Technical Consultation on a comprehensive National Hepatitis Prevention and Control Programme in India

WORLD HEPATITIS DAY: “VIRAL HEPATITIS, THINK AGAIN”

Meeting Report | 28 July 2014
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<tbody>
<tr>
<td>ANC</td>
<td>antenatal care</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>ART</td>
<td>antiretroviral treatment</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>DAA</td>
<td>direct acting antiviral (drug)</td>
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<tr>
<td>DPT</td>
<td>diphtheria, pertussis and tetanus</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<tr>
<td>eVIN</td>
<td>Electronic Vaccine Intelligence Network</td>
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<tr>
<td>eMTCT</td>
<td>elimination of mother-to-child transmission</td>
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<td>GoI</td>
<td>Government of India</td>
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<tr>
<td>HAV</td>
<td>hepatitis A virus</td>
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<td>HBIG</td>
<td>hepatitis B immunoglobulin</td>
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<td>HBeAg</td>
<td>hepatitis B e antigen</td>
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<td>HBsAg</td>
<td>hepatitis B surface antigen</td>
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<td>HBV</td>
<td>hepatitis B virus</td>
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<td>HCC</td>
<td>hepatocellular carcinoma</td>
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<td>HCV</td>
<td>hepatitis C virus</td>
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<td>HCW</td>
<td>health-care worker</td>
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<td>HEV</td>
<td>hepatitis E virus</td>
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<tr>
<td>ICTC</td>
<td>integrated counselling and testing centre</td>
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<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HMIS</td>
<td>Health Management Information System</td>
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<td>IDSP</td>
<td>Integrated Disease Surveillance Programme</td>
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<td>ILBS</td>
<td>Institute of Liver and Biliary Sciences</td>
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<td>ITSU</td>
<td>Immunization Technical Support Unit</td>
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<td>JMP</td>
<td>Joint Monitoring Programme</td>
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<td>JSY</td>
<td>Janani Suraksha Yojana</td>
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<tr>
<td>MCH</td>
<td>maternal and child health</td>
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MCTS  mother and child tracking system
NACO  National AIDS Control Organization
NAT   nucleic acid testing
NBA   Nirmal Bharat Abhiyan
NCDC  National Centre for Disease Control
NSP   needle and syringe programme
NHM   National Health Mission
NIHFW National Institute of Health and Family Welfare
OST   opioid substitution therapy
PEG-IFN pegylated interferon
PEP   post-exposure prophylaxis
PMTCT preventing mother-to-child transmission
PWID  people who inject drugs
SEARO WHO Regional Office for South-East Asia
SVR   sustained virological response
TBD   timely birth dose
TDF   tenofovir
TSC   total sanitation campaign
TWG   technical working group
UIP   Universal Immunization Programme
WHA   World Health Assembly
WHO   World Health Organization
Executive summary

The first round table consultation on “Viral Hepatitis: Gaps, Challenges and Priorities” was organized jointly by the Institute of Biliary Sciences and the World Health Organization Country Office for India on 28 July 2014, marking World Hepatitis Day 2014.

This consultation aimed at discussing policy options for accelerating efforts towards a comprehensive programme for prevention and control of viral hepatitis in India. It had participation from a wide variety of stakeholders including policymakers, programme managers from the Ministry of Health, academia, research scientists, tertiary care institutions, clinicians, social scientists, representatives of WHO, other partner agencies, private sector as well as civil society, harm reduction groups and positive patients networks.

Viral hepatitis, which is recognized as a serious global public health problem, has been silently leading to a pandemic in India. It is estimated that there are 40 million people chronically infected with hepatitis B and 12 million people chronically infected with hepatitis C in India.

Lack of comprehensive policy and planning to address the complex challenges of prevention and treatment of this group of diseases has led to an explosive situation, with many outbreaks of viral hepatitis B and C being reported from various parts of the country. This has been largely due to rampant and indiscriminate use of unsafe injections, a large population of susceptible individuals due to unacceptably low immunization coverage (30%) of hepatitis B birth dose vaccine and the vast majority of the population being unaware about disease transmission, thus failing to get tested and treated in time. Outbreaks and cases of hepatitis E and A also continue to occur as a result of continuing issues of access to safe water and sanitation.

Recognizing the importance and growing public health issues of viral hepatitis, the Government of India has prioritized viral hepatitis in its Twelfth Five Year Plan, and a new programme for viral hepatitis has been launched in 2014. However, this plan attempts to address only a few components. The national plan to prevent and control viral hepatitis needs to be more comprehensive to embrace all aspects of prevention and treatment and include components from existing programmes of the Ministry of Health, including the HIV/STI Programme and the Reproductive, Maternal, Newborn, Child and Adolescent Health Programme. The consultation deliberated on these policy gaps for viral hepatitis in India and prioritization of the next steps so that a robust and comprehensive national viral hepatitis programme could be developed quickly. The deliberations were broadly based on the WHO publication “Prevention and Control of Viral Hepatitis Infection: Framework for Global Action”. This describes the four axes of work: Axis 1 – Raising awareness, promoting partnerships and mobilizing resources; Axis 2 – Evidence-based policy and data for action; Axis 3 – Prevention of transmission; and Axis 4 – Screening, care and treatment.
The group recommended drafting a comprehensive national policy for prevention and control of viral hepatitis for India with clear targets. It recommended priority actions to be implemented during 2014–15 to improve the understanding of the burden of disease in India, drastically reduce new infections and improve access to treatment.

The utmost priority intervention for the Government of India is to improve the birth dose coverage of hepatitis B vaccine to 95% to protect the children, our future, from this largely preventable disease. The increasing institutionalization of deliveries in India provides the opportunity for rapid scale up of the birth dose coverage. The group also recommended partnering with professional associations, harm reduction groups and the private sector for advocacy and education on promoting injection safety in India.

There was wide agreement that intensive efforts needed to go into raising awareness of viral hepatitis in India, not only among the community and high-risk groups but also among the health-care providers. The group also recommended concrete actions to increase access to testing and treatment, including to the new, promising drugs for hepatitis C treatment.

The consultation threw light on the rights of the citizens of India who are facing discrimination and stigma issues on being diagnosed as positive with viral hepatitis B and C, and the need to address this component in the national programme.

The group called for partners, donors and all concerned stakeholders to work together for a “Hepatitis B-free India by 2080”.

Summary of recommendations –
top priority actions for 2014–15

Axis 1. Raising awareness, promoting partnerships and mobilizing resources
  - Draft a national strategy document for risk communication on viral hepatitis.
  - Raise awareness in the community: partner with the media and academia to produce materials with relevant technical content for education and behavioural change
  - Educate and train health-care workers: design fact sheets; provide training on the Universal Immunization Programme (UIP); educate on safe injection guidelines; creation of a dedicated web site by Integrated Disease Surveillance Programme (IDSP)/National Centre for Disease Control (NCDC)
  - Involve willing partners such as the National Institute of Health and Family Welfare (NIHFW), WHO, Institute of Liver and Biliary Sciences (ILBS), Amity University, academia and community based organizations
  - Integrate hepatitis B and C prevention and behavioural change messages into HIV material for high-risk groups by National AIDS Control Organization (NACO)
  - Mobilize resources for the implementation of the communication strategy plan and chalk out an action plan for viral hepatitis.

