Accelerating action towards a hepatitis-free future

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Foreword

Viral hepatitis is a serious public health problem that can cause chronic and potentially fatal complications including liver cancer. Among the estimated 1.38 million people dying globally due to hepatitis every year, 28% are from countries in the WHO South-East Asia Region. Unlike other communicable diseases, such as HIV and TB, hepatitis-related mortality has not declined, despite the existence of high-impact tools for prevention and treatment.

Since 2017 Member States in the Region have been implementing the Regional action plan for viral hepatitis in South-East Asia. The action plan focuses on eliminating viral hepatitis as a public health threat by 2030 by achieving the global targets of a 30% and 10% reduction in incidence and mortality, respectively, by 2020, and a 90% and 65% reduction by 2030, for chronic hepatitis B and C. The plan provides an actionable framework for evidence-based, prioritized actions along five core interventions on prevention, diagnosis and treatment.

This report provides an update on the Region’s progress on the targets identified in the plan. Commendably, almost all countries are now implementing national strategic plans that provide guidance on key prevention interventions as well as hepatitis testing and treatment. The Region has achieved 91% coverage of three doses of the hepatitis B vaccine. Bangladesh, Bhutan, Nepal and Thailand have already achieved the 2020 hepatitis B control target. Eight countries now provide the hepatitis B birth dose. Direct-acting antiviral drugs, which can cure 85-95% of hepatitis C infections, are becoming more affordable in several of the Region’s Member States.

But progress has not been uniform across countries and across all five core interventions. Many countries are yet to harness the benefits of cost reductions in hepatitis C drugs. Too often the cost of diagnostics is prohibitively high. In several countries, high-level advocacy with policy-makers is insufficient to secure the required funding. Not all new-borns are receiving the hepatitis B birth dose.

As this report notes, millions of people remain unaware of their status. To change that, key point-of-care diagnostic facilities should be more effectively harnessed. Harm reduction interventions for people who inject drugs (PWID) require more focused attention. A more precise knowledge of the disease burden is required, in addition to dedicated funding, community mobilization and a more decentralized approach that empowers primary care facilities. There is a strong need to simplify and scale up treatment for hepatitis B and to find a cure, as we have for hepatitis C.

By highlighting the Region’s progress, and identifying existing gaps and challenges, this report will provide crucial input in developing the next regional action plan, which will be implemented between 2022 and 2026. I urge all stakeholders to make full use of this report as together we sustain and accelerate progress towards a healthier, hepatitis-free South-East Asia Region for all.

Dr Poonam Khetrapal Singh
Regional Director
WHO South-East Asia Region
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### Abbreviations and acronyms

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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ANC</td>
<td>antenatal care</td>
</tr>
<tr>
<td>CPAD</td>
<td>compact pre-filled auto-disable injection device</td>
</tr>
<tr>
<td>DAA</td>
<td>direct-acting antiviral</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>Democratic People’s Republic of Korea</td>
</tr>
<tr>
<td>GBD</td>
<td>Global Burden of Disease</td>
</tr>
<tr>
<td>GHP</td>
<td>Global Hepatitis Programme</td>
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<tr>
<td>GHSS</td>
<td>Global Health Sector Strategy on viral hepatitis</td>
</tr>
<tr>
<td>GRSH</td>
<td>Global Reporting System for Hepatitis</td>
</tr>
<tr>
<td>HBlg</td>
<td>hepatitis B immunoglobulin</td>
</tr>
<tr>
<td>HBsAg</td>
<td>hepatitis B surface antigen</td>
</tr>
<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
</tr>
<tr>
<td>HCC</td>
<td>hepatocellular cancer</td>
</tr>
<tr>
<td>HCV</td>
<td>hepatitis C virus</td>
</tr>
<tr>
<td>Hep-BD</td>
<td>birth dose of hepatitis B vaccine</td>
</tr>
<tr>
<td>HepB3</td>
<td>third dose of hepatitis B vaccine</td>
</tr>
<tr>
<td>HEV</td>
<td>hepatitis E virus</td>
</tr>
<tr>
<td>IPC</td>
<td>infection prevention and control</td>
</tr>
<tr>
<td>MPP</td>
<td>Medicines Patent Pool</td>
</tr>
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<td>MSM</td>
<td>men who have sex with men</td>
</tr>
<tr>
<td>NSP</td>
<td>needle and syringe programme</td>
</tr>
<tr>
<td>OST</td>
<td>opioid substitution therapy</td>
</tr>
<tr>
<td>PEP</td>
<td>post-exposure prophylaxis</td>
</tr>
<tr>
<td>PLHIV</td>
<td>people living with HIV</td>
</tr>
<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
</tr>
<tr>
<td>PWID</td>
<td>people who inject drugs</td>
</tr>
<tr>
<td>RAP</td>
<td>Regional Action Plan</td>
</tr>
<tr>
<td>RVAP</td>
<td>Regional Vaccine Action Plan 2016–2020</td>
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<tr>
<td>SDGs</td>
<td>Sustainable Development Goals</td>
</tr>
<tr>
<td>SEA</td>
<td>South-East Asia</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>SW</td>
<td>sex worker</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>UHC</td>
<td>universal health coverage</td>
</tr>
<tr>
<td>UNDP</td>
<td>United Nations Development Programme</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive summary

Viral hepatitis is a significant health challenge globally, and in the WHO South-East Asia (SEA) Region. The number of people infected with and deaths due to viral hepatitis are more than those due to HIV and malaria combined. In addition to the high burden on health and lives, viral hepatitis entails significant financial and social costs. The SEA Region has an estimated 39 million people living with chronic hepatitis B (range 29–77 million) and around 14 million (range 8–18 million) with hepatitis C. Of the estimated 391 000 deaths due to viral hepatitis each year in the Region, 77% are attributable to the complications of chronic infection with the hepatitis B and C viruses.

Increased understanding and awareness about the disease, coupled with the availability of new treatment options, have propelled viral hepatitis to the global health and development agenda. There is greater recognition that the mortality and morbidity due to viral hepatitis can be brought down with strategic interventions for prevention, diagnosis and treatment of hepatitis B virus (HBV) and hepatitis C virus (HCV). Viral hepatitis was included in the global framework of the Sustainable Development Goals (SDGs) in 2015. SDG 3.3 specifically mentions the need to combat hepatitis, along with waterborne diseases and other communicable diseases. Accordingly, the Global Health Sector Strategy (GHSS) on viral hepatitis (2016–2021) was developed, which outlined the critical interventions required for eliminating viral hepatitis as a public health threat by 2030.

In line with the global strategy on viral hepatitis, the WHO Regional Office for South-East Asia developed the Regional Action Plan (RAP) on viral hepatitis in South-East Asia (2016–2021) in consultation with Member States of the Region. The Plan provided a roadmap for priority areas of focus and interventions needed in the health and related sectors for mounting an effective response to the prevention, diagnosis, management and care of viral hepatitis. This report summarizes the progress made by Member States in implementing the RAP. It presents epidemiological updates and responses from Member States of the Region, in consonance with the RAP and WHO monitoring framework for viral hepatitis. While progress has been made in implementing a package of essential interventions needed at the national level for prevention, diagnosis and treatment of viral hepatitis to reduce its burden, significant gaps exist. Addressing these gaps and accelerating progress in these areas in line with the global strategy and the RAP is crucial for the WHO SEA Region to move towards the 2030 elimination target and realize a hepatitis-free future.
1. Introduction

Worldwide, viral hepatitis is one of the leading causes of mortality. The global burden of viral hepatitis-related deaths was estimated to be 1.34 million in 2015. Estimates based on the Global Burden of Disease (GBD) methodology have put the number of deaths due to viral hepatitis at 1.45 million (95% uncertainty interval [UI] 1.38–1.54) in 2013. Viral hepatitis was the seventh leading cause of death worldwide in 2013, up from being the tenth position in 1990 according to the GBD report. The mortality due to viral hepatitis is comparable to the number of deaths due to tuberculosis (TB) and is higher than the mortality attributed to HIV. A World Health Organization (WHO) report published in 2018 estimated that the number of deaths due to viral hepatitis had increased by 22% since 2000. It is hard to estimate the exact number of deaths attributable to viral hepatitis due to underreporting of deaths occurring as a result of hepatitis-related cirrhosis and liver cancer. Most of the deaths due to viral hepatitis are related to chronic complications caused by hepatitis B virus (HBV) and hepatitis C virus (HCV) infections, such as cirrhosis and hepatocellular cancer (HCC).

