MEETING REPORT

THE FIFTH HEPATITIS B IMMUNIZATION EXPERT RESOURCE PANEL CONSULTATION

Convened by:

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NOTE

The views expressed in this report are those of the participants of the Fifth Hepatitis B Immunization Expert Resource Panel Consultation 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 Fifth Hepatitis B Immunization Expert Resource Panel Consultation in Manila, Philippines from 15 to 17 February 2017.
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<td>adverse event following immunization</td>
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<td>CCE</td>
<td>cold chain equipment</td>
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<td>CTC</td>
<td>controlled temperature chain</td>
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<td>DHS</td>
<td>Demographic and Health Survey</td>
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<td>EENC</td>
<td>Early Essential Newborn Care</td>
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<td>EINC</td>
<td>essential intrapartum and newborn care</td>
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<td>EMTCT</td>
<td>elimination of mother-to-child transmission</td>
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<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<td>Hepatitis B Immunization Expert Resource Panel</td>
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<td>GHSSVH</td>
<td>Global Health Sector Strategy on Viral Hepatitis 2016–2021</td>
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<td>HBeAg</td>
<td>hepatitis B e-antigen</td>
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<td>hepatitis B immunoglobulin</td>
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<td>HepB-BD</td>
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<td>MNCH</td>
<td>maternal, newborn and child health</td>
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<td>NGO</td>
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<td>OCC</td>
<td>out of the cold chain</td>
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<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
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<td>PVST</td>
<td>post-vaccination serologic testing</td>
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<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
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<td>SBA</td>
<td>skilled birth attendant</td>
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<td>TBA</td>
<td>traditional birth assistant</td>
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<td>US CDC</td>
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<td>VPD</td>
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The Fifth Hepatitis B Immunization Expert Resource Panel Consultation was held in Manila, Philippines on 15–17 February 2017. Representatives from six countries in the Western Pacific Region with previously noted slower immunization progress attended the meeting. Staff from the World Health Organization (WHO) headquarters, Western Pacific Region, South-East Asia Region and European Region presented updates on global and regional progress towards the elimination of hepatitis B in children, as well as data from hepatitis B impact serosurveys and out of the cold chain (OCC) pilot projects implemented in the Western Pacific Region. Country representatives presented programmatic updates and discussed their near- and long-term planned hepatitis B vaccination birth dose (HepB-BD) activities. The Western Pacific Region has made progress in its response to hepatitis B elimination goals through the widespread scale-up of hepatitis B immunization, in particular of HepB-BD, throughout most of the countries and areas. The seroprevalence target of 1% among immunized cohorts of children at least 5 years of age was met in advance of the 2017 goal, and immunization programmes in the Region have averted an estimated 7 million deaths and 37.6 million chronic hepatitis B cases among children born between 1990 and 2014.

The Hepatitis B Immunization Expert Resource Panel (ERP) discussed the Global Health Sector Strategy on Viral Hepatitis 2016–2021 (GHSSVH) which includes a new process indicator (90% coverage of interventions to prevent perinatal transmission by 2030) and so-called elimination targets (1% hepatitis B surface antigen [HBsAg] prevalence among children by 2020 and 0.1% HBsAg prevalence among children by 2030). In the Western Pacific Region, large disparity exists between countries that have met regional targets and those with relatively low HepB-BD and hepatitis B vaccination third dose (HepB3) coverage that have not yet achieved the 2012 or 2017 regional targets. Discussing ways to achieve and sustain post-2017 hepatitis B control targets for all countries and areas was the main focus of the meeting.

Of the 36 countries and areas in the Western Pacific Region, 19 have serosurvey evidence of <0.5% HBsAg prevalence; while 2 countries have between 0.5% and 1%; and five have >1% hepatitis B surface antigen (HBsAg) prevalence among 5-year-olds. Ten countries have no serosurvey results. Post-2017 targets tentatively include the following:

1. All countries and areas in the Western Pacific should reduce HBsAg prevalence to less than 1% among children at least 5 years of age by 2025.

2. Countries and areas in the Western Pacific that have reduced HBsAg prevalence to less than 1% among children at least 5 years of age should aim to further reduce HBsAg seroprevalence to less than 0.5% among children at least 5 years of age by 2025.

Concerted effort and direct assistance will be necessary to assist countries and areas that have not reached the 2012 and/or 2017 prevalence goals. This includes increasing coverage of HepB-BD in all countries and areas, recommending that countries use the hepatitis B vaccine OCC where infrastructure and cold chain equipment (CCE) are lacking and home deliveries are high, using innovative methods for serosurveillance among children in low prevalence settings, improving communication strategies, strengthening laboratory networks and integrating hepatitis B elimination activities with efforts towards elimination of mother-to-child transmission (EMTCT) of HIV and syphilis, other Expanded Programme on Immunization (EPI) programmes and maternal, newborn and child health (MNCH) programmes to strengthen health systems. Incorporating key health indicators and metrics could prove beneficial in the regional and global movement towards elimination of hepatitis B as a public health threat by 2030.
1. INTRODUCTION

1.1 Meeting organization

The Hepatitis B Immunization Expert Resource Panel (ERP) was created in 2007 to support efforts to reach the hepatitis B control goal in the Western Pacific Region. The panel advises on the status and strategies for achieving the regional hepatitis B control goal, supports the verification process and serves on Member State verification panels. Significant progress has been made in hepatitis B control in the Region, having achieving the 2012 and 2017 goals of reducing the regional prevalence of chronic infection among 5-year old children to less than 2% and 1%, respectively. Additional guidance is needed to sustain these achievements, set new regional targets, improve performance in priority and high-burden countries and ensure all countries in the Western Pacific Region are supported to reach both the 2012 and 2017 regional goals.

1.2 Meeting objectives

The objectives of the meeting were:

1) to review the verification status by country and provide country-specific recommendations, as necessary;

2) to review and provide guidance on progress made in national action plans developed during the 2015 Workshop on Improving and Monitoring Hepatitis B Birth Dose Vaccination, which involved six priority countries with low HepB-BD coverage; and

3) to provide guidance and review immunization targets developed in the new Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020 and the Global Health Sector Strategy on Viral Hepatitis 2016–2021 (GHSSVH).

1.3 Agenda and participants

The consultation was attended by members of the ERP, WHO Secretariat and United States Centers for Disease Control and Prevention (US CDC), representatives from the ministries of health of Cambodia, the Lao People’s Democratic Republic, Papua New Guinea, the Philippines, Solomon Islands and Viet Nam, temporary advisers and observers. Annex 1 includes the list of participants and the meeting timetable is available in Annex 2.

1.4 Appointment of officers

Dr Takaji Wakita, Deputy Director of the National Institute of Infectious Diseases, Japan, was appointed Chairperson.
2. PROCEEDINGS

2.1 Opening session

Dr Sergey Diorditsa welcomed the participants as the Responsible Officer for the ERP consultation.

Dr Susan Mercado delivered opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific Region.

Countries in the Western Pacific Region were acknowledged for their efforts in reaching the 2012 and 2017 regional goals through hepatitis B immunization. National programmes reduced chronic hepatitis B among 5-year-olds from more than 8% in 1990 to 0.94% in 2015, averting over 7 million children’s deaths between 1990 and 2014. The ERP was thanked for its direct involvement developing assessment tools, applying methods to independently verify these achievements and helping to shape regional control targets. More than 150 million people continue to live with chronic hepatitis B or C in the Region and are at risk of developing liver cancer or cirrhosis, and transmission of both diseases continues to occur. Addressing these challenges is now a key priority for WHO. Momentum for combating viral hepatitis is growing and the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020*, which was published in 2016 with input from the ERP members, was aligned with the GHSSVH in an effort to eliminate viral hepatitis as a public health threat by 2030. Despite commendable progress in the Region, there is still much work to do to eliminate hepatitis B.

Dr Mercado went on to mention that liver cancer is among the top 10 causes of cancer and death globally, and because chronic viral hepatitis is responsible for a large proportion of this disease burden in this Region, the lines between communicable and noncommunicable diseases have become blurred. Both must be addressed in a unified manner. The recommendations emanating from this meeting were eagerly anticipated.

2.2 Global overview of hepatitis B

Dr Karen Hennessey presented an overview of global initiatives related to hepatitis B control and elimination. Most important is the GHSSVH which includes a new process indicator (90% coverage of interventions to prevent perinatal transmission by 2030) and a so-called elimination target (0.1% HBsAg prevalence among children by 2030). With the introduction of the new indicator and target, modifications need to be made in monitoring programme interventions, measuring achievement of targets, such as the current recommendation to conduct nationally representative HBsAg serosurveys, and determining the validation criteria for reaching targets.

The recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE) and Immunization Practices Advisory Committee (IPAC) related to using vaccines in a controlled temperature chain (CTC) and out of the cold chain (OCC) were presented. These recommendations were a welcome step towards facilitating improved access to HepB-BD. However, further steps are needed to put these recommendations into practice. In particular, countries lacking regulatory capacity

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4 Immunization Practices Advisory Committee (IPAC) statement: Out of cold chain (OCC) and controlled temperature chain (CTC) use of vaccines; October 2016 (http://www.who.int/immunization/programmes_systems/policies_strategies/IPAC_statement_OCC_CTC_October_2016.pdf?ua=1).
or expertise on vaccine thermostability will require support to organize regulatory review and clearance to use a specified hepatitis B vaccine OCC.

Coverage with three doses of the hepatitis B vaccine (HepB3) globally has progressed, with the WHO South-East Asia Region demonstrating the biggest increase. HepB-BD coverage, while improving in the Western Pacific Region and the Region of the Americas, remains low in most other regions (Fig. 1 and Fig. 2).

Fig. 1. HepB3 coverage among infants, globally and by region, 1989–2015


Fig. 2. HepB-BD coverage, globally and by region, 2000–2015


A new requirement at the global level will be to report timely HepB-BD (birth dose given within 24 hours), as is being done in the Western Pacific Region. Countries will need to change their recording process accordingly. Guidelines for introducing and strengthening HepB-BD vaccination have been completed and are being translated into many languages.
2.3 Regional overview of hepatitis B control in the WHO European Region

Dr Liudmila Mosina reported that in the European Region 13 million people live with hepatitis B, which leads to about 60 000 deaths annually. Deaths due to hepatitis B exceed those due to all other vaccine-preventable diseases (VPDs). Key affected populations have much higher rates of hepatitis B and C than the general population. The Region comprises 53 Member States with large disparities in wealth. Countries with low disease burden are mostly in northern Europe (less than 0.5% prevalence). In mostly Central Asian countries, 5–10% of the population is chronically infected. The diversity in the Region is reflected in different immunization policies. Universal HepB-BD coverage is high in 26 high-burden countries. Some low-burden countries have universal maternal screening programmes with newborn infants born to HBsAg-positive mothers receiving HepB-BD and hepatitis B immunoglobulin (HBIG), as well as universal HepB3 vaccination for all children. Others do not implement universal vaccination, with only high-risk populations being immunized. HepB3 coverage is less than 80% in some countries because of vaccine hesitancy. This issue of vaccine hesitancy is a significant issue in the European Region.

In 2016, the European Region established its hepatitis B control goals, aiming to strengthen viral hepatitis prevention, control and treatment, with strategies and activities to be implemented by countries. WHO has set targets to measure progress and provides guidance and advocacy to Member States to strengthen hepatitis B control. Technical support is given to priority countries.

Some of the high-burden countries lack funding to conduct serosurveillance, while many low-burden countries are reluctant to do surveys and may experience public resistance, resulting in poor availability of data to monitor progress.

The European Region established a technical working group of experts to provide advice on improving hepatitis B control, monitor progress and define targets to achieve control. Plans are afoot to develop a regional standardized protocol for serosurveys to assess HBsAg prevalence using available serum specimens or convenience samples in countries with very low prevalence.

Dr Mosina was asked about the prevalence of hepatitis B among immigrants from high endemic countries living in Europe. She responded that legal immigrants are vaccinated and pregnant women are screened as part of the routine programme. However, illegal immigrants are not screened and their hepatitis B prevalence is currently unknown. In this situation, recommending universal HepB-BD may be necessary. However, some countries have resisted changing their immunization policy. A suggestion was made to screen all immigrants for HBsAg.