Axis 2. Evidence-based policy and data for action
  - Integrate hepatitis B virus (HBV)/hepatitis C virus (HBC) prevalence surveillance into HIV surveillance for populations at risk, in particular for people who inject drugs (PWID) (by NACO)
  - Update HBV/HCV maps of India based on available info, and identify gaps in epidemiological profiles (NCDC/ILBS/CMC/others)
  - Establish protocols for sentinel surveillance to estimate hepatitis prevalence in the community (NCDC/ICMR to lead)
  - Enhance laboratory capacity for viral hepatitis testing through quality assured diagnostics, validated test kits and national strategy and algorithm for standardized testing (NCDC, ILBS)

Axis 3. Prevention of transmission of hepatitis B and C
  - Achieve universal (95%) coverage of 3-dose hepatitis B vaccine, including 95% of birth dose in institutional deliveries, through:
    • education of parents in antenatal clinics by ASHAs
    • improved capacity and supervision of maternal and child health (MCH)/National Health Mission (NHM) staff (training, posters)
    • including hepatitis B timely birth dose (TBD) as part of labour room SOPs
    • ensuring availability of vaccine at all facilities conducting deliveries
    • vaccine provision for home deliveries
    • integration with preventing mother-to-child transmission (PMTCT) of HIV and congenital syphilis (antenatal care [ANC] package)
– Ensure universal hepatitis B vaccination and post-exposure prophylaxis (PEP) for health-care workers (HCWs)
– Implement safe therapeutic injection practices, universal precautions and infection control guidelines
– Train medical staff and communities on rational use of injections
– Release new national injection safety guidelines (NCDC), clear SOPs for therapeutic injections, job aids, explore newer and safer devices
– Integrate hepatitis prevention into the HIV prevention programme for high-risk groups (to be taken up on priority) and consider HBV vaccination of high-risk populations (based on evidence)

**Axis 4. Screening, care and treatment of HBV/HCV**

– Develop a standard national policy and strategy for screening and treatment of hepatitis B and C
– Identify population groups for screening, based on evidence
– Develop counselling facilities and referral to care and treatment for patients suffering from viral hepatitis
– Develop a public health approach to treatment of HBV/HCV
– Develop a decentralized model
– Strengthen lab capacity for screening
– Identify ways to increase access to hepatitis B and C treatment. Work towards improving access to hepatitis B and C medications and provision of free treatment by the government
– Work for availability/accessibility/affordability of new direct acting antiviral (DAA) for hepatitis C treatment
– Fast track registration
– Facilitate the development of new fixed dose formulations by generic companies in India (for the longer term).
Background

Globally, viral hepatitis is responsible for 1.4 million deaths every year (compared to 1.5 million deaths from HIV/AIDS and 1.2 million deaths from each of malaria and tuberculosis). Around 500 million people are currently living with viral hepatitis. Most people with chronic hepatitis B or C are unaware of their infection and are at serious risk of developing cirrhosis of the liver or liver cancer, contributing to global increases in both of those chronic diseases. Millions of acute infections with hepatitis A virus (HAV) and hepatitis E virus (HEV) occur annually and result in tens of thousands of deaths, almost exclusively in lower- and middle-income countries.

India has a 3–4% hepatitis B surface antigen (HBsAg) and 1% anti-hepatitis C virus (HCV) antibody prevalence in the general population. It is estimated that there are 40 million people chronically infected with hepatitis B and 12 million people chronically infected with hepatitis C in India. Chronic HBV and HCV infection accounts for 40–50% and 12–32% of hepatocellular carcinoma, respectively.

In 2010, the first World Health Assembly (WHA) resolution on viral hepatitis urged Member States to support or enable an integrated and cost-effective approach to the prevention, control and management of viral hepatitis. To facilitate implementation of the resolution, the Secretariat established the WHO Global Hepatitis Programme. In 2012, the Secretariat issued a framework for global action to prevent and control viral hepatitis infection, which aligned actions along four strategic axes: (1) raising awareness, promoting partnerships and mobilizing resources; (2) evidence-based policy and data for action; (3) prevention of transmission; and (4) screening, care and treatment. In 2014, WHO SEARO issued a Regional Strategy for the prevention and control of viral hepatitis in South-East Asia. In May 2014, the WHA passed a second resolution on viral hepatitis that urged Member States to develop robust strategies and goals on viral hepatitis and report on their progress. The WHO resolution is supported by a number of WHO development guidelines including surveillance and treatment guidelines.

On the occasion of World Hepatitis Day 2014, the ILBS organized a national technical consultation with the support of WHO on viral hepatitis prevention and control in India. The meeting brought together stakeholders from the government, academic and clinical experts and civil society for discussing gaps in the national response and deliberating on the priorities, policy options and mechanisms for prevention and control of viral hepatitis in India.
Meeting objective

To discuss policy options for accelerating efforts towards a comprehensive programme for prevention and control of viral hepatitis in India.
The inaugural session began with the welcome address delivered by Professor S.K. Sarin, Director of the Institute of Liver and Biliary Sciences. He emphasized the magnitude of the problem of hepatitis B, C, A and E in India and called for collective efforts to reduce the burden of disease. Dr Sarin said increasing public awareness about the disease and its symptoms and regular health check-ups for people above 40 years of age are needed to check its incidence. He stated that ILBS is committed towards making India hepatitis free by 2080.

Dr Nata Menabde, WHO Representative to India discussed the problem of viral hepatitis in South-East Asia with emphasis on the situation in India. She said that India needs reliable information on the burden of viral hepatitis to initiate preventive and controlling measures. She expressed concern over the existing ignorance regarding the disease. She emphasized that food and water sanitation needs to be intensified to ensure prevention of Hepatitis A and E. Awareness among the general public should be increased and treatment for Hepatitis B and C should be made easily available and heavily subsidized as is the case for tuberculosis and HIV. She advocated developing a comprehensive national strategy for integration with existing disease surveillance programmes (such as for HIV, noncommunicable diseases and disease surveillance and outbreak management) for prevention of transmission. Surveillance and integrated service delivery will also help in effective management of patients, including those that have co-infections.

Shri Lov Verma, Secretary Health, Government of India described the initiatives taken by the Government in setting up of regional laboratories by the National Centre for Disease Control (NCDC) for the surveillance of viral hepatitis in India, to know more about the disease outbreaks and provide laboratory support. He also stressed on focusing on the preventive aspects rather than treatment of viral hepatitis, given the limited health resources in India. Increasing mass awareness, education and setting up universal guidelines for immunization are needed to fight the disease which kills 300 000 people across the country every year.

Dr V. K. Subburaj, Secretary, Department of AIDS Control said there was a need for coordination among various agencies to eradicate viral hepatitis. Standardization of blood bank practices and introduction of nucleic acid amplification testing (NAT) is important for preventing blood transfusion-related viral hepatitis.

Dr Jagdish Prasad, Director General of Health Services emphasized on the need of constituting a national working committee to work towards eradication of viral hepatitis in India.

Dr Vasantha Kumar praised ILBS and said the Institute was the torchbearer for the country in working towards combating the menace of viral hepatitis in India. He suggested that
institutes like ILBS and other leading institutes in the country should take the lead in increasing awareness among health-care workers and improving the primary health-care system of the country.

The inaugural session was followed by the technical sessions (agenda for the meeting is given at Annex 1)

The epidemiological situation of viral hepatitis in India and the current national response were presented. There were two technical sessions – the first was on hepatitis B and C and the second on hepatitis A and E.

Following the discussion on the four axes of the WHO strategy to address viral hepatitis, discussions were held on the current gaps and challenges. The group of experts defined recommendations and key priority actions to be taken during the period 2014–15 to improve the national response.
Epidemiological situation

4.1. Viral hepatitis B
India has "intermediate to high endemicity" for HBsAg and an estimated 40 million chronic HBV infected people, constituting approximately 11% of the estimated global burden.1 Chronic hepatitis B (CHB)-associated mortality and morbidity contributes to be a high public health burden.

