Meeting Report

Workshop for Developing the Regional Action Plan for Hepatitis in the WHO South-East Asia

26th – 28th April 2016, Jakarta, Indonesia
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Acronyms and Abbreviations

AEFI  adverse effects following immunization
CSO  civil society organization
HBIG  hepatitis B immunoglobulin
HepB3  third dose of hepatitis B vaccine
IPC  infection prevention and control
PMTCT  prevention of mother-to-child transmission
UHC  universal health coverage
3TC  lamivudine
ADF  adefovir
AFP  alpha-fetoprotein
ALT  alanine aminotransferase
ANC  antenatal care
APN+  Asia-Pacific Network of people living with HIV/AIDS
APRI  aspartate aminotransferase-to-platelet ratio index
AST  aspartate aminotransferase
CDC  US Centers for Disease Control and Prevention
CMDN  Center for Molecular Dynamics
DAA  direct-acting antiviral
DBS  dried blood spot
DHIS  district health information software
DHS  Demographic and Health Survey
DNP+  Delhi Network of Positive People
EIA  enzyme immunoassay
ELISA  enzyme-linked immunosorbent assay
EPI  Expanded Programme on Immunization
ETV  entecavir
GAVI  The Vaccine Alliance
GHSS  Global Health Sector Strategy on Viral Hepatitis
GIZ  Deutsche Gesellschaft für Internationale Zusammenarbeit
Global Fund  Global Fund to Fight AIDS, Tuberculosis and Malaria
GSK  GlaxoSmithKline
HAV  hepatitis A virus
HBeAg  hepatitis B envelope antigen
HBsAg  hepatitis B surface antigen
HBV  hepatitis B virus
HCC  hepatocellular carcinoma
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>HCV</td>
<td>hepatitis C virus</td>
</tr>
<tr>
<td>HEV</td>
<td>hepatitis E virus</td>
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<tr>
<td>HMIS</td>
<td>health management information system</td>
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<tr>
<td>HSS</td>
<td>HIV sentinel surveillance</td>
</tr>
<tr>
<td>I-MAK</td>
<td>Initiative for Medicines, Access and Knowledge</td>
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<tr>
<td>IBBS</td>
<td>integrated biological and behavioural surveillance</td>
</tr>
<tr>
<td>icddr,b</td>
<td>International Centre for Diarrhoeal Disease Research, Bangladesh</td>
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<tr>
<td>ILBS</td>
<td>Institute of Liver and Biliary Sciences (India)</td>
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<tr>
<td>LDCs</td>
<td>least developed countries</td>
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<td>LMICs</td>
<td>low- and middle-income countries</td>
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<tr>
<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<tr>
<td>MCH</td>
<td>maternal and child health</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>MSF</td>
<td>Medecins Sans Frontieres</td>
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<tr>
<td>MSM</td>
<td>men who have sex with men</td>
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<tr>
<td>NAT</td>
<td>nucleic acid test</td>
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<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
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<tr>
<td>NHSO</td>
<td>National Health Security Office</td>
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<tr>
<td>NIT</td>
<td>non-invasive test</td>
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<td>NSP</td>
<td>needle–syringe programme</td>
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<td>OST</td>
<td>opioid substitution therapy</td>
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<td>PEP</td>
<td>post-exposure prophylaxis</td>
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<td>PMI</td>
<td>Indonesian Red Cross</td>
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<td>PWID</td>
<td>people who inject drugs</td>
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<tr>
<td>PWUD</td>
<td>people who use drugs</td>
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<tr>
<td>QA</td>
<td>quality assurance</td>
</tr>
<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
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<tr>
<td>RPHA</td>
<td>reversed passive haemagglutination assay</td>
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<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
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<tr>
<td>SI</td>
<td>strategic information</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>SRA</td>
<td>stringent regulatory authority</td>
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<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TBV</td>
<td>telbivudine</td>
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<tr>
<td>TDF</td>
<td>tenofovir</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Agreement on Trade-Related Aspects of Intellectual Property Rights</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>UNDP</td>
<td>United Nations Development Programme</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHO-IPD</td>
<td>WHO department of Immunization-Preventable Diseases</td>
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Introduction

Viral hepatitis affects hundreds of millions of people worldwide, causing serious illness and death from acute hepatitis infection, liver cancer and liver cirrhosis. With 1.4 million hepatitis deaths in 2014, the disease burden of viral hepatitis is comparable to that of other major communicable diseases, including HIV, tuberculosis (TB) and malaria. However, it has received less attention compared to HIV, TB and Malaria. This is set to change, with hepatitis being recognized and included in the agenda of the Sustainable Development Goals (SDGs) – “By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.” The World Health Assembly has also passed two resolutions on viral hepatitis – Resolution WHA63.9 in 2010 and WHA67.6 in 2014. These call for Member States to develop and implement coordinated multisectoral national strategies for preventing, diagnosing and treating viral hepatitis based on the local epidemiological context, and for the World Health Organization (WHO) to support these efforts.

The WHO South-East Asia Region has a high burden of disease due to hepatitis B virus (HBV) and hepatitis C virus (HCV). In addition, the Region also has a large number of cases of hepatitis A and E. Action to combat hepatitis has been weak in the Region. Lack of data and information on viral hepatitis is a hindrance for designing prevention, control and treatment programmes at the country level. Although new and more effective drugs that can provide higher cure rates for hepatitis B and C are now available, accessibility and affordability are huge barriers in this Region.

Given the burden of hepatitis within the Region, and the scientific and programmatic momentum for addressing hepatitis as a global public health problem, a regional action plan is needed for providing implementation support to Member States to combat hepatitis within their national contexts. It will also help in monitoring the health sector response to prevention, treatment and control of hepatitis. The focus of the regional action plan will be improved surveillance, prevention and treatment of all forms of viral hepatitis, while recognizing that a large part of the morbidity and mortality due to viral hepatitis is related to chronic hepatitis B and C, for which interventions have now become available, permitting reduction in morbidity and mortality at the population level.

The WHO Regional Office for South-East Asia convened a workshop for Member States in Jakarta, Indonesia from 26 to 28 April 2016 to develop a regional action plan for the prevention, control and management of viral hepatitis in the Region. The workshop had participants from all the Member States and as well as involved technical bodies, experts and nongovernmental organizations (NGOs) representing communities living with hepatitis. The workshop also provided the opportunity to share and learn the latest updates and knowledge regarding surveillance, prevention, treatment and control of viral hepatitis.
Objectives

General objective
To develop a regional action plan for the prevention, control and management of viral hepatitis in the WHO South-East Asia Region

Specific objectives
1. Share and discuss the global health sector strategy for hepatitis 2016–2021 and global technical updates
2. Share and discuss updates on the regional and country situation of and health sector response to viral hepatitis
3. Discuss the draft regional action plan for finalization and identification of priority activities at the regional and country levels.

Expected outcomes
Regional Action plan with identified priorities at regional and country levels
Global Health Sector Strategy (GHSS) on Viral Hepatitis, 2016–2021

**Vision:** “A world where viral hepatitis transmission is stopped and everyone has access to safe, affordable and effective prevention, treatment and care.”

**Goal:** Eliminate viral hepatitis as a major public health threat by 2030.

**Impact targets**

1. 90% reduction in new cases of chronic HBV and HCV infection from 6–10 million in 2015 to 900 000 in 2030 (30% reduction by 2020)
2. 65% reduction in deaths from chronic HBV and HCV from 1.4 million in 2015 to <500 000 in 2030 (10% reduction by 2020).

*Figure 1: The structure of the GHSS on viral hepatitis, 2016–2021*

The structure of the GHSS is described in Fig. 1. Under **Strategic direction 2**, the intervention package/toolbox includes hepatitis B vaccination (including birth dose); safe injection practices and safe blood; harm reduction for people who inject drugs (PWID); safer sex practices (condom promotion); hepatitis B and C treatment; and hepatitis C cure. The intervention targets are given in **Table 1**.
Table 1: Intervention targets for 2020 and 2030 versus the baseline

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Indicator</th>
<th>2030</th>
<th>2020</th>
<th>Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV vaccination</td>
<td>Childhood vaccine coverage</td>
<td>90%</td>
<td>90%</td>
<td>81%</td>
</tr>
<tr>
<td>Prevention of mother-to-child transmission of HBV</td>
<td>Birth dose vaccine coverage (or other approach to prevent mother-to-child transmission)</td>
<td>90%</td>
<td>50%</td>
<td>38%</td>
</tr>
<tr>
<td>Safe injection</td>
<td>Safe injections (needs to cover both in and out of health facilities</td>
<td>90%</td>
<td>50%</td>
<td>5%</td>
</tr>
<tr>
<td>Harm reduction</td>
<td>Number of needles distributed per PWID per year</td>
<td>300 (75% coverage)</td>
<td>200 (50% coverage)</td>
<td>20</td>
</tr>
<tr>
<td>HBV and HCV testing</td>
<td>% of persons with chronic HBV and HCV diagnosed</td>
<td>90%</td>
<td>30%</td>
<td>5%</td>
</tr>
<tr>
<td>HBV treatment</td>
<td>Treatment-eligible persons with chronic HBV treated</td>
<td>80%</td>
<td>5 million</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>HCV treatment</td>
<td>Treatment-eligible persons with chronic HCV treated</td>
<td>80%</td>
<td>3 million</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

The strategy has been formulated to stimulate global action. It will act as a strong advocacy tool, promote development of regional and national action plans, and also promote accountability. Implementing the global strategy will prevent 7.1 million deaths by 2030; 5 million deaths from HBV and 2 million from HCV. The majority of deaths will be prevented in lower-middle- and upper-middle-income countries. The cost of implementing the hepatitis strategy in low- and middle-income countries (LMICs) will peak at US$ 8.8 billion in 2025. A significant portion of these costs will be required for screening and treatment of HBV.

Action plan for viral hepatitis in the Western Pacific Region, 2016–2020

The disease burden of and deaths due to viral hepatitis are high in the WHO Western Pacific Region but are not matched by investments. The South-East Asia Region also faces a similar hepatitis epidemic and there are important lessons that can be learnt from the Western Pacific Region action plan. The Regional Action Plan for Viral Hepatitis in the Western Pacific, 2016–2020 built on the regional successes to date, and has set strong milestones and targets. The action plan was developed through a series of consultations between Member States and experts in high-burden countries and at the regional level. Estimation of disease burden, country assessments and investment case analysis were done to understand the burden of chronic hepatitis, treatment needs, and how to optimize the screening, care and treatment cascade.

The five axis of the action plan are described in Figure 2.

Figure 2: The structure of the Regional Action Plan for Viral Hepatitis in the Western Pacific, 2016–2020

<table>
<thead>
<tr>
<th>Advocacy</th>
<th>Policy</th>
<th>Data</th>
<th>Prevention</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increase awareness about viral hepatitis</td>
<td>• Ensure that national hepatitis action plans are in place</td>
<td>• Conduct national disease burden estimates and investment case</td>
<td>• Immunization</td>
<td>• Screening, diagnosis, care, and effective antiviral treatment</td>
</tr>
<tr>
<td>• Explore financing of services and medicines</td>
<td>• Strengthen standardized surveillance and data collection activities strengthening</td>
<td>• Convene around research</td>
<td>• Safe blood supply</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Prevention of nosocomial transmission</td>
<td>• Harm reduction</td>
</tr>
</tbody>
</table>
Hepatitis in South-East Asia

The WHO South-East Asia Region has an estimated 100 million people living with chronic hepatitis B (5.6% prevalence in 2011; current prevalence between 3% and 5%) and 29 million people living with chronic hepatitis C (1.6% prevalence). Every year, hepatitis B causes an estimated 1.4 million new infections and hepatitis C around half a million. Hepatitis-related mortality is particularly high in this Region, with hepatitis B causing 50% of all hepatitis-related deaths. Every year, in the Region, hepatitis B is estimated to cause about 187 000 deaths and hepatitis C 118 000 (GDB 2013). The high morbidity and mortality due to hepatitis pose a huge burden for society, and individuals and families affected by the disease face social stigma and economic hardships.

Outbreaks of water- and foodborne hepatitis A and E continue to be reported from countries in the Region and annually there are an estimated 8900 and 33 000 deaths attributed to hepatitis A and E, respectively (GDB 2013). The prevalence of hepatitis B and infection routes vary by country, within countries and by population. The prevalence of chronic hepatitis B is more than 8% in three countries: Democratic People's Republic of Korea, Myanmar and Timor-Leste. Bangladesh, India, Indonesia and Thailand have intermediate endemicity, with the prevalence of hepatitis B surface antigen (HBsAg) ranging from 2% to 7%. Bhutan, Nepal and Sri Lanka have low HBV endemicity (<2%HBsAg) (WHO 2015). The seroprevalence of HBV and HCV is high among certain populations such as PWID and people living with HIV in many countries.

