





# Fourth Gol-WHO-ILBS National Technical Consultation on Viral Hepatitis

Framework of National Program on Viral Hepatitis (NaP-VH) in India

World Hepatitis Day Institute of Liver and Biliary Sciences, New Delhi

28, July 2017



# **World Hepatitis Day**

**Institute of Liver and Biliary Sciences** 

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#### List of contributors

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#### **Abbreviations**

AASLD American Association for the Study of Liver Diseases

AIDS Acquired immunodeficiency syndrome
AIIMS All India Institute of Medical Sciences

ANC Antenatal care

anti-HBc Antibody to hepatitis B core antigen

anti-HCV Antibody to hepatitis C virus

APASL Asian Pacific Association for the Study of the Liver

ART Antiretroviral therapy
BPL Below poverty line

CDC Centres for Disease Control and Prevention

DAA Direct-acting antiviral

DCGI Drug Controller General of India

DG Director General
DH District hospital

DHR Department of Health Research

DNA Deoxyribonucleic acid

EASL European Association for the Study of the Liver ECHO Extension for Community Healthcare Outcomes

EDHS Egypt Demographic Health Survey

ELISA Enzyme-linked immunosorbent assay

GHSS Global Health Sector Strategy

GNCTD Government of National Capital Territory of Delhi

GoI Government of India

HBsAg Hepatitis B surface antigen

HBV Hepatitis B virus

HCC Hepatocellular carcinoma

HCV Hepatitis C virus

HCV RNA Hepatitis C virus ribonucleic acid

HCW Health-care worker
HEV Hepatitis E virus

HIV Human immunodeficiency virus

HRG High-risk group

ICMR Indian Council for Medical Research

ICTC Integrated counseling and testing centre

IDSP Integrated Disease Surveillance Programme

IDU Intravenous drug user

IEC Information, Education and Communication

ILBS Institute of Liver and Biliary Sciences
KAP Knowledge, Attitude and Practices

M&E Monitoring and evaluation
MCH Maternal and child health

MMPHCRF Mukhya Mantri Punjab Hepatitis C Relief Fund

MoH Ministry of Health

MoHFW Ministry of Health and Family Welfare

MTCT Mother-to-child transmission

NACO National AIDS Control Organization
NACP National AIDS Control Programme
NAP-VH National Action Plan on Viral Hepatitis

NARI National AIDS Research Institute

NAT Nucleic acid testing

NCDC National Centre for Disease Control

NGO Nongovernmental organization

NHM National Health Mission

NIV National Institute of Virology

OOP Out-of-pocket

PCR Polymerase chain reaction
PGI Post Graduate Institute
PLHIV People living with HIV
PWID People who inject drugs

RNA Ribonucleic acid

RNTCP Revised National Tuberculosis Control Programme

SGPGI Sanjay Gandhi Post Graduate Institute
STAG Strategic and Technical Advisory Group

STI Sexually transmitted infection

SVR Sustained viral response

UIP Universal Immunization Programme
US-CDC United States Centre for Disease Control
VDRL Viral Diagnostic and Research Laboratory

WCO India World Health Organization Country Office for India

WHD World Hepatitis Day

WHO World Health Organization
WHOCC WHO Collaborating Centre

#### **Executive summary**

The 4th National Technical Consultation on Viral Hepatitis, "Framework of National Program on Viral Hepatitis in India" was held on 28 July 2017 on the occasion of World Hepatitis Day 2017. The consultation was jointly organized by Govt of India (GOI), World Health Organization (WHO) Country Office for India and Institute of Liver and Biliary Sciences (ILBS), New Delhi, which is a WHO Collaborating Centre for Viral Hepatitis and Liver Diseases.

The WHO global theme for the World Hepatitis Day 2017 was "Eliminate Hepatitis". In India the focus of the meeting was on development of a "Framework of National Program on Viral Hepatitis in India". The consultation was inaugurated by the Hon'ble Union Minister of Health and Family Welfare (H&FW), GOI and presided over by the Hon'ble Minister of Health and Family Welfare, Government of National Capital Territory of Delhi (GNCTD). The Guests of honor were Secretary H&FW, GOI, WHO Representative to India, Mr. Fali Nariman, an Eminent Lawyer of the country, Director, National Centre of Disease Control, Drug Controller General of India and Director, ILBS.

The meeting included 44 speakers and about 150 delegates including senior officials from Government of India (GoI), state governments, Indian Council for Medical Research, Drug Controller General of India, academicians, experts from leading tertiary-care institutions, representatives from WHO Regional Office for South-East Asia, WHO Country Office for India, National Centre for Disease Control, National Institute of Health and Family Welfare, educational institutes, civil society, over 10 nongovernmental organizations (NGOs) and 7 Pharmaceutical companies to discuss the road map towards the national action plan and national program on viral hepatitis.

The Sustainable Development Goal of eliminating viral hepatitis as a public health problem, especially hepatitis C virus is possible for India, but every avenue has to be pursued to make it become a reality by the year 2030 with a new generation of cured hepatitis C virus cases, treated hepatitis B virus (HBV) cases and HBV immunized healthy babies growing up. Some data on the disease burden and modes of spread of viral hepatitis in India is already available. It is time to bring forth a national action plan and a national program for the control of viral hepatitis in our country.

The **key recommendations** from the consultation were that a comprehensive national action plan on viral hepatitis (NAP-VH) needs to be drafted in the next 2 months and a National Program on Hepatitis C elimination in India should be developed. During inaugural session, union health minister announced that the action plan should be converted into a **Hepatitis C Elimination program and it will be rolled out soon**. NCDC and ILBS were instructed to support the process along with technical assistance from the WHO, with the following mandates:-

- To initiate deliberations between the technical working groups (TWG) approved in the first steering committee meeting of the NAP-VH on July 25, 2017.
- To submit the draft resolutions for circulation by the end of August 2017 and finalize the draft by mid-September.
- The same is to be considered by the National Steering Committee by the end of Sept. 2017.
- The draft action plan is to be submitted by the committee for consideration and implementation as a program.

The following recommendations were made for the development and implementation of the NAP-VH and National Program on Hepatitis C:

- Development of a framework of national program on viral hepatitis was decided after discussion among stakeholders with inbuilt component of integration and strengthening of services.
- State specific strategies and state level planning will play a key role. Drugs for Hepatitis B and C must be included in the essential drug list (EDL) of medicines for State procurement.
- Strategies to engage the private sector should be considered. Public Private Partnership (PPP) model and involvement of NGOs/CBOs will help to combat viral hepatitis.
- Need to have a national level disease burden estimate, as the existing surveillance system for viral hepatitis is much fragmented and focused on Hepatitis A and E. We need to integrate and collate the isolated data sets across India. For Hepatitis B and C, we need to capture the data from leading knowledge centers for hepatitis like ILBS, SGPGI, AIIMS, CMC, etc. A national registry may help.
- Data of 5 lakh samples tested for hepatitis C is available with NACO and should be shared for better program planning and disease burden estimation.
- Awareness generation and communication strategies should be prioritized. NCDC is working to launch a national behavior change communication (BCC) camp. We need to convert science into easily communicated messages.
- The prevention component of the National Program on Viral Hepatitis should include:
  - Strengthening of existing universal immunization programme (UIP), expansion of pentavalent vaccine and to improve upon birth dose coverage to prevent mother-to-child transmission as the single best strategy for control of HBV; Mission Indradhanush program is a hope to achieve >90% coverage of HBV 3 dose vaccination.
  - o Safe drinking water and sanitation practices as a top priority; Swachh Bharat Abhiyaan is a role model project to prevent hepatitis A and E.
  - o Hepatitis A virus vaccination strategies to be revisited with the evolution of the epidemiology of the virus in the future;
  - o Need for hepatitis E virus vaccine for certain sub-groups of the population, as and when the vaccine is approved and becomes available;
  - o Safe injection practices/reuse prevention practices (RUPs) and infection control and blood safety;
  - o Harm reduction among people who inject drugs.
- The diagnosis and treatment components under the National Program on Viral Hepatitis should include the following:
  - o Screening should be instituted with due risk stratification at primary care level
    - For hepatitis B, screening of the first degree relatives
    - For hepatitis C, recall policy, by asking those who received blood or blood products before 2001 (before the HCV testing became mandatory in Indian Blood Banks).