HBsAg positivity in the general population ranges from 1.1% to 12.2%, with an average prevalence of 3–4%.2 There is a wide variation in HBsAg prevalence in different geographical regions. Analysis of HBsAg prevalence in the general population suggests that Jammu and Kashmir and Kerala have a prevalence of <2%; Karnataka, Maharashtra, Delhi, Haryana, Himachal Pradesh and West Bengal have a prevalence between 2% and 4%; and Tamil Nadu, Pondicherry, Andhra Pradesh, Madhya Pradesh, Uttar Pradesh and Arunachal Pradesh have a prevalence of >4%.2 The highest prevalence has been recorded among the natives of the Andamans and Arunachal Pradesh.3 Studies on HBV prevalence in antenatal pregnant women have shown prevalences ranging from 1% to 12.3%, with significant regional variations as for the general population.4

The replicative status of HBV in the general population as denoted by hepatitis B e antigen (HBeAg) positivity varies from 2.6% to 56% with a mean of 24.2%, with wide regional variations (Maharashtra <10%, Delhi between 10% and 20% and Tamil Nadu, Kerala and Andhra Pradesh >20%).2 HBeAg prevalence among HBV positive antenatal pregnant women varies from 7.8% to 47.8% (mean 24%) with significant regional variations as for the general population. There are various high-risk groups for HBV infection (see Annex 3). The highest prevalence rates are seen in haemodialysis patients (7.7–35.1%), thalassaemia patients (15–45%), family contacts of HBsAg positive subjects (11.3–41.5%), PWID (20–100%), professional blood donors (3.8–13.1%), truck drivers (5%), commercial sex workers (3.6%), STD patients (8.8–10.3%) and hospital personnel (1.4–16.5%).5–8 Outbreaks of acute and fulminant hepatitis B still occur mainly due to inadequately sterilized needles and syringes, as demonstrated by the recent outbreak of acute hepatitis B in Modasa town of Gujarat.9

Chronic HBV infection accounts for 40–50% of hepatocellular carcinoma (HCC) and 20–30% cases of cirrhosis in India.10,11

While there is limited evidence to inform of the percentage of people living with chronic hepatitis B who are eligible for treatment, estimates range from 10% to 25%.12

4.2. Viral hepatitis C
Population prevalence of chronic hepatitis C virus (HCV) infection in India is around 1%. Anti-HCV antibody prevalence reported among the general population ranges from 0.094% to 15.0%.13 However, there are pockets of areas where prevalence of hepatitis C has been
observed to be relatively higher in Punjab, Haryana, Andhra Pradesh, Puducherry, Arunachal Pradesh and Mizoram. The prevalence of anti-HCV antibody reported among the healthy blood donor population ranges from 0% to 4.3% among non-commercial blood donors. In India, mandatory screening of blood for HCV was introduced only in 2002. The impact of screening for hepatitis C in India was shown in a cross-sectional study from Kolkata that looked at three groups of patients. The first group comprised patients who had received multiple transfusions before 1995; the second group of patients had received transfusions only since 1995 and the third group had control patients who had never been transfused. The HCV antibody positivity rate was 16%, 6% and 2%, respectively. Prevalence rates of chronic HCV infection among high-risk groups (see Annex 3) are: in haemodialysis patients (4.3–46%), thalassaemia patients and haemophilia patients (13–26.5%), PWID (55–97%), professional blood donors (55–87.3%), commercial sex workers (0.57–21.1%), STD patients (1.0–21.4%) and hospital personnel (0–4.5%).

Besides these well-known high-risk categories, different risk factors have been highlighted which are believed to have led to the relatively higher prevalence of the condition in particular areas. In a recent study conducted in Punjab with 5.2% prevalence of HCV infection, the identified risk factors for acquiring HCV infection were a history of surgery/dental treatment/unprotected sex. Lack of awareness coupled with the unscrupulous practices of health-care providers has led to an alarming 22.6% of the population sampled being infected with the hepatitis C virus in Ratia block of Fatehabad district in Haryana. Another risk group, which is restricted to certain regions of the country, is people suffering from kala-azar who have received multiple injections. Such a group of patients was studied in a referral hospital in Delhi, though the majority of patients were from Bihar. The prevalence of HCV antibody positivity was an alarming 32.9%, as opposed to 4% in geographical controls from the same region.

The most likely culprit in these patients is inadequately sterilized needles. In some studies conducted in Andhra Pradesh, cultural practices such as tattooing, traditional medicine (e.g. bloodletting), rituals among pilgrims (e.g. scarification) and body piercing have been observed to lead to a significantly higher rate of HCV transmission. HCV prevalence rates of 1.4%, 2.02% and 6.1% have been noted in different studies conducted in tribal and other populations in Andhra Pradesh.

Chronic HCV infection accounts for 12–32% of HCC and 10–20% cases of cirrhosis in India. Approximately 60–70% of chronic HCV infected subjects are likely to need therapy at a given point in time.

4.3. **HIV–viral hepatitis B/C co-infection**

In India, 3.4–30.4% of HIV infected patients are infected with hepatitis B virus (HBV) and from 1.6% to as much as 80% are infected with HCV.

4.4. **Viral hepatitis A and E**

Hepatitis A virus (HAV) and hepatitis E virus (HEV) are important causes of acute viral hepatitis and acute liver failure in India. Since 1955, several epidemics of hepatitis have been reported. Between 2010 and 2013, 315 outbreaks of viral hepatitis were reported through the IDSP of NCDC. Of these, 99 outbreaks were reported in 2013. Although HAV and HEV, both enterically transmitted, are highly endemic in India, HEV has been responsible for most of these epidemics.
HAV is responsible for 10–30% of acute hepatitis and 5–15% of acute liver failure cases in India. Hepatitis A asymptptomatically infects most of the population in India in early childhood with lifelong immunity. The majority of adults develop symptoms following HAV infection, but more than 70% of children younger than 6 years of age are asymptomatic or develop a mild self-limiting illness. Although India has traditionally been a high endemicity area, due to altered epidemiology and decreasing endemicity, the pattern of acute HAV infection is changing from asymptomatic childhood infection to an increased incidence of symptomatic disease in the 18–40 years age group. Many studies have found evidence of epidemiological shift from high endemicity to intermediate endemicity for the affluent population in various cities across India. We now have a sign that a proportion of the population of such cities are susceptible to HAV along with a still larger proportion being infected and excreting the virus.

In the absence of appropriate steps, epidemics of hepatitis A are likely to occur in the susceptible population with severity of the disease increasing with age. Thus, there is the big divide between the rural poor population (which is characterized by poor hygiene and sanitation, 80% seroconversion rate by 5 years of age and 100% seroconversion by 10 years of age, mostly asymptomatic infection) and the urban affluent class (with good hygiene and sanitation, 20% seroconversion by 5 years of age and only 50% seroconversion by 10 years of age, severe acute HAV occurring later in life).

HEV is responsible for 10–40% of acute hepatitis and 15–45% of acute liver failure in India. Acute HEV has a high mortality rate of 15% to 25% in women in the third trimester of pregnancy. Superimposed HEV is responsible for 10–15% of cases of acute or chronic liver failure in India. Acute or chronic liver failure carries a mortality of 50–60% without liver transplantation.
Recognizing the importance and growing public health issue of viral hepatitis, the Government of India (GoI) has prioritized viral hepatitis in its Twelfth Five Year Plan. A new programme for viral hepatitis has been launched in 2014. However, this plan attempts to address only a few components. The GoI priorities focus on blood safety, laboratory strengthening and information, education and communication.

