MEETING ON THE IMPLEMENTATION OF THE REGIONAL ACTION PLAN FOR VIRAL HEPATITIS IN THE WESTERN PACIFIC

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Manila, Philippines
MEETING REPORT

MEETING ON THE IMPLEMENTATION
OF THE REGIONAL ACTION PLAN FOR VIRAL HEPATITIS
IN THE WESTERN PACIFIC

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NOTE

The views expressed in this report are those of the participants of the Meeting on the Implementation of the Regional Action Plan for Viral Hepatitis in the Western Pacific and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Meeting on the Implementation of the Regional Action Plan for Viral Hepatitis in the Western Pacific in Manila, Philippines from 13 to 14 December 2018.
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Hepatitis B / Hepatitis C / Hepatitis, Viral, Human / Regional health planning
SUMMARY

The Western Pacific Region has made significant progress in the prevention of hepatitis B through immunization, achieving the 2020 regional target for hepatitis B control ahead of time, in 2017. However, the Region bears almost half the global burden of chronic hepatitis infections, and only around one fifth of affected people are aware they are infected. Amongst those who are aware of their infection, the majority do not have access to treatment even though hepatitis medicines have become cheaper and more accessible. The Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020 sets out priority actions and measurable targets for 2020, working towards elimination targets for 2030 proposed in the Global Health Sector Strategy on Viral Hepatitis 2016–2021. With the publication in 2018 of the Regional Framework on Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis 2018–2030, the stage is set to push forward with measures to reduce mother-to-child transmission of hepatitis B towards elimination by 2030.

The Meeting on the Implementation of the Regional Action Plan for Viral Hepatitis in the Western Pacific was held to review midterm progress, focusing on a wide range of prevention measures including infection control, protection of health-care workers, elimination of mother-to-child transmission of hepatitis B and provision of services to key populations as well as strategic information, testing and treatment for viral hepatitis. Key actions to be taken by countries, WHO and partners were identified in order to accelerate progress in hepatitis control in the remaining two years of the Regional Action Plan’s term.

Substantial progress has been made in developing national actions plans and conducting disease burden estimates, but coverage of both testing and treatment is still low. There needs to be significant scale-up of testing services as well as expansion and decentralization of treatment for infected individuals in order to achieve elimination goals by 2030. More progress is required in areas including advocacy and awareness-raising among policy-makers and the general population; resource mobilization; capacity-building for health-care providers; establishment, scale-up and decentralization of laboratory and clinical services as well as strengthening and integration of hepatitis data reporting within existing health information systems.

Member States requested technical support from WHO and partner organizations to conduct disease burden analyses, develop or update national guidelines, design context-specific service delivery models, strengthen data systems, and build capacity for workforce development. Partnerships should be convened and supported to provide assistance and ensure a platform to share knowledge across countries to strengthen national responses towards achieving elimination of viral hepatitis.
1. INTRODUCTION

1.1 Meeting organization

The Meeting on the Implementation of the Regional Action Plan for Viral Hepatitis in the Western Pacific was held at the World Health Organization (WHO) Regional Office for the Western Pacific in Manila, Philippines, from 13 to 14 December 2018. The meeting was organized to review midterm progress on implementation of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* and discuss recommendations and next steps for Member States, WHO and partners to take during the remainder of the term between 2018 and 2020. The list of participants is available in Annex 1, and the meeting agenda is outlined in Annex 2.

1.2 Meeting objectives

The objectives of the meeting were:

1. to review the midterm progress on implementation of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* and discuss recommendations and next steps;

2. to share country and regional situations on hepatitis prevention, care and treatment including examples of good practice, focusing on thematic areas within prevention and health systems; and

3. to discuss and agree on priority actions to reach 2020 targets set in the Regional Action Plan to be taken by countries and support needed from WHO and partners.

2. PROCEEDINGS

2.1 Opening session

Dr Naoko Ishikawa, Coordinator for HIV, Hepatitis and Sexually Transmitted Infection Unit, welcomed participants to the meeting.

Dr Shin Young-soo, WHO Regional Director for the Western Pacific, delivered his opening remarks by video message and welcomed participants to the meeting. In the Western Pacific Region, 130 million people are living with hepatitis B virus (HBV) or hepatitis C virus (HCV); the majority are undiagnosed and unaware of their infection and therefore not accessing life-saving treatment. The Region accounts for almost half the world’s deaths due to viral hepatitis, which cause significant suffering and health-care costs for affected families. Dr Shin noted the progress that has been made in the Region towards the objectives set forth in the Regional Action Plan, with many countries having articulated their national action plans and targets and funding testing and treatment. Much more, however, was needed to reach the targets by 2020. He expressed his hope that action would be taken to accelerate and intensify the progress towards meeting the Regional Action Plan targets and goals.

Following the introductory address, Dr Amarjargal Yadam from Mongolia and Dr Gerard Belimac from the Philippines were nominated as co-chairs for the meeting.
2.2 Plenary session (Day 1): Progress overview

2.2.1 Global and regional progress towards elimination of viral hepatitis

Dr Naoko Ishikawa presented an overview of global and regional progress towards elimination of viral hepatitis, highlighting that universal health coverage (UHC), articulated in Sustainable Development Goal 3 (SDG3), is a strategic priority for WHO, in particular for the Western Pacific Region. She emphasized that this is the time to “test, treat and cure” viral hepatitis to achieve elimination by 2030.

The burden of disease attributable to hepatitis B and C in the Region is very high, and hepatitis mortality from cirrhosis and hepatocellular carcinoma is increasing. HBV prevalence in the Region (6.2%) is almost double the global prevalence (3.5%), while regional HCV prevalence (0.7%) is a little lower than the global prevalence (1%). HBV prevalence is greater than 2% in the majority of countries in the Western Pacific Region, with general population prevalence ranging from 18.8% in Solomon Islands to 0.7% in Malaysia. HCV prevalence is uniformly around 1%, except in Mongolia where general population prevalence of HCV was estimated as 6.3% in 2017. Six countries in the Region – Mongolia, Viet Nam, China, the Republic of Korea, the Lao People’s Democratic Republic and Cambodia – are among the world’s top 10 countries for liver cancer incidence.

The Global Health Sector Strategy on Viral Hepatitis 2016–2021, the Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020 and the Regional Framework on Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis 2018–2030 set impact and service delivery targets and guidance for achieving elimination of viral hepatitis as a public health threat by 2030 by reducing the incidence of viral hepatitis by 90% (equivalent to hepatitis B surface antigen, or HBsAg, prevalence among children of less than 0.1%).

Significant progress has been achieved in the Region in hepatitis B control through immunization, with coverage of the timely hepatitis B birth dose (HepB-BD) and third dose (HepB3) reaching 85% and 93% respectively in 2017; and 21 out of 37 countries and areas in the Region verified as having met the 2020 regional target of less than 1% HBsAg prevalence among children as of December 2018. Other achievements include: completion of disease burden estimates as well as country situational analyses in a number of countries, which has resulted in the development of national action plans; development of national guidelines for testing and treatment of viral hepatitis; and expanded availability and accessibility to hepatitis drugs.

However, among other targets set in the Regional Action Plan, those on harm reduction, testing and treatment have yet to be met. Coverage of testing and treatment is low, with 17% diagnosed and 20% treated for hepatitis B and 21% diagnosed and 9% treated for hepatitis C (global targets for 2020 are 30% tested and 50% of eligible persons treated).

Dr Ishikawa emphasized that now is the time to act to eliminate viral hepatitis through a public health approach. Priorities are to: expand and decentralize testing services; ensure that care and treatment are available at the primary health care level; establish and strengthen surveillance and monitoring systems; and develop sustainable mechanisms through a whole-of-system approach.

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1 Listed in descending order of liver cancer incidence among these six countries.
2.2.2 Implementation progress of the Regional Action Plan for Viral Hepatitis 2016-2020: Challenges and lessons learnt

Dr Po-Lin Chan, Medical Officer, summarized the implementation progress of the Regional Action Plan. National hepatitis plans are now available or in development in 22 countries in the Region. The costs of HBV and HCV direct acting antiviral (DAA) treatment are covered by government funding or health insurance in 12 and 10 countries, respectively. National reference laboratories for hepatitis have been designated in Australia, China, Japan, Mongolia, the Philippines and the Republic of Korea. Countries are at different stages of implementing HBV elimination of mother-to-child transmission (EMTCT) interventions beyond immunization, based on differences in hepatitis epidemiology and other contextual factors. Challenges include a general lack of awareness of viral hepatitis among policy-makers and the general population. The burden of disease is high in the Region, and large numbers of people are in need of testing services. There is limited availability of treatment for chronic HBV or HCV. The service delivery model for testing and treatment is poorly established in many countries. Domestic and international funding for hepatitis is still limited, the costs of lifelong care, disease monitoring and prices for DAAs are high, and there are many competing health priorities. In some countries, health insurance covers some care and treatment costs but out-of-pocket expenses remain a barrier. Capacity for providing hepatitis treatment is limited among health-care providers, particularly at lower levels of the health system. In some countries, infected health-care workers requiring care and treatment may add further strain to overburdened staff.