Although hepatitis B vaccine has been available since 1982, uptake in many countries has been slow and only Bhutan, Indonesia and Thailand introduced it before 2000. Currently, 10 of the 11 countries in the Region provide three doses of the hepatitis B vaccine as part of the pentavalent vaccine schedule. Thailand provides the tetravalent vaccine. Not all countries are using the birth dose, as mother-to-child transmission is low in some countries and they do not need a birth dose. Seven countries in the Region have included the hepatitis B birth dose in their vaccination schedule.

In the Region, coverage with three doses of hepatitis B vaccine was 75% in 2014, up from 4% in 1992. A closer look at country data shows that the coverage is <90% in large-population countries (India, Indonesia and Myanmar). Coverage with the birth dose varies from 44% in India to >95% in the Democratic People’s Republic of Korea, Maldives and Thailand. The overall regional coverage with the hepatitis B birth dose increased from 9% in 2009 to 52% in 2015.

Interest in and political commitment to hepatitis control are increasing in the Region. While Indonesia and Timor-Leste have developed national plans, four countries (Bangladesh, Democratic People’s Republic of Korea, Myanmar and Thailand) intend to develop their national plans. India is combining its HIV and hepatitis C programmes; surveillance activities are planned in Bhutan, and cost–effectiveness evaluations are being conducted in Thailand. The regional immunization programme is coming up with a regional hepatitis B control target that will be presented to the regional advisory group on immunization. This will provide further impetus to hepatitis B prevention in the Region.

There are significant issues and challenges limiting the response to hepatitis in the Region. Political commitment and advocacy for hepatitis is lacking; only two countries have committed full-time Ministry of Health (MoH) staff for hepatitis. There is paucity of robust representative data, especially subnational data, which is essential, as countries are not homogeneous in nature. A public health approach to hepatitis is not present; and care and treatment services are centralized. Combined with lack of awareness among the general population and health-care workers, limited financial and human resources, complex diagnostics, and high cost of care,
access to essential hepatitis services is low. About 65% and 75% of people with chronic HBV and HCV infection, respectively, are unaware of their status. Safety in health-care settings, and safe injection and blood transfusion practices need to be further evaluated and strengthened.

The Region has a short time frame of 5 years for achieving a 30% reduction in new infections and a 10% reduction in deaths caused by hepatitis. There are important lessons to be learnt from the response to TB and HIV. With a “business as usual” approach, even these programmes, which have well-formulated strategies and significant funding, will miss the SDG targets.

As a Global Fund for Hepatitis is unlikely in a scenario of limited and variable international funding, bold actions are needed to achieve bold elimination targets. These include the following:

- advocacy for and political commitment to the health sector response to viral hepatitis;
- national plans and strategies to guide action and monitor progress;
- a public health approach that includes simplification, integration, decentralization and equitable access;
- community involvement for raising awareness, advocacy, policy and service delivery.
- need to engage with the private sector where people access health services, as in Indonesia and India;
- using AIDS-related money to fund hepatitis, harm reduction and blood safety costs, and existing HIV service delivery systems to provide treatment in case of coinfection. While HCV emerges as major cause of death in people living with HIV, it is not part of the Zero AIDS Strategy;
- innovations such as a simplified treatment package, non-specialist care, community-based operational interventions and improving vaccination coverage for HBV in newborns, infants and special groups.

Box 1: Country-specific needs for Hepatitis B control

In March 2016, WHO conducted a comprehensive literature review with the US Centers for Disease Control and Prevention (CDC) and recommended some country-specific needs for hepatitis B control in Member States. One of the recommendations for all the countries includes conducting a serosurvey in children to understand the prevalence of HBV and evaluate the impact of the vaccination programme.

**Bhutan** – evaluate introduction of the hepatitis B birth dose; conduct a serosurvey in children.

**Democratic People’s Republic of Korea** – evaluate introduction of the hepatitis B birth dose; conduct serosurveys pre- and post-hepatitis B vaccination.

**India** – improve coverage of the birth dose and 3 doses of the hepatitis B vaccine; conduct a national serosurvey in children.

**Indonesia** – improve coverage of the birth dose and 3 doses of hepatitis B vaccine; conduct a national serosurvey in children.

**Maldives** – conduct a serosurvey in children.

**Myanmar** – improve coverage of 3 doses of hepatitis B vaccine; consider hepatitis B birth dose; conduct a serosurvey among pregnant women and in children.

**Nepal** – screen pregnant women in high-risk areas and vaccinate infants at birth.

**Sri Lanka** – conduct a serosurvey in children.

**Timor-Leste** – improve coverage of the birth dose and 3 doses of hepatitis B vaccine; conduct a national serosurvey in children.

Serosurveys should be nationally representative (ideally population-based), of adequate size, and follow standard laboratory procedures. Financial resources, training and standard operating procedures (SOPs) for data collection and evaluation are needed for well-planned serosurveys.
Country examples

Indonesia National Action Plan

Indonesia has moderate-to-high endemicity of hepatitis B and C. An estimated 21 million people live with HBV and HCV; 3 million of these have hepatitis C. The latest available data from surveillance systems and basic health research show the magnitude of the disease in Indonesia. The prevalence of HBsAg positivity in the general population is 7.1% and varies from 4.2% in children <4 years to 6.8% in children <14 years. HBV prevalence among different populations is as follows: pregnant women: 1–8%; health workers: 1–6%; PWID: 4–7%; transgender persons: 4–6%; and men who have sex with men (MSM): 6–11%. HCV positivity in the general population >15 years of age is 1%; for MSM and sex workers, it is 2% and <1%, respectively. HCV prevalence is high among transgender persons (2–4%) and PWID (47–78%) but low among children <5 years (0.5%).

With the goal of achieving elimination of hepatitis B and C by 2030, in 2014, Indonesia developed the National Hepatitis Strategic Plan for 2015–2019, with the general objective of implementing effective and efficient hepatitis control in order to reach the highest health status. The specific objectives of the national plan included the following:

- raising awareness and knowledge;
- reducing viral transmission (vertical and horizontal);
- improving the quality of life of people with hepatitis; and
- reducing hepatitis-related mortality and morbidity.

Hepatitis B and C control in Indonesia will target the following populations:

- populations needing special attention and at high risk, such as pregnant women, healthcare workers, PWID, sex workers, MSM, people living with HIV, those with sexually transmitted infections (STIs), patients on haemodialysis and those with haemophilia, and prisoners
- in the general population, persons without a history of hepatitis B immunization and family members with or close contacts of hepatitis patients.

Under the National Plan, targets for 2019 include the following:

1. 90% of districts conduct advocacy and awareness programmes on hepatitis;
2. 90% of districts conduct early detection of hepatitis B and C among high-risk populations;
3. 100% of provinces conduct hepatitis surveillance among high-risk populations;
4. 80% of high-risk populations receive testing for early detection;
5. 90% of neonatal HBV birth dose given within 24 hours of birth; and
6. 80% of hepatitis-positive persons are referred to health facilities to receive follow-up health services.

To combat hepatitis, especially due to HBV and HCV, several actions have been taken at the country level. Since 1992, the Indonesian Red Cross has screened blood donors to prevent HBV and HCV infections. The national programme has provided hepatitis B immunization to all children <1 year of age since 1997. Government commitment in terms of budget allocation is increasing rapidly from year to year. For the year 2016, US$ 23,950,613 is the planned budget. Hepatitis is now one of the national health programme indicators in the National Health Strategic Plan 2015–2019 and a priority in the national development workplan for 2017. Guidelines are being developed for hepatitis control programmes, surveillance, monitoring and evaluation (M&E), early detection, case management and referral of hepatitis B and C, and early warning and response to hepatitis A and E.

In 2015, the MoH released Ministerial Regulation no. 53 on the National Control of Hepatitis, which directed the central and regional (provincial and district) governments to implement national hepatitis control with community participation. Key actions to be implemented include health promotion, prevention including specific protection, control of risk factors, surveillance,
early warning, case management including early detection, and M&E. Moving forward, the government will disseminate this ministerial law. The National Strategic Plan 2015–2019 will be revised; guidelines and a plan for elimination of mother-to-child transmission of HIV, syphilis and hepatitis B will be developed; and guidelines for hepatitis C elimination will be formulated. Indonesia will also increase capacity, knowledge, awareness and commitment for hepatitis elimination; expand access to early detection, care, support and treatment (affordable diagnostic tests, drugs and monitoring tests), including developing capacity for quality diagnostics; mobilize resources; and collaborate with strategic partners, civil society and other health programmes (HIV, MCH, etc.).

**Timor-Leste**

The prevalence of hepatitis B in Timor-Leste is thought to be high. Viral hepatitis or any form of liver disease is not included in the existing public health surveillance reporting system. Limited data are available from blood banks for 2015, the integrated biological and behavioural surveillance (IBBS) 2011 and HIV sentinel surveillance 2013. HBV prevalence is higher than HIV for all populations: MSM (10%), female sex workers (8%), clients of commercial sex workers (14%), uniformed personnel (15%) and blood bank donors (6–7%). HBV prevalence in blood banks is 3–5%.

The response to the hepatitis epidemic has included provision of hepatitis B vaccine as part of the immunization schedule since 2007. The birth dose of hepatitis B was introduced in November 2015. All donated blood is routinely screened for hepatitis B and C using point-of-care rapid assays. No medicines are currently available for viral hepatitis B and C in Timor-Leste.

A National Strategic Plan for Hepatitis 2016–2020 has been developed along with a costed Action Plan, with the following five strategic priorities:

1. provide programme leadership with capacity-building at focal points and for health-care providers;
2. conduct hepatitis surveillance and develop a system for data collection, analysis and interpretation;
3. strengthen immunization for children (birth dose), high-risk groups and health-care providers with support from WHO in 2017;
4. strengthen laboratory capacity and detection facilities for HBV and HCV;
5. improve treatment care and support, including a systematic plan for patient care; capacity-building of medical professionals starting with national hospitals, referral hospitals down to community health centres; and introduce drugs for chronic hepatitis B and C treatment.

Implementation of the National Plan will be challenging in this country. There is limited awareness about hepatitis among the general population. Laboratory capacity to detect different forms of viral hepatitis is lacking and human resource capacities are limited. Competing priorities with other health-care programmes in a resource-limited setting will also pose a challenge for scale up of the hepatitis control programme in the country.

Epidemiologically, hepatitis is a public health issue in Timor-Leste. The first steps towards elimination of hepatitis in the country have been taken – a strategic plan has been drafted and a costed action plan developed. The birth dose of hepatitis B vaccine has been introduced. For the hepatitis programme to be successful and sustainable, Timor-Leste needs support from WHO and others donors to operationalize the strategic plan.
Evidence for Action: Measurement and Accountability

Viral hepatitis surveillance

In the Region, the availability of data on hepatitis is limited. The type of surveillance conducted varies by country and data may not be comparable. The ability to conduct surveillance also varies, as laboratory capacity within and among countries is different. Hepatitis surveillance is important and is needed by the health programme. In 2016, WHO published *Technical considerations and case definitions to improve surveillance for viral hepatitis* (hereinafter called surveillance document) to provide guidance to countries. It covers hepatitis A–E, is intended for a broad audience and includes acute hepatitis, chronic infection and sequelae.

Hepatitis surveillance has three main domains: (1) surveillance for acute hepatitis to detect outbreaks, monitor trends in incidence and identify risk factors for new incident infections; (2) surveillance for chronic infections to estimate the prevalence of chronic infections and monitor trends in sentinel groups; and (3) surveillance for cirrhosis and hepatocellular carcinoma (HCC) to estimate the burden of sequelae. Information from surveillance helps to identify high-risk populations or geographical areas for targeting interventions. These may include the general population in high-prevalence geographical areas, specific population groups (PWID, MSM, people living with HIV), pregnant women, blood donors, commercial and public health laboratories, HIV testing sites and clinics, and correctional facilities. Each of the three domains of viral hepatitis surveillance also helps to evaluate different types of programmes. First, information from surveillance for acute hepatitis can be used to evaluate programmes to prevent new infections, which includes vaccination, food and water safety, blood safety, condom distribution, harm reduction and infection control. Second, information from surveillance for chronic hepatitis can be used to evaluate programmes for testing and treatment. Third, information from surveillance of sequelae can be used to evaluate the ultimate impact of the programme on mortality.