5.1. Prevention of viral hepatitis transmission

5.1.1. Prevention of HBV and HCV transmission through blood transfusion and unsafe injections
Donated blood is being screened for hepatitis B and C since 2002. The risk of transmitting infection to recipients from blood products has been drastically reduced in the past decade due to improved donor selection, sensitive serological screening assays and application of viral inactivation procedures during the manufacture of plasma products.

GoI has a national policy on injection safety in health-care settings and injection safety guidelines have been issued in July 2014.30 However, unsafe injections are still highly prevalent, leading to hepatitis B and C outbreaks in health-care settings.

Prevention of HCV transmission among PWID
Unsafe injecting drug use is an important mode of spread of HCV, HBV and HIV in India. Among PWID, the risk of acquiring hepatitis C is highest in the first year of injecting, highlighting the need to target activities to those who are new to injecting.32 Needle and syringe exchange programme and opioid substitution therapy (OST) are being implemented by the National AIDS Control Organization (NACO) under the MoHFW for HIV prevention among PWID. However, the NACO programme does not integrate hepatitis B and C prevention.

5.1.2. Hepatitis B immunization programme for children
Viral hepatitis B is a vaccine-preventable disease. Universal hepatitis B immunization for children is the most cost-effective intervention to prevent the disease. In India, the hepatitis B vaccination programme including birth dose was initially launched in 2002, which was gradually expanded to cover all districts in 10 states by 2007–08.30 The programme was scaled up nationwide in 2011.

The national policy recommends that children receive 3 doses of hepatitis B vaccine, administered concurrently with diphtheria, pertussis and tetanus (DPT) and trivalent oral polio vaccine at 6, 10 and 14 weeks. In addition, a birth dose is recommended for all newborns (within 24 h of delivery) for all institutional deliveries.

However, the hepatitis B vaccination coverage of children is low. From both Health Management Information System (HMIS) data and coverage monitoring data from WHO for 2013–14, the birth dose coverage is only 34% (62% for institutional deliveries) and hepatitis B3 coverage is 71%.
5.1.3. Prevention of HBV vertical transmission
The vaccination programme including the timely birth dose within 24 hours after birth is a priority intervention to reduce vertical transmission. A national policy for prevention of vertical transmission of hepatitis B is being considered that may include additional interventions such as screening of pregnant women for HbsAg, and hepatitis B immunoglobulin (HBIG) for infants born to mothers infected with HBV.

5.1.4. Prevention of HAV and HEV transmission
Nirmal Bharat Abhiyan (NBA), previously called the Total Sanitation Campaign (TSC), is a community-led total sanitation programme initiated by GoI in 1999. Progress has been made with an increase in sanitation coverage in rural India from 21% in 2001 to 42% in 2010. Seventeen states have already achieved the MDG 7 target in 2011, which is to halve, by 2015, the proportion of people without sustainable access to safe drinking-water and basic sanitation.33

However, it is estimated that in the current situation, India will reach the MDG 7 target only by 2054.

5.2. Screening, care and treatment
Current general screening practices in India include screening of blood donors for anti-HIV, HBsAg and anti-HCV, screening of organ donors, haemodialysis patients, in cases of post-exposure prophylaxis for HCWs, antenatal screening only for HBsAg, and physician-initiated screening in adults with a history of liver disease or liver enzyme abnormalities. Treatment of chronic hepatitis B and C is currently being done at tertiary centres only.

Currently, there are no national guidelines for screening, care and treatment of viral hepatitis in India. NCDC is under the process of preparing a national guideline entitled “National Guidelines on Hepatitis: Prevention, Control and Management”.

5.3. Strategic information for policy decision
Under NCDC, there is a case reporting system for acute hepatitis A and E but not for hepatitis B and C. Outbreaks of viral hepatitis are being detected and responded through the national disease surveillance system, IDSP. The GoI has a media scanning and monitoring system to enhance disease surveillance efforts, as the first alerts of an outbreak are often picked up by the media.

However, due to the lack of nationally representative seroprevalence surveys, there is an incomplete picture of the epidemiological situation as on date.

NCDC plans to conduct sentinel surveillance of hepatitis B and C prevalence at the community and hospital levels in 10 states. The protocol is being finalized by a national technical working group (TWG). The aim is to have burden of disease estimates by 2017. A total of 12 laboratories will be strengthened for surveillance. There is no nationally representative seroprevalence surveillance planned among high-risk groups.

5.4. Awareness raising
Communication efforts of risks of viral hepatitis in India so far have been restricted to world hepatitis day or few technical events/national seminars/other workshops.
6.1. **Axis 1: Raising awareness, promoting partnerships and mobilizing resources**

6.1.1. **Gaps and challenges**
- There is a very low level of awareness about viral hepatitis viruses, routes of transmission, risk factors and their impact on human health in the Indian community among health providers3 and policy makers.
- Hepatitis continues unabated as a “silent” infection. Most affected individuals do not know that they are infected with viral hepatitis B or C. Most do not have any visible symptoms in the early stages of the disease and hence do not feel the need for intervention.
- There is no national comprehensive policy for hepatitis that addresses support and management once an individual is detected as having hepatitis B or C.
- Currently, there is no national strategy for risk communication to support control of viral hepatitis in India.
- Although many interventions for behaviour change communication are taking place for the HIV programme, this does not presently address viral hepatitis education and messages.
- Resources allocated for prevention and control of viral hepatitis in India are limited as health-care cost, especially for treatment of chronic HBV and HCV is very high leading to large out-of-pocket expenditure. This has not been factored in while working out the costing of the national programme.
- Many people infected with hepatitis B and/or C in India are getting marginalized because of stigma and additional barriers due to lack of trust in the health-care system. One result of the perceived stigma is that some infected individuals do not tell their family members of their status, which is a potential lost opportunity to screen household contacts who are at high risk of catching the infection. An enabling policy and legal environment that addresses stigma, discrimination and human rights issues will help to increase access to services and improve the health and lives of people with hepatitis B and C.

6.1.2. **Recommendations for priority actions**

Draft a national strategy for risk communication of viral hepatitis
- Constitute an expert group for risk communication.
- Integrate hepatitis prevention messages into HIV materials for high-risk groups.
- Develop clear, consistent and strong messages for all audiences.
- Develop close collaboration with the media.
- Communication strategy should also address stigma reduction and other discriminatory policies in the national strategy.
- Identify a focal point/technical institution to coordinate evaluation of the communication messages and strategy.
Raise community awareness
- Raise awareness in the community to make the silent epidemic of viral hepatitis visible through dissemination of materials for education and behaviour change.
- Partner with the media with relevant technical content.
- Address educational campaigns for stigma reduction.
- Provide testing sites that are anonymous and create enabling environments such as clinics, community centres and health fairs that provide diagnostic testing as well as facilitate subsequent management support.

Educate and train health-care workers
- Design fact sheets.
- Lay down safe injection guidelines.
- Provide training on universal precautions.
- IDSP/NCDC to develop a dedicated web site

Mobilize resources
- Develop a strategy for resource mobilization and a list of priorities for funding.
- Resource mobilization strategy must include implementation of the communication strategy as a priority.

Involve willing partners

Involve willing partners:
- for advocacy for prevention and control of viral hepatitis;
- to build strong relationships with decision makers;
- to support national meetings and symposia to advocate for resource mobilization
- to develop standard information kits for various target audiences.