Significant scale-up of services is needed, including micro-elimination approaches, for example among key populations or other population groups that require specific focus for hepatitis services. Investment cases and economic analyses are needed for advocacy with governments and policy-makers. There are opportunities for including hepatitis in essential care packages under the principle of UHC. Pragmatic approaches to inclusion of care and treatment for viral hepatitis are needed across all programmes including HIV, tuberculosis (TB), older people, dialysis patients, mobile clinics, community outreach, and populations requiring specific focus (noting that key populations for hepatitis are not necessarily the same as key populations for HIV), which may be identified through social welfare systems such as those uninsured, migrants and the poor. Cancer prevention requires integrating liver cancer prevention and control into existing cancer screening programmes. Additional resources are needed to strengthen infection control, laboratory and surveillance systems.

Progress towards elimination requires comprehensive national planning, simplified testing algorithms, integrating viral hepatitis services with other diseases such as HIV, TB and noncommunicable diseases (NCDs); decentralizing testing and treatment services to primary care under UHC, improving linkage to care and treatment, engaging the community and peer support to increase access to services, efficient procurement and supply of quality-assured diagnostics and medicines, as well as developing quality data systems for monitoring progress and outcomes. All countries are affected by viral hepatitis, regardless of socioeconomic status. All age groups must be covered, including children, adults, adolescents and older people, and surveillance should include hepatitis A virus (HAV), hepatitis D virus (HDV) and hepatitis E virus (HEV) in high-prevalence countries.

Recommendations and next steps were presented from the Third Meeting of the Strategic and Technical Advisory Committee (STAC) for Viral Hepatitis, held in Manila in September 2018, and the Informal Consultation on the Quality Improvement of Laboratory Services for Viral Hepatitis in the Western Pacific Region, held in June 2018 (see Annex 3). Continuing support to Member States from WHO was outlined, including expansion of “know your epidemic” assessments, advocacy,
technical support, strengthening of laboratory, surveillance and programme monitoring, consolidation of prevention interventions, and resource mobilization. Overall progress in the Region is summarized as an implementation dashboard that tracks country progress from the baseline of July 2014 (Annex 4).

2.2.3 Access to hepatitis medicines: case studies from seven countries in the Region

Dr Jing Sun from the Chinese Academy of Medical Sciences and Peking Union Medical College, together with Ms Karina Yong from the Third World Network, presented preliminary results from the Landscape Study on Access to Medicines for the Continuum of Hepatitis B and C Treatment in 7 Countries in the Western Pacific Region (Cambodia, China, Kiribati, Malaysia, Mongolia, New Zealand and Viet Nam) that was started in September 2018. The study aims to improve understanding of pharmaceutical and intellectual property policies related to access to hepatitis medicines at the country level, to contribute to policy for promoting access to new hepatitis treatments in resource-limited settings and to trigger further thinking on access to high-priced medicines. The study included a literature review, on-site data extraction, review of commercial data on sales of medicines, interviews of key informants and roundtable discussions. The final results of the study will be synthesized and reported by March 2019.

Preliminary results indicate that inclusion of hepatitis medicines in country essential medicines lists varies and that drug prices differ between and even within countries. Tenofovir disoproxil fumarate (TDF) is registered in all countries and generics are available, with prices ranging from approximately US$ 70 per month (China) and US$ 50 per year (Malaysia) of treatment. Information on tenofovir alafenamide (TAF) is limited; the drug is largely not registered but is already on the market in many countries, with regulatory implications. DAAs are mostly already included on country essential medicines lists. Patent protection is complicated, with many DAAs under patent until 2030. Prices vary widely; DAAs are currently particularly expensive in China. Medicines for liver cancer are mostly not registered or funded, except in China where some costs are covered. Barriers identified in some countries vary but include weak health systems, large numbers of patients requiring treatment with significant implications for financing of health and chronic care costs, weak service delivery, a lack of capacity for evaluation of new drugs, weak price negotiation capacities, low awareness of hepatitis and low testing uptake.

Recommendations include: developing comprehensive national action plans with clear targets for treatment; strong collaboration between government, civil society organizations, international organizations and pharmaceutical companies; centralized price negotiation; quality control of generic DAAs; improved service delivery; strict patentability criteria; and avoiding enhanced protection of intellectual property such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)-plus. WHO support requested by national counterparts includes: sharing experiences among countries, technical support for development of guidelines on testing and treatment; capacity-building for doctors, health facilities, laboratory systems and drug regulatory authorities; sharing of price information; and medicines patentability guideline development.

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2 HBV: entecavir, tenofovir disoproxil fumarate, tenofovir alafenamide; HCV: 15 DAAs and their combinations; Hepatocellular carcinoma: sorafenib, regorafenib, nivolumab, lenvatinib

2.2.4 Discussion

- Regulatory processes in some countries require originator drugs to be registered first before registration of generic drugs, and this can be a barrier leading to delays in access to new medicines. WHO prequalification offers manufacturers a means of accessing markets for products that meet international quality norms and standards and is an important means of expediting registration of new drugs or test kits. Updated lists of WHO prequalified products should be disseminated regularly to national regulatory authorities. The Price Information Exchange for Essential Medicines (PIEMEDS) system for the Western Pacific Region contains procurement prices in the public sector for medicines that participating countries have shared voluntarily and can help facilitate sharing of medicine price information. The ASEAN Mutual Recognition Agreements (MRA) on pharmaceuticals and medical devices could offer mechanisms to accelerate the registration of medical commodities and support better harmonization of laws, regulations, principles and policies in these areas.

- High prices of medicines are an ongoing concern. Mechanisms that support greater price reductions based on the principle of economies of scale include pooled procurement and centralized price negotiation for bulk volumes. Where there are several suppliers for products, market competition can help drive price reductions. Voluntary licensing may help promote access to generic alternatives for medicines, depending on the country context. The use of TRIPS flexibilities is another option that governments may consider.

- High-level advocacy involving all stakeholders is required to increase attention on HBV and HCV. Investment cases for elimination of viral hepatitis can show that interventions are cost-effective for many countries. Cost-effectiveness studies including budget impact analyses can be helpful to advocate to governments. WHO has online cost-effectiveness calculation tools for HBV (https://hepbcalculator.org/) and HCV (https://www.hepccalculator.org/).

- To reach regional targets for testing and treatment, rapid tests can be used to scale up testing at lower-level health facilities and may facilitate cost reductions of test kits. For example, Egypt is testing 16 million people for HCV. Six million tests were conducted in November 2018 alone using community-based rapid point-of-care testing, enabling negotiation of a test kit price of approximately US$ 1 per test. It is critical that tests used are of high quality; the WHO pre-qualification programme for diagnostics supports identification of quality-assured diagnostics kits.

- In Cambodia, Médecins Sans Frontières (MSF) is conducting a pilot demonstration project to treat people with HCV infection. Within only a few weeks of starting HCV testing, Phnom Penh Preah Kossamak national hospital experienced a huge demand for treatment with more than 2000 patients on the waiting list. This required triaging patients due to resource constraints (physical space, DAA budget and an initially “heavy” HCV care algorithm), prioritizing patients with advanced liver disease (F3 and F4) for treatment. Once patients with immediate needs for treatment were managed, others without liver disease were recalled for treatment. Currently, a simplified service delivery model with task-shifting to nurses is being piloted in remote settings.

- Dedicated funding from domestic and other sources needs to be identified and integrated service delivery harnessed so as to optimize the costs of delivery of hepatitis care under the principle of UHC and people-centred care.
2.3 Poster marketplace

The poster marketplace provided an opportunity for countries and organizations to present country information on policy, funding, epidemiology, prevention, surveillance, treatment, EMTCT, research and best practices on viral hepatitis (Annex 4) in poster format to other meeting participants.

2.4 Group work: Prevention

Group work sessions examined thematic areas in more detail, focusing on a set of key questions presented by the facilitators. Country groupings (Annex 2) were arranged to include countries with a mixture of more and less advanced hepatitis control programmes. Recommendations from all the groups were synthesized and presented to the plenary.

2.4.1 Blood safety, infection control in health-care settings and prevention among health-care providers

The aim of this session was to understand: 1) how countries are ensuring blood safety and infection control in health-care settings, looking at current issues and challenges; and 2) how hepatitis transmission among health-care workers can be prevented, focusing on provision of testing, treatment and vaccination for the non-immune and experiences of stigma and discrimination associated with hepatitis infection.

Over 26 million blood donations were collected in 2015 in the Region, including 22.7 million whole blood donations and 3.8 million plasma donations. Ten countries reported receiving more than 20 donations per 1000 population per year, while some countries have a much lower donation rate (Cambodia, Solomon Islands). Donations may include family replacement and remunerated donations.

Among 20 countries reporting data, the 2020 target of screening at least 95% of blood donated (98% units screened) was reached in 2015, although many countries do not have legislation, national policy on blood quality or a haemovigilance system, and the quality and completeness of laboratory testing varies. In 2015, among 20 countries reporting data, all countries screened 100% of donations for HBV and 17 countries screened 100% of donations for HCV; nucleic acid testing for HBV was used in 13 countries and for HCV in nine countries, and testing for HCV was not conducted in Kiribati, the Marshall Islands, Niue and Papua New Guinea.

Safe injection policies for preventing transmission of HBV and HCV in health-care settings were established in 12 countries in the Region in 2015 (eight countries did not report data); 3.2% of injections were estimated to be unsafe in 2015. The 2020 target of unsafe injections in health-care settings is zero. National policy on HBV vaccination for health-care workers is available in 17 countries that reported, but implementation and coverage is not known. This is similar to infection control as policies are established in most countries, though implementation and reporting of breaks in infection control practices such as occupational injury are issues. Poor health literacy, stigma and discrimination against infected health-care workers and fear of loss of employment due to disease status interfere with adequate protection and treatment of health-care workers against bloodborne infections.