Countries can use various methods of surveillance. One is case reporting from (a) clinicians or health facilities, and (b) laboratories. The former is used when an immediate public health response is required while the latter provides important information on the causal agent, acute or chronic disease; information that is not needed for an immediate response. Population-based surveys is another method that can be used to estimate the proportion of people with particular characteristics, evaluate public health policy at national/subnational level or the effectiveness of interventions, plan public health programmes, and compare programmes by demographic and geographical location, e.g. IBBS. Sentinel surveillance is the alternative to population-based surveillance and can be used when a complete case count is not important. It involves collecting data from select providers/hospitals and provides the opportunity to gather more specific information. It can be representative or non-representative/convenience sampling. Syndromic surveillance is a relatively new surveillance method and can complement other methods of surveillance. It uses clinical information about disease signs and symptoms when confirmation of diagnoses is not possible. A disease registry is used to study public health problems in greater depth. It can be used to improve prevention programmes and provide information on the stage of disease at diagnosis, and treatment outcomes. Surveillance can also be based on secondary sources, which include hospital discharge data, death...
certificates, blood banks, medical examinations for insurance, antenatal care (ANC) data and pharmaceutical procurement data. Obtaining such data does not require much effort, but the data may be of limited quality, and care must be taken in analysing and interpreting such data.

It is slightly harder to do surveillance for viral hepatitis than to do surveillance for other communicable diseases. However, these challenges can be addressed.

1. Viral hepatitis has multiple disease outcomes and therefore acute hepatitis, chronic infection and sequelae need to be considered.

2. Different forms of viral hepatitis can have the same clinical presentation. Acute viral hepatitis A, B, C, D and E cannot be distinguished from each other on the basis of clinical features alone. Sometimes, the clinical picture will not allow differentiation between acute and chronic hepatitis. In such cases, in vitro diagnostics may be needed.

3. Most infections with the hepatitis viruses, particularly the chronic ones, are asymptomatic. This means that biomarker surveys need to be planned.

4. The hepatitis viruses interact with the natural and human environment of each country in a different way. This leads to specific epidemiological situations. Potentially, there are multiple modes of transmission and persons at risk. In the end, as each country’s situation is unique, the response will need to be adapted.

The surveillance strategy that is adopted by a country will depend on the laboratory capacity at national/subnational level. In the case of poor laboratory capacity, national or sentinel surveillance should not be conducted and countries should consider serosurveys for important information. It is recommended that Member States in this Region have a phased approach to hepatitis surveillance, starting from ongoing or periodic seroprevalence surveys and using data collected for other purposes (e.g. blood donation). The opportunities to integrate hepatitis surveillance with other programmes should be utilized. Integration is needed because the outcomes are different, ranging from acute hepatitis to chronic infections to sequelae. Working with different programmes and professionals will also help improve routine data collection. For acute hepatitis, one would have to work with communicable disease surveillance for unspecified acute hepatitis, while surveillance for type-specific acute hepatitis may require sentinel sites in hepatology centres or other places caring for patients with acute hepatitis and providing good in vitro diagnosis. For chronic infections, one needs to coordinate with the Expanded Programme on Immunization (EPI) biomarker surveys to evaluate hepatitis B immunization; HIV surveys; or other surveys such as Demographic and Health Surveys (DHS). For sequelae, collaboration is needed among hepatology centres, vital registration and cancer registries. Post integration, countries may move to sentinel surveillance in high-prevalence areas or populations, and in areas where laboratory capacity is available. Later, countries need to establish acute viral hepatitis surveillance, depending on the need for local data, and finally consider chronic viral hepatitis B surveillance followed by that for hepatitis C.

Monitoring and evaluation

In addition to the surveillance document, WHO has also published *Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework* (known as the M&E document henceforth) in 2016. The M&E document covers only hepatitis B and C, and will guide programme managers. It focuses on prevention, testing and treatment for hepatitis B and C.

The M&E document describes the indicators for the hepatitis B and C control programme. There are 10 core indicators and 27 additional indicators. Of the 27, 10 additional indicators are for hepatitis while the remaining 17 are from other programmes (HIV, STI, immunization, blood safety, harm reduction, noncommunicable diseases). **Fig. 3** shows the 10 core indicators for initial assessment, monitoring the response and impact evaluation.
Figure 3: The core indicators for viral hepatitis along the result chain

Of these 10 core indicators, three (C3, C4 and C5) are already measured through various prevention activities. Five indicators (C1, C6, C7, C8, C9) are new but they have been formulated in a way that completely parallels the M&E framework for HIV. The remaining indicators (C2 and C10) are new and specific to hepatitis. C2 is about the testing infrastructure, which is critical to the success of a viral hepatitis programme. C10 is about mortality, which in the case of hepatitis requires specific measurement, as explained in the WHO surveillance document.

Hepatitis modelling

Modelling can have the following uses:

- to know your epidemic – to understand the current and future burden of hepatitis in the country and the main drivers of transmission;
- for planning interventions – to estimate treatment to scale up prevention interventions;
- to assess current activities – to understand what the current scale and reach will achieve in terms of impact, and whether the current strategy needs adjustment to maximize the impact; and
- for impact assessment – to measure the achievement, contribution of various intervention components to the achievement, and cost–effectiveness of what was done.

Modelling is currently being done by WHO for setting targets, to understand what needs to be done in different epidemic settings to reduce HCV mortality (by 65%) and incidence (by 90%) by 2030. It is important that mathematical modelling uses good-quality data from surveillance and M&E activities to track the progress and impact of actions.

Country examples

Opportunities for improving HCV surveillance within current systems in India

HIV surveillance activities in India are strong. The HIV sentinel surveillance (HSS) sites in India have grown since 1998 and span the entire country. The IBBS 2014–2015 also had a large geographical presence and covered MSM, PWID, female sex workers, transgenders, migrants and married women. HCV surveillance was recently integrated into HIV surveillance activities in India.
The National AIDS Control Organization and the Government of India with support from the National AIDS Research Institute and WHO undertook HCV testing among blood specimens already collected for the IBBS and HSS-ANC 2015 to get: (a) estimates of the prevalence of viral hepatitis C at national and regional/state levels in the general population and key population groups; and (b) HIV/HCV coinfection rates in different population groups. Dried blood spot (DBS) specimens collected for the IBBS were tested using Murex anti-HCV version 4.0 enzyme-linked immunosorbent assay (ELISA) kits, and serum specimens, collected for the HSS-ANC, were tested using ERBALISA HCV Gen 3 (v2) antibody test kits at national and state reference laboratories and blood banks. All the test kits were provided by WHO. Testing protocols, guidelines and algorithms were developed by NACO with support from NARI and WHO, and were shared with all participating sites, i.e. laboratories and blood banks. The entire activity, including testing and analysis, was completed by April 2016.

The National Centre for Disease Control is also working towards establishing laboratory-based surveillance for viral hepatitis in the country for collection of data. A concept plan has been developed to carry out surveillance in various geographical regions, which will be initiated through 10 laboratory networks in a phased manner.

**Challenges and opportunities for better data capture in Bhutan**

In 2013, hepatitis testing was integrated into the National HIV/AIDS and STI Control Programme of Bhutan. Hepatitis B testing is packaged with HIV and syphilis testing across all health facilities. HCV testing is limited to hospital settings. Health management information system (HMIS) data from Bhutan show that there were 537 new cases of hepatitis in 2013 compared to 399 in 2012. The data cannot be disaggregated by type of hepatitis. The actual burden of hepatitis has not been assessed, despite the increasing annual incidence. Recording and reporting on viral hepatitis is not formalized; data-based decision-making is thus not possible.

In 2015, Bhutan integrated the IBBS with hepatitis B for the following population groups: uniformed personnel, migrants, MSM/transgender persons, sex workers and PWID. Other opportunities within existing systems include (a) integrating hepatitis B and C recording into the existing HIV testing and counselling recording form; (b) integrating hepatitis reporting into the existing district health information software (DHIS) 2 system; (c) conducting a study to determine the actual burden and assess the impact of HBV vaccine introduction; and (d) developing national hepatitis prevention and treatment guidelines.

**Box 2: Recommendations for generating evidence for action**

- Surveillance for hepatitis needs to be improved in the Region. WHO’s *Technical considerations and case definitions to improve surveillance for viral hepatitis* can provide guidance to countries. The opportunities to integrate hepatitis surveillance with other programmes, especially HIV and immunization programmes, need to be actively pursued.
- The surveillance strategy adopted by the country should depend on the laboratory capacity at national/subnational level. Over time, countries need to invest in building laboratory capacity.
- Modelling and M&E activities for hepatitis need to be strengthened.
In the South-East Asia Region, with 1.4 million new HBV infections and 0.5 million new HCV infections, prevention will be an essential plank in the strategy to eliminate viral hepatitis. Universal vaccination of newborns and children is the most cost-effective intervention for HBV prevention and is being provided in the Region. But beyond this, prevention is lacking. Reaching high-risk groups with vaccination remains a challenge. Prevention strategies for hepatitis C are unknown. Safe injection practices have not been successfully implemented in both health-care and non health-care settings. Points of transmission in non-health-care settings have not been determined. There are significant social impediments to effective prevention interventions: poverty, poor awareness among people, low levels of education, lack of access to services, stigma and discrimination, cultural practices and beliefs, and poor health and civil infrastructure. The GHSS for viral hepatitis highlights new opportunities to increase public awareness and activism; harness advances in medicine, diagnostics and other technologies; engage communities; and work in partnership with multisectoral stakeholders. For this Region, two key elements that will need to underpin prevention programmes are community networks, which are still an essential element of the social fabric, and effective communication strategies that are purpose-driven, based on evidence, and capable of engaging multiple stakeholders at multiple levels.

Vaccination

The WHO recommendations on vaccination for different forms of viral hepatitis are as follows:

**Hepatitis B:**
- universal childhood vaccination and hepatitis B birth dose, regardless of endemicity
- catch-up vaccination based on epidemiology; targeted vaccination among high-risk groups

**Hepatitis A:**
- universal childhood vaccination (≥1 year of age) based on epidemiology and cost-effectiveness
- outbreak response and targeted vaccination among high-risk groups.

**Hepatitis E:**
- because of insufficient information, WHO does not recommend universal vaccination for hepatitis E but national authorities may decide otherwise
- outbreak response for high-risk groups.

Countries in the Region have integrated hepatitis B vaccination for children in their routine immunization programmes for several years already. Many countries have also achieved high coverage. The hepatitis B birth dose is provided in some countries but the coverage is low and varies widely among countries. Limited data are available on recommendations and implementation of vaccines for hepatitis A and E.

Improving the coverage of HBV vaccination requires strong intersectoral collaboration. There are opportunities to collaborate with MCH programmes during (a) ANC, so that pregnancies can be tracked to inform provision of the birth dose and advance information received on expected delivery dates of pregnant women; and (b) postnatal care, so that the birth dose
can be provided as part of the newborn care service package and postnatal visits are used to ensure timely completeness of HBV vaccination (at least two doses following the birth dose). Such collaboration requires putting in place relevant policies, ensuring that SOPs are practised, establishing feasible financing mechanisms, and creating an enabling environment. As a priority, national policies should mandate a universal birth dose within 24 hours of birth and set up national SOPs for collaboration. The national health facility policy should support collaboration by tasking and authorizing MCH personnel, staff working in the delivery room and providing postnatal care, skilled birth attendants, traditional birth attendants and private clinics/hospitals to administer hepatitis B vaccines. Capacity-building through job aids, training and supportive supervision will create an enabling environment for cadres to provide vaccines. The responsibilities regarding financing, and procuring and supplying vaccines need to be clearly divided as well. Effective management of the supply chain will ensure that vaccines are available and accessible at both health facilities and at outreach health services for births at home. Good connection with routine immunization service delivery is also needed for timely completion of hepatitis B vaccination. Opportunities for collaboration need to be explored with communities and with the birth registration system to create a demand for vaccination among underserved communities.

Historical precedents of vaccine-preventable diseases have shown that setting targets accelerates prevention efforts. Thus, the global elimination of HBV as a public health threat and regional targets for the control of HBV are steps in the right direction. What other vaccination programmes have done successfully is monitor the coverage (at district level and among high-risk groups), equity, impact and progress towards the goals, which has led to successful eradication of polio and smallpox. Approaches to monitoring, such as external reviews, coverage surveys, surveillance and programme assessments have highlighted the successes and gaps, and helped in strategic planning. Many resources on hepatitis vaccines, programme implementation and monitoring are available, which could help countries in monitoring their vaccination response.

