

REGIONAL ACTION PLAN FOR
VIRAL HEPATITIS
IN SOUTH-EAST ASIA,
2016–2021



**World Health
Organization**

Regional Office for South-East Asia

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Acronyms and Abbreviations

AEFI	adverse effects following immunization
ANC	antenatal care
CSO	civil society organization
GAVI	The Vaccine Alliance
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HAV	hepatitis A virus
HBIG	hepatitis B immunoglobulin
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HepB3	third dose of hepatitis B vaccine
HEV	hepatitis E virus
IPC	infection prevention and control
M&E	monitoring and evaluation
MCH	maternal and child health
MoH	Ministry of Health
OST	opioid substitution therapy
PEP	post-exposure prophylaxis
PMTCT	prevention of mother-to-child transmission
PWID	people who inject drugs
SDG	Sustainable Development Goal
STI	sexually transmitted infection
TB	tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UHC	Universal health coverage

Foreword

Scientific advances and breakthroughs, coupled with global solidarity and commitment, have reversed the trend for most communicable diseases and but not viral hepatitis, an infection that is preventable and yet continues to exact a large toll on human lives. Chronic hepatitis B and C claim almost 1.35 million lives each year globally. An estimated 240–360 million people in the world have chronic hepatitis B and another 150 million chronic hepatitis C.

Asia bears the highest burden of viral hepatitis in the world. The WHO South-East Asia region has almost 130 million people living with chronic hepatitis B and C and an estimated 350 000 succumb to the infection and its complications each year. Hepatitis A and E – that are water and foodborne infections – have largely been controlled due to improved water, sanitation and hygiene; however, in many countries of the Region, multiple outbreaks of these totally preventable diseases continue to be reported.



The Action Plan (2016-2021) for addressing viral hepatitis in the WHO South-East Asia Region has been developed in consultation with Member States, community stakeholders, development partners, academia and professional societies. Drawing upon the Global Health Sector Strategy for Viral Hepatitis (2016–2021) and using the framework of universal health coverage to ensure that no one is left behind, the Action Plan provides a roadmap for priority areas of focus and interventions within the health and related sectors that are needed at the national level to mount an effective and efficient response to prevention, diagnosis, management and care of viral hepatitis.

With the goal of ending viral hepatitis as a public health threat by 2030, the Regional Action Plan will provide an actionable framework for implementing evidence-based interventions at scale. It will be informed through strategic monitoring of the response, that must be equitable and sustainable and allow for innovations for acceleration and reaching out to all in need with health services. A major reduction in prices of newer drugs to potentially cure hepatitis C offers an added opportunity to work towards its elimination.

I hope that Member States, partners, communities, institutions and other key stakeholders will find this Action Plan useful and help WHO in taking the agenda of viral hepatitis forward in the Region towards realization of the goals of the Action Plan.

A handwritten signature in black ink, which reads "Poonam Khetrpal Singh". The signature is written in a cursive, flowing style.

Dr Poonam Khetrpal Singh
Regional Director

SECTION 1

INTRODUCTION

Viral hepatitis now ranks as the seventh leading cause of mortality worldwide. Although mortality due to communicable diseases has declined globally, the absolute burden and relative ranking of viral hepatitis as a cause of mortality has increased between 1990 and 2013.

Viral hepatitis causes at least as many, if not more, deaths annually compared with TB, AIDS, or malaria. Mortality due to viral hepatitis is increasing with time, while that due to TB, HIV and malaria is declining. Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections account for more than 90% of viral hepatitis-related deaths and disability, with hepatitis A and E being responsible for the remaining.

Fig. 1. Mortality due to major communicable diseases, 2013

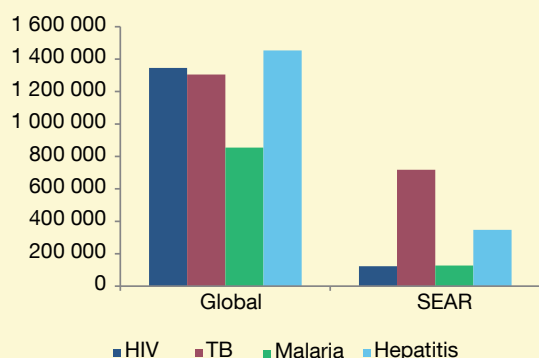
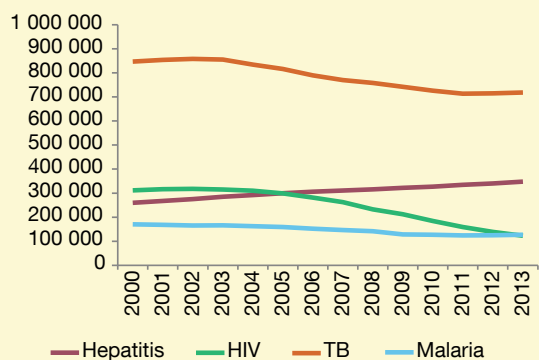


Fig. 2. Estimated number of deaths in the South-East Asia Region due to viral hepatitis, HIV, TB and malaria, 2000–2013



Source: Global Burden of Disease, 2013.

Globally, over 2 billion people, i.e. 1 out of 3 people, have been infected and an estimated 240 million people are chronically infected with hepatitis B.

Up to 686 000 people die each year from hepatitis B and its complications such as cirrhosis and liver cancer.

Globally, 130–150 million people are chronically infected with hepatitis C virus and 700 000 people die from hepatitis C each year.

Epidemiology and Burden of Disease in the South-East Asia Region

The South-East Asia Region of WHO has an estimated 100 million people living with chronic hepatitis B and 30 million people living with chronic hepatitis C.¹ Every year, in the Region, viral hepatitis is responsible for an estimated 350 000 deaths with 81% of total mortality being attributed to liver cancer and cirrhosis due to hepatitis B and C.²

The prevalence of hepatitis B and the routes of infection vary by country, within countries and by population group. The prevalence of chronic hepatitis B is above 8% in three countries: Democratic People's Republic of Korea, Myanmar

Fig. 3. Mortality due to viral hepatitis in the South-East Asia Region, 2013

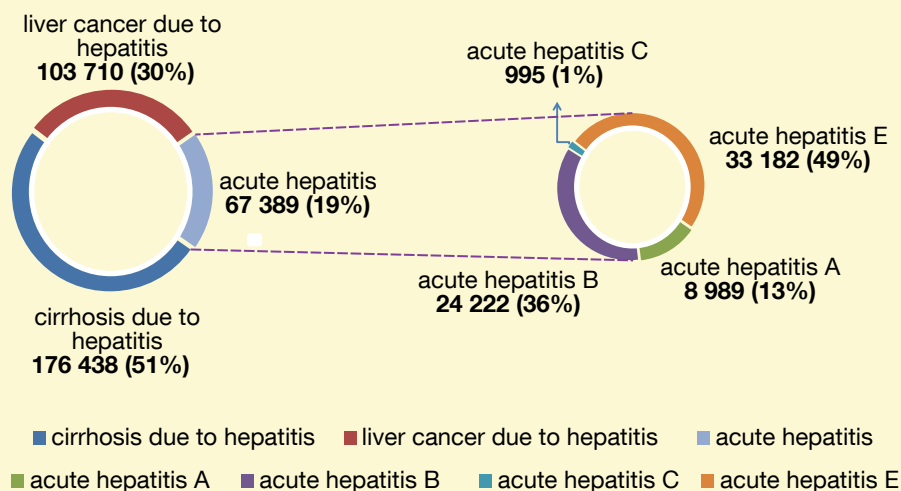
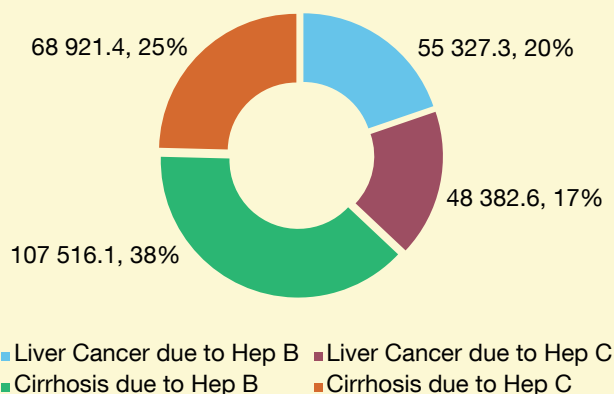


Fig. 4. Liver cancer and cirrhosis due to viral hepatitis in the South-East Asia Region, 2013



Source: Global Burden of Disease, 2013.

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, with an HBsAg positivity rate below 2%.³

A recent study estimated HCV infection rates in the general population, from highest to lowest, as follows: Thailand 2.7%, Myanmar 1.7%, Bangladesh 1.3%, India and Indonesia with 0.8%.⁴ However, a follow-up study done in Thailand estimated the prevalence to be much lower at 0.94%.⁵ For the other countries the rates are lower than those estimated in a previous study,⁶ which suggested anti-HCV positivity rates

in the Region to be in the range of 2.0–3.4%. However, people who inject drugs (PWID) are disproportionately affected by HCV; almost 50% are infected.⁷⁻⁹

Hepatitis B vaccine has been available since 1982. However, uptake has been slow in many countries. Only Bhutan, Indonesia and Thailand introduced vaccination before 2000. Currently, 10 of the 11 countries in the Region provide three doses of hepatitis B vaccine as part of the schedule for pentavalent vaccine. Thailand provides the tetravalent vaccine. Seven countries – Bhutan, Democratic People’s Republic of Korea, India, Indonesia, Maldives, Thailand and Timor-Leste have introduced the hepatitis B birth

dose. Myanmar has recently reintroduced the birth dose.