2.4 Regional overview of hepatitis B control in the WHO South-East Asia Region

Dr Sigrun Roesel shared that poliomyelitis (polio) eradication, tetanus, measles and rubella programmes have been prioritized in the South-East Asia Region. WHO estimates that about 100 million people are living with chronic hepatitis B (about 5%) in the Region, with an estimated 300 000 deaths from hepatitis B annually. All countries in the Region routinely provide HepB3.

According to the WHO–UNICEF estimates, HepB3 coverage has increased from 53% in 2010 to 87% in 2015. HepB3 coverage is estimated to be more than 90% in seven countries (Bangladesh, Bhutan, Democratic People’s Republic of Korea, Maldives, Nepal, Sri Lanka and Thailand), although it had not yet reached this level in India, Indonesia, Myanmar and Timor-Leste by 2015. Among the seven countries that provided HepB-BD in their vaccination schedule in 2015, coverage was less than 80% in Bhutan (78%) and India (44%), between 80% and 95% in Indonesia, and more than 95% in the Democratic People’s Republic of Korea, the Maldives and Thailand. Timor-Leste introduced HepB-BD in January 2016. Bangladesh, Myanmar, Nepal and Sri Lanka do not provide HepB-BD, although both Myanmar and Nepal may reconsider full or partial introduction of the birth dose as part of their national viral hepatitis control strategies.
In line with the current GHSSVH,² the WHO Regional Committee for South-East Asia recently endorsed a viral hepatitis control strategy and the Department of Communicable Diseases is finalizing a regional action plan on viral hepatitis control. Based on available seroprevalence data and modelling studies, the target of achieving 1% or less HBsAg prevalence among 5-year-old children by 2020 is feasible in the Region, subject to availability of resources and implementation of adequate preventive strategies by all stakeholders. In June 2016, the regional immunization technical advisory group recommended to adopt the global control target of 1% or less HBsAg prevalence among 5-year-old children. Accelerating hepatitis B immunization towards this regional control target will be described in a detailed activity and resource requirement plan following a comprehensive consultation process with countries, relevant experts and partners.

2.5 Regional overview of hepatitis B control in the WHO Western Pacific Region (with EPI update)

Dr Joseph Woodring presented the Global Vaccine Action Plan 2011–2020 (GVAP),⁵ which was endorsed by the Sixty-fifth World Health Assembly in 2012,⁶ and the six strategic objectives to achieve the Decade of Vaccines vision. In 2014, the Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific⁷ was endorsed by Member States, highlighting essential strategies and priority actions for achieving the goals and strengthening immunization programmes in the Region, including accelerated hepatitis control with a target to achieve a chronic infection rate of less than 1% among 5-year-olds. Coverage of HepB3 reached at least 90% in 25 countries and areas, and 95% in 18 countries and areas in the Region by 2015.

Liver cancer caused by chronic hepatitis B in the Western Pacific Region accounts for about 64% of the global liver cancer burden. China alone has about 2 million men and 700 000 women with 5-year cancer prevalence, and the hepatitis B virus (HBV) infections cause an estimated 85% of liver cancer. In the Region, deaths related to hepatitis B and C far outweigh the number of deaths from tuberculosis, malaria and HIV combined.

Twenty countries and areas in the Western Pacific Region adopted universal hepatitis B vaccination before 1990, followed by 11 countries and areas in the 1990s. An additional four countries began universal HepB3 introduction between 2000 and 2015. Last October, Japan began universal monovalent HepB3 introduction. Currently, only New Zealand and Japan selectively vaccinate children of HBsAg-positive mothers, while all other countries in the Region provide universal HepB-BD. Coverage of HepB3 and HepB-BD is high in the Region. Following a number of activities, in 2013, the target was set to reduce HBsAg prevalence to less than 1% by 2017. In May 2016, an article published in Vaccine showed that the 2017 regional goal of attaining less than 1% HBsAg prevalence among 5-year-olds was met, with an estimated regional prevalence of 0.93% among children born in 2012.⁸ As a result of immunization programmes, 7 million deaths and 37 million chronic infections have been averted among children born between 1990 and 2014.

Universal infant hepatitis B vaccination in the Pacific islands has resulted in a dramatic reduction in the prevalence of chronic hepatitis B infection, dropping from 8.4% in the 1980s to 2.5% in the 1990s and finally to 0.2% in the 2000s. Cook Islands, Niue, and Tokelau have established strong vaccination programmes towards decreasing the burden of hepatitis B among children. Kiribati still needs to improve vaccination coverage to achieve the less than 1% HBsAg target.

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⁷ Regional framework for implementation of the global vaccine action plan in the Western Pacific. Manila: WHO Regional Office for the Western Pacific; 2014 (http://www.wpro.who.int/about/regional_committee/65/documents/wpr_r65_08_epi_en.pdf?ua=1).
The World Health Assembly’s three interlinked global health sector strategies on HIV, syphilis, and hepatitis B were published in 2016, aiming to obtain zero new HIV infections among infants by 2020, fewer than 50 cases of congenital syphilis per 100,000 live births in 80% of countries by 2030, and less than 1% HBsAg seroprevalence in children by 2020.

The *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* recommends that countries should aim to further reduce mother-to-child transmission once they have achieved less than 1% HBsAg prevalence among 5-year-old children. The 2015 regional HepB-BD and HepB3 coverage is estimated at 88% and 94%, respectively, short of the 95% HepB-BD and HepB3 targets by 2017.

Furthermore, the national policy for vaccinating health-care workers (HCWs) against hepatitis B should be established in more than 80% of countries and areas by 2017 and in 100% by 2020. By 2015, 20 of 36 (56%) countries and areas indicated that they had a HCW hepatitis B vaccination policy. A survey was conducted to discover best practices and help establish and improve the national HCW hepatitis B vaccination policy among countries and areas with limited or no current HCW hepatitis B policy. The definition of HCW needs to be clarified, and those who test positive require appropriate follow-up and treatment.

Following the release of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020*, a marketing campaign was launched to raise public awareness, advocate and promote activities related to viral hepatitis and drive policy. To date, five countries have national action plans for viral hepatitis: Australia, Mongolia, New Zealand, Japan, and Viet Nam. Fiji, Kiribati, Malaysia, and Philippines are currently developing national action plans for viral hepatitis; and the WHO Regional Office for the Western Pacific has supported five countries to evaluate their viral hepatitis disease burden. Economic analyses were conducted for hepatitis B and C in China and hepatitis C in Mongolia. Country assessments of viral hepatitis situations and responses in Fiji, Kiribati, Mongolia, the Philippines, and Viet Nam have informed national policy development.

The WHO Regional Office for the Western Pacific has provided support to Member States in the following areas: increasing health facility deliveries and conducting national birth dose assessments to identify barriers to HepB-BD (Cambodia, Lao People’s Democratic Republic, Philippines, and Viet Nam); increasing hepatitis B education during antenatal care (Kiribati), improving links with communities and outreach vaccination (Kiribati, Papua New Guinea, and Viet Nam); and advocating the use of hepatitis B vaccine OCC where needed.

The Regional Office was acknowledged for the excellent progress made on hepatitis B prevention.

Participants contended that despite the evidence available for using the hepatitis B vaccine OCC, governments remain reluctant to make recommendations and implement OCC because of strict regulations limiting use outside of labelling. Technically only certain vaccines can be used OCC, and there is little motivation for companies to change the labelling. It was suggested that WHO and UNICEF might have leverage by refusing to buy vaccines from companies that will not revise labelling. The Food and Drug Administration could also be approached to assist with this issue. WHO headquarters should work with countries to improve acceptance of OCC vaccines.

It is encouraging that control goals have been set for all regions. With the imminent achievement of polio eradication, hepatitis elimination could be one of the next big achievements. New approaches need to be reviewed to avoid hepatitis B becoming another vertical target, with the goal to strengthen overall health systems in achieving national and subnational health targets. Participants recognized that improving the rate of facility births will assist with surveillance and increase HepB-BD coverage.

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2.6 Sustaining progress among verified countries

As of February 2017, 16 countries and areas in the Western Pacific Region have been verified to have reached a hepatitis B prevalence of less than 1% among children. These include (year of verification): Republic of Korea (2008), Macao SAR (China) (2008), Hong Kong SAR (China) (2011), Malaysia (2011), Australia (2012), China (2012), Mongolia (2012), New Zealand (2012), Palau (2013), Brunei Darussalam (2013), Cook Islands (2013), American Samoa (2014), Singapore (2015) and Tokelau, Guam and French Polynesia (2016).

Dr Woodring presented data for these 16 countries and areas on vaccine coverage in terms of timely HepB-BD, any HepB-BD and HepB3 coverage, as well as district-level coverage of HepB3 and timely HepB-BD.

For the 2015 fiscal year, using the World Bank’s income classification based on its Atlas method, 11 countries and areas in the Western Pacific Region were divided into low-income, lower middle-income, upper middle-income and high-income economies according to their gross national index (or GNI). 12 Fig. 3 shows the status of verified countries and areas by income classification. The vast majority that have been verified are high- and upper middle-income countries and areas.

**Fig. 3. Status of verified countries and areas in the WHO Western Pacific Region by World Bank income classification in 2015**

![World Bank Income Classification](image)

Most high-income countries that were verified as having achieved the hepatitis B control goal reported levels of any HepB-BD coverage sustained at more than 95% (Australia, Japan and New Zealand did not report HepB-BD coverage) since 2000. All countries and areas reported very high HepB3 coverage, and most reported sustained high coverage since 2010, except for Guam, the Commonwealth of the Northern Mariana Islands and Nauru. By the end of 2015, all upper middle-income countries and areas, excluding Malaysia with 88% coverage, had timely HepB-BD coverage above 95% and all achieved HepB3 coverage above 85%. Among low middle-income countries and

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12 GNI per capita is the dollar value of a country’s financial income in a year, divided by its population, reflecting the average income of a country’s citizens. Low-income economies have a GNI per capita of US$ 1025 or less; lower middle-income economies have a GNI per capita of US$ 1026–US$ 4035; upper middle-income economies have a GNI per capita of US$ 4036–US$ 12 475; and high-income economies have a GNI per capita of US$ 12 476 or more.
areas, Mongolia is the only one to have been verified, and finalized seroprevalence data from Solomon Islands are anticipated shortly. However, coverage in these countries and areas had improved to over 50% by the end of 2015, although the Philippines has the lowest HepB3 coverage (54%) which was apparently related to pentavalent vaccine stock-out that year.

Among verified countries and areas, high vaccine coverage has been maintained. However, there are insufficient data from coverage surveys to validate administratively reported coverage. The use of the World Bank categorization highlights that additional work is necessary to ensure immunization equity among all Member States in the Western Pacific Region.

2.7 Documenting impact (countries with recent or planned serosurveys for verification)

Dr Rania Tohme presented the status of hepatitis B serosurveys conducted in 2015–2016 in the Western Pacific Region and serosurveys planned for 2017. Solomon Islands conducted a school-based serosurvey among 6–7-year-old children. Preliminary results showed an HBsAg prevalence of 3.1% (95% confidence interval [CI]: 2.0–4.8%), indicating that the country has not reached the regional hepatitis B control goal of either less than 2% or less than 1% HBsAg prevalence and needs to improve timely HepB-BD coverage and HepB3 coverage. The Federated States of Micronesia is completing a school-based census survey among grade 1 students. The Republic of the Marshall Islands has recently completed the survey and will be analysing the data shortly. There are no updates from New Caledonia on the status of a survey that started in 2015. For 2017, Cambodia, Fiji and the Philippines have expressed interest or are in the process of survey design and implementation, while it has been difficult to get movement in survey implementation in Nauru, Tonga and Tuvalu.