- o National public health diagnosis and treatment guidelines for Hepatitis A to E
- o Service(s) delivery model(s) for screening and treatment of chronic hepatitis B and C and use of existing health- care delivery systems such as in Punjab, Meerut, Manipur and Haryana;
- o Treatment algorithms: Hepatitis B and C treatment regimens which could be used in majority of patients should be simple as they can be used by doctors at the district level.
- o Capacity building for Hepatitis: WHO Collaborating Centre–ILBS was identified as the Nodal Agency to develop screening and treatment training programs for clinicians, paramedics, lab technicians and nurses.
- Negotiations with pharmaceutical and diagnostic companies for bulk purchases to get better deals and obtain more affordable and accessible diagnostics and drugs. Support of the regulators, specially the DCGI's office to enable point of care testing and low cost therapies for hepatitis patients.
- Need of civil rights law to prevent discrimination or stigmatization of hepatitis patients in the country.

#### Background

Viral hepatitis is a growing global public health problem, causing serious illness and death from acute hepatitis infection, liver cirrhosis and liver cancer. Across the world, an estimated 400 million people are affected by viral hepatitis. Viral hepatitis is the seventh leading cause of death worldwide, killing more than human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome(AIDS) every year. A total of 240 million people are chronically infected with hepatitis B and 150 million with hepatitis C. Globally, nearly 1.45 million people die every year from viral hepatitis. The majority of these deaths are due to hepatitis B (686 000 deaths) and C (703 800 deaths).

In India, nearly 40 million people are chronically infected with hepatitis B virus (HBV); and based on some regional-level studies it is estimated that there are nearly 6–12 million people living with hepatitis C in the country. These infections can be largely prevented, but due to lack of awareness, the number of people living with viral hepatitis is increasing.

Nation-wide access to services for diagnosis and treatment for hepatitis B and hepatitis C continue to face significant challenges. Most people with chronic HBV or hepatitis C virus (HCV) do not have symptoms until the later stages of the infection. As a result, many Indians living with hepatitis B and C do not know they are infected and are at risk for serious liver disease, liver cancer and even death. The numbers of new HBV and HCV infections and viral hepatitis-related deaths have increased in recent years. As a nation, we are at risk of losing ground in the battle against these "silent epidemics". However, today we have more knowledge and tools than ever before to stop the spread of viral hepatitis and save lives. To harness these tools and focus our national response to viral hepatitis, a National Action Plan on Viral Hepatitis (NAP-VH) is needed to fight against viral hepatitis across the country. It will also support and encourage the complementary efforts of state governments, a wide range of partners outside the government and individuals engaged in the fight against hepatitis B and C.

On the occasion of World Hepatitis Day 2016, Institute of Liver and Biliary Sciences (ILBS) in collaboration with World Health Organization Country Office for India (WHO India) and Government of India (GoI) organized the Third National Technical Consultation on Viral Hepatitis. ILBS, New Delhi has also been designated as the WHO Collaborating Centre (WHOCC) for viral hepatitis and liver diseases.

Recent advances and new opportunities for treating hepatitis C using new direct-acting antivirals (DAAs) with a success rate of 90%, effective vaccine against hepatitis B and GoI's Swachh Bharat Mission are promising strategies to fight against viral hepatitis. With the aim of ensuring universal access to testing, diagnosis and treatment for viral hepatitis, the theme for the consultation was "Towards a National Action Plan on Viral Hepatitis (NAP-VH)".

Each year, 1.34 million people die globally and 325 million people living with the disease could eventually experience liver disease, cirrhosis or liver cancer, if left untreated. About 4% of Indians are afflicted with Hepatitis B and 1% with Hepatitis C. Put together, about 60 millions could be having Hepatitis B or C or both!

While new drugs are now available with which Hepatitis C can be treated and cured, Hepatitis B can only be prevented through vaccination.

Unfortunately, India does not have a national program for viral hepatitis yet. For the past three years, on 28th July, the ILBS-WHO-India-Government of India collaboration has been organizing consultation meetings and working concertedly towards convergence of all stakeholders to draft a path to identify issues and identify resources for a timely action plan to combat hepatitis menace in India.

The consultations over the past years have witnessed enthusiastic participation by national experts together with stakeholders from the government, academia, public health experts, research institutions, civil society, WHO and partner institutions.

As the efforts are shaping up towards development of a national program for hepatitis in India, this 4th GOI-WHO-ILBS National Technical Consultation on Viral Hepatitis aimed to develop the framework for such a program. Consequently, the chosen theme was —"Frame work of National Program on Viral Hepatitis in India".

The framework will be woven around the five strategic directions for implementation agreed at a global scale viz., information for focused action, interventions for impact, delivering for equity, financing for sustainability and innovation for action.

#### Overview of the last three years national consultations

#### Overview of the 2014 consultation

The first national technical consultation on viral hepatitis – "Viral hepatitis, think again" was held in 2014 at ILBS, New Delhi in collaboration with WHO Country Office India (WCO) India. The consultation was attended by policy makers, program makers, program managers from the Ministry of Health, academia, research scientists, clinicians, representatives from World Health Organization (WHO), other partner agencies, civil society, harm reduction groups and positive patients networks.

In the absence of a national policy on viral hepatitis, the aim of the consultation was to identify gaps and challenges in the area of viral hepatitis. This would enable prioritizing areas of work to accelerate efforts towards ensuring access to diagnosis and treatment of viral hepatitis. The consultation also aimed at discussing the prevalence of infection in various parts of the country, and the possible risk factors for the same. There were also deliberations about how the government should proceed to deal with viral hepatitis. From the discussion, it was clear that we needed to work as per the Framework for Global Action for Prevention and Control of Viral Hepatitis and focus on the four axes—raising awareness, promoting partnerships and mobilizing resources; evidence-based policy and data for action; prevention of transmission; and screening, care and treatment.

The key recommendation of the consultation was to develop a comprehensive national strategy for India for prevention and treatment of viral hepatitis, with definite targets. Improving the birth dose coverage of hepatitis B vaccination to protect children was also recommended. Another key recommendation was to develop partnerships with professional associations, harm reduction groups and the private sector for advocacy and education on promoting injection safety in India.

#### Overview of the 2015 consultation

The second national technical consultation on viral hepatitis – "Hepatitis C: can we treat all by 2020?" was organized on 28 July 2015 on the occasion of World Hepatitis Day 2015. The consultation was organized by WHO India in collaboration with ILBS, New Delhi.

The WHO global theme for World Hepatitis Day 2015 was "Prevent hepatitis: act now". In India, the focus of the event was on hepatitis C prevention and treatment-related activities so as to bring into focus the issue of hepatitis C treatment in the country. The consultation was attended by senior officials from the Gol, academicians, experts from leading tertiary-care institutions, representatives from WHO, National Centre for Disease Control (NCDC), Lawyers Collective, educational institutes, harm reduction groups, network of positive patients, civil society and pharmaceuticals and diagnostics industries.

The success rate for treatment of hepatitis C has improved significantly with the availability of newer drugs; but if not diagnosed, the consequences can be life-threatening. In view of the reduction in the costs of drugs and more efficacious treatment, it is important to establish systems to provide hepatitis C treatment for all. Emphasizing the important role of prevention-related activities, WHO Guidelines on Injection Safety were also disseminated along with the 2015 WHO Guidelines for Prevention and Treatment of Hepatitis B and C.

Some of the important concerns raised during the consultation were—lack of data on the burden of hepatitis C, limited awareness among health-care workers (HCWs) and the community about hepatitis C infection, absence of a national policy or guidelines on screening of populations for hepatitis C and lack of standardized hepatitis C testing and treatment guidelines. The objective of the consultation was to discuss and recommend various policy and strategic options for providing universal access to hepatitis C treatment in India by 2020. Prevention-related activities, including wide dissemination of WHO Guidelines on Safety Engineered Devices for all services (therapeutic and immunization) were also discussed. Besides this, a need to have a technical working group to oversee and expedite work in the area of viral hepatitis C treatment and prevention was highlighted.

#### Overview of the 2016 consultation

The third national technical consultation on viral hepatitis—"Towards a National Action Plan on Viral Hepatitis" was organized on 29 July 2016 on the occasion of World Hepatitis Day 2016 conducted in continuation to the celebrations of Global World Hepatitis Day.

The Global World Hepatitis Day was organized at Mumbai on 28 July 2016 by WHO, in collaboration with the Ministry of Health and Family Welfare (MoHFW), GoI to raise awareness about hepatitis among the general public as well as health-care providers and policy makers at the highest level.