Despite the public health burden, concerted efforts to address viral hepatitis have been historically limited. In response to the growing concern about its burden, the World Health Assembly endorsed a resolution on viral hepatitis in 2010, urging countries to observe World Hepatitis Day on 28 July with a view to promoting greater understanding of viral hepatitis as a global public health problem, and to stimulate strengthening of prevention and control measures. The resolution was followed by the creation of the Global Hepatitis Programme (GHP) in WHO as a dedicated unit to provide evidence-based support to countries for scaling up hepatitis treatment, care and prevention services. The focus spurred research on viral hepatitis globally and resulted in the development of new diagnostic and treatment modalities whose implementation has
helped improve outcomes in people infected with viral hepatitis. Such activities, coupled with a greater understanding of its burden, paved the way for inclusion of viral hepatitis in the global framework of the Sustainable Development Goals (SDGs) under the United Nations in 2015. SDG 3.3 specifically mentions the need to combat hepatitis, along with waterborne diseases and other communicable diseases. In order to work towards achieving this target, the World Health Assembly endorsed the Global Health Sector Strategy (GHSS) on viral hepatitis (2016–2021), in May 2016. The GHSS outlined critical interventions required for eliminating viral hepatitis as a public health threat by 2030. The Strategy set elimination of viral hepatitis as its overarching target, given the fact that while mortality from HIV, TB and malaria was on the decline, mortality caused by viral hepatitis was on the rise.

The GHSS on viral hepatitis defined elimination as a 65% reduction in mortality and a 90% reduction in incidence compared with the 2015 baseline. For achieving these targets by 2030, actions were proposed in five strategic directions – strategic information, interventions, equity, financing and innovation. The GHSS recognized how mortality and morbidity due to viral hepatitis can be brought down with strategic interventions for prevention, diagnosis and treatment of HBV and HCV. The five main interventions outlined in the GHSS are: immunization against hepatitis B; prevention of mother-to-child transmission (PMTCT) of HBV; blood and injection safety; prevention of transmission of HBV and HCV among people who inject drugs (PWID) through comprehensive harm reduction services; and increasing access to testing and treatment. In addition, WHO has developed a robust monitoring framework to assess the progress made by countries in the five strategic pathways outlined in the Global Strategy.

Based on the broad framework of action suggested in the GHSS, the WHO Regional Office for South-East Asia developed the ‘Regional Action Plan’ (RAP) for viral hepatitis in South-East Asia, 2016–2021. The RAP provided a roadmap for priority areas of focus and interventions needed in the health and related sectors for mounting an effective response to prevention, diagnosis, management and care of viral hepatitis.

This report provides an update on the progress, and highlights areas where progress has been challenging. It also makes recommendations for accelerated action.

**Methods**

Data were collated from multiple sources on the disease burden of viral hepatitis in Member States as well as coverage of services. Global repositories based on modelling and other national sources, including serosurveys, formed the starting point, but inputs were received from Member States through online reporting in 2019, which supplemented both disease burden estimates as well as service coverage data. Working estimates for a select set of indicators were reviewed and agreed at a WHO regional workshop on National Action Plan Development for Viral Hepatitis held in Kathmandu, Nepal in 2019. These are summarized as country profiles in Annex 4 of the workshop report.

A systematic review and meta-analysis of the published literature on hepatitis C was carried out to estimate the burden of hepatitis C in the Region, by the WHO Collaborating Centre on Viral Hepatitis at the Sanjay Gandhi Post Graduate Institute of medical sciences, Lucknow, India. Additionally, data from the Global Reporting System for Hepatitis (GRSH) have been incorporated wherever available. For arriving at the regional aggregate, if data were missing on any country from the above sources, data available with the Polaris Observatory were used. The WHO Collaborating Centre on Viral Hepatitis at the Institute of Liver and Biliary Sciences, New Delhi, India, provided support for data analysis and preparation of this report. Further, TreatAsia/amfAR provided support for the collation of cost data of key diagnostic and therapeutic commodities for hepatitis C.

**1.1 Prevalence of viral hepatitis: global scenario**

The estimated number of people living with HBV in all WHO regions is 257 million. Among the different
regions of WHO, the prevalence of HBV in the general population is the highest in the Western Pacific Region and lowest in the Region of the Americas. The South-East Asia (SEA) Region stands third among the WHO regions for the disease burden caused due to HBV, which is 39 million (range 29–77 million) (Fig. 1.1). About 1.1 million people were newly infected globally with chronic hepatitis B in 2017.10

Of the estimated 71 million people living with HCV in all WHO regions, nearly 14 million live in the SEA Region (range 8–18 million) (Fig. 1.1).1,10 The prevalence of HCV infection in the general population is highest in the Eastern Mediterranean Region and the lowest in the Region of the Americas. The SEA Region stands fourth among all WHO regions in burden of HCV infection.1 An estimated 1.75 million people were newly infected globally with HCV in 2015.1

Fig. 1.1: Prevalence of hepatitis B and C, by WHO region, 2015

Fig 1.1 a: Prevalence of hepatitis B

Fig 1.1 b: Prevalence of hepatitis C

The prevalence of viral hepatitis varies widely across population groups, indicating that the risk of getting infected with HBV and HCV differs among population groups. Since different subgroups have distinct profiles in terms of incidence, prevalence and vulnerability, tailor-made strategies may be needed to address their needs as well as to prioritize the use of available resources. The need for providing health care depends on the vulnerability of population groups for HBV and HCV infection. Hence, preventive and curative interventions need to be planned differently for each subgroup with a high risk of contracting the infection.

Keeping this in view, certain groups that face a higher risk of exposure to HBV and HCV need prioritized focus. They include PWID, sex workers (SW), men who have sex with men (MSM), people living with HIV (PLHIV), health-care workers, prisoners, migrants and indigenous peoples. Similarly, hepatitis B-positive pregnant women are at a high risk of transmitting the virus to their infants. Understanding the subtleties of the epidemic in each of these groups is critical to achieving the regional targets and reaching the global target.

1.2 Mortality related to viral hepatitis

Globally, an estimated 1.38 million deaths annually are attributed to viral hepatitis and its consequences. Of these deaths, 71% are attributed to HBV, while 25% are due to those related to HCV. The rest are due to hepatitis E and A infections, with hepatitis E virus (HEV) accounting for 3% of deaths. Chronic complications of HBV and HCV infection such as cirrhosis and HCC are responsible for the majority of deaths and illness. The proportion of acute hepatitis caused due to HEV is low. Overall, mortality due to viral hepatitis is the highest in the Western Pacific Region (33%), followed by the SEA Region, which accounts for 28% of the total mortality due to viral hepatitis. The Region of the Americas contributes the least to the global burden of mortality related to hepatitis.

Fig. 1.2: Deaths due to viral hepatitis worldwide, by virus and type of sequelae, 2016

2. Burden of viral hepatitis in the WHO South-East Asia Region

The SEA Region has an estimated 39 million people with chronic hepatitis B (range 29–77 million) and an estimated 14 million (range 8–18 million) with hepatitis C. Of the estimated 391 000 deaths due to viral hepatitis each year in the Region, 77% are attributable to the chronic complications of hepatitis B and C.

