REGIONAL WORKSHOP ON
SCALING UP HEALTH SECTOR
RESPONSE TO VIRAL HEPATITIS IN
SOUTH-EAST ASIA REGION

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1. INTRODUCTION

Viral hepatitis is one of the leading causes of death and disability worldwide and causes as many deaths annually as TB, AIDS or malaria and the burden of deaths due to viral hepatitis globally is increasing compared to other diseases, like, HIV, TB and Malaria. Viral hepatitis is the most common cause of liver cancer and cirrhosis and is a substantial contributor to premature morbidity and mortality. There were 1.34 million deaths in 2015 from hepatitis globally, 30% (408,000) of which were in the South-East Asia Region (called the Region, henceforth). Nearly 96% of the global hepatitis burden is from hepatitis B (HBV) and hepatitis C (HCV) but hepatitis E is also important for the Region. Data from 2015, shows that globally 257 million people were living with HBV infection and 71 million with chronic HCV infection. These numbers are 39 million and 10 million for the Region, respectively. In the Region, 3 countries (India, Indonesia and Bangladesh) account for more than 80% of viraemic HCV infections and around 95% of all HBsAg positive cases are in five countries of the Region (Bangladesh, India, Indonesia, Myanmar and Thailand).

Prevalence of HBV and infection routes vary by country, within countries and by population group. In the Region, the prevalence of chronic hepatitis B is above 8% in 3 countries: Democratic People’s Republic of (DPR) Korea, Myanmar and Timor-Leste. Bangladesh, India, Indonesia and Thailand have intermediate endemicity with hepatitis B surface antigen (HBsAg) prevalence ranging from 2-7%. Bhutan, Nepal and Sri Lanka have low endemicity with HBsAg positivity rate below 2%. HCV infection rates in the general population in some key countries are as follows: Myanmar 1.7%, Bangladesh 1.64%, India 1%, Thailand 0.94% and Indonesia 0.8%.
2. OBJECTIVES OF THE MEETING

In April 2017, the World Health Organization (WHO) Regional Office for South-East Asia (SEARO) organized a Regional Workshop on Scaling up Health Sector Response to Viral Hepatitis in South-East Asia Region in New Delhi, India with the following general objective: To review progress and develop action plans for scaling up health sector response for Viral Hepatitis in South-East Asia Region (SEAR). The specific objectives of the workshop were to:

• Share global and regional updates with Member States;

• Review and share experiences on development and implementation of national strategies and action plans on viral hepatitis;

• Share experiences and discuss options for sustainable service delivery and financing for scaling up prevention, diagnosis and treatment of hepatitis at all levels of health care;

• Discuss and share experiences on innovations for advocacy, community engagement, service delivery and resource mobilization, and

• Discuss and get inputs on key issues to be included in the Regional Committee discussions on viral hepatitis.

The expected outcome of the meeting was to develop a framework of action for scaling up viral hepatitis health sector response in Member States with timelines and resource needs identified.

The participants included national policy and programme representatives, academia and institutes of excellence, WHO Collaborating Centres, Development partners, and community stakeholder. The agenda is in Annexure-I and list of participants is at Annexure-II.

This report summarizes the major findings from the discussions in the meeting.

To begin the workshop, Dr Gottfried Hirnschall, Director, HIV/Hepatitis at WHO Headquarters and Dr Marc Bulterys, Team Leader, Global Hepatitis Programme at WHO Headquarters gave an overview of global epidemiological situation of hepatitis and WHO response to hepatitis.
Initially, the health sector response to hepatitis was limited to HBV immunization, which has been largely successful. Coverage of 3-dose hepatitis B vaccine in 2015 was 84% but HBV birth dose coverage was only 39%. HBV prevalence among children has reduced to 1.3% (0.7% in the Region) as a result of the 3-dose vaccine. Scientific advances have enabled effective treatments for both hepatitis B and C with a cure for the latter. Though unaffordable initially, the prices of directly acting antivirals (DAAs) have reduced significantly in low- and middle-income countries (LMICs) and many countries are developing national plan for treatment of hepatitis. By October 2016, nearly 1 million people worldwide were treated with DAAs. Yet, testing and treatment coverage for both HBV and HCV are very low. Nearly 9% of HBV-infected persons and 20% of HCV-infected persons were diagnosed. In 2015, 8% of those diagnosed with HBV were on treatment, while 7.4% of those diagnosed with HCV had started treatment.

Hepatitis elimination by 2030 requires a comprehensive public health approach: a robust political commitment matched by resources, increased role of civil society with sustainable funding for them, HBV birth dose scale-up as an essential part of post-natal care, effective infection prevention measures such as safety of blood transfusion and blood products and safety in dental and medical procedures, expanded use of point-of-care rapid diagnostic, access to medicines and manufacturing of generics, advocacy for financial and human resources, utilizing synergies with HIV, maternal and child health (MCH) and others, and more partners to collaborate for the hepatitis response.

Following the inclusion of targets for addressing hepatitis in the sustainable development goals (SDG), the WHO has developed the Global Health Sector Strategy on Viral Hepatitis 2016–2021, which calls for reducing new infections by 90% and mortality by 65% by 2030 compared to 2015 baseline. Some other targets include increasing Hepatitis B coverage to 90%, prevention of mother-to-child transmission (PMTCT) of HBV by 90%, 100% screening of blood products, use of 95% reused prevention syringe, providing 300 injection sets per person who injects drugs (PWID), 90% of those reported are diagnosed and 80% of eligible are on treatment. WHO has also developed normative guidelines on surveillance, prevention, testing and testing, which recommend evidence-based tools and strategies for ending hepatitis. WHO is providing country support for policy uptake and implementation.
and supporting access to affordable diagnostics and medicines (price reporting, pre-
qualification; patent landscape; access approaches for countries). Additionally, WHO, as a
global and regional convener on hepatitis, is fostering partnerships with a range of
stakeholders. WHO programmatic prioritizes for 2017-18 include:

- Accelerated (fast-track) action towards elimination
- Linkages of HIV, hepatitis and TB into broader communicable disease approach, and with
  the SDGs
- Enhanced technical support in countries towards greater impact
- Affordable and equitable access to testing and treatment to address critical service gaps
- Identifying and taking innovation to scale (diagnostics, new treatments, etc.)
- Integrated and differentiated service delivery
- Strategic information to inform and improve programmes
- Focus on equity, human rights and coverage under the umbrella of Universal Health
  Coverage (UHC)

The WHO SEARO Regional Director, in her speech, highlighted the progress so far. Hepatitis
prevention, care and control have been pushed to the fore of public health programming
and it is now being addressed as a key social, economic and political issue as per the Global
Strategy. WHO is also matching up to the country efforts – by issuing normative guidance,
devising a regional action plan, and providing evidence-based recommendations to
overcome difficulties on access to treatment, particularly for hepatitis C. The close
collaborations between health and development partners, civil society and academia are
proving to be a force multiplier in the battle against hepatitis. She highlighted seven points
as fundamental to our cause: robust political commitment matched by adequate resources,
greater community awareness and understanding of hepatitis, making hepatitis B vaccine
birth dose mandatory, effective infection prevention measure, making point-of-care rapid
diagnostics widely available, guarantee access to medicines, and robust surveillance and
effective monitoring and evaluation. The senior officials of all 11 Member States have
registered their desire to see HIV, TB and malaria brought under the aegis of a single,
empowered national body and we need to include hepatitis and other disease as part of this
approach.
3. REGIONAL RESPONSE

Dr Razia Pendse, Regional Adviser, HIV/STI/Hepatitis gave an overview of regional situation on hepatitis and regional action plan.

The WHO global health strategy on hepatitis has been translated into the Regional Action Plan for Viral Hepatitis in South-East Asia, 2016-2021 in consultation with the Member States. The plan provides an actionable framework of priority evidence-based interventions to support national responses for prevention, control and management of viral hepatitis within the Member States. It has been adopted (Myanmar, Indonesia and Timor-Leste) or in the process of being adopted (Bangladesh, Thailand and DPR Korea) as national plans, funded through domestic resources for an effective and coordinated response. India has also begun developing an action plan while Nepal will very soon look into developing it.

Asia Pacific Regional framework for triple elimination of HIV, hepatitis B and syphilis among pregnant women has also been developed. Indonesia recently called for triple elimination while Thailand, which has achieved dual elimination of HIV and syphilis, is discussing HBV elimination among pregnant women.

Testing guidelines for hepatitis exist in DPR Korea, Myanmar, Nepal and Timor-Leste and are planned in Bangladesh and Thailand. Treatment guidelines for HBV and HCV have been developed in DPR Korea, Indonesia, Myanmar, Nepal and Thailand. Countries are working in partnerships with international organizations to ensure affordable access to drugs to treat HBV and HCV.

Indonesia, Myanmar and Thailand have allocated domestic funding for the hepatitis response while India has requested funding from the Global Fund. Civil society dialogue and co-infection treatment are included under the Global Fund proposal.

In India, Punjab, one of the provinces has developed a public-private partnership programme model with decentralized non-specialist service delivery, ECHO clinics, and sustained virologic response (SVR) certificates. Nearly 25,000 HCV patients were put on treatment in past 9 months through state funds free at point of care. Implementation science research is ongoing in Bangladesh and planned in Myanmar.
The key issues that need to be addressed relate to data, laboratory capacity including quality assurance, human resources, capacity building, affordable diagnostics and medicines, testing strategy and treatment criteria, adherence, retention and SVR, private sector, and funding. It was also suggested to have a regional advisory committee on hepatitis and regional mechanism for drug regulation to increase access to medicine.

Based on his experience from Egypt, Dr Henk Bekedam, WHO Representative to India provided guidance on making a national plan for hepatitis. A national action plan needs a comprehensive approach that incorporates all essential components including water and sanitation, immunization, infection control including injection safety, blood safety, surveillance, information, education and communication; availability of treatment, increasing the awareness and research. The national action plan should focus on simplification, integration, decentralization and equitable access. He highlighted that to prevent hepatitis; efforts should be all encompassing with focus on prevention, care and treatment.

Dr Bekedam emphasized the need for wide ranging stake holder engagement that include policy-makers, state representatives, physician associations, academics, patient support groups, affected populations, non-government organizations (NGOs), private sector, media and citizens at large. Dr Bekedam cited, from his experience in Egypt, certain essential steps which include creating a national steering group, sub-committee of experts on each component, target setting, developing a budgeted implementation plan and setting up regular monitoring. WHO has developed a manual for developing national hepatitis plan.
4. NATIONAL PLANNING FOR HEPATITIS

This session focused on activities related to situation analysis of hepatitis, situation in Member States, steps taken so far and plans to address hepatitis with a view for elimination by 2030.

BANGLADESH

All types of hepatitis are prevalent in Bangladesh but the highest burden is due to hepatitis E (58%). An estimated 10 million people are living with viral hepatitis and there are nearly 20,000 deaths from hepatitis B and C annually. Liver disease accounts for 8-12% admission in medicine ward. Hepatitis is the 3rd leading cause of cancer deaths in the tertiary medical college hospital. Hepatitis B prevalence is 50% and 50% of PWID and hepatitis C positive. The 3-dose HBV vaccine is part of the national programme since 2007. Due to strong political commitment and as part of commitment to the SDGs, the government will introduce HBV vaccine for high-risk groups. Treatment for HCV will also be introduced. Prices of DAAs are low as local pharmaceuticals produce generic drugs and export them to over 70 countries. The “National strategy for prevention and control of viral hepatitis” and “training module on viral hepatitis for doctors” will be finalized soon. The challenges faced by the programme include lack of sero-survey, no hepB0 and <100% screening of transfused blood. Several organizations are working on the hepatitis response but collaborations and coordination between them are lacking.

DPR KOREA

Hepatitis is a public health priority. There were 104,000 cases of chronic hepatitis in 2015, including 36,900 cases with cirrhosis and 2,700 cases with hepatic cancer. The country has developed a national strategic plan. The national hepatitis control programme (NHCP) is funded by the government and aims to reduce incidence, morbidity and mortality of viral hepatitis. The roll out plan will be at 12 PHDIs, 210 CHDIs and 7237 RI hospitals. The specific objectives of the programme are:
1. To ensure the sustainable success of HepB0 (1st dose of hepatitis B vaccine given within 24 hours after birth), expand the vaccination coverage and promote the local development of vaccines.

2. To promote the preventive activities at each stage and stop the spread of the infection.

3. To scale up the curative rate by a proper combination of several health care services.

4. To intensify the advocacy and propaganda through social mobilization and scale-up public awareness.

5. To improve quality of service delivery in cooperation with other sectors/stakeholders.

6. To strengthen the co-operation with international agencies.

In 2015, the coverage of HepB0 was >98% and coverage of 3-dose hepatitis B vaccine was also high at 96%. Current activities for hepatitis control include identification of high risk group including more than 17 year olds to expand the target group for vaccination, strengthening surveillance and response for detection of suspected cases and clinical cases, formulating injection/medical instrument safety plan and transfusion safety plan, and establishing a separate blood safety system within NHCP.

However, the programme is facing challenges such as lack of funding; inadequate reagents and consumables for laboratory test, capacity, infrastructure, equipment, training and quality control; insufficient technical capacity for surveillance; lower management capacity of information system; and poor infrastructure. Moving forward, the country plans to establish the national hepatitis reference laboratory and intensify the relationship with international reference laboratory. It will also develop guidance and action plan for surveillance and information management, strengthen infrastructure and mobilize additional resources to cover the funding gap.

INDIA

The National Steering Committee on viral hepatitis has been constituted in January 2017 under chairmanship of Secretary, Ministry of Health and Family Welfare. Even though many state governments have started providing hepatitis services, the National Action Plan is currently being developed. The proposed components for the plan include:

1. Awareness generation and communication strategy,
2. Surveillance for generating evidence for policy,
3. Prevention of transmission of infection by injection safety, HBV immunization, blood safety, harm reduction and water and sanitation programmes,
4. Screening and diagnostic testing, and
5. Clinical care and treatment

The plan will have well defined targets and will be reviewed on a regular basis based on the data from monitoring and evaluation activities.

Several agencies are involved in the hepatitis programme in the country. National Centre for Disease Control (NCDC) carries out hepatitis A and E surveillance. National AIDS Control Programme (NACO) is responsible for the blood safety programme and screening the transfused blood for hepatitis B and C. The Indian Council for Medical Research (ICMR) is conducting research in the country.

At present, the National Health Mission is the backbone of health care in India and has implemented the free drug initiative to provide the essential drugs and diagnostics free of cost in the public sector. The CD SCO has given fast track approach for DAAs. However, only 10% of the population is covered by Rashtriya Swasthya Bima Yojna (national health insurance scheme) and 75% people access health care in the private sector. Hepatitis prevention includes promotion of hand washing and a large sanitation programme (led by the prime minister). Injection safety is a smaller programme comparatively but is now being implemented in the State of Punjab. In the future, areas of integration of hepatitis with HIV due to the synergies need to be explored. With many players, it will be important to clearly define who will do what and wherein the overall national hepatitis plan.