The event was graced by the august presence of Mr Amitabh Bachchan, Special Guest of Honour; along with Minister of State, WHO Regional Director for South-East Asia; WHO Representative to India, health ministers from Haryana, Himachal Pradesh, Jharkhand, Odisha, Sikkim and Uttrakhand; Secretary and Director General, National AIDS Control Organization (NACO); Director General Health Services, MoHFW; Director ILBS, and health, water and sanitation secretaries of the state governments and senior officials of the Health Ministry and WHO. Stakeholders from the academia, clinicians, public health experts, civil society and partner agencies also participated in the discussions.

Dr. Sarin, Director ILBS during his presentation shared the activities undertaken by WHOCC in last one and a half year. He informed the learned group regarding how WHOCC-ILBS is actively undertaking cohort study to generate evidence and about the capacity building activities for human resources on viral hepatitis. He also raised the concern about the high burden of chronic hepatitis B and C in the country as compared to HIV, for which, we have a huge infrastructure and a regular financial support from GOI. He said that universal access to HIV treatment is one of the greatest success stories (>15 million treated) and this must be repeated for mass treatment of Hepatitis B and C. He also requested the government and WHO to make Hepatitis B and C a notifiable disease. A legislative mechanism needs to be developed to stop discrimination and marginalization of Hepatitis B and C infected individuals, similar to HIV. He ended his talk with the slogan "No more excuses: know, prevent, and eliminate viral hepatitis"

#### The major issues raised were to:

- reach towards elimination of viral hepatitis by increasing the number of people who know their status through sound surveillance systems, including cost-effective screening and follow-up, with particular focus on hot spots with high prevalence;
- develop preventive, diagnostic and curative strategies for the country;
- have a national action plan on viral hepatitis.

On 29 July 2016, the national technical consultation was organized by WHO India in collaboration with ILBS, New Delhi. The third technical consultation proceedings were undertaken in the wake of an opportune time to bring forth a national action plan for the control of viral hepatitis (NAP-VH) in our country. The key recommendation from this consultation was to develop a comprehensive NAP-VH. ILBS and WHO were requested to support the process. It was decide to constitute of a national steering committee for NAP-VH development led by Secretary Health, MOHFW, Secretary DHR/ DG ICMR, and AS DG NACO. Expert working groups to be constituted to develop the different components of the NAP-VH e.g., surveillance, immunization, injection and blood safety, diagnosis and treatment, composed of various MOHFW divisions (NCDC, NACO, Immunization, and MNCH, ICMR, key experts and partners. Recommendation for the development and implementation of the NAP-VH also included estimation of burden of disease from existing data, investment case studies and impact modeling exercises, education and awareness initiatives, prevention of hepatitis through vaccination, safe injection practices/ infection control and blood safety, and harm reduction among people who inject drugs, diagnosis and treatment through service delivery models for screening and treatment of Hepatitis B and C (NACO and existing health-care delivery platforms), development of public health diagnosis and treatment guidelines based on latest WHO guidance, capacity building of health staff for diagnosis and treatment: WHO Collaborating Centre at ILBS was identified as a role model. Negotiations with pharmaceutical and diagnostic companies for bulk purchases for affordable and accessible drugs and diagnostics and models for financing the NAP-VH was also intended to be developed involving public private partnerships.

The 4th National Technical Consultation was held in continuation to the earlier theme to move forward towards development of a "Framework of National Program on Viral Hepatitis (NaPVH) in India". The deliberations during this meet along with the decisions taken are narrated below.

#### **Meeting proceedings**

The 4th National Technical Consultation on 28 July 2017 at ILBS was inaugurated in the august presence of the Union Minister of Health and Family Welfare (H&FW), Minister H&FW, GNCTD, Secretary H&FW, WHO India Representative, an eminent Lawyer, Director NCDC and Director ILBS. It was attended by senior officials from different ministries of the GoI and state governments, academicians, experts from tertiary-care institutions, representatives from WHO Regional Office for South-East Asia, WCO India, NCDC and educational institutes. The meeting included 40 speakers from the medical Institutes and Govt health sectors, 10 NGOs and 7 Pharmaceutical companies to discuss about the national plan.

#### **Inaugural addresses**



Dr. A.C. Dhariwal, Director, NCDC delivered the welcome address. He briefed about the decisions of the GoI taken at the last hepatitis day and formulation of the Steering Committee to overlook the development of national plan on viral hepatitis (NAP-VH). He mentioned that to control viral hepatitis, we have enough evidences on available effective interventional measures and diagnostic tools. He also assured that GoI will take quick decisions to solve the existing problems of viral hepatitis by affordable, cost effective and needed interventions.



Dr SK Sarin, Director, ILBS stated that it was a unique opportunity to have all the stake-holders; technical experts, policy makers, NGO's, industry and regulators to join hands for a common cause, i.e., Hepatitis elimination. He briefed the need of National Action Plan on Viral Hepatitis (NAP-VH). He said that 1 out of 20 people in India have either Hepatitis B or C infection. He mentioned that, in India around 200 thousand deaths occurs due to hepatitis B or Hepatitis C. He stressed the importance of birth dose vaccine against Hepatitis-B virus for its prevention. He told the audience that it takes 20-30 years for a person to know that he is suffering from hepatitis-C and sometimes it becomes too late. Hence, it is necessary to test the high risk people like those who have received blood transfusion before 2001 and people who has undergone surgery. Testing and treating will be an important strategy to eliminate hepatitis C. He pointed the importance of safe blood, safe syringes and stoppage of reuse of needles so that Hepatitis C can be prevented to some extent. He also recommended free testing of hepatitis and explained the need for free hepatitis drugs for all patients. He reinforced the need of vaccinating all health care workers including doctors and nurses against Hepatitis B. He has also described about the need of removing the stigma among people about Hepatitis B and to provide equality for all patients who are infected with viral hepatitis. He stressed upon the need of coalition between all stakeholders to combat viral hepatitis in India. Dr. Sarin expressed a strong need to convert the National Action Plan into a National program on Viral Hepatitis by the end of this year.



Dr. Henk Bekedam WHO India Representative indicated that the celebration of world hepatitis day itself shows how the world is concerned about it; though it is less talked about and supported. He mentioned that since viral hepatitis A, B, C, D & E have different modes of transmission, it is necessary to work on multiple strategies. He emphasized on the global theme of "Elimination of Hepatitis" and said that world health sector strategy in viral hepatitis will be talked more in coming years. He told that at regional level WHO is moving towards the national strategy of action. He congratulated Dr. Sarin and his team for maintaining the momentum towards the National Action Plan after the global Hepatitis event held in Mumbai. Dr. Bekedam said that globally there is a need for getting an understanding about the number of people infected with Hepatitis. He stated that the steps of elimination are prevention, treatment and championship .He told that the Prime Minister of India has pushed the hepatitis B vaccination under the Indradhanush program. He stressed on blood screening, syringe safety, and monitoring hepatitis C treatment outcomes. He delightfully mentioned that India is one of the pilot countries for injection safety.

Dr. Bekedam said that India plays a stellar role in the world in reference to access to hepatitis C drugs. He applauded the pharmaceutical companies from India to take lead in production of Sofosbuvir, daclatasvir and velpatasvir; the new drugs against hepatitis-C. He gave the example of Punjab where a commendable job has been done for providing free treatment to patients, and suggested that this model should be followed by the rest of the country. He affirmed that WHO will continue to provide technical assistance to India in dealing with Hepatitis.



Eminent Lawyer Shri Fali Nariman raised the issue of equality for hepatitis B & C patients. He said that in the present day awareness should be generated about hepatitis. He gave the example of Princess Diana that when she sat with AIDS patients, the stigma associated with the virus and the disease started to fade. He said more than the courts it is the society which causes discrimination. He stressed the importance and need for a Civil Rights Law, like the United States of America, to remove discrimination or stigmatization of hepatitis patients by the society. He volunteered to prepare a bill to be considered by the Parliament of India in this regard. He emphasized that Hepatitis infected individuals should be provided equal status and rights and should not be refused entrance in any employment and educational institute.