Advocacy for policy-makers is needed, using a standardized approach which presents investment strategies including economic analyses; demonstration that cross-sectoral benefits extend beyond health and single diseases; and the importance of epidemiology/surveillance data to support the case for strengthened blood safety. Voluntary blood donations are safer than family replacement or
remunerated donations and should be promoted. Overuse of blood transfusions should be minimized through education of health-care workers and the general population. Health literacy in the general population as well as among health-care workers may be addressed using social media to disseminate country-specific messages. Stigma and discrimination may require legislation to protect infected individuals. Lessons learnt in the response to HIV may be applied to viral hepatitis, for example identifying champions to promote, normalize the disease and reduce stigma. Policies are needed to ensure that health-care workers can access free testing for viral hepatitis, with vaccination for the non-immune and linkage to care and treatment for those infected; and that lack of education and/or commodities are not barriers for implementation of correct infection procedures.

2.4.2 Elimination of mother-to-child-transmission of HBV

This session examined the implementation of the Regional Framework for the Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis in Asia and the Pacific, 2018–2030 and specific actions needed to implement antenatal HBsAg testing and ensure linkage to care and additional EMTCT of HBV interventions for infected pregnant women and their infants. Infant vaccination has contributed to a very significant reduction in hepatitis B prevalence among children, and the 2020 regional target of less than 1% HBsAg prevalence among children was met in 2017 (0.93% HBsAg prevalence among children). However, even very high HBV vaccination coverage among infants may not be sufficient to reach the 2030 elimination of HBV target of less than 0.1% HBsAg prevalence among children 5 years of age. The WHO Guidelines on Hepatitis B and C Testing recommend routine antenatal HBsAg testing when HBsAg prevalence is at least 2% in the general population (a condition met by the majority of countries in the Region). Additional interventions to reduce EMTCT of HBV include provision of timely hepatitis B immunoglobulin (HBIG) together with timely HepB-BD and follow-up with testing for HBV-exposed infants, and linkage to care and treatment for all infected pregnant women with antivirals for women meeting eligibility criteria. Definitive WHO guidance and recommendations on additional interventions are expected in 2020.

The 16 countries represented at the meeting already have policies on antenatal HBsAg testing of pregnant women or are planning to introduce testing. Implementation of HBsAg testing integrated with antenatal testing for HIV and syphilis and partner testing of HBsAg-positive pregnant women had already started in the majority of countries. Australia, Brunei Darussalam, Cambodia, China, Fiji, Kiribati, Macao SAR (China), Malaysia, Mongolia, Singapore, the Philippines and Viet Nam conduct hepatitis B e-antigen (HBeAg) and/or HBV DNA testing of HBsAg-positive pregnant women.

Australia, Brunei Darussalam, Cambodia (pilot), China (pilot), Macao SAR (China), Malaysia (pilot), Mongolia, Singapore and Viet Nam provide antivirals to pregnant women with HBV DNA viral load above a defined threshold (or to HBeAg-positive women). Ten countries provide HBIG to HBV-exposed infants, and seven have policies for HBV-exposed infant follow-up including post vaccination serological testing (PVST).

Hepatitis B awareness is limited at the policy level and among the general population. There is a lack of cost-effectiveness and surveillance information to prioritize funding, and policy-makers are dealing with many competing priorities. Funding mechanisms vary between countries and may include government funding (national or local), health insurance (with problems for those who are not insured) and out-of-pocket expenses. Constraints identified included: 1) a lack of WHO guidance on use of maternal antivirals and infant PVST for EMTCT of HBV; 2) the need for operational guidelines, standard operating protocols for service delivery and laboratory procedures and EMTCT indicators (which should also be included in viral hepatitis response monitoring) beyond vaccination.
metrics; and 3) monitoring that links mother–baby pairs for evaluation of programme outcomes. Other problems identified by countries included: availability of quality assured test kits and constraints related to lab-based testing; the cost and availability of HBV DNA testing; supply of hepatitis B monovalent vaccine and HBIG; missed HepB-BDs due to the use of multi-dose vials in clinics with small numbers of deliveries (as health-care workers are reluctant to open vials); and difficulties with blood draw in infants.

Solutions focused on establishing a continuum of care and follow-up for women living with HBV and their infants, using the shared reproductive, maternal, newborn and child health (RMNCH) platform as an entry point for introducing antenatal HBV testing. Service delivery models need to address early access to antenatal care and infrastructure and human resource constraints. Improved access to services and more efficient use of resources can be achieved by introducing HBsAg testing where EMTCT of HIV and syphilis services are already provided, using rapid tests and point-of-care technologies, decentralizing services, and involving the community and community-based organizations, using experiences from HIV programmes. Best practice examples included counselling of infected pregnant women about HBV interventions as a minimum provision in China; co-location of testing and treatment services in Australia; use of unique patient identifiers and community health workers to track pregnant women in India; and out-of-cold-chain approaches for increasing access to timely HepB-BD in Solomon Islands.

Support needs identified included: high-level awareness-raising using strategic information and evidence-based advocacy directed at policy-makers to increase government commitment and resource allocation; donor funding; development of national plans and operational guidelines; training and mentoring of health-care workers; and quality improvement of laboratory services.

2.4.3 Key populations

Conscious of the significant burden of hepatitis and hepatitis–HIV co-infection among key populations and limitations in the regional viral hepatitis response, particularly in terms of harm reduction interventions, this session examined coverage of prevention, testing and treatment interventions for key populations. The definitions of key populations vary between countries and are usually not the same for HBV and HCV (and may be less well defined than for HIV); HBV is found mainly in the general population while HCV infection is concentrated among people who inject drugs (PWID), men who have sex with men (MSM), and among family members of infected patients. There may also be overlap of risk behaviours such as sex workers who inject drugs. Other population groups, including pregnant women, residents of institutions such as prisons and orphanages, indigenous groups, people who undergo traditional tattooing practices, servicemen, migrants, uninsured people and geographically isolated populations, require specific focus and attention depending on the epidemiological context. Older age groups exposed before the introduction of vaccination, infection control and safe medical injection practices and blood safety measures are also at higher risk of viral hepatitis.

Key populations are often difficult to reach and data are limited, but coverage of testing is patchy and generally low. Punitive laws and drug crackdowns are detrimental for programming and access to services for PWIDs in some countries in the Region. Integrated data are lacking in many countries. Sentinel surveillance data show that HCV prevalence is higher among MSM than in the general population in China and that HCV prevalence among PWID in all countries is high. In general, HBV prevalence is not higher in key populations. The global core hepatitis indicator for harm reduction (C.4) sets a target of 200 injection sets provided per PWID per year in 2020; in 2015, only 57
injection sets were provided per PWID per year in the Region. However, China has already reached the 2020 regional target as each PWID is provided with more than 230 injection sets per year.

Programmes on prevention, education and access to integrated testing and treatment services need to address the main drivers of the HIV and hepatitis syndemics among key populations. This requires strengthened programme monitoring, analysis of data for decision-making and involvement of civil society organizations and community peer networks to support services. Programme improvement requires: education of health-care workers and the general population; improved coverage of prevention interventions, integration of services (Brunei Darussalam and Macao SAR (China) offer routine HIV/HBV/HCV testing in TB clinics) and linkage to community-based testing; and decentralized treatment services for key populations (pilot studies are being conducted in Malaysia and Philippines). “Treatment as Prevention” strategies among key populations should expect reinfection and allow for retreatment, and be conducted together with prevention interventions (needle substitution programmes or NSP, opioid substitution therapy or OST). Micro-elimination approaches with a focus on key populations may be appropriate when funding is limited.

2.5 Plenary session (Day 2): Data systems

2.5.1 Progress and challenges in establishing surveillance and programme monitoring in the Region

Dr Linh-Vi Le, Epidemiologist, outlined the monitoring and evaluation framework for HBV and HCV elimination, which includes 10 core indicators and acute and chronic hepatitis and sequelae surveillance, stressing the importance of strategic information for disease response planning and monitoring.

Acute surveillance captures outbreaks, monitors incidence and identifies risk factors for new infections. National notification systems collect demographic data and case reports but cannot differentiate acute from chronic disease. Enhanced case reporting from sentinel sites is more costly and labour-intensive but can differentiate between acute and chronic disease and HAV, HEV, HBV and HCV infections by measuring type-specific IgM levels. China and Japan have 200 and 500 sentinel sites respectively, and Mongolia collects data on all inpatient cases of hepatitis. Most countries monitor HBsAg prevalence among 5-year-old children as a proxy measure of HBV incidence.

Surveillance for chronic infection depends on population-based seroprevalence surveys. Mongolia regularly conducts seroprevalence surveys, and Viet Nam is currently completing a national serosurvey. Countries with strong surveillance systems use case reports to model prevalence: Australia and New Zealand can model down to the state/territory level. A number of different models are available, but it can be challenging to decide which estimate most accurately reflects the real situation. Representative population-based surveys are expensive to conduct, but integration of several diseases can reduce costs, for example combining hepatitis surveys with child HBsAg, immunization, demographic and health, nutrition or noncommunicable disease (NCD) surveys.