In 2014, coverage with three doses of hepatitis B vaccine was 75% in the Region, an increase from 4% in 1992. Coverage is <90% in countries with large populations, such as India, Indonesia and Myanmar. Coverage with the birth dose is low and varies from 44% in India to >95% in the Democratic People's Republic of Korea, the Maldives and Thailand with a regional average of 52% in 2015.³

Outbreaks of waterborne and foodborne hepatitis due to hepatitis viruses A and E continue to be reported from countries in the Region, and there are an estimated 8900 and 33 000 deaths per year attributed to hepatitis A and E, respectively.² Outbreaks of hepatitis A have been reported from the Region, including 54 outbreaks from 2011 to 2013 in India,¹⁰ and a large outbreak with over 13 000 cases in 2009 in Sri Lanka.¹¹ Hepatitis E is endemic in Bangladesh, India and Nepal.¹²⁻¹⁴ In these countries, this virus is the most common cause of sporadic acute hepatitis, and outbreaks occur frequently. The outbreaks are often large, and may affect several thousand people. The mortality rate is low in the general population, but is high in specific subgroups, such as pregnant

women and persons with pre-existing liver disease (see Annex 3).

In 2011, the WHO Regional Office for South-East Asia developed a regional document – *Viral hepatitis in the WHO South-East Asia Region, 2011–2015*.¹⁵ The strategy was developed with key stakeholders and made a case for greater attention to be paid to viral hepatitis – know it; confront it. It called upon Member States to prioritize viral hepatitis and strengthen surveillance to know the burden of disease and to respond. During the lifetime of the strategy, major scientific breakthroughs, especially for hepatitis C treatment, and advocacy by the World Hepatitis Alliance on the disconnect between the massive burden of disease and lack of global commitment for viral hepatitis propelled a global momentum that culminated in the development of the Global Health Sector Strategy for Viral Hepatitis, 2016–2021 endorsed by all Member States at the World Health Assembly in May 2016.

This WHO South-East Asia regional action plan builds on the previous strategy, and integrates newer science and information that has since become available.

SECTION 2

REGIONAL ACTION PLAN

Goal

To eliminate viral hepatitis as a major public health threat in the Region by the year 2030

Purpose

To provide an actionable framework of evidence-based, priority interventions to support national responses for prevention, control and management of viral hepatitis

Guiding principles

- Government stewardship
- Universal health coverage
- Evidence-based policies, programmes and interventions
- Continuum of care and services
- Equity and respect for human rights
- Public health approach
- Partnership and collaboration with relevant sectors
- Involvement of communities and people living with viral hepatitis.

Strategic Directions

STRATEGIC DIRECTION 1: INFORMATION FOR FOCUSED ACTION

Robust data and information are critical for advocacy, political commitment, awareness, community mobilization, prioritization of interventions and populations, and monitoring to improve quality and outcomes.

Areas for intervention

- i. understanding the epidemic and the response
- ii. developing and implementing national plans of action for hepatitis.

Understanding the epidemic and the response

In view of the limited resources in the South-East Asia Region, it is important to target various interventions, services and investments strategically, keeping in view local epidemic. Information to guide action include the following:

- a. main modes of transmission of each hepatitis virus and risk factors for acquisition;
- b. specific populations and groups that are the most vulnerable, most at risk and most affected;
- c. stigma and discrimination faced by people infected with hepatitis B and C in health care, education and employment settings;
- d. disease burden, specifically of cirrhosis and hepatocellular carcinoma (HCC);
- e. coverage, quality and use of essential hepatitis services;
- f. identification of barriers in access to testing and clinical management services by people with, or at risk for viral hepatitis.

The hepatitis information system needs to be integrated into the national health information system to ensure standardized and coordinated reporting.

Country actions

- a. Identify a focal point and unit for viral hepatitis and convene a stakeholder group that includes people living with viral hepatitis for data-driven action needed for advocacy, planning, policy and programme implementation.
- b. Integrate viral hepatitis surveillance activities and indicators within national health information systems and tools, including for outbreak surveillance.
- c. Assess the national and, where indicated, subnational prevalence and burden of all forms of hepatitis and their sequelae, and develop a monitoring framework to help assess progress and monitor trends over time.
- d. Use modelling adapted to the local context for prioritizing interventions, geographical locations and populations.
- e. Monitor access to, uptake and quality of viral hepatitis services, disaggregated by different populations and geographical locations to guide service improvement.
- f. Ensure community participation and engagement led by the national programme and key stakeholders to obtain critical socio-behavioural information, and identify challenges and opportunities for improving access to services.
- g. Create or strengthen structures within the national programme to ensure participation of people infected with and affected by viral hepatitis to inform all aspects of service delivery from the perspectives of affected communities.
- h. Strengthen or establish a disease registry at the national level for liver cirrhosis and HCC (liver cancer).

WHO actions

- a. Support countries in adapting WHO normative guidance and tools on hepatitis surveillance, and monitoring and evaluation (M&E).
- b. Support countries in strengthening health information systems, including target-setting, planning, implementing, monitoring and evaluating the health sector response along the cascade of viral hepatitis prevention, care and treatment services.
- c. Provide technical support for the development of national estimates, and assessment of existing and required health system capacity for scaling up interventions for viral hepatitis.

- d. Support countries in modelling, projections, economic analyses and making an investment case for viral hepatitis.

TARGETS

By 2018, all Member States with high burden of viral hepatitis have completed national disease burden estimates.

By 2020, all Member States have hepatitis surveillance and M&E systems aligned with WHO guidance.

Developing and Implementing Evidence-Informed National Hepatitis Plan

The national hepatitis plan should be ideally integrated with the national health plan, and allow for a coordinated and efficient response with clear accountability and lines of responsibility at various levels of the health system. The plan also needs sustainable allocation of resources.

The national plans should have a clear advocacy, communication and resource mobilization strategy.

Country actions

- a. Convene a stakeholder group led by the Ministry of Health (MoH), specifically including people with viral hepatitis to develop and/or revise the national plans.
- b. Establish a national governance structure and coordination mechanism to oversee the national hepatitis response, integrated within the national health programme.
- c. Develop a national plan on viral hepatitis with costing to make a case for securing domestic financing and to mobilize external resources.
- d. Set national targets and define indicators to monitor and evaluate, and to report on the national hepatitis response.
- e. Optimize approaches to ensure a coordinated and integrated framework of action to ensure efficient and effective resource use.
- f. Engage with communities and key stakeholders across various national programmes, such as immunization, infection control, harm reduction, drug policy, food, water and blood safety, HIV and cancer, for an integrated health sector response.
- g. Engage with other sectors, such as education, immigration, police, labour and justice to reduce stigma and discrimination.

- h. Address regulatory issues in registration and use of drugs to improve access to affordable diagnostics and medicines for scaling up the viral hepatitis response.
- i. Use modelling to inform priority interventions.
- j. Regularly review the national hepatitis response.

WHO actions

- a. Provide technical assistance to countries for developing and/or revising their national plans, target-setting and prioritization, and provide support for implementation, monitoring and review.
- b. Convene meetings of stakeholders, including communities, civil society, people living with viral hepatitis, development partners and opinion leaders for ongoing consultation and dialogue to generate demand for services and address stigma and discrimination.
- c. Increase awareness of viral hepatitis through organizing activities, such as World Hepatitis Day.
- d. Provide technical support for modelling, cost-effectiveness and economic analyses.
- e. Support national programmes to strengthen regulatory and procurement issues.

National advocacy, communication and awareness-raising are important, as lack of information fuels stigma and discrimination, and deters health-seeking behaviours. A national communication strategy for advocacy and awareness among policy-makers and communities would help in increasing the demand for services for viral hepatitis, political commitment and resource mobilization. It would also help to reduce stigma and discrimination, including within health settings, through wider involvement of communities and other key stakeholders.

TARGETS

By 2018, all high-burden Member States have developed national action plans for viral hepatitis.

By 2020, all high-burden Member States have started implementation of national action plans that include a communication and advocacy strategy.

STRATEGIC DIRECTION 2: INTERVENTIONS FOR IMPACT

An essential intervention package for viral hepatitis prevention, treatment and care services is critical for planning scale up of implementation and for advocating inclusion in the national health benefit package. The package should include diagnostics, medicines and commodities relevant to the local context – both epidemiological and in terms of resource availability. Interventions should be driven by evidence and based on effectiveness, acceptability, feasibility, demand and ethical considerations.

Areas for intervention

- Prevention of transmission – vaccination, ensuring blood safety, prevention of viral hepatitis in health-care settings, prevention of mother-to-child transmission (PMTCT), prevention of transmission through injecting drug use, prevention of sexual transmission, access to safe water and safe food
- Diagnosing hepatitis infection and linking to care
- Access to and scaling up clinical management and care of chronic liver disease.

Prevention Of Transmission

1. Vaccination

Effective and safe vaccines are available for three hepatitis viruses – hepatitis A, B and E. Further, hepatitis D can be prevented through vaccination against hepatitis B.

Vaccination against hepatitis B is the most prevalent and also the most important. All countries in the South-East Asia Region have in place universal childhood immunization programmes against hepatitis B. However, implementation varies, particularly for the timely birth dose of hepatitis B vaccine due to multiple barriers, including policy, availability of supplies and personnel, home births, community acceptance, etc.

Country actions

- a. Strengthen routine immunization services to achieve and sustain a high coverage of the timely birth dose followed by two or three doses of hepatitis B vaccine as per the national childhood immunization schedule.