Country examples

Unject for expanding hepatitis B birth dose vaccination in Indonesia

In 1996, a field trial of Unject began in West Nusa Tenggara and Bali in Indonesia. It was introduced in the other provinces between 2000 and 2002 in phases, and scaled up to all provinces and districts by April 2003. Unject for the HBV birth dose vaccine was introduced in Indonesia due to the challenges faced by the country in reaching 5 million newborns per year across 17 000 islands. A large proportion of deliveries, especially in remote areas, were home-based and far from health centres; attendance at immunization sessions was low; cold chain facilities for outreach services were less than adequate; vaccine wastage was high; and health workers were hesitant to open a vial for a single child. Unject provided the opportunity for midwives at the village level (who lived in the community and knew where and when births take place) to provide vaccines to newborns at home. A single-dose prefilled Unject vaccine was made available and stored at midwives’ home. The cost of delivering HBV vaccine at home using Unject (US$ 6.52) was less than the cost of delivering HBV vaccine at health facilities using disposable syringes.

Unject had the following advantages.

(a) It reached all newborns in hospitals and those who were delivered at home. Unject out of the cold chain has helped to reach newborns in remote areas in collaboration with the MCH programme.

(b) As the vial was prefilled with one dose, it ensured that the correct dosage was delivered and the vaccine wastage rate was negligible. For the EPI programme, providing Unject was very cost effective.
(c) It improved safety and prevented contamination, as an activation mechanism kept the needle covered until injection. The handling needed is less, thus reducing the risk of contamination of the needle or needlestick injury to health workers. The vaccine cannot be reused, thus eliminating the risk of disease transmission to the community.

(d) It reduced the logistics workload and diminished the risk for stock-outs, as syringe and vaccine are integrated in one injection system.

Coverage expanded from 2% in 2000 to 31% in 2003, the year when Uniject was available in all provinces. Coverage has increased rapidly to reach 85% in 2015. The most important lesson from this programme was that bringing the vaccine closer to newborns using the existing service delivery systems helped increase coverage.

However, some barriers need to be addressed. Delivery of the birth dose within 24 hours is difficult in various settings. The effectiveness of the Uniject programme depends on high coverage of neonatal home visits. Village midwives and cadres should conduct field monitoring to identify pregnant women and newborns in their areas and ensure that babies delivered at home receive immunization. Finally, data recording and reporting need to be strengthened, including data from the private sector and traditional birth attendants.

Safe injection use

Twenty-five percent of new hepatitis infections in the Region are due to unsafe injections. Unsafe practices include reuse of injection equipment, overuse of injections and needlestick injuries in health-care workers. Safety syringes are well established and available in global markets. The 2015 WHO guideline on the use of safety-engineered syringes in health-care settings was issued to prevent the injection-related transmission of deadly viruses, particularly HIV, hepatitis C and hepatitis B. Transition to these devices needs to be made by 2030. Steps have also to be taken to reduce the demand for injections and raise awareness on injection overuse. In many countries of this Region, where a large unregulated private sector exists, controlling injection use is a major challenge and needs to be addressed.

Prevention in health-care settings

Transmission in health-care settings can occur due to interactions between health-care workers and patients, patients and patients, and the health-care setting and general public. Therefore, it is necessary to take adequate measures to prevent transmission through all possible interactions. Safe infection control practices in Sri Lanka and the Maldives, along with the challenges, are discussed below.

Sri Lanka

A three-tiered organizational structure has been established in health-care settings for the prevention and control of infections. The Infection Control Committee is responsible for a long-term strategy, and ensuring infrastructure and other resources for infection control. The Infection Control Team is the execution arm of the Committee while infection control nurses carry out the work on a daily basis. All health-care workers are immunized and tested for antibodies (1–2 months after completion of three doses) and those who do not respond to the first series are given a second series and tested for antibody levels. Vaccination is also provided to patients in long-term care (such as those undergoing dialysis, with cancer, etc.), and to MSM, sex workers who are PWID and who are HIV-positive or attend STI clinics. Standard precautions are practised, covering areas such as handwashing, use of gloves and personal protective equipment, cleaning patient care equipment, managing spills, handling linen, managing occupational exposure. The MoH has enforced a colour-coded system for health-care waste management to assure a uniform system throughout the country.
However, certain gaps and challenges remain. A coordinated approach is lacking – regulations, circulars and practices need to be harmonized. There is a need for raising awareness among health-care workers, patients and the general public, plus strengthening infection control and prevention at all levels of health-care settings. This requires investment in infrastructure, logistics and human resources.

### The Maldives

The Maldives recommends strong infection control practices, which include the following:

1. safe injection practices – avoiding excessive/unnecessary injections; single use of injection equipment; and safe disposal of sharps;
2. blood safety – testing of all donated blood for HIV, hepatitis B, hepatitis C and syphilis; and access to safe blood (given the high prevalence of thalassaemia);
3. hygiene – pre-surgical hand hygiene and use of gloves when in contact with body fluids;
4. equipment safety – adequate and safe cleaning of equipment that needs to be reused;
5. waste management – safe disposal of sharps and infectious waste.

Protocols and guidelines have been developed to reduce and manage needlestick injuries, and for provision of PEP. No data are available to evaluate implementation of these policies. Monitoring infection control practices needs to be strengthened. Periodic training should be provided to health-care workers on these guidelines and continuous quality control needs to assured in low-prevalence settings like the Maldives.

### Prevention of hepatitis A and hepatitis E

Hepatitis A virus (HAV) and hepatitis E virus (HEV) are the results of rapid development, so these types of viral hepatitis are seen in low-income countries. South-East Asia lags behind in sanitation. Nearly 82% of the one billion people practising open defecation in the world live in 10 countries, which include India, Indonesia and Nepal.

A “vaccine only” prevention approach can drive the market with a biological solution but may not be a socially relevant and sustainable answer to the problem in South-East Asia. It is critical to transcend to an integrated health system and an intersectoral approach. HAV and HEV prevention approaches need to be integrated with broader water safety issues, sanitation and hygiene. Improving access to safe water, sanitation and hygiene needs to be accompanied by monitoring of quality, and reduction/elimination of inequalities of diverse kinds (primarily economic, but also those based on gender, education, marginalization, religion, etc.). Political will and increased financial outlay in the social sector and participation of civil society, NGOs, and self-help groups will help ensure equitable access.

**Box 3: Recommendations for prevention of hepatitis B**

- Countries should scale up immunization for HBV among high-risk populations such as health workers, sex workers, PWID, recipients of blood/plasma transfusions, and/or contacts of HBsAg-positive persons.
- Catch-up vaccination for children <5 years who missed immunization as infants and in unvaccinated children should also be considered for HBV control. This requires advocacy, social mobilization, effective vaccine management and a sustainable vaccine financing plan.
- As the Vaccine Alliance (GAVI) does not support hepatitis B birth dose under its vaccine investment strategy, other means need to found to support the birth dose. The birth dose is not expensive and countries need to invest their own resources in this important prevention intervention.
- Collaboration and coordination with other programmes like MCH for timely birth dose need to be systematically strengthened to improve coverage. With such actions, the goal of an HBsAg prevalence <1% in children <5 years by 2020 can be achieved in the Region.
Improving Access to and Simplifying Diagnostics for Hepatitis

Despite the large burden of undiagnosed HBV and HCV infections globally, testing services are limited – public health response lags behind the need and demand, even in resource-rich settings. There are multiple reasons for low testing coverage. Rapid diagnostic tests (RDTs) are expensive, vary in quality and are limited in number. No HBV and HCV RDT has been WHO prequalified. Nucleic acid tests (NAT) are also expensive, complex and limited in availability. There is a lack of knowledge and awareness among the community, general population and health workers about hepatitis. Stigma and discrimination are also reasons for the low uptake of hepatitis testing.

WHO hepatitis testing guidelines

WHO is currently developing new guidelines on hepatitis testing. These guidelines will provide recommendations on the following:

1. How to screen – selecting assays, tests and algorithms; quality assurance of testing; and procurement and supply chain. All testing services will be provided within the 5 Cs: Consent, Confidentiality, Counselling, Correct diagnosis and Connection (linkage to prevention, care and treatment).
2. Who to screen – populations and settings to be prioritized; service delivery approaches; and linkage to care and treatment.
3. Country strategic planning for testing
4. Surveillance and M&E.

Simplifying diagnostics and ensuring quality assurance

There is a pressing need to simplify diagnostics, given the lack of access to testing and lack of demand. A variety of diagnostics are available that differ in sensitivity, specificity, predictive value and reproducibility. Of them, ELISA is the simplest as it has high quality, sensitivity, specificity, reproducibility, and predictive value; pre-standardized kits are available commercially; it gives a lot of information and can be used for other diseases; and quality control is well established and comparatively easy to monitor.

In addition to simplified diagnostics, quality assurance (QA) is a very important requirement. QA not only ensures minimum quality, greater efficiency and optimized resource utilization but also provides dependable data for public health interventions, planning and policy decisions. QA requires selecting a testing strategy (i.e. which tests will be done) based on prevalence, validating the testing algorithm, selecting the products to be used, and conducting post-market surveillance to monitor the products used. It is a dynamic and ongoing process. As countries scale up testing for hepatitis, QA needs to be ensured by (a) maintaining quality control, (b) establishing and smoothly running the quality management system, (c) being constantly vigilant, and (d) continuous quality improvement.
Country examples

Opportunity for hepatitis testing in the national programme in the Democratic People’s Republic of Korea

In the Democratic People’s Republic of Korea, it is difficult to analyse the prevalence of hepatitis B. All patients who attend the hospital for medical review, TB patients, pregnant women in ANC and blood donors are tested for hepatitis B. RDTs and reversed passive hemagglutination assay (RPHA) for HBsAg screening are used; routine ELISA is not used. However, the testing modality is not consistent and data give mixed results. Under the national TB programme, all HBsAg-positive patients are referred to hepatitis services but data are not analysed and used. Testing for hepatitis A, C, D and E is limited. Challenges faced include limited capacity and infrastructure, lack of consumables and equipment, absence of proper training and quality control, limited financial resources, and poor procurement system. Steps are being taken to improve training, build capacity and renovate laboratories. A national strategic plan for hepatitis control is being developed and a hepatitis B treatment demonstration project is under discussion.

Box 4: Recommendations for the Regional Action Plan to scale up testing

- Provision of technical support to countries is needed for adaptation of global guidance at the country level.
- There is an urgent need for simple, reliable, inexpensive WHO-prequalified tests for HBsAg, HBV viral load, HCV antibody and HCV antigen.
- Use of online courses and guided self-paced learning can help build the capacity of healthcare workers. These courses can be developed and implemented at the country level through institutional collaboration and partnerships.
- Innovative education programmes are needed to increase awareness. In China, some measures have proven to be effective, such as posters and videos in hospitals to expose workers and doctors to hepatitis B, use of ANC visits and family planning classes to educate pregnant women, messages with hepatitis B knowledge on highways and in buses.
- Crowdsourcing is a new approach that can solicit case studies and innovative testing programmes. For example, the 2016 Hepatitis Testing Innovation Contest solicited descriptions of hepatitis B and C testing models to inform the WHO hepatitis testing guidelines. The global contest received 64 entries from 27 countries. Themes included engaging local communities, learning from and adapting HIV testing systems in place, digitizing medical recording and clinical reminders, using social media and mHealth, and integrating hepatitis testing with criminal justice, courts and prisons.
Improving Access to Care and Treatment

WHO Guidelines for the screening, care and treatment of persons with chronic hepatitis B and C infection

In 2015, WHO released guidelines for prevention, care and treatment of persons with HBV infection. A summary of the guidelines is presented in Table 2.