Sequelae surveillance typically collects information on liver cancer (hepatocellular carcinoma or HCC) from cancer registries or vital registration systems. These are often weak, with incomplete information on death certificates. Most countries lack systems to estimate the proportion of

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4 The core indicators cover context (epidemic characteristics), input (policy, laws, health systems and financing), output and outcome (prevention, testing and treatment/cure), and impact (incidence of and mortality from HBV and HCV).
cirrhosis/HCC attributable to hepatitis viruses. National cancer registries exist in most countries but rarely include information on the aetiology of HCC. China conducts routine mortality surveys in some provinces, and clinicians regularly publish the proportion of cirrhosis and HCC attributable to viral hepatitis, which can be used to generate population-based estimates of hepatitis sequelae.

Programme data track patients across the cascade of care and cure. Australia uses multiple sources for reporting including national five-yearly census data, data from the National Notifiable Diseases Surveillance System, the Medicare Benefit Schedule and the Pharmaceutical Benefits Scheme. Mongolia has a national database tied to health insurance reimbursement, which can provide real-time data on testing and treatment. Some countries have low-quality notifiable disease surveillance and multiple, fragmented information systems with significant cost and human resource implications for inclusion and integration of viral hepatitis data. WHO has recently introduced the Global Reporting System for Hepatitis (GRSH) for online reporting of information on country policy and guidelines, in addition to aggregated reporting of the cascades of care and cure for HBV and HCV.

Significant support for coordination and integration to strengthen surveillance and monitoring systems is needed by many countries to move away from reliance on modelling to real data to understand the impact of interventions on incidence and prevalence of viral hepatitis.

2.6 Group work: Systems

2.6.1 Strategic information

The purpose of this session was to identify gaps in strategic information which need to be prioritized and addressed before 2020 and look at how viral hepatitis surveillance and program monitoring can be integrated into existing surveys and health information systems. The focus was on moving away from reliance on modelling to collecting data on core global hepatitis indicators for the cascade of care, specifically the proportion of the population diagnosed (C.6), the proportion treated (C.7), treatment effectiveness (C.8), and mortality from liver disease attributable to HBV and HCV infection (C.10). The reference and alternative methods for ascertaining each indicator were presented.

To estimate the proportion of the population diagnosed, most countries rely on notifications of viral hepatitis (which cannot differentiate acute cases) or a patient database as the numerator, expressed as a proportion of prevalence estimates. Hong Kong SAR (China) (2001) and New Zealand had conducted population-based surveys (the reference method). Hong Kong SAR (China) plans to capture data on viral hepatitis as part of a government survey on NCDs planned for 2020. To assess the proportion of people with chronic hepatitis on treatment and treatment effectiveness, the majority of countries were using a patient database or aggregated reports from treatment centres. Information to assess impact comes from national vital statistics data and cancer registries and estimates of the fraction of liver cancer deaths attributable to HBV and HCV. For countries lacking this information, estimates are available from the WHO Global Burden of Disease studies.

Most countries had multiple and fragmented surveillance systems including case-based data, data from laboratories and blood banks, integrated biological and behavioural surveillance surveys and cancer registries, bringing challenges of linkage and interoperability. Mongolia has a large health insurance-based viral hepatitis patient database, which includes data from the private sector. Data are collected on all cascade components, but there are gaps between screening, treatment and treatment effectiveness, and the database still needs to be linked to other systems, including the cancer screening information system.
Discussions focused on using national health insurance databases to collect data on diagnosis and validate data on treatment, including: laboratory confirmation of hepatitis infection (serology and viral load) into notifiable disease systems; how to include hepatitis into population-based surveys, particularly if blood samples are not collected; and how to mobilize funds for developing or integrating viral hepatitis databases (including laboratory information systems) into national health information systems. It may be difficult to obtain precise responses to questions about viral hepatitis, because hepatitis is often asymptomatic and jaundice is non-specific. In addition, people may report having had a blood test or a vaccination but are often unaware of the specific test or vaccination.

Specific funding for viral hepatitis is often not available, but national systems for HIV may be well-developed, allowing for integration of viral hepatitis into HIV systems. Electronic information systems permit data extraction if resources allow. In countries with a significant private sector, mandated reporting by private health facilities can be used to improve completeness and representativeness of data. Mongolia conducts cascade-of-care workshops, which include private sector practitioners. National cancer registries often do not include aetiological information on liver cancer, but linkage to pharmacy databases can be useful (Mongolia). Data on cirrhosis are rarely captured, but Australia does collect data on cirrhosis from sentinel sites. Support is needed to advocate with governments to prioritize data capture on hepatitis and provide information technology (IT) solutions to coordinate and integrate multiple information systems.

### 2.6.2 Testing and linkage to treatment

This session looked at policies and strategies on testing and linkage to treatment. Diagnosis of HBV (17% in 2017) and HCV (21% in 2017) in the Region falls short of the 30% target for 2020. The service delivery model established in Japan in 2002 was presented: free hepatitis testing is provided using a voucher system to everyone aged between 40 and 70 years every five years. Costs are shared between central and local government. Since 2007, hepatitis screening has been provided on an opt-in basis through regular health-check programmes at prefecture and district levels and at workplaces. If found to be infected with hepatitis B or C, patients consult primary care physicians and are then referred to specialist institutes for assessment and initiation of treatment if indicated. Their data are shared by local hospitals with the local public health office, which conducts monitoring and follow-up of patients. Antenatal HBsAg testing has been offered since 1985.

Most countries in the Region are providing hepatitis testing for specific populations, which may include pregnant women, hospitalized and/or TB patients, blood donors, high-risk populations such as people living with HIV (PLHIV), PWID and patients on haemodialysis, older people, health-care workers, and inmates of prisons and other institutions. Policies specifying who should be prioritized for testing are often lacking, funding is limited, and testing is not universally free even for key populations. Systems for linkage to care for infected individuals vary between countries, but treatment is often hospital-based and expensive. Stigma and discrimination limit access to care in some countries, and there are concerns about wasted resources due to reinfection among high-risk individuals; asymptomatic individuals may not wish to start lifelong treatment.

Opportunities for increasing access to testing and treatment include: advocacy, awareness-raising and education in the community and capacity-building among health-care workers; providing testing to the non-insured; decentralizing testing using point-of-care/rapid tests to reduce turnaround time and loss to follow-up; and addressing treatment costs through inclusion in essential care packages for health insurance coverage. Successful solutions include the use of needle substitution programmes to recruit people for testing and treatment, peer advocacy, community education including harm minimization education, and supporting community prescribing (though this approach may encounter
resistance from overburdened primary health-care workers). There is a role for WHO to play in global price negotiations for diagnostics and hepatitis medicines and supporting development of guidelines for testing and treatment and training of health-care workers.

2.6.3 Treatment and access to medicines

Treatment for chronic hepatitis B is currently lifelong with significant implications for hepatitis programming and for patients. This session looked at how to expand treatment services closer to where patients live and what the barriers to treatment, access to medicines and long-term care are. Treatment data indicate that countries in the Region are still a long way from reaching treatment targets for HBV and HCV. There are widespread barriers to access across the entire continuum of care, including: low awareness on viral hepatitis in the general population and among health-care workers; significant stigma and discrimination in some countries; insufficient financing; and inequitable access to testing and treatment due to financial, geographical or social factors.

Current government funding is generally insufficient to cover all hepatitis interventions and not all countries have health insurance schemes. Even in countries with health insurance, there may be inequitable benefit packages with a high threshold before reimbursement starts and reimbursement of hospitalization-only and not outpatient costs; marginalized populations are often uninsured and there may be a perception that key populations are undeserving of publicly funded health care. Some countries experience difficulties with drug regulatory mechanisms and the cost of hepatitis medicines and diagnostics generally remains high, and there is a lack of transparency around drug prices, especially DAAs. Fragmented procurement practices whether due to decentralization or pharmaceutical policies exacerbate high costs of medicines and diagnostics. Small-volume procurements or a lack of registered generics result in difficulties negotiating favourable drug prices. Currently, there are only two WHO pre-qualified HBsAg tests available; the cost of viral load testing is high; GeneXpert® machines are only suitable for low-volume testing; and FibroScan® and ultrasound machines are lacking in some countries.

Scale-up of testing will identify many more patients requiring treatment and may overwhelm health systems and human resources. Dependence on centralized models of care will result in increased waiting times for assessment and treatment due to insufficient numbers of specialist physicians, but decentralization may overburden primary care physicians. Additional training will be required in countries where primary care physicians are not permitted to prescribe hepatitis medicines.

Solutions require a focus on health as a human right, the principle of UHC, inclusion of hepatitis in the essential care package, investment in existing health services and review of health insurance policy. National data registries should be developed and linked for use for advocacy and leverage with government. Phased expansion and decentralization of services includes orienting specialists for public health delivery, capacity-building of primary care physicians through training and mentoring, and changing legislation and regulations to facilitate prescribing of hepatitis medicines.

In Australia, 38% of DAA prescriptions for treatment of HCV were provided by primary care physicians in 2018 and a recent policy authorizes nurse practitioners experienced in the treatment of chronic HCV infection to prescribe DAAs independently. Malaysia is developing a decentralized service delivery model with simplified treatment algorithms, aiming to reduce waiting times and loss to follow-up.