Viral hepatitis is an important public health challenge in the Region as the number of deaths due to viral hepatitis are more than those due to HIV and malaria. In addition to the heavy burden on health and lives, viral hepatitis entails significant financial and social costs.

2.1 Prevalence of hepatitis B

Most Member States of the SEA Region have an intermediate-to-low prevalence of hepatitis B in the general population. Indonesia has reported a high prevalence of hepatitis B in the general population (>7%). Bangladesh, Bhutan, the Democratic People’s Republic of Korea (DPR Korea), Myanmar, Thailand and Timor-Leste have an intermediate prevalence of 2–7%, while the remaining countries have recorded a prevalence of below 2% in the general population (Fig. 2.1).
2.2 Prevalence of hepatitis C

In the SEA Region, the prevalence of hepatitis C ranges between 0.28% (Sri Lanka) and 2.81% (Myanmar). Most of the countries have a prevalence in the range of 0.28–0.75%, except Indonesia, Myanmar and Thailand, where it is more than 2%. (Fig. 2.2). The incidence of hepatitis C in the SEA Region in 2015 was 14.8 (12.5–26.9) per 100 000 population.\(^1\)

**Source:** Disease burden estimation of HCV in the WHO South-East Asia Region, 2020 Reviewed and agreed by the Strategic and Technical Advisory Group (STAG) on viral hepatitis in the WHO South-East Asia Region. Prevalence is calculated for those above 15 years.
2.3 Mortality due to hepatitis B

The Global health estimates, 2016, reported that an estimated 296,031 deaths were attributable to hepatitis B in the SEA Region.\textsuperscript{11} Of these, the majority of deaths (65\%) were due to cirrhosis, while 21\% of mortality was attributed to acute hepatitis B and 14\% to HCC. However, deaths due to HCC were higher than those due to cirrhosis in DPR Korea and Thailand (Fig. 2.3).

2.4 Mortality due to hepatitis C

In the SEA Region, the mortality attributable to hepatitis C is estimated to be 69,583, according to the Global health estimates, 2016.\textsuperscript{11} Of this, over three fourths of the deaths (77.5\%) are due to cirrhosis, 20.6\% due to HCC and 1.9\% due to acute hepatitis C. In DPR Korea and Thailand, however, deaths due to HCC are higher than those due to cirrhosis (Fig. 2.4).

Fig. 2.3: Mortality due to hepatitis B in the WHO SEA Region

![Fig. 2.3: Mortality due to hepatitis B in the WHO SEA Region](source)


Fig. 2.4: Mortality due to hepatitis C in the WHO SEA Region

![Fig. 2.4: Mortality due to hepatitis C in the WHO SEA Region](source)

2.5 Prevalence among specific population groups

As certain population subgroups, such as key populations, are at higher risk of hepatitis, understanding the prevalence of viral hepatitis among these groups is important from the point of view of elimination.

People who inject drugs. Injection drug use is one of the common risk factors for viral hepatitis, particularly HCV. The prevalence of HCV among PWID is relatively high compared to that of HBV. It ranges widely between 0.5% and 67% in the Region. A similar range of 0.12–63.5% prevalence of HCV antibody was seen in Member States, according to a recent burden estimation exercise carried out in the Region. In Thailand and Indonesia, the prevalence of HCV among PWID is higher, at estimated 59% and 64%, and about 52% and 56% in India and Myanmar respectively. In comparison, the prevalence of HBV in this subgroup ranges from 0.8% to 14% (Fig. 2.5).

Men who have sex with men. The risk of exposure to viral hepatitis, particularly HBV, is elevated among MSM compared to general population. However, scant data are available on the prevalence of hepatitis in this subgroup in the SEA Region. Robust estimates for the prevalence of hepatitis B and C among MSM are not available for most Member States in the Region. Based on representative samples, it is estimated that the prevalence of hepatitis B among MSM ranges between 6% and 7.6%, whereas the prevalence of hepatitis C ranges between 0.23% and 28%.9,10

Sex workers. Hepatitis B and C infection can be transmitted through sexual contact. Though prevalence among heterosexual individuals in the general population is usually low, special subgroups such as SWs are at high risk. Estimates for the prevalence of hepatitis B and C among SWs are not available for most Member States of the SEA Region. In four countries from where the data are available, the prevalence of hepatitis B among SWs ranges from 2.8% to 8.3%. The prevalence of HCV among SWs ranges from 0.23% to 3.78%.9,10

People living with HIV. Globally, a significant number of people living with HIV (PLHIV) also have chronic HBV and HCV infection. Liver disease is known to be a leading cause of death and illness among PLHIV coinfected with viral hepatitis. Data available from five countries show that the prevalence of hepatitis B among PLHIV ranges from 0.3% to 8.7%. The prevalence of HCV among PLHIV ranges from 0.1% to 48.2% in the Region.8

Fig. 2.5: Prevalence of HBV and HCV in PWID in comparison to the general population in Member States of the SEA Region (all values are percentages)

Fig. 2.5 a) HBV prevalence among PWID compared to general population


**Fig. 2.5 b) HCV prevalence among PWID compared to general population**

<table>
<thead>
<tr>
<th>Country</th>
<th>HCV Prevalence % in General Population</th>
<th>HCV Prevalence % in PWID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>0.72</td>
<td>40.89</td>
</tr>
<tr>
<td>India</td>
<td>0.49</td>
<td>51.48</td>
</tr>
<tr>
<td>Indonesia</td>
<td>2.03</td>
<td>63.50</td>
</tr>
<tr>
<td>Myanmar</td>
<td>2.65</td>
<td>56.00</td>
</tr>
<tr>
<td>Nepal</td>
<td>0.38</td>
<td>27.48</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>0.23</td>
<td>5.57</td>
</tr>
<tr>
<td>Thailand</td>
<td>2.28</td>
<td>58.86</td>
</tr>
</tbody>
</table>


**Prisoners.** Estimates for the prevalence of HBV and HCV among prisoners are not available in most Member States of the SEA Region. Data for HBV are available from only two Member States. The prevalence of hepatitis B among prisoners is 0.3% in Sri Lanka and 3.6% in Indonesia. The estimated prevalence of hepatitis C among prisoners ranges between 0.29% and 17.5%, with five countries – India, Indonesia, Myanmar, Sri Lanka and Thailand – having a prevalence of more than 5%.

**Blood donors.** Blood safety was identified as a public health priority in 2000, with a thrust on the promotion of voluntary donation and screening of all donated blood for a range of infections. All Member States of the SEA Region have policies in place for screening blood and blood products for hepatitis B and C with quality-assured techniques. The prevalence of hepatitis B among blood donors was found to range between 0.8% and 6.7%, and that of hepatitis C between 0.1% and 3.5%.

The Regional Action Plan (RAP) for viral hepatitis in South-East Asia (2016–2021) provides a roadmap to an effective and efficient response for the prevention, diagnosis, management and care of viral hepatitis. It outlines a package of essential interventions adapted to the country context for prevention, diagnosis and treatment of viral hepatitis in order to reduce its burden, with the objective of achieving regional and global targets.

The interventions include scaling up hepatitis B vaccination, PMTCT of hepatitis, ensuring blood safety, prevention of viral hepatitis in health-care and other settings, prevention of transmission among special subgroups, and increased access to diagnosis and treatment services. For each of these actions, specific targets were set. Table 3.1 summarizes the targets set in the RAP and the current status.