Dr Henk Bekedam from WHO India emphasized that an hepatitis programme need to have following key components:

a. Standardized treatment protocols (for public and private sector), which are regularly revised.

b. Notification of Hepatitis C (and B) treatment

c. Setting up a database that can monitor treatment outcomes, capturing SVR 12 outcomes.
d. Issuing a cure certificate to patient when there is a non-detectable HCV RNA 12 weeks after completion of treatment. This is important for compliance to SVR 12 test and possible support to the patient in future application of work in environment where there is discrimination against hepatitis C.

**INDONESIA**

Indonesia belongs to a region with moderate to high endemicity of hepatitis B and C. An estimated 18 million people are infected by hepatitis B and 2.5 million with hepatitis C. The results from 2013 Basic Health Research show that the HBsAg positive prevalence is 7.1% in adults and 4.2% in children <5 years. The HCV antibody (anti-HCV) prevalence is 1.01% in adults and 0.5% in children <5 years.

The country is committed to elimination of hepatitis B and C by 2030. The National Policy on Viral Hepatitis Control was endorsed in 2015 and guidelines on hepatitis surveillance, early detection for hepatitis B and C, and diagnostic and treatment for hepatitis B and C have been developed. In 2016, the hepatitis B early detection (PMTCT programme) was included in the basic antenatal care (ANC) services and neonatal/child health services package or the Health Services Standard. Minister of Health circular on elimination of Mother-to-Child Transmission of HIV, Syphilis and Hepatitis B in Indonesia by 2020 was recently launched, asking all provinces and all districts health leaders to plan and prepare for triple elimination. These regulations allow local government to propose funding and resources needed.

The National Hepatitis Strategic Plan 2015–2019 aims for an effective and efficient Hepatitis Control Programme in order to reach the highest health status, with three specific objectives:

Raising awareness and knowledge on hepatitis, reducing of viral transmission (vertical and horizontal), and increasing the quality life of people with hepatitis. The 2019 targets are:

1. 80% of high risk population will be detected,
2. 90% of neonatal or new born received hepB0 within 24 hours, and
3. 80% diagnosed hepatitis B and C positive are referred to healthcare services (hospitals).
To achieve the objectives and targets, Indonesia will implement hepatitis control programme, hepatitis B and C early detection in pregnant women and other high-risk group, and early warning system to prevent hepatitis A and E outbreak in up to 90% districts by 2019. Hepatitis surveillance among high-risk groups (such as pregnant women, healthcare workers, PWID, sex workers, men have sex with men (MSM), people living with HIV, STI patients, Haemodialysis, Hemophilia, prisoners) will be conducted in all districts.

Currently, the National Virus Hepatitis Control Programme is focusing primarily on hepatitis B early detection during ANC for 1.5 million pregnant women, scaling up hepB0 within 24 hours, (current coverage is 42%) hepatitis B and C screening among high-risk group, and providing access to hepatitis C diagnostic and treatment, including for PWID and people living with HIV.

In 2017, DAAs were provided to 6,000 patients in Jakarta province and will be expanded to 6 provinces with high PWID population this year. The hepatitis programme is integrated with existing health priority programmes, such as mother and child health program through family approach (Pendekatan Keluarga), harm reduction, HIV and TB programmes, immunization, patient safety, blood safety, and public health insurance scheme. Hepatitis diagnosis and treatment are covered by National Health Insurance scheme since 2014. By the end of 2016, 67% of national population is covered by this insurance.

Indonesia has a substantial burden of hepatitis B and C, with varying geographical and health capacity and limited resources. Therefore innovations, affordable diagnostics and medicines, more efficient programme strategy tailored to the local capacity, infrastructures, social-economics, culture and geographical situation, and increased support from stakeholders are needed to achieve the goals and targets. Also, the country needs to invest in implementing standardize recording and reporting format and real-time data collection from 514 districts.

**MYANMAR**

According to the national survey conducted in 2015, prevalence of mono-infection of HBV and HCV in general population is 6.51% and 2.65%, respectively and is higher for PWID.
Currently, Myanmar has nearly 1 million HCV viremic people and 25,000 new infections each year. Co-infection of HIV and HBV/HCV is also high at 20.7%. The country has committed to the goal of elimination of hepatitis by 2030. Blood screening is happening in Myanmar since 2000 and since 2006, vaccination is provided in all institutional deliveries (at 2 months, 4 months, 6 months). The hepatitis prevention and control activities have been enhanced since 2014 with issuance of guidance from the Ministry to establish a national hepatitis control programme in November 2014 for provision of comprehensive services for viral hepatitis. The national hepatitis control programme follows a simplified programmatic approach with four key axes: Increasing awareness for policy makers, health professionals, donors and stakeholders; evidence-based policy and advocacy; prevention of primary, secondary and tertiary transmission through blood safety, hepatitis B vaccination, and screening, care and treatment for hepatitis B and C. The programme has components of capacity building of staff and robust strategic information.

Myanmar’s National Plan for Viral Hepatitis (2016-2020) has been developed in line with the Global Health Strategy with the focus on UHC, the continuum of hepatitis services and a public health approach. Simplified treatment guidelines on hepatitis B and C infection have been updated in January 2017, a costed operational plan on the 4 years National Strategic Plan has been developed along with a monitoring and evaluation plan, testing guidelines for viral hepatitis infection have been drafted, and Open Medical Record System (OpenMRS) database for the patient monitoring has been established. Also, Myanmar is developing public awareness materials for prevention of viral hepatitis infection, training advanced trainers on treatment of hepatitis C, and formulating standard operating procedures for screening.

In mid-2017, the country is planning to start the treatment for 2,000 HCV infected patients (1,200 mono-infected and 800 HIV/ HCV co-infected) with oral DAAs (Daclatasvir and Sofosbuvir in combination therapy) at 8 designated hospitals (in Yangon, Mandalay & Nay Pyi Taw) in phase I by government support. Treatment for HCV in the private sector is available but is expensive and many people cannot afford it. In the future, public sector hepatitis C treatment programme will be expanded in a phased manner, an international procurement and importing mechanism for hepatitis drugs and diagnostics will be set up,
public sector Hepatitis B treatment programme will also start, and the country will invest in capacity building and operational research.

NEPAL

Nepal is a low burden country, however the available data on viral hepatitis indicate that HCV prevalence among PWID is at 47.5% and 0.1-.07% among blood donors. The data are fragmented and collected mostly from the blood banks and by academic institutes. Programmes such as blood safety, injection safety, needle and syringe programme for PWID, prevention of vertical transmission and creating awareness and conducting advocacy are well functioning and being taken care of by the HIV/AIDS programme. The coverage of 3-dose HBV vaccine has reached 97% but Nepal does not have policy for hepatitis B birth dose vaccination. Private sectors (liver foundation) along with other organizations are also involved in the treatment and management of viral hepatitis but collaboration is weak. Recently, a steering committee was formed to guide the development of national strategy for hepatitis that will finalize the plan in the next 6 months. The focus of the plan will be on evidence generation; test, treat and care for hepatitis; strategic information; and mapping the resource need.

THAILAND

To establish the viral hepatitis programme at the national level, a planning team of experts and technical consultants was assigned to assess the needs for viral hepatitis in the country and identify the possible responsible departments. A Viral Hepatitis Unit has been set up under the Bureau of AIDS, TB and sexually transmitted infections (STI). Thailand National Strategy on Viral Hepatitis Prevention and Control (2017 – 2021) has been developed with support from WHO country office, community-based organizations, and National Health Security Office (NHSO). It mirrors the global strategy and will be the backbone of the national hepatitis response in the next 5 years. Planning phase for implementation of the national programme began in 2016. Activities such as development of efficient viral hepatitis surveillance, strengthening harm reduction services, prevention of mother-to-child transmission using Tenofovir, and identification of target population for screening for hepatitis B or C are ongoing. National guidelines for chronic hepatitis B and C will be
developed by end of the year and by end of September 2017, a technical subcommittee will be established. The country is considering including DAAs as essential drugs but in Thailand prices of DAAs are very high compared to some other countries in the Region and high cost is a perceived barrier in significant scale up of programme.

**TIMOR-LESTE**

The 5-years National Strategic Plan was formulated in 2015 and implementation phase started in 2016. The country started with piloting integrated surveillance in 6 of the 13 municipalities. The viral hepatitis programme is integrated with MCH – the policy exists and all pregnant women in ANC or those coming for PMTCT of HIV services get tested for hepatitis B. HepB0 was introduced in April 2016 and coverage is around 42%. Timor-Leste will reintroduce vaccination for health care works in mid-2017. It was done before in 2009 but stopped due to lack of vaccines. The country has 69 community health centres, 5 regional hospitals and 1 national hospital. Hepatitis B testing has started in 17 out of 69 CHC all while hepatitis C testing is in 6 hospitals. The National hospital has set up a national hepatitis committee and is the centre for reference for all hepatitis patients. Based on the hospital data, plan will be drawn for drug procurement. There are three gene expert machines but no staff at present to run it. A National Lab consultant will be appointed and trained using funding from the Global Fund.
5. PREVENTION OF HEPATITIS B AND C

INJECTION SAFETY

Injections are an integral part of health services – globally an estimated 16 billion+ injections are used each year but a large proportion of these injections are unnecessary and nearly 50% of all injections are unsafe. In 2015, WHO issued guidelines on the use of safety-engineered injection devices in therapeutic care, which recommend the use of injection devices with sharp injury protection feature (SIPs) or reuse prevention feature (RUPs) by healthcare workers delivering intramuscular, subcutaneous or intradermal injectable medications. At the national level, countries need to take comprehensive measures for safe injections. Policy on safe and appropriate use of injections needs to be introduced along with roadmap for introduction of safe injections, costing, budgeting, financing, monitoring and evaluation, and assessment of injection and waste disposal practices. Emphasis is needed on healthcare worker safety, education and training; training and supervision for waste management; and public awareness-raising and patient education and involvement. WHO is supporting Injection safety projects in 3 countries- Egypt, Uganda and India-, which will provide opportunities for improving not only injection safety but also infection prevention and control practices, patient safety and quality of healthcare, and healthcare waste management. The process will be documented and disseminated for programmatic use.

Country example – India

India contributes 25-30% of global injection load – an estimated 3 -4 billion injections are used per year (average 2.9 injections per person per year). In year 2002-03 study, nearly 2/3rd injections are unsafe due to inadequate sterilization, use of faulty techniques, and unsatisfactory healthcare waste disposal. As injections are perceived to be more efficacious by patients and are thus overprescribed. On World Hepatitis Day 2016, the India Injection Safety Implementation Project (2016-18), to be jointly implemented by WHO Country Office for India and Ministry of Health and Family Welfare was launched. The project follows a holistic approach and the activities proposed to be done at the union level include:
- Technical assistance for development and adaptation of the policy and stakeholder engagement
- Attention on both injection safety and healthcare waste management
- Attention on both public and private sector, along with the unorganized private sector
- Baseline assessment/situation analysis of injection practices and healthcare waste management practices
- Knowledge, attitude and practice (KAP) study on beneficiary preference; patient involvement including development of communication material for behavior change
- Development of implementation plan
- Training and capacity building of healthcare staff including developing training material
- Monitoring and evaluation

This project is being implemented in Punjab state of India. WHO Country office for India is coordinating with the Government of Punjab for implementing the project. HCV prevalence is high in the state and new hepatitis infections are coming from unsafe injection used during surgery and dental procedures, etc. A national Technical Expert Group (TEG) on injection safety (has been constituted by the government of India. In Punjab, state technical expert group (STEG) on injection safety was established. The STEG had a series of deliberations which led to initiation of series of field based studies and also recommended to the state government on adoption of RUP syringes in therapeutic care in the state. Background work on setting up innovative Model Injection Centers (MICs) in all district hospitals, medical colleges and nursing colleges of Punjab state is ongoing. In collaborations with academic institutes, economic analysis of burden of unsafe injections and improper healthcare waste management in Punjab state and in India and a community-based KAP study on therapeutic injections in Punjab State are being planned. While the state government is leading the activities under the project, WHO is providing technical and financial support. The procurement of RUP syringes is by the government and the project is linked with overall hepatitis prevention and treatment efforts.

BLOOD SAFETY
There are around 4,227 blood centers in the Region (2,545 in India). An estimated 15.9 million blood units are collected each year against an estimated need of 18 million. Blood usually goes to treat younger patients, pregnant women during childbirth with blood loss and children with anaemia. The prevalence of transfusion transmitted infections (TTIs) in the blood donations in the Region are as follows: HBV 0.322%, HCV 0.232%, syphilis 0.163% and HIV 0.051%. TTIs can be prevented by preventing infected person from donating blood, testing the donated blood for TTIs, rationalizing the use of blood, integrating quality at all steps of blood transfusion services and implementing these steps through national services that are regulated, accessible to all and efficiently managed.

The Region is facing many challenges with blood transfusion services. National blood policies/ strategies/ operational planning are absent or inadequately implemented. There is a lack of funds, trained staff and coordination between agencies. Additionally, health systems and infrastructure are poor. Legislation and regulations are not in place to control the system. Though the Region is screening 100% blood for TTIs (except in Bangladesh), quality control system of screening is not in place in some centres. Supply of kits is erratic and procurement of good quality equipment and reagents is not regular. Also, some countries do not have adequate facilities for separating blood into its components to use it more rationally. Hemovigilance is almost non-existent and the status of data management and information systems is unknown.

WHO is playing a major role in advocating and providing technical assistance for strengthening blood transfusion services. WHO Global Strategy for blood safety was developed in 2000 to reduce global burden of diseases due to unsafe blood transfusions. All Member States have endorsed the global strategy. WHO has also supported development of national blood policies, guidelines on various aspects of blood transfusion services, and norms and standards. The WHO Collaborating Centers are strengthening blood transfusion services in the Member States. In the Region, National Blood Centre, Bangkok, Thailand, provides training in Blood Transfusion Services and Bureau of Lab Quality & Standards, Ministry of Public Health, Thailand provides accreditation of health laboratories.

In summary, ensuring optimized usage of safe and sufficient blood supply that comes from 100% voluntary unpaid donations and is 100% quality-assured tested for TTIs requires
strong political commitment, international collaborations, community involvement and health systems strengthening. Presently, only DPR Korea, Sri Lanka and Thailand have 100% voluntary donation.

HEPATITIS B IMMUNIZATION

The recommended global immunization strategies for hepatitis B control include:

1. The 3-dose hepatitis B vaccine (HepB3) in infants – the table 1 describes the current schedule for hepatitis B vaccination in the countries in the Region. Coverage of HepB3 vaccine has increased steadily in the Region to reach 87% in 2015 and is high in all the Member States.

2. HepB0 (ideally within 24hrs), as part of 3-4 dose schedule – HepB0 is recommended in all countries except Bangladesh, Nepal and Sri Lanka (Table 1). Timor-Leste introduced birth dose in February 2016 (and Myanmar re-introduced it in 2016. The regional coverage is 34% and varies significantly across the countries. While DPR Korea, Maldives and Thailand are reaching nearly 100% coverage, coverage is 42% in Timor-Leste and 47% in India. Challenges with birth dose are related to high rates of home deliveries without skilled birth attendance, lack of awareness and/or training among health staff at birthing facilities, incomplete integration of hepB0 in newborn care package, false contraindications, fears among parents about adverse events following immunization, weak coordination between MCH and expanded programme on immunization (EPI), vaccine supply, cold chain equipment, and incomplete participation of the private sector.