2.8 Verifying achievement of low HBsAg seroprevalence targets

Dr Tohme shared potential methods that could be used to verify the achievement of hepatitis B control goals of less than 0.5%. Thus far, 19 countries and areas in the Western Pacific Region have less than 0.5% serosurvey-derived HBsAg prevalence; two countries have 0.5–1% HBsAg prevalence; five countries have more than 1% HBsAg prevalence (four with more than 2% HBsAg prevalence); and 10 countries are awaiting serosurvey data. Nationally representative cluster serosurveys have been the norm so far to verify hepatitis B control. However, the sample size required to verify the achievement of 0.5% or less HBsAg prevalence (precision: ±0.25%, design effect=1.5; non-response: 15%) is about 6000 children, while the estimated sample size required for less than 0.1% HBsAg prevalence (precision: ±0.05%, design effect=1.5; non-response: 15%) would be more than 27 000 children. Therefore, alternative methods for verification need to be explored.

One alternative method is the use of classification serosurveys based on the updated WHO vaccination cluster survey guidelines. The first approach is to conduct classification serosurveys either at the national or lower levels to classify seroprevalence as very likely below “pass” or as above a target “fail” rather than having a precise estimate of seroprevalence. These classification serosurveys require a smaller sample size (for less than 0.5% HBsAg prevalence about 2000 children and for less than 0.1% HBsAg prevalence about 10 000 children), are less costly and require fewer clusters per strata (typically 15) compared to traditional serosurveys (typically 30). In addition, when classification surveys are implemented in more than one district, it is possible to combine data from the lowest levels to estimate point seroprevalence at the higher level.

Another method for verification of low HBsAg targets is to implement a two-step approach. In the first step, the country is classified as high, medium or low risk for HBV infection based on preset criteria such as HepB-BD and HepB3 coverage, chronic HBV prevalence among women of childbearing age, hepatitis B e-antigen (HBeAg) prevalence, proportion of high-risk groups,

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proportion of home births with skilled birth attendants (SBAs), etc. In the second step, an HBsAg classification serosurvey is conducted in only high-risk areas. If those high-risk areas “pass” (by achieving an HBsAg prevalence less than a specified target), it is assumed that the whole country or area has passed and can be verified as meeting a specific target. This two-step approach can also be used in countries and areas that already have low HBsAg prevalence but want or need to track progress in underperforming areas. It is important to note that the accuracy of the two-step method depends on the availability, quality, representativeness and timeliness of the data collected during the first step. Therefore, the two-step approach might not be applicable to all countries and areas.

A third approach to save resources is to include hepatitis B testing in other planned surveys such as the Demographic and Health Survey (DHS), Multiple Indicator Cluster Survey (MICS), and HIV, hepatitis and malaria surveys. This approach would enable testing for other VPDs and diseases of interest to the country and, when using platforms such as the multibead assay, could simultaneously test for several diseases with a minimal amount of dried blood spots.

Dr Tohme was asked about studying small populations such as in the Pacific island countries and recommended that because of their small size, serosurveillance in these countries would not be the same as in bigger countries. In such a situation, Dr Tohme suggested that the whole population could be studied.

An ERP member raised concerns that focusing on hepatitis B prevalence at a subnational level and on high-risk populations in each country may deter countries from continuing universal vaccination. However, Dr Tohme assured the participants that the objective of these types of surveys is to identify underperforming areas rather than emphasize only high-risk populations. Well-performing areas must also be sampled, to ensure that they continue to perform. An approach to measuring programmatic achievement at a national level is required. Conducting traditional serosurveys in countries with low prevalence is and will remain extremely resource intensive. Traditional surveys usually require 30 clusters, whereas the classification method requires only 15 clusters.

This two-step classification method will be first implemented in Colombia in 2017.

2.9 Development in prevention of mother-to-child transmission (PMTCT) of hepatitis B in China

Dr Cui Fuqiang explained that China had an estimated population of 1.36 billion in 2015, with more than 16 million children under the national child health-care scheme. The presentation covered three main issues: consolidating the routine hepatitis B vaccination programme; enhancing EMTCT of HIV, hepatitis B and syphilis (or triple elimination) under the maternal and child health platform; and augmented interventions for mothers at risk for hepatitis B transmission during birth. In the past two decades, China has implemented a universal infant hepatitis B vaccination project, and great progress has been documented from three nationwide serosurveys. Even though fewer than 1% of children have a chronic hepatitis B infection, because of large numbers in China, about 50 000 infants become infected each year. China conducted a post-vaccination serologic testing (PVST) pilot project launched in 2016 in four provinces in collaboration with the WHO Representative Office in China to evaluate the effect among those infants born to HBsAg-positive mothers who were given timely HepB-BD plus HBIg and to collect evidence for future policy-making. Since 2015, China has implemented a national policy covered by the central government annual budget to provide free screening to pregnant women for HIV, syphilis and HBV. As of 2015, 96% of the pregnant women were screened, and vaccines and HBIg were given to those infants born to HBsAg-positive mothers. In addition, in order to further reduce mother-to-child transmission of hepatitis B, national experts have introduced an operational research study called the Shield Project and are providing antiviral treatment for pregnant women with high hepatitis B DNA in the third trimester (normally after 28 weeks), to reduce the hepatitis B viral load and further prevent mother-to-child transmission (PMTCT).
Dr Cui was asked about stopping antivirals after initial treatment during pregnancy. He responded that these antivirals are continued if the mother is determined to need them, but typically antivirals are stopped after birth.

The hepatitis B DNA threshold for starting antivirals was discussed and this is still being debated. In Australia, the threshold to start antiviral therapy in pregnant women is 10 million copies/mL.

In response to a question about systems for tracking infants and linkage to other programmes, Dr Cui mentioned that current studies on antivirals in pregnant women in China are being conducted in the academic sphere and are not part of routine government services. However, results from these studies might impact future government programmes.

Hepatitis B DNA testing is not available at the county level in China, with the more cost-effective HBeAg testing currently recommended. HBeAg testing can be done as a rapid test. If a mother is HBeAg-positive, then hepatitis B DNA testing is recommended to decide whether to initiate antiviral therapy.

A participant commented that in the future the antiviral agent tenofovir disoproxil fumarate (TDF), used in the HIV programme, may be an option instead of HBIg as it remains unavailable in many countries. TDF is relatively cheap if used for 3 months. It was again emphasized that for some countries and areas where antivirals and HBIg are largely unavailable focus should remain on improving vaccination coverage, especially timely HepB-BD. Countries will require assistance with making decisions about interventions for PMTCT of hepatitis based on data that are becoming available regarding the use of antivirals in pregnant women. A suggestion was made for WHO to develop and provide evidence-based decisions for countries with high HepB-BD coverage to determine the incremental cost of increasing their perinatal programmes to either include antiviral therapy for mothers with high viral loads during their third trimester or HBIg to newborns of HBsAg-positive mothers. This guidance should also include instruction on when countries should consider expanding their perinatal programmes and when to remain focused on improving HepB-BD coverage to a certain threshold. Programmatic responses from studies in China should provide more results on which to base recommendations.

2.10 OCC pilot projects

Dr Tohme presented the evaluation of an OCC HepB-BD pilot project that was implemented in three provinces in Solomon Islands during August 2015 through February 2016. A total of 14 health facilities were selected from three provinces (Guadalcanal, Makira and Western). In each health facility, single-dose monovalent hepatitis B was kept OCC for 28 days with regular monitoring of temperature and vaccine wastage. Overall, cumulative 24-hour HepB-BD coverage increased by 156%, from 23% during the 6 months prior to implementation of OCC to 59% after implementation of the pilot project. A significant increase in timely HepB-BD coverage was observed for both health facility (30% to 68%) and home births (4% to 24%). Temperature deviations over 37 °C were rare (0.03% of recorded time points). Vaccine wastage was high, however, with 34% of vaccine doses discarded at 28 days. Vaccine stock-outs were also a challenge, with HCWs unable to pick up vaccines regularly from provincial stores. HCWs reported that using OCC HepB-BD facilitated availability but that vaccine delivery and forecasting needed to be improved. Recently, the Interagency Coordinating Committee endorsed scaling up the use of OCC HepB-BD nationwide in Solomon Islands.

The WHO Regional Office for the Western Pacific recommends using OCC HepB-BD where needed with approval of the national regulatory authority. There is an increasing body of evidence to support the thermostability of the hepatitis B vaccine and the contribution of OCC to significantly increasing timely HepB-BD coverage. Nevertheless, there has been no progress in scaling up the implementation of OCC HepB-BD at the national level in countries that have high rates of home births or lack adequate cold chain capacity. Countries in the Western Pacific that still have low HepB-BD coverage
and have not reached regional control goals should consider nationwide implementation of the OCC policy, especially now that the recent SAGE recommendation encourages use of the OCC policy for HepB-BD if countries follow IPAC recommendations.3,4

Based on results from numerous OCC studies conducted throughout the Region, it remains compelling to implement OCC programmes to improve HepB-BD coverage.

A suggestion was made to look at innovative methods to deliver the vaccine and manage vaccine stocks, such as hiring laypeople to assist with vaccine delivery to each clinic usually staffed by a sole HCW who cannot readily close a clinic to get the vaccine from the provincial store; learn how to manage vaccine stocks; and ensure that midwives who attend home deliveries have a stock of vaccine that can be used OCC.

A recommendation was made that for countries that lack regulatory authorities WHO should assist with the pre-qualification process and provide a tool or product to assist countries with decision-making. In addition, WHO should consider urging procurement agencies to include in their tender requirements and on their labels the suitability for CTC use of monovalent hepatitis B vaccines. This requirement would be similar to the 2007 WHO/UNICEF joint policy statement urging all vaccine self-procuring countries and donor agencies to include vaccine vial monitors among the minimum requirements for vaccine purchases and vaccine donation agreements.

### 2.11 Establishment of the viral hepatitis laboratory network with examples of other WHO-coordinated VPD laboratory networks in the EPI for the WHO Western Pacific Region

Ms Varja Grabovac discussed several guiding principles that should be considered when establishing a laboratory network: develop clear objectives, roles and responsibilities; utilize existing structures; map and assess capacity of existing laboratories; and identify and secure resources, both financial and human. It is essential to standardize testing methods and protocols, develop manuals and training programmes, validate assays, and establish strong quality assurance/control programmes and data management and reporting systems.

In WHO, the EPI coordinates several laboratory networks for VPDs, including polio, measles and rubella, Japanese encephalitis, rotavirus and invasive bacterial VPDs. These VPD laboratory networks are built on a three-tier, pyramid structure: the first tier, the backbone, is made up of national/subnational laboratories responsible for primary testing which are in direct communication with national programmes; the second tier consists of regional reference laboratories responsible for more advanced characterization of pathogens, quality control of national labs and training; and the third tier includes global specialized laboratories responsible for advanced testing and confirmation, provision of reference materials and standards, quality control testing, training and development of new technologies. Laboratory networks are linked to surveillance and global strategy and goals, provide evidence of burden of disease and vaccine introduction, evaluate disease control and strengthen quality assurance in participating laboratories.

For some time, the ERP has recognized that the development of a regional laboratory network for viral hepatitis is essential in the Western Pacific, modelled on similar long-standing networks such as those for polio and measles. This need has become more urgent given the recent endorsement of the global and regional viral hepatitis strategies that contain specific indicators and targets relating to laboratory capacity, access to diagnosis and need for laboratory support for strategic information systems. Indeed in the Regional Action Plan for Viral Hepatitis in the Western Pacific, the establishment of a regional laboratory network is a 2017 milestone.

Dr Ben Cowie discussed the substantial progress since the last ERP meeting in the development of a regional laboratory network, with contribution of funds and staff resources to the WHO Regional Office for the Western Pacific by the Korea Centers for Disease Control and Prevention to facilitate
its establishment. Together with partners including regional collaborating centres and the US CDC, the regional laboratory network will establish and formalize relationships between regional and national reference laboratories; facilitate quality control processes to broaden access to reliable viral hepatitis diagnosis and monitoring; and ensure that capacity exists in focus countries to gather essential strategic information for national hepatitis programmes. On this last aspect, a range of surveillance- and laboratory-focused workshops are being planned in several initial countries, commencing in Mongolia in April 2017, combining both strategic information and laboratory capacity elements.

Responding to concern that laboratory capacity would be largely unavailable in smaller countries, Dr Cowie stated that the establishment of a viral hepatitis network in high-burden countries should be able to support smaller countries and areas as well. Development of capacity in larger countries is a first step and the plan is to extend capacity beyond this in the future. There is a need to expand capacity also in a stepwise fashion starting with core testing and then adding on capacity to perform more complex investigations in a gradual fashion.