3.1 Coverage of timely hepatitis B birth dose

Vaccination against hepatitis B is an important tool in preventing HBV transmission, especially from a hepatitis B-positive mother to her new-born baby. Most chronic HBV infections are acquired in infancy through perinatal or early childhood transmission. Of these, 80–90% of infections acquired prior to the age of 1 year will progress to chronic infection. WHO recommends at least three doses of hepatitis B vaccine (HepB), with the first dose ideally given within 24 hours of birth (HepB-BD) followed by two to three additional doses to prevent perinatal and childhood infections with an interval of at least 4 weeks between doses.
### Table 3.1: Progress on key targets of the RAP for viral hepatitis in the WHO SEA Region

<table>
<thead>
<tr>
<th>South-East Asia</th>
<th>Indicator</th>
<th>Baseline estimates in the SEA Region (2015)</th>
<th>Targets in the RAP (By 2020)</th>
<th>Progress on the RAP targets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B vaccination</td>
<td>HepB3 coverage</td>
<td>87%</td>
<td>95%</td>
<td>91%&lt;sup&gt;15&lt;/sup&gt;</td>
</tr>
<tr>
<td>HBV PMTCT</td>
<td>Hep B birth dose coverage</td>
<td>34%</td>
<td>90%</td>
<td>54%&lt;sup&gt;15&lt;/sup&gt;</td>
</tr>
<tr>
<td>Blood safety</td>
<td>Proportion of non-remunerated voluntary blood donations.</td>
<td>77% (2011–2012 data)</td>
<td>100%</td>
<td>80%&lt;sup&gt;16&lt;/sup&gt; (2013–2015 data)</td>
</tr>
<tr>
<td>Injection safety</td>
<td>Proportion of unsafe injections</td>
<td>5.2%</td>
<td>0%</td>
<td>5.2–6.6%&lt;sup&gt;17,18&lt;/sup&gt;</td>
</tr>
<tr>
<td>Harm reduction</td>
<td>Number of syringes and needles distributed/PWID/ year</td>
<td>29</td>
<td>200</td>
<td>157 [3–366]&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
<tr>
<td>Testing services</td>
<td>Proportion of HBV-infected diagnosed</td>
<td>3%</td>
<td>50%</td>
<td>10.5%</td>
</tr>
<tr>
<td></td>
<td>Proportion of HCV-infected diagnosed</td>
<td>9%</td>
<td>50%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Treatment</td>
<td>Proportion of HBV diagnosed persons initiated on treatment</td>
<td>NA</td>
<td>75%</td>
<td>4.5%</td>
</tr>
<tr>
<td></td>
<td>Proportion of HCV diagnosed persons initiated on treatment</td>
<td>7%</td>
<td>75%</td>
<td>23.8%</td>
</tr>
</tbody>
</table>

Source: Details of the sources of these data are provided in the respective narrative sections for each of the interventions.

The following three immunization targets were set under the RAP for all Member States:

- By 2018, all countries should have included and scaled up implementation of HepB-BD coverage up to 75% and three doses of HepB (HepB3 coverage) up to 90%.
- By 2020, all countries that have a HepB-BD policy should have reached 90% coverage and 95% HepB3 coverage.
- By 2020, all countries should have started implementation of routine HepB vaccination among high-risk groups, including health-care workers.

Hepatitis B vaccination is also covered under SEA Regional Vaccine Action Plan 2016–2020 (RVAP) with the following coverage targets: ≥90% for the third dose of hepatitis B vaccine (HepB3) and birth dose nationally and ≥80% in all districts. The priority sequence of interventions followed in the RVAP is universal HepB3, timely HepB-BD, catch-up vaccination in younger children and vaccination of high-risk groups. All national immunization programmes follow RVAP targets. In 2016, the SEA Region Immunization Technical Advisory Group (ITAG) endorsed a regional hepatitis B control goal with a target of achieving ≤1% hepatitis B surface antigen (HBsAg) seroprevalence by 2020 among children aged at least 5 years, which is in line with the WHO GHSS. By December 2016, all 11 Member States in the Region had introduced HepB3 in their national immunization schedules and eight countries had included universal HepB-BD. This report is focused on targets set under the RAP for viral hepatitis.
Universal administration of hepatitis B vaccination to new-borns, ideally within 24 hours of birth, is part of national immunization policies in all Member States of the SEA Region, except in Bangladesh, Nepal and Sri Lanka. The HepB-BD coverage in countries where vaccination is administered ranged between 17% and 99% in 2019 (Fig. 3.1). During 2016–2019, the regional HepB-BD coverage increased from 34% in 2016 to 54% in 2019.15

Three countries in the Region – DPR Korea, Maldives and Thailand – achieved the WHO 2020 regional target of 90% coverage in 2019 itself. The remaining countries – Bhutan, India, Indonesia, Myanmar and Timor-Leste – are yet to reach the target. One of the main reasons cited for low coverage is the large number of deliveries taking place at home or at subcentre level where a cold chain is not available for vaccine storage. Vaccine wastage from the use of multidose vials, lack of training of health-care workers, fear of the side-effects of injections given right after birth and limited knowledge among health-care providers of the requirements for and importance of timely HepB-BD are some other challenges. Bangladesh, Nepal and Sri Lanka do not have a birth dose policy but rely on high HepB3 coverage.

**Fig. 3.1: Coverage of hepatitis B vaccination at birth (BD), 2019 (all values are percentages)**

![Chart showing hepatitis B vaccination coverage at birth by country, 2019](image)

**Note:** Green: 2018 target achieved; Yellow: not yet achieved | Bangladesh, Nepal and Sri Lanka do not have a birth dose policy.


**Innovation helps to overcome challenges**

Improving coverage of the timely hepatitis B vaccine birth dose is essential to prevent mother-to-child and early horizontal transmission of hepatitis B but is not always easy to achieve. Countries are adopting innovative ways of overcoming challenges, particularly for deliveries outside of health facilities. The use of an open vial policy to reduce the wastage of monovalent hepatitis B vaccine in India has helped improve the birth dose coverage. Promoting deliveries in health facilities is known to increase timely birth dose coverage. It is also important to adequately train health-care workers on various aspects of immunization, including management of adverse events and ensuring the availability of the vaccine and cold chain in delivery wards. Standing orders need to be in place assigning responsibility for vaccine administration,
along with the availability of skilled birth attendants. Pursuing such comprehensive strategies will help India to bring the birth dose coverage (56%) to the same level as of births taking place in health facilities (80%).

To reach out to infants born outside health facilities and to enable midwives and traditional birth attendants administer the birth dose, national policies in Indonesia and Timor-Leste mandate the use of compact pre-filled auto-disable injection device (CPAD) for delivering the vaccine. Another challenge is the lack of a cold chain for vaccine storage to enable vaccinations for home births. Indonesia has implemented the use of CPAD outside of the cold chain in hard-to-reach areas. Yet another intervention that is helping to increase timely vaccination of birth dose in remote, hard-to-reach areas is educating mothers about the importance of a timely birth dose during their antenatal care (ANC) visits. Community health workers are also being linked to health facility staff to inform them of recent births. Birth dose vaccination is also being integrated with essential maternal and new-born care.

### 3.2 Coverage of the third dose of hepatitis B vaccine

According to WHO recommendations, the timely HepB-BD should be followed by two to three additional doses with an interval of at least 4 weeks between doses to prevent perinatal and early childhood infections. All Member States of the SEA Region have national policies for including hepatitis B vaccination in their routine immunization schedules. The target set under the RAP was to achieve 90% HepB3 coverage by 2018.

**Regional target for HepB3 coverage:** To achieve 90% coverage by 2018 and 95% coverage by 2020

Nine countries reported ≥90% HepB3 coverage in 2018; the remaining two (Indonesia and Timor-Leste) achieved coverage rates of 85% and 83% respectively (Fig. 3.2). Six countries in the Region – Bangladesh, Bhutan, DPR Korea, Maldives, Sri Lanka and Thailand – have achieved 95% HepB3 coverage, which is the target for 2020.

**Fig. 3.2: Coverage of third dose of hepatitis B vaccine, 2019 (all values are percentages)**

![Graph showing coverage of HepB3 for various countries in 2019](https://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucovareghepb3.html)

**Note:** Green: 2018 target achieved; Yellow: not yet achieved

Achieving HepB3 coverage of ≥90% over a period of 5 years would be essential to reach the hepatitis B control target of achieving a prevalence of less than 1% HBsAg in 5-year-old children by 2020. Four countries – Bangladesh, Bhutan, Nepal and Thailand – have been verified by an independent expert panel to have achieved the 2020 regional hepatitis B control goal by December 2019.