3. Catch-up vaccination of older children up to a specified age born before HepB vaccination started, children <5 years who missed immunization as infants and unvaccinated children at school entry – Limited information on policy and programmes related to catch-up vaccination is available from the countries. Some experts were of the opinion that this may not be required.

4. Policies on Immunization of high risk adult population groups such as healthcare workers, sex workers, PWID, recipients of blood/plasma transfusions, and contacts of
HBsAg positive persons varies in countries HBV vaccination for health care workers is a policy in Bhutan, DPR Korea, Nepal, Sri Lanka and Thailand.

Table 1: Use of hepatitis B vaccine in national immunization programmes

<table>
<thead>
<tr>
<th>Country</th>
<th>Year vaccine introduced</th>
<th>Birth dose (year)</th>
<th>Current vaccine formulation used</th>
<th>Current Hep B vaccine schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>2003-2005</td>
<td>None</td>
<td>DTwPHibHepB</td>
<td>6, 10, 14 weeks</td>
</tr>
<tr>
<td>Bhutan</td>
<td>1997</td>
<td>2011</td>
<td>HepB/DTwPHibHepB</td>
<td>Birth/ 6, 10, 14 weeks</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>2003-2004</td>
<td>2003</td>
<td>HepB/DTwPHibHepB</td>
<td>Birth/ 6, 10, 14 weeks</td>
</tr>
<tr>
<td>India</td>
<td>2002-2011</td>
<td>2008</td>
<td>HepB/DTwPHibHepB</td>
<td>Birth/ 6, 10, 14 weeks</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1987-1997</td>
<td>Prior 2000</td>
<td>HepB/DTwPHibHepB</td>
<td>0-7 days/ 2, 3, 4, 18 months</td>
</tr>
<tr>
<td>Maldives</td>
<td>1993</td>
<td>Prior 1998</td>
<td>HepB/DTwPHibHepB</td>
<td>Birth/ 2, 4, 6 months</td>
</tr>
<tr>
<td>Myanmar</td>
<td>2003-2005</td>
<td>2016</td>
<td>DTwPHibHepB</td>
<td>2, 4, 6 months</td>
</tr>
<tr>
<td>Nepal</td>
<td>2002-2005</td>
<td>None</td>
<td>DTwPHibHepB</td>
<td>6, 10, 14 weeks</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>2003-2005</td>
<td>None</td>
<td>DTwPHibHepB</td>
<td>2, 4, 6 months</td>
</tr>
<tr>
<td>Thailand</td>
<td>1989-1992</td>
<td>Prior 1998</td>
<td>HepB/DTwPHepB</td>
<td>Birth and 1 month (HBsAg mother)/ 2, 4, 6 months</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>2007</td>
<td>2016</td>
<td>HepB/DTwPHibHepB</td>
<td>Birth/6, 10, 14 weeks</td>
</tr>
</tbody>
</table>
Moving forward, strategies are required for achieving high hepB3 and hepB0 coverage in infants. Thresholds for vaccine coverage levels for achieving certain HBsAg seroprevalence goals need to be estimated using mathematical modeling. In addition, strategies are also required to support safe, consistent and effective vaccine use by promoting self-reliance on vaccine financing, developing an effective vaccine management system, and investing in advocacy, social mobilization, and monitoring and evaluation (sero-surveys, community surveys, AEFI surveillance, birth dose assessment and process/impact evaluation). The SEAR ITAG (Immunization Technical Advisory Group) recommended in 2016 to achieve less than 1% HBsAg prevalence among 5-year-old children by 2020 and to reach 90% Hep B coverage in all countries. The key indicators for monitoring are % with HepB0; % with HepB3 and % drop out between 1st and 3rd dose.

TRIPLE ELIMINATION OF MTCT OF HIV, SYPHILIS AND HEPATITIS B

The current public health response to HIV, hepatitis and STI is characterized by an increased emphasis on sustainability and efficiency. Due to existence of a common platform of maternal, neonatal and child health (MNCH) care and similar interventions across the three diseases, triple elimination of mother-to-child transmission (eMTCT) of HIV, hepatitis B and syphilis is achievable. But currently, services are not always provided as a standard component of MNCH care and planning, implementation, and reporting do not always occurs in coordination. As a result, services are less favourable and not accessible to women, children and their family leading to infants born with preventable infections.

The current situation in the Region is as follows:

- Low ANC coverage (e.g., India, Myanmar, Nepal, Bangladesh) and poor quality of ANC in some countries
- Low HIV testing coverage of pregnant women in all countries except Thailand and Sri Lanka. Also, a significant gap exists in identifying HIV-positive pregnant women. Dual testing of HIV and syphilis is not happening in majority of the countries.
- Low skilled birth attendant in some countries (Nepal and Timor-Leste)
- Low postnatal care coverage especially for newborn leading to missed opportunity for providing hepB0, antiretroviral prophylaxis for PMTCT of HIV and early infant diagnosis
Other major challenges for the Region in scaling up a spectrum of interventions for triple elimination include policy gaps, weak health systems (financing, human resources, supply of essential medicines and products, information system), poor linkage and integration of PMTCT and MNCH services to be cost-effective, vertical HIV programmes, and other common barriers to access and utilization of health services.

- Effective coverage of PMTCT and MNCH is reliant on health systems, midwives and engaging family and communities, which the countries need to invest in for achieving triple elimination goals.
- In addition, countries need to ensure that HIV/syphilis/HBV services for pregnant women are included in the UHC, as part of care delivery systems and health insurance/benefits package.
- Tracking referrals between HIV service delivery points, ANC/MCH clinics, antiretroviral treatment (ART) centres, laboratories, vaccination points and paediatrician clinics also needs to be established.
- Lastly, triple elimination would not be possible without utilizing opportunities for improving adolescent participation, community engagement, male partner involvement, and quality of care. For good quality care, essential infrastructure, equipment, medicines, other supplies and lab support; appropriate number, competent and motivated healthcare workers; standard guidelines; and patient satisfaction are needed. Quality of care improvement is a systematic process and requires countries to regularly identify the problems, do root cause analysis, develop and implement solutions, and reassess the impact of the solutions.

As countries are moving or considering moving towards triple elimination, the first steps include updating the national policies, strategy and guidelines, capacity building of the workforce, ensuring essential supplies, and strengthening convergence between the different health programmes. The Regional framework for triple eMTCT of HIV, syphilis and hepatitis B in Asia and the Pacific 2018-2030 is also being developed by WHO for a coordinated response in the countries. It is a participatory process involving 17 countries, 2 partner organizations, 3 WHO regional offices and WHO headquarters. The final draft is
currently being developed and will be shared with the Member States in the Regional Committee Meeting in September this year.

The triple elimination framework (2018-2030) aims to achieve following targets:

i. HIV – <50 paediatric infection/100,000 live births: transmission rate <5% (breast feeding) or 2% (non-breast feeding) infants.

ii. Syphilis – <50 cases of syphilis/100,000 live births

iii. Hepatitis – <0.1% prevalence of HBsAg among 5 year old children

Triple elimination would not be possible without quality MCH care in the Region. Coverage of evidence-based interventions across target populations and quality of care (QOC) ensure effective coverage. In the high priority countries, there is a significant variation in coverage across the reproductive, maternal, newborn, child and adolescent health (RMNCAH) life-course, especially ANC 4 visits, skilled attendants at birth, and post-natal care visit within 2 days for mothers. Gaps along the RMNCAH continuum of care exist even in countries with high coverage (Maldives and Sri Lanka). WHO defines quality of care as the extent to which healthcare services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, healthcare needs to be safe, effective, timely, efficient, equitable, and people-centered. For good quality care, countries need to ensure (a) essential infrastructure, equipment, medicines, other supplies and lab support; (b) appropriate number, competent and motivated health staff; (c) adoption and implementation of standard treatment guidelines; and (d) patient participation and satisfaction. Based on these principles, the WHO Regional Framework for QOC recommends a seven-step systematic process for implementation of quality of care:

1. Getting started: Establish national-subnational QOC structures with roles at various levels; national coalition; plan of Action

2. Develop / adapt national standards of care

3. Assessment of current QOC

4. Improvement process: Identify problem, do root cause analysis, & implement solutions

5. Reassessment: implement solution and find out if it led to improvement

6. Build a learning platform

7. Scale up
WHO has recently revised its treatment guidelines for both hepatitis B and hepatitis C. The new directions/priorities for HBV treatment guidelines are use of antivirals for PMTCT, simplification of treatment criteria, use of tenofovir alafenamide (TAF) and the cure agenda. For HCV treatment guidelines, the directions/priorities include pan-genotypic regimens, use of non-invasive tests (APRI or FIB4) for assessment of liver fibrosis, recommending ‘treat all’ with prioritization (patients with increased risk of death/fibrosis, extra hepatic manifestations, psychosocial morbidity), second line/salvage therapy recommendations, use of DAAAs in pregnant women, and pediatric treatment (priority regimens and formulations based on weight/age and 8-weeks short course).

In February 2017, WHO issued hepatitis B and C testing guideline recommendations covering who to test for HBV and HCV and testing approaches, testing algorithms, service delivery models (based on lessons learnt from HIV), use of dried blood spot specimens, point-of-care Nucleic Acid testing (NAT) among others. This document also provides guidance to support implementation of these recommendations at country level in two key areas: how to organize hepatitis testing laboratory services (systems for selection and evaluation of assays and quality assurance systems) and how to strategically select testing approaches and services.

The ‘who to test’ recommendations are based on limited evidence. A narrative review of 19 HCV and 32 HBV cost-effectiveness studies was done comparing different testing approaches but majority were from high-income countries or in pre-DAA era. The guidelines recommend offering focused testing to individuals from populations most affected by HBV or HCV infection. In settings with a ≥2% or ≥5% seroprevalence of HBsAg or anti-HCV, it is recommended that all adults have routine access to and be offered testing (general population testing approach), or use “birth cohort” testing for specific age groups with higher anti-HCV seroprevalence. The different testing approaches should make use of existing facility-based (such as ANC clinics, HIV or TB services) or community-based testing.
services and opportunities. Also, countries should optimally use the existing lab and diagnostics capacity, especially HIV and TB.

While considering adopting these recommendations in the national guidelines, countries (a) need to map the equipment and utilization and existing testing facilities, (b) have a sample referral network and equipment maintenance contracts, and (c) have a phased approach starting with focused and then general population.

KEY ISSUES WITH HEPATITIS TESTING AND TREATMENT

There is a large burden of undiagnosed and untreated hepatitis B and C. The key barriers to expanding testing and treatment for hepatitis are:

- Lack of awareness, knowledge, understanding
- Stigmatization and discrimination
- Lack of testing services: Testing for hepatitis is at the core of care, prevention and treatment cascade. Simple and affordable HCV diagnostic solutions are lacking and present a major barrier to treatment access especially in low- and middle-income countries. The 2015 data suggest that only 8.7% of the estimated people with HCV in the Region were diagnosed and 7.1% of those diagnosed received treatment.
- Complex testing algorithm: HCV diagnosis algorithm is a multi-step process and remains complex. Also, serological tests are of variable quality and NAT-based diagnostic tools are expensive and available only in central labs. There are 2 HCV rapid diagnostic tests that have been prequalified (PQ) by WHO (3 in process) and the HCV RNA (Ribonucleic acid) using GeneXpert has also been PQ in April 2017 (1 other in process). There is an urgent need for PQ of HBV DNA, better diagnostics and strategies to incentivize PQ submission of quality products.
- Affordability of drugs: Innovative new medicines have become available that can cure HCV in 12 weeks. Even though prices of hepatitis C drugs are falling rapidly, they are high and vary considerably across countries.
- HCV programmes are not in place, including the data, policies, guidelines and budget, leading to lack of demand for HCV interventions.
Goals and vision of GHSS on VH (2016-21) – 90% decrease in incidence; <65% in mortality by 2030 and 2017

SCALING UP HEPATITIS C DIAGNOSIS AND TREATMENT IN PUNJAB

In June 2016, a collaborative HCV public health programme under the state government funding was launched in Punjab. Punjab has an urban prevalence of 3.09% for hepatitis B and 2.9% as per blood bank data. This programme has been successful so far in delivering standardized HCV services along the care continuum. Its salient features include:

- Contact tracing and high risk group identification
- Decentralized model of screening at district and sub-district hospitals using rapid diagnostic tests.
- In collaboration with Foundation for Innovative New Diagnostics (FIND), 4 GeneXperts for viral load testing have been made available in the state and all districts are linked to these 4 centres. Moreover, sample is collected from 160 sites across the state, preventing travel time and cost for the patient.
- Simplified and decentralized treatment provided free of cost to patients through the public health system (22 district hospitals and 3 medical colleges). Counseling related to treatment adherence, treatment completion, and SVR and its importance is provided.
- Health care providers were trained on hepatitis C treatment using ECHO model.
- Treatment programme monitoring: A cure certificate has been designed to be given to those with SVR. It ensured that patients returned for SVR checks
- Individual patient data system and drug inventory management are required for treatment programmes. Clinton Health Access Initiative (CHAI) has led development of tools and robust information management systems to monitor treatment outcomes and enable regular monitoring and evaluation of the Punjab programme to inform policy makers. CHAI is also supporting development of SOPs and treatment cards

In phase 1, the following were screened: HIV-positive patients attending Integrated Counselling and Testing Centres (ICTCs), PWID at Opioid Substitution Therapy (OST) centres and targeted interventions (TIs) sites, patients on Haemodialysis, thalasaemics and jail inmates. In phase II, all healthcare workers and pregnant women attending ANC will be
covered. As of April 2017, there were over 27,000 people identified with HCV of whom 25,217 have been initiated on treatment and 10,438 have completed the treatment. SVR has been done in 8377 and there is a success rate of around 93%. Genotype 3 was the most prevalent type and 13% patients were cirrhotic at registration.

This good practice model from Punjab state will be helpful for national level discussions and informing the national plan. Also, as the programme matures, more planning will be needed. For example, prevalence varies across the districts and a strategy of test all in high prevalence districts will need to be evaluated.

### HCV TREATMENT IN PUBLIC SECTOR IN MYANMAR

There is strong political commitment to address hepatitis C as a public health problem in collaboration with other programmes and international organization. HCV treatment in public sector began this year (2017). In the preparatory phase, Myanmar is developing testing and simplified treatment guidelines, national strategic plan based on WHO framework, costed operational plan, monitoring and evaluation plan, Open MRS database for patient monitoring, and public awareness information, education and communication (IEC) materials. Due to the scarcity of human resources and funding, Myanmar will expand treatment in a phase-by-phase manner. A treatment eligibility criterion has been setup, genotype testing is not recommended and quota system for treatment will exist for some years. This year, 8 government hospitals will provide hepatitis C treatment in Yangon, Nay Pyi Taw and Mandalay to 1,200 mono HCV infected patients and 800 HIV and HCV co-infected patients. By 2020, the plan is to scale-up treatment to 30,000 people with HCV. While consultant Hepatologist will provide treatment, community based clinical management can be done by international non-government organizations and township hospitals. HCV treatment programme in Myanmar is in its nascence and a multimodal approach for prevention, increased case diagnosis and enhanced treatment is needed to have a major impact on burden of HCV disease. The government has also planned for hepatitis B treatment but is looking for funding sources.
SCALING UP HEPATITIS C DIAGNOSIS AND TREATMENT IN INDONESIA

As Indonesia begins implementing its HCV testing and treatment programme, the challenges are similar to those faced by other countries in the Region. These include:

- Lack of knowledge and awareness among people, healthcare workers, and policy-makers
- Inadequate surveillance and recording/reporting system; poor data management
- Unfriendly geographical situation – distribution of patients in different islands and administrative regions
- Sophisticated and costy tests (viral load, genotype)
- High-cost treatment, complicated procedure
- Only 165 hepatologists to serve 2.5 million HCV and 18 million HBV patients
- Delay in drug registration or budget realization – Daclatavir, grazoprevir and ebasvir are waiting for approval and Veltaspavir will be registered at the end of 2017

However, the increasing government commitment at national and local level, availability of cheaper DAAs, and support from other health programmes, professional associations and social societies present opportunities to provide and scale-up HCV treatment. The guidelines have been developed and trainings have been provided to medical and health staff, nurses, laboratory personnel and recording and reporting staff. A total of 367 units of GeneXpert have been distributed to 34 provinces and will be used integrated with TB and HIV programmes.