In Cambodia, the MSF HCV project is also decentralizing care, using videos to educate and disseminate information, simplifying treatment algorithms, reducing the number of doctor visits, increasing the capacity of nurses and primary care physicians, and using peer educators for adherence counselling. Countries developing their hepatitis response can apply lessons learnt from HIV and consider integration with HIV and other services. More favourable drug prices can be negotiated through increased transparency and sharing of prices of medicines and diagnostics between countries, central or pooled procurement with increased volumes, and licensing of generics to increase competition.

2.7 Plenary session: Key messages and recommendations

Key messages and recommendations for countries and WHO and partners developed during the group work discussions were compiled and presented for each thematic area:

2.7.1 Blood safety, infection control and prevention among health-care providers

Key messages

1. Blood safety targets of the Regional Action Plan are primarily met; however, increasing voluntary non-remunerated blood donation rate is essential.

2. Hepatitis B vaccination for all health-care workers and health profession students should be ensured.

Action points for countries

1. Blood safety: Promote voluntary blood donation by developing policies that reduce family replacement donation and remunerated donations; mobilize resources for clinical laboratories for blood screening to improve access, efficiency and quality and decrease cost; and establish accreditation systems for blood banks across all levels of laboratories.

2. Vaccination and protection of health-care workers: develop policy on inclusion of hepatitis B vaccination for health-care workers and students in employment and education systems; address discrimination through normalizing hepatitis among the general population; and increase health literacy for both health-care workers and general populations. Provide treatment for infected health-care providers with safeguards against stigma and discrimination.

3. Infection control: implement active monitoring of unlicensed medical practices and adherence to the policy; and ensure adequate stock of universal precaution commodities in facilities.

Action points for WHO and partners

1. Support countries to collect data for evidence-based policy and advocacy including vaccination among health-care workers, sources of new infections, infection control data, etc.

2. Support countries to establish laboratory services for screening blood donations.

3. Support countries to mobilize resources for targeted programmes for HBV immunization among health-care workers and treatment policies for those infected.

4. Support countries to set a target in the Regional Action Plan for health-care worker vaccination coverage (beyond the current policy target).
2.7.2 Elimination of mother-to-child transmission

Key messages

1. All countries have either already introduced antenatal HBsAg screening linked to antenatal screening for HIV and syphilis or have plans to do so.
2. Linkage to care for hepatitis B-infected pregnant women and their infants and additional interventions should be standardized and simplified as much as possible.
3. WHO recommendations on EMTCT of HBV interventions are needed.

Action points for countries

1. Allocate resources for antenatal HBsAg screening and additional EMTCT of hepatitis B interventions to achieve universal coverage and to ensure that cost is not a barrier to access.
2. Decentralize services and build capacity at the primary care level to ensure that all infected pregnant women receive counselling and are linked to care and that the timely birth dose and infant follow-up are prioritized.

Action points for WHO and partners

1. Provide technical advice and support interventions for EMTCT of hepatitis B based on existing evidence and country experiences pending global guidance.
2. Strengthen and facilitate collaboration across different programmes within WHO and with partners to provide harmonized support.
3. Advocate accelerated WHO pre-qualification of point-of-care diagnostics including multiplex tests.

2.7.3 Key populations

Key messages

1. Populations considered at risk of infection are different for HBV (mostly general population) and HCV (specific populations and in some countries, the general population because of unsafe injection practices).
2. Strategy of “Treatment as Prevention” for HCV, especially among key populations such as PWID and prisons (which allow retreatment and expect reinfection), must be conducted in conjunction with prevention interventions (clean needles and syringes, OST).

Action points for countries

1. Take a data-driven approach to programming towards the main drivers of the hepatitis epidemic (including HIV/hepatitis coinfections). Consider strategies such as micro-elimination approaches for some subgroups, for example HCV among PWID/MSM/HIV co-infected people/prisoners. Strengthen programme monitoring and analysis of data for decision-making.
2. Provide integrated service delivery, improve coverage of prevention interventions and link to testing and treatment for key populations. This includes support for community-based testing and decentralized services, with linkage to treatment for hepatitis services.

Action points for WHO and partners

1. Support countries to strengthen key population-specific service delivery including prevention, testing and treatment.
2.7.4 **Strategic information**

**Key messages**
1. For 2020, countries would like to prioritize data collection for the cascade of diagnosis, treatment and viral suppression/cure.
2. Information systems which track patient care need to link to or include information on sequelae.

**Action points for countries**
1. Harmonize indicators across different systems to enable cascade analysis.
2. Invest in case-based patient databases which capture positive diagnoses, treatment outcomes as well as sequelae.

**Action points for WHO and partners**
1. Provide guidance on questions to use in surveys to capture accurate responses on testing history in order to obtain the proportion of people diagnosed in the population.
2. Provide technical assistance on how to integrate systems and analyse data.

2.7.5 **Testing and linkage to treatment**

**Key messages**
1. Most countries are providing testing for certain populations including pregnant women, hospitalized patients, populations with high risk such as PLHIV, PWID, blood donors and patients on haemodialysis.
2. Barriers to linkages from testing to treatment include: confirmatory testing, limited availability and access to treatment services (for example, drugs, restriction of prescribers, distance to medical facilities and cost), and fragmented data systems.

**Action points for countries**
1. Raise awareness about viral hepatitis among the general population and implement capacity-building for testing, counselling and treatment for health-care workers.
2. Scale-up and decentralize confirmatory testing including use of point-of-care technology to shorten turnaround time and improve linkages to care and treatment.
3. Harness the power of people living with hepatitis (for example, patient groups, civil society, groups of PLHIV) and involve them in decision-making, for example by including them in national working groups/committees for viral hepatitis.

**Action points for WHO and partners**
1. Develop and disseminate training modules on viral hepatitis to build the capacity of primary care providers in order to expand access to testing and treatment.
2. Support countries to ensure the quality of laboratory services for viral hepatitis including facilitating the registration of quality-assured diagnostics and establishing laboratory networks in country.
3. Support countries to conduct operational research to understand barriers and improve access to testing and treatment. Facilitate sharing of good practices, experiences and tools (for example, online training modules).
2.7.6 Treatment and access to medicines

Key messages

1. Barriers to access to medicines include: high-cost of medicines and diagnostics; lack of transparency of drug prices; non-equitable health insurance benefit packages; and procurement and supply issues.

2. Barriers to treatment expansion and decentralization include: limited human resources and capacity; service delivery model which precludes general practitioners from prescribing hepatitis treatment or involvement of other cadres of health-care providers such as nurses in the care provision; lack of data to drive programme expansion; and difficulties in navigating public and private delivery of services.

Action points for countries

1. Disseminate and share country good practices, experiences and lessons learnt, including how countries overcome issues with access to hepatitis medicines. One key area is transparency of drug prices because countries report only retail or published prices, but the actual prices may differ.

2. Establish integrated service delivery models for hepatitis within existing programmes and services as part of universal health coverage. The essential service package must include hepatitis care.

3. As there is a lack of specific donor support for hepatitis (for example, Global Fund), countries should continue to advocate for additional resources domestically, while looking for opportunities for cross-funding and integrated funding from other programmes including HIV, TB, NCD, etc.

Action points for WHO and partners

1. Provide technical support for price negotiations and ensuring platforms to share drug prices.

2. Continue to provide technical support for data-driven programme implementation of treatment expansion, guidelines, capacity-building and service delivery models including task-shifting.

3. CONCLUSIONS

The Meeting on the Implementation of the Regional Action Plan for Viral Hepatitis in the Western Pacific demonstrated that significant progress on control of viral hepatitis has been made by countries in the Region, with most countries having national hepatitis action plans and many implementing preventive interventions including hepatitis B immunization for children, ensuring blood safety and antenatal testing for HBsAg. Gaps remain in harm reduction, access to testing and treatment as well as in health information systems, including monitoring of patient outcomes. Challenges also include inadequate investment, insufficient human resources, and a lack of awareness of hepatitis among policy-makers and the general population. There is an urgent need to scale up and roll out testing and treatment services across the Region to achieve regional targets by 2020.

In order to achieve expansion of testing and treatment services, high-level advocacy, supported by investment cases and cost-effectiveness data, is needed to raise the profile of hepatitis elimination among policy-makers. Integration of hepatitis in the essential package of services and inclusion of hepatitis medicines in essential medicines lists can be used to mobilize resources under the principle
of UHC and ensure that cost is not a barrier to access to services. Awareness-raising among the general population and capacity-building among health-care providers are also needed. Task-shifting to general practitioners and nurses enables appropriately trained health workers to provide education, support and clinical management to people with liver disease. This service delivery model can contribute significantly to the scale-up phase of national hepatitis programmes. Community engagement, including peer education, is important to reduce stigma and discrimination and remove barriers to access to services. Programme implementation should be data driven, which requires strengthening and integration of data systems for hepatitis.

WHO and partners can facilitate and support sharing of best practices, development of national action plans, technical and operational guidelines, provision of training, and advocacy for accelerated WHO pre-qualification of point-of-care diagnostics and favourable drug prices.