Table 2: Recommendations from the WHO HBV guidelines, 2015

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staging/non-invasive test (NIT)</td>
<td>Aspartate aminotransferase (AST)-to-platelet ratio index (APRI) preferred NIT to assess for the presence of cirrhosis</td>
</tr>
<tr>
<td></td>
<td>• Decompensated cirrhosis or cirrhosis (clinical criteria or APRI score &gt;2), regardless of alanine aminotransferase (ALT) levels, hepatitis B envelope antigen (HBeAg) or HBV DNA</td>
</tr>
<tr>
<td>Who to treat</td>
<td>• No cirrhosis but persistently abnormal ALT levels ± ongoing HBV replication (HBV DNA &gt;20 000 IU/mL or HBeAg +ve)</td>
</tr>
<tr>
<td>First-line treatment</td>
<td>• Drugs with a high barrier to resistance (tenofovir [TDF] or entecavir [ETV])</td>
</tr>
<tr>
<td></td>
<td>• ETV in children aged 2–11 years</td>
</tr>
<tr>
<td>Treatment failure</td>
<td>Switch to TDF if evidence of resistance to lamivudine (3TC), ETV, adefovir (ADF), telbivudine (TBV)</td>
</tr>
<tr>
<td>Treatment discontinuation</td>
<td>• Never discontinue in persons with cirrhosis</td>
</tr>
<tr>
<td></td>
<td>• If no cirrhosis, discontinuation on case-by-case basis (persistent HBeAg and/or HBsAg loss or undetectable HBV DNA)</td>
</tr>
<tr>
<td>Monitoring (treatment response/toxicity)</td>
<td>• On or pre-treatment: ALT + HBV DNA (HBsAg, HBeAg + APRI pre-treatment) annually. More frequent monitoring if cirrhosis</td>
</tr>
<tr>
<td></td>
<td>• Assessment of baseline renal function prior to treatment initiation</td>
</tr>
<tr>
<td>Monitoring for HCC</td>
<td>Ultrasound + alpha-fetoprotein (AFP) every 6 months in persons with cirrhosis and/or family history of HCC</td>
</tr>
</tbody>
</table>

WHO released its HCV treatment guidelines in April 2014 on screening, care, and treatment. Since the release of the guidelines, new drugs known as direct-acting antivirals (DAAs) have been approved. Prices of these were initially very high, but have fallen now and generics have been introduced in the market. WHO issued updated guidelines in 2016, recommending that DAA regimens be used for the treatment of persons with HCV. The use of boceprevir- or telaprevir-containing regimens is no longer recommended for the treatment of persons with HCV. Regimens with high safety and efficacy and with “high” or “moderate” acceptability were “preferred” (Table 3). In April 2015, all newly available innovative oral treatments for hepatitis C were included in the nineteenth WHO Essential Medicines List.
Even though there is no formal recommendation on whom to treat, everyone should be considered for treatment. Patients at increased risk of decompensation and death, morbidity, stigma and discrimination, and transmitting the virus should be prioritized for treatment.

Table 3: Recommendation on preferred regimens for hepatitis C, WHO HCV guidelines, 2016

(a) Without cirrhosis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Sofosbuvir/ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>12 weeks</td>
<td>12 weeks*</td>
<td></td>
</tr>
<tr>
<td>Genotype 2</td>
<td>12 weeks</td>
<td></td>
<td>12 weeks</td>
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<tr>
<td>Genotype 3</td>
<td>12 weeks</td>
<td></td>
<td>24 weeks</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>12 weeks</td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Genotype 5</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 6</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Treatment may be shortened to 8 weeks if baseline HCV RNA <6x10^6 IU/mL

(b) With cirrhosis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Daclatasvir/sofosbuvir/ribavirin</th>
<th>Ledipasvir/sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>24 weeks</td>
<td>12 weeks</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 3</td>
<td>24 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 4</td>
<td>24 weeks</td>
<td>12 weeks</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Genotype 5</td>
<td></td>
<td>24 weeks</td>
<td></td>
</tr>
<tr>
<td>Genotype 6</td>
<td></td>
<td>24 weeks</td>
<td></td>
</tr>
</tbody>
</table>

*If the platelet count is <75 x 10^3/µL then 24 weeks treatment with ribavirin should be given

Country examples

Inclusion of hepatitis B and C treatment in the national benefit package – opportunities and challenges in Thailand

Under the National Health Security Act 2002, the health care of all Thai citizens is covered by public insurance with the national health security scheme, which covers nearly three fourths of the population. This scheme is funded by the government and has a special fund arrangement for HIV/AIDS, hepatitis C, cancer, among others. The estimated number of HBsAg-positive people is 2–3 million and those positive for anti-HCV is <1 million in Thailand.

According to the national HBV guidelines released in 2015, all people with chronic hepatitis B are eligible for treatment if

- they are HBsAg-positive for at least 6 months (whether they are HBeAg-positive or not)
- have HBV DNA > 2000 IU/mL
- the ALT level is >twofold of the normal level (done twice with a gap of 3 months)
- the fibrosis stage is META VIR >2 or there is clinical evidence of cirrhosis or hepatic compensation.

The WHO-recommended oral first-line drug for oral medication is ETV or TDF. First-line treatment for HBV is included in the Thai benefit package. Pegylated interferon (PEG-IFN)
is recommended in cases with ALT >twofold the normal level and a low viral load, but not in decompensated cirrhosis.

Guidelines for HCV treatment were released in April 2016. All cases should be treated but due to budget constraints and limited number of experts, the current recommendation is to prioritize treatment in case of decompensated cirrhosis, cirrhosis (META VIR score 3), HIV/HCV coinfection, transplantation, relapse of HCV and other serious conditions. The second priority should be given to cases with significant fibrosis, i.e., META VIR score 2, and those on renal dialysis and pregnant women. DAA regimens are recommended for the treatment of persons with HCV but regimens with PEG-IFN and ribavirin are also recommended. The latter regimens are included in the Thai health benefit package and the target is to provide treatment to 3000 cases annually.

The inclusion of treatment for hepatitis B and C in the health benefit package ensures equity and better access to treatment but challenges remain in improving coverage. Screening services are not widely available, treatment is expensive, skilled medical personnel are limited in number, and data to monitor progress are not collected. Moving forward, Thailand plans to develop a national strategic plan on viral hepatitis and practical guidelines for health personnel. Collaboration among multiple stakeholders such as the National Health Security Office (NHSO) and other purchasers, civil society and pharmaceutical industry is needed. Price negotiations for effective drugs that are less toxic and have fewer side-effects will improve accessibility and affordability, and save money for the government.

Expanding access to treatment through partnerships in Nepal

In Nepal, cross-sectoral collaboration between national and international organizations has played an important role in generating evidence from local experience to assist the development of strategies for hepatitis. The prevalence of HBV is below 1% in the general population but is concentrated in certain ethnic groups (Tibetans, Manangies and Sherpa), high-risk groups (PWID, commercial sex workers, close relatives of HBsAg carriers), and geographical areas. Collaborative studies have also shown a high prevalence of HBV in populations living in mountainous areas of Nepal and call for targeted interventions for these populations. A 2014 study by the WHO department of Immunization-preventable Diseases (WHO-IPD), CDC, Child Health Division (CHD) EPI and Center for Molecular Dynamics Nepal (CMDN) has shown a very low prevalence of HBsAg: <0.3% pre-vaccination versus 0.1% post vaccination, and some evidence of mother-to-child infection. There is not enough evidence to introduce birth dose vaccination in Nepal and it makes sense to continue with the current three-dose vaccination programme.

A 2011 study by the United Nations Development Programme (UNDP) along with the Joint United Nations Programme on HIV/AIDS (UNAIDS), WHO-IPD and CMDN showed a high prevalence of HCV in people living with HIV visiting treatment centres. Another study conducted in 2015 among PWID in three regions of Nepal by CMDN, the Global Fund and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) showed a 42% HCV RNA prevalence rate. Based on the results, a study titled “Response-guided, short-course, interferon-based HCV therapy for HCV mono-infected and HIV-HCV co-infected individuals in Nepal” was started in 2014 by CMDN, GIZ, the Global Fund, Save the Children Nepal and other stakeholders. Findings from this study will enable better guideline development; it will bring more HCV patients into treatment with DAAs; and this experience can be used as a platform for nationwide treatment and follow up.

These projects are clear examples of a collaborative approach between the government, private sector, civil society and international development partners in a resource-limited setting to find solutions at the national and regional levels.

Innovations to reach the unreached in Bangladesh

The prevalence of HCV in Bangladesh is low; it is between 0.2% and 0.9% among adults in different urban and rural areas of Bangladesh, and 0.2% in blood donors. High rates of HCV infection among PWID have been found (30.2%, 2011 data). The prevalence among PWID varies considerably and is higher in the northern part of the country.
Mathematical modelling has shown that coupling HCV treatment with access to testing and prevention measures such as needle–syringe programmes (NSP) and opioid substitution therapy (OST) can reduce the HCV disease burden and transmission. Bangladesh has been running a harm reduction programme since 1998 with a strong NSP. At present, approximately 71% of the estimated 25,000 PWID are covered by the NSP and >200 needles were distributed per PWID in 2014. OST services using methadone are limited and just over 600 PWID are receiving methadone in Dhaka.

Bangladesh has planned a project for treating hepatitis C-infected PWID. It is a collaborative study between International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b); Centre for Health Evaluation and Outcome Sciences (CHEOS), Canada; Canadian Institutes of Health Research Canadian Trials Network (CTN), Canada; British Columbia Centre for Disease Control (BC CDC), Canada; Save the Children International (SCI), Bangladesh; and WHO. A cohort of 1000 people who use drugs (PWUD) accessing harm reduction services from three drop-in centres in Dhaka will be recruited and DAAs will be administered to an estimated 400–500 participants infected with HCV. HCV patients without cirrhosis will be treated with daclatasvir+ sofosbuvir (12 weeks). This study will:

- generate real-world data on the feasibility and impact of providing DAAs to PWUD;
- determine treatment adherence, sustained virological response, overall impact on HCV transmission, and health resource use and costs;
- use real-world data captured to conduct the first cost–effectiveness analysis of DAAs for HCV among PWUD in the developing world.

A pilot project will initially be conducted, which would later inform the larger study.

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**Box 5: Recommendations for the Regional Action Plan to scale up treatment**

- WHO guidelines are based on need, sound evidence and public health values. Countries can use the guidelines as an opportunity to start a broad-based dialogue for national action on hepatitis and development of national guidelines.
- Cheaper and good-quality medicines are needed to improve access to treatment.
- The Region needs to explore the option of having a common mechanism for financing DAAs.
- Stigma and discrimination have to be addressed to generate a demand for testing and treatment.
- Systems strengthening is needed for decentralized service delivery for diagnosis and management of viral hepatitis B and C.
- Treatment outcomes and drug toxicities should be monitored.
- Advocacy should be conducted for inclusion of testing and treatment for viral hepatitis in the universal benefit package.
Access to Affordable Medicines and Diagnostics

Expanding access to affordable drugs

The high costs of hepatitis drugs are an issue in all countries.

For LMICs, ways to increase access to affordable drugs are being increasingly used.

- Freedom to operate (FTO) – this offers the legal possibility to locally produce a generic version, especially in countries that do not grant patents (e.g. Bangladesh). FTO may not be clear where patents are filed and granted.
- Prices can be negotiated with the originator company.
- Patent oppositions and local production – e.g. the Initiative for Medicines, Access and Knowledge (I-MAK) has opposed a sofosbuvir patent in India.
- Compulsory licenses – countries can issue them to locally produce or import a medicine. Abusive prices can be a legitimate reason for granting licenses. However, producing an active pharmaceutical ingredient can be a challenge.

Pharmaceutical companies are also supporting increased access to medicines for poor countries. GlaxoSmithKline (GSK), in March 2016, expanded a graduated approach to patents and intellectual property to widen access to medicines in the world’s poorest countries. For least developed countries (LDCs) and low-income countries, GSK will not file patents for its medicines. For LMICs, GSK will file for patents but will seek to grant licenses to allow supplies of generic versions of its medicines for 10 years. Over the past eight years, the company has made significant changes to its business model to support increased access to medicines – tiered pricing models, prioritized investment in research and development for diseases of the developing world, and imposing price caps on its patented medicines in LDCs at no more than 25% of developed world prices.