- b. Coordinate with maternal and child health (MCH) programmes to improve access to immunization for births outside of health facilities; and consider catch-up hepatitis B vaccination for children or adolescents with low coverage.
- c. Vaccinate priority adult population groups – contacts and families of people with hepatitis B, health-care workers and other high-risk groups, e.g. men who have sex with men, transgender people, sex workers, PWID, recipients of repeated blood/plasma transfusions, etc.
- d. Ensure an uninterrupted supply of quality vaccine to prevent vaccine stock-outs, prevent vaccine damage due to freezing or heat through improved training of staff, and promote the use of a controlled temperature chain for delivery of the hepatitis B birth dose where available.
- e. Improve data collection and mapping to identify poorly performing areas.
- f. Conduct advocacy and social mobilization to raise awareness among policy-makers, health providers, community workers, family members and caregivers on hepatitis vaccines.
- g. Measure programme performance through monitoring immunization coverage rates, including timely birth dose coverage, and impact, through hepatitis B seroprevalence surveys.

WHO actions

- a. Provide technical support to increase the coverage of hepatitis B vaccination, especially timely birth dose, and conduct quality hepatitis B sero-prevalence surveys to measure the impact of immunization.
- b. Update strategies for the control of hepatitis B such as through immunization, advocacy materials, implementation of the birth dose.
- c. Set up regional goals for hepatitis B immunization and control.
- d. Conduct advocacy to promote access to all hepatitis vaccines through expanding coverage of vaccines already in the national schedule, and include additional vaccines in the national schedule where relevant.
- e. Build capacity for surveillance of and response to adverse effects following immunization (AEFI).
- f. Conduct operational research to identify innovative strategies for increasing immunization coverage, especially for home births.

TARGETS

By 2018, all Member States have included and scaled up implementation of hepatitis B birth dose up to 75% and Hep B3 dose up to 90%.

By 2020, all Member States that have policy have reached 90% coverage with birth dose and 95% coverage with Hep B3.

By 2020, all Member States have started implementation of routine Hep B vaccination among high-risk groups including health-care workers.

2. Ensuring blood safety

Hepatitis B and C can be transmitted through contaminated blood and blood products and hence the need for strengthening blood safety. Ensuring availability of safe blood and blood products is one of the critical interventions for reducing transmission of hepatitis B and C.

Country actions

- a. Review and strengthen national policies and practices on blood safety that promote rational use of blood and blood products.
- b. Put in place mechanisms and systems for quality assurance of laboratory testing for viral hepatitis B and C to ensure a reliable supply of quality-assured screening assays.
- c. Strengthen systems for surveillance, haemovigilance^a and monitoring of the incidence and prevalence of viral hepatitis infections in blood donors, and monitor the risk of post-transfusion hepatitis.
- d. Conduct advocacy and communication to encourage nonremunerated voluntary blood donation, and rational use of blood and blood products.

WHO actions

- a. Provide technical support to countries for strengthening the management of safe blood supplies and the linkages between blood transfusion services and viral hepatitis services.

^a Haemovigilance is required to identify and prevent the occurrence or recurrence of transfusion-related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient.

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- b. Support countries with tools and technical assistance to establish systems for surveillance, haemovigilance and monitoring supplies of blood and blood products.
- c. Communicate the need and advocate for promoting nonremunerated, voluntary blood donations.
- d. Provide technical support and advocate for the rational use of blood and blood products.
- e. Provide technical support and advocate for measures, including universal precautions and safe biomedical waste management.
- g. Raise awareness of viral hepatitis transmission among health workers and auxiliaries, and advocate for the importance of **injection** safety and infection prevention.
- h. Address disinfection and sterilization practices in non-health settings, such as tattoo clinics, barber shops.
- i. Raise awareness and advocate among the public to reduce the demand for unnecessary injections.

TARGETS

By 2018, all Member States in the Region have haemovigilance systems in place and all donated blood is tested for HBV and HCV.

By 2020, all Member States have 100% nonremunerated voluntary blood donations.

3. Prevention of viral hepatitis infection in health-care and other settings

Hepatitis B and C can be transmitted through unsafe injection practices and other health-care procedures. In the South-East Asia Region, this route may account for the majority of transmission of HBV and HCV. In addition, some high-risk groups, such as PWID, patients on maintenance haemodialysis, are at particular risk of such transmission. WHO has launched an injection safety policy and global campaign to address this issue.¹⁶ It has also released a document on safety-engineered syringes for use in health-care settings.¹⁷

Country actions

- a. Establish or strengthen the national regulatory body on infection prevention and control.
- b. Strengthen and sustain routine infection prevention and control practices in health-care settings (public and private), including in laboratories, dental clinics, endoscopy clinics and haemodialysis units.
- c. Develop and implement a national safe injection policy and practices and, where feasible, promote the use of WHO prequalified safety-engineered injection devices.
- d. Ensure health-care provider safety, including access to immunization and post-exposure prophylaxis.
- e. Monitor outbreaks of infection in health-care settings.
- f. Allocate adequate resources and build staff capacity for infection prevention and control

WHO actions

- a. Provide technical support for developing, updating, implementing and monitoring infection prevention policies in health-care settings, including outreach services.
- b. Provide technical support for implementing WHO's injection safety policy, introduce safe injection devices, and monitor implementation and impact.
- c. Provide technical support for investigation of hepatitis infection outbreaks.
- d. Provide technical support for setting up and maintaining adequate regulatory structures for infection prevention and control.

TARGETS

By 2018, all Member States have adopted and implemented safe injection and infection prevention and control (IPC) policies.

By 2020, 50% of all injections in Member States are administered with safety-engineered devices.

4. Prevention of mother-to-child transmission

Hepatitis B is often transmitted from infected mothers to their infants around the time of childbirth. Vaccination against hepatitis B using the birth dose within 24 hours of birth followed by two–three doses of the vaccine within the first 6 months of life is an effective method of preventing vertical transmission. About 70–90% of perinatally infected newborns become chronic carriers. Screening of pregnant women and use of hepatitis B immunoglobulin (HBIG) in infants born to mothers with active infection is also helpful. There is emerging evidence that it may be possible to prevent mother-to-child transmission

through additional measures, such as the use of antiviral drugs, especially for mothers with a high viral load, although standard global guidance on this is awaited.

Country actions

- a. Introduce and improve coverage of a timely birth dose of hepatitis B vaccine, including coverage of births happening outside of health-care facilities, followed by immunization of infants with 2 or 3 doses as per the national schedule.
- b. In collaboration with the MCH programme, update national policies and guidelines on maternal and neonatal health, based on evolving WHO guidance on elimination of mother-to-child transmission of viral hepatitis.

WHO actions

- a. Provide technical support for advocacy and implementation of the hepatitis B birth dose followed by 2 or 3 doses of vaccine as per the national immunization schedule.
- b. Conduct implementation science research to improve access to vaccination for home births, including the use of a controlled temperature chain.
- c. Provide technical support to countries to implement an evidence-based package of interventions to eliminate mother-to-child transmission of hepatitis B, in coordination and collaboration with the MCH and immunization programmes.

TARGETS

By 2018,

75% of newborns covered with the HepB birth dose vaccination within 24 hours of birth achieved in all Member States implementing this policy.

75% of pregnant women screened for hepatitis B and post-exposure prophylaxis (PEP) provided to exposed newborns in Member States implementing such policies.

By 2020,

95% of newborns in Member States are covered with the birth dose within 24 hours.

5. Prevention of transmission through the sharing of injecting equipment

In PWID, a package of harm reduction services can help reduce the transmission of hepatitis C and B¹⁸. HCV is more easily transmissible than HIV. Harm reduction services need to be scaled up to provide an enhanced package of harm reduction interventions.

Country actions

- a. Ensure access to harm reduction services for people who use drugs.
- b. Address HBV and HCV-related stigma and discrimination while providing harm reduction services.
- c. Accelerate implementation of a comprehensive harm reduction programme, and expand it to cover prevention and testing for hepatitis B and C among vulnerable populations.
- d. Review and modify laws that restrict or criminalize activities of drug users and address institutional barriers for expanding harm reduction services.
- e. Link hepatitis and harm reduction services to facilitate integrated prevention, treatment and care for people who use drugs.
- f. Facilitate community engagement to reach unreached populations, improve access and reduce stigma.
- g. Ensure access to opioid substitution therapy (OST) for opioid-dependent individuals, including in closed settings.
- h. Ensure access to safe injections and needles, such as low dead-space syringes.
- i. Collaborate with communities to develop service delivery models to reach PWID with prevention, screening, treatment and care services for viral hepatitis.
- j. Integrate viral hepatitis services with those for TB, HIV, substance use and mental health.

WHO actions

- a. Provide technical support for designing, implementing and monitoring a comprehensive package of harm reduction interventions for the prevention of hepatitis B and C.
- b. Conduct advocacy for harm reduction interventions, and political commitment to facilitate access, including review of restrictive policies and institutional barriers.
- c. Advocate for political commitment and resource allocation for programmes with PWID.
- d. Provide technical support for assessing barriers to implementation of effective harm reduction interventions and provision of health services for PWID.

TARGETS

By 2018, all Member States with a high burden of viral hepatitis have developed and implemented comprehensive and expanded harm reduction services for PWID.

BY 2020, all Member States have achieved the target of at least 200 syringes/PWID and at least 40% of opioid-dependent PWID have received OST.

6. Prevention of sexual transmission

Hepatitis B and C can be transmitted through sexual contact. Although the contribution of heterosexual sex to the overall burden of infection is small, some population groups, such as men who have sex with men and heterosexual persons with multiple sex partners, are at increased risk.

