other duty assigned by nodal officer.

5. Peer supporter

Qualification: The peer supporter should be a person preferably with or recovered from the disease (hepatitis B or hepatitis C), with a minimum of intermediate (12th) level education. S/he must also have sound knowledge of the local language and working knowledge of English.

Job responsibilities of peer supporter:

1. S/he has to work under the guidance and supervision of nodal officer /MO
2. Be the first interface with patient at centre
3. Ensure entries in the visit register
4. Be a peer educator for patients at centre and provide psycho-social support to newly registered patients
5. Provide assistance to patients enrolled at the centre, within the hospital (OP and IP)
6. Discuss the importance of adherence to treatment and need of viral load at 12 weeks post treatment (SVR) with the patients , Keep track of drug adherence of patients , counselling them on the importance of regularity of visits and timely investigations
7. Follow up the patients and assist in patient retrieval, where necessary and as far as possible
8. Undertake data entry in absence of the data entry operator
9. Any other duty related to the initiative assigned by nodal officer/MO

Annexure 4: Summary of financial allocations

S. No	Type of facility	Areas covered	Unit Cost for the facility (Rs)	Remarks
1.	State Coordination unit	Manpower	As described in the table above	To be adapted as per state need.
		Other grant to state -Equipment (one time grant for computer set ,printer, photocopier and scanner) Other administrative expenses (meeting/travel/contingency)	12.87 lakhs (2.7 lakhs for small states- Goa, Uttarakhand , Sikkim and Tripura)	As per need
2.	State Laboratory	Manpower as per the state NHM norms and other administrative expenses(meeting/travel/contingency)	17.24 lakhs	Refer to national laboratory guidelines on viral hepatitis testing for more details
3.	Model Treatment Centre	Human resource as per the state norms (described above), contingency, grant-in-aid, meetings and training cost	21.72 lakhs	Refer to operational guidelines for roll out of Hepatitis C treatment for more details
4.	Treatment Centres	Human resource as per the state norms (described above), contingency, grant-in-aid, meetings and training cost	5.335 lakhs	Refer to operational guidelines for roll out of Hepatitis C treatment for more details
5.	Procurement		Test kits and Drugs – to be centrally procured.	
6.	District lab		Need based provision of one lab technician at state NHM norms	

Annexure 5: Patient entry and service availability at various levels of health care

Level		Patient entry	Diagnostics			Management	
			Screening (RDT)	Diagnosis(ELISA/ CLIA; LFT; molecular	Advanced diagnostics / Quality Control	Uncomplicated	Complicated
Below District	H &WC						
	PHC				<input type="checkbox"/> (Dispensing)		
	CHC				<input type="checkbox"/> (Dispensing)		
District level	District Level						
State Level	MTC/ State lab						

List of Contributors

1. Mr Manoj Jhalani, Additional Secretary & Mission Director, NHM, MoHFW
2. Dr Manohar Agnani, Joint Secretary, MoHFW
3. Mr Lav Agarwal, Joint Secretary, MoHFW
4. Mr Vikas Sheel, Joint Secretary, MoHFW
5. Dr S.K. Sarin, Director, ILBS, Delhi
6. Dr S.K. Singh, Director, NCDC, DteGHS, MoHFW
7. Dr Sandhya Kabra, Additional Director, NCDC, DteGHS, MoHFW
8. Dr Partha Rakshit, Deputy Director, NCDC, DteGHS, MoHFW
9. Dr Hema Gogia, Deputy Assistant Director, NCDC, DteGHS, MoHFW
10. Dr Preeti Madan, EIS Officer, NCDC
11. Dr Nicole Seguy, Team leader Communicable Diseases, WHO India
12. Dr Vimlesh Purohit, National Professional Officer, WHO India
13. Dr Rekha Jain, Consultant
14. Technical Resource Groups on
 - Care Support and Treatment
 - Laboratory Services
 - Surveillance
15. Representatives from community and civil society
16. Members of the working groups for preparation of National Action Plan-Viral Hepatitis