Members were asked to send recommendations regarding requirements for the establishment of the viral hepatitis regional laboratory network and lessons learnt from other programmes such as HIV which could apply.

2.12 Country presentations

2.12.1 Lao People’s Democratic Republic: HepB-BD improvement activities

Mr Phommachanh gave a presentation on HBV which is highly endemic in the Lao People’s Democratic Republic, with an estimated prevalence rate of over 8%. A quadrivalent vaccine including hepatitis B was introduced in 2001 and monovalent HepB-BD was first introduced in 2004 with phase-wise national expansion by 2008. The current vaccination schedule is monovalent HepB-BD within 7 days, and a pentavalent vaccine (diphtheria, tetanus, pertussis, haemophilus influenzae type B and hepatitis B, or DTP-Hib-HepB) at 6, 10 and 14 weeks after birth. Challenges to administering within 24 hours include the following: most births occur at home usually without an SBA, the terrain is difficult with scattered populations that are hard to reach and cold chain capacity is inadequate in parts of the country. HepB-BD coverage has increased from 24.2% in 2012 to 50% in 2015.

The presentation focused on a pilot study of using OCC HepB-BD that was conducted in the country.14 Two provinces and two districts in each province were selected, with 15 villages randomly selected in each district. Children aged 2–8 months (born during study) and 14–20 months (born before study) were eligible. A vaccine was provided OCC during the study period and interviews were conducted with HCWs. A significant increase in timely HepB-BD coverage was noted during the intervention, from 12% before the study to 40% during. Children in the most remote villages were the least likely to get HepB-BD. The vaccine was stable for 28 days; however, there was a large amount of wastage of vaccine due to use of multidose vials. Interviews demonstrated that HCWs were well informed about OCC use of vaccines. Vaccines could be retrieved monthly from the district, and SBAs were more likely to bring the vaccine with them if the hepatitis B vaccine is stored OCC.

The Lao People’s Democratic Republic is planning to scale up the use of OCC HepB-BD to districts that lack CCE. The implementation will be evaluated within a year. WHO was requested to support the country’s development of national guidelines on OCC and the development of standard operating procedures for HCWs and district managers, which have been sent to the national regulatory authority and the Ministry of Health. Training of HCWs on OCC is ongoing. Monthly monitoring is required by the national EPI team with development partners.

The presenters for the country were asked about using OCC on a national scale. Participants heard that WHO is assisting with the development of a national guideline for OCC which is awaiting approval from the Ministry of Health.

At the moment, timely HepB-BD is not being recorded separately from any HepB-BD and the country representatives were asked about this, responding that once this is changed in the national guidelines, HCWs will then follow the guideline.

Concern was raised about why HepB-BD coverage did not increase in remote areas. It was reported that HCWs needed to be notified of delivery in remote areas and rely on this from village health volunteers who may be delayed. During the rainy season, even if they are aware of births, HCWs cannot travel because of poorer access to these remote villages.

2.12.2 Papua New Guinea: HepB-BD improvement activities

Mr Johnnie Arava reported that Papua New Guinea has a population of 7.8 million people, with 89 districts and over 800 ethnic groups. There are over 600 islands, making access to rural areas difficult and costly. Although there are many facilities and health-care staff spread around the country, three people currently work on EPI with 22 provincial vaccine stores. Immunization coverage for HepB3 is about 60%, but timely HepB-BD coverage is only about 20%. HepB-BD is not given in all of the 766 facilities that offer immunization. Insufficient supervision, lack of CCE, poor information among public workers and HCWs, and high dropout rates are factors affecting vaccination rates.

Papua New Guinea has developed four strategies and related activities to improve hepatitis B vaccine coverage:

- **Strategy 1**: The health department mandated that all facilities provide HepB-BD within 24 hours of delivery with special microplans to target hard-to-reach areas. Village health volunteers, women’s groups, chiefs and elders have been engaged to assist with encouraging institutional deliveries and delivery notification within 6 hours at the health facilities. It is now compulsory for all school-age children enrolling in school to be fully immunized.

- **Strategy 2**: The provincial authorities agreed to mobilize resources to ensure vaccines are provided at all health facilities, procure CCE, and train HCWs on Early Essential Newborn Care (EENC), with 42% of birthing facilities currently covered in the training. Plans are in place to introduce OCC for hard-to-reach areas in consultation with WHO partners, and to shift to single-dose vials to avoid wastage.

- **Strategy 3**: Communication strategies using print media and mobile telephone networks are in development to advocate for EENC and HepB-BD.

- **Strategy 4**: Plans are afoot at a national level to identify low-performing provinces or districts and to provide regular supervision, on-the-job training and quarterly monitoring and evaluation.

*Next steps*

- Use the OCC strategy for HepB-BD in hard-to-reach areas across the country.
- Continue with monitoring and evaluation of Special Integrated Routine EPI Strengthening Program (SIREP) strategies.
- Train HCWs on vaccine management, community outreach and data management across the country.
- Provide CCE for all health facilities across the country.

The presenters were asked about the approval process in Papua New Guinea to use vaccine OCC in the country. Working in conjunction with WHO, UNICEF and faith-based organizations, a proposal
was submitted to the Interagency Coordinating Committee and further to the child health advisory committee to use OCC in the country. The proposal is awaiting approval by the senior executive management level in the health secretariat. In response to a question from a meeting member whether Uniject™ OCC is available in the region, presenters explained that Uniject™ was originally available in one province in Papua New Guinea as part of a project; however, this pilot could not be scaled up due to the high costs associated with purchasing and shipping Uniject™. The company that makes Uniject™ has not made it available at scale.

Meeting participants discussed ways of working across EPI and maternal and child health programmes to motivate mothers to deliver in health facilities by informing them about HepB-BD and encouraging them to receive this as part of EENC and childcare. Karen Hennessey mentioned that countries with access to Gavi funds may include requests for support for innovative ways of increasing and strengthening facility births as a mechanism for health systems strengthening. Examples from China were cited where collaboration between EPI and maternal and child health programmes helped encourage women to deliver in hospitals and then increased HepB-BD coverage. Dr Joe Woodring cited examples of education programmes to teach women and communities about the importance of hepatitis B vaccination in Kiribati by village health volunteers and by HCWs.

2.12.3 Viet Nam: HepB-BD improvement activities

Professor Dang Duc Anh discussed the scaling up of immunization in Viet Nam since 1997 when immunization started in two provinces. Since 2010, 63 provinces have provided HepB-BD, followed by a pentavalent vaccine at 2, 3 and 4 months. Viet Nam conducted a serosurvey in 2011 that showed a 2% prevalence of HBsAg among 5-year-old children. HepB3 coverage reached 95% in 2016 although coverage has previously intermittently dropped following adverse events following immunization (AEFIs) and stock-outs. HepB-BD was implemented in 2003 and timely birth dose has been reported since 2005. In 2015, HepB-BD coverage was 74% and timely birth dose coverage was 70%. AEFIs in 2007 and 2013 have resulted in decreases in HepB3 and timely birth dose coverage. In 2013, the Viet Nam Ministry of Health withdrew the HepB3 vaccine for several months following AEFIs that were ultimately not related to HepB-BD vaccine. Following declines in both HepB-BD and HepB3 coverage in 2013, HepB3 coverage has improved to over 90% since 2014 and coverage of HepB-BD was almost 70% in 2016.

Interventions to improve HepB-BD coverage in Viet Nam in 2016

In the annual plan for the national EPI programme, prioritization was given to improve timely HepB-BD. Official documents from the Ministry of Health and from the Prime Minister have been released to support timely birth dose in provinces with low coverage and for mobile vaccination teams to be placed in most of the hard-to-reach areas.

Interventions to improve HepB-BD coverage were conducted in three northern mountainous provinces with support from WHO. Starting in March 2016, these activities included training HCWs, meeting village HCWs, integrating communication about HepB-BD into antenatal care, setting up immunization posts in polyclinics with supply of CCE, and providing HepB-BD in commune health centres and polyclinics. Supportive supervision and monthly feedback from provincial health service centres to all district health centres and provincial hospitals were provided.

As a result of this programme, HepB-BD coverage increased in Yen Bai province from 31% in 2015 to 56% in 2016, and from 19% in 2015 to 60% in 2016 in Cao Bang province, with select districts showing significant increases in HepB-BD coverage.

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Challenges for HepB-BD in Viet Nam

In the mostly mountainous provinces and some urban provinces, HepB-BD coverage remains below 50%. In mountainous areas, where the rate of home deliveries is still high, people have difficulty accessing services and obtaining a constant supply of the vaccine. In the urban areas that were affected by the AEFIs, some HCWs remain reluctant to vaccinate, hospitals are inconsistently implementing timely HepB-BD and some families refuse vaccination.

Activities to address the low HepB-BD coverage in Viet Nam with the support of WHO include:

- Strengthening management at provincial and district levels to improve collaboration between curative and preventative sectors;
- Scaling up activities in other mountainous provinces;
- Holding technical workshops for doctors at hospitals in urban areas with very low vaccine coverage;
- Collaborating with MNCH to explore methods to improve facility deliveries;
- Integrating communication on HepB-BD into antenatal care at health facilities;
- Exploring ways to improve awareness about the benefits of the hepatitis B vaccine for mothers and HCWs;
- Training journalists about vaccines;
- Securing supplies of the hepatitis B vaccine to avoid stock-outs;
- Improving the supply of CCE at all facilities; and
- Enhancing provincial review committee training for appropriately and timely review of AEFIs.

The ERP members acknowledged the efforts to improve HepB-BD coverage in Viet Nam. However, with concern that coverage in 2016 was still below 70% and stock-outs occurred last year, a question was raised about processes to reduce stock-outs. The response was that improved efforts are being made this year to work more closely with domestic manufacturers to provide sufficient supply. However, HCWs need to get the vaccine from district supplies to babies delivered at home, which remains challenging.

One of the barriers discussed at previous meetings was the need for doctors to sign a form taking responsibility for giving the vaccine. This form remains a requirement in some areas and is a deterrent for doctors who in other countries and areas in the Region have standing orders for HepB-BD administration.

Viet Nam has not changed the regulation that requires vaccination to be done only at health centres, but attempts are being made to improve this by sending mobile teams to vaccinate at home and HCWs are receiving training for vaccination. The solution to improve HepB-BD in Viet Nam is for babies to access EENC as part of MNCH, which has timely HepB-BD integrated into it.

The hepatitis B vaccine is free of charge in Viet Nam and the national policy is to produce the vaccine locally. Quality assurance has been given by WHO. Some families, fewer than 5% in large cities, prefer to get vaccinated privately, agreeing to pay out of pocket. There is a perceived lack of trust in the domestically produced vaccine, which is used as part of EPI, and anti-vaccine groups are influential in Viet Nam. Irresponsible media coverage has contributed to the negative public perception of hepatitis B vaccines. To address this issue, workshops were held in 2016 to brief journalists about the safety and efficacy of vaccines. As a result, reporting has improved and more positive media coverage is occurring. The European Region reported having a similar experience and has a communication team with prepared documents on how to build resilience, get media on board, talk to patients and provide HCW training on vaccine safety and efficacy. The US CDC is developing material on how to provide timely and risk communication responses when AEFIs occur after HepB-BD. These materials will be available to be shared with other countries and regions.
Dr Tohme suggested that key affected populations or behavioural studies should be performed in Vietnam to identify remaining obstacles for timely HepB-BD administration.

2.12.4 Cambodia: HepB-BD improvement activities

Mr Ork Vichit described the hepatitis B vaccination schedule in Cambodia, which includes timely HepB-BD within 24 hours or a catch-up dose within 7 days of birth. This is followed by a pentavalent vaccine at 6, 10 and 14 weeks. Cambodia stopped the OCC vaccination policy (2009–2012) because nurses were keeping vaccines beyond the specified period and the country preferred to concentrate on getting women to deliver at facilities. Collaboration of EPI and midwives is working well in some places, but in others, midwives will vaccinate. A public–private partnership exists whereby the government provides vaccines to some private polyclinics free of charge, with the commitment that the numbers immunized will be reported into the government information system. HBsAg screening of pregnant women is only done at selected hospitals.