Shri CK Mishra, Secretary, Health, MoHFW said that the policies have been made for hepatitis elimination and will now be implemented with full force, although this should have happened many years ago. He told the importance of home based deliveries as key area to focus upon. He stressed in the need of birth dose vaccination in home delivered babies. He also mentioned about the need of strong backup of safe injection practices without which the program will fail to achieve their goals. Mr. Mishra stated that we need to run an intensified IEC awareness campaign against Hepatitis B and C. He assured of full Government support for the IEC campaigns to spread the awareness uniformly across the country. Sh Mishra also enumerated the steps taken by the GoI in the fight against hepatitis. These included formation of a national steering committee which is giving directions to develop the national action plan. He said the country is getting ready for the launch of a stand alone program on viral hepatitis separate from NACO.



Minister H&FW, GNCTD Shri. Satyendra Jain said that the information about liver is scanty and not many people know about this, and there are many misconceptions. He said that considering the importance of liver functionality, it should be kept on the top list of vital organs, above heart, brain, lungs, etc. He said that awareness should be spread among people about liver and liver diseases. He told the audience that the Delhi government has already made all the hepatitis medicines free, and in fact, Delhi is the only state where both Hepatitis B and C drugs are freely available in Govt. hospitals. He assured that the GNCTD will continue to support all initiatives to make Delhi hepatitis free. Shri Jain also spoke about the Mohalla clinics in Delhi, which will also be equipped to treat hepatitis patients.



Shri J.P. Nadda, Union Minister of Health and Family Welfare (H&FW), congratulated ILBS for taking the lead in initiation and development of a frame work of National Program on viral hepatitis in India. He assured that the recommendations of the National Consultative Meeting would be implemented in letter and spirit by the GoI. He agreed to take policy decisions against any discrimination of hepatitis patients. He stated that Government is committed to zero discrimination. He stressed on the need for prevention of water and food borne hepatitis, Hepatitis A and E, as part of the Swachh Bharat Abhiyaan. He told that in the next 2-3 years, birth dose for hepatitis B vaccination will go up to 90%. He asked that the National Action plan should be ready in next 2 months. He declared that on December 25 the "National Viral Hepatitis Program" will be implemented along with rolling out of plans in the next one year to reach out to even at the PHC level, to eliminate hepatitis C. The program would include full financial support by the GoI to provide for education, screening, testing and treatment of hepatitis C. He reiterated the need for screening for hepatitis at the peripheral level. He has appreciated the aspect of screening, consultation and surveillance of viral hepatitis discussed in the technical consultation. He also briefed about the Indradhanush program of the GoI for immunization against the 7 communicable diseases.

On the occasion of the WHD, 2 radio jingles were launched by the Union Minister of Health and Family Welfare (H&FW), **Shri Nadda Ji** – one on "Food and water borne viruses Hepatitis A and E", and the second on "Hepatitis B and C viruses".

The inauguration, followed the technical sessions that were held during the day from 9:30-17:00.

Agenda for the meeting is at Annex 1. A list of participants is at Annex 2.

#### 4 Existing Stakeholders: Present and Future Roles in National Action Plan on Viral Hepatitis (NAP-VH)

**Dr SK Sarin , Director, ILBS** welcomed all the invited experts, officials, NGOs, media and pharma groups on the WHD. He gave an overview of the past three national consultations 2014, 2015 and 2016, and the outline of the 4th National Consultative meeting to develop a National Program on viral hepatitis. He appraised of the steps taken in 2017, namely, formation of a National Steering Committee by the GoI and the Technical working groups. He informed the deadline given by the Steering committee of the NAP-VH to develop the national action plan is Sept. 2017. He stressed the need for involvement of the general public and media to accept the interventions proposed in the National Program.

This session was chaired by Dr A C Dhariwal (Director, NCDC), Dr. B. C. Sharma (Professor, ILBS), Dr. N. K. Ganguly and Mrs Vinita Shrivastava (GOI).

#### a. Burden of viral hepatitis in India

Dr. Rakesh Aggarwal, SGPGI discussed about the burden of viral hepatitis is India. He initially gave an introduction to viral hepatitis and to the viruses that cause viral hepatitis (Hep A-E). Speaking about Hepatitis A, he mentioned that the outcome depends on the age of the person infected. Its occurrence is occasional in children and even rarer in adults. Then he spoke about Hepatitis E. He mentioned that hepatitis E can occur both in outbreaks and sporadic cases. The disease occurs mostly in people aged between 15-40 years. Mortality is otherwise low in general population but extremely high in pregnancy. He also stated that many outbreaks are not even reported. Hepatitis E accounts for about one-third to half of sporadic outbreaks. This disease affects economically productive age group and the infected person, on an average, loses about 4-6 weeks of work once inflicted. Then he discussed about Hepatitis B. He mentioned that in 1990s the prevalence was estimated to be about 4.7% but subsequent meta-analyses reported the prevalence to be between 2.4% to 3.7%. He also mentioned that the rates were much lower in other systematic review and meta-analyses. However, the possibility that there might be much bias in the estimates cannot be ruled out, as true reduction in frequency is much unlikely. Speaking about Hepatitis D, he stated that studies on HDV have given markedly different frequencies. He also discussed that this infection exists but seems to be quite rare in India. Then he discussed about Hepatitis C. He mentioned about an undergoing Systematic review in SGPGI by A Goel et al. He also commented on the possible bias in community based studies and blood donor studies available. The prevalence in IDUs is much high, especially with concurrent HIV. He discussed the existence of hot spots possibly due to unsafe injection use. The total population positive for anti HCV antibody is estimated to be around 7-14 million of which about 2/3rd may be viraemic. These viraemic patients need treatment. He quoted The Lancet 2016 for Global Burden of disease estimated for India. He mentioned that All cause deaths in both sexes at all ages is numbered 10,28,691. Acute hepatitis frequency was found as HBV, HEV, HAV and HCV in decreasing order. The occurrence of cirrhosis with HBV was found to be more than that due to HCV. He also reinforced that HBV is the largest killer accounting for about 1-2% of all deaths in the country. To summarize, viral hepatitis causes 2% of deaths in India. HBV alone causes 118000 deaths annually.

#### b. Health Sector Response to viral hepatitis and WHO Global and Regional Guidelines

**Dr Nicole Seguy (WHO)** discussed on Health Sector Response to VH and WHO Global and Regional Guidelines. She discussed on the strategy towards eliminating VH as a major public health threat by 2030. She mentioned that the components of Public Health Response to VH are: (a) evidence for policy and action: surveillance and research, (b) prevention of virus transmission by immunization, blood safety, injection safety, harm reduction, safe water and sanitation, (c) screening and diagnostic testing: the usual gap in national implementation, and (d) care and treatment. She said that the priority actions for surveillance and research necessary as Evidence for Policy and Action are: prevalence and burden estimates for VH, acute hepatitis

surveillance and outbreak investigation, sequelae surveillance, KAP Studies, modelling of impact and costeffectiveness, regular report on the VH situation and response and regular review of the national hepatitis response. She appreciated India's contribution in the global research on simplified diagnostics and treatment. She reinforced the priority actions for prevention of virus transmission as: expansion of immunization (vaccination for Hepatitis B, consider role of Hepatitis A and E in future), behavioral and structural interventions (safer sex, safe injection practices, safe blood transfusion, harm reduction for drug users), safe food and water and proper waste disposal. She also stated that as these components are already a part if the existing program, so, mostly this is an integrated piece. Discussing about the screening, care and treatment, she put forth the priority actions. She mentioned that the new drug for HCV are being produced in India at a low cost, so there is a possibility to scale up rapidly in times of need. She enforced the simplified screening and treatment approach and guidelines. She also insisted on strengthening lab system, decentralization for rapid scale up of services, continuum of care and retention cascade and attention to vulnerable people so that there can be equitable access to services. She informed the group that the priority actions for Awareness Generation and communication Strategy can be: increasing community/ health professional awareness of ways to prevent VH and manage chronic conditions. For this NCDC can launch a national BCC camp. She also emphasized on the importance of a brand ambassador. She also summarized the discussion with opportunities available in the forms of Swachh Bharat Abhiyan which will be a great boost to prevent Hepatitis A and E, Mission Indradhanush (expansion of pentavalent vaccine in UIP). She also had a discussion on understanding the gaps in Hepatitis B birth dose, generic production of drugs for Hepatitis B/C and Reuse Prevention syringes. She also gave examples of state initiatives in Punjab and Community engagement in Manipur. She also recommended commitment by GOI for NAP-VH. She also briefed about the targets sets for 2020 and 2030 under Target setting in Global Health Sector Strategy. She described for service coverage: India can achieve by 2020 regional targets esp. for 3-dose HBV vaccination. For treatment, she showed concern that we may fall behind regional targets. She ended with the requirement of doing much progress with treatment as we have the opportunity

