Meeting Report

SECOND MEETING OF THE STRATEGIC TECHNICAL ADVISORY COMMITTEE FOR VIRAL HEPATITIS IN THE WESTERN PACIFIC

25–27 January 2016

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WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

MEETING REPORT

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Convened by:

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NOTE

The views expressed in this report are those of the participants of the Second Meeting of the Strategic Technical Advisory Committee 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 Second Meeting of the Strategic Technical Advisory Committee for Viral Hepatitis in the Western Pacific in Hanoi, Viet Nam from 25 to 27 January 2016.

CONTENTS

Keywords:

/ Hepatitis, Viral, Human—prevention and control / Hepatitis B / Hepatitis C / Regional health planning

ABBREVIATIONS

ADB	Asian Development Bank
DAA	direct-acting antiviral
ERP	Expert Resource Panel
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
IFN	interferon
MSM	men who have sex with men
PEG-IFN	pegylated interferon
PWID	people who inject drugs
RBV	ribavirin
STAC	Strategic Technical and Advisory Committee
SVR	sustained virologic response
WHO	World Health Organization

SUMMARY

The Second Meeting of the Strategic and Technical Advisory Committee (STAC) on Viral Hepatitis in the Western Pacific Region was convened by the World Health Organization (WHO) Regional Office for the Western Pacific in Hanoi, Viet Nam from 25 to 27 January, with a joint session with the Expert Resource Panel for Hepatitis B Control through Immunization (ERP) held on the last day.

The objectives of the meeting were to review the status of the viral hepatitis burden in the Region, to discuss implementation considerations for the Region's first action plan for viral hepatitis, and to discuss cross-cutting viral hepatitis issues between STAC and ERP, with a focus on Viet Nam.

Presentations and discussion focused on implementation of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020*, following its endorsement by Member States at the Regional Committee meeting in Guam in October 2015, as well as aligning and adapting the *Global Health Sector Strategy on Viral Hepatitis 2016–2021* and recent global guidance on hepatitis surveillance to the Region. Access to hepatitis medicines was a major topic of review and discussion, and several sessions were held to discuss country-specific situations and how the WHO Regional Office could support these high-burden countries to address viral hepatitis. Recommendations from the STAC to the WHO Regional Director were made in each of the five priority action areas of the draft Regional Action Plan: (1) broad-based advocacy and awareness; (2) national policy; (3) data and surveillance; (4) prevention; and (5) screening, care and treatment. In addition, country specific recommendations were also made.

1. INTRODUCTION

1.1 Meeting organization

The Second Meeting of the Strategic and Technical Advisory Committee (STAC) for Viral Hepatitis was held in Hanoi, Viet Nam from 25 to 27 January 2016, with a joint session with the Expert Resource Panel for Hepatitis B Control through Immunization (ERP) on the final day. The meeting was attended by STAC members and the WHO secretariat from the Regional Office for the Western Pacific. The list of participants is available in Annex 1 and the meeting agenda in Annex 2.

1.2 Objectives

The objectives of the meeting were:

1) to review the status of the viral hepatitis burden in the Western Pacific Region;
2) to discuss implementation considerations for the Region's first action plan for viral hepatitis; and
3) to discuss cross-cutting viral hepatitis issues between STAC and ERP, with a focus on Viet Nam.

2. PROCEEDINGS

2.1 Opening session

Dr Masaya Kato, Technical Officer, WHO Representative Office in Viet Nam, gave the opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific. He emphasized that hepatitis is a major public health challenge that causes a disproportionate number of deaths in the Western Pacific Region. He acknowledged accomplishments to date, particularly in regional hepatitis B immunization progress, as well as the development of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020*, now endorsed by 37 Member States. He emphasized the need to address the ongoing burden of chronic hepatitis infections and liver cancer, as well as transmission of hepatitis C, particularly in health-care settings. He highlighted that new highly effective medicines for hepatitis B and C remain inaccessible to many patients due to high prices, regulatory barriers and lack of public health treatment programmes. He noted global and regional momentum on viral hepatitis and looked forward to the synergies created from the joint session of the STAC and ERP.

Dr Henry Lik Yuen Chan, Hong Kong Special Administrative Region (China), and Dr Rosmawati Mohamed, Malaysia, were appointed co-chairs of the meeting. Dr Henry Chan welcomed participants, thanked the Regional Director for his opening remarks and invited all participants to introduce themselves. Dr Sergey Diorditsa presented the administrative announcements. Following a break in the programme, STAC and ERP began separate meetings in adjoining rooms for days 1 and 2.

2.2 Overview

Dr Nick Walsh presented the STAC meeting objectives and presented the declarations of interest. Seven members declared interests. The secretariat concluded that there were no serious conflicts of interest and that all members could participate in discussions. However, recommendations regarding

selection of diagnostic tests or treatment regimens could not be made by those with declared interests, namely, Charles Gore, Henry Chan, Wei Lai, Stephen Locarnini, and Janus Ong.

2.2.1 Regional overview: Regional progress and key achievements in 2015

Dr Ying-Ru Lo presented a summary of hepatitis disease burden and progress in advocacy, action plans, prevention and treatment access in the Western Pacific Region.
Globally, around 2 billion people have been infected with hepatitis B, with 258 million chronic infections and 686 000 annual deaths (GBD, 2015). More than one third of global mortality from hepatitis occurs in the Western Pacific Region. This is higher than mortality from other major communicable diseases such as HIV, tuberculosis and malaria. The burden of hepatitis is spread across several low-, middle- and high-income countries in the Region, including Cambodia, China, Japan, the Republic of Korea, the Lao People's Democratic Republic, Malaysia, Mongolia, the Philippines and Viet Nam.

Progress in advocacy and awareness has been made. Meetings and assessments have taken place in China, Hong Kong SAR (China), Kiribati, Mongolia, and the Philippines, as well as at regional and global levels. Advocacy has also occurred through World Hepatitis Day events, social media, websites, and published peer-reviewed articles.

The *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* has been endorsed by 37 Member States. National action plans currently exist in Australia, Japan, Mongolia and Viet Nam, and are undergoing development in several other Member States. Disease burden estimation and economic analysis are being undertaken in several countries. A significant achievement was the ratification of proposed elimination of hepatitis C by 2030 by the Government and Parliament of Mongolia.

There has been progress in hepatitis prevention. To date, 13 out of 20 countries are verified to have achieved less than 1% hepatitis B surface antigen (HBsAg) seroprevalence among 5-year-old children. WHO has also supported outbreak investigations in Roka, Cambodia in collaboration with various partners.

National hepatitis B and/or C treatment guidelines are available in five countries: China, Fiji, Kiribati, Mongolia and Viet Nam. A regional survey on access to hepatitis medicines and mapping of the registration status of direct-acting antivirals (DAAs) are being undertaken. A laboratory gap analysis on access to and quality of serology for HIV, syphilis and hepatitis was completed. In addition, the first WHO Collaborating Centre for Viral Hepatitis in the Western Pacific Region has been established with the Doherty Institute, Melbourne.

Since early 2014, progress has been achieved through commitment with various partners in the Region. Dr Lo thanked these partners and expressed hope that, moving forward, these and other partnerships would continue to develop.

2.2.2 Regional overview: Outline of background documents and questions to STAC

Dr Nick Walsh highlighted key points in the Regional Committee resolution on viral hepatitis (WPR/RC66.1). The resolution highlighted the importance of developing national action plans, strengthening surveillance systems, addressing the high cost and lack of availability of hepatitis medicines and diagnostics, and mobilizing technical and financial resources to address viral hepatitis.

Participants were given an overview of background documents and questions to STAC. A full list of the background documents can be found in Annex 3.

Finally, the rationale for the joint session with ERP was detailed. It was explained that STAC and ERP were being brought together for the first time to facilitate synergistic collaboration. Three potential crossovers between the two groups were mentioned, namely: a regional hepatitis laboratory network for surveillance, prevention, treatment and monitoring; discussion about issues regarding Viet Nam; and potential collaborations in other countries relevant to both STAC and ERP groups. Viet Nam was chosen as the meeting's location in recognition of various factors, including challenges in birth dose coverage in previous years, opportunities to engage in prevention strategies, and challenges and opportunities for hepatitis treatment.

2.2.3 Global overview: Hepatitis prevention and control: from historical work in immunization to elimination plans

Dr Yvan Hutin presented an overview of ongoing progress in hepatitis from a global perspective, including the proposed WHO *Global Health Sector Strategy on Viral Hepatitis 2016–2021*.

There has been continued success in improving hepatitis B immunization coverage since 2000, and progress in the Region may be a promising lead for global gains in coverage. However, there is still a high burden of viral hepatitis. Globally, it is the seventh leading cause of mortality (GBD, 2015), with 1.4 million deaths reported in 2013. While effective prevention strategies and medicines are available, and the need to scale up support persists, there are challenges in securing funding and resources. However, it was emphasized that action delivers more cost savings than inaction.

There are now calls for the elimination of viral hepatitis as a public health problem. The Sustainable Development Goals ratified in September 2015 have identified hepatitis as a priority. There is a growing movement around hepatitis from various stakeholders including policy-makers, technical experts and global partners in civil society and nongovernmental organizations.

The proposed global strategy envisions viral hepatitis elimination (transmission) and universal access to safe, affordable and effective care and treatment. Impact targets for elimination are 90% reduction in new incidence of chronic hepatitis B virus (HBV) and hepatitis C virus (HCV) infection and 65% reduction in mortality by 2030. To achieve these targets, the strategy provides a breakdown of service coverage targets in prevention (vaccination, mother-to-child transmission, safe injection, harm reduction), testing, and treatment. Progress towards achieving these targets will also require monitoring and evaluation using the global indicators outlined in the upcoming WHO publication, *Monitoring and evaluation for viral hepatitis B and C: Recommended indicators and framework*.

The global strategy proposes five key components (strategic directions):

1) information for focus and accountability (the "who" and "where");
2) interventions for impact (the "what");
3) delivering quality and equity (the "how");
4) financing for sustainability (the financing); and
5) innovation for acceleration (the future).

The costs of implementing the global hepatitis strategy in low- and middle-income countries have been estimated, assuming sufficient self-funding capacity of higher-income countries. Enhancing the affordability of elimination strategies will require multiple approaches: stopping current ineffective practices; radically reducing costs of effective treatments; and cost-sharing with other related areas (e.g. harm reduction, immunization, blood safety and HIV coinfection). Future innovations will also be crucial in achieving this goal.

While energy and commitment exists, resources remain a crucial challenge. Other aspects needed include a public health approach, innovations, multisectoral partnerships and concrete tailored national plans. The latter in particular is a potential area for potential WHO and STAC contribution.

Out of 10 indicators described in the monitoring and evaluation framework, nine are easy to integrate with existing HIV systems. However, burden estimates, particularly liver cancer and cirrhosis attributable to HBV and HCV, are areas for further development.

In summary, the time has come to propose hepatitis elimination, both as a public health problem and to minimize the short-term and mortality impacts. So far, WHO has examined the feasibility, formulated a strategy, estimated costs, outlined the monitoring and evaluation approach, and initiated implementation. Positive advances have been made in the Western Pacific, especially in Mongolia, where the target of HCV elimination has been endorsed by the government.

2.2.4 Discussion

Participants discussed hepatitis as a public health challenge and a target of elimination. The term 'elimination' as a public health issue was clarified to mean reduction in incidence. Participants affirmed the importance of quantifiable targets. It was noted that countries selected for disease burden analysis were chosen based on a significant burden of hepatitis as well as the national capacity to respond.

The issue of stigma was discussed. Professional medical associations and other health associations can contribute to minimizing stigma and discrimination within the health sector. The observation was made that stigma from hepatitis originates from the disease itself, in contrast to HIV, where it is more typically associated with behavioural practices. There is also an issue of self-imposed stigma: patients who fear a positive result may be unwilling to test. Participants welcomed the need for further understanding of the various issues surrounding stigma. A suggestion was made to develop quantifiable stigma or discrimination reduction targets; however, implementing and measuring stigma could be difficult.

In China, stigma is a significant barrier preventing access to testing and treatment. Stigma varies by region in China, in part due to differences in transmission routes. Furthermore, there is a clear lack of knowledge of hepatitis in rural areas. Collaboration with media would be useful, but it would cost money.

The prevention of hepatitis B transmission in China – given its significance regionally – was discussed in relation to stigmatization. For example, offering counselling and stigma-reducing services to pregnant women following HBV diagnosis could help to prevent mother-to-child transmission.

Mr Wang Sheng Li, ZeShan Foundation, illustrated a project in China to eliminate mother-to-child transmission of HIV, hepatitis B and syphilis, following an earlier government announcement to implement such a programme nationwide. The project was undertaken in one province (Hainan) to demonstrate how national coverage could be achieved. Women found to have a high viral load upon antenatal screening receive antiviral treatment. A follow-up study of 3000 cases is underway to assess hepatitis B outcomes of children from this study. A participant commented that successes could be made when there is political will and funding.

2.3 Viral hepatitis disease burden and economic analyses

2.3.1 Overview of hepatitis disease burden and economic analyses in the Philippines, Viet Nam, China, Mongolia, and Kiribati

Dr Nick Walsh presented an overview of the methods and key findings of hepatitis disease burden and economic analyses undertaken in several countries, as well as the practical and policy implications. Various collaborating partners have contributed to these analyses.

Mongolia was highlighted as an example of how hepatitis C disease burden and economic analyses could result in national policy change. China completed disease burden analyses for hepatitis B and C in 2015. Kiribati was selected for disease burden and economic analyses because of the high adult prevalence of hepatitis B (15–20%), its small population, and funding availability. Although Kiribati has only 100 000 residents, an estimated 2500 people are in need of treatment. Kiribati could serve as an epidemiological and public health model for other Pacific island countries and areas.