Country actions

- a. Ensure access to comprehensive and evidence-based sexual and reproductive health services, including health promotion, education, prevention and management of sexually transmitted infections (STIs) for all, with specific focus on key and vulnerable populations.
- b. Strengthen sexual partner involvement and management, ensuring confidentiality and access to counselling, testing and treatment of STIs.
- c. Advocate for and communicate the importance of consistent condom use, especially for key populations, and ensure a continuous supply of quality condoms and lubricants.
- d. Engage with community organizations and networks to increase the demand for STI services and reach out to key populations.

WHO actions

- a. Provide technical support and guidance on comprehensive STI prevention and treatment services, especially for key and vulnerable populations.
- b. Provide support for reducing barriers to access to STI services, such as condoms and

TARGETS

By 2020, all Member States have programmes in place to provide comprehensive STI services, including access to condoms, lubricants, HIV and viral hepatitis testing, and linkage to care.

lubricants for key populations.

7. Ensuring access to safe water and safe food

Hepatitis A and E viruses are excreted in the faeces of infected persons and are transmitted primarily by the faecal–oral route. Several countries in the South-East Asia Region report periodic outbreaks of hepatitis A and E. Although self-limiting, some of these infections can lead to acute fulminant hepatitis and liver failure resulting in death. The risk of fulminant hepatitis is higher among the elderly and pregnant women with hepatitis E.

Country actions

- a. Ensure intersectoral collaboration with the water, sanitation and agriculture departments to ensure access to safe water, safe food, hygiene and sanitation.
- b. Advocate for and communicate the importance of safe food, water, hygiene and sanitation.
- c. Improve access to safe sanitation facilities and educate the public on safe disposal of human faeces.
- d. Put in place effective surveillance and outbreak response and reporting systems for hepatitis A virus (HAV) and hepatitis E virus (HEV).
- e. Engage and communicate with communities on prevention of transmission and early case-reporting.

WHO actions

- a. Support risk assessment and management of water supplies, food, sanitation and hygiene.
- b. Provide technical support for intersectoral collaboration to improve water and food quality.
- c. Provide technical support for outbreak investigation and reporting and monitoring of outbreaks.

TARGETS

By 2020, all Member States have effective outbreak response and surveillance systems in place to monitor HAV and HEV outbreaks and outcomes.

Diagnosing Hepatitis Infection

Early diagnosis is critical to timely initiation and scale up of treatment for viral hepatitis. Inadequate public and health-care provider awareness; the asymptomatic nature of infection during the early stages; limited laboratory capacity, quality assurance mechanisms and simplified point-of-care diagnostic tests; and lack of standard diagnostic algorithms are some of the challenges to scaling up testing for viral hepatitis. The diagnosis of people with viral hepatitis provides health services with a unique opportunity to provide these people with accurate information that will reduce the burden of infection on them and the community. Testing and diagnosis of people with viral hepatitis must be of benefit to the person being tested.

Country actions

- a. Develop evidence-based viral hepatitis testing guidelines and testing algorithms at the national level.
- b. Integrate viral hepatitis testing into health settings where feasible, e.g. HIV, antenatal care (ANC), key population intervention sites, noncommunicable diseases and cancer screening and treatment services.
- c. Prioritize populations and locations for testing, and modify testing approaches and strategies according to these.
- d. Strengthen the national laboratory system to ensure quality assurance for testing, including laboratory and point-of-care diagnostics, and confidentiality of test results.
- e. Improve the availability of affordable, quality diagnostic test kits for the diagnosis of viral hepatitis.
- f. Increase awareness and build capacity among primary care providers on testing for HBV and HCV.
- g. Establish and strengthen linkages between testing and other services.
- h. Engage with communities and conduct public awareness and advocacy for increasing the demand for testing services, especially for key and vulnerable populations.
- i. Develop and implement national testing policy with details on who will diagnose viral hepatitis, their roles and responsibilities, particularly for informing people that they are infected.

WHO actions

- a. Provide technical support for developing and validating national diagnostic algorithms for testing.
- b. Develop a regional network of quality-assured

- laboratories for expanding quality assurance, building capacity and horizontal collaboration.
- c. Provide technical support for developing testing guidelines, including decentralized testing approaches, and establishing quality assurance mechanisms.
- d. Facilitate access to quality-assured diagnostics, including point-of-care rapid tests and viral load testing.
- e. Develop best practice model of testing for viral hepatitis.

TARGETS

By 2018, all Member States with high burden of viral hepatitis have national viral hepatitis testing policies aligned with WHO guidelines.

By 2020, 50% of all persons with HBV and HCV know their status.

Enhancing Clinical Management of Chronic Liver Disease

Effective antiviral agents against hepatitis B have been available for some time and have been proven to reduce liver disease. In recent years, with the breakthroughs in highly successful treatment and cure for hepatitis C and price reductions, the landscape for the treatment of HCV has changed dramatically. There is a potential for dramatically reducing morbidity and mortality, including from coinfection with HIV. The availability of safe, oral, fixed-dose pangenotypic combinations provide a historic opportunity for fast-tracking and scaling up the public health response to HBV and HCV.

Patients with chronic viral hepatitis infection may require a range of health services, such as for chronic liver disease, cancer care, psychosocial support and end-of-life care.

Country actions

- a. Ensure access to clinical management for hepatitis B and treatment for hepatitis C in the public sector.
- b. Ensure availability of diagnostics for staging of chronic liver disease to prioritize and plan treatment and clinical management.
- c. Ensure registration and licensing of newer medicines and necessary national legislations for improving access to affordable medicines for treating viral hepatitis.

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- d. Make effective use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to improve affordable access to oral antiviral medicines for treating hepatitis B and C.
- e. Develop standard guidelines, plans and protocols for treatment of various forms of hepatitis in line with the latest evidence and guidance from WHO.
- f. Build capacity of health-care providers in the use of newer medicines and follow-up of patients on treatment.
- g. Review the infrastructure of existing health systems and strengthening it where necessary for implementing and scaling up treatment for viral hepatitis, and conduct research to identify barriers to access.
- h. Prioritize and focus on designing phased implementation of treatment programmes.
- i. Engage with the private sector to implement national standards, reporting and price regulation.
- j. Expand access to quality standard treatment through decentralization and public–private partnerships.
- k. Strengthen M&E for timely treatment initiation, response to treatment, drug toxicity and adverse events.
- l. Monitor the cascade of treatment and care to identify and address barriers to early linkage and retention in care.
- m. Address common comorbidities, including HIV infection and risk factors that may accelerate progression of liver disease, and improve access to palliative and end-of-life care.
- n. Post-treatment/cure, monitor patients for cirrhosis and HCC, including the need for liver transplantation.

WHO actions

- a. Provide technical assistance and support to countries for developing and updating standard treatment guidelines and protocols.
- b. Identify the barriers to management and care services for people with viral hepatitis.
- c. Provide technical assistance to build capacity for decentralized service delivery.
- d. Conduct implementation science research for innovations in diagnostics and service delivery.
- e. Expand partnerships and collaborations with communities and civil society organizations (CSOs) for advocacy and resource mobilization for hepatitis.
- f. Provide technical support for registration of newer medicines and devices, price negotiations and use of TRIPS flexibilities for improved and affordable access.

TARGETS

By 2018,

All Member States with a high burden of viral hepatitis have updated clinical treatment guidelines for HBV and HCV that are aligned with WHO guidelines.

National disease burden and treatment needs are estimated in all high-burden Member States.

By 2020,

75% of all patients are diagnosed with chronic hepatitis and those eligible begin treatment.

90% of HCV patients treated achieve viral suppression and cure.

STRATEGIC DIRECTION 3: DELIVERING FOR EQUITY

In the era of the Sustainable Development Goals (SDGs) and universal health coverage (UHC), it is imperative to have national plans that aim to provide equitable services within an enabling environment. This strategic direction looks into optimized service delivery and health-care models that reach all people in need under the UHC framework and respects human rights.

The areas that need to be looked into to deliver for equity include the following:

- improving viral hepatitis services
- strengthening human resources
- promoting an enabling environment.

Improving Viral Hepatitis Services

Country actions

- Identify and prioritize most affected populations and locations for expanding access to services and service delivery.
- Engage with the community and involve people infected with and affected by viral hepatitis to inform policy-making, programme implementation and monitoring for impact.
- Conduct implementation research for community engagement in policy-making and developing innovative service delivery models.
- Ensure quality assurance through implementation and monitoring of evidence-based norms and standards in the public and private sectors.
- Strengthen monitoring and information systems to include indicators that capture the quality and equity of services, including access to services and use by different populations and in different settings.
- Initiate dialogues with key stakeholders such as Industry, Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the Vaccine Alliance (GAVI) to improve access to viral hepatitis prevention, care and treatment services.
- Optimize and rationalize distribution of testing and treatment services to reach all those in need.
- Use existing diagnostic platforms in other disease control programmes such as GeneXpert from TB or HIV viral load platforms for diagnosis of viral hepatitis.
- Include viral hepatitis services in the universal benefit package.

WHO actions

- Provide technical support for implementation research on community involvement and decentralized service delivery.
- Provide technical support for developing innovative service delivery models to expand access to testing and treatment for viral hepatitis, and reach hard-to-reach population groups.
- Provide technical support for monitoring the continuum and quality of care for prevention, control, diagnosis and treatment of viral hepatitis.
- Provide technical support for evaluating the use of existing diagnostic platforms to expand diagnostics for viral hepatitis.

TARGETS

By 2018, all high-burden Member States have expanded services for prevention, control and treatment of viral hepatitis to the district level.

By 2020, 50% of Member States have included viral hepatitis services in the UHC benefit package.