Fig. 4 shows that HepB-BD has greatly increased since 2006 and was 90% in 2016. This increase was in conjunction with a rise in health facility deliveries and presence of SBAs. HepB3 has remained above 90% since 2008. Almost all vaccines are given in health facilities throughout Cambodia, with 5% from facility outreach. The drop in HepB-BD in 2013 was due to a stock-out (Fig. 4).

**Fig. 4. Hepatitis B vaccination coverage (timely HepB-BD and HepB3), SBAs, and health-care facility delivery rates in Cambodia, 2006-2016**

*Source: Demographic and Health Survey 2014.*

**Improvement activities**

Guidelines on HepB-BD have been printed and distributed to all health-care levels. Training has been conducted with midwives and new staff on HepB-BD for national and referral hospitals. During the 2013 World Immunization Week, the WHO Regional Office for the Western Pacific helped develop a video and radio spot on HepB-BD for airing on public media.

Raising community awareness has been addressed through several mechanisms, and media coverage has improved. Midwives receive an incentive of US$ 15 per delivery from the government. Health infrastructure along with other infrastructural facilities including roads, electricity, water and transport have also been improved and upgraded.
Challenges

High staff turnover, migration from rural to urban areas, children living with grandparents or caregivers other than parents who may not take them for vaccination, and low priority given to communication and education activities remain programmatic challenges.

Next steps

- The immunization policy needs to be updated.
- Continuous effort is needed to maintain the high coverage of routine vaccination.
- Training on immunization must be ongoing, given the high staff turnover.
- Strengthening of EPI and midwife collaboration is required.
- Vaccines should be provided directly to private doctors and incentives should be provided to refer children to public clinics for vaccination.
- The first nationally representative hepatitis B serosurvey is planned to be conducted in March–April 2017 to ascertain HBsAg prevalence among 5–7-year-olds and their mothers.

Cambodia was congratulated for its improvement in HepB-BD and HepB3 coverage.

The government has been proactive in managing adverse events, and it supports and protects staff so that there is no panic in case AEFIs occur. A committee was formed to properly manage misinformation and communication. Cambodia was also previously dependent on nongovernmental organizations (NGOs) to provide immunization, and NGOs are still currently assisting in some remote areas. With improved accessibility, however, the role of NGOs has now become more of a technical support rather than implementation.

The incentives given to midwives were discussed. Generally, midwives use the money from their incentives to improve women’s access to health facilities; sometimes they pay the transport fees of pregnant women or they pay the traditional birth assistants (TBAs) to bring women to the facility for delivery. TBAs have played an important role in home deliveries, but increasingly more TBAs refer mothers to facilities for delivery after receiving training. In the past, many partners did not support the idea of incentives for midwives. However, the Cambodian government implemented and paid for this and it has been a successful programme. Cambodia achieved the Millennium Development Goal to improve maternal health (MDG 5) in 2015.

2.12.5 Philippines: HepB-BD improvement activities

Dr Maria Wilda Silva discussed the high endemicity of hepatitis B in the Philippines, with an estimated 9% prevalence. Approximately 58 million people are exposed and 7.3 million are chronically infected, of whom about 2.1 million will develop chronic liver disease. The average treatment cost is about 550 million Philippine pesos per year and about 450 million pesos is lost in wages per year.

The hepatitis B vaccine was introduced in 1991 and HepB3 adopted in 1994. In 2005, the government committed funds and a policy for timely HepB-BD was disseminated by 2006, which was introduced in a phased manner. In 2012, a compulsory order for timely HepB-BD was mandated.

Before 2005, HepB3 coverage was variable and showed improvement from 2005 to 2007 which coincided with the Government of the Philippines fully funding the hepatitis B vaccine in 2005. Pentavalent coverage decreased from 90% in 2013 to 60% in 2015 due to stock-outs. Coverage of HepB-BD has improved since 2007, but remains at only 60% as of 2015 with reported stock-outs continuing to occur (Fig. 5).
The DHS data show some improvements in health facility delivery and deliveries attended by SBAs, but a high rate of home deliveries remains, especially in rural areas where it continues to be difficult to vaccinate infants within 24 hours. There is still no policy for immunizing at home and no OCC policy. However, data show that increased facility-based deliveries have resulted in an increase in HepB-BD.

Remaining challenges include poor vaccination recording, unsafe injection practices, poor compliance with proper timing of HepB-BD administration in health facilities where the EENC package is not in place, lack of implementation of timely HepB-BD in some hospitals, non-availability of CCE in all health facilities, and vaccine stock-outs.

**Progress**

Hepatitis B immunization has been included in the health insurance package of newborn care. Also, a mandatory law specifying that children should be given HepB-BD by a SBA in all facilities is in place. Secure, stable funding for procurement of the hepatitis B vaccine has been allocated and will hopefully prevent vaccine stock-outs. Poor families can obtain conditional cash transfers upon completion of all childhood immunization. Public–private collaboration encourages private facilities now to provide HepB-BD and the Bacillus Calmette–Guérin (BCG) vaccine at no cost, as long as these are reported. Community health workers increasingly refer pregnant women for delivery at health facilities, and tracking pregnancy and deliveries from antenatal care visits has improved. A health facility enhancement programme has been developed with improved education of midwives and SBAs and improved facility-based deliveries. Finally, the inclusion of HepB-BD has become an incentive for facilities to obtain business licences.

**Next steps**

- Intensify integrated field monitoring in coordination with maternal child health services to review compliance with HepB-BD policy in hospitals and lying-in clinics.
- Implement a serosurvey later in 2017.

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• Continue to improve HepB-BD and routine immunization, by generating awareness of the benefits of the vaccine. The “Baby come back” campaign aims to convince women to bring the babies back for immunization in general.
• Continue to maintain a regular supply of vaccines to avoid stock-outs.

To a question about whether subnational analysis by region exists, the response was that this has been looked at and that there is a lot of variability between and within regions and between rural and urban areas, but not at the facility level. A suggestion was made to look in depth at where the discrepancies lie, to try to improve HepB-BD coverage. Some work has already been done to uncover why some areas are poorly performing. In these areas, there is hesitancy among midwives to give HepB-BD within 24 hours, and some facilities refer babies to another health facility to get their HepB-BD.

Discussion about the use of OCC revealed that there is concern in the Philippines that OCC may be incorrectly translated to other vaccines. To address this, cold chain capacity has been expanded to all facilities.

Subnational data are fed back to the areas to try and improve coverage in low-coverage areas. Local governments provide incentives for fully immunizing children, but HepB-BD is not included as an item to be rewarded. There is a move to include this as an incentive. There was a suggestion that HepB-BD be included as part of quality assessment of EENC, with the presenter agreeing to consider this.

2.12.6 Solomon Islands: HepB-BD improvement activities

Dr Divinal Ogaoga explained that Solomon Islands is a double-chain archipelago of more than 900 islands in the southwest Pacific Ocean, with a population of 605,985. The best estimate by the WHO Regional Office for the Western Pacific of hepatitis B seroprevalence in the country is 21% from 2007.

Vaccine management training has been held for over 100 HCWs, and 7 out of the 10 provinces received supportive supervision to improve HepB-BD coverage. Coverage of HepB-BD has improved from 42% in 2013 to 65% in 2016. Delays in ordering at the provincial level and then in dispatching the vaccine to provinces remain one of the major challenges in vaccine management. HCWs believe that if they miss HepB-BD in the first 24 hours, then the child has missed their birth dose and will wait for the next routine multidose vaccine that contains the hepatitis B vaccine to be given.

In the absence of CCE, an OCC pilot project was conducted in three provinces resulting in increased HepB-BD in 2015 (see section 2.10 above). The data were presented to the executive committee of the Ministry of Health, which endorsed OCC for national rollout. CCE installation has been delayed since 2013, but solar direct-drive refrigerators are replacing gas fridges with support from Gavi and UNICEF. There is a plan in place to scale up OCC HepB-BD in a phased manner. The aim is to generate demand for immunization by generating a communication plan concentrating on hepatitis B and measles, mumps and rubella (MMR). Solomon Islands is investigating opportunities to improve HepB-BD under the EENC umbrella.

It remains challenging to reach remote populations because of lack of transportation, but the government has provided small boats for nurses to reach out to these populations. Assistance has been provided with microplanning, outreach and stock management, and over 150 nurses have been trained, especially in low-performing provinces. However, logistics support remains a problem.

Collaboration with NGOs is ongoing and likely to improve social mobilization. An EPI communication strategy is being finalized with emphasis on hepatitis B, and information and educational materials are also being developed. The EPI has access to the district health information system, regularly providing feedback to provinces. A nationwide hepatitis B serosurvey was recently conducted in school-age children. Reporting issues from clinics to surveyed facilities and delays in data entry at provincial headquarters have resulted in delays finalizing the serosurvey data and report
in 2016. Another issue is that there is high staff turnover with limited country base staff to support surveys. The findings of the serosurvey need to be reviewed to identify hepatitis B-positive children and manage them appropriately.

The response by the Solomon Islands government to address the challenges in trying to scale up HepB-BD was acknowledged. A question was asked about the high turnover of nursing staff and this was regarded as problematic, especially at the facility level.

2.12.7 Japan: Introduction of hepatitis B vaccine into the national routine immunization programme

Screening of blood and blood products for hepatitis B has been in place in Japan since 1972. Since 1986, all pregnant mothers have been routinely screened for HBsAg and exposed babies are selectively given HBIg and HepB-BD to prevent vertical hepatitis B transmission. Through this programme, mother-to-baby hepatitis B infections were significantly reduced. However, recent surveillance of HBsAg and hepatitis core antibody among children has suggested that horizontal infections are still occurring. To prevent hepatitis B infections among children, Japan decided to introduce universal HepB3 vaccination for all infants beginning 1 October 2016. Three doses of the vaccine are given at 2, 3 and 7–8 months after birth (covered by the routine immunization programme) and women continue to be routinely screened for HBsAg, with HBIg and HepB-BD vaccine given to exposed infants (covered by national health insurance).

When asked whether PVST is performed among exposed babies, Dr Wakita responded that this has been implemented but no data are available.

Concern was raised that a small proportion of women who are at higher risk may not be screened for hepatitis B. While it is uncertain how adults are getting infected, genotype A is increasing largely from sex workers migrating to Japan. If HBsAg screening of pregnant women is incomplete, a small proportion of women may be missed and these may be at increased risk of transmitting the disease to their children. In the United States of America, this was a reason for implementing a universal HepB-BD programme, because there was uncertainty whether all infected women were being identified.

Dr Wakita was asked whether a breakdown of prevalence by age and ethnicity was available for Japan, to which he responded that immigrants from South-East Asia may have a higher HBsAg prevalence, but all pregnant migrants are screened.

2.12.8 China: Public knowledge attitudes and practices about hepatitis B

Dr Samuel So discussed how public knowledge in China about hepatitis B remains poor. People who are chronically infected with hepatitis B face discriminatory practices in educational facilities and in some cases have been denied employment opportunities. Celebrities have been enlisted to help promote awareness of the hepatitis B vaccine.

A joint initiative led by the Asian Liver Center at Stanford University in California together with the Global Business Group on Health, IBM, GE, Intel and Hewlett Packard aimed to build fully inclusive workplaces free from hepatitis B discrimination and to educate employees about hepatitis B and the importance of vaccination, care and treatment. In April 2016, an awareness campaign for hepatitis under the Jade Ribbon was launched across colleges in 20 cities in China.

The Asian Liver Center in collaboration with WHO China, the Chinese and Beijing Centers for Disease Control and Prevention, the Chinese Preventive Medicine Association, Wu Jieping Medical Foundation and China Foundation for Hepatitis Prevention and Control, using the Jade Ribbon as the symbol, promoted a World Hepatitis Day campaign using social media and developing catchy slogans that received a very favourable response. The largest World Hepatitis Day awareness campaign was launched in Beijing with 69 million views within two weeks. Popular actors, including Jackie Chan,
attracted a large social media response. Many activities continue to be held in China to maintain the awareness and education around hepatitis B.