The disease burden and economic analyses serve as advocacy and policy tools to facilitate implementation of public health treatment strategies. The disease burden analysis utilizes a Markov model for disease progression. Various intervention scenarios are modelled, including baseline (without intervention), reduction of mortality, and elimination. Multiple stakeholders including government, health insurance and individual payees are incorporated into the costing and financial analysis. The cost of testing and treatment varies widely in the private sector in many countries. Care and treatment packages were standardized for the purpose of modelling going forward, with current costs based on current practices. Additionally, the sharing of costs through different financing mechanisms was modelled, and sensitivity analyses were carried out.

Several lessons were learnt. The process of the analyses is strongly driven by the urgency of the perceived need, as demonstrated in Mongolia and Kiribati. Most treatment currently occurs in the private sector. Furthermore, the present government health expenditure in hepatitis treatment is very low in low- and middle-income countries, so it is harder to achieve a return on investment. An initial up-front 'bolus' investment may be needed to realize these gains in future years, presenting policy challenges. Partial funding of treatment may be more realistic, and especially necessary for HCV compared to HBV.

2.3.2 Hepatitis B and C disease burden and economic analysis in China

Dr Wang Xiao Chun presented the key findings of the disease burden analysis of hepatitis B and C and the investment case for treatment in China.

Case-reporting surveillance indicates that hepatitis B and C incidence is increasing. Liver cancer is the second most common cause of cancer morbidity and mortality in men, and the fifth most common in women (Ferlay J et al, 2012). Furthermore, China contributes more than half of the global burden of liver cancer in numbers of cases and deaths.

Currently in China, an estimated 90 million people are living with chronic hepatitis B and up to 10 million with chronic hepatitis C. Current strategies are based on prevention, as treatment access is limited and few highly effective medicines are available. The national consensus prioritizes patients in urgent need of treatment in the next five years for hepatitis B and C due to advanced liver disease, estimating 7 million for hepatitis B and 2.5 million for hepatitis C.

The hepatitis investment case for China proposed a standardized package of essential treatment and monitoring services compared with current practices. The current costs of treatment were assessed through a field survey that informed the epidemiology and economic modelling.

Disease burden estimates show that while childhood hepatitis B prevalence is declining, overall hepatitis B-related mortality is expected to rise. A comprehensive approach to treatment, prevention, diagnosis and active case finding will be necessary to counter both new infections and deaths.

Economic modelling demonstrated that current practices for hepatitis treatment are unaffordable, exceeding catastrophic health expenditure thresholds for low socioeconomic percentiles. Under a standardized (recommended) package of services, new highly effective tenofovir and DAAs will help prevent further cases of cirrhosis, liver cancer and deaths. Funding remains a challenge. However, any combination of sustained virologic response (SVR) (80–90%) and DAA price is cost-effective, according the two-way sensitivity analysis. Ultimately, treating now will save money in the long run, due to the expenses averted from managing advanced liver disease.

Establishing and scaling up a broader, public health-based treatment programme will allow China to invest in the future health of the population and control the hepatitis epidemic. Lives and costs can be saved by reinvesting current expenditures into more effective programmes and addressing priorities such as drug pricing and market access, health insurance inclusion, and government structure.

2.3.3 Economic analysis of hepatitis C treatment in Mongolia

Dr Nick Walsh reviewed the epidemiology of viral hepatitis in Mongolia, and presented the results of the disease burden and economic analyses for hepatitis C.

Epidemiological data for viral hepatitis in Mongolia were used to generate the baseline scenario and to calibrate the model. Mongolia has a high burden of viral hepatitis, with an estimated HCV viraemic prevalence of 200 000. Only 200 people are treated annually with pegylated interferon (PEG-IFN) and ribavirin (RBV), mostly in the private sector. The hepatitis burden is greatest among older age cohorts. Over 98% of those with chronic HCV infection have genotype 1b. For those infected with hepatitis B, HBV/HDV coinfection prevalence is around 70%. Both direct costs (managing infection and sequelae) and indirect costs (lost productivity) were taken into account. It was assumed that the combination DAA price would decline over time from US$ 1200 (per treatment course of 12 weeks) at present to around US$ 200 in 2030, due to competition among voluntary licensed generic manufacturers.

Various scenarios were modelled and compared with the baseline scenario. Without further intervention, the total number of infections would decline, but mortality, liver cancer and cirrhosis would increase by 2030. The treatment scenarios would replace the current practice of PEG-IFN/RBV or traditional medicine with new DAA therapies, using different public health objectives: (1) reduce mortality by treating patients with advanced disease; or (2) eliminate hepatitis by treating all infected patients.

The reduction of mortality scenario projects a marked decline in total infections, as well as morbidity and mortality. The elimination scenario projects even greater declines. However, elimination requires an increase in the number of diagnosed and treated patients, which presents implementation challenges. The Ministry of Health and Sports requested a combination strategy that aims to reduce mortality for the first five years, and switches to elimination over the next 10 years. This would reduce total infections by more than 90% and mortality by more than 85%, saving more than 10 000 lives.

Economic analysis demonstrated substantial cost-savings for Mongolia when both direct and indirect costs are included. However, currently there is minimal public sector expenditure on HCV treatment, mostly traditional medicine reimbursement. While the combination strategy would require an initial increase in spending, government expenditure would decline as the pool of cirrhotic patients is depleted. Furthermore, this increase in spending on HCV treatment would be offset by overall savings in health-care costs, by preventing high costs of managing advanced untreated liver disease. Limiting a co-pay to the catastrophic health expense threshold for the poorest 5% of families would

further lessen costs to the public sector, although these families themselves would need additional support.

When all costs are combined, expanding treatment would be more effective than doing nothing each year, except for 2018 (when treatment is expanded from 1000 to 8500 treated annually).

Disease burden and economic modelling can facilitate implementation through policy, as exemplified by the endorsement of the combination strategy by the Ministry of Health and Sports in Mongolia in November 2015. Further progress in funding mechanisms is the next step in this project.

2.3.4 Hepatitis models in other countries

Dr Homie Razavi presented examples of hepatitis modelling in other countries, including Malaysia, Egypt, Belgium and the Philippines. Various collaborating partners worldwide were thanked for their contributions.

The Center for Disease Analysis has undertaken various modelling analyses in more than 65 countries. Disease burden, economic impact and transmission models for HCV are completed, while vaccination and disease burden models for HBV are undergoing development. These models have been used to assist the development of national hepatitis strategies.

Disease burden analysis was undertaken in Malaysia. The estimated viraemic prevalence in 2009 was 389 400, and most cases were genotype 3 (62%) and genotype 1 (36%). The importance of age and sex distribution was noted, referring to higher prevalence among older males. The baseline scenario projects that mortality, liver cancer and decompensated cirrhosis will increase, especially as the population ages. Providing new therapies and increasing numbers treated using a "reasonable increase treatment" scenario would decrease total infections and mortality by 45% and 60%, respectively. The elimination strategy aims for a greater than 90% mortality reduction, and then determines the assumptions to achieve this target: increasing SVR, expanding eligibility criteria, and reducing annual incidence. Incidentally, this strategy would also decrease the burden of liver-related mortality and morbidity by 95%.

Disease burden and economic impact analyses for HCV were also undertaken in Egypt. To achieve HCV elimination in 15 years, treatment needs to be increased to 350 000 patients annually by 2030 (from 120 000 in 2013), and diagnoses need to increase to 500 000. A promising finding was that Egypt is currently on track for elimination. Indirect costs significantly contribute to total economic costs, often 4–10 times higher than direct costs. Greater upfront investment in elimination strategies could substantially reduce future direct costs. Furthermore, elimination strategies in Egypt were found to be not only cost-effective, but also cost saving compared to the baseline: expenditure would only exceed current levels for one year.

Hepatitis C transmission in high-risk populations was modelled in Belgium. The majority of transmission occurs among people who inject drugs (PWID) and men who have sex with men (MSM), with an estimated incidence of 160 among PWID in 2015. Without behavioural changes accompanying treatment strategies, secondary infections are projected to increase. This would occur until HCV prevalence reaches zero, when the viral pool is depleted. Only then would the "treatment as prevention" phenomenon become evident.

Hepatitis B transmission in the Philippines was illustrated. It was noted that HBsAg prevalence among infants is currently 2%. In order to achieve less than 1% prevalence, the Philippines would need to increase birth-dose vaccination from 55% coverage now to 90% and increase treatment of mothers with high viral load.

Overall, the disease burden of hepatitis C is projected to rise over time in the Western Pacific Region as the population ages, with the exception of a few countries with high treatment coverage. Consequently the economic burden to the health-care system will also increase. Initial costs of

investing in treatment can be offset by savings in health-care costs, lengthened life expectancy and fewer years lived with disability. In addition, new infections among PWID and MSM will initially increase after treatment in the absence of risk behavioural changes. Ultimately, HCV elimination is feasible but will also require substantial increases in screening and testing.

2.3.5 Discussion: viral hepatitis disease burden and economic analyses

Participants discussed the impact of screening on the modelled scenarios. Screening costs for various tests are based on local data collection. The models indicate that as prevalence decreases, the costs of diagnosis and screening (absolute and proportional) become much higher, as it requires more resources to find fewer cases. High screening costs are a challenge in many countries, especially for molecular confirmation. However, simple, cheaper point-of-care testing may play a role in future screening. Future models could incorporate different screening scenarios.

There is the potential for differences in real-world circumstances and the modelled scenarios. A recommendation was made to support the incorporation of more "worst-case" scenarios in future modelling, such as poorer responses to or high costs of screening, poor laboratory quality, and suboptimal treatment responses. Future consideration for an external panel independent of local stakeholders was also suggested to assist the use of robust scenarios. Another suggestion was to offer scenarios that would be easier for countries to initially address ("low hanging fruit"), and perhaps more feasible to implement. As a counter argument, the example of Mongolia was given, where the government requested more rigorous and ambitious scenarios after initially presented with more conservative mortality reduction estimates. Finally, key or vulnerable populations should be consulted in countries where HBV or HCV affects certain populations.

The issue of monitoring was discussed, noting that the scenarios had not taken into consideration continuation of monitoring for complications such as hepatocellular carcinoma (HCC) in post-treatment stages. This may become increasingly relevant as DAAs become more widely used. However, WHO does not currently have a clear recommendation on the frequency of post-SVR HCC monitoring.

It was acknowledged that financing would be a significant obstacle to implementation of various modelled scenarios. At present a large proportion of treatment occurs in the private settings, and the capacity of health insurance in many low- and middle-income countries to contribute to private as well as public costs is limited. Treatment roll out may need to be phased in through engagement of primary care physicians going forward to outcome programmatic limitations. Finally, the issue of pricing was discussed, and the importance of lower prices to allow appropriate financing for hepatitis programming.

2.4 Treatment access

2.4.1 Treatment access in the Western Pacific

Dr Nick Walsh presented on access to hepatitis treatment in the Western Pacific Region. He described the targeted triadic approach of WHO action in the Region consisting of access to treatment, national action plans and disease burden estimates.

WHO is exploring ways to facilitate treatment access. The WHO Regional Office for the Western Pacific undertook a survey of access barriers including regulatory and pricing structures in late 2015. Regulatory barriers include the requirement of domestic clinical trials, and the registration of tenofovir in several countries for HIV but not HBV. Reducing prices will require increased demand, which pooled or joint procurement mechanisms could help to facilitate. Some form of centralized procurement to facilitate both public and private procurement could be considered.

WHO's role in medicines pricing needs to be clarified. For example, in 2016, there is a temporary importation quota of 40 000 bottles of sofosbuvir into Viet Nam. These medicines are not prequalified, and procurement was fragmented within Viet Nam, resulting in higher prices.

2.4.2 Community perspectives on hepatitis treatment

Giten Khwairakpam presented on hepatitis C treatment access in the Region, including DAAs and emerging generic drugs, pricing and availability, and current ways in which governments and affected persons are currently accessing DAAs.

Government programmes for hepatitis C treatment (including PEG-IFN and DAAs) currently exist in Asia and the Pacific. For example, in India, there are state-managed programmes; in Indonesia, the national health insurance covers 100% of the cost of PEG-IFN, although challenges to access exist in provinces; in Thailand, PEG-IFN is included in universal health; and in Viet Nam, up to 30% of the cost of PEG-IFN is reimbursed in some centres. However, these existing programmes are currently limited. Some DAAs have been registered in Thailand and Malaysia, while in Viet Nam the requirement of a domestic clinical trial is delaying registration. In India, the requirement of a local trial was waived for sofosbuvir, ledipasvir and daclatasvir in October 2015, which facilitated more rapid entry of these medicines into the market.

Where registration of DAAs has not yet occurred, there are a number of ways to access these medicines. Special import licenses can occur at the hospital level, and a doctor's prescription can allow patient-level access to Indian generic medicines when they are not publicly available in the country of origin ("named patient import"). Other access pathways include buyers' clubs and ordering from large pharmacies in India.

Price and availability of generic DAAs were discussed, with focus on Indian pricing at individual purchasing rates. The lowest current market price for sofosbuvir was US$ 103/month from Strides Acrolab. Nine companies are currently manufacturing generic sofosbuvir/ledipasvir, with the lowest price of US$ 205/month from Zydus Heptiza. Seven companies are marketing generic daclatasvir, at a price of US$ 61/month.

Various challenges remain. While tenofovir is available, it remains inaccessible except for those without HIV coinfection. Diagnostics are another considerable expense, especially for those with chronic HBV requiring more frequent monitoring, presenting a significant financial burden for those paying out-of-pocket.