Strengthening Human Resources For Hepatitis

There are opportunities for integrating viral hepatitis services within the broader health services. Simplified testing and treatment provide an opportunity for decentralizing viral hepatitis services to health workers, including those at the primary level, provided they are trained and have the requisite skills. Community and peer-led interventions and approaches play an important role in reaching out to key and vulnerable populations, and form a critical link between people and health systems. HIV programmes could provide important lessons for community mobilization and involvement, and existing networks could be used for scaling up services for viral hepatitis, especially coinfections.

Country actions

- Review and strengthen pre-service and in-service curricula of health-care cadres to include knowledge, skills and capacity-building for managing viral hepatitis at various levels of health-care service delivery.

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- b. Identify opportunities for task-shifting and task-sharing to extend the capacity of the health workforce, including community health workers, while ensuring supportive supervision and mentoring for frontline service delivery.
- c. Implement measures to reduce the risk of transmission of viral hepatitis in health-care settings, and ensure the safety and security of health-care providers.
- d. Ensure access to PEP and treatment for health-care providers infected with viral hepatitis B and C.
- e. Increase awareness and training of health-care workers to reduce stigma and discrimination in health-care settings.

WHO actions

- a. Provide technical guidance and support for training health-care workers.
- b. Provide technical support for designing, implementing and monitoring decentralized service delivery.
- c. Support national accreditation bodies to review and update pre-service and in-service curricula to include knowledge of and skills in diagnosing and treating viral hepatitis.
- d. Advocate for reducing stigma and discrimination against health-care workers living with viral hepatitis.

Ensuring Access to Quality and Affordable Hepatitis Vaccines, Medicines, Diagnostics and Other Commodities

An uninterrupted supply of high-quality vaccines, diagnostics, medicines and other commodities is essential for an effective and equitable hepatitis programme. This requires efficient systems for quality assessment, product registration in countries, procurement at reasonable prices, and an efficient supply chain management and pharmacovigilance. These ensure that all the necessary goods can be delivered at points of health-care delivery in a timely manner and in adequate amounts, while avoiding wastage.

Country actions

- a. Strengthen the national hepatitis procurement and supply management structures and processes by ensuring that they are integrated into the broader national procurement and supply management systems.
- b. Ensure the procurement of quality-assured hepatitis vaccines, medicines, diagnostics,

condoms, and other hepatitis-related commodities, including through the use of WHO prequalification.

- c. Plan and implement an access strategy for hepatitis medicines and commodities to reduce the prices of hepatitis-related commodities, such as fast-tracking registration of new medicines, negotiating prices and using the provisions of TRIPS flexibilities.

WHO actions

- a. Support innovative strategies to reduce the prices of vaccines, medicines, diagnostics and other commodities for viral hepatitis.
- b. Provide technical support to countries to forecast the need for essential commodities related to viral hepatitis.
- c. Support national regulatory authorities in pre-market assessment and registration of new medicines and diagnostics for viral hepatitis, with post-market surveillance.
- d. Provide technical support for quality assurance of diagnostics and medicines.
- e. Provide technical advice on joint procurement mechanisms and access to generic medicines.
- f. Promote information-sharing on medicines and diagnostics prices across Member States through online price reporting systems.

TARGETS

By 2018, all high-burden Member States have registered the medicines for HBV and HCV, and have negotiated the prices of medicines.

Promoting an Enabling Environment

Legal, institutional and social barriers prevent access of certain population groups to preventive and curative services. People with viral hepatitis may face stigma and discrimination, social marginalization, and restricted access to education and employment opportunities as a result of the infection.

Existing laws and legislations and service delivery mechanisms will need to be reviewed and adapted to provide an enabling environment wherein people in need can access services without fear.

Country actions

- a. Review laws, policies and institutional mechanisms that restrict access to hepatitis prevention and treatment interventions for most affected and vulnerable groups.
- b. Address stigma and discrimination, especially in health-care, education and employment settings.
- c. Include indicators in the M&E plans to measure quality and equity (including gender equity) of services.
- d. Collaborate and partner with CSOs and other stakeholders to create an enabling environment for effective, equitable and efficient programme scale-up.

WHO actions

- a. Provide technical support for reviewing laws and policies to ensure that they are in line with WHO guidelines on gender, equity and human rights.
- b. Provide technical support for measuring the equity and quality of service delivery, stigma and discrimination faced by affected communities, including in health-care settings.

TARGETS

By 2020, all high-burden Member States have identified legal barriers, and reviewed and revised restrictive laws and policies limiting the full participation of people with viral hepatitis within society.

STRATEGIC DIRECTION 4: FINANCING FOR SUSTAINABILITY

People should receive the hepatitis services they need without experiencing financial hardship.

There is a need for sustainable financing models, innovative financing and enhancing efficiencies within existing systems through a linked and integrated response.

Adequate resources would be needed to end viral hepatitis as a public health problem and yet there are very few international donors for it. There is increased reliance on domestic resources that are already strained in responding to communicable diseases as countries graduate from receiving funding from GAVI and the Global Fund.

In the era of sustainable development, countries must ensure that they include the essential services for viral hepatitis within the UHC package.

Country actions

- a. Develop a national investment case for viral hepatitis to advocate for and make a case for adequate resource allocation.
- b. Include essential interventions for hepatitis prevention and management within the universal benefit package.
- c. Ensure sustainable financing for harm reduction interventions.
- d. Explore alternative and innovative financing mechanisms to reduce catastrophic health expenditures.
- e. Identify opportunities for resource-sharing, such as infrastructure, human resources and finances in other related programmes for scaling up implementation of viral hepatitis interventions effectively and efficiently, e.g. coinfection management in HIV, MCH and immunization programmes for vaccination and PMTCT, harm reduction services, blood and injection safety, infection prevention services, surveillance and M&E.

WHO actions

- a. Provide technical assistance and support to develop investment cases.
- b. Advocate for inclusion of essential prevention, diagnostics and clinical management of viral hepatitis in the universal benefit package.
- c. Support countries in assessing and monitoring health service costs and cost-effectiveness.

- d. Advocate for increased political commitment to increase allocation of domestic resources and mobilize resources from external development partners.
- e. Review and assess existing resources, including infrastructure and human resources within national health systems, which would be leveraged for implementing the national viral hepatitis strategy and plan.

TARGETS

By 2018, at least 50% of high-burden Member States have developed national investment cases for viral hepatitis.

By 2020, all Member States implementing UHC have included viral hepatitis services in the national benefit package.

STRATEGIC DIRECTION 5: INNOVATION FOR ACCELERATION

The targets set for 2020 and 2030 are ambitious. There is a need for innovations to scale up and expand services, and make better use of existing resources, including community resources. Newer methods such as crowdsourcing,^{b,19} and use of information technology can help scale up interventions and reach the communities and populations most in need. Innovations can also help improve the efficiency and quality of services for better impact and outcomes.

Some areas for research and innovation

- Prevention of viral hepatitis, such as hepatitis B vaccine including birth dose, safe injection equipment and practices, use of medicines for prevention of viral hepatitis, especially for PMTCT and prevention benefit of treatment
- Expanding testing, including point-of-care and rapid testing technologies
- Optimizing and simplifying diagnostic algorithms for improving early linkage to care for those in need
- Methods for decentralizing and simplifying service delivery across the hepatitis continuum of care
- Service delivery models, including task-shifting of clinical and nonclinical services and community-based approaches
- Identifying optimal ways to identify, recognize and sustain innovations within service delivery (e.g. innovation challenge contests)
- Use of crowdsourcing for spreading awareness, generating demand, monitoring service use and identifying innovative financing mechanisms.

Country actions

- a. Promote viral hepatitis as an important research area and allocate or raise the necessary resources.
- b. Embed implementation research in implementation plans to answer questions on scaling up coverage with quality, equity and ensuring financial protection.
- c. Ensure intersectoral collaboration across programmes for integrated service delivery models.
- d. Interlink monitoring systems for strengthening viral hepatitis data capture, analysis and use.
- e. Disseminate and use research findings to better inform programme planning and implementation.

^b Crowdsourcing is when a group of people, instead of a single expert, solves a problem.

WHO actions

- a. Provide technical support for designing implementation research projects within national plans.
- b. Provide technical support for monitoring, and documentation and dissemination of results.
- c. Facilitate intercountry and inter-institutional collaboration.
- d. Advocate for and facilitate innovations and implementation research within and across countries.
- e. Ensure knowledge management and maintain a repository of best practices and lessons learnt in innovations and use of newer technologies.

TARGETS

By 2020, all high-burden Member States have implementation science research projects for innovations in programme planning and service delivery.