Projects have been launched in two provinces to increase the capacity of the health system for PMTCT with online training courses linked to continuing medical education credit. Pregnant women are also being educated about the benefits of vaccinating their children. A project was launched to conduct routine PVST at the time of the measles vaccination.

In response to a question about whether these communication strategies can be extended beyond China, Dr So reported that work is beginning with Viet Nam to promote vaccination to prevent cancer.

2.12.9 Integration of programmes: MNCH collaboration with EPI

Dr Maria Asuncion Silvestre gave a presentation on the technical assistance provided by an NGO to the Philippines Department of Health to improve essential care of the mother and the newborn in the early peripartum period. To derive the maximum benefit for newborns, the essential intrapartum and newborn care (EINC) interventions should be delivered not just as a package of interventions, but sequenced methodically. Some immediate newborn care practices have led to deaths in infants because SBAs were not always providing appropriate care for babies at the correct time.

In an earlier study by Sobel et al. (2011),¹⁷ HepB-BD coverage in the Philippines was shown to improve when there were standing orders for the health facility, when a copy of the hepatitis B vaccination policy was in place and after staff had been trained on hepatitis B. The interventions provide HCWs with a time-bound framework of early postpartum and newborn care with the aim of reducing mortality among mothers and infants. SBAs are trained to change their practices and follow the step-by-step practices to improve the quality of care. Included in this package is the provision of a time frame in which to properly dry infants, to allow uninterrupted skin-to-skin contact with the mother, to ensure safe cord clamping and completion of the first breastfeed, as well as the correct time frame for delivery of the timely HepB-BD. Emphasis is on keeping the baby together with the mother.

This model is being adopted in the WHO Western Pacific Region and the UNICEF East Asia and Pacific Region in the Action Plan for Healthy Newborn Infants in the Western Pacific Region (2014–2020). This includes a checklist with timely HepB-BD included in the package.

The integrated service approach described was praised. In response to a question on the topic, it was acknowledged that the monitoring and evaluation requirements to ensure that services are being provided were the biggest challenge because the Philippines has a devolved health-care system. In many regions and islands, getting local government buy-in poses a challenge; meanwhile, human resources are also scarce. Nevertheless, hospital assessments are being planned. With support from WHO, they are anticipated to take 7 years to scale up.

A comment was made that 100% of deliveries at facilities should receive HepB-BD and that facilities need some form of accountability if they are underperforming on this. Disaster-prone countries and areas should have HepB-BD available OCC.

2.12.10 Integrated framework for the triple EMTCT of HIV, hepatitis B and syphilis

Several new strategy documents were released post-2015 calling for highest attainable standards of health and well-being for children at every age.

HIV, hepatitis and sexually transmitted infections have interlinked global strategies targeting:

- zero new HIV infections among infants by 2020
- ≤50 cases congenital syphilis per 100,000 live births in 80% of countries by 2030
- 0.1% HBsAg prevalence among children by 2030.

The Western Pacific Region has worked hard to eliminate HIV in children with limited success. Since 2009, there has been only a 27% reduction in new HIV infections among children, mainly because not enough women were provided antenatal testing. A significant gap exists in the treatment cascade for HIV-infected pregnant women resulting in low HIV treatment coverage. Reporting for syphilis has generally been poorer than for HIV, but an increasing trend in sexually transmitted infections in Asia and the Pacific has been reported, with some countries reporting an increase in congenital syphilis. Global criteria have been developed for EMTCT of HIV and syphilis, which include impact and process indicators to eliminate both diseases as a public health threat.

In June 2016, Thailand became the first country in Asia and the Pacific to be verified for EMTCT of HIV and syphilis, and the WHO South-East Asia Region is expecting more countries to be validated in the coming years. The Western Pacific Region has made great strides in reducing HBV infection to a prevalence of less than 1% in 5-year-old children. The rationale for integrating the goals for triple elimination of HIV, syphilis and hepatitis B is that this programme offers the opportunity for more complete protection from these three largely preventable illnesses; improved quality MNCH care which includes EMTCT interventions as a standard component, seamless care for women, children and their families; and a coordinated and collaborative approach among MNCH, immunization and diseases control programmes, by building on existing mechanisms and investments on MNCH (e.g. EENC), EMTCT of HIV and syphilis, and hepatitis B control through vaccination.

An integrated regional framework for triple EMTCT of HIV, hepatitis B and syphilis in Asia and the Pacific for 2018–2030 was suggested. It will set targets and goals for each of the three diseases, define key interventions, propose harmonized elimination criteria, and develop a minimum set of indicators for monitoring and evaluation. Positive feedback on what will be early versions of the drafted framework has been received from countries. This will be further developed and reviewed during an expert consultation meeting in the coming week. It is anticipated that a final draft will be submitted for review and possible endorsement to the October 2017 WHO Regional Committee Meeting for the Western Pacific. The process for validating EMTCT of HIV and syphilis is well developed. Integration of hepatitis B into this process will be further developed in the coming months.

Concern was raised that screening and treatment for hepatitis B may detract from the success of the vaccination programme. Integrating programmes should still focus on what is working, i.e. increasing and maintaining HepB-BD coverage. From an EPI perspective, the focus on HepB-BD coverage remains a cornerstone for the elimination of hepatitis B.

Conversely, it was suggested that the triple elimination could be an opportunity to systematically screen the adult population, which could benefit strategic information and the health of women if treatment linkages are assured. Many countries need extra resources for screening, however, and would need a clear strategy for how to manage women testing HBsAg positive. It was acknowledged that pregnant women would benefit from screening as part of the adult population, and that elimination of hepatitis B is not possible without also targeting adults.

Emphasis was put on the importance of the quality and standardization of screening tests for women. A suggestion was made that the monitoring for elimination of hepatitis B could be developed under the ERP which already has a verification process in place.

Concern was raised about the additional burden on midwives and the need for clear guidance on what to do if the mother tests positive, as in most countries treatment for hepatitis B is not provided by governments and is an out-of-pocket expense.
2.12.11 Setting regional control goals beyond 2017 and evaluation methods

Impact targets were established in the recent monitoring and evaluation for viral hepatitis B and C technical report (90% reduction in new cases of chronic hepatitis B and C and a 65% reduction in deaths). Baseline data to benchmark progress of national hepatitis screening, care and treatment cascades are required.

Vaccination of infants and neonates is already driving a large decrease in new infections, however, without scale-up of existing interventions. A model by Nayagam et al. (2016) showed that there will be a cumulative 63 million new cases of chronic infection and 17 million HBV-related deaths between 2015 and 2030 due to ongoing transmission in some regions and poor access to treatment for people already infected. Scaling up the coverage of infant HepB3 vaccination (to 90% of infants), HepB-BD (to 80% of neonates), use of peripartum antivirals (to 80% of HBeAg-positive mothers) and population-wide testing and treatment (to 80% of eligible people) could make the global impact targets achievable.

The GHSSVH set service targets for 90% HepB3 coverage and 90% PMTCT by 2030 with a reduction in the global incidence of hepatitis B prevalence to 0.1% in children, including a target to reduce the prevalence of chronic HBV infection in children to less than 1% by 2020. Each region has interim-term goals that have been independently established. Monitoring countries towards these targets has become more complicated as the prevalence gets lower. Large sample sizes will be required if traditional methods for doing serosurveillance are used, which will be human resource-intensive and very costly.

In the Western Pacific Region, 19 of 36 countries (52%) have serosurvey data showing less than 0.5% prevalence among 5-year-olds. Seroprevalence in Hong Kong SAR (China) of 0.5–1% from 2011 is now likely to be even lower. There are five countries with seroprevalence higher than 1%, four of which (apart from Kiribati) were represented at the meeting. Results from 10 countries’ serosurveys are pending. Cambodia will undertake the first nationally representative serosurvey in March 2017 and both Fiji and the Philippines are planning to undertake serosurveys later in 2017.

Questions for discussion included: Which methodology would be best to use to measure progress towards the elimination targets going forward? Should an interim regional target of 0.5% in the Western Pacific Region be set along the way to the 2030 target of 0.1%, and by which year? Should high-burden areas within countries be the focus for assessing progress? Considering health equity, should all countries and areas be expected to achieve the same specified target?

Participants deliberated the above topics. For those countries that have already reached 0.5% prevalence, it may not be feasible to make them conduct another survey unless issues of concern arise, such as unforeseen changes in coverage. If countries want to target higher-burden areas, they may conduct classification serosurveys in specific areas. In addition to serosurveys, other methods such as modelling may also be used as a tool for progress assessment.

Participants felt that it is feasible to set the target at 0.5%, as this is biologically possible and desirable. Others felt that, since many countries have already achieved less than 1% prevalence, the target should be more ambitious and suggested 0.3%. It is proportionally due to the low prevalence in China, which has achieved 0.32% prevalence among one to four-year-olds in the 2014 serosurvey, that the Region has achieved the 2017 target of less than 1% among 5-year-olds. There is large disparity between countries and areas, however, so this target may be ambitious to apply for all areas and discourage those countries which have not met the less than 2% or less than 1% targets to strive to

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attain yet a lower seroprevalence goal. The possibility of setting the regional goal separately from country goals was discussed.

Consideration was given to ensuring that the target year was not too early to achieve programmatic change; for example, the target year 2022 means that the 5-year-old children to be surveyed are being born in 2017, which does not provide sufficient time to implement programmatic improvements. To give countries a chance to intensify efforts, 2024 or 2025 was considered as the next target year on the continuum of meeting the 0.1% goal in 2030 set by the GHSSVH.

The most important issue was how to bring along the countries that are as of now underachieving. While the regional goal will be achieved, due largely to the proactive and successful track record of China, there was concern that some countries may be left behind. In this case, the question would center on how to assist those countries that have not been meeting prior coverage targets. Aspirational targets are good, but countries need additional resources to achieve these lower prevalence targets. Countries that have not yet achieved the 2012 and 2017 goals need particular attention, including with consultation to discuss resource requirements and additional strategies required to achieve lower prevalence targets.

In this light, the Member States that were represented at the meeting discussed their reaction to the proposed regional target.

Solomon Islands

It was felt that ambitious targets can be demoralizing, but on the other hand may also be motivating. Another way to set achievable targets may be to aim at a proportional reduction from the current level, rather than targeting a defined number.

Viet Nam

The target would need to be discussed in the country, as additional resources will need to be mobilized to achieve the new target. However, Viet Nam felt that a target of 0.5% prevalence by 2024 is reasonable.

Papua New Guinea

Concerns were raised that the target of 0.5% prevalence by 2024 might not be achievable in the country.

Lao People's Democratic Republic

The proposed regional target would be difficult to achieve due to the need for additional resources and capacity. It was felt that some country targets should be higher than others.

Cambodia

The Cambodian representatives agreed that the target should vary by country – and even within countries. If subnational coverage is considered, some districts have poorer coverage than others. The representatives felt that the strategy and target should be set individually.

Philippines

The Philippines continues to struggle to increase HepB-BD coverage and country representatives felt that the 0.5% target for 2024 may not be realistic and that it should be set differently for countries. The Philippines still has a lot of work to do to achieve the 2017 target. It was also suggested that setting a target of around 50% reduction from the current level may be more feasible.
Next steps for countries and WHO

- The discussion about targets should be held with the Regional Technical Advisory Group for EPI.
- Country representatives at the meeting will need to discuss new potential targets within their own countries.
- WHO will need to work with countries and areas that still have not achieved less than 1% prevalence to improve vaccine coverage. This could include increasing health facility rates, using OCC with proper oversight and national regulatory authority approval, addressing supply issues to prevent stock-outs, and dedicating more resources to national plans to strengthen health systems and quality control.
- Equity must be a primary component for setting any new regional target, and countries and areas will need varying levels of support to achieve these new targets.

2.12.12 Final remarks

Participants thanked the ERP members and temporary advisers for their valuable input, which will contribute to the regional outcomes. Thanks were also given to the country representatives for their reports and feedback that were useful in driving efforts to improve coverage in all countries. WHO regional and country staff were also acknowledged and a call for increased presence in countries was made.