India, Indonesia, Myanmar and Timor-Leste are not likely to achieve the hepatitis B control target despite the progress made in scaling up immunization. This is mainly due to low coverage at subnational levels; even in countries that have reached the coverage target at the national level. For example, in India and Indonesia, less than 80% of districts have achieved HepB3 coverage of ≥80%. In Nepal, national coverage was ≥90%; however, only 69% of districts achieved ≥80% HepB3 coverage.

Countries lagging in coverage at the subnational level could learn from strategies used successfully by other countries in the Region. These include mapping high-risk areas to identify all children and reduce drop-outs; verifying complete vaccination on school entry; involving the private sector by provision of free vaccines; and addressing vaccine hesitancy by enhancing communication and social mobilization.

The RVAP also recommends catch-up immunization of older children in countries that have demonstrated sustained high vaccination coverage among infants through routine immunization, including timely birth dose, and those countries have additional financial and human resources for enhanced hepatitis B control. Vaccination catch-up activities to reach the unvaccinated would be useful in improving HepB3 coverage in all districts to ≥80% and addressing persisting inequities.

### 3.3 Routine hepatitis B vaccination among high-risk groups and health-care workers

Five out of the 11 Member States in the SEA Region – India, Indonesia, Myanmar, Sri Lanka and Timor-Leste – have a policy of providing routine hepatitis B vaccination to high-risk groups (Table 3.2). Almost all (9/11) Member States in the Region have initiated routine hepatitis B vaccination among health-care workers (Table 3.2). However, coverage has not been evaluated in Member States where health-care workers are routinely vaccinated.

#### Table 3.2: Status of policy for routine hepatitis B vaccination among high-risk groups and health-care workers

<table>
<thead>
<tr>
<th>Policy for routine hepatitis B vaccination</th>
<th>Bangladesh</th>
<th>Bhutan</th>
<th>DPR Korea</th>
<th>India</th>
<th>Indonesia</th>
<th>Maldives</th>
<th>Myanmar</th>
<th>Nepal</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Timor-Leste</th>
</tr>
</thead>
<tbody>
<tr>
<td>high-risk groups</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>health-care workers</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

3.4 Prevention of mother-to-child transmission

Timely vaccination can help to prevent transmission of infection from infected pregnant women to their infants at the time of childbirth. Keeping this in view, the RAP identified PMTCT as a key area of the Strategy, with the following targets to be achieved by countries:

- By 2018, 75% of new-borns covered with the HepB-BD vaccination, ideally within 24 hours of birth, achieved in all countries implementing this policy;
- 75% of pregnant women screened for hepatitis B and post-exposure prophylaxis (PEP) provided to exposed new-borns in countries implementing such policies;
- By 2020, 90% of new-borns in countries are covered with the birth dose within 24 hours.

For achieving these targets, strategies devised for PMTCT are focused on the following actions – screening of pregnant women for hepatitis B infection; provision of post-exposure prophylaxis to exposed new-borns; in addition to administration of three doses of hepatitis B vaccination under the routine immunization schedule beginning with one dose within 24 hours of birth. Recently, WHO has recommended provision of tenofovir to HBsAg-positive pregnant women with a high viral load.\(^{23}\)

**Screening of pregnant women for hepatitis B infection:** The regional target was to reach 75% coverage for screening of hepatitis B among pregnant women by 2018.

**Regional target on PMTCT:** The regional target in the RAP for viral hepatitis was to achieve 75% coverage for screening of hepatitis B among pregnant women by 2018.

Most Member States of the Region have developed policies for screening pregnant women for hepatitis B. However, coverage estimates are not yet available from these Member States. On the other two interventions for PMTCT, the percentage of infants covered with the birth dose and HepB3 has already been described in Fig. 3.1 and 3.2.

**Post-exposure prophylaxis for exposed new-borns:** One of the strategies to prevent mother-to-child transmission is to provide post exposure prophylaxis with Hepatitis B immune globulin (HBlg) to new-borns exposed to infection. The regional target was to have a policy related to PEP in all Member States of the SEA Region by 2018. However, no data are available on policies for PEP in any Member State of the Region. Currently, Thailand is providing HBlg, in addition to the HepB-BD to infants whose mothers have a high viral load.

3.5 Blood and injection safety

The risk of transmission of hepatitis B and C through blood and blood products is high. Transmission of viral hepatitis through this route can be effectively prevented by encouraging universal screening of blood meant for transfusion, and blood donation by voluntary non-remunerated donors. All Member States of the SEA Region have formulated policies to ensure screening of all blood and blood products for hepatitis B and C by deploying quality-assured processes. Blood donors found positive for either or both these infections are notified of their status through haemovigilance, under the policies followed in those countries. The target is to have 100% non-remunerated blood donation in all Member States by 2020. According to the Regional Office report on blood transfusion services published in 2018, blood donation from non-remunerated donors had improved to 80% by 2015 from 77% in 2011–2012.\(^{16}\)

**Regional target for injection safety:** The regional target was to have a safe injection policy and policy related to infection prevention and control by 2020 in all Member States.
Injection safety in health-care settings was another challenge addressed in the RAP for action by countries, since HBV and HCV can spread through unsafe injection practices. Policies that encourage and promote injection safety and avoidance of unnecessary injections as well as infection control are vital for reducing the horizontal transmission of hepatitis B and C.

All the Member States in the SEA Region have adopted and are implementing safe injection as well as infection prevention and control (IPC) policies. However, no data are available on the percentage of injections administered through safety-engineered devices. The target under the RAP is to achieve administration of 50% of all injections with safety-engineered devices by 2020. An alternative indicator used to measure injection safety is the proportion of unsafe injections. A similar approach was used in the Global hepatitis report, 2017, i.e. in the absence of data on safety-engineered injection devices, data were presented on the proportion of unsafe injections with targets at 0% for 2020 and 2030. The regional average estimated for this indicator is in the range of 5.2–6.6% based on data available from four Member States in the Region.\(^1\)\(^{17,18}\)

3.6 Harm reduction among people who inject drugs

Harm reduction refers to a comprehensive package of services and interventions for PWID, including those aimed at prevention, treatment and care of infections such as HCV and HIV. The services range from information and education to access to the means of prevention – such as provision of clean needles and syringes, condoms – as well as an expanded range of treatment options, including opioid substitution therapy (OST). The RAP has prioritized sterile needle and syringe distribution programmes as well as OST among its targets. It has also set a target for overall adoption of harm reduction services by countries.

**Needle and syringe distribution.** One of the key interventions in the harm reduction package for PWID is distribution of sterile needles through structured needle and syringe programmes (NSP). The target for all countries was to develop and implement comprehensive harm reduction services by 2018. Six countries have developed and are implementing comprehensive and expanded harm reduction services for PWID, as shown in Table 3.3.