In conclusion, patients are slowly attaining greater access to generic DAA treatment through private clinicians and referral hospitals. However, widespread access will first require registration of the DAAs by national regulatory agencies. Many countries lack fast-tracking processes. Pricing will need to be further reduced for national programmes to be able to adopt and implement large-scale treatment programmes; this is a potential area for the STAC to consider for recommendations.

2.4.3 Hepatitis B treatment: key interventions and needs for HBV treatment in the Western Pacific

Dr Henry Chan provided a medical perspective on the key interventions and treatment needs for hepatitis B.

The minimum diagnostic requirements to assess disease activity are complete blood count, liver biochemistry, HBV DNA and ultrasound. The preferred available tests are HBeAg, fibroscan and liver histology. Successful diagnosis of cirrhosis, especially compensated cirrhosis, is still a challenge.

The cost-effectiveness of antiviral treatment needs to be analysed in different countries, and generic therapies should be examined as a way to improve cost-effectiveness. Reimbursement of first-line antiviral therapies without time limits should be encouraged. HCC surveillance programmes are still necessary among patients on antiviral treatment.

A cost-effectiveness analysis of antiviral therapy in Hong Kong SAR (China) showed that entecavir was more cost-effective than tenofovir. It was emphasized that liver cancer surveillance is still necessary, considering the annual HCC progression risks from cirrhotic individuals.

The need for country-specific cost-effectiveness analysis was emphasized. GDP per captia, prices and reimbursement policies vary by country, so the input variables and most cost-effective scenarios may be different between countries.

2.4.4 Hepatitis C treatment: key interventions and needs for HCV treatment relevant to the Western Pacific

Dr Tatsuya Kanto presented the current status of anti-HCV therapy and management system for hepatitis patients in Japan. HCC-related deaths peaked around 2005, and have fallen since, mostly relating to the time of acquisition but also improved access to cancer screening and treatment. In Japan, four IFN-free regiments are available, all of which were registered in 2014-2015 and are very costly to the state. But after the introduction of DAAs and interferon (IFN)-free regimens, the SVR rate among treated patients has increased more than 90%. For patients with genotype 1 (GT-1), ledipasvir/sofosbuvir fixed-dose combination for 12 weeks is recommended as the first choice of the therapy according to the guidelines proposed by the Japan Society of Hepatology.

To provide support to hepatitis patients, Japan established a national hepatitis programme. The Basic Act on Hepatitis Measures was issued in 2009, and Basic Guidelines for Promotion of Control Measures for Hepatitis became active in 2011. Five key strategies being used to control hepatitis in Japan are: 1) providing subsidies for hepatitis treatments; 2) facilitating hepatitis testing; 3) developing a consultation system; 4) disseminating accurate information to the public; and 5) ensuring further hepatitis-related research, the budget for which would be approximately US$ 189 million in 2016.

For hepatitis patients who should be treated with IFNs, DAAs or nucleosides/nucleotides, special coverage programmes are available in Japan. In general, 70–90% of net medical expenses for patients are covered by the public medical insurance system. Moreover, most of the uncovered expenses are covered by central and local governments (split by 1:1). Therefore, monthly out-of-pocket expenses range from US$ 84 to US$ 168, even if patients undertake expensive DAA therapy. Annually, one million persons receive the hepatitis blood test for free for the first time, which is also covered by central and local governments; however, only 50% of the Japanese population have been tested so far. Epidemiological study revealed that half million hepatitis patients remain undiagnosed without access to care. Further efforts are needed to identify this hidden population at risk of cirrhosis or cancer and provide appropriate care and treatment.

2.4.5 Discussion: Treatment access

Participants acknowledged that there are various challenges across the Region regarding access to diagnostics and treatment, including costs and availability. These challenges are especially evident in many rural areas where health infrastructure is limited.

Addressing high medicine pricing is an issue not only in low- and middle-income countries, but also in high-income countries such as Japan. It was recognized that many people purchase medicines overseas (e.g. India, Bangladesh) due to unaffordability or inaccessibility in their own countries. It was strongly emphasized that the cost of diagnostics needs to be lowered, and that some countries have shown this to be possible. For example, in India, diagnostic costs can be included within certain treatment packages.

The molecular epidemiology of viral hepatitis in Asia and the Pacific (e.g. genotyping) needs to be better understood in order to quantify specific treatment needs in the region. Laboratory network support or alternative/novel diagnostics could overcome these barriers. The WHO Regional Office for the Western Pacific is undertaking a laboratory survey to assess hepatitis capacity at both national

and subnational levels. More support may be necessary to obtain information at the primary health care levels. The Guidelines Development Group for the standard guidelines of hepatitis B and C testing and the potential future role of HCV core antigen testing and GeneXpert were also discussed. The possibility of demonstration projects for testing and treatment was raised, using generic medications. Mongolia and Viet Nam were suggested as potential sites.

Regulatory processes that could facilitate access to medicines and promote quality assurance such as prequalification were discussed. Prequalification is a costly and lengthy process that can take up to six years. It was asked whether WHO could reduce some of the requirements. Furthermore, it was noted that while prequalification is instrumental in raising demand, it also requires a large demand to be justified. For example, if the volume of procurement is too low, the strategic value of investing in the high cost of prequalification is reduced.

Quality assurance mechanisms apart from prequalification were also raised. A suggestion was made for the WHO Regional Office to facilitate parallel importation of products patented/registered in other countries using the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities. Other potential mechanisms are import permits, more clinical trials, and exploring conditions for compassion use/early entry of generic medicines.

Interim measures, such as setting up expert resource panels pending formal WHO prequalification, could also serve to review quality data/dossiers. The existence of such internal, national bodies could negate the need for further external (WHO) mechanisms. The needs of countries may vary – some may benefit from assistance with external panels (for example, where the cost of prequalification is prohibitively high), while others may be able to operate more independently. Collaborative regulation would require an approach that does not impose upon a country's decision-making rights.

Patent issues are complex, sometimes requiring multiple applications as well as covering processes beyond the product itself. This is a barrier to some countries. It was noted that the Trans Pacific Partnership might have implications to access as it also focuses on strengthening intellectual property protections.

The role of a regional procurement body was discussed. Participants recognized that there is limited availability of pricing information and poor linkage between buyers and manufacturers. It was suggested that a regional body could contribute by: 1) identifying the source of medications, including product information and availability; 2) identifying mechanisms to procure medications, including parallel routes, in the absence of regulatory mechanisms; and 3) negotiating prices. Centralized procurement mechanisms would be difficult set up without clear confirmation of demand, though a price-per-batch mechanism could overcome this. Also, WHO is not able to directly negotiate drug prices, so this should fall to a separate entity. Finally, it was suggested that the WHO Regional Office for the Western Pacific could learn from the lessons of the WHO Regional Office for the Americas regarding central vaccine procurement through a regional strategic fund.

2.5 Viral hepatitis surveillance and data

2.5.1 Outbreak and surveillance in Singapore

Dr Francisco Averhoff presented preliminary findings of an outbreak investigation of HCV in a hospital in Singapore that affected renal dialysis patients in 2015. Out of more than 1000 renal dialysis patients who were admitted to one of two wards, 25 became infected with HCV, and eight of those died. The investigation revealed that most likely cause of the outbreak was a lapse in infection control during a period of time when patients were being temporarily managed in an adjacent ward. The investigation methodology employed epidemiological, observational, environmental and phylogenetic methods to clearly demonstrate that this outbreak was single source and transmission and did not involve multiple viral introductions. Corrective measures were taken and the outbreak ceased. The outbreak demonstrated the importance of HCV surveillance of renal patients to detect

such outbreaks, the importance of infection control to prevent such outbreaks, and the importance of advanced molecular techniques in defining the source. Renal dialysis patients are at particular risk for blood-borne pathogen outbreaks because they are immunocompromised and receive frequent phlebotomy and invasive dialysis.

2.5.2 New WHO viral hepatitis surveillance guidance

Dr Yvan Hutin, strategic information officer for the Global Hepatitis Programme at WHO headquarters, presented on the new WHO global hepatitis surveillance guidance: *Technical considerations and case definitions to improve surveillance for viral hepatitis*.

There is a need to improve viral hepatitis surveillance. Currently, there is limited information to guide such initiatives, with issues such as fragmented systems and lack of in-vitro diagnosis. Viral hepatitis surveillance is unique from other diseases, with multiple disease outcomes, such as acute, chronic infection and sequaelae. There are also different types of hepatitis (A, B, C, D, E) with similar clinical presentation, and many of these are asymptomatic. Modes of transmission differ, and it is important to tailor the response to the epidemiological pattern relevant to the national situation.

There are three purposes (three domains) of surveillance, namely: 1) to detect outbreaks, monitor trends in incidence, and identify risk factors for new infections by surveillance of acute hepatitis; 2) to estimate prevalence of chronic infections and monitor trends in sentinel groups, by surveillance of chronic infections; and 3) to monitor sequelae, by surveillance of sequelae.

Acute hepatitis surveillance guides prevention of new infections, focusing on acute cases in health-care settings. Chronic hepatitis surveillance guides testing and treatment of chronic cases.

Differentiating incidence and prevalence will be a key technical consideration.

2.5.3 Discussion: viral hepatitis surveillance and data

Participants welcomed the suggestion to build on existing data systems rather than generating new systems. Existing data are available in many countries; however, these data need to be managed and collated centrally for ongoing surveillance.

Currently, surveillance is a lower investment priority than other areas including treatment. It was suggested that the STAC and WHO Regional Office should encourage greater investment in surveillance, emphasizing its importance for monitoring and evaluation in the national hepatitis plan. In addition, the focus should be on high quality data, noting that limited information is preferable to poor quality data.

There were requests for more guidance from WHO for outbreak surveillance or management. It was noted that health care-associated outbreaks of hepatitis C have the challenge of delay in seroconversion, many asymptomatic infections, and difficulty monitoring sequelae. It was agreed that any WHO initiative should focus on more than just outbreaks and also include blood-borne virus transmission surveillance in healthcare settings. Regular surveillance in sentinel populations for HCV such as dialysis patients with frequent hospital contact could also form an earlier detection mechanism for nosocomial outbreaks.

Addressing transmission in traditional (non-formal or para-health) health practices was also raised. In addition, unnecessary injections for medical treatment are a concern and often appear to be driven by the need for a service charge or increased monetary compensation from the patient rather than a clear medical indication. There continues to be a need for greater awareness about the need for reducing unnecessary injections and increasing consumer demand for safe injection practices.

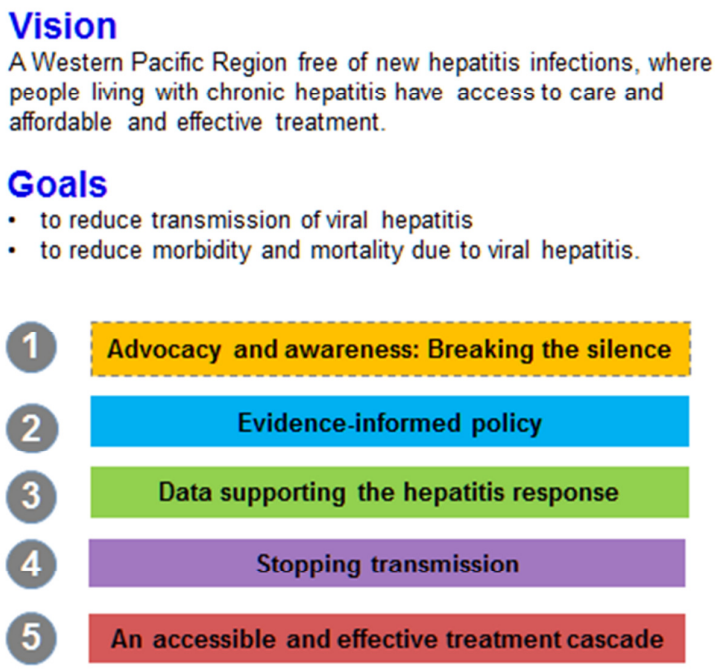
Finally, given the large amount of data that could potentially be collected, a set of minimal data and surveillance reporting needs could be established, based on milestones and targets contained in the Global Health Sector Strategy and Regional Action Plan for Viral Hepatitis.

2.6 Regional Action Plan implementation

2.6.1 Draft WHO HBV and HCV elimination goals and regional milestones and targets

Dr Ying-Ru Lo presented the vision, goals and five priority areas of the Regional Action Plan for Viral Hepatitis (Fig. 1), and highlighted the link to the global hepatitis strategy. The proposed 2017 milestones and 2020 targets were detailed.

Fig. 1. **Vision, goals and** priority areas of action **of** the Regional Action Plan for Viral Hepatitis



Three areas of prevention of transmission were highlighted – immunization, health sector, and high-risk groups.

To frame the discussion, several questions were posed to STAC on the proposed milestones, targets and indicators including:

1) Are the regional targets and milestones and outlined activities adequate towards achieving global HBV and HCV elimination goals?
2) What are the priority steps WHO should focus on in 2016 to work towards global and regional goals, targets and milestones?
3) What are the regional success factors and key partnerships?
4) Which countries should we focus on?
5) How should WHO track progress toward the broader set of elimination goals?
6) Who should take on the tracking of country progress?

2.6.2 Discussion: Regional Action Plan implementation

Advocacy for and awareness of viral hepatitis were discussed. The problem of poor community awareness across the Region was noted. Recommendations on awareness raising were also developed at the first STAC meeting in April 2015 (Annex 4).