6.1.3. Top priority actions for 2014–15
- Draft a national strategy document for risk communication on viral hepatitis
- Raise awareness in the community—materials for education and behaviour change; partner with the media and academia with relevant technical content
- Educate and train health-care workers—design fact sheets, training on the Universal Immunisation Programme (UIP); safe injection guidelines; dedicated web site (IDSP/NCDC)
- Involve willing partners: NIHFW (health portal), ILBS, academia, community-based organizations, WHO, Amity University, academia, like-minded pharma
- Integrate hepatitis B and C prevention and behaviour change into HIV materials for high-risk groups (NACO)
- Communication strategy—reduction of stigma and discriminatory messages
- Mobilize resources for the implementation of the communication strategy and action plan for viral hepatitis.

6.2. Axis 2: Evidence-based policy and data for action

6.2.1. Gaps and challenges
- Without a strong situational analysis of burden of disease, it is difficult to convince policy makers and mobilize human and financial resources for hepatitis prevention and control.
- The current data on HBsAg and anti-HCV prevalence is not representative. There is a need to identify the burden of hepatitis B and C by geographical areas and by population groups to guide priorities for prevention, screening and treatment
activities. The lack of data on the economic burden of viral hepatitis in India also impedes decision-making. Stigma and discrimination against people living with viral hepatitis B and C is a major issue but this is not measurable.

- Data on the national response coverage is lacking. There is no clarity on the proportion of people with CHB and CHC who are diagnosed, proportion receiving antiviral treatment and incidence of complications of chronic HBV and HCV as well as mortality.
- Laboratory capacity for surveillance and programme is limited. In particular, there is no designated national reference laboratory for viral hepatitis.
- India lacks a comprehensive surveillance plan and a monitoring and evaluation plan for assessing the national viral hepatitis control plan and activities.

### 6.2.2 Recommendations

- Before nationally representative data is available, it is possible to conduct a comprehensive situation analysis and mapping using existing data to identify gaps in epidemiologic profiles. This should be done in 2014.
- NCDC should establish a sentinel surveillance system to estimate hepatitis B and C prevalence in the general community. In addition, it would be cost-efficient to integrate HBV and HCV prevalence surveillance into HIV surveillance for populations at risk, in particular for PWID, implemented by NACO. The data generated by sentinel surveillance will help the generation of burden of disease estimates.
- Behavioural surveillance encompassing risk behaviour, prevention practices, testing and treatment uptake for priority populations is important to inform policy and programme needs. Integrated bio-behavioural surveillance conducted by NACO among groups at risk should include viral hepatitis B and C serology and related behaviour.
- Reporting of newly acquired and chronic hepatitis B and C infections needs to be emphasized. Hepatitis B and C should be made reportable. Reporting of mortality and morbidity attributed to chronic hepatitis B and C should be prioritized, such as the proportion of liver cirrhosis, HCC and deaths attributed to hepatitis B and C.
- Laboratory capacity should be built for surveillance and programme implementation. A least one national reference laboratory should be designated for hepatitis in the country, validating available test kits, developing testing strategies and algorithms and ensuring quality assurance/quality control.
- Finally, surveillance activities should be included in national hepatitis control action plans and strategies. A comprehensive monitoring and evaluation framework with indicators for monitoring prevention, screening and treatment activities needs to be established. Monitoring the impact of stigma, discrimination, legal and human rights should be part of this framework.

### 6.2.3 Key priority actions for 2014–15

- Integrate HCV/HBV prevalence surveillance into HIV surveillance for populations at risk, in particular for PWID (NACO).
- Update HBV/HCV maps of India based on available info, and identify gaps in epidemiologic profiles (NCDC/ILBS/CMC/others).
- Establish protocols for sentinel surveillance to estimate hepatitis prevalence in the community (NCDC/ICMR to lead).
— Enhance laboratory capacity for viral hepatitis testing through quality assured diagnostics, validated test kits, and national strategy and algorithm for standardized testing (NCDC, ILBS).

6.3. Axis 3: Prevention of viral hepatitis transmission

6.3.1. Gaps and challenges
Routine hepatitis B immunization for children
Hepatitis B vaccination coverage of children is low—only 34% for the birth dose within 24 hours after birth (62% for institutional deliveries) and 71% for hepatitis B3. The third assessment of hepatitis B vaccination conducted in India in 2009 summarized the challenges faced in the introduction of hepatitis B vaccine in the UIP in India. There are still many challenges remaining to be addressed, including lower coverage with the three doses of hepatitis B vaccine than the similarly timed three doses of DPT vaccine.

The various reasons for reported lower coverage are:
— poor stock management;
— incomplete recording and reporting;
— perceived high cost and related fear of wastage of vaccine while using 10 dose vials
— incomplete knowledge of the health staff about the vaccination schedule
— lack of knowledge among health workers about birth dose administration
— lack of mechanisms for recording the birth dose
— insufficient training, official communication and coordination at various levels.

Adult immunization
India does not have a policy for free vaccination of adults at risk. In particular, this affects the health staff. A large proportion of HCWs in India are unvaccinated and many are unaware of their vaccination status, thus making them vulnerable to blood-borne infections.34

Prevention of HBV vertical transmission
India has low hepatitis B birth dose vaccination coverage due to lack of community awareness of the benefits of birth dose and lack of operationalization of the birth dose policy.

Prevention of HCV transmission among PWID
HIV prevention messages for PWID do not integrate hepatitis prevention. Screening of PWID for HCV is not integrated with the HIV screening programme.

Prevention of HBV and HCV transmission through unsafe injections
Approximately 60–90% of total injections administered in India are estimated to be unsafe.35 The majority of therapeutic injections are unnecessary. One third of all injections in India (31.6%) carry the risk of transmitting blood borne viruses. Reuse of injection devices (needles and syringes) without adequate sterilization is of particular concern as it may transmit HBV, HCV and HIV attributing to 33%, 42% and 2%, respectively of new infections per year.35 Inadequately sterilized needles and syringes are still an important cause of transmission of hepatitis B in India, as demonstrated by the recent outbreak of hepatitis B in Modasa Town of Gujarat.9

Prevention of HBV and HCV transmission through blood transfusion
Despite systematic screening of blood donors, there still remains a residual risk of hepatitis
B and C transmission due to the window period. Blood safety is a challenge in India because of the high prevalence of HCV and HBV, the relatively low percentage of volunteer donors and the lack of standardization of screening procedures among the multitude of blood collection centres.37

Prevention of HAV and HEV
Every Indian city is surrounded by urban slums. These are areas of poor sanitation, with poor disposal of solid and liquid waste including excreta, houses with inhuman living conditions and no drainage systems. Rural India, where 70% of the total population resides, has very meagre sanitary facilities, with high scope for feco-oral transmission. Tribal India has even worse sanitary conditions due to superstitions, unavailability of protected water supplies and sanitary facilities and drinking of unprotected waters from streams, canals and rivers.

6.3.2 Recommendations
Universal hepatitis B immunization of children
A number of actions can be taken to significantly improve the coverage of hepatitis B universal immunization for children.