From April-May 2017, DAAs will be provided in Jakarta and then expanded to North Sumatra, West Java, Central Java, East Java, and Makassar. Sofosbuvir, simeprevir and ribavirin will be given to a target of 6,000 patients free of charge through assigned hospitals and prescribed by hepatologists or certified internists. Later, DAAs will be introduced in National Health Insurance (BPJS) and also sold at cheap prices (USD 300-400) through private medical services on prescription of hepatologist (in places that have hepatologists).
7. ACCESS TO AFFORDABLE DIAGNOSTICS AND MEDICINES

Various factors can influence access to affordable medicines for viral hepatitis. These include registration of medicines and diagnostics, procurement mechanisms, integrity of supply chain, patent situation (voluntary licensing, compulsory licensing, parallel imports, patent pools, etc.), and price transparency and price negotiation.

The regulatory status of various DAAs in the different countries is as follows:

- **Sofosbuvir**: is approved in India, Indonesia, Bhutan, Nepal, Myanmar, and Sri Lanka while it is under the registration process in Indonesia
- **Ledipasvir/sofosbuvir**: is approved in India and Myanmar and under the process in Sri Lanka
- **Daclatasvir**: is approved in India, Myanmar and Nepal and under the process in Sri Lanka
- **Velpatasvir**: is approved in India and Nepal and under the process in Myanmar

Table 2 presents the status of DAAs in the Region. Generics are available in many countries. In 2017, one of the priorities for WHO will be to PQ quality assurance of sofosbuvir and daclatasvir generics. The steepest price decrease is observed in countries with generic competition, confirming previous experience with HIV antiretroviral treatment. Price reductions trends in Indian generic HCV medicines show a decline from USD 330 in 2015 to USD 60 in 2017 per bottle for sofosbuvir in the private sector. Similarly, the price for daclatasvir has reduced from USD 92 in 2016 to USD 23 per bottle in 2017. This fall in prices has been steeper in the government procurement, where sofosbuvir was procured for USD 24 and daclatasvir for USD 12. Comparatively, price per bottle of sofosbuvir is USD 289 in Indonesia and USD 220 in Myanmar and for daclatasvir is USD 135 in Indonesia and USD 90 in Myanmar. The prices remain very high in Thailand.
Table 2: Status of DAAs in the Member States of WHO South-East Asia Region

<table>
<thead>
<tr>
<th>Country</th>
<th>Medicines</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>Sofosbuvir</td>
<td>Sovaldi and generic sofosbuvir approved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other DAAs under special import</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>Sofosbuvir, daclatasvir, ledipasvir + sofosbuvir, sofosbuvir + velpatasvir</td>
<td>All generic forms available including sofosbuvir +daclatasvir &amp; sofosbuvir + velpatasvir</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Sofosbuvir, ledipasvir + sofosbuvir, daclatasvir</td>
<td>Generics approved</td>
</tr>
<tr>
<td>Nepal</td>
<td>Sofosbuvir, daclatasvir, ledipasvir + sofosbuvir, sofosbuvir + velpatasvir</td>
<td>Generics available</td>
</tr>
<tr>
<td>India</td>
<td>Sofosbuvir</td>
<td>Sovaldi, 15 companies marketing generics</td>
</tr>
<tr>
<td></td>
<td>Ledipasvir + sofosbuvir</td>
<td>14 companies marketing generics</td>
</tr>
<tr>
<td></td>
<td>Daclatasvir</td>
<td>14 companies marketing generics</td>
</tr>
</tbody>
</table>

REGIONAL INITIATIVE FOR ACCESS TO AFFORDABLE MEDICINES

The number of medical product manufacturers has increased rapidly, both domestically and internationally. It poses challenges for regulatory authorities in guaranteeing the quality, safety and efficacy of the medical products and conducting inspections of facilities. The South-East Asia Regulatory Network (SEARN) has been established and has the following objectives:

- Information sharing: enhance communication and information sharing on regulatory policies, guidelines, standards, procedures, outputs and regulated products and entities as approved by network members.

- Systems strengthening: Facilitate and support regulatory capacity development to enhance regulatory skills and competencies and strengthen regulatory systems in the Region.

- Convergence: Promote convergence and alignment of regulatory approaches and requirements based on international standards and good regulatory practices.
• Collaboration: Identify and develop potential work sharing and reliance processes to help address common work areas and optimize use of existing regulatory capacities and expertise available.

**India – Negotiating affordable access to diagnostics and medicines for HCV in Punjab**

In 2014-15, the government of Punjab procured the interferons and distributed them through the Jan aushadi stores at subsidized cost to the patients. However, the prices were still very high with a single injection costing around USD 46 and a complete course of 48 weeks around USD 2,300. In June 2016, a collaborative HCV public health programme was launched. The programme has undertaken rate contracts for DAAs and with the laboratories for viral load and genotype testing (in cirrhotic patient). The standard baseline investigation package is available free from the health system. The mechanism of rate contract has helped the programme to negotiate and get extremely competitive pricing from Dr Lal Path Lab (a private lab): USD 31 for viral load (quantitative) and USD 43 for genotype (for cirrhotics). SVR is done free of cost by the lab. A comparison of prices for the retail purchases in open market by patients with the government procurement prices show that there is extensive variation (Table 3). The programme is also considering core antigen which is equally sensitive and cheaper <$10

**Table 3: Price comparison of DAAs**

<table>
<thead>
<tr>
<th>Drug</th>
<th>MRP (USD)</th>
<th>Market Price (USD)</th>
<th>Punjab Govt Rates (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ledipasvir + sofosbuvir</td>
<td>357</td>
<td>143</td>
<td>64</td>
</tr>
<tr>
<td>Daclatasvir</td>
<td>100</td>
<td>64</td>
<td>13</td>
</tr>
<tr>
<td>Sofosbuvir</td>
<td>260</td>
<td>157</td>
<td>22</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>129</td>
<td>71</td>
<td>8</td>
</tr>
</tbody>
</table>
Thailand – possible options for reducing costs of HCV medicines

Thailand is the only country without access to affordable medication for Hepatitis C treatment in the Region. Thailand has tried to negotiate with pharma companies and other stakeholders but were not very successful and recently, Gilead had further increased the price of Sofosbuvir. A12 was treatment in Thailand costs US $ 9000 against US $ 200 in India. This has further affected the budget for the national programme. Hence, it is proposed to include the DAAs in essential drug list. With HIV, the push from communities played a major role in driving down the prices of ART. There are several commonalities between HIV and hepatitis in different countries including intellectual property rights and regulatory barriers. Some possible options for Thailand are community activism and/or sourcing the generic from Bangladesh. Use of compulsory licensing can also be explored. It does not need to be an emergency situation for compulsory licensing to be used.

ROLE OF PARTNER ORGANIZATIONS

There are various partner organizations working towards hepatitis in the Region. For example, UNITAID is a donor agency with a specific agenda and is providing initial funding to the governments to scale-up hepatitis programmes. There are various UNITAID funded HCV projects in the Region, which are trying to address the different challenges identified in HCV and HIV/HCV.

Partner organizations’ projects in the Region include:

1. UNITAID- FIND Project (October 2016 – January 2020)

The UNITAID-funded FIND project has a goal to contribute to WHO target through four outputs:

Output 1: Bring new fit-for purpose HCV diagnostics to the market

Output 2: Facilitate HCV diagnostic tests and treatment availability in the project countries health systems i.e. implement HCV testing in project countries and link to treatment

Output 3: Increase affordability of HCV testing and treatment
Output 4: Consolidate & share evidence to support policy change and scale-up

With the aim to unlock the market for HCV diagnostics in project countries (output 2), FIND is conducting demonstration projects in many countries, including India and Myanmar from the Region. The projects will demonstrate the following:

- Optimized diagnostic algorithm that is affordable, simple, and uses one-step sampling with one or two-step diagnosis strategy depending on the prevalence
- Feasibility of the optimized algorithm across varied care settings (such as ART centres, drug treatment centres, etc.)
- Combination of centralized and decentralized testing strategies and service delivery models depending on best fit and local needs.

Post the demonstration projects, FIND will also support integration of HCV testing into existing polyvalent lab platforms, develop and guide implementation of a minimum quality assurance and proficiency testing scheme, and ensure use of innovative connectivity solution in some countries/project sites fully integrated with existing IT solutions. These initiatives will guide national policy and scale-up.

2. Coalition Plus (C+) HIV/HCV Drug Affordability Project

Funded by UNITAID, the C+ HCV project has an objective to improve access to HCV treatment for HIV co-infected patients in 7 low- and middle-income countries, including Thailand, Indonesia and India. One of its main activities is to improve access to diagnostic and treatment through removal of cost barriers through price reductions and greater reimbursement coverage. Till date, six campaigns have been launched and this project has been successful in getting DAAs included in national guidelines in some project countries (Indonesia), supporting anti-monopoly efforts (patent rejection and competition lay) and discount negotiations (Thailand), and advocating with key policymakers for cheaper DAAs. However, there is a long lead-time to start activities in countries and complex political landscape has posed challenges to the project. But there are signs of progress in many countries. With collaborations and sustained work over the next few years to address the price barriers, the targets can be achieved.
3. CHAI HCV Programme in Asia

CHAI is currently supporting 3 countries in the Region (India, Myanmar, Indonesia) to catalyze HCV treatment scale-up by demonstrating the feasibility of public sector hepatitis C treatment programmes. CHAI has negotiated price reductions with antibody test suppliers, viral load suppliers and generic treatment suppliers for the government programmes. To address the major in-country bottlenecks to starting treatment programmes, CHAI is supporting countries on:

- Testing and treatment guideline revision
- National strategic plan development and costing
- Decision-making and financing decisions
- Advocating for expedited registration and providing pricing transparency to the governments
- Problem-solving on supply chain bottlenecks
- Building systems/processes for patient referral, viral load testing, integration of services and sample transportation
- Developing paper and electronic monitoring and evaluation tools for site supervision and mentorship.
- Site supervision and mentorship

CHAI is also working to simplify diagnostic algorithm, provide market intelligence to generic drug manufacturers and diagnostic companies, and catalyze development of quality-approved commodities. Currently, Myanmar and Indonesia are in the final stages of public programme preparation to launch treatment in Q2 2017; screening is ongoing and being scaled-up.

4. Use of global procurement fund to provide low cost/ quality medicines and diagnostics
The Global procurement (GPRO) fund has been created to provide access to low cost, quality medicines and diagnostics for low- and middle-income countries through pooled procurement. The system is designed to be sustainable over the long term with no or minimal reliance on donors. Countries and/or private insurance companies can apply for GPRO membership and GPRO negotiates prices on their behalf with the manufacturers based on large volumes. Manufacturers pay 5% of the total payment received for drugs/diagnostics to GPRO and this money (after subtracting the overhead costs) goes into the GPRO Fund. GPRO Fund is used to provide interest free loans to low- and middle-income countries and free drugs and diagnostics to low-income countries. Most of the countries in the region are eligible to utilize the facility.

5. Hepatitis C Buyers Clubs and Medical Tourism

Generic DAAs can be bought readily online and prices are declining. Medicines are sent worldwide from India, China, Egypt and Bangladesh and most countries allow some form of personal medication importation. As part of medical tourism, “Tour n’ Cure” treatment packages are offered in Egypt.

Other UNITAID funded projects are described in Table 4.

**Table 4: UNITAID funded HCV projects in the South-East Asia Region**

<table>
<thead>
<tr>
<th>Project</th>
<th>Main objectives</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Médecins Sans Frontières (MSF)</td>
<td>Demonstrate feasibility of HCV cure in HIV-positive people in resource limited settings, and develop simplified models of care that improve access to care at lower cost</td>
<td>India, Myanmar</td>
</tr>
<tr>
<td>Medicines Patent Pool</td>
<td>Enable development of generics &amp; accelerate their launch</td>
<td>Daclatasvir license in all countries (except Thailand)</td>
</tr>
<tr>
<td>WHO pre-qualification</td>
<td>Verify quality of medicines &amp; diagnostics</td>
<td>All countries</td>
</tr>
<tr>
<td>WHO enabler</td>
<td>• Support with guidance, data, technical assistance</td>
<td></td>
</tr>
</tbody>
</table>

38
| **Facilitate high-quality research to inform product approval and use, and inclusion in WHO guidelines** |
| **Strategic information to facilitate forecasting** |
| **Coordinate knowledge sharing** |
| **Technical assistance to focus/early adopter countries** |

The important role played by other organizations includes:

- **United Nations Children’s Fund (UNICEF)** is working towards procuring hepatitis B birth dose vaccine at a lower cost and supply chain management for the same. It is also raising awareness on hepatitis B in the communities, especially in ANC settings among pregnant women.

- **TREAT Asia/amfAR** is providing training on use of DAAs, specially focusing on HIV/HCV co-infections. They also work on using social media for advocacy and developing pricing briefing and policy research.

- **Thai Red Cross** is addressing HIV, hepatitis and tuberculosis together. They are working towards strengthening testing and treatment care models for MSM and PWID. Collaborations have been formulated with pharmaceutical companies and National Institutes of Health to conduct a treatment simplification study. Also, Thai Red Cross is working with other partners on development and implementation of guidelines.

- **The Institute of Liver and Biliary Sciences (ILBS), New Delhi** is a WHO collaborating centre (CC). They have developed laboratory manuals and are supporting capacity building at the country level. In collaboration with educational institutions, they are providing training programmes, some of which are online and available free of cost. They are also involved in operational research (with FIND and MSF) and supporting advocacy efforts for National Strategic Plan in India.

- **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**, India is also a WHO CC and is providing need-based technical assistance to the Member States. They can support countries in training, advocacy, mathematical modeling, primary and secondary research, data collation and analysis, etc.
The countries reported that the major areas in which they need support from partner organizations include good baseline assessment, costed national plans, developing political agenda and opportunities, and supporting civil society and activism.
8. STRATEGIC INFORMATION FOR HEPATITIS ELIMINATION

WHO GUIDANCE ON MONITORING AND EVALUATION (M&E) AND SURVEILLANCE

The Global Health Sector Strategy on Hepatitis has set targets for 2030 for coverage of key interventions and to measure impact. To monitor and evaluate the strategy, WHO proposed an M&E framework, which contains a set of 10 core indicators to monitor the health sector response to HBV and HCV along the result chain. They include prevalence estimates, prevention indicators (immunization coverage, needle and syringe for PWID, blood and injection safety), indicators along the cascade (diagnosed, on treatment, viral suppression for HBV, cure for HCV), and mortality and incidence estimates. Data systems to monitor these indicators are hepatitis surveillance and programme data.