World Hepatitis Day was established as a community initiative in 2008, and has been recognized officially since 2010 following the adoption of a global resolution. However, there have been practical difficulties such as managing workloads with the WHO communications team. Sharing materials and templates is intended and may assist this. Participants discussed World Hepatitis Day initiatives to date in the Region, emphasizing that the annual theme should correspond with key priorities (e.g. diagnosis and testing, hospital-level infection control). Additionally, various groups within countries should be allowed to promote messages they identify as priorities.

There is need for greater advocacy beyond World Hepatitis Day. Mr Charles Gore described the aim for 2016 to integrate World Hepatitis Day within the broader movement to eliminate viral hepatitis by 2030. The use of a country report card to measure awareness-raising was emphasized, and a suggestion was made to include the role of civil society. STAC members were encouraged to contribute to sharing this workload, acknowledging the limited human and financial resources of the WHO Regional Office team.

Participants discussed strategies for broader dissemination of the Regional Action Plan. The plan was developed through extensive consultation with Member States, stakeholders and civil society. It was endorsed by Member States in October 2015 at the WHO Regional Committee meeting and is currently in pre-publication format. The inclusion of a dissemination package within the plan was discussed. Identifying targets such as high-risk populations may be a key focus of dissemination for policy-makers in the ministry of health. A staged approach to implementation was suggested for countries not yet in a position to implement the plan in its entirety.

Participants discussed hepatitis surveillance including targets, linkages to related data repositories, and the type of information collected. While surveillance systems are linked to data repositories in many high-income countries, the linkages do not exist in many low- and middle-income countries.

Limitations in current hepatitis surveillance were discussed. Laboratory surveillance and reporting is often fragmented. Hepatitis-related deaths are often unreported, as recording of hepatitis B and C as a cause of death is often not done. Tracking cirrhosis cases is challenging. Data for compensated cirrhosis is more challenging than decompensated given the more indirect link to death. Some countries such as Australia monitor cirrhosis and liver transplants, and several studies have assessed the aetiology of these conditions. If this kind of data were available in other countries in the Region, this information could be triangulated with other data sources to formulate better estimates of hepatitis disease burden.

The hepatitis B targets for the Western Pacific Region are to reduce HBsAg seroprevalence to less than 1% among 5-year-old children and to ensure at least 95% coverage with three doses of hepatitis B vaccination. The Regional Action Plan and resolution WPR/RC66.1 added another target: to achieve national policies of vaccinating health-care workers in more than 80% of countries by 2017 and in all countries by 2020. It was noted that there has been greater uptake of immunization since the release of the Purple Book[a] for vaccine guidance. Tracking immunization rates in high-risk populations is difficult. In addition, vaccine responses may be suboptimal in some high-risk populations. This was the case in New South Wales, Australia and consequently vaccine protocols were updated.

[a] Marshall GS. The Vaccine Handbook: A Practical Guide for Clinicians "The Purple Book". Saint Paul, MN: Immunization Action Coalition; 2012.

The treatment cascade was discussed. The feasibility of the targets was questioned, noting low current diagnosis rates, and it was reinforced that the regional target of diagnosing 30% of the estimated population living with HBV/HCV was already more conservative than the global targets of 50%. While these may seem ambitious, within the Region only China has commented as such. Dr Homie Razavi noted that modelling analyses generally indicate a diagnosis rate of around 15% in low- and middle-income countries of estimate total viraemic infections. Cohort data from several countries in the Region indicated that one quarter to one third of the affected community are currently in need of urgent treatment, according to WHO treatment criteria. The regional treatment cascade proposes treating 50% of those eligible who are considered high priority, rather than the global target of 80%. While it may be more appropriate to develop separate cascades for HBV and HCV, they were combined to simplify targets. Currently, a footnote to the targets in the Regional Action Plan describe the proportion of individuals actually needing viral hepatitis treatment now; however, these estimates and also confusing, so it was suggested to remove this footnote. The STAC suggested using proportions rather than absolute numbers for targets of the cascade.

Screening policies for viral hepatitis varied across the Region. For example, screening commonly occurs among young married couples in China and among new employees in the Philippines. Going forward, countries may require assistance in collecting and collating screening data and may need support from an external panel to track progress towards targets. WHO viral hepatitis surveillance guidance was intended to empower countries in deciding what data to collect rather than to impose external verification mechanisms. External datasets may also be useful as sources of core indicators. Three potential data sources mentioned were Globocan, Polaris (a HBV and HCV observatory) and IMS data (sales data from manufacturers).

Key priorities for STAC and WHO were also discussed. Participants supported the approach of WHO to focus on countries with high burden of hepatitis and those with capacity to serve as models for the Region. A potential area of collaboration with ERP was parallel collection of data. Verifying targets will require a procedure/panel with data such as prevalence and numbers treated. There is a potential role for the STAC to monitor the countries' or the Region's progress toward targets, similar to that of the ERP.

2.7 Country-specific discussions – China, Mongolia

2.7.1 Update on viral hepatitis action in China

Dr Wang Xiao Chun from the Chinese Center for Disease Control and Prevention presented an update on viral hepatitis in China.

China bears a high burden of hepatitis. Annually there are almost 400 000 liver cancer cases, with 80% due to HBV and 10% to HCV (2012 estimates).

Reported cases of hepatitis B and C have been increasing since 1990, but the level of case reporting among children remains low (2014 data). Analysis of sentinel surveillance data from 2015 among key populations has found high HCV antibody positivity among PWID (33.4%), as well as high rates of HIV/HCV coinfection. Higher rates of HCV antibodies were also found among sex workers (0.6–0.7%), male STI patients and MSM.

Current prevention strategies focus on safe infecting practices (both medical and non-medical), universal precautions in health-care settings, antenatal screening, safe blood screening, infant vaccination (>90% coverage), harm reduction for PWID and public education.

Significant gaps remain in hepatitis testing and the treatment cascades. An HCV survey among 250 PWID in Yunnan Province found that 46.8% had presented for hepatitis care at health clinics, around 20% were HCV RNA positive, 18% received HCV treatment, yet only 4% achieved SVR.

A national hepatitis C action plan is currently being developed. A needs assessment on prevention, care and treatment will be conducted, and pilot studies of testing and treatment are to be conducted in several provinces. There is a focus on strategies to strengthen leadership and advocacy, public education, testing, diagnosis and case reporting, infection control in health settings, and other areas across multiple sectors.

Progress has been made in hepatitis C prevention and treatment. National guidelines have been updated on diagnosis and reporting, laboratory systems have been strengthened, health-care provider capacity has been improved through training, surveillance has been strengthened (including early warning and response to hepatitis outbreaks), and the addition of nucleic acid testing (NAT) has improved blood bank testing. Prevention interventions to reduce transmission in health-care settings and among PWID have been strengthened.

Current hepatitis C surveillance reporting requires the reason for the HCV test, epidemiological history such as risk factors, laboratory and clinical tests, and clinical diagnosis including cirrhosis.

Challenges remain in hepatitis C prevention and treatment. There are multiple infection sources and risk factors. The majority of HCV-infected people are unaware of their infection. The huge demand for treatment cannot be met because of the unavailability of DAAs and high cost of antiviral treatment. Finally, there are misconceptions in the general community about the disease. The next steps will include advocacy and awareness campaigns, policy-making and strategic planning.

2.7.2 China discussion

Participants discussed progress made in China in responding to hepatitis and ongoing challenges particularly in hepatitis medicines access. Immunization coverage in China is greater than 90%, with childhood prevalence less than 1%. Regional differences in vaccine coverage have also been reduced.

Despite these gains, the hepatitis disease burden is very high. Tenofovir has recently been approved for use in China, though entecavir is widely used as a generic product. The number of individuals being prescribed IFN-based therapies is falling. While prices have been reduced, first-line therapies remain unaffordable for many, especially for hepatitis C. In response, buyers groups travel to neighbouring countries such as India and Bangladesh to purchase generic DAAs. Price barriers impact rural populations more than urban populations. For hepatitis B, the challenges are different. Tenofovir is priced at US$ 13.50 for HIV but much higher for its use in HBV treatment.

There are licencing challenges peculiar to China. Tenofovir is sold by GSK under licence from Gilead Sciences. Recently there have been allegations of corruption within pharmaceutical companies in China, which has made the situation even more challenging. One key issue raised is that suboptimal or ineffective medicines are being marketed for HBV. For example, lamivudine and adefovir are being offered as front-line therapies by parts of the industry, while these drugs are not recommended by WHO, underscoring the disconnect between policy and practice.

A public health approach could be used to introduce tenofovir into China. Approval of DAAs is urgently needed for hepatitis C treatment. It was suggested that WHO could engage directly with the Ministry of Health. A public statement from WHO on the need for public health action in China may also be effective. Convening an advocacy event together with a public announcement from the government could also assist in focusing efforts on hepatitis action. It was acknowledged that once prices are reduced, it would become easier to facilitate national public health policy.

Finally, there was discussion about surveillance issues and needs. It was noted that one-time disease burden estimates are insufficient, and iterative analyses will be necessary. Furthermore, transmission issues will need to be addressed in future modelling.

2.7.3 Mongolia update and review

Dr Nick Walsh presented an update on hepatitis in Mongolia. An estimated 200 000 people are living with HBV and approximately the same for HCV. There has been substantial success in HBV control through immunization. Tenofovir is available, though entecavir is not. Sofosbuvir and ledipasvir are approved and available. However, hepatitis medicines are not subsidized by the national health insurance system.

A timeline of progress was presented. Since 2014, Mongolia has prepared a national situation assessment, held meetings and dialogues, and developed new HCV treatment guidelines (with DAAs). An investment case for HCV was undertaken with continued dialogue with the Ministry of Health and Sports, with budget allocations projected for the Ministry of Health and Sports and the Ministry of Finance. As a consequence of this work, the government endorsed the goal of elimination of HCV by 2030 in November 2015. Next steps include undertaking an investment case for HBV to commence in February 2016. Harvoni is currently available in Mongolia in private settings. Tenofovir, previously priced at US$ 250/month, was negotiated to a price of US$ 25/month for the originator brand product and US$ 7/month for the generic product.

WHO has worked tirelessly to align the national viral hepatitis programme in Mongolia with the Regional Action Plan. Since most treatment occurs in the private sector, the national viral hepatitis programme also had to include the private sector, particularly in regards to testing and treatment.

Challenges remain in collecting quality data, ongoing HCV transmission, and a limited understanding of co-factors in liver cancer. The magnitude of transmission through unsafe injection practices, including outside the public sector, remains unclear. There is ongoing investigation into the potential for antiviral therapy in cirrhosis and liver cancer prevention, with mathematical modelling being used to examine this question.

2.7.4 Mongolia discussions

The high burden of hepatitis, issues with treatment and budget concerns were discussed. There has been positive support and enthusiasm from the public and government, including the endorsement of the national action plan by Parliament. Treatment is currently limited and mostly provided by the private sector. Training to improve quality control in private settings could play a role. Introducing daclatasvir as well as sofosbuvir in the near future could also be considered.

There is a high burden of liver cancer in Mongolia, with many co-factors besides viral hepatitis. The National Institutes of Health is considering potential areas of research to assist in supporting activities in Mongolia. This includes a pilot case-control study to investigate the plethora of factors contributing to liver disease (e.g. alcohol, obesity, diet). A comment was made about the role of education, for example, considering the widespread alcohol consumption.

It was noted that Mongolia has a high prevalence of HBV-HDV coinfection, with 80% of those with liver cancer coinfected with HDV. A comment was made that coinfected individuals could be considered a potential priority group for treatment. Furthermore, future disease burden analysis may need to incorporate HDV infection, as this information became available following the completion of the most recent analysis. There is also need to build surveillance capacity, including acute surveillance, injection control, and HDV testing, the latter of which is not currently in the global surveillance guidance.

A key remaining concern is identifying financing for diagnostics and treatment. Budget projections were developed as part of the economic analysis using a combined strategy of initial mortality reduction, followed by elimination. Health insurance may assist in covering the cost of diagnostics, but not antiviral therapies. The difficulty of allocating 22% of the health insurance budget in 2018, as part of the budget projection, was highlighted. In response to a question about mechanisms to secure

funding, the Asian Development Bank (ADB) was suggested. It was noted that ADB would likely require robust information to confirm that it would be an upfront investment, and that costs would reduce over time.

Demonstration projects for integrated testing and treatment delivery in Mongolia were suggested. This could take place in two centres (one in Ulanbataar capital, one in an eastern province), with potential to inform system development. The purpose of such a study was questioned, highlighting the difficulty of measuring quantifiable short-term outcomes (e.g. reducing liver cancer, prevalence). However, it was emphasised that the project would be more of a health systems exercise to investigate service delivery and prepare for a broader-scale treatment implementation. Learning from demonstration projects in other countries (e.g. Pakistan), understanding transmission patterns may be important. In Mongolia, this is likely attributed to infection in medical and paramedical settings. Political will is an important factor for feasibility, and identifying more local partners to drive this may be necessary.

2.8 JOINT STAC AND ERP SESSION

2.8.1 Strategic and Technical Advisory Committee for Viral Hepatitis and Expert Resource Panel Combined Meeting

2.8.2 Global overview of viral hepatitis control and surveillance

Dr Yvan Hutin of the Strategic Information office in the Global Hepatitis Programme gave a global overview of the vision and targets for the elimination of viral hepatitis as a public health threat.