Intensified efforts of Member States, WHO and partners are urgently required to strengthen implementation of the regional action plan to achieve 2020 targets aiming at elimination of viral hepatitis by 2030.
ANNEXES

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Annex 2. Meeting agenda and group work schedule

Day 1: December 13, 2018

<table>
<thead>
<tr>
<th>Time</th>
<th>Sessions</th>
<th>Speaker/Moderator</th>
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<tbody>
<tr>
<td>08:30 – 09:00</td>
<td>Registration</td>
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</table>
| 09:00 – 09:30   | Opening                     Welcome remarks                  Opening remarks                               | Naoko Ishikawa
|                 |                            Self-introduction and objectives of the meeting               | Regional Director                      |
|                 |                            Administrative announcements                           | Po-Lin Chan                            |
| 09:30 – 10:00   | Group photo and coffee break                                             |                                        |
| 10:00 – 10:15   | **Plenary: progress overview**                                           | Naoko Ishikawa                         |
|                 | Global and regional progress towards elimination of viral hepatitis      |                                        |
|                 | 2016-2020: challenges and lessons learned                               |                                        |
| 10:35 – 10:50   | Access to hepatitis medicines: case studies from 7 countries in the Region | Jing Sun/Yokeling Chee                 |
| 10:50 – 11:20   | Discussion                                                               |                                        |
| 11:20 – 11:25   | Introduction to group work                                               | Po-Lin Chan                            |
| 11:25 – 12:40   | **Lunch**                                                                |                                        |
| 12:40 – 13:40   | **Poster Marketplace**                                                   |                                        |
|                 | [Representatives to stand by the poster]                                 |                                        |
|                 | Group 1 [12:40 – 13:10]                                                  |                                        |
|                 | Group 2 [13:10 – 13:40]                                                  |                                        |
| 13:40 – 15:25   | **Group work: Prevention**                                               | Facilitated sessions                   |
|                 | (approx. 50 min per topic)                                               |                                        |
|                 | **Prevention-1:** Blood safety, infection control in healthcare settings  |                                        |
|                 | and prevention among healthcare providers                                |                                        |
|                 | **Prevention-2:** Elimination of mother-to-child-transmission of HBV     |                                        |
|                 | **Prevention-3:** Key populations                                        |                                        |
| 15:25 – 15:40   | **Coffee break**                                                         |                                        |
| 15:40 – 16:30   | Continuation of group work                                               |                                        |
| 16:30 – 17:30   | Report preparation for plenary: Day 1 group work                         |                                        |
|                 | (Facilitators, rapporteur, secretariat)                                  |                                        |
| 17:30 – 19:30   | **Regional Director's Reception**                                        |                                        |
## Day 2: December 14, 2018

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<tr>
<th>Time</th>
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<tr>
<td>08:00 – 08:30</td>
<td>Secretariat meeting</td>
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<tr>
<td>08:30 – 08:50</td>
<td><strong>Plenary: data systems</strong>&lt;br&gt;Progress and challenges in establishing surveillance and programme monitoring in the Region&lt;br&gt;Group work announcement</td>
<td>Linh-Vi Le&lt;br&gt;Po-Lin Chan</td>
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<tr>
<td>08:50 – 11:30</td>
<td><strong>Group work: Systems</strong>&lt;br&gt;Systems 1. Strategic information&lt;br&gt;Systems 2. Testing and linkage to treatment&lt;br&gt;Systems 3. Treatment and access to medicines</td>
<td>Facilitated session</td>
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<tr>
<td>09:40 – 10:10</td>
<td>Coffee break</td>
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<tr>
<td>11:30 – 12:00</td>
<td>Report preparation for plenary: Day 2 group work&lt;br&gt;(Facilitators, rapporteur, secretariat)</td>
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<tr>
<td>11:30 – 13:30</td>
<td>Lunch</td>
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<td>13:30 – 14:30</td>
<td><strong>Plenary</strong>&lt;br&gt;Report by topic (10 min each)</td>
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<td>14:30 – 15:00</td>
<td>Discussion</td>
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<td>15:00 – 15:30</td>
<td><strong>Coffee break</strong></td>
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<tr>
<td>15:30 – 16:00</td>
<td>Summary and conclusion</td>
<td>Rapporteur</td>
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<tr>
<td>16:00 – 16:30</td>
<td>Closing remarks</td>
<td>Naoko Ishikawa</td>
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### Group Work

**Day 1: December 13, 2018**

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<tr>
<th>Prevention</th>
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<th>212</th>
<th>Upper conference lounge</th>
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<tbody>
<tr>
<td><strong>Thematic area</strong></td>
<td>1. Blood safety, infection control and prevention among healthcare providers</td>
<td>2. Elimination of mother-to-child transmission of HBV</td>
<td>3. Key populations</td>
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<tr>
<td><strong>Facilitators:</strong></td>
<td>Donghyok Kwon &lt;br&gt; Melissa Kelly (Albion Centre)</td>
<td>Naoko Ishikawa/Anne Brink &lt;br&gt; Kenichi Komada (NCGM)</td>
<td>Po-Lin Chan &lt;br&gt; Chris Munoz (Yellow Warriors)</td>
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<tr>
<td><strong>Note taker:</strong></td>
<td>Linh-Vi Le</td>
<td>Anne Brink/Naoko Ishikawa</td>
<td>Takeshi Nishijima</td>
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<tr>
<td><strong>Contributors:</strong></td>
<td>Shanghai Blood Centre</td>
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<td>Margaret Hellard (Burnet)</td>
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<tr>
<td><strong>Facilitators:</strong></td>
<td>Linh-Vi Le, &lt;br&gt; Shinsuke Miyano (NCGM)</td>
<td>Naoko Ishikawa &lt;br&gt; Tatsuya Yamashita (Kanazawa)</td>
<td>Po-lin Chan &lt;br&gt; Jing Sun (Third World Network)</td>
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<tr>
<td><strong>Note taker:</strong></td>
<td>Anne Brink</td>
<td>Donghyok Kwon &lt;br&gt; Melissa Kelly (Albion Centre)</td>
<td>Takeshi Nishijima &lt;br&gt; Karina Yong (Third World Network)</td>
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<td><strong>Contributors</strong></td>
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<td>Kanazawa, MSF</td>
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**Group Assignments for Group Work:**

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<thead>
<tr>
<th>Group A:</th>
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<tr>
<td>Brunei Darussalam</td>
<td>Singapore</td>
<td>Mongolia</td>
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<td>Hong Kong SAR (China)</td>
<td>China</td>
<td>Cambodia</td>
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<td>Malaysia</td>
<td>Lao People’s Democratic Republic</td>
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<td>Fiji</td>
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<td>Solomon Islands</td>
<td>Viet Nam</td>
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Annex 3. Recommendations from previous meetings

THIRD MEETING OF THE STRATEGIC AND TECHNICAL ADVISORY COMMITTEE (STAC) FOR VIRAL HEPATITIS, 17-20 SEPTEMBER 2018

RECOMMENDATIONS FOR PREVENTION OF VIRAL HEPATITIS

1) **Regional action plan:** Support Member States to implement the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* under UHC, including development of scalable national costed hepatitis action plans, initiating discussions on the next regional action plan, and actively involving people living with hepatitis and civil society.

2) **Stigma and discrimination:** Support Member States to address stigma and discrimination towards people living with viral hepatitis including monitoring legislation that addresses stigma and discrimination.

3) **Advocacy and communication:** Support Member States and work with partners and civil society to pursue advocacy and communications to increase public awareness of viral hepatitis including stigma and discrimination, and interventions for prevention, testing and treatment of viral hepatitis. Encourage Member States to allocate national resources for advocacy and communications activities. Support countries to develop patient literacy materials and trainings for health-care providers.

4) **Prevention:** Support Member States to focus on prevention of viral hepatitis through hepatitis B immunization, harm reduction, blood and transfusion safety, and prevention of health-care-associated infections. Support Member States to promote approaches for integration of services, including the *Regional Framework for the Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis in Asia and the Pacific, 2018–2030*.

5) **Testing:** Provide technical support to Member States to adapt WHO guidelines to expand access to quality-assured testing services, including within primary health services. Develop evidence-based testing strategies; facilitate access to affordable quality-assured diagnostics and laboratory services. Disseminate diagnostics pricing data among Member States.

6) **Treatment:** Support Member States to expand access and linkage from diagnosis to care and treatment services. Facilitate access to medicines and disseminate information on prices. Support training of health-care providers, development of simplified guidelines and decentralized service delivery models, in particular integration of treatment into primary care.

7) **Strategic information and progress monitoring:** Develop an operational guide providing guidance on data sources that may be used to develop the national cascade of care and monitor impact indicators (that is, incidence and mortality) and stigma and discrimination. Encourage the inclusion of hepatitis indicators into the national disease surveillance system.

8) **Laboratory:** Encourage Member States to participate in existing regional laboratory networks and to establish or identify national reference laboratories to support testing capacities. Follow up on recommendations of the Informal Consultation on the Quality Improvement of Laboratory Services for Viral Hepatitis in the Western Pacific Region.

9) **Resource mobilization and collaboration:** Seek resources to support national hepatitis responses; advocate allocation of national resources for viral hepatitis; expand partnerships and networks, including WHO representation at regional and subregional meetings to provide normative and technical guidance.

10) **Other hepatitides:** Respond to outbreaks of all forms of hepatitis and provide technical assistance to Member States when requested. Where applicable, support countries to understand the epidemiology of other hepatitides, with particular attention to hepatitis D.

11) **Implementation science and evidence generation:** Identify priority questions and provide support for implementation research on viral hepatitis to inform policies and decision-making to
advance the hepatitis response. This may include adaptation and implementation of global recommendations, and integration of hepatitis-related services into existing health systems.