1. Viral hepatitis surveillance is divided into three categories:
   - Acute hepatitis surveillance – to detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections. Countries usually do syndromic surveillance but enhanced case reporting is needed to describe trends and identify risk factors.
   - Surveillance for chronic infection – to estimate the prevalence of chronic infections and monitor trends in sentinel groups. Information on prevalence can be collected through biomarker surveys, data mining or reporting on chronic cases (which only estimates the quantity of cases diagnosed). While reporting of chronic cases, it is important to clearly differentiate between newly infected cases of chronic and acute hepatitis.
   - Surveillance for cirrhosis and hepatocellular carcinoma (HCC) – to estimate the burden of sequelae. The fraction of cirrhosis and HCC coming from HBV and HCV (from two different sources) can be used to claim attributable deaths.

2. Data on prevention indicators is routinely collected from programme data or using specific surveys (e.g. immunization, injection safety). Patient registries (patient cards and databases) are the data source for monitoring the care and cure cascade.
While WHO guidance is available for surveillance and monitoring prevention indicators, guidance on patient registries is work in progress. Myanmar will start with patient registries and is the first country to have a registry.

### HEPATITIS SURVEILLANCE IN INDIA

The burden of viral hepatitis in India is not well characterized. There is no mechanism for national data collection on hepatitis B and C but the government is committed to work on this aspect. Integrated Disease Surveillance Programme (IDSP) is investigating hepatitis B and C outbreaks in the country. Population-based surveys are scarce. Data on hepatitis C prevalence is available from population-based studies, which shows high prevalence in Punjab (5.2%), some tribal populations [Lisu tribe in Arunachal Pradesh (7.89%) and Bharia tribe in central India], and intravenous drug users or IVDUs (50-66%). Cultural practices such as tattooing, traditional medical practices such as blood letting and scarification, and closed community marriages may explain the higher prevalence of HCV in tribal populations. In Kolkata, HCV prevalence among IVDUs has increased from 17% to 80% over seven years despite an ongoing harm reduction programme. High prevalence among this at-risk population has also been reported from northeastern states of Manipur, Nagaland and Mizoram that are bordering Myanmar. In Manipur, majority of IVDUs injected heroin whereas the main injection drug used in Nagaland was dextropropoxyphene. Unsafe therapeutic injections and blood transfusion are the predominant mode of transmission of HCV in India.

**Sequelae Surveillance for Chronic Hepatitis B and C in India**

Institute of Liver and Biliary Sciences (ILBS), a WHO collaborating centre initiated a sequelae surveillance project for chronic HBV and HCV infections in India, developed with help of WHO and in network with 13 centres of excellence in the country. Under this project, a suitable sample of cirrhosis and HCC patients were recruited and their HBV and HCV status was assessed to calculate the proportion infected with HBV or HCV or both. Variables determining the development of specific sequelae; such as duration of infection, viral loads, genotypes, availability of treatment and development of complications, were also looked at.
The case definitions were decided and ethical approval was taken by each centre. Sample size calculation was done as follows: Estimating the frequency of chronic infection (about 10%) with 5% absolute precision among patients would require 139 cirrhosis and 139 HCC over one year for a 95% confidence interval (No design effect). As a first approximation, 300 patients [cirrhosis (150) and HCC (150)] will be required from each centre. The study results are shown in Table 5.

**Table 5: Etiology in cirrhotic and HCC cases, 2016**

<table>
<thead>
<tr>
<th></th>
<th>Retrospective data</th>
<th>Prospective data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cirrhosis (n=9,223)</td>
<td>Cirrhosis (n=150)</td>
</tr>
<tr>
<td>HBV</td>
<td>8.3%</td>
<td>3.2%</td>
</tr>
<tr>
<td></td>
<td>HCC (n=1,159)</td>
<td>HCC (n=41)</td>
</tr>
<tr>
<td></td>
<td>25.4%</td>
<td>35.7%</td>
</tr>
<tr>
<td>HCV</td>
<td>5.9%</td>
<td>18.5%</td>
</tr>
<tr>
<td></td>
<td>5.3%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

Challenges faced by the project were related to contribution from all centres, due to which the prospective data is very centre (ILBS) specific. Achieving the target of 139 HCC per centre per year was also difficult. No national mortality estimates are available for cirrhosis/HCC. Civil Registration and Vital Statistics (CRVS) is one of the neglected areas in India. As per Office of Registrar General of India, only 71% deaths are registered and cause of death is assigned to 20% of registered deaths. As per report on Medical Certification Of causes Of Death, 2013, no data on deaths due to cirrhosis were available and deaths due to “Malignant neoplasm of liver and intrahepatic bile ducts” were 2,259 (under reporting).

**SERO-SURVEY TO ESTIMATE THE PREVALENCE OF HEPATITIS IN BHUTAN**

In 1997, Bhutan conducted one round of HBV serosurvey that documented 5.9% prevalence of HBsAg in the general population. Following the survey, the country integrated hepatitis B vaccine into EPI. Hepatitis Prevention and Control Programme was rolled out in 2011. In 2016, Bhutan still faced a large number of chronic liver diseases among adults. To determine burden of disease and impact of vaccination programme, the country is conducting a cross-sectional nationally representative 3-stage cluster sero-survey in 3 age groups, integrated
with measles and rubella. The fieldwork for serosurvey began in April 2017 and its objective is to determine:

- Prevalence of chronic HBV infection in 3 age groups (pre and post-vaccine introduction)
- Prevalence of past infection (anti-HCV) and current infection (HCV RNA) in older children (5-17 years) and adults (20+)
- Impact of vaccination in children
- % with chronic HBV and HCV that are aware of status
- Potential factors associated with being infected (healthcare work, invasive traditional healing, blood transfusion)

Thirty clusters from 13 districts were chosen by probability proportional to size, meaning that bigger places were more likely to be chosen and could be picked up multiple times (more household from such a cluster). From each adult or parent of <18 years old, consent was obtained for participation in a survey [demographics, vaccination history, knowledge of HBV/HCV status, high-risk behaviours] and agreement to store blood for later testing. Preliminary results are expected in September 2017 and will help in development of national action plan, costed operational plan, and treatment and management guidelines. Bhutan requires technical assistance for developing the action plan and dissemination of survey findings. Also, despite funding from different sources (e.g., EPI programme) more funding is needed for the ongoing serosurvey.

DISEASE BURDEN ANALYSIS IN SOUTH-EAST ASIA

The Center for Disease Analysis model was used in South-East Asia to evaluate the impact of improved testing and treatment on HCV infections, liver-related deaths (LRD), HCC and decompensated cirrhosis (DC). Assumptions in base scenario were 83% SVR, keeping those diagnosed constant, and reduce number treated by 50% from 2016-2020. In base scenario, between 2014-2030, HCV infections will decline by 2%, while LRD, HCC and DC will increase by 95-100%. In the WHO target scenario (96% SVR, expanded screening to diagnosed 90% cases by 2030 and increased treatment), HCV infections will decline 90% by 2030 while LRD will decline by 70% (Figure 1). This same analysis in Myanmar shows that with 90% SVR and
expanded screening and treatment, new infections will fall from 27,420 (2015) to 2,300 (2026).

**Figure 1: HCV infections, LRD, HCC and DC in South-East Asia**

It is feasible to eliminate HCV infection in the Region. For that, treatment has to be increased to ~7% of total infections (coupled with active screening). Also, screening and treatment has to encompass all HCV infected individuals (fibrosis stage ≥F0) as most new infections occur among younger individuals who are in fibrosis stage F0 or F1. Reducing liver-related deaths in the Region poses a challenge – mortality is currently projected to increase by 100% by 2030. Over half of infected individuals are between 40-60 years of age and are likely to advance to late-stage liver disease and/or mortality over the next 15 years. Targeting interventions to this age range would be an effective way to reduce liver-related deaths.
In India, cheap and effective DAAs are available but numbers of persons treated are still low. Cost-effectiveness data are not available from areas with generic HCV DAAs and will be important to make decisions regarding expanding HCV treatment programme in countries. A Markov state-transition model: MATCH (Markov-based Analyses of Treatments for Chronic Hepatitis C) was modified for India to determine cost-effectiveness of generic DAAs. The population was HCV0infected persons in India up to 35 years of age with genotype 3 in 63.4% and cirrhosis (F4) in 13%. The disease progression model was adapted from Chhatwal et al Annals Intern Med 2015. The model inputs on treatment regimens and medical costs are shown in Table 6 and 7, respectively.

Results show that treatment with DAAs at mentioned prices improved patient outcomes (life-span and quality-adjusted life years) for all patients with and without cirrhosis and irrespective of genotype. DAA HCV treatment was cost-effective within years of treatment and lifesaving within ~10 years of treatment irrespective of patient age. DAAs became cost saving earlier (within 5 years) in patients with cirrhosis than in those with lesser stages of fibrosis. There were reductions in liver events (DC, HCC and LRD). Results did not change under sensitivity analysis. In conclusion, the study shows that HCV treatment should be a priority from both public health and economic perspectives in areas with drug availability at such prices.

Table 6: Treatment regimens

<table>
<thead>
<tr>
<th>HCV genotype</th>
<th>METAVIR fibrosis stage</th>
<th>Treatment drugs</th>
<th>Treatment duration (weeks)</th>
<th>SVR (%)</th>
<th>Treatment discontinuation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1</td>
<td>F0-F3</td>
<td>Sofosbuvir + Ledipasvir</td>
<td>12</td>
<td>98.1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>F4</td>
<td></td>
<td></td>
<td>93.2</td>
<td></td>
</tr>
<tr>
<td>G3</td>
<td>F0-F3</td>
<td>Sofosbuvir + Daclatasvir</td>
<td>12</td>
<td>97</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>F4</td>
<td></td>
<td></td>
<td>86</td>
<td>2</td>
</tr>
</tbody>
</table>
### Table 7: Medical Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost (US$)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment workup (genotyping, fibrosis, others)</td>
<td>119</td>
<td>0.5-0.2 fold</td>
</tr>
<tr>
<td>DAAs cost for 4 weeks</td>
<td>100</td>
<td>1-9 fold</td>
</tr>
<tr>
<td>Test during and after treatment</td>
<td>89</td>
<td>0.5-0.2 fold</td>
</tr>
<tr>
<td>Annual cost of test and drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. F0-F3</td>
<td>30</td>
<td>0.5-0.2 fold</td>
</tr>
<tr>
<td>2. Compensated cirrhosis</td>
<td>149</td>
<td></td>
</tr>
<tr>
<td>3. DC/HCC</td>
<td>596</td>
<td></td>
</tr>
</tbody>
</table>

**BENEFIT PACKAGE FOR HEPATITIS MANAGEMENT IN THAILAND**

There are 3 health insurance schemes covering 100% population in Thailand:

1. Civil servant medical benefit scheme for government employees, dependents and retirees
2. Social security scheme (SSS) for private sector employees
3. Universal coverage (UC) scheme for rest of the population (covering 75% population)

Each scheme guarantees access to a basic benefit package of health services, including medicines listed on the National List of Essential Medicines (NLEM).
All hepatitis B and C treatment regimens are included in the first scheme. Under the UC benefit package, medicines listed for HBV treatment include Lamivudine and Tenofovir. They are included in NLEM under category D: drugs for use by specialists on signature of a hospital director. Cost of treatment with these drugs is included in the capitation/disease-related costing for inpatients. Medicines listed for HCV treatment include Peginterferon alpha 2a or 2b and ribavirin (PR) in NLEM category E2 (high risk, costly drugs for use by a senior specialist). Government Pharmaceutical Organization centrally procures these medicines and distributes them to hospitals via a vendor-managed inventory system. Cost of reimbursement per patient is around USD 2,411-4,681 (depending on type of infection). New HCV infected patients utilizing this scheme has increased overtime and >5,500 have used it so far.

Sofosbuvir was clearly an important technology advance and has also shown to be cost-effective at the conventional cost-effective thresholds in various countries and populations. The high price of sofosbuvir in Thailand has led to many concerns around budget impact in the long run and whether health system can afford to pay for the drug in the short term. So cost-effectiveness analysis may not be enough and budget impact analysis is more important. See Table 8 for results from budget impact analysis.

**Table 8: Budget Impact Analysis for inclusion of DAAs in NLEM**

<table>
<thead>
<tr>
<th>Treatment Coverage</th>
<th>PR</th>
<th>Sofosbuvir+PR (All Genotype)</th>
<th>Sofosbuvir+daclatasvir (All Genotype)</th>
<th>Sofosbuvir+PR (G3)</th>
<th>Sofosbuvir+ledipasvir</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>10.64</td>
<td>17.18</td>
<td>26.45</td>
<td></td>
<td>17.32</td>
</tr>
<tr>
<td>10%</td>
<td>21.29</td>
<td>34.36</td>
<td>52.9</td>
<td></td>
<td>34.64</td>
</tr>
<tr>
<td>15%</td>
<td>31.94</td>
<td>51.54</td>
<td>79.35</td>
<td></td>
<td>51.95</td>
</tr>
</tbody>
</table>

Note: In USD million. Calculations show 74,510 people meet eligibility for treatment.
There are many unanswered questions for the country related to inclusion of sofosbuvir or new DAAs in NLEM, use of generic products, price negotiations, international price reference, prioritization of populations, and innovative payment mechanisms. Price negotiations for DAAs are starting; Thailand has a threshold of the price they want and will wait till they get that price. Some other possible options were presented during various discussions during the meeting.
10. SUSTAINABLE FINANCING

Countries have different systems of financing health for health Sector Response and Inclusion in the Health Benefit Package. This varies in different countries.

- **Bangladesh**: Hepatitis B vaccination for infants and high-risk groups is covered by government funds (tax revenue) and also supported by the World Bank funds. The country wants to include HCV treatment with DAAs for high-risk populations.

- **Bhutan**: There is no private health sector in the country and government provides health services from its revenue free of cost. Immunization is covered and with initiation of hepatitis control programme, testing and treatment will also be included. Health Trust Fund was started in 1998 by the King of Bhutan so that basic health services are provided even if donor funding stops. Target is to achieve USD 30 million. When the fund was started, donors were from high-income countries. People and corporates also donate to this fund. Additionally, government creates awareness to generate fund for trust each year. Interest generated from the fund is used for medicines.

- **DPR Korea**: The government, from domestic finances, covers all health services. There are gaps in the hepatitis programme – there are no national guidelines and lack of reagents and syringes is a common problem. The country needs external support to improve the laboratory services.

- **India**: Health funds are provided by the central government to the state government based on the plans submitted by the state. Both central and state funds go into health. There are many insurance schemes in the country. Majority of the people are insuring with the four major national insurance schemes but hepatitis is not covered. In the southern state of Tamil Nadu, insurance cards are given to the poor that could be used for public and private sector. Hepatitis B and C were included recently and the state government is procuring for the private sector. Also, India requested funds for HCV treatment for HIV/HCV co-infected patients in the Global Fund concept note.