There has been a call for the elimination of viral hepatitis as a public health problem. This is the primary goal of the WHO Global Health Sector Strategy on Viral Hepatitis (GHSSVH) and this vision is echoed in the Sustainable Development Goals ratified at the UN General Assembly in 2015. The GHSSVH includes key impact targets. These are the reduction of hepatitis-related mortality by 65% and 90% reduction of new cases by 2030. Key steps to achieving this are investing in upscaled HBV vaccination, harm reduction, testing and treatment. The framework document outlined some of the recommended indicators for monitoring and evaluation for viral hepatitis B and C. It had been said that the HBsAg prevalence targets of 0.1% by 2030 may be overly ambitious. Regarding immunization, targets from other WHO Regions are in various stages of development. The African Region has set the goal of reducing chronic hepatitis B prevalence to less than 2% by 2020 among children under 5, while the Eastern Mediterranean Region has set the goal of reducing the prevalence to less than 1% among children under 5 by 2015. Other regions are considering setting a target for hepatitis B control through immunization. The Western Pacific Region must now look at how to proceed following achievement of the 1% target. Strategies may include improving equity in vaccination target achievements, for example between national and subnational levels. In addition, estimating hepatocellular carcinoma and cirrhosis cases attributable to hepatitis B and C may require synergy with cancer registries and other data repositories.

Key questions for discussion included how to harmonize regional EPI targets with GHSSVH targets, how to measure and verify achievement, and ways to reconcile two different public health approaches to vision, advocacy and planning.

2.8.3 Regional laboratory networks

According to Dr Sergey Diorditsa, the *Global Vaccine Action Plan 2011-2020* set goals and targets for disease eradication, elimination and control. Laboratory networks for various vaccine-preventable diseases currently exist in the Western Pacific Region including for poliomyelitis, measles and

rubella, Japanese encephalitis, rotavirus, and invasive bacterial-vaccine preventable diseases (IB-VPD). The potential impact of VPD laboratory networks on national immunization programs is considerable, including providing evidence of disease burden and vaccine introduction, contributing to the evaluation of disease control and confirmation of cases/outbreaks, strengthening quality assurance and enhancing capacity building.

The VPD laboratory network is a tiered system, with regional and national reference laboratories, as well as provincial laboratories in countries such as China. The laboratory networks are highly functional with various quality assurance measures in place.

The existing laboratory networks consist of national and subnational/sentinel laboratories (first tier), regional reference labs (second tier), and global specialised labs (third tier). Data and specimens are sent to upper levels, and training can be provided to lower levels. Differences in functional capacity also exist. For example, the first tier usually performs primary testing (virological and bacterial) and participates in active laboratory surveillance. Most laboratories have molecular capacity and can perform polymerase chain reaction (PCR) testing. Second tier laboratories can perform differential diagnostic assays, evaluate testing kits, develop standard operating procedures, provide external quality assurance (EQA) and take part in global EQA. The third tier, consisting of global specialized laboratories, typically provide the following functions: quality control for the whole network, reagents and standards; preparation of proficiency testing panels, developing laboratory manuals, providing training and conducting research. There are extensive management and feedback mechanisms intentionally built into the different levels.

Advantages of establishing a laboratory network include the following:

- Laboratory networks are linked to surveillance and regional and global strategies and goals;
- Laboratories use the WHO-recommended testing algorithm, and standardized data management and reporting, providing hands-on training and consultations to update developments and review a performance;
- Strong external quality assurance programme to include annual proficiency testing, confirmatory testing, and accreditation; and
- Integration of laboratory functions with shared infrastructure and expertise.

Creating a viral hepatitis laboratory network and strengthening existing laboratory services are priority areas in the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015). The Regional Action Plan for Viral Hepatitis in the Western Pacific Region sets milestones and targets for strengthening hepatitis surveillance and laboratory quality systems and establishes targets for diagnosis and treatment. Diagnosis and treatment are dependent on laboratory services. The Western Pacific Region is the first WHO Region to establish hepatitis B control goals of reducing the prevalence of chronic hepatitis B to less than 1% among cohorts of children at least 5 years of age. Serosurveys that measure the prevalence of chronic hepatitis B markers have been conducted in many countries to verify the achievement of the regional hepatitis B control goal. To ensure survey results are reliable and comparable between countries, quality laboratory services using assays with adequate sensitivity and specificity are needed. Despite the importance of laboratory services, a *laboratory gap analysis* commissioned in 2014 by Western Pacific Regional Office of Cambodia, Fiji, the Lao People's Democratic Republic, Mongolia, Papua New Guinea, the Philippines and Viet Nam suggested that capacity on viral hepatitis B and C serology testing is generally poor and quality assurance systems are inadequate in these countries. Currently, no hepatitis laboratory network exists in any WHO Region. The creation of a laboratory network within the WPR could encourage other regions to establish similar laboratory networks, and the experience can be shared globally. A

hepatitis laboratory network can support hepatitis surveillance programs and serosurveys, improve quality and coverage of diagnosis and treatment, and enhance blood safety.

Functions of a hepatitis laboratory network can include:

- Improve accuracy and promote standardization of laboratory testing;
- Ensure quality control and quality assurance are in place at all tier levels;
- Provide external quality assurance programmes;
- Develop standardized operating procedures and provide training;
- Identify gaps in diagnostic testing in resource-limited settings;
- Develop hepatitis reference diagnostic capacity in national laboratories; and
- Support national labs in developing domestic capacity at subnational levels.

In the discussion on laboratory networks, and the implementation of new WHO surveillance guidance in the Western Pacific, ERP and STAC participants readily recognised the need for a regional laboratory network and capability to build upon diagnostic/testing capacity in order to meet the ambitious screening targets in the Region. Diagnosis and testing has been a significant challenge, and many countries currently lack laboratory capacity to provide the tests needed. Furthermore, while it may be possible to test those who present clinically, the majority of sub-clinical cases are not tested. Many laboratories also struggle with molecular diagnostics. The proposed global goals for screening 90% of hepatitis B and C by 2030 are highly ambitious and in theory would require screening everyone worldwide. Conducting hepatitis screening on such a mass scale would not be possible without a laboratory network. It was noted that while laboratory networks currently exist for other vaccine preventable diseases (VPD), the scale demanded for hepatitis would be much greater. It was however suggested that the cost of not having a regional laboratory network in terms of vaccine escape, drug resistance and treatment failure should also be borne in mind.

Quality assurance was discussed, with participants noting the urgent need for updated evaluation of rapid testing and ELISA kits. Re-testing could be expanded to support hepatitis serosurveys. Questions were raised about what kind of kits should be used, and the need for more information was expressed. WHO has developed viral hepatitis surveillance and testing guidelines, with future guidance anticipated on rapid and point of care testing. The use of rapid tests in the field as evidenced by recent field experiences was discussed. Multiple country assessments found many poor quality rapid tests were being used, with unknown sensitivity and specificity. This was especially worrying as they were being used for blood donation and antenatal screening. In some instances, only mothers who tested positive through these unreliable kits were indicated for birth dose vaccination.

The recent outbreak of hepatitis in the Republic of Korea due to malpractice in a small clinic was mentioned. It was affirmed that regardless of regional initiatives, Korea will be taking steps to develop a national hepatitis reference laboratory. The existing quality assurance systems of clinical laboratories and licensed diagnostic products were discussed. Commercial laboratory services in China which usually do not participate in the national quality assurance programme remain a challenge in assuring diagnostic accuracy.

Various implementation issues were also discussed. Establishing such a laboratory network will require substantial support from WHO, with funding and logistical resources identified a priori. Participants discussed the need to further clarify the purpose of the laboratory network, define the scope of laboratory technical support needed by Member States, and identify the foremost needs. However, steps could be initiated in a few countries at first, with countries requesting greater

laboratory assistance could be at the top of the list. Progress can also be made with surveillance by assigning certain functions to national laboratories, which have linkages to national surveillance systems. There is a need to distinguish between acute, sentinel surveillance and the chronic/community-based surveillance, including the use of molecular diagnostics and point of care testing. Compared to other VPDs, hepatitis requires a significant focus on testing and involvement on a sub-national, provincial level, especially in light of local testing kit concerns. There also was also emphasis on the question of which assays would be used, and the need to ensure appropriate quality assurance.

2.8.4 Viet Nam National Action Plan on Viral Hepatitis

Dr Vu Ngoc Long presented an update to on national action planning for viral hepatitis in Viet Nam.

Viral hepatitis is the fourth leading cause of mortality in Viet Nam. A high prevalence of HBV exists in the general population (6-25%), while HCV is concentrated among PWID (54%).

Progress has been made in prevention, achieving less than 2% HBsAg in under 5 year olds in 2011 and moving towards the regional target of below 1%. Harm reduction among PWID and blood screening for HBV and HCV measures are also taking place. Surveillance reporting and existing evidence from past studies are under review. A more systematic approach is needed to guide policy, investment and action.

Treatment for HBV and HCV is available in large cities, but coverage is limited due to affordability, access and diagnostics. The first national hepatitis B and C treatment guidelines are available, recommending preferred regimens of tenofovir/entecavir (HBV) and Peg INF + ribavirin (HCV). Financing for hepatitis treatments includes health insurance reimbursements at standard rates of 80% for HBV and 70% for HCV (currently being piloted at one national hospital). However, application varies among provinces and more must be done to develop a health insurance benefit package for viral hepatitis diagnosis and treatment in a formal way.

The National Action Plan on Viral Hepatitis 2015-2019 aims to reduce transmission and enhance access to affordable prevention and treatment services. This involves five key solutions: human resource development; scientific research; investment; professional and technical solutions; and policy development and social mobilization - the last of which is an overarching, central focus.

Challenges remain in the response to viral hepatitis. They include limited investment from external and domestic funding sources; the need for systematic surveillance; and low awareness among health staff and patients due to the “silent” nature of the disease. Expanding diagnosis and treatment is costly for government and patients, and many people with chronic infection are unaware of their status. Improved testing algorithms, quality management from a laboratory perspective, and greater coordination among multiple stakeholders are also necessary. Moving forward, there is need to mobilize funds for activities and evidence for investment cases; to develop human resources; and to monitor progress of national action plan implementation. Lessons can be learned from other countries.

Proposed activities include:

- communication workshops; training for provincial health staff and local health-care workers; educational materials and mass media; and the hepatitis prevention campaign on World Hepatitis Day;
- developing surveillance guidelines;
- finalising modelling for the disease burden estimate and the investment case;

- updating national treatment guidelines and providing training;
- evaluating hepatitis assays and developing a testing algorithm;
- assessing laboratory capacity at provincial level;
- developing standards for hepatitis laboratories; and
- developing and training in standard operating procedures, including for blood screening.

2.8.5 Hepatitis B Vaccination in Viet Nam: progress, challenges and plans

Dr Duong explained that hepatitis B vaccination programmes have expanded since their commencement in 1997. Over the period since 2003 hepatitis B birth dose coverage has been below 50%; however, two episodes of AEFI (2007-2011, 2013-2014) and a stock shortage in 2010 resulted in suboptimal coverage. Three deaths due to program error in 2013 decreased birth dose coverage from 76% to 56% after the events were publicized in media and the finalized investigation took 15 months to complete. HepB3 coverage has also been influenced by such events, with pentavalent vaccine temporarily withdrawn after the 2013 AEFIs. Furthermore, AEFIs have also had impacts among health-care workers (e.g. perceptions of contraindications). Some hospitals stopped giving birth dose vaccination. A hospital-based delivery strategy was adopted to provide the birth dose, but community health centres and polyclinics in most areas are unable to provide birth dose vaccinations as of January 2016.

Key recommendations made from the Third Hepatitis B ERP Consultation in 2015 included:

- Conduct a proactive media campaign to regain public and health-care workers' confidence in the birth dose vaccine in Viet Nam.
- A recommendation for hepatitis B health-care worker vaccination: Hepatitis B vaccination for health-care workers may form the basis for further action addressing other infectious disease vaccination initiatives for health-care workers.

Responses from the Ministry of Health include several guidelines and an official letter on birth dose vaccination and AEFIs, along with the distribution of posters about hepatitis B vaccination to health facilities, and training for health-care workers and the Provincial Review Committees on AEFIs. Supportive supervision has been developed and cold chain equipment supplied to some clinics. Educational materials were developed and mass media messages about vaccination broadcasted through TV, the radio website, newspapers and online forums.

Viet Nam has the political commitment to reach the regional target of less than 1% HBsAg prevalence among children, as well as other targets set in the Regional Action Plan for Viral Hepatitis. However, there is a gap in hepatitis B birth dose coverage, with government policy precluding polyclinics and remote clinics from providing birth dose vaccinations. In 2015, the timely birth dose coverage was 64.8% nationally, compared to the target of 95%. While 80-90% of children born in hospitals received their birth dose, 10-20% were believed by health-care workers to have contraindications. Children born at home, community health centres and polyclinics in mountainous areas still have limited access to birth dose vaccination. The national policy on health-care worker vaccination remains to be addressed.

Strengthening management at the provincial and district level, and working on the model of birth dose delivery at polyclinics and commune health centres in mountainous areas, are part of the plan for improving hepatitis B vaccination. Other focus areas include securing vaccine supply, improving the

cold chain for birth dose, communication for mothers and health-care workers, integration of the birth dose into the Viet Nam National Strategy on Reproductive Health Care 2016–2020, mobilising resources from local governments for birth dose vaccination, and collaborating with international partners.

2.8.6 Viral hepatitis treatment and care: progress, challenges and plans

Dr Nguyen Trong Khoa presented an overview of progress and challenges in viral hepatitis treatment and care in Viet Nam.

Viet Nam has a high prevalence of hepatitis B in the general population (10-20%), while the prevalence of hepatitis C is mostly concentrated in high-risk groups such as PWID, haemodialysis patients and blood transfusion recipients.