- For ensuring universal birth dose immunization for institutional deliveries, it is imperative to give clear instructions for timely administration of birth dose within 24 hours of birth at the institution; to link distribution of the Janani Suraksha Yojana (JSY) fund for promoting safe deliveries with birth dose vaccination; and to distribute communication material on birth dose at postnatal wards.
- For identifying the unreached, it is important to start a special drive in the form of an “immunization week” developed for poorly performing areas/blocks to improve immunization coverage; to formulate exclusive immunization strategy for migrant populations and urban slums based on polio micro-plans; and to strengthen intersectoral coordination.
- In order to improve tracking of every mother and every child, the web-based mother and child tracking system (MCTS) is one of the key strategies to prevent left outs and dropouts, using name-based tracking of all pregnant mothers with contact details including mobile number. SMS alerts in the local language regarding due date of vaccination for the child, and advance preparation of village-wise due list for the scheduled immunization session using tracking bags, should be prioritized.
- Social mobilization efforts should include the use of more than the 860 000 ASHA workers who are in position for such purposes. ASHA incentives should be linked with mobilization and performance; health workers should be trained on immunization; fear of adverse events should be addressed; and demand side issues should be addressed by state- and district-level communication strategies.
- The expansion of pentavalent vaccination in the whole country is underway. Nine states are currently providing pentavalent vaccinations under UIP. Eleven states will introduce pentavalent vaccination in the national immunization schedule by the end of 2014; the remaining states will do so in the year 2015.
- Improving logistics and supply chain and cold chain system will require implementation of temperature monitoring data loggers with SMS alerts and Electronic Vaccine Intelligence Network (eVIN) system for real time vaccine logistics information.
Programme monitoring and evidence generation is important. State and district task force immunization meetings to review performance of health facilities for administration of hepatitis B birth dose should be conducted. Administration of hepatitis B birth dose should be included in all monitoring checklists. Monitoring should be conducted through immunization dashboards.

Health Systems Improvement needs improving service delivery through second ANMs and alternate vaccinators, convergence of polio and routine immunization microplans and setting up of the Immunization Technical support Unit (ITSU) to strengthen UIP.

Hepatitis B immunisation of adults at risk
The GOI should have a policy for free hepatitis B vaccination of health staff. Post-exposure prophylaxis (PEP) should also be available for health staff with HBIG. Opportunistic testing of priority populations followed by vaccination for those who remain susceptible should be emphasized. Priority populations to be considered include household contacts of people diagnosed with chronic hepatitis B, tribal populations, men who have sex with men, people living with HIV, PWID, and people serving custodial sentences. Better awareness about vaccination would enable effective promotion through education of priority populations, through integrated safe sex programmes and safe injecting health promotion and education programmes.

Prevention of hepatitis B vertical transmission
The most effective intervention to reduce vertical transmission is to increase the coverage of hepatitis B vaccine timely birth dose. An additional intervention can include routine hepatitis B screening of pregnant women at the ANC at the same time as HIV and syphilis screening and the provision of HBIG to infants born to HbsAg positive mothers. The community at large, as well as providers, needs to be educated about the risks that hepatitis B-infected pregnant women face, including the risk of perinatal transmission of the virus. Development of targeted educational materials for providers to improve screening and reporting of pregnant women, managing hepatitis B positive women during and after pregnancy, and ensuring appropriate prophylaxis to prevent perinatal hepatitis B transmission is needed. Clear guidelines for the case management of hepatitis B positive pregnant women are an essential component of eliminating perinatal transmission.

Injection safety
There is urgent need for implementation of safe injection practices in Indian health-care settings. Health professionals also need adequate training on the prevention of health-care associated hepatitis B infections.

Blood safety
The window period accounts for at least 90% of the residual risk of viral hepatitis transmission. Nucleic acid testing (NAT) is currently used in conjunction with serological tests in many countries in North America, Europe, Australia and Asia. As a screening tool, individual donor NAT detects infection before serological tests 10–16 days earlier for HIV-1, 49–65 days for HCV, and 25–36 days for HBV.38

Centralised NAT screening centres are hugely successful all over the world. A centralised testing site where all the blood banks of a city can send samples may be considered. Test
results can be sent electronically to respective blood banks. This model has worked very well in Thailand which has a fragmented blood banking system like India. This tool could provide the next large step in improving the safety of blood supply in India.

Prevention of HCV transmission among PWID

Needle and syringe programmes [NSPs] are cost-efficient and highly effective at reducing transmission of hepatitis C and other blood borne viruses, such as HIV.

The involvement of peers in the distribution of NSP equipment is cost-effective. NSPs play an important role in providing education and health promotion to PWID, including prevention education and referral and linking to testing and clinical services. Peer education plays an important role in reducing the risk of hepatitis C transmission. Peers are credible, trusted sources of mother and child tracking system information and can assist in reaching some hard to reach populations by overcoming some of the physical and socio-cultural barriers. With appropriate training and support, people with or at risk of hepatitis C are well placed to communicate prevention messages. Continued peer education and support by and for PWID is needed. Strengthening peer networks to provide education programmes and information on prevention is an effective way to increase accessibility to NSP services.

There is increasing evidence that OST and NSPs reduce infection prevalence among PWID. OST is a highly effective way to reduce hepatitis C transmission, as it decreases the need to inject drugs. Increasing use and access to OST in all settings is strongly supported.

Since NACO is already in charge of NSP and OST to prevent HIV transmission among PWID, it is recommended that NACO integrate HCV prevention messages for PWID.

Prevention of hepatitis A and E transmission

In highly endemic countries, large-scale immunization efforts are not recommended; and in low endemicity areas, immunization of high-risk populations is recommended. India has traditionally been a high endemicity area and although there is some evidence of changing epidemiology in select areas, mass or targeted HAV vaccination cannot be recommended for India as a public health policy.

Accelerating the improvement of sanitation and safe drinking water is important for preventing HAV and HEV. The WHO/UNICEF Joint Monitoring Programme (JMP) for Water Supply and Sanitation is the formal instrument to measure the MDG 7C target: to halve, by 2015, the proportion of people without sustainable access to safe drinking water and basic sanitation.

6.3.3. **Key priority actions for 2014–15**

**Prevention of transmission of hepatitis B and C**

- Achieve 95% (universal) coverage of 3-dose hepatitis B vaccine, including 95% of birth dose in institutional deliveries through:
  - education of parents in antenatal clinics and by ASHAs;
  - improved capacity and supervision of MCH/NHM staff (training, posters, include hepatitis B TBD as part of labour room SOPs);
• ensuring availability of vaccine at all facilities conducting deliveries;
• vaccine provision for home deliveries; and
• integration with elimination of mother-to-child transmission (eMTCT) of HIV and congenital syphilis antenatal clinic [ANC] package).
  – Ensure universal hepatitis B vaccination and PEP for HCWs
  – Implement safe therapeutic injection practices, universal precautions and infection control guidelines by the following:
    o train medical staff and communities on rational use of injections;
    o new national injection safety guidelines to be released (NCDC), clear SOPs for therapeutic injections, job aids, explore new safer devices.
  – Integrate hepatitis prevention into the HIV prevention programme for high-risk groups (PWID as a priority) and consider HBV vaccination of high-risk populations (based on evidence).

Prevention of transmission of hepatitis A and E
  – Ensure safe water and sanitation
  – Strengthen surveillance, preparedness, detection and response of outbreaks based on good practices (NCDC)
  – Strengthen the capacity of public health labs
  – Improve access to safe drinking water and ensure proper disposal of sewage within communities
  – Promote hand-washing with safe water
  – Health promotion approaches.