RECOMMENDATIONS FOR EMTCT OF HBV

1) EMTCT of HBV: Develop and provide guidance to Member States for interventions, monitoring and assessment of EMTCT of HBV considering the technical recommendations provided through the consultation.

2) Validation of HBV EMTCT: Incorporate the HBV EMTCT validation process into existing mechanisms for EMTCT of HIV and syphilis and conduct validation at the regional level as feasible, through active collaboration between the ERP/STAC and HIV/syphilis programmes, and cross-cutting collaborations with MNCH and health systems. A standardized assessment scheme should be developed by the ERP, STAC and relevant experts.

Technical recommendations and considerations for EMTCT of HBV

1) EMTCT interventions

   Key issues for the provision of routine antenatal hepatitis B screening and opportunities for linkages with antenatal HIV and syphilis testing

Recommendations:

1. Adoption of antenatal HBsAg testing of pregnant women should be in addition to the delivery of the timely birth dose and completion of the hepatitis B vaccine series for all infants, not only those born to HBsAg-positive mothers.

2. Antenatal HBsAg testing should be conducted using a WHO pre-qualified test or a quality-assured test which has been shown independently to have high sensitivity and specificity. If testing is conducted using a rapid test, subsequent confirmatory testing could be considered, if available.

3. Antenatal HBsAg testing should be universally and routinely offered to all pregnant women (together with antenatal HIV and syphilis testing) in both public and private health facilities. Testing should be conducted in every pregnancy at no cost to the individuals.

4. Confidentiality of test results must be ensured and all women should receive counselling and education. Steps must be taken to prevent stigma and discrimination against women living with hepatitis B, both in health-care settings and in general, including applying lessons learnt in the programmatic response to these issues in the context of HIV.

5. Test results must be made available at ANC and at the place of delivery and of postnatal follow-up. Policies supported by standing orders should ensure that health-care providers in the delivery facility are trained and authorized to give HepB-BD, to facilitate timely delivery of HepB-BD.

6. Women identified as HBsAg-positive should be linked to timely and appropriate care and informed of the importance of facility-based delivery, timely HepB-BD for their newborns, completion of the hepatitis B vaccine series and follow-up for themselves and their infant.

7. HBsAg testing should be offered and made available to partners, family and household contacts of HBsAg-positive pregnant women.

8. All women who are diagnosed with hepatitis B antenatally must be entered in the national hepatitis case notification system, including those women who were diagnosed through rapid testing during labour and delivery.

9. Monitoring (data) of mother–baby pairs should be linked, so that the HBsAg status of the mother and the vaccination status of the infant are known.

10. Consideration may be given to offering hepatitis B vaccination to women at risk of hepatitis B infection who remain susceptible to hepatitis B.
11. Countries would need to undertake workforce development to provide appropriate care to HBsAg-positive pregnant women identified through antenatal screening and must ensure proper training of all staff involved in EMTCT, including the use of algorithms and training in the use of antiviral drugs if available.

**Minimum intervention package for HBsAg-positive pregnant women and their infants**

**Recommendations:**
The minimum intervention package should include the following:

1. Timely HepB-BD, given to the infant as soon as possible after birth (and definitely within 24 hours), followed by completion of the hepatitis B vaccine series according to the national immunization schedule.
2. Additional interventions to reduce the risk of MTCT of hepatitis B:
   a. HBIG given to the infant, where available, or
   b. HBIG for the infant and antiviral drugs given to the mother, or
   c. (pending research results) antiviral drugs given to the mother alone.
3. PVST for infants born to HBsAg-positive mothers and linkage to appropriate care for infants diagnosed with hepatitis B.
4. Counselling and education and linkage to care for infected women (either during pregnancy or postpartum).
5. Promotion of partner/family/household contact testing and linkage to care.

**Key issues to be considered for HBIG use**

**Recommendations:**

1. If a country decides to use HBIG as a measure to reduce MTCT of hepatitis B, the quality and safety of HBIG should be ensured through national regulatory, procurement and supply systems.
2. The cost of HBIG should be borne by the programme, not by the individual family.
3. HBsAg-positive women should be encouraged and supported to deliver at the health facility level where HBIG is available to ensure that HBIG can be given in a timely manner.

**Key issues to be considered for antiviral use**

**Recommendations:**

1. TDF is the preferred drug in the setting of prevention of MTCT of hepatitis B. Before treatment is initiated, testing should be conducted to confirm adequate baseline renal function, in line with national treatment guidelines.
2. HBIG (if available) should be given to the newborns of women who present late in pregnancy, at labour or delivery and are determined to be HBsAg-positive, as antivirals will have insufficient time to work.
3. HIV–HBV coinfected pregnant women should be on a TDF-containing antiretroviral combination regimen.
4. The cost of antiviral treatment should be borne by the programme, not by the individual family.
5. Antivirals should not be stopped at delivery in women who need treatment for their own health. HBsAg-positive mothers should be linked to care during pregnancy and after delivery.
6. Consideration can be given to the use of HBeAg testing where HBV DNA viral load testing is not available to indicate need for additional antiviral therapy.
7. If the availability of specialist physicians in-country is limited and antivirals are prescribed predominantly by primary care physicians, training should be provided in the use of the drugs, monitoring procedures and follow-up.

**Follow-up of exposed infants**

**Recommendations:**

1. PVST of infants for HBsAg should be conducted not less than two months after the last dose of hepatitis B vaccine and before 18 months of age, at a time which takes advantage of existing health-care interventions for the child (for example at the time of measles vaccination, that is, 9 months).
2. The use of WHO pre-qualified tests or tests that have been shown independently to have high sensitivity and specificity is recommended. Approved rapid diagnostic tests can be used if available.
3. At minimum, an HBsAg test should be conducted. If a rapid test is used and the result is positive, confirmatory testing should be conducted if available.
4. Countries may choose to offer anti-HBs testing (in addition to HBsAg testing) if available. Anti-HBs testing should be conducted before 24 months as antibody levels decline with time after vaccination. Infants who are both anti-HBs and HBsAg-negative should be considered for revaccination.
5. Infants found to have HBV infection should be linked to appropriate care.
6. Family and household members should be identified, offered HBsAg testing and vaccination if found to be susceptible.

**2) Monitoring and assessment**

**Metrics of EMTCT of HBV**

**Recommendations:**

1. The metric of EMTCT of HBV is the proportion of babies born to HBsAg-positive women who, at 9–12 months*, are HBsAg-positive.
   * where this timing must satisfy: more than 2 months since last dose of hepatitis B vaccine and age less than 18 months

**Justification:**

- The ~5-year-old prevalence metric (0.1% HBsAg-positive) in the general population reflects overall health systems strengthening/Sustainable Development Goal targets and all prevention efforts (including but not limited to MTCT) and only reflects on MTCT indirectly and after a time-delay.
- This ~5-year-old prevalence metric needs to remain prominent in any EMTCT framework and country report and should be included as an additional overall measure.

2. An MTCT rate of hepatitis B less than 2% represents EMTCT of HBV.

**Justification:**

- This MTCT rate is achievable, based on available data from Thailand and China, which have greater than 95% vaccination coverage, including that of HepB-BD.
- This MTCT rate is expected to be consistent with the 2030 target of less than 0.1% HBsAg prevalence among ~5-year-old children.
- This is consistent with the HIV EMTCT target in the Region.

Note: This is not eradication, but represents a very low level of risk and a low level public health problem.
Evidence of MTCT rate of HBV <2%

Recommendations:

Packages of data which may constitute an acceptable level of evidence for a MTCT rate of HBV less than 2% include:

1. A nationally representative prospective cohort of HBsAg-positive mothers and their babies followed to 12 months of age, with high levels of follow-up.

2. A high-quality estimate of MTCT using routine programmatic data, such as a retrospective cohort of HBsAg-positive, mothers’ census or a nationally representative sample (including over 90% capture of ANC events; over 90% ascertainment of mother’s HBsAg status; and over 90% of ascertainment of child’s outcome). [Metrics TBD]

3. A high-quality estimate of MTCT using routine programmatic data supplemented with active follow-up and testing of a representative sample of hepatitis B-exposed infants at 9–12 months to improve ascertainment. [Metrics TBD]

4. Triangulation of more than one estimate as described above, where data packages include moderate limitations.

Additional modelling estimates of MTCT based on high-quality programme service coverage data, including mothers tested, maternal HBsAg seroprevalence, mothers treated, newborn and infant vaccines, etc. would be useful particularly where data sources are limited.

Note: Data packages 1–3 are the preferred methodologies.

The role of modelling in judging achievement of EMTCT

1. Contributes to the evidence base for the MTCT rate of hepatitis B – but not in isolation.

2. Helps design data collection/analysis to measure the MTCT rate of hepatitis B.

3. Provides “consistency” checks for data.

Notes:

- Models should be peer-reviewed, of high quality and with demonstrated validity for the setting and application.
- There may be a role for comparing outputs from more than one model (currently, there is no hepatitis B consensus model such as Spectrum for HIV).

The role and details of programme data in validation of EMTCT of HBV

Recommendations:

1. Every evaluation of EMTCT should incorporate programme data and should include ANC attendance and screening, timely birth dose coverage, hepatitis B vaccine three-dose coverage, HBIG uptake, linkage to care and treatment for HBsAg-positive mothers, antivirals (when available) and PVST coverage and outcome for infants.

2. Estimates should be population-based and consider women who have not been captured by the system.

3. Programme data from multiple sources should be triangulated; this can be through modelling.

Note: The above indicators need to be further defined.