Bangladesh, India and Myanmar have already reached the 2020 target of distributing more than 200 syringes per PWID, while Indonesia, Nepal and Thailand have been distributing less than 100 syringes per PWID (Table 3.3).\(^19\) Based on these data, the average number of needles and syringes distributed per PWID in the Region is approximately \(^{19,17}\) ranging from 3 to 366 needles and syringes distributed per year. Even for countries with a higher coverage, it must be noted that the reported numbers are national averages, i.e. the average number per PWID per year in the respective countries. It is possible that within such good national averages, there could be some pockets that may have low coverage resulting in a higher incidence of bloodborne infections. Hence, it is important to ensure that distribution is equitable under the NSP.
Table 3.3: Needle and syringe distribution and provision of OST among PWID

<table>
<thead>
<tr>
<th>Target</th>
<th>Bangladesh</th>
<th>Bhutan</th>
<th>DPR Korea</th>
<th>India</th>
<th>Indonesia</th>
<th>Maldives</th>
<th>Myanmar</th>
<th>Nepal</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Timor-Leste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy of distribution of sterile needles and syringes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>At least 200 syringes/PWID/year provided</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>366</td>
<td>3</td>
<td>-</td>
<td>351</td>
<td>85</td>
<td>-</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>At least 40% of opioid-dependent PWID receive OST</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>19.5</td>
<td>10.5</td>
<td>-</td>
<td>17.2</td>
<td>2.8</td>
<td>-</td>
<td>5.3</td>
<td>-</td>
</tr>
</tbody>
</table>


Provision of OST for opioid-dependent PWID. Six countries – Bangladesh, India, Indonesia, Myanmar, Nepal and Thailand – are providing OST services to opioid-dependent users. In Maldives, where it was included as part of the National Strategic Plan for HIV, and implementation initiated, certain challenges have resulted in the closure of this service. None of the Member States of the SEA Region have achieved the 2020 target of providing OST to at least 40% of opioid-dependent PWID (Fig. 3.3)\(^4\).

Fig. 3.3: Opioid substitution therapy among PWID

Source: Global AIDS Monitoring (GAM) 2019 (https://digitallibrary.un.org/record/3801751?ln=en, accessed 11 September 2020) and UNAIDS Key populations atlas. (https://kpatlas.unaids.org/dashboard, accessed 11 September 2020). Most recent year estimates are used for population size (denominator) for all countries, except India, where 2012 estimates are used in line with the national AIDS programme.
3.7 Progress and gaps in diagnosis and treatment

Early diagnosis of hepatitis infection is critical for effective treatment and management of viral hepatitis. However, the asymptomatic nature of the infection, along with lack of awareness among those infected, makes early diagnosis highly challenging. Millions of people living with chronic viral hepatitis are simply not aware of their infection status. Globally, at the end of 2016, only 10% of the people (27 million) living with HBV knew their status, whereas for HCV this figure was 13.1 million, or 19% of the people living with HCV by the end of 2017.10

The GHSS, therefore, had emphasized the need for making those infected aware of their status and initiating treatment among those diagnosed. For this, it had proposed a target of diagnosing 30% of all people living with the hepatitis viruses by 2020 and 90% by 2030. Of those diagnosed, 5 million people living with HBV and 3 million people living with HCV are to be treated by 2020. The Strategy called for treating 80% of those eligible for HBV and HCV treatment by 2030. Current WHO guidelines suggest treatment for all people living with chronic HCV, irrespective of stage of liver disease. For HBV, treatment of non-cirrhotic patients commences when the viral DNA level is over 20 000 IU/mL.

Keeping this global approach in mind, the RAP (2016–2021) for the SEA Region recognized the need for Member States to develop national treatment guidelines, prepare disease burden estimates and frame testing policies by 2018. The RAP aimed that 50% of all those living with HBV and HCV should know their hepatitis status by 2020. Of those diagnosed with hepatitis B and eligible for treatment, 75% should be put on treatment and retained in care. Similarly, for hepatitis C, 75% of those diagnosed and are viraemic (confirmed to be infected with HCV) should be initiated on treatment and 90% of those treated should be cured. These targets were set considering the availability of pangenotypic direct-acting antivirals (DAAs) for HCV and effective medicines for HBV, and evidence of their proving to be critical in addressing viral hepatitis. Member States were urged to make use of these treatment options to achieve targets set under the RAP by registering these medicines and negotiating affordable prices with suppliers.

**Regional targets for diagnosis and treatment policy:**

1. By 2018, all countries with a high burden of viral hepatitis should have updated clinical treatment guidelines for HBV and HCV, which are aligned with the WHO guidelines.
2. The national disease burden and treatment needs are estimated in all high-burden countries.
3. By 2020, 50% of all persons with HBV and HCV know their status.

**Regional progress**

The first step towards achieving the RAP targets on diagnosis and treatment for Member States was to develop clinical guidelines and prepare estimates of disease burden as well as treatment needs. Nine Member States in the Region – Bhutan, India, Nepal, Indonesia, Myanmar, DPR Korea, Maldives, Thailand and Timor-Leste – have developed national treatment guidelines for viral hepatitis (Table 3.1). Nine out of the eleven Member States have developed testing policies as well, but data on screening for viral hepatitis in the general population are not available from any of them. Disease burden estimates for hepatitis C have recently been completed in the Region, while estimates for overall prevalence and the number who need hepatitis B treatment are still under development.

The progress on testing coverage for hepatitis B and C is slow in the SEA Region, as indicated in Table 3.1. Nine countries – Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Bhutan and Timor-Leste – have...
testing policies in place, while policy development is under way in Bangladesh and Sri Lanka. Since the SEA RAP had set a target of 50% of people living with HBV or HCV knowing their status, all Member States need extensive efforts to scale up testing and diagnosis. On the treatment front too, progress in the SEA Region needs to be accelerated. The coverage for hepatitis B and C is shown in Fig. 3.4.

**Treatment of viral hepatitis**

Effective antiviral agents against viral hepatitis B and C have the potential to dramatically reduce morbidity and mortality. Treatment with antiviral drugs such as Tenofovir can effectively suppress the virus among those with chronic hepatitis B infection. These antivirals are safe and can be given orally but need to be administered lifelong. The introduction of pangenotypic regimens of DAAs in 2013 revolutionized the treatment of chronic hepatitis C. DAAs can help to achieve high cure rates of over 95% with few side-effects. By 2019, six generic manufacturers had at least one DAA prequalified by WHO and a total of 62 low- and middle-income countries had registered at least one version of sofosbuvir + daclatasvir, sofosbuvir/ledipasvir and sofosbuvir/velpatasvir from the originator or generic manufacturers.

The RAP urged all countries with a high burden of viral hepatitis to have updated clinical treatment guidelines for HBV and HCV that are aligned with the WHO guidelines by 2018. The RAP aimed for 50% of all those living with HBV and HCV to know their hepatitis status by 2020. Of those diagnosed and eligible for treatment for hepatitis B, 75% should be put on treatment and retained in care. Similarly, for hepatitis C, 75% of those diagnosed and viraemic (needing treatment) should be initiated on treatment and 90% of those treated should be cured.

At the end of 2018, most of the Member States in the SEA Region had made little progress in achieving the target related to treatment (Fig. 3.4a and 3.4b).

**Fig. 3.4 HBV and HCV treatment cascade**

**Fig. 3.4a: HBV treatment cascade**

Source: the denominator for HBV (58.9 million) has been calculated based on the updated prevalence data provided in country profile annexes of the 2019 Kathmandu workshop report cited in this report, whereas the estimate of 39 million people living with chronic HBV mentioned elsewhere in this report is based on 2015 regional data in Global hepatitis report, 2017. Diagnostic and treatment data are from the following sources: Global reporting system for hepatitis (GRSH); country profile annexes of the 2019 Kathmandu workshop report, and Polaris Observatory.
Making treatment accessible and affordable

The availability of safe and effective treatment for HCV was a key motivating factor behind the move to put viral hepatitis on the global agenda of elimination. However, progress on this target is slow, as reflected in the huge gaps in treatment. This could be for several reasons. It appears that while most countries have registered generic medications for HBV, the recommendations relating to diagnosis and monitoring of patients with HBV are extensive and expensive. Many countries do not have a publicly funded programme for HBV diagnosis and treatment.

The RAP had addressed imperatives in universal health coverage (UHC) such as equity while setting targets for improving viral hepatitis services. It proposed that all Member States with a high burden of viral hepatitis should include recommended medical products for HBV and HCV testing and treatment in their respective national lists of essential medicines and essential diagnostics by 2019. This should be done based on updated clinical treatment guidelines. Member states could, alternatively, allow public procurement of medicines by relevant national formularies or health insurance coverage to ensure equity in access to viral hepatitis treatment. DAAs, which can potentially be a game-changing tool in addressing viral hepatitis, are part of the 2019 Essential Medicine List (EML) of WHO.