ANNEX 1

TARGETS FOR THE REGIONAL ACTION PLAN

Priority area	Targets	Timeline
1. Information for focused action		
Understanding the epidemic and the response	All Member States with high burden of viral hepatitis have completed national disease burden estimates.	2018
	All Member States have hepatitis surveillance and M&E systems aligned with WHO guidance.	2020
Develop and implement evidence-informed national hepatitis plans	All high-burden Member States have developed national action plans for viral hepatitis.	2018
	All high-burden Member States have started implementation of national action plans that include a communication and advocacy strategy.	2020
2. Interventions for impact		
Prevention of transmission	All Member States have included and scaled up implementation of hepatitis B birth dose up to 75% and Hep B3 dose up to 90%.	2018
	All Member States that have policy have reached 90% coverage with birth dose and 95% coverage with Hep B3.	2020
	All Member States have started implementation of routine Hep B vaccination among high-risk groups including health-care workers.	2020
	All Member States in the Region have haemovigilance systems in place and all donated blood is tested for HBV and HCV.	2018
	All Member States have 100% nonremunerated voluntary blood donations.	2020
	All Member States have adopted and implemented safe injection and infection prevention and control (IPC) policies.	2018
	50% of all injections in Member States are administered with safety-engineered devices.	2020
	75% of newborns covered with the HepB birth dose within 24 hours of birth achieved in all Member States implementing this policy.	2018
	75% of pregnant women screened for hepatitis B and post-exposure prophylaxis (PEP) provided to exposed newborns in Member States implementing such policies.	2018
	95% of newborns in Member States are covered with the birth dose within 24 hours.	2020
	All Member States with a high burden of viral hepatitis have developed and implemented comprehensive and expanded harm reduction services for PWID.	2018
	All Member States have achieved the target of at least 200 syringes/PWID, and at least 40% of opioid-dependent PWID have received OST.	2020

Priority area	Targets	Timeline
	All Member States have programmes in place to provide comprehensive STI services, including access to condoms, lubricants, HIV and viral hepatitis testing, and linkage to care.	2020
	All Member States have effective outbreak response and surveillance systems in place to monitor HAV and HEV outbreaks and outcomes.	2020
Diagnosing hepatitis infection	All Member States with a high burden of viral hepatitis have national viral hepatitis testing policies aligned with WHO guidelines.	2018
	50% of all persons with HBV and HCV know their status.	2020
Enhancing hepatitis treatment and care of chronic liver disease	All Member States with a high burden of viral hepatitis have updated clinical treatment guidelines for HBV and HCV that are aligned with WHO guidelines.	2018
	National disease burden and treatment needs are estimated in all high-burden Member States.	2018
	75% of all patients are diagnosed with chronic hepatitis and those eligible begin treatment.	2020
	90% of HCV patients treated achieve viral suppression and cure.	2020
3. Delivering for equity		
Improving viral hepatitis services	All high-burden Member States have expanded services for prevention, control and treatment of viral hepatitis to the district level.	2018
	50% of Member States have included viral hepatitis services in the UHC benefit package.	2020
Ensuring access to good-quality and affordable hepatitis vaccines, medicines, diagnostics and other commodities	All high-burden Member States have registered the medicines for HBV and HCV, and have negotiated the prices for medicines.	2018
Promoting an enabling environment	All high-burden Member States have identified legal barriers, and reviewed and revised restrictive laws and policies limiting the full participation of people with viral hepatitis within society.	2020
4. Financing for sustainability		
Sustainability	At least 50% of high-burden Member States have developed national investment cases for viral hepatitis.	2018
	All Member States implementing UHC have included viral hepatitis services in the national benefit package.	2020
5. Innovation for acceleration		
Innovations	All high-burden Member States have implementation science research projects for innovations in programme planning and service delivery.	2020

ANNEX 2

TABLE OF ACTIONS

Priority area	Country actions	WHO actions
1. Information for focused action		
1.1. Understanding the epidemic and the response	<ol style="list-style-type: none"> 1. Identify a focal point and unit for viral hepatitis and convene a stakeholder group that includes people living with viral hepatitis for data-driven action for advocacy, planning, policy and programme implementation. 2. Integrate viral hepatitis surveillance activities and indicators within national health information systems and tools, including for outbreak surveillance. 3. Assess the national and, where indicated, subnational prevalence and burden of all forms of hepatitis and their sequelae, and develop a monitoring framework to help assess progress and monitor trends over time. 4. Use modelling adapted to the local context for prioritizing interventions, geographical locations and populations. 5. Monitor access to, uptake and quality of viral hepatitis services, disaggregated by different populations and geographical locations to guide service improvement. 6. Ensure community participation and engagement led by the national programme and key stakeholders to obtain critical socio-behavioural information, and identify challenges and opportunities for improving access to services. 7. Create or strengthen structures within the national programme to ensure participation of people infected with and affected by viral hepatitis to inform all aspects of service delivery from the perspectives of affected communities. 8. Strengthen or establish a disease registry at national level for liver cirrhosis and HCC (liver cancer). 	<ol style="list-style-type: none"> 1. Support countries in adapting WHO normative guidance and tools on hepatitis surveillance, and monitoring and evaluation. 2. Support countries to strengthen health information systems, including target-setting, planning, implementing, monitoring and evaluating the health sector response along the cascade of viral hepatitis prevention, care and treatment services. 3. Provide technical support for the development of national estimates, and assessment of existing and required health system capacity for scaling up interventions for viral hepatitis. 4. Support countries in modelling, projections, economic analyses and making an investment case for viral hepatitis.

Priority area	Country actions	WHO actions
1.2. Develop and implement evidence-informed national hepatitis plan	<ol style="list-style-type: none"> 1. Convene a stakeholder group led by the MoH and specifically include people with viral hepatitis to develop and/or revise national plans. 2. Establish a national governance structure and coordination mechanism to oversee the national hepatitis response, integrated within the national health programme. 3. Develop a national plan on viral hepatitis with costing to make a case for securing domestic financing and to mobilize external resources. 4. Set national targets and define indicators to monitor and evaluate, and to report on, the national hepatitis response. 5. Optimize approaches to ensure a coordinated and integrated framework of action for efficient and effective resource use. 6. Engage with communities and key stakeholders across various national programmes, such as immunization, infection control, harm reduction, drug policy, food, water and blood safety, HIV and cancer, for an integrated health sector response. 7. Engage with other sectors, such as education, immigration, police, labour and justice, to reduce stigma and discrimination. 8. Address regulatory issues arising from the registration and use of drugs for improving access to affordable diagnostics and medicines for scaling up the viral hepatitis response. 9. Use modelling for informing priority interventions. 10. Regularly review the national hepatitis response. 	<ol style="list-style-type: none"> 1. Provide technical assistance to countries for developing and/or revising their national plans, target-setting and prioritization, and provide support for implementation, monitoring and review. 2. Convene stakeholders, including communities, civil society, people living with viral hepatitis, development partners and opinion leaders, for ongoing consultation and dialogue to generate demand and address stigma and discrimination. 3. Increase awareness of viral hepatitis through organizing activities such as World Hepatitis Day. 4. Provide technical support for modelling, cost-effectiveness and economic analyses. 5. Support national programmes to strengthen regulatory and procurement issues.
2. Interventions for impact		
2.1. Prevention of transmission		
2.1.1. Vaccination	<ol style="list-style-type: none"> 1. Strengthen the routine immunization services to achieve and sustain a high coverage of timely birth dose followed by 2 or 3 doses of hepatitis B vaccine as per the national childhood immunization schedule. 2. Coordinate with the MCH programme to improve access to immunization for births outside of health facilities; and consider catch-up HBV vaccination for children or adolescents in areas with low coverage. 3. Vaccinate priority adult population groups – contacts and families of people with hepatitis B, health-care workers and other high-risk groups, such as men who have sex with men, transgender people, sex workers, PWID, recipients of repeated blood/plasma transfusions, etc. 4. Ensure vaccine supply and quality to prevent vaccine stock-outs, vaccine freezing or heat damage through improved training of staff, and promotion of the use of a controlled temperature chain for delivery of the hepatitis B birth dose where available. 5. Improve data collection and mapping to identify poorly performing areas. 	<ol style="list-style-type: none"> 1. Provide technical support for increasing hepatitis B vaccination coverage, especially timely birth dose, and conducting quality hepatitis B sero-prevalence surveys to measure the impact of immunization. 2. Update strategies for the control of hepatitis B through immunization, advocacy materials, implementation of the birth dose, etc. 3. Set up regional hepatitis B immunization and control goals. 4. Conduct advocacy to promote access to all hepatitis vaccines through expanding coverage of vaccines already in the national schedule, and include additional vaccines in the national schedule where relevant. 5. Build capacity for surveillance of and response to AEFI. 6. Conduct operational research to identify innovative strategies to increase immunization coverage, especially for home births.

Priority area	Country actions	WHO actions
	<ol style="list-style-type: none"> 6. Conduct advocacy and social mobilization to raise awareness among policy-makers, health providers, community workers, family members and caregivers. 7. Measure programme performance through monitoring of immunization coverage rates, including timely birth dose coverage, and impact through hepatitis B seroprevalence surveys. 	
2.1.2. Ensuring blood safety	<ol style="list-style-type: none"> 1. Review and strengthen national policies and practices on blood safety that promote the rational use of blood and blood products. 2. Put in place mechanisms and systems for quality assurance of laboratory testing for viral hepatitis B and C to ensure a reliable supply of quality-assured screening assays. 3. Strengthen systems for surveillance, haemovigilance and monitoring of the incidence and prevalence of viral hepatitis infections in blood donors, and monitor the risk of post-transfusion hepatitis. 4. Advocate for and communicate the need for nonremunerated voluntary blood donation, and rational use of blood and blood products. 	<ol style="list-style-type: none"> 1. Provide technical support to countries for strengthening the management of safe blood supplies and linkages between blood transfusion services and viral hepatitis services. 2. Support countries with tools and technical assistance to establish systems for surveillance, haemovigilance, and monitoring of supplies of blood and blood products. 3. Communicate and advocate for promoting nonremunerated, voluntary blood donations. 4. Provide technical support and advocacy for rational use of blood and blood products.
2.1.3. Prevention of viral hepatitis infection in health-care settings	<ol style="list-style-type: none"> 1. Establish or strengthen the national IPC regulatory body. 2. Strengthen and sustain routine IPC practices in health-care settings (public and private), including in laboratories, dental clinics, endoscopy clinics and haemodialysis units. 3. Develop and implement a national safe injection policy and practices and, where feasible, use WHO prequalified safety engineered injection devices. 4. Ensure health-care provider safety, including access to immunization and PEP. 5. Monitor outbreaks of infection in health-care settings. 6. Allot adequate resources and build the capacity of staff in infection prevention and control measures, such as universal precautions and safe biomedical waste management. 7. Raise awareness and advocate among health workers and auxiliaries on viral hepatitis transmission, and the importance of infection safety and infection prevention. 8. Address disinfection and sterilization practices in non-health settings, e.g. tattoo clinics, barber shops. 9. Raise awareness and advocate among the public to reduce the demand for unnecessary injections. 	<ol style="list-style-type: none"> 1. Provide technical support for developing, updating, implementing and monitoring infection prevention policies in health-care settings, including outreach services. 2. Provide technical support for implementing WHO's injection safety policy, introduction of safe injection devices, and monitor their implementation and impact. 3. Provide technical support for investigation of infection outbreaks. 4. Provide technical support for setting up and maintaining adequate regulatory structures for IPC.