- **Indonesia**: Treatment for hepatitis B and C is covered by national health insurance schemes. There are 2 national insurance schemes in the country; one scheme (BPJS) covers general population (57% population covered). However, diagnosis is less supported by the insurance.
• **Maldives**: Health services in the country are 100% government funded. Maldives has the highest health spending in the Region and has sufficient funds. Hepatitis prevalence is very low. Commercially, no hepatitis medicines are available as there is no profit for pharmacies to import and sell very small number of medicines. But migrants (such as Bangladeshis) are poor, have high hepatitis B prevalence and are not covered by insurance.

• **Myanmar**: Health is financed mostly by government budget and support is available from many different sources. Hepatitis management is mainly with donor support. Hepatitis B vaccine was supported by donation from Chinese government. For hepatitis C drugs, donation came from UNITAID and CHAI. National health insurance is not there in Myanmar and private insurance started recently. For government employees, there is social security but it covers only 1% population.

• **Nepal**: Health is financed through domestic funding, Global Fund, USAID, GAVI and bilateral funding. Health insurance scheme is there in the country but does not cover hepatitis. Viral hepatitis national policy and guidelines will be developed very soon and implementation will start thereafter. Currently, some non-governmental organizations (NGOs) are providing some hepatitis services to PWID and expenditure is mainly out of pocket.

• **Sri Lanka**: Health is financed by the government (taxes) and all health services in public sector are free at the point of delivery. Separately, services can be obtained from private sector also (out of pocket).

• **Thailand**: There are 3 health insurance schemes covering 100% population in Thailand, with UC scheme covering majority of the people. HBV treatment and HCV treatment with Peginterferon and ribavirin are covered by the insurance but DAAs are not included in NLEM.

• **Timor-Leste**: Hepatitis B prevalence is high in the country. The government largely funds the hepatitis programme and its implementation involves many other departments such as MCH and surveillance. Support from GAVI for vaccines is available. Testing is done in the national labs. There are three GeneXpert machines, which were donated by KOIKA, a Korean donor and are used for hepatitis viral load testing. However, there are problems on how to afford treatment drugs for hepatitis B and C.
11. ROLE OF CIVIL SOCIETY

One of the most important lessons learnt from the HIV response is that community engagement at all stages, from planning to implementation to monitoring, has been a key factor to HIV success story. Civil society has been continuously involved in advocacy and activism, raising awareness, treatment literacy and retention in care, fighting stigma and discrimination, and many other activities. In this Region too, community has been at the forefront of the HIV response in the Member States. The hepatitis response is no different and there are many success stories on the indispensable role of the civil society.

ADVOCACY AND NETWORKING

Advocacy is about making a good case persistently. In the hepatitis response, the question is no longer whether to do something about it but how to do it. The hepatitis advocacy started from a very low base with no dedicated external funding and at a time when there was a global shift away from vertical disease-specific programmes and communicable diseases. But there were opportunities as well: the world had signed up for elimination, an M&E framework was developed to track progress, and transformational HCV drugs were available and prices were falling. Building on these opportunities, NOhep was started as a civil society’s global campaign to respond to WHO’s global strategy with the aim of eliminating viral hepatitis by 2030. It is a global awareness raising and advocacy platform with multi-stakeholders. In November 2017, the World Hepatitis Summit will be held in Sao Paulo, Brazil.

POLICY REFORM AND CAPACITY BUILDING

Civil society has been actively involved in each step of the policy reform and advocacy process. For example, the Coalition to Eradicate Viral Hepatitis in Asia-Pacific (CEVHAP) was formed in 2010 to reduce the significant health, social and economic burden of viral hepatitis in Asia-Pacific. Its objective is to harness the collective knowledge and expertise of members to bridge gap between science and policy and build the case for policy reform. They are focusing on: 1. Education and capacity-building through policy workshops, providing inputs on global and regional policy and building links to policy makers and
influencers, 2. Policy research (survey, situation analysis, social policy research, and evidence generation to inform policy), and 3. Advocacy campaigns to disseminate information and raise awareness. However, compared to other global health issues, hepatitis still has low recognition and is poorly resourced. There is a lack of critical mass and cohesion in community response (apart from HIV co-infection) and stigma and discrimination prevail. These challenges need to be overcome to translate the evidence into policy and policies into action.

IMPLEMENTATION SCIENCE RESEARCH

In Bangladesh, HCV prevalence is low but among PWID, it is ~30% and as high as 40% in Dhaka. There are an estimated 33,000 PWID in the country, mostly concentrated in 6 districts (including city of Dhaka). Nearly 60% of PWID living with HIV are co-infected with HCV. The pilot study on HCV treatment among people who use opioid drugs (PWUD) in Dhaka was started to assess the feasibility of treating HCV infection in PWUD (HIV-negative) and measure SVR, adherence to treatment with DAAs, factors associated with good adherence, and behavioural risk factor associated with new HCV infections. PWUD were approached in drop-in centres, 28 were enrolled for screening and 5 tested positive for HIV. Of the remaining 23, 10 were HCV ELISA positive, 7 were HCV RNA positive, and 5 started DAAs. The study faced certain challenges since drugs were not received on time, HCV awareness was low, and intense follow-up was required to ensure adherence. Even though certain steps were taken to reduce waiting time, give drugs at drop-in centres and awareness raising by the physician, an awareness programme and more outreach workers were required. The findings from this pilot study could inform programmes for HCV treatment for PWUD worldwide.

SERVICE DELIVERY –BY COMMUNITY IN MANIPUR, INDIA

In the eastern state of Manipur in India, HCV prevalence among PWID and HIV/HCV co-infections are very high but there is low awareness among PWID and poor access to HCV prevention, testing, diagnosis and treatment services. Community Network for Empowerment (CoNE), established in 2011, is a state level network of 13 community-based organizations (CBOs) of people who use drugs in Manipur. They have been organizing
awareness campaigns and testing campaigns in the state (using public-private partnership model) to:

- Encourage voluntary testing for HCV in PWID community and general public
- Inform about HCV prevalence across the state
- Use data from the testing camp for advocacy purpose
- Facilitate access of those diagnosed positive to treatment
- Link people in need of treatment to state health scheme
- Facilitate price reduction of HCV medicines through negotiations with pharmaceutical companies

Entire continuum of care from antibody testing, PCR confirmation, liver staging and treatment using DAAs were offered. There was no cost to participants, except for DAAs, which is out of pocket and cost USD 240-288 for 12 weeks therapy (sofosbuvir + daclatasvir/ledipasvir). Of the 1,532 people tested, 561 were confirmed HCV RNA positive and 123 initiated treatment of whom 29 achieved SVR. CoNE has also organized 8 HBV testing and vaccination camps. Of 216 PWID tested, 32 were HBsAg positive and 40 among those testing negative completed vaccination using WHO recommended rapid regimen.

The lessons learnt from this project were that community of people living with HIV and PWID can play a vital in mobilizing people for testing, investment is important in awareness raising, involvement of key stakeholders is important, price reductions are possible with competition, and complete cascade of care is a must. However, dependence on pharmaceutical companies raises questions on sustainability and there needs to be more active case finding for HBV. CoNE will continue to mobilize people, mobilize resources for free treatment, reach out to those with confirmed HCV to link them to treatment and provide psychosocial support to those on treatment. They will also advocate for state-specific guidelines, inclusion of DAAs in the drug list, and improving diagnostic access and price reductions of medicines.
COMMUNITY MOBILIZATION AND ENGAGEMENT

Besides working on improving access to affordable diagnostics and treatment, Coalition-Plus is also working on community mobilization and engagement to create social demand for hepatitis-related services. Its main activities to increase awareness, reduce stigma and empower communities in the Region include:

• Mobilisation campaign on World Hepatitis Day
• Advocacy training and support activities for HCV patients
• Advocacy and mobilisation events on HCV diagnostics and treatment access involving PWID and people living with HIV
• Community trainings on the disease, intellectual property, and access to medicines
• Healthcare worker training
• Advocacy activities aiming at the publication of national guidelines
• Advocacy to improve screening, diagnostics, treatment
• Development of policy briefs and situation papers

In summary, noise on hepatitis has been created and community involvement is needed for a variety of reasons, including ensuring equity, to achieve the targets globally, nationally, sub-nationally and for the most affected communities. Also, the civil society is becoming more sophisticated and strategic. But the hepatitis community right now is synonymous with PWID but should also include patients on haemodialysis, thalasaemics and jail inmates. As seen in TB, momentum is often lost when people are cured and do not associate with a disease anymore.
12. CONCLUSIONS AND RECOMMENDATIONS

➢ Momentum for control of viral hepatitis, especially hepatitis B and C, has been building in the region but needs to be translated into action. The member states have committed to the Global Health Sector Strategy on Viral Hepatitis but the policies are still in the development phase in many of them. There is an urgent need for action since the time period left for achieving the goals is short.

➢ Awareness and advocacy are needed to leverage political commitment and resource allocation.

➢ Better data are essential for decision-making – the member states need to strengthen their surveillance for hepatitis, develop monitoring and evaluation systems, ensure reporting from the private sector and effectively use the surveillance data to guide the hepatitis control programme. Hepatitis B and C sequelae surveillance programme is required in each country to identify regional variables in development of specific sequelae, such as duration of infection, viral load, genotype, availability of treatment, type of complication and mortality. Definitions of cirrhosis and its etiology in the International Classification of Disease code need to be clear.

➢ Effective community engagement with adequate financial support and inclusion of representatives of the community in policy, programme, service delivery, monitoring and advocacy is essential for scaling up interventions. It should be a priority within national plans and programmes.

➢ Hepatitis B infant immunization and birth dose coverage need to be scaled up. In low hepatitis B prevalence countries that are not yet offering birth dose, it should be implemented. The public health response to HBV is primarily directed at preventing chronic HBV infection and not acute infection. Since older children and adults do not usually get chronic infection following exposure to HBV, immunization of such groups for HBV is not a public health priority (except in high risk groups such as healthcare workers, MSM, etc.).
Policies for injection safety and safe disposal of biomedical waste are in place but their implementation remains an issue, especially in rural areas and in the informal health sector. Member states may consider adoption of WHO guidelines (2015) on adoption of safety engineered injection devices i.e. Re-Use Prevention (RUP) and Sharp Injury prevention (SIP) for therapeutic care in both public and private sector. The consistent use of reuse-prevention injection devices and reduction in irrational injection use are important preventive measures that need to be implemented by the member states. Also, safety of blood transfusion and blood products, harm reduction services, and other infection control measures in healthcare settings need to be ensured.

There is interest on triple elimination of mother-to-child transmission of HIV, syphilis and hepatitis B in most countries. While some countries are already thinking about adding hepatitis B to their existing dual elimination plans, other countries too can consider it.

Hepatitis testing bottlenecks still exist and this means that, people diagnosed to have hepatitis B or C are not linked to treatment services. Laboratory capacity building and quality assurance for viral hepatitis testing are needed. Convergence of testing for viral hepatitis with other disease programmes, such as the use of GeneXpert as a multiplex platform rather than only for TB, needs to be actively explored. Simplified tests, such as HCV rapid tests and use of testing on dried blood spots, are becoming available; however, these will need to be nationally approved and included in the national strategies and guidelines for scale-up. Focus on HCV rapid tests, viral load point-of-care technologies and dried blood spot testing is needed for decentralizing HCV testing and treatment. Also, there is a need for simplified diagnostic algorithms focused on reducing the cost, turnaround time and improved access to testing. Testing strategies that prioritize populations and geographies and maximize yield should be developed based on country context.

Diagnostic tests for hepatitis are still expensive and people are required to pay for them in many countries. Access to testing and diagnostics should be free and there should be no user charges in the public sector. In the private sector, market-based mechanisms and public-private partnerships can increase access to affordable diagnostics.
Additionally, market research can be useful to determine global volumes for screening and confirmatory diagnostic tests for HCV and these can be leveraged for negotiating subsidized pricing for existing tests and drive investments for development of newer tests. Also, the processes need to be developed to improve confidentiality of testing.

- Cost of medicines varies between and within countries, and between public and private sectors. Low-cost generic antivirals are not available to all countries (e.g., Thailand). More efforts to lower costs of and to increase access to medicines are needed. They include inclusion of medicines in essential medicines list, rapid in-country registration of newer drugs and drug combinations, and developing standardized treatment protocols (for both public and private sector), which need to be periodically revised. Bulk/pooled/tender-based procurement mechanisms for affordable access should be actively pursued where feasible.

- To improve treatment coverage and treatment outcomes among patients, it is important to set up a system for notification of cases of chronic hepatitis B and C, and monitoring treatment completion and outcomes such as sustained virological response (SVR). Based on a good practice model from Punjab, India, it appears that issuing a “cure” certificate (with a caveat that reinfection is possible) to patients who are tested at 12 weeks after completion of treatment and found to be negative for HCV RNA (SVR12) may help improve compliance with SVR12 test. Also, stigma and discrimination against hepatitis B and C patients need to be addressed in the member states.

- Health systems, especially in the public sector, need to be strengthened to expand access to prevention, testing and treatment for viral hepatitis. Emphasis should be on integrated service delivery approaches, specifically strengthening existing service delivery platforms such as reproductive, maternal, newborn, child and adolescent health, and immunization services.

- While a comprehensive public sector programme is needed to attain universal access for all those who need access to HBV management and HCV cure, public private partnerships can ensure rapid scale-up along with equity, quality and financial protection. Member States to utilize the existing service delivery platforms like
antenatal and perinatal services, newborn and child health services as well as Immunization services to integrate the prevention and treatment interventions for hepatitis B and C.

- Due to diverse nature of the viral hepatitis epidemic across different population groups, different service delivery models may be needed in different settings. However, service delivery needs to be decentralized for scaling up with links to higher institutions not only for referral but also for mentoring, continued technical support and capacity building. Also, possibilities of sharing and shifting of tasks (e.g., moving treatment from specialist services to primary physicians) need to be explored. We need to maximize resources by using integrated approaches for prevention and treatment of hepatitis B and C and strengthen the existing RMNCAH and immunization services.

- Financing for viral hepatitis should be looked at in the context of overall health sector financing, since as there is no specific external funding stream for viral hepatitis in the near future and none is expected. Along with government investment, innovative financing models and approaches need to be explored by member states. It may be possible to obtain funding from agencies such as UNITAID/FIND, CHAI, and MSF for financing some projects or for providing treatment in some countries. Countries can also utilize opportunities of including HIV/hepatitis co-infection management in harm reduction in the Global Fund funding requests.

- Partnerships are key to a sustainable public health response to hepatitis. Through only a few United Nations organizations and others partners are currently involved in hepatitis sector, but their number is increasing over time. Better coordination and coherence between them and with the civil society, vulnerable communities and other related health programmes for both advocacy and programme scale-up are critical.