The meeting brought together the immunization and the MNCH programmes to reach newborn babies with a basic care package including essential vaccines. ERP members will also participate in the upcoming Expert Consultation on Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis in the Asia Pacific, moving forward on multiple fronts towards meeting the regional goal to further control and eventually eliminate hepatitis B infection in children, and to coordinate these efforts with MNCH colleagues. WHO remains committed to providing the necessary assistance for countries to reach the shared hepatitis control and elimination goals, with millions depending on the implementation of activities to achieve these ends.

3. CONCLUSIONS AND RECOMMENDATIONS

The Fifth Hepatitis B Immunization ERP Consultation was attended by representatives from six countries in the Western Pacific Region who participated in the 2015 Workshop on Improving and Monitoring Hepatitis B Birth Dose Vaccination and presented their progress in implementing the meeting’s recommendations and discussed their near- and long-term planned HepB-BD activities. WHO staff from headquarters, the Western Pacific Region, the South-East Asia Region and the European Region presented updates on regional and global activities. Participants learned from US CDC presentations about hepatitis B impact serosurveys and OCC pilot projects that were implemented in the WHO Western Pacific Region. It was generally recognized that the Region leads the way in its response to hepatitis B elimination goals through the widespread scale-up of hepatitis B immunization, in particular the use of HepB-BD throughout most of the countries and areas in the Region.

The ERP discussed the GHSSVH which includes a new process indicator (90% coverage of interventions to prevent perinatal transmission by 2030) and a so-called elimination target (1% HBsAg prevalence among children by 2020 and 0.1% HBsAg prevalence among children by 2030). Recognizing the disparity among the Region’s countries which continue to meet new regional targets and those with relatively low HepB-BD and HepB3 coverage which have not yet met the 2012 or

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20 Workshop on improving and monitoring hepatitis B birth dose vaccination. Manila: WHO Regional Office for the Western Pacific; 2015 (http://iris.wpro.who.int/bitstream/handle/10665.1/11713/RS_2015_GE_02_LAO_eng.pdf?ua=1). The workshop was held in Vientiane, Lao People’s Democratic Republic from 10 to 12 March 2015.
2017 regional targets, participants focused on how best to achieve and sustain the post-2017 hepatitis B control targets for all countries and areas in the Region. The meeting also discussed the ERP’s role in the triple elimination of HIV, hepatitis B and syphilis and the use of the classification method for verification of low HBsAg prevalence.

3.1 Conclusions

The ERP is extremely pleased by the report in the May 2016 issue of Vaccine that the 2017 seroprevalence target of 1% among immunized cohorts of children at least 5 years of age was met and immunization programmes in this Region have averted an estimated 7 million deaths and 37.6 million chronic hepatitis B cases among children born between 1990 and 2014.

The ERP discussed developing post-2017 hepatitis B control targets for the WHO Western Pacific Region, recognizing the disparity between countries and areas that continue to meet new regional targets and those with relatively low HepB-BD and HepB3 coverage that have not yet met the 2012 or 2017 targets. Of the 36 countries and areas in the Region, 19 countries have serosurvey evidence of having less than 0.5% HBsAg prevalence among 5-year-olds; two countries have HBsAg prevalence between 0.5% and 1%; five countries are above 1%, with four of these above 2%; and the 10 remaining countries do not have serosurvey results. Post-2017 targets tentatively include the following:

1. All countries and areas in the Region should reduce HBsAg prevalence to less than 1% among 5-year-old children by 2025.

2. Countries and areas in the Region that have reduced HBsAg prevalence to less than 1% among 5-year-old children should aim to further reduce HBsAg seroprevalence to less than 0.5% among 5-year-old children by 2025.

Concerted effort and direct assistance will likely be necessary to assist countries and areas that have not reached the 2012 and/or 2017 prevalence goals. These efforts are ultimately geared towards reaching the GHSSVH goal of eliminating viral hepatitis as a public health threat through the adoption of a global target of 0.1% by 2030.

The ERP recommends that efforts to eliminate hepatitis B infection should not be conducted in a vertical programme. Linking with other programmes, such as EMTCT efforts for HIV and syphilis, other EPI and MNCH programmes, among others, could help strengthen health systems. Incorporating key health indicators and metrics could prove beneficial in the regional and global movement towards elimination of hepatitis B as a public health threat by 2030.

3.2 Recommendations

3.2.1 Recommendations for Member States

The ERP acknowledges the tremendous efforts by high-burden countries to implement national HepB-BD plans developed during the 2015 Workshop on Improving and Monitoring Hepatitis B Birth Dose Vaccination. By country, the ERP recommends the following actions be taken:

Cambodia

1) The ERP congratulates Cambodia on successfully increasing their HepB-BD and HepB3 coverage over the past 5 years.

2) The ERP will support the country’s planned programmatic activities to sustain successful outcomes, including conducting their first nationally representative hepatitis B serosurvey in 2017.
Japan

1) The ERP commends Japan’s recent introduction of hepatitis B vaccination into their routine immunization programme at 2, 3 and 7–8 months after birth. This inclusion was based on well-researched findings that showed hepatitis B core antibody seroprevalence among teenagers was higher than HBsAg prevalence among immunized younger child populations, suggesting that horizontal transmission was a potential source of transmission.

2) The ERP recommends continuation and evaluation of the HBsAg screening programme to ensure all pregnant women are screened and all children of HBsAg-positive mothers are given HepB-BD and HBlg treatment.

3) With an estimated hepatitis B prevalence among children of 0.03% (9 out of 27 240), Japan should consider submitting their application for verification of meeting the regional 2017 target of 1%.

Lao People’s Democratic Republic

1) The ERP encourages the national regulatory authority and Ministry of Health in the Lao People’s Democratic Republic to endorse national guidelines including the use of OCC vaccines.

2) The ERP commends the country’s efforts to scale up OCC HepB-BD and recommends ongoing reporting on progress and outcomes.

3) As previously described, the WHO Regional Office for the Western Pacific and WHO headquarters will be assisting the country to amend guidelines that contain recommendations for using OCC HepB-BD.

4) The ERP recognizes that reaching remote populations is an ongoing challenge in the Lao People’s Democratic Republic and commits to working with the country to determine methods to improve HepB-BD coverage in these regions.

New Zealand

1) Given the increasing number of migrant populations and foreign-born women of childbearing age, discussions with New Zealand’s National Immunization Technical Advisory Group and Ministry of Health should be performed to ascertain whether timely HepB-BD could be universally provided to all newborns.

2) The ERP recommends that New Zealand implement a universal hepatitis B immunization programme including HepB-BD for all infants.

Papua New Guinea

1) The ERP commends Papua New Guinea on the development of strategies to improve HepB-BD coverage in the country.

2) The ERP, the WHO Regional Office for the Western Pacific and WHO headquarters will assist in obtaining approvals for using OCC HepB-BD.

3) Recognizing the importance of community awareness, the ERP will work with the country to develop effective public awareness campaigns to encourage women to deliver at health facilities and receive timely HepB-BD.
4) The ERP recognizes that reaching remote populations is an ongoing challenge in Papua New Guinea and commits to working with the country to determine methods to improve HepB-BD coverage in these regions.

**Philippines**

1) The ERP acknowledges some of the steps taken by the Philippines to try to improve HepB-BD coverage, including the recent change to use UNICEF to procure HepB3 and thereby avoid HepB3 stock-outs that have been a factor in persistently low HepB3 coverage in recent years.

2) The ERP recommends that the Philippines focus on improving timely HepB-BD coverage among all health facility births.

3) The ERP commends and supports the country on the imminent implementation of a hepatitis B seroprevalence survey in children 5 years old and above in late 2017 or early 2018.

4) The ERP recommends that the country intensify integrated field monitoring in coordination with the MNCH programme in priority areas.

5) The ERP will support the government in scaling up HepB-BD and routine immunization by sharing materials targeted at public workers and HCWs on the importance of HepB-BD in preventing liver cancer and cirrhosis.

**Solomon Islands**

1) The ERP supports Solomon Islands in attempts to scale up OCC HepB-BD in a phased manner.

2) The ERP commends the country’s efforts to raise awareness and create a demand for immunization by the public.

3) The ERP, the WHO Regional Office for the Western Pacific and WHO headquarters will assist in the efforts to obtain approvals for using the OCC hepatitis B vaccine.

4) The ERP recognizes that reaching remote populations is an ongoing access challenge in Solomon Islands and commits to working with the country to determine methods to vaccinate children in these hard-to-reach regions.

**Viet Nam**

1) The ERP commends the efforts in Viet Nam to improve HepB-BD coverage.

2) The ERP acknowledges the steps that the country has taken in mitigating negative publicity about hepatitis B vaccines through programmes such as training of journalists.

3) The ERP recommends that Viet Nam enhance public workers and HCW awareness programmes using a broad range of strategies to provide information about the benefits of the hepatitis B vaccination programme. Materials for improving awareness, how to build resilience, proactive involvement of media, communication with patients and improving HCWs’ response to vaccine refusals will be shared from the WHO Regional Office for Europe and the CDC.

4) The ERP will work with Viet Nam to integrate the aforementioned activities with MNCH efforts to encourage more facility deliveries.
5) The ERP will continue to assist Viet Nam with plans to reach populations in remote areas, including strategies to use OCC HepB-BD.

6) The ERP urges Viet Nam to include standing orders to administer HepB-BD and to remove the neonatal screening form 2301/QD-BYT, which erroneously precludes neonates from receiving a HepB-BD by listing false contraindications and forcing a physician to sign this form before HepB-BD can be administered.

7) The ERP commends current efforts in Yên Bái province to expand HepB-BD coverage among polyclinics and commune health clinics to other districts and to scale up to other provinces with low HepB-BD coverage, prioritizing polyclinics that have proper cold chain monitoring in place and commune health clinics with high delivery rates.

3.2.2 Recommendations for WHO

Achieving and maintaining high HepB-BD and HepB3 coverage remain the cornerstones to achieving current and projected elimination targets

The ERP commends the progress towards higher coverage of HepB-BD immunization, even among high-burden countries and countries or areas with previously low HepB-BD coverage. Several challenges towards achieving high HepB-BD coverage still exist in order to address these challenges:

1) Countries and areas should comply with the new reporting requirement at the global level to report in their Joint Reporting Form on Immunization both timely HepB-BD, which will be defined as HepB-BD given within 24 hours, and HepB-BD given after 24 hours.

2) While HepB-BD is most effective against perinatal transmission if given within 24 hours after birth, the ERP recommends that HepB-BD still be administered and recorded if given after 24 hours, as non-timely HepB-BD will still interrupt other routes of transmission.

3) The ERP recommends ongoing staff training in effective vaccine management and maintenance of vaccine stocks to prevent or minimize the occurrence of stock-outs.

4) The ERP reaffirms the recommendations from the Workshop on Improving and Monitoring Hepatitis B Birth Dose Vaccination, noting the importance of the fifth recommendation for Member States:

   “It is much easier to deliver a timely BD at facility deliveries. Many countries have greatly increased coverage of timely BD by increasing the proportion of deliveries in health facilities, attended by a SBA. Such efforts are recommended to improve HepB-BD coverage, reduce maternal and neonatal mortality, and benefit mothers and newborns.”

- The ERP recognizes that large numbers of migrants in the Western Pacific Region are at risk of not having access to services and urges all countries and areas in the Region to develop plans to ensure that migrant children receive HepB-BD and routine hepatitis B vaccination, and to develop systems to ensure that immunization of these vulnerable populations is recorded.

- For countries that still implement selective HepB-BD, the ERP recommends that they evaluate and assess whether all pregnant women are screened for HBsAg and whether all newborns of HBsAg-positive mothers are vaccinated with timely HepB-BD.
CTC and OCC

Despite evidence demonstrating that monovalent hepatitis B vaccines OCC are safe and effective and can significantly increase timely HepB-BD coverage especially among home deliveries, OCC HepB-BD pilot studies in the Region have to date not been scaled up nationally within any country or area. While awaiting manufacturers to incorporate CTC thermostability data on their labels, the ERP reaffirms the importance of using vaccines OCC in remote and hard-to-reach areas; in regions where inadequate CCE exists; among countries with a high proportion of home deliveries; and for vaccinating babies born at home, preferably within 24 hours of birth.