6.4. Axis 4: Screening, care and treatment

1.4.3. Gaps and challenges
  – There are barriers to accessing appropriate testing for hepatitis B and C. Laboratory capacity for testing is limited. Other barriers to accessing appropriate testing for hepatitis B and C for high-risk population groups include lack of awareness, limited access to health-care services in their region, cultural barriers and low levels of education and health literacy.
  – It is likely that more than half of the people living with chronic hepatitis B and C have not been diagnosed. High-risk groups for HBV and HCV, including people with HIV coinfection, are not identified. Late diagnosis leads to ongoing transmission and poor health outcomes, as opportunities to prevent progression to advanced liver disease and cancer are missed.
  – India neither has a public health policy nor any standardized guidelines. There are no laid-down targets for screening, care and treatment. There are no GoI guidelines for the management of chronic hepatitis B or C patients.
  – Trained manpower for treatment is grossly inadequate. Treatment availability, access and uptake have not been measured and are estimated as low.
  – As compared to other diseases such as HIV, there are limited patients, policy makers and health-care workers. Community awareness and engagement in viral hepatitis treatment is also low.
  – Stigma and discrimination (employment, social status, access to health insurance for chronic HBC and HCV infected subjects) is important.
  – The cost of medications, especially for HCV, is an important issue as well as accessibility to newer direct acting antivirals (DAAs) for HCV treatment.
1.4.4. Opportunities
Hepatitis C treatment will change markedly in the coming years as highly effective and tolerable direct-acting antivirals become available. Treatment efficacy will be greatly improved. Treatment will involve single daily oral doses, eventually removing the need for injections; treatment durations will also reduce substantially. The new antiviral drugs, known as directly acting antivirals or DAAs, have much higher levels of cure as compared with the current standard of care with pegylated interferon and ribavirin. If used in combination, they also offer the opportunity to eliminate the need to use the injectable drug pegylated interferon, which can be difficult to administer and causes many serious side effects. Some of these new oral DAAs are effective against all genotypes of the virus.

WHO has issued public health guidelines for screening and treatment of hepatitis C in 2014. This gives countries a road map for screening and treating HCV.

6.4.5. Recommendations
Viral hepatitis screening
Improvements in testing in priority populations are needed to identify undiagnosed infections and provide appropriate monitoring and treatment to maximize health outcomes. Improving testing rates among high-risk and high-prevalence priority populations requires specific, targeted, culturally appropriate education and awareness initiatives.

Evidence-based recommendations should be produced on whom to test, how to test and the interpretation of results. A policy and other standard guidance should be promoted among health-care professionals to ensure nationally consistent testing, result reporting and follow-up procedures. Testing strategies and models will need to be reviewed and updated regularly. Development of improved testing technology, including point of care tests will assist in simplifying the testing process for individuals, including addressing improved access and acceptability for priority populations. Screening and testing should be voluntary and confidential with a referral system for further management and treatment.

Reviewing models of care used by HIV and drug services to include hepatitis C and B testing may increase the uptake of treatment and identify clients that require additional management services. As PWID are less likely to access regular care, onsite access to hepatitis B and C testing and hepatitis B vaccination at these services would be advantageous. Dovetailing can be done with infrastructure and human resources of some finished and existing programmes. HIV integrated counselling and testing centres (ICTCs) can be used for screening, counselling and referral services.

Increased testing in priority populations will lead to an increase in the identification of people with hepatitis B and C. The information and support needs of people who are newly diagnosed must be discussed and met to assist them to manage their hepatitis over their lifetime, in partnership with health-care providers. To maximize opportunities for increasing the number of people living with hepatitis B and C diagnosed, the public health response should include appropriate testing and vaccination of household contacts and sexual partners of infected people, and the provision of information to reduce the risk of ongoing transmission.
Strengthen lab capacity for screening
It is recommended to identify and accredit laboratories with competence for screening and diagnosis. Development of infrastructure, manpower education and training and ensuring quality assurance/quality control are other measures to be taken.

Care and treatment
Chronic hepatitis B and C are dynamic diseases. All people with chronic hepatitis B and/or C require lifelong regular monitoring to guide decisions regarding antiviral treatment and to detect progressive liver disease and complications of infection including liver cancer.

Improved access to culturally and linguistically appropriate support and information about treatment options are required to address low levels of hepatitis B and C awareness and knowledge in communities at risk. Improving understanding of hepatitis B and C and of the health services available is essential for people living with chronic hepatitis B and/or C to stay healthy and avoid health risks. Given the complexity of chronic hepatitis B and C, innovative, sustainable and culturally appropriate health communication activities are required. A person with hepatitis B and/or C who has a good understanding of the impact of chronic hepatitis infection, the purpose of treatment and the clinical process for treatment is more likely to adhere to the recommendations on lifelong monitoring and treatment and respond effectively to clinical advice.

Capacity building of the workforce is required to ensure knowledge and competence. It is important to target clinical education and public health programmes to address hepatitis B and C where the burden is greatest, in areas where there is a higher proportion of residents belonging to priority populations. Difficulties of primary health-care workers in accessing virological tests and non-invasive diagnostic technology to assess liver fibrosis need to be addressed. An important element of care is the 6-monthly monitoring for hepatocellular carcinoma in certain individuals and introduction of antiviral therapy when appropriate.

Management of chronic hepatitis B and C is complex, including a spectrum of care ranging through diagnosis, education, support, regular monitoring and (where appropriate) antiviral therapy. The delivery of comprehensive, yet flexible and culturally appropriate care requires a multidisciplinary team approach. The assessment of people for appropriate management, including initiation of antiviral therapy, requires a combination of monitoring viral load and assessing the severity of liver disease including liver function testing. An important component of this is liver imaging or scanning. To be effective, community-based specialist hepatitis and primary care services must be physically accessible and culturally responsive to the specific needs of the priority populations. Communities need resources incorporating references and experiences that translate relevant complex biomedical information into accessible language.

Relationships with the local health workforce and community organizations will strengthen care delivery as well as personal and community level support for the individual. Communities play a pivotal role in ensuring that people with hepatitis B and/or C are effectively supported in promoting their health and maintaining compliance with clinical management. Programmes that support these communities who have the knowledge and skills to deliver these activities are important.
The management of chronic hepatitis B and C requires a shift in focus from tertiary care to community and primary care settings. This could also include an exploration of alternative arrangements for care, including possible roles for nurse practitioners or hepatitis coordinators, besides primary care doctors. Primary care services, particularly those working in high-prevalence areas, and community organizations providing support and advice to priority populations will need to play an increasingly important role in hepatitis B and C testing and monitoring. Better understanding of hepatitis B and C and its management is also required for some primary care practitioners and non-hepatology specialists such as those involved in antenatal care, where in some cases maternal treatment can significantly reduce the risk of transmission of HBV to the baby.

Targeting service delivery to target populations is important. This can be partially addressed by expanding options for hepatitis B and C diagnosis and management to include sites such as drug treatment services and NSPs and HIV treatment centres. Programmes may be built upon existing medical infrastructures for HIV/PWID health, e.g. community health centres, OST clinics and general practitioners. Tribal populations have a higher rate of hepatitis B and C and lower rates of treatment than other populations. Specific efforts are required to improve management and treatment in these communities. Co-infection with HIV and hepatitis complicates care and ongoing monitoring is critical. Models of care for hepatitis B and C should continue to consider how all aspects of care and support can be incorporated. In addition to primary and specialist health care, drug and alcohol services and community health services have an important role to play.

Access to new drugs for hepatitis C
A critical aspect now is implementing the WHO hepatitis C treatment guidelines in India, and this hinges on not only the timely registration of new oral drugs in India and other developing countries, but also on ensuring that access to the DAAs is not hampered by patent barriers that undermine low-cost generic production and supply to developing countries. The problem that we know from our experience in the case of HIV is that just because drugs are in the pipeline does not mean that they get to where they are needed. India potentially offers a solution. DAAs can be produced generically in India and supplied to governments at very affordable prices, just like antiretrovirals (ARVs) used in the treatment of HIV. First-line generic versions of antiretroviral drugs for HIV today costs under $200 per person per year; but just over a decade ago, first generation HIV drugs alone costed as much as $10 000 per person per year.

In the US, Gilead has set the price for sofosbuvir at $84 000 per treatment or $1000 per pill and is now offering a few select governments like Egypt a price of $900 for the same three month regimen. The price seems very attractive but in the long run this could prove to be much higher than what can be achieved with generic competition.