Priority area	Country actions	WHO actions
2.1.4. Prevention of mother-to-child transmission	<ol style="list-style-type: none"> 1. Introduce and improve coverage of a timely birth dose of hepatitis B vaccine, including coverage of births taking place outside of health-care facilities, followed by immunization of infants with 2 or 3 doses as per national schedule. 2. In collaboration with the MCH department, update national policies and guidelines on maternal and neonatal health, based on evolving WHO guidance on elimination of mother-to-child transmission of viral hepatitis. 	<ol style="list-style-type: none"> 1. Provide technical support for advocacy and implementation of the hepatitis B birth dose followed by 2 or 3 doses of vaccine as per the national immunization schedule. 2. Conduct implementation science research for improving access to vaccination for home births, including the use of a controlled temperature chain. 3. Provide technical support to countries for implementation of an evidence-based package of interventions to eliminate mother-to-child transmission of hepatitis B, and coordination and collaboration with the MCH and immunization programmes.
2.1.5. Prevention of transmission through injecting drug use	<ol style="list-style-type: none"> 1. Ensure access to harm reduction services for people who use drugs. 2. Address HBV and HCV-related stigma and discrimination while providing harm reduction services. 3. Accelerate implementation of a comprehensive harm reduction programme, which has been expanded to cover the prevention of and testing for hepatitis B and C among vulnerable populations. 4. Review and modify laws that restrict or criminalize activities of drug users and address institutional barriers for expanding harm reduction services. 5. Link hepatitis and harm reduction services to facilitate integrated prevention, treatment and care for people who use drugs. 6. Ensure community engagement to reach unreached populations, facilitate access to services and reduce stigma. 7. Ensure access to OST for opioid-dependent individuals, including in closed settings. 8. Ensure access to safe injections and needles such as low dead-space syringes. 9. Collaborate with communities to develop service delivery models to reach PWID with viral hepatitis prevention, screening, treatment and care services. 10. Implement integrated services for PWID, linking with services for viral hepatitis, TB, HIV, substance use and mental health. 	<ol style="list-style-type: none"> 1. Provide technical support for designing, implementing and monitoring a comprehensive package of harm reduction interventions for prevention of hepatitis B and C. 2. Conduct advocacy for harm reduction interventions, and ensure political commitment to facilitate access, including review of restrictive policies and institutional barriers. 3. Advocate for political commitment and resource allocation for programmes targeting PWID. 4. Provide technical support for assessing barriers to the implementation of effective harm reduction interventions and health service provision for PWID.
2.1.6. Prevention of sexual transmission	<ol style="list-style-type: none"> 1. Ensure access to comprehensive and evidence-based sexual and reproductive health services. These should include health promotion, education, prevention and management of STIs for all, with a specific focus on key and vulnerable populations. 2. Strengthen the involvement and management of sexual partners, ensuring confidentiality and access to counselling, testing and treatment of STIs. 3. Conduct advocacy and communication for consistent condom use, especially for key populations, and ensure continuous and quality supply of condoms and lubricants. 4. Engage with community organizations and networks for increasing the demand for STI services and reaching out to key populations. 	<ol style="list-style-type: none"> 1. Provide technical support and guidance on comprehensive STI prevention and treatment services, especially for key and vulnerable populations. 2. Support countries in reducing barriers to access to STI services, including condoms and lubricants for key populations.

Priority area	Country actions	WHO actions
2.1.7. Ensuring access to safe water and food	<ol style="list-style-type: none"> 1. Ensure intersectoral collaboration with the water, sanitation and agriculture departments to ensure access to safe water, safe food, hygiene and sanitation. 2. Advocate for and communicate the need for safe food, water, hygiene and sanitation. 3. Improve access to safe sanitation facilities and educate the public on safe disposal of human faeces. 4. Put in place effective surveillance and outbreak response systems, and reporting systems for HAV and HEV. 5. Engage and communicate with communities on prevention of transmission and early case reporting of outbreaks. 	<ol style="list-style-type: none"> 1. Support risk assessment and management of water supplies, food safety, sanitation and hygiene. 2. Provide technical support for intersectoral collaboration to improve water and food quality. 3. Provide technical support for outbreak investigation, reporting and monitoring actions on recommendations.
2.2. Diagnosing hepatitis infection	<ol style="list-style-type: none"> 1. Develop evidence-based viral hepatitis testing guidelines and testing algorithms at the national level. 2. Integrate viral hepatitis testing into health settings where feasible, e.g. HIV, ANC, key population intervention sites, noncommunicable diseases and cancer screening and treatment services, etc. 3. Prioritize populations and locations for testing, and modify testing approaches and strategies according to these. 4. Strengthen the national laboratory system to ensure quality assurance for testing, including laboratory and point-of-care diagnostics, and confidentiality of test results. 5. Improve the availability of affordable, quality diagnostic test kits for the diagnosis of viral hepatitis. 6. Increase awareness and capacity-building among primary care providers on testing for HBV and HCV. 7. Establish and strengthen linkages between testing and other services. 8. Engage with communities and conduct public awareness and advocacy for increasing the demand for testing services, especially for key and vulnerable populations. 9. Develop and implement national testing policy with details on who will diagnose viral hepatitis, their roles and responsibilities, particularly for informing people that they are infected. 	<ol style="list-style-type: none"> 1. Provide technical support for developing and validating national diagnostic algorithms for testing. 2. Develop a regional network of quality-assured laboratories for expanding quality assurance, capacity-building and horizontal collaboration. 3. Provide technical support for developing testing guidelines, including decentralized testing approaches and establishing quality assurance mechanisms. 4. Facilitate access to quality-assured diagnostics, including point-of-care rapid tests and viral load testing. 5. Develop best practice model of testing for viral hepatitis.

Priority area	Country actions	WHO actions
2.3. Enhancing hepatitis treatment and care of chronic liver disease	<ol style="list-style-type: none"> 1. Ensure access to clinical management for hepatitis B and treatment for hepatitis C in the public sector. 2. Ensure availability of diagnostics for staging of chronic liver disease to prioritize and plan treatment and clinical management. 3. Ensure registration and licensing of newer medicines and necessary national legislations to improve access to affordable medicines for treating viral hepatitis. 4. Make effective use of TRIPS flexibilities to improve affordable access to oral antiviral medicines for treating hepatitis B and C. 5. Develop standard guidelines, plans and protocols for treatment of various forms of hepatitis, in line with the latest evidence and guidance from WHO. 6. Build capacity of health-care providers in the use of newer medicines and follow-up of patients on treatment. 7. Review the infrastructure of existing health systems and strengthen them where necessary to implement and scale up treatment for viral hepatitis. Conduct research to identify barriers to access 8. Prioritize and focus on designing phased implementation of treatment programmes. 9. Engage with the private sector for implementation of national standards, reporting and price regulation. 10. Expand access to quality standard treatment through decentralization and public-private partnerships. 11. Strengthen monitoring and evaluation for timely treatment initiation, response to treatment, drug toxicity and adverse event monitoring. 12. Monitor the cascade of treatment and care to identify and address barriers to early linkage and retention in care. 13. Address common comorbidities, such as HIV infection and risk factors that may accelerate progression of liver disease, and improve access to palliative and end-of-life care. 14. Post treatment/cure, monitor patients for cirrhosis and HCC, including the need for liver transplantation. 	<ol style="list-style-type: none"> 1. Provide technical assistance and support to countries for developing and updating standard treatment guidelines and protocols. 2. Identify the barriers to management and care services for people with viral hepatitis. 3. Provide technical assistance for capacity-building in decentralized service delivery. 4. Conduct implementation science research for innovations in diagnostics and service delivery. 5. Expand partnerships and collaborations, including with communities and CSOs, for advocacy and resource mobilization for hepatitis. 6. Provide technical support for registration of newer medicines and devices, price negotiations and use of TRIPS flexibilities for improved and affordable access to medicines.