Progress has been made on viral hepatitis treatment and care, thanks to new national guidelines for diagnosis and treatment of HBV and HCV, as well as training materials. Capacity building among health staff through assessment has improved, along with the establishment of a technical assistance group and training. Other areas of capacity building have included establishing a network for viral hepatitis treatment, improving infrastructure and resources for diagnosis and treatment, and standardising and enhancing the capacity of laboratories. In respect of access to treatment, there has been discussion with social security authorities for health insurance approaches to support patients, and a cost-effectiveness study of HCV treatment. Challenges remain in access to treatment and care, as many people are not aware of their status, health insurance coverage is limited and treatment is largely concentrated in large cities. Furthermore, registration and importation of new drugs is difficult due to requirements for clinical trials and the prohibitive costs of new DAA drugs.

Plans to increase access to treatment for viral hepatitis reflect the progress made and addressing remaining challenges. These include updating HCV treatment guidelines, as well as monitoring and assessing the implementation of national guidelines, enhancing the potential of the health staff, generating evidence for policy development through research, improving laboratory capacity, and establishing a quality assurance programme. Setting up the right mechanisms and legal frameworks may assist with access to new and effective HCV drugs. Increasing health insurance coverage in this area will be part of the move towards universal health insurance.

2.8.7 Hepatitis Disease Burden in Viet Nam

Dr Homie Razavi presented an update of the HCV disease burden and the economic analysis for Viet Nam. The Viet Nam hepatitis working group, WHO and CDA are working together to develop consensus estimates for the current and future HCV and HBV disease burdens; and to examine the impact of different intervention scenarios - prevention, vaccination and treatment. Epidemiological data is being collected and calibrated for the HCV disease burden and economic analysis, as well as the newly-developed HBV vaccination model. A baseline scenario had also been run for HCV. Further treatment scenarios would be discussed in a disease burden modelling meeting after the closure of the STAC meeting, scheduled tentatively for March 2016.

The base scenario for current HCV treatment predicts that while total infections will decline by 7%, HCC, decompensated cirrhosis and liver-related deaths will rise by 55-65%. Strategies analysed in Mongolia may offer a template for those used in Viet Nam. Dr Razavi recalled the combination scenario, initially targeting advanced liver disease patients (minimise mortality), then increasing treatment to all infections (elimination of hepatitis). Economic analysis for intervention scenarios has been found to be cost-saving when compared to a baseline in other countries, including Mongolia. Other considerations include the household financial capacity and public health sector budget requirements. It will be imperative to address high drug costs to make intervention strategies more affordable from a budget perspective.

Discussion - Viet Nam

Congratulations were extended to Viet Nam for being one of the first countries to develop a national action plan. In addressing a wide scope of areas and considering multiple stakeholders, there are plans to expand treatment for the whole country, and a staged approach could be considered. The Viet Nam government is working to develop a benefit package including vaccination and treatment of certain diseases with insurance coverage. The need for evidence around specific treatment and diagnoses may afford STAC an opportunity to provide technical advice. The effectiveness of treatment and complexity of management, the development and monitoring of clinical guidelines and the role of WHO were all discussed. Viet Nam has made progress. Support for initiatives beyond treatment was also broached, as was communication, education, health-care worker training, and addressing discrimination. Sites such as the National Hospital for Tropical Diseases and other government-designated hospitals have been identified as educational sites for health-care workers.

Challenges and suggestions regarding hepatitis birth dose immunisation were discussed. Delaying birth dose for false contraindications (e.g. low birth weight) is commonplace in Viet Nam. Some health-care workers advise mothers that the birth dose is not necessary. The reasons for contraindication (e.g. recording low birth weight in infants) should be documented. It was suggested that increasing the birth dose coverage should be given priority over circumferential issues. It was recognised that hard work is being done to address the loss of public confidence following the AEFIs. Viet Nam had an estimated 5.6% of home births in 2012, while in most areas hepatitis B vaccine is provided only in hospitals. This will remain a systematic barrier until policy issues are addressed to facilitate vaccine access to such people.

Antiviral pricing and availability was also discussed. Some antivirals are available in Viet Nam but they come at a high price. Partial health insurance provides nearly 80% coverage for treatment costs in Viet Nam. Sofosbuvir, which has a license but no registration number, and is priced at around US$ 600-900, has some availability. Tenofovir is also available, and is cheaper for those with health insurance at US$ 200 per year, as opposed to US$ 1000 for those without. Pegylated interferon costs around US$ 310 per vial, with patients paying around US$ 30 000 for treatment, and patients can receive a reimbursement of around US$ 3000 (10%). However, the side effects of medication and in-patient management increases costs. Using 12-week DAA treatment, higher cure rates can be achieved with lower costs and side effects, and this will be factored into the cost-effectiveness analysis.

Access to medicines is complex and many LMICs encounter difficulties. There are resources such as the Essential Medicines list to assist in licensing negotiation and pricing issues. However, the focal points for hepatitis within governments are often not directly involved in complex drug procurement issues. Local clinical trials are a significant barrier for drug registration, taking years for medicines to become formally available. Amending laws or exploring waivers may be necessary to bypass clinical trials. A draft amended pharmaceutical law proposes to remove the requirement of a local clinical trial to facilitate access to medicines. The Viet Nam Department of Drug Authority may also be able to expedite the registration processes of new drugs.

Interim measures such as special import licenses were also discussed. Viet Nam imports medicines from three companies using such procedures. These licenses may address short-term issues, but are conditional and limited to number, time, place and company. Other longer-term mechanisms will need to be considered. Indonesia uses the same companies as Viet Nam and has been able to fast-track registration processes through special import licenses. Furthermore, prices in Indonesia are cheaper at US$ 250 for a bottle of Sofosbuvir compared to US$ 600. It was argued that costs in Viet Nam should be lower than in Indonesia, considering the higher demand. There was discussion of a suggestion to appeal to Gilead for a patent waiver in Viet Nam. Establishing a committee within the Ministry of Health for price negotiation and emergency drug support may also allow legal association with suppliers to lower prices. It was commented that generic manufacturers are in a position to set prices that drive prices down; this was seen in other countries where CDA conducted analyses. A

suggestion was made to engage in price negotiations with Indian generic companies; this may allow more people to receive treatment. More information needs to be exchanged. Additionally, Western Pacific Regional Office may be able to learn from PAHO about driving down regional prices.

Pricing is a challenge for patients and introducing a central procurement system may reduce this burden. It was noted that availability also plays a part. There should also be health insurance policies to ensure that costs are covered following the introduction of medicines. A move towards central procurement could also be considered. Caution was voiced against excessive focus on price at the expense of other significant needs such as upscaling of testing, and the importance of national planning in strategic coordination was emphasised.

The case for investment in treating now was highlighted. There is economic as well as health value in early-life prevention of adulthood diseases. A trend in disease burden is being observed whereby incidence is declining but hepatitis-related mortality is increasing. Providing treatments that can reduce mortality gives an opportunity to boost achievements in prevention, strengthening the investment case to treat now. There is the additional benefit of stimulating the economy by investing in public health activities.

Other points raised included:

- in the early stages of hepatitis prevention and control in Viet Nam, lessons can be learnt from other Member States and WHO;
- the need to improve quality of laboratory testing; provincial lab systems have some capacity but there are difficulties with the lower district level (e.g. ELISA);
- blood screening: need for quality assurance improvement in the laboratory network in Viet Nam;
- future surveys to assess the prevalence of HBV and HCV in Viet Nam; and
- information about other types of hepatitis such as D and E: mobilizing surveillance as little is currently known or available in hospitals, and a greater understanding of the epidemiological patterns is called for.

Concluding remarks from Viet Nam pointed out that Viet Nam is in the early stages of hepatitis prevention and control, and there can be lessons learnt from other Member States and WHO. In the national action plan, targets were set up in line with WHO guidelines. Objectives should be set up to improve the laboratory system and tests, and provide reasonably priced drugs. Many difficulties and constraints had to be faced, such as in surveillance, with the low coverage of newborn vaccination. Provincial-level laboratory systems have some capacity but the lower district level remains problematic for testing methods such as ELISA. In future years, there will be more training opportunities. The price of antivirals in Viet Nam is still high. Various measures are to be implemented, such as setting up a reference laboratory for testing and for training. To date, a national hepatitis program for disease prevention and control has not been established such as for other diseases such as dengue, despite the recognised high burden of hepatitis. With the national action plan, engagement with stakeholders may help to inform priorities in coming years. Thanks were due to those who had performed the disease burden estimate and modelling. The value of this to raise awareness about the community and in securing political commitment should not be underestimated. Appreciation was expressed for overall support from WHO and to the technical groups for coming together to debate these issues.

Facilitated discussion: STAC/ERP joint discussion

The WHO Regional Office for the Western Pacific, having made significant progress, is in a position to lead the agenda as example for other regions. It was commented that Western Pacific Regional Office may be in a position to set regional goals more ambitious than the current global ones, for example in immunization, although this is to be determined by EPI. Participants also discussed mechanisms to monitor the progress of Member States in achieving targets in the Regional Action Plan, such as annual reporting, or panel verification. Where applicable, STAC could consider learning from verification mechanisms employed by ERP.

Collaboration between the STAC and ERP was discussed. Notable areas of overlap were identified, including perinatal and healthcare-related transmission. Existing cross-over in the three members who are part of both STAC and ERP was highlighted. A recommendation was made to consider formulating a sub-group to address the shared area of preventing perinatal transmission.

Given the achievements in immunization thus far, the next steps to be considered in prevention may include the prevention of maternal transmission by upscaling antenatal screening and treatment services. Although guidelines exist for antiviral treatment during pregnancy, greater clarity is needed (e.g. types of antivirals used, treatment duration). Furthermore, in reality, treatment practices often differ from the recommendations. One example is the wide use of lamivudine and adefovir rescue therapy. HBsAg screening is important for defining prevalence, but there may be need to decide to what extent it will be undertaken to find the last remaining cases. Increasing screening, diagnosis and treatment of pregnant women will entail costs; and countries may take different positions about whether or not to upscale from birth dose to more rigorous PMTCT programmes, including treatment of pregnant women with high viral loads.

Prevention strategies must continue to appropriately address target populations and current challenges relative to the national and sub-national contexts. Regarding Viet Nam, a recommendation was made that WHO assist the Viet Nam government to develop communication strategies and policies to restore public confidence and improve health-care workers' implementation of birth dose immunization. Furthermore, WHO should specifically address the issue of inappropriate birth dose contraindications. A suggestion was made for novel strategies or incentives such as a maternal immunization allowance to boost public confidence. There may be need for further clarity in defining target groups for immunization, while also recognising differences in transmission/risk populations between countries (e.g. HCV among PWID in most countries compared to nosocomial/parahealth transmission patterns in Mongolia). Treatment strategies should also incorporate prevention approaches, particularly among key populations such as PWID and MSM.

2.8.8 Regional laboratory network

Participants supported the need for a regional laboratory network to address various challenges including surveillance, screening, diagnostics and treatment. It was suggested that the priority needs for the region be identified first, so that the network can be tailored towards addressing them. The purpose should be raising the standard, promoting quality and reliability, and facilitating information and technology transfer by building networks and relationships. Quality assurance was discussed extensively, noting its importance in improving diagnostic quality across the Region, such as for rapid diagnostic kits/point of care testing. A suggestion was made to consider a demonstration project in Viet Nam for field validation of rapid diagnostic kits. The need to coordinate testing and surveillance with various stakeholders on a national level was noted. A recommendation was made to request the WHO Regional Office for the Western Pacific to assist in the establishment of, and explore funding opportunities for such a network. The recommendation was made for the WHO Regional Office for the Western Pacific to assist Member States to designate a national hepatitis reference laboratory and provide linkage to peripheral laboratories within the country. A staged implementation of the laboratory network was discussed as an alternative to waiting for all Member States to indicate voluntary interest if early progress can be made in a few countries with interest and funding capacity.

Current procurement mechanisms in Viet Nam are highly decentralised and various approaches to improving medicines access were suggested. These include centralising procurement, strengthening capacity for negotiations with generic manufacturers, and running a demonstration project in supply-procurement partnerships.

Another novel suggestion was to consider utilising shared HIV and hepatitis testing services (e.g. voluntary testing and counselling centres) as a platform for viral hepatitis demonstration projects in Viet Nam. Surveillance could be a potential topic for a demonstration project, considering the future need to develop passive surveillance/notification systems as testing increases. Surveillance of other issues such as HDV coinfection (e.g. Mongolia) may also need to be considered.

2.8.9 Final remarks

Dr Ying-Ru Lo offered closing remarks, thanking participants for making the collaboration possible. Gratitude was due to the Viet Nam country office, including from the WHO Regional Office for the Western Pacific. Dr Youngmee Jee provided final remarks from ERP, noting the positive discussions around the opportunities to work towards hepatitis control in the Western Pacific Region, and echoing the thanks to the hosts.

3. CONCLUSIONS AND RECOMMENDATIONS

Full recommendations of the STAC to the WHO Regional Director are presented in Annex 5.

- STAC applauds the development of the regional action plan and WHO's work to address viral hepatitis in the Western Pacific Region.
- STAC discussed specific areas of work including implementation of the regional action plan, hepatitis disease burden analysis and investment case work, access to affordable hepatitis diagnostics and medicines, hepatitis surveillance and data, and China, Mongolia and Viet Nam as specific case studies.
- STAC and the ERP discussed synergies to assist implementation of the regional action plan and tools to monitor progress.