Gilead Sciences has signed international voluntary licensing agreements with 11 Indian generic manufacturers that will allow these companies to manufacture sofosbuvir in India and sell it in 101 countries. The lowest market price of sofosbuvir is US$ 108 (Tables 4 and 5). A highly dynamic price scenario exists for other hepatitis C drugs as well. Voluntary licenses have been issued and generics of ledipasvir/sofosbuvir (Harvoni) and daclatasvir are being manufactured. The lowest market price of Indian generic Harvoni and daclatasvir are US$ 180 and US$ 51, respectively. However, registration is a bottleneck.
Table 4: Prices of Indian generic sofosbuvir*

<table>
<thead>
<tr>
<th>Marketing Company</th>
<th>Brand name</th>
<th>Gilead Licensee</th>
<th>Manufacturer</th>
<th>Printed price, USD*</th>
<th>Market price, USD*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Mylan</td>
<td>Sovaldi</td>
<td>N/A</td>
<td>Gilead</td>
<td>$305</td>
<td>$305</td>
</tr>
<tr>
<td>2 Biocon</td>
<td>Cimivir</td>
<td>Yes</td>
<td>Hetero</td>
<td>$307</td>
<td>$215</td>
</tr>
<tr>
<td>3 Dr Reddy’s</td>
<td>Resof</td>
<td>No</td>
<td>Hetero</td>
<td>$308</td>
<td>$215</td>
</tr>
<tr>
<td>4 Abbott India</td>
<td>Viroclear</td>
<td>No</td>
<td>Hetero</td>
<td>$323</td>
<td>$192</td>
</tr>
<tr>
<td>5 Hetero</td>
<td>Sofosvir</td>
<td>Yes</td>
<td>Hetero</td>
<td>$299</td>
<td>$185</td>
</tr>
<tr>
<td>6 Zydus Heptiza</td>
<td>SoviHep</td>
<td>Yes</td>
<td>Natco</td>
<td>$306</td>
<td>$185</td>
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<tr>
<td>7 Cipla Limited</td>
<td>Hepcovir</td>
<td>Yes</td>
<td>Hetero</td>
<td>$306</td>
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<tr>
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<td>Mytlep</td>
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<td>Natco</td>
<td>$306</td>
<td>$163</td>
</tr>
<tr>
<td>9 Emcure</td>
<td>Specra</td>
<td>No</td>
<td>Natco</td>
<td>$306</td>
<td>$154</td>
</tr>
<tr>
<td>10 Ranbaxy/Sun Pharma</td>
<td>Sofab</td>
<td>Yes</td>
<td>Hetero</td>
<td>$306</td>
<td>$154</td>
</tr>
<tr>
<td>11 Natco</td>
<td>Hepcinat</td>
<td>Yes</td>
<td>Natco</td>
<td>$306</td>
<td>$149</td>
</tr>
<tr>
<td>12 Strides Arcolab</td>
<td>Virso</td>
<td>Yes</td>
<td>Natco</td>
<td>$306</td>
<td>$108</td>
</tr>
<tr>
<td>13 Aurobindo Pharma</td>
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<td>Yes</td>
<td>TBD</td>
<td>TBD</td>
<td>N/A</td>
</tr>
<tr>
<td>14 Laurus Laboratories</td>
<td>TBD</td>
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<td>TBD</td>
<td>TBD</td>
<td>N/A</td>
</tr>
<tr>
<td>15 Sequent</td>
<td>TBD</td>
<td>Yes</td>
<td>TBD</td>
<td>TBD</td>
<td>N/A</td>
</tr>
<tr>
<td>16 Wockhardt</td>
<td>Novisof</td>
<td>No</td>
<td>Natco</td>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>

*Data extracted from powerpoint presentation by Mr. Giten Khwairakpam, TREAT Asia/amfAR

Table 5: Voluntary licenses and generics of hepatitis C drugs (February 2016)

<table>
<thead>
<tr>
<th>Sofosbuvir</th>
<th>Ledipasvir/ Sofosbuvir</th>
<th>Daclatasvir</th>
<th>Ombitasvir/ Paritaprevir/ ritonavir/ Dasabuvir</th>
<th>Simeprevir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary licensing (VL)</td>
<td>11 companies/ 101 countries</td>
<td>11 companies/ 101 countries</td>
<td>4 companies/ 112 countries</td>
<td>0 companies</td>
</tr>
<tr>
<td>Regulatory approval</td>
<td>14 VL countries</td>
<td>4 VL countries</td>
<td>0 VL countries</td>
<td>6 LMIC</td>
</tr>
<tr>
<td>Generics</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Country examples

Increasing access to HCV drugs by using flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in India

In the 1970s, India introduced patents on processes. There were no patents on products, due to which the generic industry flourished and India became the pharmacy of the developing world. India introduced product patents in 2005, which covered pharmaceutical products as well. TRIPS flexibilities were introduced into the Patent Act, 1970.

At present, the patent for sofosbuvir has been applied for by Gilead. Under the TRIPS flexibility, pre-grant oppositions has been filed by Sankalp, HepCon and the Asia-Pacific Network of people living with HIV/AIDS (APN+, represented by the Lawyers Collective), the Indian Pharmaceutical Alliance, I-MAK and the Delhi Network of Positive People (DNP+). In 2015, the Delhi Patent Office rejected the patent application for a pro-drug of sofosbuvir but on challenge in the Delhi High Court, the matter was remanded to the Patent Controller. Similarly, for daclatasvir, patent application by Bristol Myers-Squibb, pre-grant opposition has been filed on the base compound by Sankalp, HepCoN and APN+.  

Attempts have been made to weaken India’s use of TRIPS flexibilities. As per the US 301 report, India is listed among the countries with an inadequate intellectual property regime and targets the use of Section 3(d) of the patent act, which is a deterrent against evergreening of patents and subsequent monopoly of drug companies. Voluntary licenses also undermine the use of TRIPS flexibilities as they allow control of generic competition, plus there are fewer or no generic patent oppositions. Voluntary licenses may weaken government resolve to issue compulsory licenses and divert attention from a larger call for patent law reforms.

Countries like India need to be encouraged and provided technical support for increased use of TRIPS flexibilities, especially pre-/post-grant oppositions and compulsory licenses.

**Box 6: DAAs in the South East Asia Region**

- **India** – Sovaldi sofosbuvir available. Indian companies are marketing generic versions of sofosbuvir, ledipasvir + sofosbuvir, and daclatasvir. Between 2015 and 2016, nearly 42,000 people received HCV treatment with DAAs (0.042% treatment coverage).
- **Indonesia** – Sovaldi sofosbuvir in pre-submission stage; generic companies have also filed for registration while other DAAs are in the process of registration.
- **Myanmar** – generics filed registration for sofosbuvir in December 2015.
- **Nepal** – generic forms of sofosbuvir, ledipasvir + sofosbuvir, and daclatasvir are available.
- **Thailand** – registration for sofosbuvir (Sovaldi) and daclatasvir (Daklinza) was approved in 2015.

**Expanding access to affordable diagnostics**

Diagnostics for hepatitis C are available in <1% of LMICs. Existing diagnostic algorithms are complex and expensive. More than 50 serological RDTs are available, of which 12 are undergoing WHO pre-qualification but none have been approved to date. RDTs vary in sensitivity and specificity based on the test used, population and the setting; they diagnose prior exposure to hepatitis C and do not differentiate active disease from exposure. Confirmatory molecular tests are available but expensive. Point-of-care molecular tests are still in the development stage. The hepatitis C core antigen assay can also serve as a test for confirmation of disease but is currently available only on the Abbott Architect platform for centralized use. Several groups are exploring the feasibility of a decentralized antigen assay but none are in advanced stages of development.

Limited demand for testing, low focus on the private sector, lack of integration of new products, commercialization of products and non-evaluation of pre-market readiness are some of the key challenges to improving access to diagnostics. The following actions are recommended to drive access to diagnostics:

- integration between diagnosis and treatment to achieve maximum impact;
- integration of laboratory services at the country level;
- awareness among patients and prescribers to drive demand;
- a comprehensive implementation package inclusive of pricing, training, service support, supply chain, quality assurance, connectivity and information technology, and M&E.

**Role of international agencies in improving access**

To improve “access”, countries need to provide the right **products** at the right **prices** and in the right **quantities** in the right **places** and at the right **time**. International organizations can address the current challenges and help countries improve access to diagnostics and medicines (Table 6).
### Table 6: Role of international organizations in addressing challenges and improving access to diagnostics and medicines

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Role of international organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originators often make products suited to high-income markets, not taking into account different needs in LMICs due to lack of a reliable cold chain, high rates of paediatric infection, different genotypes, and high-throughput laboratories.</td>
<td>• Keep companies informed of market trends (i.e. guideline changes)</td>
</tr>
<tr>
<td>• Originators have very different access strategies, which limit the number of territories and the conditions under which the originator and generic versions of their products can be sold.</td>
<td>• Work with companies to develop the right products</td>
</tr>
<tr>
<td>• Generics/diagnostic companies must see high volumes to reduce prices.</td>
<td>• Support clinical trials for products/formulations</td>
</tr>
<tr>
<td>• Originators have very different access strategies, which limit the number of territories and the conditions under which the originator and generic versions of their products can be sold.</td>
<td>• Advocate with international community to include specific patient populations in trials.</td>
</tr>
<tr>
<td>• Companies have small sales forces in LMICs and often have little knowledge about the markets they are serving, especially in new disease areas.</td>
<td>• Lobby for originator companies to be accountable for certain standards of access to their products.</td>
</tr>
<tr>
<td>• Country governments often do not have the human resources to maintain adequate market intelligence to support negotiations.</td>
<td>• Support countries to challenge patents or issue compulsory licenses.</td>
</tr>
<tr>
<td>• There are varying degrees of stringency in regulatory evaluation of bioequivalence and quality control practices.</td>
<td>• Identify opportunities to use pooled procurement or volume guarantee deals to bring prices down.</td>
</tr>
<tr>
<td>• The market may include medicines or tests of varying quality, notwithstanding the potential for counterfeit medicines.</td>
<td>• Address the information asymmetry between suppliers and purchasers.</td>
</tr>
<tr>
<td>• Product scale up is complex and requires careful planning to address concerns of expiries and stock-outs, patient and healthcare worker acceptability, and more.</td>
<td>• Provide companies with credible market forecasts.</td>
</tr>
<tr>
<td>• Slow product scale up contributes to higher prices.</td>
<td>• Encourage product registration in markets with demand.</td>
</tr>
<tr>
<td>• Companies have small sales forces in LMICs and often have little knowledge about the markets they are serving, especially in new disease areas.</td>
<td>• Provide countries with market intelligence (products available and in the pipeline, market prices, tender best practices).</td>
</tr>
<tr>
<td>• Originators have very different access strategies, which limit the number of territories and the conditions under which the originator and generic versions of their products can be sold.</td>
<td>• Lobby for originators to require stringent regulatory authority (SRA) approval of any licensed product.</td>
</tr>
<tr>
<td>• There are varying degrees of stringency in regulatory evaluation of bioequivalence and quality control practices.</td>
<td>• Incentivize companies to apply for SRA approval.</td>
</tr>
<tr>
<td>• The market may include medicines or tests of varying quality, notwithstanding the potential for counterfeit medicines.</td>
<td>• Advocate for rapid SRA approval of key products.</td>
</tr>
<tr>
<td>• Product scale up is complex and requires careful planning to address concerns of expiries and stock-outs, patient and healthcare worker acceptability, and more.</td>
<td>• Educate purchasers on the benefits of purchasing SRA-approved products.</td>
</tr>
<tr>
<td>• Slow product scale up contributes to higher prices.</td>
<td>• Support countries to select the best medicines/diagnostics for their context.</td>
</tr>
<tr>
<td>• Slow product scale up contributes to higher prices.</td>
<td>• Analyse the cost impact of switching to different medicines or diagnostics.</td>
</tr>
<tr>
<td>• Companies have small sales forces in LMICs and often have little knowledge about the markets they are serving, especially in new disease areas.</td>
<td>• Support operational planning for and execution of product scale up.</td>
</tr>
<tr>
<td>• There are varying degrees of stringency in regulatory evaluation of bioequivalence and quality control practices.</td>
<td>• Link with civil society to create demand.</td>
</tr>
</tbody>
</table>

### Country example

#### Country experiences in price negotiations and access to generics in LMICs

Indonesia is one of the countries where sofosbuvir is priced at US$ 300 per bottle and is one of the 101 countries in which generics will be marketed. To bring the prices of medicines down, the country started negotiations with pharmacies, showing them the evidence, national strategic plan and their commitment towards hepatitis control. In 2016, the government budget allocated Indonesian Rupiah 90 billion (US$ 6.6 million) for DAAs but procurement has not started as registration is not yet over. Diagnostics are still expensive in Indonesia. With scaling up, these prices are expected to come down.
Box 7: Recommendations for the Regional Action Plan to improve access to affordable diagnostics and medicines

- The constitutionally enshrined right to health needs to be used better. Human rights principles should be recognized and incorporated in regional and national action plans.
- Streamlined regulatory processes are urgently required across the Region. A regional network for information-sharing can be developed for regulators. If regulators approve a drug in one country, information on it can be shared with other countries. Trust among regulators is needed. The requirement for local clinical trials can also be relaxed. For example, Myanmar needs only 12-month stability data to register a drug. Originators should be held accountable for registration of their products. Steps are needed to ensure that it is not an expensive process for small generics producers.
- The hepatitis programme can access the existing diagnostics capacity belonging to specific disease programmes, e.g. expand viral load capacity using Cephied platforms. Integration of laboratory programmes across different diseases can improve access and save costs.
- A paradigm change in needed in the way drugs are developed and marketed. The public sector and universities can invest in drug development.
- Countries need to be encouraged and provided with technical assistance to use TRIPS flexibilities.
- Open access to information on trade agreements will have an impact on prices. Price transparency will improve and better prices can be negotiated resulting in better outcomes.
- A regional procurement mechanism can be established, which involves the private sector in pool purchasing to improve demand.
- The private sector should be made a part of the regional discussions and plan.
Advocacy for Action

Creating and seizing global and national advocacy opportunities: World Hepatitis Day and World Hepatitis Summit

We are caught in a cycle of inaction. Due to lack of awareness, hepatitis is not given priority or funding and thus there are no good data, no action and no awareness. World Hepatitis Day and World Hepatitis Summit were initiated by the World Hepatitis Alliance to raise awareness and share experiences to drive action. NOhep, a global movement to eliminate viral hepatitis, will be launched on World Hepatitis Day on 28 July 2016. This elimination movement is an advocacy tool to get funding, attention and spread knowledge. The World Hepatitis Day theme also resonates with WHO’s GHSS goal of eliminating viral hepatitis as a public health threat by 2030. The first World Hepatitis Summit was held in Glasgow in 2015 to “support the development and implementation of comprehensive, funded national plans and programmes”. The next World Hepatitis Summit is scheduled for March 2017 in Sao Paulo and will support the implementation of the GHSS for viral hepatitis.