Priority area	Country actions	WHO actions
3. Delivering for equity		
3.1. Improving viral hepatitis services	<ol style="list-style-type: none"> 1. Identify and prioritize most affected populations and locations to expand access to services and service delivery. 2. Ensure community engagement and involvement of people infected with and affected by viral hepatitis to inform policy-making, programme implementation and monitoring for impact. 3. Conduct implementation research on community engagement in policy-making and developing innovative service delivery models. 4. Ensure quality assurance through implementation and monitoring of evidence-based norms and standards in the public and private sectors. 5. Strengthen monitoring and information systems to include indicators that capture the quality and equity of services, including access and service use by different populations and in different settings. 6. Initiate a dialogue with key stakeholders such as Industry, the Global Fund, GAVI to improve access to viral hepatitis prevention, care and treatment services. 7. Optimize and rationalize distribution of testing and treatment services to reach all those in need. 8. Use existing diagnostic platforms in other disease control programmes such as GeneXpert from TB or HIV viral load platforms for diagnosis of viral hepatitis. 9. Include viral hepatitis services in the universal benefit package. 	<ol style="list-style-type: none"> 1. Provide technical support for implementation research on community involvement and decentralized service delivery. 2. Provide technical support for developing innovative service delivery models to expand access to testing and treatment for viral hepatitis, and reach hard-to-reach population groups. 3. Provide technical support for monitoring the continuum and quality of care for prevention, control, diagnosis and treatment of viral hepatitis. 4. Provide technical support for evaluating the use of existing diagnostic platforms for expanding diagnostics for viral hepatitis.
3.2. Strengthening human resources for hepatitis	<ol style="list-style-type: none"> 1. Review and strengthen pre-service and in-service curriculums of health-care cadres to include knowledge, skills and capacity-building for managing viral hepatitis at various levels of health-care service delivery. 2. Identify opportunities for task-shifting and task-sharing to extend the capacity of the health workforce, including community health workers, while ensuring supportive supervision and mentoring for front-line service delivery. 3. Implement measures to reduce the risk of transmission of viral hepatitis in health-care settings, and ensure the safety and security of health-care providers. 4. Ensure access to PEP and treatment for health-care providers infected with viral hepatitis B and C. 5. Raise awareness and conduct training of health-care workers to reduce stigma and discrimination in health-care settings. 	<ol style="list-style-type: none"> 1. Provide technical guidance and support for training health-care workers. 2. Provide technical support for designing, implementing and monitoring decentralized service delivery. 3. Support national accreditation bodies for reviewing and updating pre-service and in-service curricula to include viral hepatitis knowledge and skills. 4. Advocate for reducing stigma and discrimination against health workers living with viral hepatitis.

Priority area	Country actions	WHO actions
3.3. Ensuring access to quality and affordable hepatitis vaccines, medicines, diagnostics and other commodities	<ol style="list-style-type: none"> 1. Strengthen the national hepatitis procurement and supply management structures and processes by ensuring that they are integrated into the broader national procurement and supply management systems. 2. Ensure the procurement of quality-assured hepatitis vaccines, medicines, diagnostics, condoms, and other hepatitis-related commodities, including through the use of WHO prequalification. 3. Plan and implement a hepatitis medicines and commodities access strategy to reduce the prices of hepatitis-related commodities, and include fast-tracking registration of new medicines, price negotiations and use of TRIPS flexibilities. 	<ol style="list-style-type: none"> 1. Support innovative strategies to reduce the prices of vaccines, medicines, diagnostics and other commodities for viral hepatitis. 2. Provide technical support to countries to forecast the need for essential commodities related to viral hepatitis. 3. Support national regulatory authorities in pre-market assessment and registration of new medicines and diagnostics for viral hepatitis, with post-market surveillance. 4. Provide technical support for quality assurance of diagnostics and medicines. 5. Give technical advice on joint procurement mechanisms and access to generic medicines. 6. Promote information-sharing on the prices of medicines and diagnostics across Member States through online price reporting systems.
3.4. Promoting an enabling environment	<ol style="list-style-type: none"> 1. Review laws, policies and institutional mechanisms that restrict access to hepatitis prevention and treatment interventions for most-affected and vulnerable groups. 2. Address stigma and discrimination in settings such as in health care, education and employment. 3. Include indicators in the M&E plans to measure quality and equity (including gender equity) of services. 4. Collaborate and partner with CSOs and other stakeholders to create an enabling environment for effective, equitable and efficient programme scale-up. 	<ol style="list-style-type: none"> 1. Provide technical support for review of laws and policies in line with WHO guidelines on gender, equity and human rights. 2. Provide technical support for measuring equity and quality of service delivery, stigma and discrimination faced by affected communities, including in health-care settings.
4. Financing for sustainability		
Sustainability	<ol style="list-style-type: none"> 1. Develop a national investment case for viral hepatitis to advocate for and make a case for adequate resource allocation. 2. Include essential interventions for hepatitis prevention and management within the universal benefit package. 3. Ensure sustainable financing for harm reduction interventions. 4. Explore alternative and innovative financing mechanisms to reduce catastrophic health expenditures. 5. Identify opportunities for resource-sharing, including infrastructure, human resources and finances in other related programmes for scaling up implementation of viral hepatitis interventions effectively and efficiently, e.g. coinfection management with the HIV programme, MCH and immunization programme for vaccination and PMTCT, harm reduction services, blood and injection safety, infection prevention services, surveillance and M&E. 	<ol style="list-style-type: none"> 1. Provide technical assistance and support to develop investment cases. 2. Advocate for inclusion of essential prevention, diagnostics and clinical management of viral hepatitis in the universal benefit package. 3. Support countries in assessing and monitoring health service costs and cost-effectiveness. 4. Advocate for increased political commitment to allocation of domestic resources and resource mobilization from external development partners. 5. Review and assess existing resources, including infrastructure and human resources within national health systems, which could be leveraged for implementing the national viral hepatitis strategy and plan.

Priority area	Country actions	WHO actions
5. Innovation for acceleration		
Innovations	<ol style="list-style-type: none"> Promote viral hepatitis as an important research area and allocate or raise necessary resources. Embed implementation research in implementation plans to answer questions on scaling up coverage with quality and equity, and ensuring financial protection. Ensure intersectoral collaboration across programmes for integrated service delivery models. Interlink monitoring systems for strengthening viral hepatitis data capture, analysis and use. Disseminate and use research findings to better inform programme planning and implementation. 	<ol style="list-style-type: none"> Provide technical support for designing implementation research projects within national plans. Provide technical support for monitoring, and documenting and disseminating results. Facilitate intercountry and inter-institutional collaboration. Advocate for and facilitate innovations and implementation research within and across countries. Ensure knowledge management and create a repository of best practices and lessons learnt in innovations and use of newer technologies.

ANNEX 3

DISEASE BURDEN OF HEPATITIS IN THE SOUTH-EAST ASIA REGION

HEPATITIS A

Data on hepatitis A in the WHO South-East Asia Region are limited. Based on these, hepatitis A disease is not a major public health problem in most Member States, although transmission of the hepatitis A virus (HAV) appears to be common. This is because most people in the Region are exposed to HAV in early childhood, when the infection is usually asymptomatic, leading to lifelong immunity against reinfection. However, with the ongoing improvement in standards of living and hygiene in the Region, the age at which HAV infection occurs is likely to increase, leading to an “epidemiological transition” with increased frequency of and mortality due to hepatitis A disease.

Data from the Region already show some signs of epidemiological transition, with reduced HAV seroprevalence and shift of HAV infection from childhood to adulthood.¹⁸⁻²⁰ In addition, outbreaks of hepatitis A continue to be reported from the Region, including 54 outbreaks across India between 2011 and 2013,²¹ and a large outbreak with over 13 000 cases in 2009 in Sri Lanka.²²

Vaccination against hepatitis A in the South-East Asia Region is quite low. Vaccines against hepatitis A, both inactivated and attenuated types, are available. Two intramuscular doses are recommended, beginning not before 12 months of age and separated by 6 months, though recently the use of a single dose has also been suggested. It is highly immunogenic and protection lasts for several years, possibly the entire lifetime. Its use is recommended in high-risk groups. Its use as a childhood vaccine needs consideration in areas where moderate HAV endemicity is associated with frequent occurrence of hepatitis A cases and high vaccine coverage is possible, but not in areas where HAV infection is highly endemic but the disease is infrequent.

HEPATITIS B

The prevalence of hepatitis B varies widely in countries of the Region. The prevalence and infection routes vary by country, within countries and by population. The prevalence of chronic hepatitis B is above 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 HBsAg ranging from 2% to 7%. Bhutan, Nepal and Sri Lanka have low HBV endemicity (<2%). No data are available from the Maldives.²³

Data on routes of transmission of hepatitis B from the Region are limited. In the high-endemic countries, a majority of new cases of chronic hepatitis B are believed to be related to mother-to-child transmission.

HEPATITIS C

Data on hepatitis C in the Region are limited. The prevalence of HCV in India among blood donors has been variously reported as 0.15%²⁴ to 0.43%.²⁵ Other countries with published data also report a prevalence among blood donors of <1%, except for Sri Lanka, with 1.06%.²⁶

A recent study²⁷ estimated HCV infection rates in the general population as follows: Myanmar 1.7%, Bangladesh 1.64%, India 1.0% and Indonesia 0.8%. These rates are lower than those estimated in a previous study,²⁸ which suggested anti-HCV positivity rates in countries of the Region to be in the range of 2.0–3.4%.

Prevalence is higher among injection drug users. In countries where studies have been done, more than half of all PWID are infected with hepatitis C.²⁹⁻³¹

HEPATITIS D

Data are sketchy on the frequency of hepatitis D virus infection, and morbidity and mortality due to it. Hence, no estimates of the burden of disease are yet available. In a recent study from India, hepatitis D infection was not found in any of the hepatitis B carriers.³²

HEPATITIS E

Hepatitis E is endemic in, Bangladesh, India and Nepal. In these countries, HEV is the most common cause of sporadic acute hepatitis, and outbreaks occur frequently. The outbreaks are often large, and may affect several thousand people. The mortality rate is low in the general population, but is high in specific subgroups, such as pregnant women and persons with pre-existing liver disease. In other countries, though data are limited, the disease appears to be infrequent.

A recent hepatitis surveillance report from India reported an anti-HEV antibody prevalence rate of 10.4%.²³ A hospital-based study in India identified HEV infection as the cause of nearly 40% of cases with acute viral hepatitis.³³ In Bangladesh, two studies have reported anti-HEV prevalence rates of 22.5% and 26.6%.^{34,35} In Nepal, during 2014, an outbreak of hepatitis E affected over 7000 individuals and caused 14 deaths.³⁶ HEV infection also contributes to maternal and fetal mortality and morbidity.

A vaccine for hepatitis E is available and has been licensed in China. It is not yet approved for use in any other country globally.

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