#### c. Updates on Surveillance of VH in India

Dr Sandhya Kabra, made the presentation on behalf of Dr. A S Dhariwal, Director, NCDC on Updates on Surveillance of VH in India. She initially gave an overview of VH in the SDGs context. She mentioned that India has already designed the National monitoring framework for SDG. She informed the group on the ongoing Integrated Disease Surveillance Project and its objective (Strengthening of disease surveillance system), Components and Structure. She explained the epidemiological features relevant for VH Surveillance. She also described varied disease dynamics (concern with variations in nature of diseases due to different hepatitis viruses), similar clinical presentation, and difficulty in diagnosing clinically, the etiological diagnosis, asymptomatic infections, multiplicity of infections as well as chronicity of infections. She also presented the case definitions of VH, the P form (provisional) and L form (laboratory; confirmatory). She informed the group that between 2014 and 2016, 267 outbreaks of VH were reported of which 219 (82%) were confirmed 219 (82%). However, it may not reflect actual figures in the field. This is estimated on the basis of the reports by different states. She also explained the action taken by GOI and State Govt. In terms of Technical Research Group, there has been formulation of plan for acute surveillance. As many district hospitals do not have the lab capacity to diagnose, NCDC identified 10 sentinel sites for the surveillance. There has been ongoing NHM-NCDC lab strengthening at district level under IDSP not only for Hepatitis but for other diseases of public health importance as well. She also stated about the possibility of collaborating with ICMR with an intent to leverage from the collaboration without duplication of activities. NACO already has screening all blood banks for HBV and HCV. Data is being captured from blood banks. In terms of Immunization division under the chairmanship of Secy MOHFW, to ensure safe injection practices, a meeting was help with AD syringe manufacturer. She also mentioned about HBV vaccination. She appreciated the state initiatives, especially the Punjab model, which is leading. She also announced that 6 other states are adopting the Punjab model. The she spoke about the way forward. She said that an integrated approach for VH prevention and control is necessary, which will include, Swachh Bharat for Water and Sanitation, safe injection, HBV vaccination, extensive IEC and BCC campaign

with all stakeholders and resources, monitoring using IPHS, treatment for HCV by the states (Punjab model), operational research studies on disease burden, impact of interventions, point of care diagnostics, state specific strategies and collating isolated data sets across India.

#### d. State led service delivery model on HIV and HCV infection in Manipur

**Dr Lucy from Manipur** discussed the State led service delivery model on HIV and HCV infection in Manipur. She gave an introduction to state demographic profile while emphasizing that it borders Myanmar (has much implications for the data). She demonstrated data on HIV prevalence among different population groups. HIV prevalence among IDUs as per HSS report has been declining consistently since 1997 due to the efforts by NACO interventions (the current prevalence being 12.7%). She also stated that ear wise HIV prevalence among blood donors has also come down to 0.1% due to untiring efforts by NACO. But the HCV prevalence among blood donors is still higher (0.9%) than HIV. In October 2012, state Govt. added Hep C in the list of diseases under the Manipur State illness assistance fund through which some PLHIV in need of treatment could apply for reimbursement of the treatment costs up to a limit Rs 1.5 lakhs. She also pointed out that trying to get a BPL card in order to go for the reimbursement was a barrier. Later, even the 1.5 lakhs was reduced to 50K. She also showed the draft letter of understanding (LoU) with MSF and Manipur State AIDS Control Society which would provide for free HCV Rx for 350 HIV/HCV co-infected PLWHA enrolled at ART plus centre district hospital Churachandpur for a period of 18 months. The LoU also includes screening, diagnostics, lab, monitoring, treatment and care to ensure adherence to treatment. Testing was mentioned to be supported by MSF. She also gave a brief overview on how the program is functioning in Manipur. She also informed the group about the collaborative arrangement for Free HCV Rx in Imphal East, Imphal West and Churachandpur District, Manipur by YR Gaitonde Centre for AIDS Research and Education (YRGCARE), Chennai. YRGCARE is already doing IEC in these districts, making the state expect that people will turn out for treatment in good numbers. They were planning to do screening of 10,000 people who inject drug and their spouses. She recounted that a total of 2000 HCV positive patients from the PWIC community were offered free treatment. However, this is a small number as the expected number seeking care is much high. Apart from these three districts, Okhral, also has quite a lot of HCV, especially those bordering Myanmar. She reinforced the fact that the access to treatment of HCV is far below in comparison to the burden of HCV that Manipur had. She concluded stating that she hopes to have better treatment and care to hepatitis patients as essential drug list for Manipur has included DAAs (Sofosbuvir, Daclatasvir, Ribavirin) in June 2017 to improve access to HCV mono and HCV-HIV co-infection.

#### e. Service Delivery at District Level

Dr PK Bansal from Meerut discussed about Service Delivery at District Level. He started with a brief overview of MSF. He explained that the objective was to demonstrate feasibility and effectiveness of simplified Hepatitis C care at district and community level. The rationale as pointed out by him states that WHO goal of elimination of HCV by 2030 requires: (a) Access to treatment, (b) Decentralization to district and CHC level and (c) Prevention. He informed the group about the phased implementation of the program. The activities in the first phase (Phase I) would consist of: HCV RDT screening, HBV HIV screening for HCV positive, HBV vaccination, Linking to ART Centre at LLRM Medical college, Confirmatory Testing (Viral Load for HCV with or without HBV), Baseline testing and Counseling. The key characteristics at district hospital should be Simplified diagnostics and treatments and counseling for individuals and family. The phase 2 would include further decentralizing and community based testing and treatment at CHC level, community based IEC activities, implementing preventive harm reduction strategies, capacity building and consequent referral and Operational Research. The operational Research would in turn involve demonstration of simplified model of care at district and community level, cost effective analysis of model of care and population based data. He also showed a datasheet of patient statistics from 25th Jan 2017 to 21st July, 2017. Discussing about the challenges, he mentioned that they could treat only 2000-3000 patients in the project lifetime, in pilot mode. But they faced overwhelming number of patients which resulted in long waiting list. He also emphasized on engaging private sector as well as engaging MSF in regularizing and standardizing treatment.

#### f. NACO: Opportunities for Synergies and Plan for viral hepatitis

Dr RS Gupta, Deputy Director General, NACO presented on NACO: Opportunities for Synergies and Plan for VH. He initially made a disclosure that though they had some data, they cannot be disclosed or presented. He mentioned about the uncertainty regarding the use of HSS and HRG samples for HBV and or HVC. Then he went on to compare HIV and Hepatitis. He stated that, HIV is just one virus and that too not many people treat HIV (unlike TB where we have so many providers). On the other hand, the burden of hepatitis is much more when seen in terms of multiple viruses with different modes of transfer. He also explained that it is difficult to synergize HAV and HEV as primarily these infections are acute and more prevalent, have outbreaks. In HBV and HCV: synergies in key populations are seen. HCV may not be as common in pregnant women but it is quite high in IDUs. He then discussed the possible areas of synergies between HBV and HCV. He said that though there can be surveillance for chronic infection. But this will only be a smaller component in overall surveillance for hepatitis. He emphasized that for a national program, surveillance, diagnosis and treatment should be under one roof. Talking about prevention, he stated that, the blood samples are being screened for 5 diseases mandatorily across India. Those infected could be immediately identified and followed up. For key population, he reinstated that there be harm reduction for IDU and sexual transmission. Then he discussed about treatment and while doing so mentioned that majority of hepatitis infected do not have HIV but the reverse is common. HIV-HBV/HCV coinfection forms only a small proportion. He also presented concern that HCV treatment for non HIV at ART needs further thinking with implications on capacity and stigma associated with the disease. He also suggested that why the stigma can't be removed associated with having a 'separate' ART centre. He also appreciated the Punjab model through district hospitals. He also said that they are planning to include HIV-HCV co-infection in the revised National HIV Plan. They have also kept some money in the Global Fund for screening and treatment

#### g. Leveraging Existing Training Programs at ILBS

**Dr Ekta Gupta (ILBS)** presented on Leveraging Existing Training Programs at ILBS. She described the existing programs: PALM, ILBS-ECHO, WHO CC (HIP HUP), HBSCE, Dedicated NSI PEP for Delhi. She mentioned about the ILBS mandate of capacity building at different tiers, i.e. Doctors, Lab Technicians, Nurses, etc. She described about the WHO CC Hepatitis Induction Program which would be conducted at different levels viz. Level 1: Executive course (1-3 days), 2: Standard hepatology (2 weeks), 3: Advanced Hepatology (4-12 days), 4: Hepatology Associate Program. Discussing about the WHO CC Hepatitis Update Program she mentioned that it would be a distance (Web based) learning which would consist of update for various levels (L1-4). It would be of one year duration and enrolment would be done through ILBS-ECHO. She also described about short term training and observership. She gave a detailed description of the ILBS-ECHO program. She described that Hepatitis B screening, counseling and education program (HBSCE) is an OPD based IEC activity. It consists of 4-step counseling. It is an excellent support system between serology positive state till confirmatory molecular testing is done. She also gave a brief overview about the Laboratory Support Program

The House was then declared open for discussion.