STAC recommends to the Regional Director that WHO:

1) Work with Member States to disseminate the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020*, noting different stakeholders are required to implement the plan, giving priority in implementation to countries and sub-regions with high disease burden.
2) Examine the feasibility of a resolution or statement at the WHO Regional Committee for the Western Pacific specifically addressing stigma and discrimination and guide the development of appropriate indicators and targets to measure progress in addressing stigma and discrimination.
3) Assess the benefits and challenges of treatment programme implementation and service delivery in selected countries through pilot/demonstration projects. The implementation experience and service delivery models can be used to inform national expansion and serve as a model for other countries.
4) Continue to work with Member States on country-specific disease burden and transmission models to inform national action plans, such as the hepatitis C model in Mongolia.
5) Provide technical support to Member States to improve access to affordable diagnostics and medicines, including by:
    a) providing information about current and upcoming prices of generic medicines;
    b) facilitating, through novel means, pooled purchasing or pooled negotiations arrangements through exploring collaborating partners for essential medicine; and
    c) supporting Member States to access interim means for access to hepatitis medicines including temporary waivers of registration requirements.

6) Assist Member States to develop and implement strategies for national surveillance based on the WHO viral hepatitis surveillance guidelines and assist Member States to establish indicators to evaluate surveillance efforts.
7) Request annual reports on process indicators by Member States for analysis, dissemination and action.
8) Assist Member States to respond to "outbreaks" of viral hepatitis and work with Member States to reinforce infection control programmes to stop health-care associated transmission of hepatitis B and C virus.

STAC, in response to requested country-specific recommendations, recommends to the Regional Director that WHO:

China

1) Continue to advocate the need for a public health approach to hepatitis in China.
2) Work with the Government of China to address the high disease burden and challenges of hepatitis treatment by learning from the example of Gavi, the Vaccine Alliance, tuberculosis and HIV programmes and replicating the approach of piloting demonstration projects to scale public health initiatives addressing viral hepatitis.
3) Support the Government to develop national hepatitis treatment guidelines and address the residual mother-to-child transmission of hepatitis B.

Mongolia

1) Continue to support Mongolia to address the high burden of viral hepatitis, in particular enhancing diagnostic capacity to inform treatment and care approaches for people living with viral hepatitis in Mongolia.
2) Provide technical support for implementation of surveillance and treatment guidance and testing algorithms for viral hepatitis.

Viet Nam

1) Consider working with Viet Nam to build hepatitis testing into voluntary HIV models, including for key populations where possible.
2) Support Viet Nam to carry out an inventory and validation of hepatitis B and C diagnostics, including rapid diagnostic tests and work with Viet Nam to investigate novel mechanisms to facilitate access to hepatitis medicines and diagnostics.
3) Strengthen the capacity for centralization of procurement and negotiated procurement.

Regarding cross-over areas in their work, STAC–ERP recommend to the Regional Director that WHO:

1) Specify the roles of STAC and ERP in addressing and verifying progress in hepatitis in the Region, including the regional action plan.
2) Explore funding opportunities for a regional hepatitis laboratory network to support laboratory-based research across the Region. Research areas may include surveillance, screening, diagnosis and treatment. The laboratory network could assist to identify priority laboratory needs for the Region (e.g. to provide quality control/assurance, validate testing strategies and validate or approve tests). Priority should be given to standardizing molecular testing.
3) Assist Member States to designate one or more national hepatitis reference laboratories with links to domestic laboratories and surveillance systems in countries.
4) Establish a sub-group of ERP-STAC members to focus on the prevention of perinatal hepatitis transmission. Other areas of common interest between both groups include health-care worker vaccination, post-vaccination serologic testing and advocacy.

ANNEXES

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MEETING PROGRAMME

Hanoi, Viet Nam **ENGLISH ONLY**
25–27 January 2016

Day 1: Monday, 25 January 2016

Time	Topic	Presenter
08:30–09:00	**Registration**	
09:00–09:45	**Session I: Opening (Joint Session with STAC/ERP)**	
09:00–09:05	Welcome	Sergey Diorditsa, EPI,[b] WPRO
09:05–09:15	Opening remarks	WR, on behalf of the WHO Regional Director
09:15–09:35	Introduction of participants	All
09:35–09:45	Administrative announcements	Sergey Diorditsa, EPI, WPRO
09:45–10:15	Group photo and coffee break	
10:15–11:05	**Session II: Overview (STAC only)**	
10:15–10:25	Regional overview: Regional progress and key achievements in 2015	Ying-Ru Lo, HSI[c], WPRO
10:25–10:35	Regional overview: Outline of background documents and questions to STAC	Nick Walsh, HSI, WPRO
10:35–10:50	Global overview: Hepatitis prevention and control: From historical work in immunization to elimination plans.	Yvan Hutin, WHO HQ
10:50–11:05	Discussion	
11:05–12:15	**Session III: Viral hepatitis disease burden and economic analyses (Objective 1)** **Background paper:** #1 Disease burden ex China, #2 China disease burden policy brief	
11:05–11:10	Overview of process and methods on hepatitis disease burden in the Philippines, Viet Nam, China, Mongolia	Nick Walsh, HSI, WPRO
11:10–11:25	Hepatitis B and C disease burden and economic analysis in China	Wang Xiao Chun, Chinese Center for Disease Control and Prevention
11:25–11:35	Hepatitis C treatment economic analysis in Mongolia	Nick Walsh, HSI, WPRO
11:35–11:45	Hepatitis models in other countries	Homie Razavi, Center for Disease Analysis

[b] EPI is Expanded Programme on Immunization, Division of Communicable Diseases.
[c] HSI is HIV, hepatitis and STI unit, Division of Communicable Diseases.

Time	Topic	Presenter
11:45–12:15	Discussion ***Questions to STAC:*** 1. *What additional public health intervention scenarios should we be modelling?* 2. *What financing strategies should we be modelling?* 3. *What are the terms of reference of the models we should be using?* 4. *How can we use the findings of the model to inform budget and planning for hepatitis treatment?*	
12:15–13:00	Lunch	
13:00–15:00	**Session IV: Treatment access (Objective 2)** **Background paper:** #3 Access to Treatment	
13:00–13:10	Treatment access in the Western Pacific	Nick Walsh, HSI, WPRO
13:10–13:20	Community perspectives on hepatitis treatment	Giten Khwairakpam, TREAT Asia
13:20–13:30	Hepatitis B treatment: key interventions and needs for HBV treatment in the Western Pacific	Henry Chan, The Chinese University of Hong Kong
13:30–13:40	Hepatitis C treatment: key intervention and needs for HCV treatment relevant to the Western Pacific	Tatsuya Kanto, Research Center for Hepatitis and Immunology
13:40–15:00	Discussion ***Questions to STAC:*** 1. *What are rapid interim options for introduction of new medicines/diagnostics in countries with slow regulatory processes? How can WHO/WPRO support these options?* 2. *What are the requirements for development and implementation of novel procurement and funding mechanisms for hepatitis medicines in the Western Pacific?* 3. *Who can facilitate development and implementation of novel procurement and funding mechanisms for hepatitis medicines in the Western Pacific?* 4. *What information needs to be made available to countries/ donors/ international agencies to reduce access barriers in countries and how can WHO reduce information failures both on the demand and supply side to increase access?*	
15:00–15:15	Coffee Break	

Time	Topic	Presenter
15:15–17:00	**Session V: Viral hepatitis surveillance and data (Objective 1, 2)** **Background paper:** WHO global viral hepatitis surveillance guidance	
15:15–15:35	New WHO viral hepatitis surveillance guidance	Yvan Hutin, WHO HQ
15:35–15:50	Outbreak investigation and response	TBD
15:50–16:50	Discussion ***Questions to STAC:*** 1. *What are the next steps to implement the new WHO surveillance guidance in the region?* 2. *How best to build on existing surveillance systems?* 3. *How should WHO help identify and address ongoing healthcare associated HCV transmission?*	
18:00	WHO Reception Dinner	

Day 2: Tuesday, 26 January 2016

Time	Topic	Presenter
09:00–10:15	**Session VI: Regional Action Plan implementation (Objective 2)** **Background paper:** Regional Action Plan for Viral Hepatitis 2016-2020; draft Global Health Sector Strategy on Viral Hepatitis 2016–2021; WHO guidance manual for development and assessment of national plans	
09:00–09:15	Draft WHO HBV and HCV elimination goals and regional milestones and targets	Ying-Ru Lo
09:15–10:15	Discussion ***Questions to STAC:*** *1. Are the regional targets and milestones and outlined activities adequate towards achieving global HBV and HCV elimination goals?* *2. What are the priority steps WHO should focus on in 2016 to work towards global and regional goals, targets and milestones?* *3. What are the regional success factors and key partnerships?* *4. Which countries should we focus on?* *5. How should WHO track progress toward the broader set of elimination goals?* *6. Who should take on the tracking of country progress?*	
10:15–10:45	Coffee Break	
10:45–12:00	**Session VII: Country discussions–China, Mongolia (Objective 1)** **Background paper:** #2 China disease burden policy brief, Mongolia country report	
10:45–11:30	China discussion: • Update on viral hepatitis action in China • Discussion ***Questions to STAC:*** *1. What are the next steps in China?* *2. What kind of support is needed?* *3. How can WHO support these efforts?* *4. Who are potential funders?* *5. Who are potential partners?*	Wang Xiao Chun, Centers for Disease Control and Prevention Wei Lai, Peking University

Time	Topic	Presenter
11:30–12:00	Mongolia discussion • Update and review • Discussion ***Questions to STAC:*** *1. What are the next steps in Mongolia?* *2. What is the feasibility of a 'demonstration project' in a district/province in Mongolia?* *3. Who are potential funders?*	Nick Walsh, HSI, WPRO
12:00–13:00	Lunch	
13:00–15:00	**Session VIII: Development of recommendations**	
15:00–15:30	Coffee Break	
15:30–16:00	**Session IX: Recommendations and closing**	
15:30–15:50	Meeting recommendations	Henry Chan, The Chinese University of Hong Kong
15:50–16:00	Closing remarks	Ying-Ru Lo, HSI, WPRO Henry Chan, The Chinese University of Hong Kong

Day 3: Wednesday, 27 January 2016

Joint Meeting with STAC Viral Hepatitis & ERP (Objective 3)

Time	Topic	Presenter
08:30–09:30	**Session I: Global and Regional crossover in hepatitis** Background paper: WPRO hepatitis laboratory network summary; Laboratory gap analysis paper	
08:30–08:45	Global overview of viral hepatitis control and surveillance	Yvan Hutin, WHO HQ
08:45–09:00	Regional laboratory networks	Sergey Diorditsa, EPI, WPRO
09:00–09:30	Facilitated discussion on laboratory network, and implementation of new WHO surveillance guidance in the Western Pacific	
09:30–09:45	Coffee Break	
09:45–12:00	**Session II: Viet Nam session**	
09:45–10:05	Viet Nam National Action Plan on Viral Hepatitis Prevention and Control	Vu Ngoc Long, General Department of Preventive Medicine, Ministry of Health
10:05–10:25	Hepatitis B immunisation in Viet Nam: progress, challenges and plans	Duong Thi Hong, National EPI programme, Ministry of Health
10:25–10:45	Viral hepatitis treatment and care: progress, challenges and plans	Nguyen Trong Khoa, Viet Nam Administration of Medical Service, Ministry of Health
10:45–11:00	HBV and HCV disease burden estimates in Viet Nam	Homie Razavi, Center for Disease Analysis
11:00–12:00	Facilitated discussion ***Questions:*** 1. *What are potential mechanisms to address and finance the prevention of healthcare related of HBV and HCV transmission and access to treatment in Viet Nam?* 2. *What are potential technical collaborations for WHO and Viet Nam Ministry of Health in viral hepatitis to support achievement of regionaland global targets?*	
12:00–13:00	Lunch	

Time	Topic	Presenter
13:00–15:00	**Session III: STAC/ERP joint discussion**	
13:00–15:00	Facilitated discussion: STAC/ERP collaborations for other countries and the Regional Action Plan ***Questions:*** *1. What are potential countries for collaboration?* *2. What are potential collaborative areas of work? (Healthcare transmission, surveillance etc.)* *3. What are the specific roles of STAC/ERP in addressing and verifying progress in hepatitis in the Region?* *4. Formulation of recommendations from the joint session*	
15:00–15:15	Coffee Break	
15:15–15:40	**Session VIII: Recommendations and closing**	
15:15–15:35	Meeting recommendations	Youngmee, Korean Centers for Disease Control and Prevention
15:35–15:40	Closing remarks	Ying-Ru Lo, HSI WPRO

LIST OF DOCUMENTS

KEY DOCUMENTS: PRINTED

WPR/DCD/HSI(01)/2016/IB/1&2	Information Bulletins
WPR/DCD/HSI(01)/2016.1	Provisional Agenda
WPR/DCD/HSI(01)/2016/2	Background document 1: Disease burden modelling paper (*Public health and economic impact of population based approaches to HBV and HCV treatment in Mongolia, Viet Nam, Philippines, Kiribati*) (Session III)
WPR/DCD/HSI(01)/2016/3	Background document 2: China policy brief on disease burden modelling (Session III, VII)
WPR/DCD/HSI(01)/2016/4	Background document 3: Access to medicines (Session IV)
WPR/DCD/HSI(01)/2016/5	Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020 (Session VI)
WPR/DCD/HSI(01)/2016/6	Background document 5: regional hepatitis laboratory network (Joint Session I)
WPR/DCD/HSI(01)/2016/INF./1	Recommendations from the First Meeting of the Strategic Technical Advisory Committee for Viral Hepatitis in the Western Pacific
WPR/DCD/HSI(01)/2016/INF./2	First Strategic Technical Advisory Committee for Viral Hepatitis in the Western Pacific Meeting Report
WPR/DCD/HSI(01)/2016/INF./3	Initial Member State Consultation on the Draft Regional Action Plan for Viral Hepatitis in the Western Pacific Meeting Report
WPR/DCD/HSI(01)/2016/INF./4	Executive Board report on draft global health sector strategies
WPR/DCD/HSI(01)/2016/INF./5	Draft global health sector strategy on viral hepatitis, 2016–2021 - the first of its kind
WPR/DCD/HSI(01)/2016/INF./6	Regional Committee Resolution WPR/RC66.1R1 on Viral Hepatitis
WPR/DCD/HSI(01)/2016/INF./7	Strategic and Technical Advisory Committee Group on Viral Hepatitis Terms of Reference (2015–2017)