Validation of EMTCT of HBV

Recommendations:

1. The ERP and external experts should assist countries by providing guidance on what is required for validation.

2. The validation process should be transparent and in partnership with countries.
3. Countries should be encouraged to undergo validation of EMTCT for HBV, HIV and syphilis in combination, where feasible.

4. The validation process should be incorporated into existing mechanisms (for example, ERP), and should mirror how progress towards elimination is currently reviewed by country.

5. The validation process should be led by the ERP but must incorporate external experts and be done in collaboration with HIV and syphilis, MNCH and health systems experts and groups.

6. A new standardized marking scheme should be developed to assess EMTCT by the ERP, STAC and relevant experts, and should include assessment of indicators (programme data), MTCT rate and modelling.

**Working across existing regional and global validation systems**

**Recommendations:**

1. Regional
   - There should be active collaboration between the ERP/STAC and HIV/syphilis groups, and cross-cutting collaborations with MNCH and health systems, such as formation of joint working groups.
   - Validation should be conducted at the regional level, where feasible.

2. Global
   - Global and regional validation activities should be aligned.
   - Revision of the Orange Book for triple EMTCT to include validation of EMTCT of hepatitis B should draw on regional and national expertise and experience.
3.2 Recommendations

3.2.1 Recommendations for Member States

Member States are encouraged to do the following:

1. Consider developing national strategic plans on strengthening laboratory services for both clinical and public health (surveillance) purposes as well as laboratory data reporting and management.

2. Establish and support development of in-country quality assurance systems, including in-house assessment and verification of test kits over the longer term. This effort should involve multiple stakeholders and reflect capacities and available resources.

3. Identify key national laboratories that can facilitate EQA in country. These laboratories should have the capacity to prepare proficiency test panels using panel samples received from regional laboratories (or create panels by their own), to distribute them to subnational laboratories within the country, and to provide feedback and training on EQA.

4. Use EQA as an opportunity to improve services by providing feedback and refresher courses to laboratories. Learn from the experiences of HIV testing services including quality assurance and apply these lessons on quality laboratory services for viral hepatitis and other infections through close collaborations with country stakeholders and regional partners.


6. Ensure the availability of human resources for quality management by adding quality assurance to the roles of supervisors and assigning dedicated quality managers.

7. Quality improvement of laboratories including EQA should involve private laboratories within the country. Manufacturers could support quality improvement through tender agreements that include EQA and service agreements, considering/addressing potential conflicts of interest and approaches to mitigate them.

3.2.2 Recommendations for WHO and partners

WHO and partners are requested to do the following:

1. Support countries in advocating for high-level commitment for quality laboratory services (for example, generation of evidence on cost-effectiveness of quality laboratory services and allocation of domestic resources) and sustained domestic funding. Adopt a tiered approach to provide support to countries reflecting their laboratory capacities.

2. Enhance cooperation within and across countries and with collaborating partners by establishing networks using existing systems. WHO collaboration centres and partner laboratories can provide support for strengthening national reference laboratories, which can then provide support for subnational and other laboratories.

3. Establish communications among regional laboratories. WHO and WHO collaborating centres to share information and improve efficiencies, and encourage regional partner laboratories to support countries to assess and develop national testing algorithms (for example, HIV and hepatitis testing algorithms) in line with WHO guidance.

4. Make EQA more efficient and sustainable by avoiding duplication of EQA from multiple institutions (for example, for HIV), and providing support to national-level laboratories to provide in-country EQA.

5. Strengthen dissemination of information and provide support to countries with interested diagnostics manufacturers to enhance applications for the WHO prequalification programme.
(http://www.who.int/diagnostics_laboratory/events/en/) and consider putting up a special call for HBV and HCV priority products.

6. Consider creation of dedicated posts for laboratory experts in WHO regional/country offices to advocate for the importance of laboratory services and provide technical support.

7. Consider formation of a technical working group for hepatitis testing to improve laboratory services for viral hepatitis case finding and surveillance in collaboration with other laboratory services and existing platforms.

8. Enhance integration and collaboration across programmes including sharing of resources. Laboratory services for hepatitis and sexually transmitted infections can be strengthened by building on established HIV laboratory services and by distributing tools and materials (for example, job aids) for laboratory services in a format that is appropriate for laboratory settings.

9. Support countries in their expansion of hepatitis testing services by disseminating WHO recommendations, advocating for development and registration of quality diagnostic assays, and sharing lessons and experiences from the expansion of testing for HIV and other communicable diseases.

10. Seek donors and identify opportunities for external funding for laboratory strengthening in collaboration with countries and partners.

11. Develop collaborative research with countries to address public health issues related to laboratory services.

3.3 Next steps
The following next steps were proposed:

1. Establish effective communication channels among WHO, country laboratories and partners (for example, linking to LabNet – the network of public health laboratory services under PacNet, https://www.pphsn.net/Services/LabNet/intro.htm), taking into account the specific needs of countries.

2. Establish an informal technical working group for hepatitis testing. The priority is to initiate discussion on the terms of reference of the group with key partners then expand and link with other existing networks supporting laboratory services in the Region.
Recommendations for Member States

Member States are encouraged to:

(1) urge decision-makers to translate commitments made on the global targets for HIV, viral hepatitis and STIs into financial and human resources, and engage stakeholders including communities and the private sector towards elimination of HIV, viral hepatitis and STIs, including EMTCT, as public health threats by 2030;

(2) determine baseline data, particularly for viral hepatitis and STIs; set country-specific targets for HIV, viral hepatitis and STI; and develop and implement road maps to achieve targets;

(3) increase demand for HIV, viral hepatitis and STI services by raising awareness among the public and health-care workers about new evidence and improvements in prevention, testing and treatment;

(4) update and implement national guidelines on HIV, viral hepatitis and STIs in line with WHO recommendations and based on local evidence and context with the participation of the affected community;

(5) intensify efforts for epidemiological targeting, and improve quality, coverage and accessibility of current and new approaches towards elimination;

(6) explore and promote synergies and collaboration among HIV, viral hepatitis and STIs and other health programmes, for example provision of integrated services, within a whole-of-systems approach to achieve universal health coverage and elimination;

(7) strengthen surveillance and monitoring systems across disease control programmes by:
   a) establishing interoperable health management information systems,
   b) expanding HIVDR and gonococcal antimicrobial resistance surveillance, and
   c) developing a comprehensive framework for hepatitis strategic information;

(8) strengthen laboratory service capacities and expand the application of point-of-care diagnostics and molecular diagnostics using multi-disease diagnostic platforms;

(9) promote uptake of HIV, viral hepatitis and STI testing by capitalizing on existing services while introducing new approaches for active case finding (for example, partner notification and self-testing) and case management;

(10) ensure access to affordable essential diagnostics and medicines, ensure procurement meets demand and strengthen supply management to prevent stock-out; and

(11) sustain disease control responses to meet elimination through a phased transition to adequate allocation of domestic resources in a transparent manner by increasing health insurance coverage and ensuring efficiency and integration of essential services into existing health systems.
Recommendations for WHO

WHO is requested to:

(1) support countries to translate commitments made on the global targets for HIV, viral hepatitis and STIs into action, including supporting countries in their advocacy with decision-makers, engagement of stakeholders including communities and the private sector, allocation of adequate domestic resources for elimination plans in a transparent manner and integration of essential services into existing health systems;

(2) set clear definitions and criteria of elimination as a public health threat and support countries to set national targets, and develop operational tools for elimination, starting with HIV, and potentially for STIs and viral hepatitis, to provide guidance to countries on approaches and suggested actions to achieve elimination;

(3) support countries to increase demand for HIV, viral hepatitis and STI services by raising awareness among the public and health-care workers about new evidence and improvement in prevention, testing and treatment;

(4) support countries to update and implement national guidelines on HIV, viral hepatitis and STIs in line with WHO recommendations based on country context with participation of the affected community;

(5) support countries to develop road maps or operational plans to achieve elimination, determine baselines for targets, implement actions to intensify efforts for epidemiological targeting, and improve quality and coverage of current and new approaches towards elimination;

(6) support countries to promote synergies among HIV, viral hepatitis and STI and other health programmes within a whole-of-systems approach to achieve universal health coverage;

(7) support countries to strengthen surveillance and data monitoring systems across disease control programmes including HIV drug resistance and gonococcal antimicrobial resistance surveillance;

(8) support countries to strengthen laboratory services and to introduce or expand the use of molecular diagnostics, including but not limited to multi-disease diagnostic platforms;

(9) support countries to obtain affordable diagnostics and medicines and to strengthen their supply management systems and capacities;

(10) support countries to develop sustainable financing mechanisms for disease control programmes including development of transition plans in particular for HIV; and

(11) facilitate technical collaboration including implementation research, sharing of information and experiences between countries through bilateral or regional platforms such as the Association of Southeast Asian Nations (ASEAN) to suggest actions towards elimination.
Annex 4. Implementation heat map

<table>
<thead>
<tr>
<th>Countries</th>
<th>Updated: 12 Dec 2018</th>
<th>Support establishment of comprehensive response</th>
<th>Prevention</th>
<th>Testing/reimbursement/access to care</th>
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**Note:** Some countries have established systems for hepatitis testing, treatment, and prevention, but the specifics vary widely. The table above provides a general overview of the current status in each country. For more detailed information, please refer to the official data sources linked in the report.