**Licensing of treatment products.** Though most Member States have licensed medications for the treatment of hepatitis B, they are witnessing a large gap between the number of people diagnosed with hepatitis B and number initiated on treatment. This can be attributed to the fact that the medications available are costly and are yet to be made widely available in public health-care systems. In two countries – DPR Korea and Maldives – medications for hepatitis B are yet to be made available.

For HCV treatment, the updated 2018 WHO guidelines recommend the use of pangenotypic regimens – sofosbuvir/daclatasvir, sofosbuvir/velpatasvir and glecaprevir/pibrentasvir. While Member States have worked out registration of these medicines at the national level, much work remains to be done to ensure the availability of quality-assured medications in national programmes at affordable costs. Sofosbuvir has received regulatory approval in most Member States, but other medicines that need to be administered with sofosbuvir are yet to be registered. The glecaprevir/pibrentasvir combination is yet to find a generic manufacturer, although a voluntary license was signed through the Medicines Patent Pool (MPP) in November 2018.

**Source:** Denominators for HCV are from the prevalence estimates from a systematic review conducted in 2020 described in earlier sections of the report. Diagnostic and treatment data are from the following sources: Global reporting system for hepatitis (GRSH); country profile annexes of the 2019 Kathmandu workshop report, and Polaris Observatory.
Overall, most Member States need to rapidly scale up treatment of HCV, levering increased national regulatory approvals and availability of DAAs.

**Affordability of treatment.** Treatment costs are high, as reflected in the estimates for the annual cost of treating one hepatitis B patient available for a few Member States in the Region. Drug costs are the lowest (US$ 115) in India, and the highest (US$ 360) in Bangladesh (Fig. 3.5). In Myanmar, the annual cost of the treatment in the private sector is estimated to be US$ 187 per patient. Most Member States in the Region are yet to design financing mechanisms to ensure universal affordability of these drugs.

**Fig. 3.5 Annual cost of treating a patient with hepatitis B with tenofovir (in US$)**

![Fig. 3.5 Annual cost of treating a patient with hepatitis B with tenofovir (in US$)](image)


The estimates for annual cost of treating a patient with hepatitis C (for a 12-week treatment regimen) is available for six countries (Fig. 3.6). The 12-week treatment cost varies widely and is lowest at US$ 30 in India while it is the highest in Thailand at US$ 1248.

**Fig. 3.6: Cost of hepatitis C treatment in the SEA Region (in US$)**

![Fig. 3.6: Cost of hepatitis C treatment in the SEA Region (in US$)](image)

**Source:** Information shared by Member States with WHO Regional Office in August 2020
Tackling hepatitis C through the universal health coverage (UHC) approach

In India, around 40 million people are infected with hepatitis B and at least 6 million with hepatitis C. About 176,000 people die each year due to complications of hepatitis B and C infection. This is twice the number of estimated annual deaths due to HIV and malaria together. Some Indian states have taken the lead in addressing this problem, using the UHC approach. The Mukhya Mantri (Chief Minister’s) Hepatitis C Relief Fund launched in 2016 in Punjab state is a good example. In about three years, over 33,000 persons have received free hepatitis treatment and care via a decentralized network of over 22 district hospitals and three government medical colleges. Over 19,000 persons had completed treatment by 2019, with a cure rate of more than 92%. Under this innovative service model, patients are systematically registered, given free treatment with DAAs and provided a certificate once they become hepatitis-free. As part of the initiative, health workers are trained in the requisite skills for detection and treatment of viral hepatitis C. For promoting prevention, the state is collaborating with the WHO Country Office for India in WHO’s injection safety project. This has made India one of three countries globally where this project is being implemented. It aims at increasing awareness and adoption of reuse prevention (RUP) syringes, using such syringes manufactured locally in India.26
4. Towards a hepatitis-free South-East Asia Region

With just over a decade to reach the SDG 3.3 goals for hepatitis, the urgency of adopting a “business unusual” model when addressing hepatitis B and C cannot be overstated. Progress in the SEA Region has been significant, though variable, with notable differences within and across countries. At the same time, some interventions have received much more attention than others – with marked improvements in HepB vaccination coverage when compared to the diagnosis and treatment of hepatitis B and C. Interventions such as HepB vaccination need to be sustained, and additional focus is needed on the birth dose. While the implementation of hepatitis B vaccine birth dose started relatively late in few Member States, coverage can be enhanced further through innovative and coordinated approaches by the maternal and new-born health services as well as immunization services. Progress in harm reduction and injection safety has also not been uniform. While single-use syringes are routinely used in vaccination programmes, they are not used universally within the health-care delivery system. With reference to harm reduction, opportunities to improve uptake of services through more user-friendly practices such as take-home doses of OST, are yet to be fully leveraged.

At the end of 2018 in the SEA Region, less than 5% of eligible chronically infected people with hepatitis B, and less than 24% of those with hepatitis C had received treatment with antivirals and DAAs respectively, despite access to generic drugs. Access to diagnosis and treatment of hepatitis B and C remains poor in several high disease burden Member States in the Region, and not all countries have been able to avail equally of opportunities to address barriers related to pricing, patents, product regulation and demand creation.
With the rapid progress in science and improved access to hepatitis screening and treatment technology, the Region is well positioned to mount an affordable and rapid response. Egypt, with the largest burden of hepatitis C infection in the world, has made advances since 2018 towards hepatitis C elimination through a massive countrywide effort to screen the entire population aged 18 years or older (a target population of 62.5 million people) within one year and link those in need to care. Nearly 50 million adults were screened, and 1 million additional persons were started on treatment by mid-2019. Other countries such as Georgia, Mongolia, Pakistan and Rwanda have also greatly expanded their programmes and shown a steely resolve in moving towards a hepatitis-free future.

Factors that have allowed this to happen can be context-specific and variable, but a common thread of strong political commitment and domestic resource allocation is clearly visible. Additionally, a comprehensive public health response that addresses patent- and regulation-related challenges specific to the country context, along with a meaningful partnership with civil society, are fundamental for advocating consistently for the rights of patients and those who are the most vulnerable.

**Ensuring political commitment**

Viral hepatitis needs to be accorded high priority within national health policies and programmes, given that it affects more people than HIV and TB combined. This can be done only if there are high-level champions within the political structure who make the investment case for additional resources and continue to advocate for an integrated and rights-based response. The creation of a political momentum around hepatitis will need not just high-level political advocacy at the head of state or ministerial level, but also within the echelons of the health and finance ministries where policy-makers juggle multiple priorities and allocate budgets and staffing.

**Engaging all partners through advocacy and communication**

Advocacy and communication campaigns on different aspects of viral hepatitis are critical to not only help raise awareness and generate demand but also galvanize a range of partners to engage in the elimination process. Successful templates from HIV and TB advocacy and communication campaigns may become useful and, wherever feasible, joint strategies for viral hepatitis, TB/HIV and sexually transmitted infections (STIs) could be considered. Influential public personalities as goodwill ambassadors for hepatitis in SEARO – as has been done in India with the Indian film legend Amitabh Bachchan – is one option. Using the virtual space of social media judiciously and working with the large private sector in the Region to foster effective partnerships for demand generation and effective service delivery would also contribute to more people testing and coming forward for treatment. Collaboration with the private sector has been routinely established in the TB programme with significant success in Member States of the SEA Region. Important lessons on how both traditional and non-traditional medical practitioners can be used to deliver accurate diagnosis and treatment in the community, with the use of judicious incentives, voucher systems and call centres to follow up patients, can be leveraged by hepatitis programmes.