Much more action is needed at the country and regional levels to make hepatitis programmes sustainable. Meetings that bring together the government, patients, society, public health researchers and global funders need to be organized for experience-sharing among stakeholders. WHO has to play the role of a catalyst to help countries with their national plans.

Lessons learnt from the HIV response

Like HIV, HCV is prevalent among vulnerable populations, associated with stigma and discrimination, and can have life-threatening consequences. But HCV and HIV differ in significant ways (for example, HCV can be cured with short-course treatment while HIV treatment is lifelong). However, there are important lessons learned from AIDS activism that can inform or have informed the growing HCV activist movement. The HIV response has highlighted the indispensable role of community mobilization and direct participation, a peer-led rights-based approach, low-cost quality generics, and addressing structural barriers (stigma, discrimination, punitive laws).

The role of communities in the response to viral hepatitis

Community organizations have played key roles in advocating for action, providing direct service delivery and contributing to the national plan. Important examples from the Region include the following:

- In 2015, Medecins Sans Frontieres (MSF) and 19 community organizations applied for inclusion of daclatasvir in the WHO Essential Medicines List.
- TREAT Asia with 25 community organizations requested the Drug Controller General of India for a waiver of local clinical trials for approval of DAAs in September 2015. Due to the waiver, the drugs hit the market in December 2015, which otherwise would have taken one-and-a-half years.
- Lawyers Collective, APN+, and DNP+ filed patent opposition requests for sofosbuvir and daclatasvir in India.
- Nearly 33 organizations have requested the Board of the Global Fund to include hepatitis C in its strategic plan.
Based on the request of 107 Asian organizations to Merck and Co. for pricing PEG-IFN and ribavirin in Asia at US$ 2000, reduction was granted to 57 countries.

PKNI, an organization working with PWID in Indonesia, worked with the MoH to include HCV testing in HIV biobehavioural surveys in the country.

Community Network for Empowerment (CoNE) in Manipur, India organized a testing campaign in Manipur for PWID and people living with HIV.

Dreamlopments is working with Ozone, Raks Thai, and other institutions to conduct a large a test-and-treat study (C-FREE study) for PWID in Thailand.

The community has to play an important role in the future to raise awareness and provide hepatitis prevention, testing and treatment services for marginalized patients. Community-led advocacy is also needed to bring down the prices of hepatitis diagnostics and medicines.

Country examples

Community actions toward affordable hepatitis C medicines in Indonesia

Given the current epidemic, the objectives of community actions for HCV in Indonesia are threefold:

- raise awareness among doctors, patients and society;
- provide affordable generic hepatitis C medicines; and
- advocate for the inclusion of new DAA medicines into health insurance.

In line with these objectives, community actions for HCV treatment have focused on patent law reforms, patient education on intellectual property and TRIPs flexibilities, and media campaigns to increased hepatitis C literacy and advocacy. The Indonesian Affordable Medicines Coalition was also formed not just for hepatitis but also to advocate for other diseases that are treated with unaffordable medicines. A Patient Information Centre and Indonesia Buyers’ Club, a community initiative to facilitate parallel importation from India, were established. A treatment literacy programme for doctors and patients was initiated.

These actions ensured that a special access scheme (or parallel importation) was granted for DAA medicines, and sofosbuvir was included in fast-track registration (approval awaited). Despite these successes, challenges remain. Treatment literacy is low; DAAs are still expensive and not widely available; the number of hepatologists is limited; and there are potential threats from the Patent Law reform and Free Trade Agreement. To address these gaps, community actions in the future will:

- advocate for adoption of WHO guidelines on hepatitis C into national guidelines;
- scale up the treatment literacy programme;
- monitor the registration process of DAAs; and
- continue to work with UNDP, UNAIDS and Anti-Trust Commission to get DAA medicines included in national health insurance.

The role of institutional and clinical networks in capacity development and sustainability in the clinical setting

Institutional and clinical networks can play an important role in the following areas:

1. raising awareness among clinical, laboratory and research institutions (government, professional and private) about viral hepatitis and the socioeconomic determinants of those affected by the disease. This will help address stigma and promote understanding, sympathy and support towards people affected by hepatitis.

2. engaging and supporting communities and key affected populations. This will help improve access to important prevention, diagnosis and treatment services, and reduce stigma and discrimination. For HCV control, clinical societies can take the lead in engaging with PWID
to promote harm reduction, educate them about the benefits of treatment, and promote access to treatment and care. Engagement with communities affected by HBV presents challenges and needs thought, discussion, ambition and determination to effectively link with relevant programmes (e.g. MCH);

3. educating and training of the health-care workforce;

4. promoting best practices, quality assurance and sustainability, and helping in implementation of programme M&E.

**Country examples**

**Garnering political commitment in Myanmar**

The evidence from the national prevalence survey on hepatitis (2015) shows that HBV and HCV prevalence in Myanmar are 6.5% and 2.6%, respectively. Given the magnitude of the problem, government commitment and financial support are needed to develop a national hepatitis programme for prevention of transmission and of hepatitis-related deaths. Institutional/clinical networks and civil society have laid a strong foundation for successful advocacy and service delivery. The National Liver Foundation, Gastro-Intestinal and Liver Society and the Myanmar Medical Association conducted community campaigns providing screening tests and hepatitis B vaccination. Myanmar Positive Group is one of the leading organizations for increasing community awareness. Mass media campaigns are held to provide information on hepatitis B and C treatment and hepatitis B vaccine.
As a result of these efforts, a roadmap for a national hepatitis programme was developed. The Director General of the Department of Public Health, Myanmar declared hepatitis as a public health issue in Myanmar at the Sixty-eighth World Health Assembly in 2015. National liver physicians and HIV specialists affiliated with international universities formed a network for capacity-building in treatment. Simplified treatment guidelines for hepatitis B and C were released for the township level. WHO, development partners, international organizations such as MSF supported the Department of Public Health in developing a national strategic plan for hepatitis and costing it. Next, commitment from the new government will be sought for mobilization of national and international resources.

Box 9: Recommendations for a regional action plan on advocacy for action

- A budget needs to be allocated for advocacy.
- Stakeholder mapping is needed, which should define their power and influence. This might help build alliance with non-traditional stakeholders. The right messaging should be developed for stakeholders, and what is needed from them (funding, technical support, etc.) should be well defined.
- Successful translation of the regional action plan to national plans has to be ensured. There is a need to document evidence from countries and develop comprehensive advocacy plans, depending on the country situation, to better engage donors.
- Harm reduction advocacy should not take a backseat as it is an important prevention intervention and also improves engagement in care.
- Research helps generate sound evidence that can establish a solid base for advocacy. Researchers and advocates should increasingly engage in joint problem-solving around key research issues to ensure adoption and implementation of evidence-backed policies.
- Investment in operational research/implementation science research should be a priority to effectively scale up hepatitis prevention, testing and treatment interventions.
### Group Work

#### Table 7: Summary of the gaps, actions for countries, actions for WHO and best practices listed by the six working groups on topics related to measurement, community engagement, innovations, health systems, prices of drugs and diagnostics, and financing

<table>
<thead>
<tr>
<th>Gaps</th>
<th>Actions for Country</th>
<th>Actions for WHO</th>
<th>Best Practices</th>
</tr>
</thead>
</table>
| **Measurement – regional indicators and targets** | • Convene data-mining consultations and exercises involving a broad range of stakeholders  
• Systematic assessment of key data sources that are and are not available currently  
• Plan and prioritize actions to acquire key data and mobilize resources required to collect these data  
• Collation and production of (annual) reports of progress against indicators – one document, widely available and used by all stakeholders  
• Ensure data-quality processes and audits are in place | • Capacity development for Member States in data mining, collection and analysis – templates  
• Guidance regarding possible funding mechanisms  
• Develop a systematic reporting mechanism – information technology (IT) solutions for consistent reporting across countries  
• Share lessons learned by countries – best practices/dos and don’ts  
• Technical assistance | • Bangladesh – documenting equity in service delivery  
• Bhutan – HBV testing within HIV service delivery – integrated reporting  
• India – hospital-based registries of cirrhosis and HCC by type of viral hepatitis/other causes  
• Nepal – disaggregating prevalence estimates within priority populations  
• Thailand – systematic and comprehensive documentation of data  
• Timor-Leste data integration – IBBS data used for hepatitis |
| **Community Engagement and Addressing Special Groups** | • Mass awareness campaigns on World Hepatitis Day and World AIDS Day and linking with other Days  
• Systematic involvement of community organizations in formulation and implementation of action plans  
• Inclusion of most-at-risk groups in health insurance schemes  
• Easy process of registration and regulation of the community organizations | • WHO can expand support beyond technical assistance and play a major role in advocacy  
• Mobilize finances for community organizations  
• Facilitate coordination of all stakeholders and allow engagement of communities | • Engagement of community in polio vaccination in India  
• Peer-outreach in HIV programmes |

*continued on next page*
<table>
<thead>
<tr>
<th>GAPS</th>
<th>ACTIONS FOR COUNTRY</th>
<th>ACTIONS FOR WHO</th>
<th>BEST PRACTICES</th>
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</thead>
<tbody>
<tr>
<td>Innovation – Preparing for the future</td>
<td>Implementation research: Promote regional, country, and local implementation science research to answer questions about scale up, equity, and quality</td>
<td>Technical support for designing implementation research as part of national and regional plans</td>
<td>Process and outcomes metrics that could be used across the region</td>
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<td></td>
<td>Inter-programme collaboration: Inter-program collaboration across programmes for integrated service delivery models (with chronic diseases, with HIV, with others) and interlinked and integrated monitoring systems and diagnostic platforms</td>
<td>Technical support for monitoring and evaluation</td>
<td>Stakeholder mapping for hepatitis is important to build alliances among community advocates, physicians, and policy makers (e.g., Nepal)</td>
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<td></td>
<td>Co-infection and mono-infection service innovations: Encourage innovations for co-infected and mono-infected individuals</td>
<td>Identify synergies between programs and agencies to facilitate inter-program collaboration and innovation</td>
<td>Hepatitis service delivery may be linked to HIV service delivery wherever feasible</td>
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<tr>
<td></td>
<td>Identify innovations: Organizing open calls for innovative pilot programs in order to recognize, evaluate, and scale up effective programs</td>
<td>Work collaboratively with the country on advocacy to increase awareness and resources for hepatitis</td>
<td>Innovation contests/crowdsourcing as a simple way to identify new concepts (e.g., #HepTestContest)</td>
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<td></td>
<td>Build capacity: Establish a legal, regulatory, and policy ecosystem that promotes innovation</td>
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<tr>
<td>Health systems preparedness for implementing evidence based interventions</td>
<td>National action plan and national focal point</td>
<td>National action plan and hepatitis working group</td>
<td>Myanmar: buy in by professional societies, liver foundation and medical associations</td>
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<tr>
<td></td>
<td>Costed plan with a budget</td>
<td>Budget to support the national action plan</td>
<td>Thailand: universal healthcare coverage for infant hepatitis B vaccination and treatment of chronic hepatitis B and C</td>
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<tr>
<td></td>
<td>Lab capacity, costs and quality</td>
<td>Training of all level of healthcare workers</td>
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<td></td>
<td>Surveillance and information system</td>
<td>Fast track approval and registration of all antiviral drugs and made available at affordable price</td>
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<td></td>
<td>Public and healthcare workers’ awareness</td>
<td>Information and monitoring system for surveillance and care</td>
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<td></td>
<td>Access to care by internists etc. (other than GI specialists)</td>
<td>Build on and maximize use of existing infrastructure and human resources</td>
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<td></td>
<td>Affordable drugs and adult vaccination</td>
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<td></td>
<td>Engagement and partnerships with the private sector</td>
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### Table 7: continued