**Dr Gangakhedkar (NARI)** mentioned that between 1988-89, there were much intervention for HIV awareness. Perhaps, hence the GBD decided to split its data as pre and post 1989. In early 1990s, we were reluctant to share the data for HIV as they were much likely to change. Even the government was unwilling to accept it; we used it for advocacy much before the program came up. We should do the same with HCV: use whatever data is available even with caveats even if the program is yet to come

**Dr Rakesh Aggarwal (SGPGI)** discussed that he is not sure why they split 1989. I don't think the changes in epidemiological rates were due to the HIV interventions as these would take years to show any impact. Incidence may change due to control rates but prevalence will take years to change

**Dr Jayanthi Shastri(Mumbai)** asked that for Hepatitis testing, the main challenge is the standardization of testing methods. Different labs use different tests. Dr Kabra has been able to standardize HIV testing across centers—surveillance become fool proof. We could think for standardizing Hepatitis testing. Also she enquired about HCW vaccination.

**Dr Haldar** discussed that DGHS letters have mandated that HCW at risk must be vaccinated. The question is that who will provide? As per the National Immunization Program all hospitals may include these vaccines in their essential drug list so that they have the vaccine in supply

**Dr BC Sharma** discussed that for prevention of stigma, Hepatitis should be dissociated from HIV. Hepatitis is a bigger problem with lesser stigma, national program must be different from HIV

#### 5: Prevention and Diagnosis as Components of NAP-VH

The session was chaired by Dr. Venkatesh from NACO, Dr. Priya Abraham from CMC vellore, Dr. Sandhya Kabra from NCDC and Dr. Sharda Patra from LHMC.

The first speaker was **Dr. Pradeep Haldar (GoI)**. He spoke on Prevention of hepatitis B through immunization. He discussed the rationale of Hepatitis B immunization program in India and a he spoke about how Hepatitis B made it to the Universal Immunization Programme. He discussed the importance of auto disable syringes in the program. He resonated with the importance of the hepatitis B immunization and how to prevent a child from hepatitis B immediately after the delivery. He discussed how various other national programs like Janani Suraksha Yojana have collaborated to increase the coverage of immunization. He discussed the how open vial policy has helped in increasing the coverage area. He suggested that there should be a survey data along with monitoring program. He enlightened on how mission indradhanush has a target of December 2018 to achieve a coverage of 90% for all vaccine within 1st year of life. He further discussed the strategies for improving Hepatitis B immunization coverage with which he closed the topic by inciting how the vaccination can prevent the disease and how it can lower the burden of disease with giving a hope of how it can be strategized to have an increased coverage.

The second speaker was **Dr. Madhur Gupta from WHO**, who discussed at stretch the importance of injection safety in India and global evidence about it. He spoke on Ministry of health and family welfare adopted the policy recommendations on Safety engineered syringes for more than a year. Director General of Health services had meeting with manufacturers and providers on how to move to new technology for safety of syringes by July 2019, he briefed about Government of India initiatives for safe injection practices and how government is trying to scale up the manufacture of auto disable syringes in India. Further he spoke about WHO strategies and recommendations for a safe and appropriate use of injections, WHO guidelines on safety engineered syringes 2015- new recommendations, WHO awareness Campaign and WHO Injection safety project. He spoke about National Health Policy 2017 and how they are actively contributing to the safe injection practices and he finally concluded the talk by making the people aware about the current challenges and what next steps can be taken to combat them and have the injection safety as much as possible.

**Dr. Meenu Bajpai** took the next talk on safe blood in which she emphasized on the role of counseling with regards to blood donation process. She spoke about the general challenges of blood donation and its screening, how lack of single specific test is a big challenge. She emphasized on the problems of consenting. She spoke about the algorithms for blood donor screening. She spoke about the transfusion transmitted infections and other issues concerning the blood donation such as ethical issues, logistics, manpower, infrastructure, confidentiality. She also spoke the progressions that have been made in preventing blood donation related infections like HBV, HIV and HCV. She further gave an insight about the need to have organized referral and training of laboratory personnels.

**Dr. Surinder Singh (NIB)** spoke on the integrated diagnostic platforms. He mentioned about the automated single platform which are robust, rapid, easy to use and have the potential to change the point of care and diagnostic laboratories. He spoke about M-CHIP which allows testing of HBV and HCV and multiple pathogens (HIV, syphilis), can test on low sample amount and incurs low cost as well.

The last speaker in the session was **Dr. Nivedita Gupta (ICMR)** who spoke on the role of ICMR on viral research and diagnostics. She gave an overview of viral research and diagnostic Laboratories and the objectives of these laboratories and the structure of the diagnostic laboratories. She gave the details about distribution of the 45 functional laboratories. She discussed the priorities such as improving vaccine strategies, assessment of impact of high coverage and build follow up cohorts of HBV and HCV to understand transmission.

The house was further open to discussion in which the chairpersons and other members in the house contributed as follows. Dr. Rakesh Aggarwal suggested the need to reduce un-indicated use of injections, deferring testing of contacts/ spouses should be evidence based and in order to reduce the number of injections, we must reach to mass media and community beyond the health care workers.

Dr. Sarin suggested of having a pragmatic approach towards the problem. Dr. Ritu Chauhan suggested that communication is more important that just promoting RUS, inter-ministerial coordination is important to discourage unsafe injections.

Dr. Sharda Patra suggested that we must ensure HCW must be vaccinated before they start their first clinical exposure, she further emphasized on vaccination of all the antenatal women.

Dr. Priya Abraham emphasized on the importance of biomedical waste management. Dr. Gangakhedkar suggested that we must have a strategy to immunize reservoirs, which are seronegative.

Thus the session was successfully concluded with the positive suggestions from all the house members.

#### 6. Surveillance in Viral Hepatitis

Chairpersons of this session were Dr J K Das (NIHFW), Dr. Rakesh Aggarwal (SGPGI), Dr. A C Dhariwal (NCDC)

#### Experience from States on outbreaks of Hepatitis A & E

The session started with **Dr Aparajita Sondh** from Haryana who discussed the activities that are carried out regarding viral hepatitis surveillance in Haryana. She pointed out that for HAV and HEV, an IDSP outbreak data is maintained in Haryana and specially mentioned that water pumps are regularly checked for cleanliness. For HBV, her team is covering all districts under Mission Indradhanush. Regarding HCV, she mentioned that Hepatitis C program was initially started for only BPL families with peg IFN but now it has been extended to include all population (including prisoners) and all districts along with the adoption of new treatment policy. She also emphasized that her team is conducting ECHO program from PGI Chandigarh every 15 days.

**Dr Subhaluxmi** subsequently discussed her experience regarding viral hepatitis surveillance in Telengana. She mentioned that very few outbreaks of viral hepatitis have occurred in Telengana in recent years with a prevalence of only 500 sporadic cases per year. But she said that her staff, however, maintains good laboratory practices and in case of any positive reports, surveillance is done through IDSP. She said that mostly water-borne cases have been reported from her state and three medical colleges of the state are involved in giving treatment support.

#### Sequelae Surveillance in Chronic Viral Hepatitis

Dr Ajeet Bhadoria (ILBS) started the topic by telling about the NCDC nodal agency for national surveillance plan which conducted its first consultation meeting on October 7, 2016. He emphasized that first TRG meeting was held on April 18, 2017 in which he said that a proper plan for the country is in the process of being developed. He specifically mentioned that a Sequelae Surveillance project was developed with 13 centres of excellence in India where the following points were discussed: objectives of the project; National mortality data for cirrhosis and HCC; sampling procedure, methodology, online data collection form and the responsibilities of the WHO ILBS CC. He said that retrospective analysis of data showed that interpretation could be biased and not generalized to the country. He also discussed about the challenges which the project is facing in which he said that there is no dedicated staff to support the program at the participating centers, contribution from all centers will not probably meet the required sample size, no national mortality estimates are available for cirrhosis/HCC and Medical certification of cause of death does not adequately and uniformly record the data. He also talked about leveraging on WHO data sources and GHE and enumerated the outcomes of the Project. All stakeholders agreed to the need of such a program and appreciated the pilot protocol developed by ILBS. It was suggested that the, if found suitable, the same could be expanded globally.