**Improving access to diagnosis and treatment at the primary care level**

Despite the availability of treatment for HBV and HVC, there is a huge treatment gap in the Region, even in Member States with a sizeable burden of disease. It is evident that unless screening for HCV and HBV is undertaken at the primary care level, with effective referral mechanisms and decentralized treatment provision, the dream of a hepatitis-free future will remain just a dream. This can be done only with effective amplification of technology to leverage scarce resources (e.g. using rapid multiplex platforms for diagnostic screening), task-sharing (using all health cadres effectively for screening, counselling and treatment support), telemedicine (to reduce costs to patients and make treatment possible in hard-to-reach areas) and innovative
capacity-building measures such as digital learning (e.g. use of the Extension for Community Healthcare Outcomes [ECHO] Platform for case management and knowledge outreach). Examples of rapid scale up of HCV diagnosis and treatment at the community level such as in Punjab (India) utilizing the ECHO Platform demonstrates that this is feasible in low- and middle-income settings.

In line with global advocacy and good practices, countries such as Nepal and Thailand have also demonstrated effective treatment of HCV in community settings. In the absence of complications, and the ability to monitor patients effectively, treatment of hepatitis B and C does not need to be in tertiary care settings. A WHO systematic review on HCV provides compelling evidence for moving treatment out of speciality clinics, decentralizing testing and treatment, and using the “one-stop shop” approach.

Additionally, micro-elimination in specific populations – PWID, prisoners, adolescents, HIV/HCV coinfected, patients with haemophilia and those undergoing dialysis – is a real opportunity. These population groups are either already in contact with health facilities or relatively easy to reach. Many already know their status. Mobile units with same-day test-and-treat approaches can also be used in remote and hard-to-reach areas. Many countries in the Region already use this approach effectively for TB, where a vehicle with a cartridge-based nucleic acid amplification test such as the Xpert MTB/RIF assay system, or the TrueNAT MTB system, provides same-day diagnosis and opportunity for treatment commencement.

**Developing context-specific screening and diagnostic strategies**

Considering the low coverage of testing and diagnosis, there is an urgent need to accelerate and innovate on this front. In addition to awareness generation and efforts towards stigma reduction in health-care settings, prioritized strategies are required to ramp up testing and thereby increase the proportion of people living with chronic hepatitis who know their infection status. The question of which populations to screen using which screening and testing algorithm needs to be considered carefully in each country. In doing so, key considerations are: epidemiological evidence, laboratory infrastructure, resources and staffing available. In the SEA Region, few Member States have a hepatitis C burden exceeding 2% prevalence, and in these, careful consideration needs to be given to who receives which screening test, and at which level of the health system by national programmes, in consultation with civil society and the affected community. Each country needs to map laboratory resources and articulate clearly where and what the additional needs to investment are as part of a costed national action plan. Once laboratory capacity has been mapped and resources for testing are clearly visible to all providers in an area (e.g. by using an online tool), rapid sample transportation can be used to fully utilize existing capacity for diagnosis. Excellent new tools such the FIND Diagnostic Calculator as well as prequalification by WHO of dry blood spot technology providers (e.g. Abbott) can be effectively utilized as part of a wider strategy to improve access to screening and diagnosis.

**Integration with UHC**

Viral hepatitis has emerged on the global development and health agenda in the backdrop of the need to address diseases that affect the marginalized and poor, and the need to bring them under the umbrella of UHC. Integration of diagnosis, treatment and care services for hepatitis under UHC may help in reaching out to high-risk population groups and to those in underserved regions. Screening and diagnosis for HBV and HCV need to be included in the minimum package of essential health services. Testing and treatment for viral hepatitis can be progressively integrated with the health-care system in a decentralized manner. Similarly, existing vertical platforms such as for HIV and TB, as well as OST for PWID, provide further opportunities. Integration with UHC does not remove the need for strong technical and policy guidance from a central authority, whose role can range from standard-setting to monitoring, advocacy, regulation and procurement guidance. Core competence and staffing to address all these areas are essential and require investment. In the SEA Region, current levels of staffing for hepatitis programmes are variable, but generally suboptimal.
A key component of universal access is targeting the most vulnerable and hard to reach. In this context, stigma and discrimination are massive barriers to access, as they prevent people from seeking services, increase loss to follow up and impact treatment completion. Many Member States in the Region have documented the challenges of discrimination within the health system as well as in the community and families themselves. The protection of patient rights, confidentiality and respect need to be the cornerstone of service delivery – yet there is limited investment in this area by health facilities as well as by national programmes. Each programme can clearly outline a patient charter and include that as part of the standard of care for HCV and HBV in the country. Where possible, this work should be integrated with existing efforts that may be occurring within the health system, or leverage the vast experience of the HIV, mental health, TB and leprosy programmes in this area.

**Effective procurement and supply chain for diagnostics and drugs**

All Member States in the SEA Region have access to generic drugs or voluntary licence agreements. This has meant significant price reductions for drugs, but not for diagnostics. Therefore, the Region faces the dual challenge of not only needing to source quality-assured affordable drugs, but also leverage indigenous diagnostic platforms to help reduce the cost of diagnosis and treatment monitoring.

Four Member States in the Region have small populations while the remainder have large populations or land areas. This presents a different set of challenges for procurement and supply chain maintenance. The smaller Member States do not automatically benefit from price reductions associated with high-volume purchasing or the monopolistic purchasing power of large countries or health insurance schemes. To address this challenge, the United Nations Development Programme (UNDP) provides a procurement facility for quality-assured drugs at competitive prices where Member States can procure smaller volumes. Pooled purchasing is also an option, but this will require a coalition across these Member States, which will result in the need for a coordination mechanism to articulate demand and financing options.

For large countries, the issue of centralized versus decentralized procurement is an important one and both approaches have benefits and challenges. However, last-mile transportation, storage and stock management for hepatitis should be integrated where possible into the existing procurement system. Vendor-managed inventory systems (such as in Thailand under the National Health Security Office), can prevent stock-outs and wastage.

**Investing in strategic information and using data for effective decision-making**

Given that elimination of hepatitis B and C has become part of national plans relatively recently, it is understandable that investments in strategic information may be limited and variable in the Region. An incremental approach to generation of strategic information can be taken – starting with addressing the most basic information needs of disease burden at the national level and what health resources are available and where in the existing health system. Investing in burden estimations need not be hugely cumbersome or a stand-alone survey – where possible, this should be integrated into any national health survey. In the short term, aggregate data using a District Health Information Software (DHIS-2) system can be generated, which can progress in the medium term to an electronic case-based reporting system.

For any elimination programme, it is critical to target the disease in identified key populations. In the case of viral hepatitis too, key populations need to be addressed on a priority basis. In the Region, the extent of disease in such subgroups – attendees of ANC, blood donors, SWs, PWID, MSM, PLHIV – is not fully known. Only one subgroup, that of blood donors, has received consistent attention so far. Gaps in data on prevalence in other groups need to be plugged on an urgent basis so that their needs can be addressed with appropriate interventions.
Hepatitis B and C need to be integrated into existing surveillance systems – this is already the case in many Member States of the SEA Region, but these systems have tended to be passive surveillance systems. More recently, some Member States have also integrated HBV and HCV surveillance as part of integrated biological and behavioural surveys in PWID, MSM and SWs. However, other important groups remain unaddressed and each Member State may wish to identify other priority groups for surveillance.

Lastly, existing data need to be analysed regularly and used effectively for decision-making. Many Member States in the SEA Region have outstanding data analysis and visualization capacity used effectively in many health programmes or as part of national epidemiological bureaus. The first step is to work with the key nodal epidemiology agency for identifying core data needs and institutionalizing data collection and analysis on hepatitis B and C.

A partnership between hepatitis programmes and key academic and research organizations can also be formalized to support data analysis and operational research. Hepatitis-related research for practice to policy and policy to practice is relatively nascent in some Member States and documentation of good practices in the field (what worked, how and with what resources) in countries can contribute to policy-making.
References


Accelerating action towards a hepatitis-free future