<table>
<thead>
<tr>
<th>GAPS</th>
<th>ACTIONS FOR COUNTRY</th>
<th>ACTIONS FOR WHO</th>
<th>BEST PRACTICES</th>
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</thead>
<tbody>
<tr>
<td><strong>Access to affordable drugs and diagnostics</strong></td>
<td><strong>Promote the rational use of injections – training, awareness, campaigns.</strong>&lt;br&gt;<strong>Auto-destructible syringes and re-use preventable devices</strong>&lt;br&gt;<strong>Remove legal and institutional barriers</strong>&lt;br&gt;<strong>Integrating Viral Hepatitis testing into the healthcare system</strong>&lt;br&gt;<strong>Legal options- encourage use TRIPS flexibilities for price reduction and wider access</strong></td>
<td><strong>Develop accreditation mechanism at a regional level</strong>&lt;br&gt;<strong>WHO role in ensuring quality diagnostics</strong>&lt;br&gt;<strong>WHO to provide technical assistance for using TRIPS flexibilities</strong>&lt;br&gt;<strong>Provide legal and technical support to address issues of equity</strong></td>
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<tr>
<td><strong>Funding</strong></td>
<td><strong>Bring together linked ministries to identify synergies and cost sharing or resource pooling</strong>&lt;br&gt;<strong>Identify budgets in other areas that might be reallocated</strong>&lt;br&gt;<strong>Meet with major industries to develop public-private partnerships and look at mandating employee health insurance covers hepatitis</strong>&lt;br&gt;<strong>Ensure that private health care insurers cover hepatitis</strong>&lt;br&gt;<strong>Ensure that hepatitis is included specifically in health budgets</strong>&lt;br&gt;<strong>Ensure (through the legal framework) new construction projects fund safe and adequate water and sewage systems</strong></td>
<td><strong>Expand capacity to help countries with financing</strong>&lt;br&gt;<strong>Lobby with global donors</strong>&lt;br&gt;<strong>Make hepatitis a regional/global priority</strong>&lt;br&gt;<strong>Help establish a regional hepatitis fund</strong></td>
<td><strong>None</strong></td>
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</table>
Conclusions & Recommendations

Time has come for Hepatitis. Country ownership is increasing and there is an opportunity to combat the hepatitis epidemic.

- Data and information are needed for evidence-based action. Countries need to build on existing systems and bridge the gaps for improved surveillance and data capture on Viral Hepatitis. Modeling can help identify priorities, monitor progress and evaluate outcomes.
- Prevention of Viral Hepatitis is key to elimination. Vaccination, especially birth dose for Hepatitis B, safe injections, safety in health care settings for health care providers and clients, water sanitation, and hygiene need to be scaled-up.
- Diagnostics for hepatitis need to be simplified and expanded to identify those in need of treatment. Identifying synergies and links with existing diagnostic platforms currently used for other diseases
- Laboratory capacity strengthening and quality assurance is critical to scale-up of health sector response to Viral Hepatitis.
- Multi-stakeholder engagement including politicians, policy makers, private sector, academic institutions, civil societies, community networks, drug regulators, private foundations, etc. will be essential for a sustainable response.
- Integration and convergence across health programmes including MCH, communicable diseases, immunization, chronic care, cancer care etc. are needed for a comprehensive response to viral hepatitis.
- Innovations for public awareness, increased demand for testing and treatment
- Innovative models of service delivery, decentralization, task shifting and online or e-courses are needed for scaling up the health sector response and reaching out to marginalized and hard to reach populations.
- The region needs to explore innovative options for price reductions like regional pooled procurement.
- Registration of drugs in countries is important for reducing prices.
- Implementation of WHO guidelines at country level needs to be ensured.

Key recommendations

- Member states to consider issuing a joint statement for WHA to endorse and affirm commitment on addressing Viral Hepatitis.
- All Member States in the region should develop/update national action plans in line with the latest WHO guidance and ensure implementation of evidence-based interventions.
- Countries need to develop and/or adapt data systems for better data collection, analysis and use for scaling-up response to viral hepatitis.
- Discussions with key stakeholders are important to advocate for inclusion of hepatitis prevention and treatment within the ‘Universal Health Coverage’ benefit package.
- Communities need to be actively engaged in policy making, designing and implementing interventions.
- Equitable access to health care services for hepatitis for marginalized and most affected populations needs to be ensured.
- Increased allocations of domestic financing for health in general and Hepatitis in particular are needed.
- WHO has to play an important role by:
» Setting up a regional advisory committee on Hepatitis.
» Supporting countries in developing and implementing national action plans.
» Developing a regional mechanism, involving drug regulators, for improving access to affordable diagnostics and medicines for hepatitis.
» Collaborating with institutions of excellence for strengthening laboratory capacity and QA in the Region.
Annex 1: Meeting agenda

<table>
<thead>
<tr>
<th>DAY 1</th>
<th>Presenter/Facilitator</th>
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<tbody>
<tr>
<td><strong>Session 1: Registration, Opening and Introduction</strong></td>
<td>Nelsy Siahaan</td>
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<tr>
<td>0830 – 0900</td>
<td>• Registration</td>
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<td>0900 - 1000</td>
<td>• Welcome remarks by</td>
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<td>» Secretary, Jakarta Province</td>
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<td>» Director General Disease</td>
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<td>Control and Prevention</td>
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<td>• Message from the Regional</td>
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<td>Director – WHO SEAR</td>
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<td>• Message on behalf of</td>
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<td>communities</td>
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<td>• Meeting objectives, themes</td>
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<td>and outcomes</td>
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<td>• Introduction of participants</td>
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<td>• Admin announcements</td>
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<td>1030 - 1100</td>
<td><strong>BREAK AND PHOTO</strong></td>
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<tr>
<td>1100 – 1230</td>
<td><strong>Session 2 and 3 Co-chairs -</strong></td>
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<td>Sumet Ongwadee and Thandar</td>
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<td>Lwin</td>
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<td>• Global Health Sector Strategy</td>
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<td>for Hepatitis 2016-2021 (15’)</td>
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<td>• Regional Action Plan for</td>
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<td>Hepatitis in WHO WPR (10’)</td>
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<td>• Country updates on developing</td>
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<td>national strategies</td>
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<td>» Indonesia (10’)</td>
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<td>» Timor Leste (10’)</td>
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<td>• Regional situation of hepatitis</td>
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<td>B control through</td>
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<td>immunization (15’)</td>
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<td>• SEAR Regional overview of</td>
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<td>Viral Hepatitis and linkage</td>
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<td>to UHC and SDGs (10’)</td>
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<td></td>
<td><strong>Plenary discussion– 20’</strong></td>
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<tr>
<td>1230 – 1330</td>
<td><strong>LUNCH</strong></td>
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</table>
1330 – 1500  **Session 3: Evidence for action – Measurement and accountability**
- Surveillance for Hepatitis including outbreaks (15’)
- Data as an intervention – Generating, analyzing and using quality data (15’)
- Modelling for estimating burden, investment case and target setting (15’)

Panel discussion
Overview - Use of data for public health programming (5’)
Facilitated panel discussion (25’)
Opportunities for improving HEP surveillance within current systems
Challenges and opportunities for better data capture
Use of modelling for prioritizing interventions and cost effectiveness analyses
Impact measurement through vaccination coverage and seroprevalence data

- Plenary inputs – 15 minutes

1500 – 1530  **BREAK**

1530 – 1730  **Session 4: Prevention of Transmission**
Overview and introduction to the session - 10’

Panel discussion – 60’
- Role of vaccination and monitoring response for prevention of Viral Hep (A, B, E)
- Intersectoral collaboration – Immunization and MCH for prevention of mother to child transmission and expanding vaccination for Hep B
- Innovations (Uniject) for expanding Hepatitis B vaccination in Indonesia
- Prevention of health care associated infections – opportunities and cost of inaction
- Ensuring safety in health care settings
- Prevention of water borne Hepatitis – Intersectoral linkages with water sanitation and hygiene

- Addressing needs of most at risk populations

Plenary inputs – 20’

1800  **RECEPTION**
### DAY 2 (Co-chairs – Session 5 and 6 – Abdus Sabur and David Muljono; Session 7 and 8 – Wiendra Waworuntu and Shiv Kumar Sarin)

**0830 – 1000**  
**Session 5: Improving access and simplifying diagnostics for HEP**
- HEP Testing guidelines (10’)
- Simplifying diagnostics and ensuring quality assurance (10’)
- Regional Gap Analysis for testing (10’)
- Opportunities for scaling up testing for VH in existing national programmes (10’)
- Crowd sourcing for expanding testing - #HeptestContest (10’)
- Capacity building at sub-national levels through online courses (10’)

Plenary discussion – 30’

**1000 – 1030**  
BREAK

**1030 – 1200**  
**Session 6: Improving access to care and treatment**
- Updated Treatment guidelines – 15’
- Capacity building for Hep B and C treatment – role of institutions (10’)
- Inclusion of HEP B and C treatment in national benefit package – opportunities and challenges (10’)
- Expanding access to treatment through partnerships (15’)
- Innovations to reach the unreached (10’)

Plenary Discussion – 30’

**1200 – 1300**  
LUNCH

**1300 - 1500**  
**Session 7: Reducing costs – access to affordable medicines and diagnostics:**
- Expanding access to affordable drugs and diagnostics - opportunities and challenges (10’)
- Expanding affordable diagnostics (10’)
- Role of international agencies in improving access (10’)

Panel discussion: 50’

- Access to generic DAAs and low cost quality diagnostics in the region – opportunities and challenges.
- Reducing barriers to access – Legislative options
- Country experiences in price negotiations and access to generics in LMIC
- Price negotiations in MIC – Experience from Thailand
- Price negotiations in HIC – Experience from Canada

Moderator – Charles Gore

Plenary inputs – 20’

**1500 - 1530**  
BREAK
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Speakers</th>
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<tbody>
<tr>
<td>1530 - 1700</td>
<td>Session 8: Advocacy for Action</td>
<td>Charles Gore</td>
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<tr>
<td></td>
<td>▪ Creating and seizing global and national advocacy opportunities: World Hepatitis Day</td>
<td>Nicolas Durier</td>
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<td>and World Hepatitis Summit (10’)</td>
<td>Shamila Sharma - moderator</td>
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<td>▪ Reflections on role of communities (10’)</td>
<td>Win Win Swe</td>
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<td>▪ Panel Discussion: 30’</td>
<td>Aditya Wardhana</td>
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<td></td>
<td>Garnering political commitment</td>
<td>Karyn Kaplan</td>
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<td>Lessons learnt from HIV</td>
<td>Mark Boyd</td>
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<td>Community led advocacy</td>
<td>Anchalee Avihingsanon</td>
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<td>Role of institutional and community based networks</td>
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<td>Role of research in advocacy</td>
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<td>Plenary inputs – 35’</td>
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**DAY 3**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>0830 - 1030</td>
<td>Session 9: Simulation Exercise – National plans, priorities and accelerating</td>
<td>Hande Harmanci</td>
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<td>implementation</td>
<td>All participants</td>
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<tr>
<td>1030 - 1100</td>
<td>BREAK</td>
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<tr>
<td>1100 - 1230</td>
<td>Session 10: Regional Action plan discussions</td>
<td>Razia Pendse</td>
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<td>Breakout groups – 45 mins</td>
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<td>Feedback and discussion - 20’</td>
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<tr>
<td>1230 - 1330</td>
<td>LUNCH</td>
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<tr>
<td>1330 - 1430</td>
<td>Session 11: Conclusion and Recommendations</td>
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<tr>
<td>1430 - 1500</td>
<td>Closing</td>
<td>MOH INO/WHO</td>
</tr>
</tbody>
</table>
Annex 2: List of participants

Bangladesh
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