**WHO will help the member states implement these important recommendations by:**

- Clarifying the recommendations and providing guidance on hepatitis B vaccine birth dose for low prevalence countries
- Providing guidance on strategies and intervention to reach home births with birth dose
- Encouraging greater collaboration across programmes, within WHO and across departments within the ministries of health
- Providing implementation support for scaling up testing and treatment for viral hepatitis
- Provide guidance in strategies for focusing on vulnerable communities
- Provide technical support for adoption of safety engineered syringes in therapeutic care
- Supporting access to affordable medicines
- Supporting innovative service delivery models and implementation science research
- Acting as a convener across partners and civil society
- Providing timely updates of the WHO guidelines for treatment of hepatitis C and recommending regimens based on direct-acting anti-viral agents that are effective against all HCV genotypes, thereby eliminating the need for and expense of pre-treatment genotypic testing
- Providing technical support on inclusion of essential antiviral drugs in essential medicines list, and
- Ensuring timely prequalification of antiviral drugs for HBV and HCV.
## ANNEX 1: PROGRAMME

### Regional Workshop on Scaling up Health Sector Response to Viral Hepatitis in SEAR

New Delhi, 10 – 12 April 2017

<table>
<thead>
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<th>D1 – Monday, 10 April 2017</th>
<th>0830 – 0900</th>
<th>Registration</th>
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<td>0900 – 1000</td>
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<td>Remarks from World Hepatitis Alliance</td>
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<td>Remarks from WHO HIV GHP Director</td>
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<td>Objectives of the meeting</td>
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<td>Introductions</td>
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<td>Admin Announcements</td>
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<td>Launch of the Regional Action Plan</td>
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<td>Swarup Sarkar</td>
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<td>Poonam Khetrapal Singh</td>
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<td>Charles Gore</td>
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<td>1000 – 1030</td>
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<td>1030-1100</td>
<td><strong>Updates</strong></td>
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<td>Regional Situation Analysis</td>
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<td>Gottfried Hirnschall</td>
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<td>Razia Pendse</td>
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<td></td>
<td>1100 - 1230</td>
<td><strong>National Planning for Hepatitis</strong></td>
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<td>Planning roll out of public health sector program</td>
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<td><strong>Country updates</strong></td>
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<td>Rolling out the national HCV program – lessons learnt from Georgia</td>
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<td><strong>Panel Discussion</strong></td>
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<td>Sudhir Gupta, Sendya Dwisangka, Frederico Bosco dos Santos, Sanya Tahmina Jhora, Rajendra Prasad Pant</td>
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<td>Plenary discussion</td>
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<td>Facilitator – Gottfried Hirnschall</td>
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<td>Henk Bekedam</td>
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<td>Kayla Laserson</td>
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<td>1230 - 1330</td>
<td>Lunch</td>
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<td></td>
<td>1330 - 1500</td>
<td><strong>Prevention of Hepatitis B and C</strong></td>
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<td>HO Injection safety programme in Punjab</td>
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<td>Blood Safety</td>
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<td>Regional progress and control goal for HEP B vaccination</td>
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<td>Discussion</td>
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<td>Prevention of mother to child transmission</td>
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<td>Asia Pacific Framework for triple elimination</td>
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<td>Convergence and integration with MCH platform</td>
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<td>Opportunities and Challenges</td>
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<td>Quality of MCH care and EMTCT</td>
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<td>Facilitator – Swarup Sarkar/Bobby John</td>
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<td>Chnadradant Lahariya/RK Dhiman</td>
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<td>Aparna Singh Shah</td>
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<td>Sigrun Roesel</td>
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<td>Ying Ru Lo</td>
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<td>Kyoko Shimamoto/Sufang Guo</td>
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### 1500 - 1530
**Tea/Coffee**

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<tr>
<th>Time</th>
<th>Discussion</th>
<th>Facilitator – Bobby John</th>
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<tbody>
<tr>
<td>1530 - 1800</td>
<td><strong>Access to affordable diagnostics and medicines</strong>&lt;br&gt;Overcoming Barriers to Hep C treatment&lt;br&gt;Regional initiatives for access to affordable medicines&lt;br&gt;Prices and regulatory status of Hep B and C medicines in Asia&lt;br&gt;Negotiating affordable access to diagnostics and medicines in Punjab</td>
<td>Marc Bulterys&lt;br&gt;Manisha Shridhar&lt;br&gt;Klara Tisocki&lt;br&gt;Giten Khwairakpam&lt;br&gt;Gagandeep Grover</td>
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### Panel discussion
Leena Menghaney, Chase Perfect, S K Sarin, Anchalee Avihingsanon

### Opportunities for expanding access to diagnostics and medicines
Catherine Timmermans<br>Florence Camus-Bablon<br>Taryn Baker<br>Homie Razavi

### Questions

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<th>Time</th>
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### D2 – Tuesday, 11 April 2017

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<tr>
<th>Time</th>
<th>Data for decision making</th>
<th>Facilitator – B. B. Rewari</th>
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<tbody>
<tr>
<td>0830 - 0930</td>
<td><strong>WHO guidance on M and E and surveillance</strong>&lt;br&gt;<strong>National Surveillance for Hepatitis in India</strong>&lt;br&gt;<strong>Sequelaes surveillance</strong>&lt;br&gt;<strong>Hepatitis B sero-survey – Bhutan</strong>&lt;br&gt;<strong>Discussion</strong></td>
<td>Yvan Hutin&lt;br&gt;India&lt;br&gt;S K Sarin&lt;br&gt;Namgay Tshering</td>
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<tr>
<th>Time</th>
<th>Measurement and Impact</th>
<th>Facilitator – Mukta Sharma</th>
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<tbody>
<tr>
<td>0930 - 1030</td>
<td><strong>Disease burden analysis</strong>&lt;br&gt;<strong>Cost effectiveness of Hepatitis C treatment – India scenario</strong>&lt;br&gt;<strong>Resource need analysis and priority setting at country level</strong>&lt;br&gt;<strong>Discussion</strong></td>
<td>Homie Razavi&lt;br&gt;Rakesh Aggarwal&lt;br&gt;Kantisak Chantrapipat, Thailand</td>
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<td>1100 - 1230</td>
<td><strong>Expanding Diagnosis and Treatment</strong></td>
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<td>Scaling up Hepatitis C diagnosis and treatment – opportunities and challenges</td>
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<td><strong>Panel Discussion</strong></td>
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<td></td>
<td>Leveraging private sector and academic institutions for scaling up testing and treatment for Viral hepatitis</td>
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<tr>
<td>1230 - 1330</td>
<td>Lunch</td>
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<td>1330 - 1500</td>
<td><strong>Role of Civil Society</strong></td>
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<td>Lessons learnt from the HIV response</td>
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<td>Advocacy and networking</td>
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<td>Policy Reform and capacity building</td>
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<td>Implementation Research on treatment of PWIDs for Hepatitis C from Bangladesh</td>
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<td>Service Delivery - Experience from Manipur</td>
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<td>Community mobilization and engagement</td>
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<td>Simplifying Global Guidance</td>
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<td><strong>Discussion</strong></td>
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<td>1500 - 1530</td>
<td>Tea/Coffee</td>
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<td>1530 - 1700</td>
<td><strong>Sustainable financing for health sector response and inclusion in benefit package</strong></td>
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<td>Health Care Financing in the context of UHC</td>
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<td>Universal Health coverage for Viral Hepatitis in Thailand</td>
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<td>Innovative financing and PPP – what could be the resource mobilization strategy for Viral Hepatitis in the region</td>
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<td><strong>Discussion</strong></td>
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<tr>
<td>D3 - Wednesday, 12 April 2017</td>
<td>Group work – World Cafe</td>
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<td>0830 - 1230</td>
<td>4 groups; 4 areas</td>
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<td>Data driven programming - Hep Surveillance, M and E, modelling, interlinked monitoring systems</td>
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<td>Prevention interventions and Triple elimination</td>
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<td>Scaling up diagnosis and treatment</td>
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<td>Service delivery models including private sector engagement, linkages with other disease programs</td>
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<td>(Tea/Coffee – in between GW)</td>
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**Facilitators and Group Rapporteurs:**

- Nicole Seguy
- Philippa Easterbrook
- Henk Bekedam
- Gagandeep Grover
- Win Naing
- David Muljono
- Abhijit Chaudhary
- Mamun-al Mahtab
- Rino A Gani
- Win Naing
- R.K. Dhiman
- Anil K. Mishra
- B. B. Rewari
- Charles Gore
- Jennifer Johnston
- Mustafiz Rahman
- Aslam Anis
- Nalinikanta Rajkumar
- Maria Donatelli
- Giten Khwairakpam
- Alaka Singh (via webex)
- Suchada Jiamsiri
- Bobby John
- Yvan - Facilitator
- B. B. Rewari - Group rapporteur
- Marc – Facilitator
- Razia – Group Rapporteur
- Mukta – Facilitator
- Vimlesh – Group Rapporteur
- Nicole – Facilitator
- Sonam – Group Rapporteur
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<td>1230 - 1330</td>
<td>Lunch</td>
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<td>1330 - 1430</td>
<td>Group work presentations</td>
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<td>1430 - 1530</td>
<td>Panel discussion – Role of Partners – WHO CC, Thai Red Cross, Treat Asia, CDC, CDA, UNICEF, UNAIDS, UNITAID, MSF, CHAI, FIND Facilitator – Bobby John</td>
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<tr>
<td>1530 - 1600</td>
<td>Tea/Coffee</td>
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<tr>
<td>1600 - 1700</td>
<td>Conclusions, recommendations and next steps</td>
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<td>Closing Remarks</td>
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<td>Razia Pendse</td>
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<td>Gottfried</td>
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<td>Hirnschall, Swarup Sarkar</td>
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**ANNEX 2: LIST OF PARTICIPANTS**

### Bangladesh

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Annex 3: Hepatitis country factsheets

Bangladesh Country Fact Sheet

Epidemic

Prevalence of Hepatitis B

- 5.5% General Population
- 1.4% Blood Donors
- 0.4% Transfused Blood
- 6.2% Transplant Recipients
- 4.2% Other High Risk Groups

Prevalence of Hepatitis C

- 0.6% General Population
- 0.1% IDU
- 0.7% Transfused Blood
- 30% Transplant Recipients
- 61% Other High Risk Groups


*Sm = representative sample; **FEd = non-representative sample; MSM = men who have sex with men and PWID = people who inject drugs

Mortality

- Cirrhosis HBV
- Liver cancer HBV
- Acute

- Cirrhosis HCV
- Liver cancer HCV
- Acute

Source: WHO GHE, 2016

Policies

- Hepatitis B vaccine
  - Birth dose of Hep B vaccine - Yes
  - Hep B immunization included in routine infant immunization schedule - No
  - Vaccination for HCWs - Yes
  - Vaccination for high-risk groups (key populations) - No

- Blood & Injection safety
  - Donated blood screened for Hep B & Hep C - Yes
  - Use of RUP syringes - Yes
  - Needle and syringe distribution program for PWID - Yes

- Hepatitis testing
  - Is there official guidance for diagnosing HBV - No
  - Is there official guidance for diagnosing HCV - No

Access to medicines

<table>
<thead>
<tr>
<th>Availability of medicines for Hep B treatment</th>
<th>Generic product licensed</th>
<th>Availability of DAA's for Hep C treatment</th>
<th>Annual cost for Hep B drugs/person</th>
<th>Annual cost for Hep C drugs/person</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

Health sector response

- National Plan for viral hepatitis - No
- Coverage of 3-dose Hep B vaccine schedule (2014) - 93%
- Coverage of Hep B vaccine for newborns - N/A
- Needles and syringes distributed per PWID in the last one year - 243

Source: Country survey

World Health Organization, South-East Asia Region

June 2017
**Bhutan**

**Country Fact Sheet**

**Epidemic**

**Prevalence of Hepatitis B**

- National Population: 5.60%
- Blood donors: 0.75%
- Tattoo parlours: 0.75%
- MSM: 5.40%
- PWID: 1.40%
- Other: 0.05%

**Prevalence of Hepatitis C**

- National Population: 1.30%
- Blood donors: 0.08%
- Tattoo parlours: 0.08%
- MSM: 0.10%
- PWID: 0.10%
- CMW: 0.02%
- PLWV: 0.02%


**Mortality**

<table>
<thead>
<tr>
<th>Cirrhosis HBV</th>
<th>Liver cancer HBV</th>
<th>Acute</th>
</tr>
</thead>
<tbody>
<tr>
<td>75%</td>
<td>7%</td>
<td>18%</td>
</tr>
</tbody>
</table>

*Source: WHO GHE, 2015*

**Policies**

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine: YES
- Hep B immunization included in routine infant immunization schedule: YES
- Vaccination for HCWs: YES
- Vaccination for high risk groups (key populations): NO

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C: YES
- Use of RUP syringes: NO
- Needle and syringe distribution program for PWID: NO

**Hepatitis testing**
- Is there official guidance for diagnosing HBV: NO
- Is there official guidance for diagnosing HCV: NO

*Source: Country survey
Abbreviations: HCWs = health care workers, PLWV = people living with HIV, RUP = re-use prevention

**Access to medicines**

- Availability of medicines for Hep B treatment
- Generic product licensed
- Generic product available
- Annual cost for Hep B drugs/person
- Availability of DAAs for Hep C treatment
- Generic product available
- Annual cost for Hep C drugs/person

**Health sector response**

- National Plan for viral hepatitis: NO
- Coverage of 3-dose Hep B vaccine schedule (2014): 95%
- Coverage of Hep B vaccine for newborns: 95%
- Needles and syringes distributed per PWID in the last one year: NA

*Source: Policy survey

June 2017

World Health Organization, South-East Asia Region

56
**Epidemic**

Prevalence of Hepatitis B – Data not available

Prevalence of Hepatitis C

Source: *Blue – representative sample; Red – non-representative sample; MSM – men who have sex with men and PWID – people who inject drugs

**Mortality**

Estimated deaths

Source: WHO GHE, 2015

**Policies**

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine: YES
- Hep B immunization included in routine infant immunization schedule: YES
- Vaccination for HCWs: YES
- Vaccination for high risk groups (key populations): No

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C: Yes
- Use of RUP syringes: No
- Needle and syringe distribution program for PWID: No

**Hepatitis testing**
- Is there official guidance for diagnosing HBV: Yes
- Is there official guidance for diagnosing HCV: Yes

Source: Country survey
Abbreviations: HCWs – health care workers, PLHIV – people living with HIV, RUP – re-use prevention

**Access to medicines**

Availability of medicines for Hep B treatment: No
Annual cost for Hep B drugs/person: NA

Availability of DAAs for Hep C treatment: No
Annual cost for Hep C drugs/person: NA

**Health sector response**

National Plan for viral hepatitis: Draft
Coverage of 3-dose Hep B vaccine schedule (2014): 98%
Coverage of Hep B vaccine for newborns: 90%
Needles and syringes distributed per PWID in the last one year: NA

Source: Country survey

**June 2017**

World Health Organization, South-East Asia Region
India

Epidemic

Prevalence of Hepatitis B

- 3.7%
- 1.0%

Prevalence of Hepatitis C

- 40%
- 37.0%

Mortality

- Cirrhosis HBV: 71%
- Liver cancer HBV: 8%
- Acute: 22%

- Cirrhosis HCV: 84%
- Liver cancer HCV: 3%
- Acute: 13%

Source: WHO (2015)

Policies

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine: Yes
- Hep B immunization included in routine infant immunization schedule: Yes
- Vaccination for HCWS: No
- Vaccination for high risk groups (key populations): No