Affirming that countries and areas should dedicate support to improve cold chain capacity, the ERP also endorses the incentive for countries and areas to increase health facility delivery rates. Nevertheless, in settings and environments where home births are still occurring or CCE is scarce, countries and areas should use the hepatitis B vaccine OCC to improve HepB-BD coverage.

New developments at the global level are that SAGE has strongly urged manufacturers of the monovalent hepatitis B vaccine to pursue regulatory approval for CTC as soon as possible. SAGE also supports countries that chose to pursue an OCC policy and strongly recommended that, when doing so, they follow the current IPAC recommendations for OCC and CTC use of vaccines. In order to address this, the ERP urges WHO headquarters and UNICEF to do the following:

1) Support countries seeking regulatory approval for using OCC hepatitis B vaccines.
   a) The Western Pacific Region has extensive experience in conducting successful OCC pilots in Cambodia, China, the Lao People’s Democratic Republic, Papua New Guinea, Solomon Islands and Viet Nam. To date, none of these projects has been scaled up nationally. The ERP recommends that the Regional Office for the Western Pacific monitor the interest and ability of countries and areas to scale up successful OCC pilots, starting with potential consideration to assisting the Lao People’s Democratic Republic. The Regional Office should explore the mechanisms and capacity to obtain OCC regulatory approval in key countries interested in using OCC vaccines. The lessons learnt on OCC scale-up barriers and possible solutions should be shared with WHO headquarters and among countries that may have fully functional regulatory bodies.
   b) WHO headquarters should draft reports synthesizing findings and conclusions of available thermostability data for hepatitis B vaccines that could be used OCC, including suggested peak temperatures and the number of days at maximum temperature. The purpose of these product-specific reports would be to serve as a resource for EPI programmes, regulatory authorities and national immunization technical advisory groups.

2) Perform actions related to manufacturers.
   a) Based on prior experience with UNICEF only procuring vaccines with vaccine vial monitors, WHO headquarters and UNICEF should explore the potential for preferential procurement of WHO prequalified monovalent hepatitis B vaccines that have been relabelled for CTC use by manufacturers, including vaccines presented in compact prefilled nonreusable injection devices.
   b) In relation to the ERP’s concern that manufacturers may not be incentivized to take the steps required for CTC prequalification, WHO headquarters should communicate with the Regional Office for the Western Pacific and other regions if manufacturers require data or information on programme demand for a prequalified CTC product.
   c) WHO headquarters should contact manufacturers of vaccines in compact prefilled auto-disable injection devices (CPAD) to explore product availability and cost.
d) WHO headquarters should investigate opportunities for Gavi to support manufacturers with costs related to CTC prequalification and market shaping for affordable CTC vaccines.

**Monitoring and evaluation of progress**

The ERP continues to play a role in monitoring the progress of verified countries and areas and in ensuring current targets are sustained with movement towards the elimination of hepatitis B. To ensure movement towards elimination, verified countries should maintain high HepB-BD and HepB3 coverage, and regularly monitor HBsAg seroprevalence among children. Consideration was given to the challenges of conducting serosurveys in under-resourced countries and areas, since lowered prevalence targets will significantly increase the required sample sizes required, which in turn increases logistics and financial requirements to conduct large and challenging serosurveys. Suggestions for new methods to monitor progress in low seroprevalence targets include:

1) WHO should provide countries and areas with clear methodological survey guidance and use of other strategic information to develop estimates of impact. The ERP encourages the Western Pacific Region to gain experience in using new methods to measure low HBsAg prevalence targets, including classification serosurveys, which are based on the updated WHO vaccination cluster survey guidelines, a two-step risk assessment and verification serosurvey method that has been used for verification of neonatal tetanus elimination; and incorporating hepatitis B serosurveys into other national coverage surveys such as DHS or MICS or potentially other HIV/AIDS and malaria serosurveys.

2) The ERP affirms the need for WHO to conduct cost-effectiveness analyses and incremental cost-effectiveness ratios to help countries and areas ascertain which potential interventions, including multiple interventions, are programmatical and financially feasible. In addition to the cost-effective inclusion of HepB-BD, potential intervention options include universal antenatal screening (including HBeAg screening), antiviral therapy (including the threshold to commence treatment) and HBIG treatment and PVST among children born to HBsAg-positive mothers. However, antiviral therapy for PMTCT of infections currently remains controversial, given the paucity of published research to establish virological thresholds for starting treatment.

**Communication strategies**

The ERP continues to recommend that countries mitigate negative perceptions of hepatitis B immunization through proactive risk communication planning and health education outreach. ERP members acknowledge the proactive work of Viet Nam in this regard since the previous ERP meeting in Hanoi in January 2016.

The ERP encourages vaccine education for journalists, community awareness campaigns through social media and ongoing training of HCWs. Positive examples of this were demonstrated by Viet Nam and by Project Jade, which was presented by Dr Sam So who described widely publicized, celebrity-endorsed awareness campaigns being conducted throughout China using social media. One of the major aims of these campaigns is increasing public health awareness of hepatitis B and its link with liver cancer as well as reducing the stigma against people who are chronically infected with hepatitis B.

The ERP recommends that public awareness campaigns directly linking hepatitis B transmission in infancy to potentially developing liver cancer or cirrhosis later in life may motivate parents to have

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their infants vaccinated at birth and during routine immunizations. Communication and advocacy activities are needed to draw public attention to hepatitis B and its consequences. WHO could mobilize the resources, by collaborating with NGOs and academic institutions, to assist with translating evidence into best practice. Traditional and social media, celebrity engagement and visits by high-ranking officials are all methods to be considered in raising public awareness about hepatitis B vaccination.

**Vaccination of HCWs**

The ERP reaffirms the need for countries and areas to develop HCW policies for hepatitis B vaccination. This remains in line with the goal of the Regional Action Plan for Viral Hepatitis in the Western Pacific that a national policy of vaccinating HCWs against hepatitis B should be established in over 80% of countries by 2017 and in all countries by 2020.

**Health systems strengthening and integrating programmes**

The ERP notes that the upcoming triple elimination meeting held by the Regional Office for the Western Pacific has important implications for strategic interventions where hepatitis B control through vaccination can be extended and linked to other existing programmes. The ERP is supportive of integrating these efforts, strongly recommending that WHO ensure that the primary role of universal HepB-BD-inclusive infant vaccination programmes for the elimination of hepatitis B is maintained and extended in all Member States.

Pending resource and programmatic considerations in Member States, the ERP acknowledged that adding hepatitis B screening to existing HIV and syphilis screening programmes for pregnant women will have additional benefits in increasing access to diagnosis and treatment for hepatitis B, in line with the targets in the GHSSVH and the Regional Action Plan for Viral Hepatitis in the Western Pacific. Antenatal HBsAg screening could benefit strategic information systems in the development of disease burden estimates for ongoing surveillance and monitoring purposes. ERP members discussed the importance for countries to link HBsAg-positive pregnant women to care and treatment.

**Laboratory network**

Since the last ERP meeting in January 2016, substantial progress in the development of the regional laboratory network has been made. The Western Pacific Region’s viral hepatitis regional laboratory network will include national reference laboratories for viral hepatitis in initial focus countries (Cambodia, China, Mongolia, the Philippines and Viet Nam) and high-performing laboratories in the Region that will be designated as regional reference laboratories for viral hepatitis. These high-performing laboratories currently exist in Australia, Japan and the Republic of Korea, with a plan to include other countries over time.

The regional laboratory network commits to the following:

- Support Member States of the Western Pacific Region in ensuring the accuracy of test results to enhance viral hepatitis surveillance, diagnosis, treatment monitoring and evaluation.
- Coordinate and facilitate quality control and quality assurance of laboratories performing viral hepatitis diagnostic testing and carrying out surveillance-related activities.
- Enhance viral hepatitis diagnosis, treatment monitoring and disease surveillance in the Region.
- Develop laboratory capacity within countries to enable gathering of essential strategic information necessary to develop a national hepatitis programme.
• Provide hands-on training workshops in 2017 on the laboratory diagnosis, surveillance, monitoring and evaluation of hepatitis B and C (and if needed for hepatitis A, D and E) to improve the quality of testing and assist health officials in conducting surveillance, monitoring and evaluation activities.
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## MEETING TIMETABLE

<table>
<thead>
<tr>
<th>Time</th>
<th>Wednesday, 15 February 2017</th>
<th>Time</th>
<th>Thursday, 16 February 2017</th>
<th>Time</th>
<th>Friday, 17 January 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30–09:00</td>
<td>Registration</td>
<td>08:30–09:00</td>
<td>12. Lao People’s Democratic Republic presentation(s) on birth dose improvement activities</td>
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<tr>
<td>09:00–09:30</td>
<td>1. Opening ceremony</td>
<td>09:00–09:15</td>
<td>Discussion</td>
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<td></td>
<td>• Welcome remarks by the Responsible Officer</td>
<td>09:15–09:45</td>
<td>13. Papua New Guinea presentation(s) on birth dose improvement activities</td>
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<td></td>
<td>2. Opening remarks of the Regional Director</td>
<td>09:45–10:00</td>
<td>Discussion</td>
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<tr>
<td></td>
<td>• Opening remarks of the Ministry of Health</td>
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<td></td>
<td>• Self-introduction, Election of Chair</td>
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<td></td>
<td>• Administrative announcements</td>
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<tr>
<td>09:30–10:00</td>
<td>GROUP PHOTO AND COFFEE BREAK</td>
<td>10:00–10:30</td>
<td>14. Viet Nam presentation(s) on birth dose improvement activities</td>
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<tr>
<td>10:00–10:15</td>
<td>2. Global overview of hepatitis B</td>
<td>10:30–11:00</td>
<td>Discussion</td>
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<tr>
<td>10:15–10:30</td>
<td>3. Regional overview of hepatitis B control in EURO</td>
<td>11:00–11:15</td>
<td>15. Cambodia presentation(s) on birth dose improvement activities</td>
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<td>10:30–10:45</td>
<td>4. Regional overview of hepatitis B control in SEARO</td>
<td>11:15–11:45</td>
<td>Discussion</td>
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<td>10:45–11:15</td>
<td>5. Regional overview of hepatitis B control in WPRO (with EPI update)</td>
<td>11:45–12:00</td>
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<td>11:15–11:40</td>
<td>Discussion</td>
<td>11:00–11:30</td>
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<tr>
<td>11:40–13:00</td>
<td>LUNCH BREAK</td>
<td>11:30–12:00</td>
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<td>13:00–13:20</td>
<td>6. Sustaining the progress among verified countries</td>
<td>13:00–13:30</td>
<td>16. Philippines presentation(s) on birth dose improvement activities</td>
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<td>13:20–13:40</td>
<td>Discussion</td>
<td>13:30–14:00</td>
<td>Discussion</td>
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<td>13:40–14:00</td>
<td>7. Documenting impact (countries with recent or planned serosurveys for verification)</td>
<td>14:00–14:30</td>
<td>17. Solomon Islands presentation(s) on birth dose improvement activities</td>
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<td>14:00–14:20</td>
<td>8. Verifying regional control achievements for low HBsAg seroprevalence targets</td>
<td>14:30–15:00</td>
<td>Discussion</td>
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<td>14:20–14:40</td>
<td>9. China’s development in preventing mother-to-child transmission</td>
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<td></td>
<td>Discussion</td>
<td>15:00–15:30</td>
<td>18. Japan’s introduction of hepatitis B vaccine into the national routine immunization programme</td>
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<td>14:40–15:10</td>
<td>COFFEE BREAK</td>
<td>15:30–15:45</td>
<td>Discussion</td>
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<tr>
<td>15:10–15:30</td>
<td>10. Out of cold chain pilot projects</td>
<td>15:45–16:00</td>
<td>19. Update on communication activities</td>
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<td>15:30–16:00</td>
<td>11. Development of the Western Pacific Region viral hepatitis laboratory network</td>
<td>16:00–16:30</td>
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<tr>
<td>16:00–16:30</td>
<td>Discussion</td>
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<tr>
<td>17:00–18:00</td>
<td>Regional Director’s reception</td>
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