- Dr Sarin supported and appreciated the project and said that the Sequelae surveillance has been able to bring liver centric facilities together.
- After that, Dr P.K. Bansal raised a question that should we need to promote condom use among jail inmates since there is high rate of HCV among them. Dr Aggarwal answered his question by saying that sexual transmission for HCV among jail inmates is not a major cause since HCV transmission can also occur among IDU and unsafe injections, which are the more probable modes by which they have got the infection. He claimed that even commercial sex workers without HIV / IDU do not have high rates of transmission of HCV (HBV may be high).
- But in contrast to Dr Aggarwal's statement, Dr Jayanthi Shastri said that data shows that HCV prevalence in isolation among STI clinic attendees is high.

#### 7: Treatment Protocols

Dr. Rakesh Aggarwal (SGPGI) & Dr. C. E. Eapen, (CMC Vellore) chaired this session.

#### Treatment algorithm for HCV

**Dr. Samir Shah** (Global Hospital, Mumbai) presented on "Treatment algorithms for HCV". He presented the current INASL and WHO Guidelines for the treatment of HCV. He said luckily we have pangenotypic regimen data like daclatasvir/ sofosbuvir, velpatasvir/ sofosbuvir etc. and we can go away with Genotype specific treatment in modern age. He also compared daclatasvir/ sofosbuvir regimen with velpatasvir/ sofosbuvir for the effectiveness and current practice protocols. He worried that Triple DAA (Direct Acting Antiviral) combinations for HCV treatment are yet not available in India. He discussed about the various choices of treatment/ regimen available in different clinical situations as per the requirement, this includes those who have received treatment in past and those who are confirmed HCV patients but never received any treatment for the same.

#### Treatment algorithm for HBV

Starting the talk on treatment algorithm for HBV, **Dr. Manoj Kumar Sharma (ILBS)** underlined the challenges. Like indications for treatment, which drug for how long? He detailed the baseline assessment to find out the severity of the liver disease and decoded the algorithm for the diagnosis and treatment of HBV.

He discussed about the interferon nucleoside analogues and combination drugs, He discussed about the various choices of treatment/regimen available in different clinical situations as per the requirement, he mentioned about the importance for Cirrhosis and HCC early diagnosis and monitoring after one is infected with HBV.

Starting the discussion Dr. Sarin pointed out the three important variables; virus, inflammation and fibrosis of the liver due to the HBV. He detailed the protocol that when one should start treatment for confirmed HBV patients. It was decided that clinical protocols will be shared with all the experts for their inputs before finalizing national guidelines.

#### 8. Role of WHOCC, Educational Institutes, NGOs in Viral Hepatitis

The session was chaired by **Dr R S Gupta (NACO)**, the moderators for the session were **Dr. Swarup Sarkar (WHO)** and **Dr Bharat Rewari (WHO)**.

Role of WHO CC Networks in Viral Hepatitis: Dr. Swarup Sarkar started the session on the Role of WHO CC Network in Viral Hepatitis, He said there are more than 800 WHO collaborating centers in the world working on various global issues. Further elaborating the role he said each one of the collaborating centers has to work as an extended arm of WHO and fulfill the mandate of WHO as agreed upon in ToR, providing their own resources. He said ILBS is the first collaborating centre from the South Asia which dealt with very advanced clinical capacity which is needed for the development of NAP (National Action Plan). He advised that focusing on birth dose vaccination is the key to help preventing the extra pocket cost due to treatment of cirrhosis and HCC at tertiary care level. He undertakes that we need to have at least one CC in each state to rapidly roll out the Hepatitis prevention programs effectively.

Dr. Sarin questioned about the convergence connections with people who are engaged in different health care services and among the CCs.

In reply, Dr. Swarup Sarkar said we are connecting with the respective CCs, we are also trying to develop champions among the CCs who can run the network effectively. We don't want to create a top down approach, he added.

#### **Role of Educational institutions:**

Instead of Dr. Ashok Chauhan (AMITY) Dr Sanjeev Kumar (IHMR) presented the talk on role of educational institutions in Viral Hepatitis Elimination. He pointed out the various factors that includes student's health; he discussed every student needs to be educated about the ways to protect their own health. Education of students on prevention, screening and management of those infected with virus should be imparted. He said there is need of spreading awareness among students and through them to parents and the community about the viral hepatitis, we actually need to convert science into easily communicated messages, he gave example of Swachh Bharat Abhiyan for the effective mechanism.

He further elaborated the role of educational institutions that can also play critical role in simplifying 'science communication' with use of easy-to-understand messages targeted at the community. He advised NGOs can also help in this regard. Elaborating the role of Institutions he said they can also help in imparting advanced training for capacity building of health care providers through residential, telemedicine and outreach programs. Each medical institution can also ensure that students are vaccinated before they enter clinics. The institutions must ensure that the vaccine is available to the students and employees, and even the drugs for post exposure prophylaxis, free of cost.

He added educational institutions can also undertake operational research studies by working closely with the government, other academic institutions, civil society organization and other stakeholders, to scale up interventions.

Role of NGOs in Viral Hepatitis elimination: Ms. Vibhuti Sharma, Transplant Coordinator, ILBS presented the talk on role of NGOs in Viral Hepatitis; support and awareness said we need to build a coalition of NGOs those who are engaged in similar activities to scale activities/interventions/programs rapidly. She concluded that NGOs can help in reaching out to high risk groups and also in fighting stigma and discrimination through awareness campaigns.

#### 8. Role of Regulators, Industry and Media in Viral Hepatitis

This session was commenced with Shri. Ram Kripal Singh and Dr. Surinder Singh as Chairpersons with Dr. Henk Bekedam and Dr. R.K. Vats as Moderators.

**Dr. N Singh (DCGI)** enlightened on the topic "Fast tracking low cost new diagnostics for Viral Hepatitis in India". He also spoke on the need to bring down the cost of diagnostics and treatment so that we could build a strong case for funding by the Government and also Partner coordination for Viral Hepatitis testing may be led by the Government. He emphasized that costing and financing needs to be with due customization as per the states' requirements. He mentioned that it is necessary to form a group to come out with the issues related to affordability and accessibility to treatment of hepatitis. He was consistent about scaling up use of Gene Xpert Machines for testing. **Dr. Ritu Chauhan (WHO)** spoke on "Tools for advocacy and communication" mentioned that the pharma industry is ready to work with the other stakeholders in this initiative for elimination of hepatitis and Cipla has been able to bring down cost of drugs to less than \$3 a day within 2 years time. Whereas the media should prioritize this initiative for elimination of Viral Hepatitis in their coverage and support campaigns. She also laid importance on the health education for students as to what they can do to protect their own health. Education of students on prevention, their own screening and management of those with the hepatitis virus should be carried on intensively.

The panel discussion was on the Role of Foundations and Pharma: Gilead Sciences, Cipla, Abbott Diagnostic Research, Mylan foundation, BMS foundation, Novartis and NATCO in Viral Hepatitis.

Discussion regarding the health education for students leads to the view that there will be an increase in awareness among the students, which in turn increases the awareness among the students and their parents, this in turn increases the awareness in the community. Swachh Bharat Abhiyan will be a good example through which the awareness can be spread in the community regarding Hepatitis prevention. Educational institutions can also play critical role in simplifying 'science communication' with use of easy-to-understand messages targeted at the community. NGOs can also help in this regard. Institutions can also help in imparting advanced training for capacity building of health care providers through residential, telemedicine and outreach programs. Medical institutions can also ensure that students are vaccinated before they enter clinics. The institutions must ensure that the vaccine is available to the students and employees, and even the drugs for post exposure prophylaxis, free of cost. Educational institutions can also undertake operational research studies by working closely with the government, other academic institutions, civil society organization and other stakeholders, to scale up interventions. Also when hepatitis related adverse events are encountered, they may be collected under the Pharmacovigilance Program of India with guidance from ILBS.As India is a huge network of mobile users, we could also think of leveraging on this clientele as regards to collecting Hepatitis related adverse events. Available resources should also be pooled to design a comprehensive IEC and BCC campaign.