Source: Country survey

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C: YES
- Use of RUP syringes: YES
- Needle and syringe distribution program for PWID: YES

**Hepatitis testing**
- Is there official guidance for diagnosing HBV: No
- Is there official guidance for diagnosing HCV: No

* RUP being implemented as a pilot in Punjab

Access to medicines

- Availability of medicines for Hep B treatment: Generic and branded products
- Annual cost for Hep B drugs per person: $250 (TDF) and $400 (ETV)
- Availability of DAAs for Hep C treatment: Cost for Hep C drugs per person: $110-200 (Punjab) (12 week treatment)

Health sector response

- National Plan for viral hepatitis: No
- Coverage of 3-dose Hep B vaccine schedule (2014): 88%
- Coverage of Hep B vaccine for newborns: 47%
- Needles and syringes distributed per PWID in the last one year: 259

Source: Country survey

World Health Organization, South-East Asia Region

June 2017
Indonesia

Country Fact Sheet

Epidemic

Prevalence of Hepatitis B

- General Population: 7.1%
- Blood Donors: 1.5%
- Antenatal Clients: 2.9%
- MSM: 7.8%
- PWID: 2.9%
- CW: 2.9%
- PLHIV: 2.9%

Prevalence of Hepatitis C

- General Population: 0.1%
- Blood Donors: 0.4%
- Antenatal Clients: 0.7%
- MSM: 0.4%
- PWID: 0.4%
- CW: 0.4%
- PLHIV: 0.4%

Source: Basic health research (2013), Blood services program 2015 data, MoH data, sentinel surveillance
*Blue = representative sample; *Red = non-representative sample; MSM = men who have sex with men and PWID = people who inject drugs

Mortality

- Cirrhosis HBV
- Liver cancer HBV
- Acute

Estimated deaths in Indonesia

Source: WHO GHE, 2015

Policies

Hepatitis B vaccine
- Birth dose of Hep B vaccine
- Hep B immunization included in routine infant immunization schedule
- Vaccination for high risk groups (key populations)

Blood & Injection safety
- Donated blood screened for Hep B & Hep C
- Use of RUP syringes
- Needle and syringe distribution program for PWID

Hepatitis testing
- Is there official guidance for diagnosing HBV
- Is there official guidance for diagnosing HCV

Access to medicines

Availability of medicines for Hep B treatment
- Generic & branded products
- Annual cost for Hep B drugs/person
USD 646-1346

Availability of DAAs for Hep C treatment
- Generic & branded products
- Annual cost for Hep C drugs/person
USD 1200-1350 for 12 weeks

Health sector response

National Plan for viral hepatitis
- YES

Coverage of 3-dose Hep B vaccine schedule
- YES

Coverage of Hep B vaccine for newborns
- YES

Needles and syringes distributed per PWID in the last one year
- 9

Source: 1) Immunization Program Report, MoH 2015, 2) GARPIL, 2016

June 2017

World Health Organization, South-East Asia Region
Maldives

Country Fact Sheet

Epidemic

Prevalence of Hepatitis B

<table>
<thead>
<tr>
<th>Population Type</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Population</td>
<td>7%</td>
</tr>
<tr>
<td>Blood Donors</td>
<td>6%</td>
</tr>
<tr>
<td>Antenatal Clients</td>
<td>0.8%</td>
</tr>
<tr>
<td>MSM</td>
<td>0%</td>
</tr>
<tr>
<td>PWID</td>
<td>0%</td>
</tr>
<tr>
<td>PLWH</td>
<td>0%</td>
</tr>
</tbody>
</table>

Prevalence of Hepatitis C

<table>
<thead>
<tr>
<th>Population Type</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Population</td>
<td>1%</td>
</tr>
<tr>
<td>Blood Donors</td>
<td>0%</td>
</tr>
<tr>
<td>Antenatal Clients</td>
<td>0.7%</td>
</tr>
<tr>
<td>MSM</td>
<td>0%</td>
</tr>
<tr>
<td>PWID</td>
<td>0%</td>
</tr>
<tr>
<td>PLWH</td>
<td>0%</td>
</tr>
</tbody>
</table>

Source: RSS (2006), National HBV register
*Eus = representative sample; **Red = non-representative sample; MSM = men who have sex with men and PWID = people who inject drugs

Mortality

<table>
<thead>
<tr>
<th>Maldives</th>
<th>Estimated deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cirrhosis HBV</td>
<td>67%</td>
</tr>
<tr>
<td>Liver cancer HBV</td>
<td>20%</td>
</tr>
<tr>
<td>Acute</td>
<td>13%</td>
</tr>
</tbody>
</table>

Source: WHO GHE, 2015

Policies

Hepatitis B vaccine
- Birth dose of Hep B vaccine - YES
- Hep B immunization included in routine infant immunization schedule - YES
- Vaccination for HCWs - YES
- Vaccination for high risk groups (key populations) - NO

Blood & Injection safety
- Donated blood screened for Hep B & Hep C - NO
- Use of RUP syringes - YES
- Needle and syringe distribution program for PWID - YES

Hepatitis testing
- Is there official guidance for diagnosing HBV - NO
- Is there official guidance for diagnosing HCV - NO

Access to medicines

Availability of medicines for Hep B treatment

- Available

Annual cost for Hep B drugs/person

USD 168

Availability of DAAs for Hep C treatment

Not available

Annual cost for Hep C drugs/person

NA

Health sector response

National Plan for viral hepatitis
- NO

Estimate of facilities offering serological testing (HBsAg) for HBV
- 91

Coverage of 3-dose Hep B vaccine schedule (2014)
- 98%

Estimate of facilities offering nucleic acid testing (NAT) for HBV
- 0

Coverage of Hep B vaccine for newborns
- 99%

Estimate of facilities offering serological testing (Anti-HCV) for HCV
- 91

Needles and syringes distributed per PWID in the last one year
- NA

Estimate of facilities offering nucleic acid testing (NAT) for HCV
- 0

Source: Country survey

June 2017

World Health Organization, South-East Asia Region
**Epidemic**

**Prevalence of Hepatitis B**
- General Population: 6.5%
- Blood Donors: 3.7%
- Artisanal Fishermen: 9.2%
- MSM: 7.1%
- PWID: 7.1%
- MHW: 7.1%
- COW: 7.1%
- PLUV: 7.1%

**Prevalence of Hepatitis C**
- General Population: 0.7%
- Blood Donors: 0.7%
- Artisanal Fishermen: 50%
- MSM: 2.7%
- PWID: 50%
- COW: 0.7%
- PLUV: 0.7%

*Blue = representative sample; **Red = non-representative sample; MSM = men who have sex with men and PWID = people who inject drugs*

**Mortality**

**Estimated deaths in Myanmar**
- Cirrhosis HDV: 76%
- Liver cancer HBV: 17%
- Acute: 7%

**Estimated deaths in Myanmar**
- Cirrhosis HCV: 70%
- Liver cancer HCV: 20%
- Acute: 10%

*Source: WHO GHE, 2015*

**Policies**

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine
- Hep B immunization included in routine infant immunization schedule
- Vaccination for HCWs
- Vaccination for high-risk groups (key populations)

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C
- Use of RUP syringes
- Needle and syringe distribution program for PWID

**Hepatitis testing**
- Is there official guidance for diagnosing HBV
- Is there official guidance for diagnosing HCV

*Source: Country survey*

**Access to medicines**

**Availability of medicines for Hep B treatment**
- Annual cost for Hep B drugs/person: USD 72/year

**Availability of DAAs for Hep C treatment**
- Annual cost for Hep C drugs/person: USD 756 for 12 weeks treatment

**Health sector response**

**National Plan for viral hepatitis**
- YES

**Coverage of 3-dose Hep B vaccine schedule (2014)**
- 75%

**Coverage of Hep B vaccine for newborns**
- 2%

**Needles and syringes distributed per PWID in the last one year**
- 223

*Source: Country survey*

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**June 2017**

**World Health Organization, South-East Asia Region**
Nepal
Country Fact Sheet

Epidemic

Prevalence of Hepatitis B

Prevalence of Hepatitis C

"Blue = representative sample; "Red = non-representative sample, MSM = men who have sex with men and PWID = people who inject drugs.

Mortality

![Mortality Graph]

Source: WHO GHE, 2015

Policies

Hepatitis B vaccine

- Birth dose of Hep B vaccine - NO
- Hep B immunization included in routine infant immunization schedule - YES
- Vaccination for HCWs - NO
- Vaccination for high risk groups (key populations) - NO

Blood & Injection safety

- Donated blood screened for Hep B & Hep C - YES
- Use of RUP syringes - YES
- Needle and syringe distribution program for PWID - YES

Hepatitis testing

- Is there official guidance for diagnosing HBV - NO
- Is there official guidance for diagnosing HCV - YES

Access to medicines

<table>
<thead>
<tr>
<th>Availability of medicines for Hep B treatment</th>
<th>Branded products</th>
<th>Availability of DAAs for Hep C treatment</th>
<th>Branded products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual cost for Hep B drugs/person USD 360/year</td>
<td></td>
<td>Annual cost for Hep C drugs/person USD 1500 for 12 weeks treatment</td>
<td></td>
</tr>
</tbody>
</table>

Health sector response

- National Plan for viral hepatitis - NO
- Coverage of 3-dose Hep B vaccine schedule (2014) - 92%
- Coverage of Hep B vaccine for newborns - NA
- Needles and syringes distributed per PWID in the last one year - 61

Source: Country survey

June 2017
World Health Organization, South-East Asia Region
Sri Lanka

Epidemic

### Prevalence of Hepatitis B

- General Population: 2.0%
- Blood Donors: 0.3%
- Antenatal Clients: 0.0%
- MSM: 1.9%
- PWD: 7.6%
- CSW: 0.5%
- PLWHA: 0.3%

### Prevalence of Hepatitis C

- General Population: 0.0%
- Blood Donors: 0.0%
- Antenatal Clients: 0.0%
- MSM: 0.4%
- PWD: 0.2%
- CSW: 0.2%
- PLWHA: 0.2%

Source: Country survey

*Blue – representative sample; **Red – non-representative sample; MSM – men who have sex with men; PWD – people who inject drugs

Mortality

- Estimated deaths
  - Cirrhosis HCV: 20%
  - Liver cancer HCV: 0%
  - Acute: 5%

Source: WHO GHE, 2015

Policies

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine: YES
- Hep B immunization included in routine infant immunization schedule: YES
- Vaccination for HCWs: YES
- Vaccination for high risk groups (key populations): YES

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C: YES
- Use of RUP syringes: NO
- Needle and syringes distribution program for PWID: NO

**Hepatitis testing**
- Is there official guidance for diagnosing HBV: NO
- Is there official guidance for diagnosing HCV: NO

Source: Country survey

Abbreviations: HCWs – health care workers, PLHIV – people living with HIV, RUP – re-use prevention

Access to medicines

<table>
<thead>
<tr>
<th>Availability of medicines for Hep B treatment</th>
<th>Branded products</th>
<th>Availability of DAAs for Hep C treatment</th>
<th>Branded products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual cost for Hep B drugs/person</td>
<td>?</td>
<td>Annual cost for Hep C drugs/person</td>
<td>?</td>
</tr>
</tbody>
</table>

Health sector response

- National Plan for viral hepatitis: NO
- Coverage of 3-dose Hep B vaccine schedule (2014): 100%
- Coverage of Hep B vaccine for newborns: NA
- Needles and syringes distributed per PWID in the last one year: NA

Source: Country survey

June 2017

World Health Organization, South-East Asia Region
Thailand

Country Fact Sheet

Epidemic

Prevalence of Hepatitis B

- General Population: 3.5%
- Blood donors: 2.6%
- Prisoners: 3.4%
- MSM: 14%
- PWID: 8.7%

Prevalence of Hepatitis C

- General Population: 0.30%
- Blood donors: 0.50%
- Prisoners: 0.90%
- MSM: 90%
- PWID: 9%

*Blue = representative sample; *Red = non-representative sample; MSM = men who have sex with men and PWID = people who inject drugs

Mortality

- Cirrhosis HBV: 43%
- Liver cancer HBV: 54%
- Acute: 2%

Source: WHO GHE, 2015

Policies

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine - YES
- Hep B immunization included in routine infant immunization schedule - YES
- Vaccination for HCWs - YES
- Vaccination for high risk groups (key populations) - ?

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C - YES
- Use of RUP syringes - YES
- Needle and syringe distribution program for PWID - YES

**Hepatitis testing**
- Is there official guidance for diagnosing HBV - YES
- Is there official guidance for diagnosing HCV - YES

Source: Country survey

Abbreviations: HCWs = health care workers, PLHIV = people living with HIV, RUP = risk-reduction prevention

Access to medicines

**Generic and Branded products**
- Availability of medicines for Hep B treatment
- Annual cost for Hep B drugs/person: ?

**Availability of DAAs for Hep C treatment**
- Annual cost for Hep C drugs/person: USD 6000

Health sector response

**National Plan for viral hepatitis**
- YES

**Coverage of 3-dose Hep B vaccine schedule (2014)**
- >99%

**Coverage of Hep B vaccine for newborns**
- NA

**Needles and syringes distributed per PWID in the last one year**
- 88

Source: Country survey

June 2017

World Health Organization, South-East Asia Region
**Epidemic**

**Prevalence of Hepatitis B**

- General Population: 6.7%
- Blood Donors: 10.0%
- Antenatal Clients: 8.3%

**Prevalence of Hepatitis C**

- General Population: 3.5%
- Blood Donors: 6.5%
- Antenatal Clients: 2.2%


*Blue = representative sample; *Red = non-representative sample; MSM = men who have sex with men and PWID = people who inject drugs

**Mortality**

**Cirrhosis HBV**
- 63% of deaths due to liver cancer
- 31% of deaths due to acute HBV
- 6% of deaths due to cirrhosis HBV

**Cirrhosis HCV**
- 65% of deaths due to liver cancer
- 22% of deaths due to acute HCV
- 3% of deaths due to cirrhosis HCV

Source: WHO GHE 1.2015

**Policies**

**Hepatitis B vaccine**
- Birth dose of Hep B vaccine - YES
- Hep B immunization included in routine infant immunization schedule - YES
- Vaccination for high-risk groups (key populations) - NO

**Blood & Injection safety**
- Donated blood screened for Hep B & Hep C - YES
- Use of RUP syringes - YES
- Needle and syringe distribution program for PWID - NO

**Hepatitis testing**
- Is there official guidance for diagnosing HBV - YES
- Is there official guidance for diagnosing HCV - YES

Source: Country survey

**Access to medicines**

- Availability of medicines for Hep B treatment: Not available
- Annual cost for Hep B treatment: Not available
- Availability of DAAs for Hep C treatment: Not available
- Annual cost for Hep C treatment: Not available

**Health sector response**

- National Plan for viral hepatitis: YES
- Estimate of facilities offering serological testing (HBsAg) for HBV: 67
- Estimate of facilities offering nucleic acid testing (NAT) for HBV: 0
- Estimate of facilities offering serological testing (Anti-HCV) for HCV: 0
- Estimate of facilities offering nucleic acid testing (NAT) for HCV: 0


**June 2017 World Health Organization, South-East Asia Region**