KEY DOCUMENTS: USB DRIVE ONLY

WPR/DCD/HSI(01)/2016/7	Background document 4: WHO global viral hepatitis surveillance guidance (*Technical considerations and case definitions to improve surveillance for viral hepatitis)* (Session V)

WPR/DCD/HSI(01)/2016/8	WHO guidance manual for the development and assessment of national viral hepatitis plans (Session VI)
WPR/DCD/HSI(01)/2016/9	Mongolia country report (Session VII)
WPR/DCD/HSI(01)/2016/10	Laboratory gap analysis (*Improving the quality of and access to HIV, syphilis and hepatitis B and C testing: laboratory gap analysis in selected countries of the Western Pacific Region*) (Joint Session I)

REFERENCE MATERIALS

WPR/DCD/HSI(01)/2016/INF./7	UNITAID Hepatitis C Medicines Technology and Market Landscape – Update
WPR/DCD/HSI(01)/2016/INF./8	Médecins Sans Frontières Briefing Document on Strategies to Secure Access to Generic Hepatitis C Medicines
WPR/DCD/HSI(01)/2016/INF./9	Disparity in market prices for hepatitis C virus direct-acting drugs, *The Lancet*
WPR/DCD/HSI(01)/2016/INF./10	The hepatitis C treatment revolution: how to avoid Asia missing out, *Journal of Virus Eradication*
WPR/DCD/HSI(01)/2016/INF./11	Kiribati meeting report (*Technical meeting on raising awareness, surveillance, prevention and management of viral hepatitis in Kiribati*)
WPR/DCD/HSI(01)/2016/INF./12	WHO HQ monitoring and evaluation indicators and framework (*Monitoring and evaluation or viral hepatitis B and C: Recommended indicators and framework*)
WPR/DCD/HSI(01)/2016/INF./13	Advocacy material: “Join us to fight hepatitis” brochure
WPR/DCD/HSI(01)/2016/INF./14	Advocacy material: “Invest in hepatitis” flyer
WPR/DCD/HSI(01)/2016/INF./15	Advocacy material: “Stop liver cancer” flyer

RECOMMENDATIONS OF THE FIRST MEETING OF THE STRATEGIC AND TECHNICAL ADVISORY COMMITTEE (STAC) FOR VIRAL HEPATITIS IN THE WESTERN PACIFIC REGION (STAC-HEP-WPR) TO THE REGIONAL DIRECTOR

Recommendations of the first STAC-HEP-WPR on 27 April 2015.

The STAC-HEP-WPR takes note of:

i. the World Health Assembly resolutions on viral hepatitis (63.18 in 2010 and 67.6 in 2014) which call for Member States to develop and implement coordinated multisectoral national strategies for preventing, diagnosing and treating viral hepatitis based on the local epidemiological context;

ii. the proposed Post-2015 Sustainable Development Goal 3.3: to end by 2030 the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases, and combat hepatitis, water-borne diseases and other communicable diseases; and

iii. the need to accelerate regional and national hepatitis responses and address the crisis of unmet demand for chronic hepatitis B and C antiviral treatment as a matter of *urgency* in the Western Pacific Region.

STAC affirms to the Regional Director that:

STAC unanimously endorses the Global Health Sector Strategy on Viral Hepatitis and its targets, and the Regional Action Plan for Viral Hepatitis, and proposes that the WHO Regional Office for the Western Pacific develop regional targets consistent with proposed global targets, but with a nearer-term time horizon. STAC agrees there is sufficient overlap between the Global Health Sector Strategy on Viral Hepatitis and the Regional Action Plan for Viral Hepatitis.

STAC recommends to the Regional Director that the WHO Regional Office for the Western Pacific:

Broad-based advocacy and awareness

1) Work with all Member States to ensure that action to eliminate stigma and discrimination forms a central part of all efforts to address viral hepatitis.

2) Work with all Member States to ensure advocacy and awareness activities are not limited to World Hepatitis Day, and establish a minimum set of requirements for addressing advocacy and awareness needs. Noting the differing needs of countries and stakeholder groups across the Region, and recognizing the need for concerted advocacy and awareness action, STAC considers the draft Regional Action Plan for Viral Hepatitis advocacy and awareness targets are not sufficiently ambitious, or sustainable. STAC suggests there be indicators for Member States to submit a report on awareness and advocacy actions undertaken; this may take the form of a report card detailing minimum requirements annually.

3) Work with all Member States to increase targeted advocacy in high-risk populations.

National policy

1) Work with Member States through the Regional Action Plan for Viral Hepatitis, which may serve as the framework for implementation of the hepatitis response in countries.

2) Work with Member States to develop and implement comprehensive costed and funded national hepatitis action plans, and establish a national hepatitis taskforce with an organizational structure including designated personnel within the ministry of health.

Representation in the taskforce should include civil society, clinical care providers, researchers and policy-makers, among others.

3) Support countries to develop their own country-specific action plans with prevention and treatment targets, including harm-reduction targets, noting the challenges in providing specific guidance for national hepatitis action plans, given inter-country variability.

4) Establish core monitoring requirements in collaboration with WHO headquarters for countries to track their progress in hepatitis programme implementation. Work with Member States to support implementation, with progress reports on meeting targets sent to the Regional Office and the Regional Committee, should the Action Plan be endorsed at the Regional Committee Meeting in 2015.

5) Assist Member States to develop a country-specific investment case for hepatitis, including antiviral treatment, based on national disease burden estimates.

Data and surveillance

1) Encourage Member States to collate currently available viral hepatitis-related data, including integration, expansion and links to programmes for other infectious diseases (HIV, tuberculosis) and services targeting people who inject drugs.

2) Establish an initial milestone for Member States involving the calculation of the baseline status of patient retention in country-specific screening, care and treatment cascades at the population level to inform future treatment targets, noting the lack of hepatitis treatment cascade data.

Prevention

1) Ensure all efforts are made to prevent health sector transmission, noting the central importance of this action, and the challenging nature of measuring incident HCV infections attributable to this mode of transmission.

2) Ensure all efforts are made to increase birth dose hepatitis B vaccine coverage, noting the crucial importance of timely birth dose administration in preventing hepatitis B transmission.

3) Ensure rapid response mechanisms exist to address ‘so-called’ adverse events related to hepatitis B vaccination.

4) Ensure that more prominence is given to harm-reduction measures.

Screening, care and treatment

1) Assist and support the implementation of viral hepatitis screening, care and treatment as a national public health programme to address hepatitis-related mortality at the population level.

2) Set specific screening targets, as testing and diagnosis is a critical bottleneck in increasing antiviral treatment in the Region.

3) Develop mechanisms to facilitate industry utilization of collaborative regulatory procedures, including the WHO prequalification system, noting the lack of quality assurance mechanisms for diagnostics and generic antivirals for hepatitis.

4) Work with Member States to address challenges in regulatory approval and overcome price barriers to antiviral treatment access. STAC noted the lack of transparency in antiviral price

negotiation, which impedes countries' negotiating position, and recommends steps be taken to address this. This may depend on country-specific legislation.

5) Compile an inventory of which countries have access to key antivirals, including tenofovir, and which ones do not.

RECOMMENDATIONS OF THE SECOND MEETING OF THE WESTERN PACIFIC REGION STRATEGIC AND TECHNICAL ADVISORY COMMITTEE FOR VIRAL HEPATITIS (STAC-HEP-WPR) TO THE REGIONAL DIRECTOR

Recommendations of the second STAC-HEP-WPR on 25 and 26 January 2016.

The STAC-HEP-WPR applauds the development of Regional Action Plan and the WHO Regional Office's efforts to address viral hepatitis in the Western Pacific region.

STAC recommends to the Regional Director that the WHO Regional Office for the Western Pacific:

Regional Action Plan implementation

1) Continue to support Member States in developing national plans.
2) Examine the feasibility of a resolution or statement at the WHO Regional Committee meeting specifically addressing stigma and discrimination in relation to viral hepatitis.
3) Work with Member States to disseminate the Regional Action Plan for Viral Hepatitis, 2016–2020, noting that different stakeholders are required to execute the implementation of the plan.
4) Integrate a dissemination strategy into the communication package of the Regional Action Plan.
5) Establish a mechanism for regular reporting of progress for milestone and goal achievement, including a report card on progress on priority action areas of the Regional Action Plan.
6) Support efforts to develop appropriate indicators and targets to measure progress in addressing stigma and discrimination.
7) Prioritize countries and subregions with high disease burden to support implementation of the Regional Action Plan.

Viral hepatitis disease burden and economic analyses

1) Continue to work with Member States on country-specific disease burden estimates and transmission models to inform national action plans and to replicate the process undertaken for hepatitis C in Mongolia (Impact of a population-based approach to HCV treatment in Mongolia) in other countries in the Region.
2) Support development of disease burden and transmission models that include sensitivity analysis of "worst case scenarios" (e.g. poor response to, or high cost of, screening; poor laboratory quality and suboptimal treatment responses).

Access to quality and affordable hepatitis diagnostics and treatment

1) Provide technical support to Member States to improve access to affordable diagnostics and medicines by:
    a) encouraging the use of prequalified diagnostics and medicines where applicable;
    b) providing information about current and upcoming prices of generic medicines;
    c) promoting generic competition including through national patent law;
    d) facilitating pooled purchasing or pooled negotiations arrangements through novel means, including exploring collaborating partners for essential medicines; and

e) supporting Member States to access interim means for access to hepatitis medicines, including temporary waivers of registration requirements, and use of all TRIPS flexibilities.

2) Assist the implementation of viral hepatitis programmes by:

a) developing demonstration projects in selected countries to assess the benefits and challenges of treatment programme implementation; these models can be used to inform policy in other countries; and

b) championing and supporting the study of high-quality, simplified care and treatment models with the potential to improve access and coverage and lower the costs of all aspects of the programme beyond the cost of drugs when broadly implemented.

Viral hepatitis surveillance and data

1) Work with Member States to utilize existing data inventories to estimate the disease burden of viral hepatitis.

2) Work with Member States to adapt WHO surveillance guidelines and recommended indicators, ensuring only good quality data are utilized to avoid misleading results.

3) Assist Member States to develop and implement strategies for national surveillance based on the Technical Consideration and Case Definition of Viral Hepatitis Surveillance.

4) Request annual reports on viral hepatitis surveillance processes and indicators by Member States for analysis, dissemination and action.

5) Assist Member States to respond to 'outbreaks' of viral hepatitis.

6) Work with Member States to reinforce infection control programmes to prevent health-care-associated transmission of hepatitis B and C virus.

Country-specific recommendations

In response to a request for recommendations for the following countries, STAC recommends to the Regional Director that the WHO Regional Office for the Western Pacific:

China

1) Work with the Government of China to address the high disease burden and challenges of viral hepatitis treatment by learning from the example of GAVI, TB and HIV programmes and replicate the approach of these, piloting demonstration projects to scale up the public health initiatives addressing viral hepatitis.

2) Support the Government of China to develop national hepatitis B and C treatment guidelines.

3) Support the Government of China to address residual mother-to-child transmission of hepatitis B.

Mongolia

1) Continue to support Mongolia to address the high burden of viral hepatitis; especially with respect to funding strategies for a national viral hepatitis action plan.

2) Establish a surveillance system incorporating coinfection of HBV-HDV and HCV-HBV.

3) Enhance diagnostic capacity to inform treatment and care approaches for people living with viral hepatitis in Mongolia.

RECOMMENDATIONS FROM THE EXPERT RESOURCE PANEL (ERP) HBV January 2015 TO STAC-HEP-WPR (yet to be formed)

Recommendations of the 3rd Western Pacific Region Hepatitis B Expert Resource Panel Meeting, 12-13 January 2015, Seoul, Republic of Korea

In January 2015, the Western Pacific Region Hepatitis B ERP for hepatitis control through immunization met in Seoul, Republic of Korea. At the time, the STAC-HEP-WPR was being formed and had not yet met.

The ERP took the opportunity to make several recommendations to the STAC-HEP-WPR in advance of its first meeting, scheduled for April 2015. These were shared with STAC-HEP-WPR members during the STAC meeting on 27 April 2015 and are:

ERP coordination with comprehensive viral hepatitis work:

The ERP welcomes and supports the development of the Regional Action Plan for Viral Hepatitis that will cover the four axes of the framework for global action for prevention and control of viral hepatitis.

1) The ERP recommends that the viral hepatitis working group developing the Regional Action Plan for Viral Hepatitis be aware of the work of the ERP and that the work of the ERP be reflected in the Regional Action Plan for Viral Hepatitis.

2) The ERP recommends that the viral hepatitis working group share the draft Regional Action Plan for Viral Hepatitis with ERP members for review and feedback as soon as possible.

3) The ERP recommends that membership of the ERP and the STAC overlap, and that the work of both should be complementary and coordinated. Some of the areas of common interest include diagnostics, prevention, advocacy and sharing meeting reports.

4) The ERP recommends that regular ERP and STAC meetings be held back-to-back, with one day of overlap to discuss common issues and ensure coordination of efforts.

5) The ERP recommends that it write to the Regional Director and the global STAC-HEP to advocate for increased membership of hepatitis B advocates/specialists on the WHO Global Hepatitis Programme civil society reference group.

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