The meeting concluded with a sincere note of thanks from the Director ILBS, to the Hon'ble Minister of Health, GoI, Hon'ble Minister of Health GNCTD, Secretary Health, GoI, WR WHO and other officials from GoI, WHO for their contributions to finalize the draft of the National Action Plan for Viral Hepatitis in India.

#### Annexures

# Annexure 1: Agenda 4<sup>TH</sup> GOI-WHO-ILBS National Technical Consultation on Viral Hepatitis "Frame work of National Program on Viral Hepatitis in India" New Delhi Friday, 28th July 2017

0915	Registration and Fellowship			
	(Venue: MPH, Upper Basement, I	-		
0945	Session I: Existing Stakeholders: Present and	Speakers		
	Future Roles in National Action Plan on Viral			
	Hepatitis (NAP-VH)			
	Chairpersons: Dr A C Dhariwal (NCDC), Dr. B.			
	C. Sharma (ILBS), Dr. N. K. Ganguly and Mrs			
	Vinita Shrivastava (GOI)			
0945	Welcome	Dr S. K. Sarin, ILBS		
0955	Burden of Viral Hepatitis in India	Dr. Rakesh Aggarwal, SGPGI		
1010	Health sector response to viral hepatitis	Dr. Nicole Seguy, WHO Dr. A C Dhariwal,		
1020	Updates on Surveillance of viral hepatitis in India	NCDC		
1030	Service Delivery models(5 min. each)	Dr Lucy, Manipur		
	1. State led Model	Dr P K Bansal, DH-		
	2. District level model	Meerut		
	3. NACO: Opportunities for synergies and plan	Dr. R S Gupta, DDG		
101-	for VH	NACO (CST)		
1045	Leveraging existing training programs at ILBS	Dr. Ekta Gupta, ILBS		
1050	Discussion			
1100	Session II: Prevention and Diagnosis as	Speakers		
	Components of NAP-VH Chairpersons: Dr Venkatesh (NACO), Dr Priya			
	Abraham(CMC), Dr Sandhya Kabra (NCDC)			
	and Dr Sharda Patra (LHMC)			
	Prevention( under NHM):(5 mins each)			
1100	1. Immunization	Dr Pradeep Haldar, GOI		
1107	2. Injection Safety	Dr. Madhur Gupta, WHO		
1115	3. Safe blood	Dr. Meenu Bajpai, ILBS		
1122	Diagnosis: Integrated diagnostic platforms: scope and opportunities	Dr. Surinder Singh, NIB		
1132	Diagnosis: Role of ICMR viral diagnostic labs	Dr. Nivedita, ICMR		
1140	Discussion			
1200	Session III: Surveillance in Viral Hepatitis	Speakers		
	Chairpersons: Dr J K Das (NIHFW), Dr. Rakesh	1		

	Aggarwal (SGPGI), Dr. A C Dhariwal (NCDC)	
1200	Surveillance: Experience from States on outbreaks	SSO (IDSP) from
	of Hepatitis A & E (5 min each)	different States
	1. Haryana	
	2. Telangana	
	3. Jammu &Kashmir	D 41 . G1 1 D1 1 1
1215	Sequelae Surveillance in Viral Hepatitis	Dr. Ajeet SinghBhadoria,
1220	Disconnica	ILBS
1220	Discussion  Session IV Treatment Protects	Charlens
1230	Session IV: Treatment Protocols Chairs: Dr. C. E. Eapan (CMC), Anoop Saraya	Speakers
	(AIIMS), Dr. Seema Alam (ILBS)	
1230	Treatment algorithms for HCV	Dr. Samir Shah, Global
1230	Treatment argorithms for the v	Hosp.
1242	Treatment Algorithms for HBV	Dr Manoj Kumar
		Sharma, ILBS
1255	Discussion	
1315	<b>Lunch (Phase 2, 1st Floor)</b>	
1400	Session V: Role of WHOCC, Educational	Moderators:
	Institutes, NGOs in Viral Hepatitis	Dr. Swarup Sarkar
	Chairpersons: Dr R S Gupta (NACO), Dr N S	(WHO)
	Dharamshaktu (GOI), and Dr Sanjeev Kumar	
	(IIHMR)	
1400	Role of WHO CC Network in Viral Hepatitis	Dr. Swarup Sarkar, WHO
1410	Role of Educational Institutes in Viral Hepatitis Elimination	Dr. Ashok Chauhan, AMITY
	Elimination	AMITY
1410 1420		·
	Elimination  Role of NGOs in Viral Hepatitis; support and	AMITY
1420	Elimination  Role of NGOs in Viral Hepatitis; support and awareness	AMITY
1420	Elimination  Role of NGOs in Viral Hepatitis; support and awareness  Panel Discussion:	AMITY
1420	Elimination  Role of NGOs in Viral Hepatitis; support and awareness  Panel Discussion:  FIND, MSF,CHAI, DNDI, BMGF, WHOCC-ILBS,	AMITY
1420	Elimination  Role of NGOs in Viral Hepatitis; support and awareness  Panel Discussion:  FIND, MSF,CHAI, DNDI, BMGF, WHOCC-ILBS, WHOCC-SGPGI, WHOCC-National AIDS Research	AMITY
1420 1430	Role of NGOs in Viral Hepatitis; support and awareness  Panel Discussion: FIND, MSF,CHAI, DNDI, BMGF, WHOCC-ILBS, WHOCC-SGPGI, WHOCC-National AIDS Research Institute, WHOCC-National Tuberculosis Institute  Session VI: Role of Regulators, Industry and Media in Viral	AMITY Mrs. Vibhuti, ILBS
1420 1430	Role of NGOs in Viral Hepatitis; support and awareness  Panel Discussion: FIND, MSF,CHAI, DNDI, BMGF, WHOCC-ILBS, WHOCC-SGPGI, WHOCC-National AIDS Research Institute, WHOCC-National Tuberculosis Institute  Session VI: Role of Regulators, Industry and Media in Viral Hepatitis Chairpersons: Sh. Manoj Jhalani	AMITY Mrs. Vibhuti, ILBS  Moderators:
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1420 1430 1500	Role of NGOs in Viral Hepatitis; support and awareness  Panel Discussion: FIND, MSF,CHAI, DNDI, BMGF, WHOCC-ILBS, WHOCC-SGPGI, WHOCC-National AIDS Research Institute, WHOCC-National Tuberculosis Institute  Session VI: Role of Regulators, Industry and Media in Viral Hepatitis Chairpersons: Sh. Manoj Jhalani (NHM), Sh. Navdeep Rinwa (GOI), Sh. Ram Kripal Singh and Dr Surinder Singh	AMITY Mrs. Vibhuti, ILBS  Moderators: Dr. B B Rewari (WHO)
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1520	Tools for advocacy and communication	Dr. Ritu Chauhan, WHO
1530	Panel Discussion: Role of Foundations and Pharma Gilead Sciences, Cipla, Abbott Diagnostic Research, Mylan Foundation, BMS Foundation, Novartis, NATCO	
1600	Session VII: Summary and Conclusions	Dr S K Sarin (ILBS) and Dr. Vimlesh Purohit (WHO)
1630	Group Photo & Tea	

Rapporteur: Dr Archisman Mohapatra and Dr Ajeet Singh Bhadoria

## Inaugural session Venue: APJ Abdul Kalam Auditorium

	Agenda						
1700	Welcome	Dr. A C Dhariwal					
	• Report on 4 <sup>th</sup> GOI-WHO-ILBS Workshop	Dr. Shiv Kumar Sarin					
	Message from WHO India Representative	Dr. HenkBekedam					
	• Equality for Hepatitis B and C Patients (Eminent Lawyer)	Sh. Fali Nariman					
	<ul> <li>Address by Secretary (H&amp;FW, GOI)</li> </ul>	Sh. C K Mishra					
	<ul> <li>Key Note Address: Hon'ble Minister H&amp;FW, GNCTD</li> </ul>	Sh. Satvendra Jain					
	• Chief Guest's Address: Hon'ble Union Minister for H&FW	Sh I P Nadda					
	• Vote of Thanks	Dr Ajeet Singh Bhadoria					
1830	Group Photo and High T	ea					

#### **Annexure 2: List of participants**

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63	Dr Pankaj Bhatnagar		WHO	
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