With the implementation of the WTO's TRIPS Agreement, pending patents on new HCV drugs are likely to hinder the production of more affordable generic versions in India, a country with a critically important manufacturing capacity. Early intervention on the part of the Indian government and civil society will be essential to overcome patent barriers and avoid treatment being priced out of reach for most people in developing countries who need them.
Egypt has already publicly stated its intention not to grant the patent for sofosbuvir as the claims do not meet the patentability criteria. Egypt has registered not only Gilead’s sofosbuvir but generic versions as well. In India, civil society groups have started identifying patent status of critical drugs like sofosbuvir and filed patent oppositions in India to ensure affordability and generic supply for the developing world. However, these actions by civil society will require additional support. Various steps need to be taken by the Indian government, making use of all public health flexibilities in international trade rules, enshrined in the World Trade Organization’s TRIPS Agreement, including encouraging the use of the bolar provision to facilitate the development and registration of a fixed dose formulation of the two most promising drugs – sofosbuvir/daclastavir – by generic companies.

6.4.4. Top priorities for 2014–15

- Develop a standard national policy and strategy for screening and treatment of hepatitis B and C.
- Identify population groups for screening based on evidence.
- Develop facilities for counselling and referral to care and treatment.
- Develop a public health approach to treatment.
- Develop a decentralized model.
- Strengthen the existing lab capacity for screening.
- Identify ways to increase access to hepatitis B and C treatment. Work towards improving access to hepatitis B and C medications and provision of free treatment by the government.
- Work towards the availability/accessibility of new DAA for hepatitis C treatment:
  - Facilitate fast track registration
  - Encourage the development of new fixed-dose formulations by generic companies in India (longer term).
References


### Annex 1

**Meeting agenda**

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<td>Dr Shiv Sarin, Director, ILBS</td>
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<td>Professor Jagdish Prasad, DGHS, GOI</td>
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<td>Dr. Vasantha Kumar, Addl. Secretary, Health &amp; FW, GNCTD</td>
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<td>WHO viral hepatitis strategy and recommendations for India</td>
<td>Dr Nicole Seguy, WHO Country Office for India</td>
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<td>Access to antivirals and vaccines for viral hepatitis in India</td>
<td>Dr G.N. Singh, DCGI</td>
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<td>9:45–12:30</td>
<td>Technical session I: Viral hepatitis B and C, India</td>
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<td>Dr Shashi Khare, NCDC</td>
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<td>Shri Ram Kripal Singh, Nav Bharat Times</td>
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<td>Dr Manoj Kumar Sharma, ILBS</td>
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<td>Mother to child transmission of HBV</td>
<td>Dr Seema Alam, ILBS</td>
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<td>Group discussion and Summary</td>
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<td><strong>Axis 4: Screening, care and treatment Screening</strong></td>
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<td>Screening for hepatitis B</td>
<td>Dr M S Chadha, NIV Pune</td>
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<td>Screening for hepatitis C</td>
<td>Dr Ekta Gupta, ILBS</td>
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<td>Group discussion and summary</td>
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<td>12:30–13:15</td>
<td>Lunch</td>
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<td>13:15–15:00</td>
<td>Technical session I (continued)</td>
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<td><strong>Axis 4: Screening, care and treatment Management</strong></td>
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<td>Management of hepatitis B</td>
<td>Dr B C Sharma, G B Pant</td>
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<td>Management of hepatitis C</td>
<td>Hospital</td>
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<td>Management of hepatocellular carcinoma (HCC)</td>
<td>Dr D. Amarapurkar, Mumbai</td>
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<td>Group discussion and summary</td>
<td>Dr Yogesh K Chawla, PGIMER</td>
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<td>Time</td>
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<td>15:00–15:40</td>
<td>Technical session II: Viral hepatitis A and E, India</td>
<td>Dr Jai Narain, Senior Advisor, Epidemiology and EIS, NCDC</td>
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<td>Epidemiology and response to viral hepatitis A</td>
<td>Dr Pradeep Khasnobis, IDSP</td>
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<td></td>
<td>Epidemiology and response to viral hepatitis E</td>
<td>Dr Rakesh Aggarwal, SGPGI</td>
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<td>Group discussion and summary</td>
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<td>15:40–16:15</td>
<td>Summary: Action points and responsibilities</td>
<td>Dr Shiv Sarin, ILBS</td>
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<td>16:15</td>
<td>Coffee break</td>
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Annex 2

List of participants

Dr Shiv Sarin  
Director, Institute of Liver and Biliary Sciences  
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Dr Nata Menabde  
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Medical Associate, Cipla Ltd, India

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Becton Dickinson, Haryana
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WHO, SEARO, New Delhi

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Assistant Director, National Centre for Disease Control (NCDC)

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Assistant Director, National Centre for Disease Control (NCDC)
Dr J.S. Arora  
National Thalassemia Welfare Society

Dr Tripurari Kumar  
EIS officer, NCDC, IDP

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Senior Gastroenterologist  
Bombay Hospital & Medical Research Centre, Mumbai

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Director; Head (Surgical Oncology)  
Tata Memorial Centre, Mumbai

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DCGI, New Delhi

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Shri Varun Choudhary  
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WHO Country Office for India, New Delhi
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WHO Country Office for India, New Delhi

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WHO Country Office for India, New Delhi

Shri Ram Kripal Singh,  
Nav Bharat Times, New Delhi

Shri Durgesh Nandan Jha  
Times of India, New Delhi

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National Institute of HLFW

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State Surveillance officer , J& K

Shri Lorn Gangte  
DNPT

Ms Mini Pakma  
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Regional Head – South Asia  
MSF – Access Campaign

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Director, Sankalp Rehabilitation Trust, Mumbai
Shri Ketho Angami
Hepatitis Coalition of Nagaland (HepCoN), Nagaland

Dr Shobha G
Health Specialist, Policy & Planning, UNICEF

Dr Alpana Mittal
UNICEF

Dr Kayla Laserson
Resident Advisor - India EIS Program, US CDC
Annex 3

High risk and priority population groups for hepatitis B and C interventions

High risk and priority populations for HBV

- Tribal populations
- Pregnant women
- Children born to mothers with chronic hepatitis B and children and adults with chronic hepatitis B
- Men who have sex with men
- Sex workers
- People who inject drugs
- Partners and other household and intimate contacts of people who have acute or chronic hepatitis B infection
- People in custodial settings
- Incarcerated people
- People with HIV or hepatitis C or both
- Persons needing cytotoxic or immunosuppressive therapies
- Persons on haemodialysis
- Prior recipients of transfusions or organ transplants

STD patients

- Persons who received a tattoo or body piercing, dental work or shaving in an unregulated setting
- Persons who received multiple injections or invasive medical procedures in an unregulated setting with substandard infection control practices
- Health-care, emergency medical and public safety workers
- Unexplained chronic liver disease and chronic hepatitis including elevated alanine aminotransferase levels

High risk and priority populations for HCV

- Individuals who are part of a population with high HCV seroprevalence (> 3.5%)
- All persons with behaviour, exposure and conditions associated with an increased risk of HCV infection such as:
  - injection or intranasal drug use
  - long-term haemodialysis
  - received a tattoo or body piercing, dental work or shaving in an unregulated setting
  - received multiple injections or invasive medical procedures in an unregulated setting with substandard infection control practices
- Health-care, emergency medical and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-infected blood
- Children born to HCV-infected women
- Prior recipients of transfusions or organ transplants
- HIV infection or HBV infection
- Unexplained chronic liver disease and chronic hepatitis including elevated alanine aminotransferase levels
- Incarcerated people
- People in custodial settings