

## First Hepatitis B Expert Resource Panel (ERP) Consultation



Tagaytay, Philippines  
21 to 22 February 2011



**WORLD HEALTH ORGANIZATION**  
REGIONAL OFFICE FOR THE WESTERN PACIFIC



**REPORT**

**FIRST HEPATITIS B EXPERT RESOURCE PANEL (ERP) CONSULTATION**

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**REPORT**  
**FIRST HEPATITIS B EXPERT RESOURCE PANEL (ERP) CONSULTATION**

Convened by:

**WORLD HEALTH ORGANIZATION  
REGIONAL OFFICE FOR THE WESTERN PACIFIC**

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## **NOTE**

The views expressed in this report are those of the participants in the First Hepatitis B Expert Resource Panel (ERP) Consultation and do not necessarily reflect the policies of the World Health Organization.

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This report has been prepared by the World Health Organization Regional Office for the Western Pacific for the participants of the First Hepatitis B Expert Resource Panel (ERP) Consultation, which was held in Tagaytay, Philippines, from 21 to 22 February 2011.

## SUMMARY

The First Hepatitis B Expert Resource Panel (ERP) Consultation was held at Taal Vista Hotel in Tagaytay, Philippines from 21 to 22 February 2011, to support the regional milestone of reducing chronic infection rates to less than 2% by 2012. The Western Pacific Region has made tremendous progress towards this goal through strong vaccination efforts; chronic infection rates among children have dramatically dropped from 8%–10% to less than 2%. However, critical work remains as nine countries will not meet the regional milestone.

The main objectives of the consultation were:

- (1) to review and discuss the certification process, country seroprevalence data and methods for serologic surveys; and
- (2) to identify strategies for increasing hepatitis B vaccination coverage in priority countries.

Key recommendations made by the panel were: (1) the term "verification" should replace "certification" to better reflect the continuum of hepatitis B control; (2) tools to standardize and increase transparency of the verification process should be piloted and finalized for use; (3) six countries and areas should begin the verification process, namely, American Samoa, Australia, China, Fiji, New Zealand and Tonga; (4) five additional countries and areas could be ready for verification depending on further clarification, namely, Japan, the Marshall Islands, the Commonwealth of the Northern Mariana Islands, Palau and Singapore; (5) the Western Pacific Region should engage the ERP to support countries to increase immunization coverage; and (6) the target year for the 1% goal should be established in 2012.

## LIST OF ACRONYMS

EPI	Expanded Programme on Immunization
ERP	Expert Resource Panel
GAVI	Global Alliance for Vaccines and Immunization
HBeAg	Hepatitis B “e” antigen
HBIG	hepatitis B immunoglobulin
HbsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HepB3	three doses of hepatitis B vaccine
JRF	UNICEF/WHO Joint Reporting Form
LQAS	lot quality assurance sampling
NIP	National Immunization Programme
RED	Reaching Every District
TAG	Technical Advisory Group

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## 1. INTRODUCTION

In 2003, the Regional Committee decided that measles elimination and hepatitis B control should be two new pillars to strengthen the Expanded Programme on Immunization (WR/RC54.R3). In 2005, the Regional Committee decided that the Region should reduce chronic hepatitis B infection in children aged at least 5 years to less than 2% by 2012, as an interim milestone towards the final of goal of less than 1% (WR/RC56.R8).

To support the regional milestone and goal, the WHO Regional Office for the Western Pacific convened an expert working group meeting on hepatitis B in Tokyo, Japan in March 2007. The meeting developed guidelines for certification of achievement of hepatitis B control. These guidelines stipulated constitution of an expert resource panel from which experts could be drawn to form a three- to four-member certification panel upon receipt of a request for certification from a Member State.

During 2007 and 2009, experts were invited by the Regional Director to serve as members of the Western Pacific Region Hepatitis B Expert Resource Panel (ERP).

The ERP consists of nine members with the following terms of reference:

- (1) to serve in an honorary capacity and advise on the status of hepatitis B control in WHO Member States in the Western Pacific Region;
- (2) to serve on the certification panel when a request is received from a Member State for certification of the hepatitis B control milestone;
- (3) to help with the certification process which may involve a desk-review of the documents submitted by a country or visits to Member States; and
- (4) to advise on various issues related to hepatitis b control and achievement of the milestone of hepatitis B control in the Region.

Despite the broad terms of reference, panel members have mainly been on stand-by to serve on certification panels when countries initiate the certification process. In 2009, the Technical Advisory Group (TAG) in Immunization and Vaccine Preventable Diseases in the Western Pacific Region recommended that ERP should hold quarterly teleconferences and annual meetings to monitor and facilitate continued progress towards the 2012 milestone.

In response to this recommendation, WHO and ERP proposed to increase the panel's role and activities and agreed to convene consultation. As a result, the First Hepatitis B Expert Resource Panel (ERP) Consultation was held at Taal Vista Hotel in Tagaytay, Philippines from 21 to 22 February 2011. An agenda and list of participants can be found in Annexes 1 and 2, respectively.

### 1.1 Objectives

- (1) To review criteria and the process for certification of hepatitis B control and improve as needed.
- (2) To review country prevalence data and provide guidance on whether countries should initiate certification or gather more prevalence data.

- (3) To provide guidance on acceptable seroprevalence survey methods for certification of up to 13 Pacific island countries.
- (4) To provide guidance on seroprevalence survey methods for programme assessment and monitoring.
- (5) To formulate guidance for the regional goal to reduce chronic hepatitis B to less than 1%; and to identify ways in which ERP can help increase hepatitis B vaccination coverage in priority countries.

## 1.2 Session 1: Opening ceremony

Dr David Snaidack, Acting Team Leader, opened the meeting and introduced Dr Shin Young-soo, WHO Regional Director, who gave the opening speech. Dr Shin noted that the Western Pacific Region has made a bold commitment to and substantial progress in combating chronic hepatitis B infection among children. Through strong vaccination efforts, chronic infection rates among children in this Region have dramatically dropped from 8%–10% infection rate to less than 2%. However, he remarked that critical work remains as nine countries will not meet the regional milestone of reducing chronic infection rates to less than 2% by 2012.

To support this work, the 19th Technical Advisory Group on Immunization and Vaccine Preventable Diseases in the Western Pacific Region recommended that ERP should increase its role in facilitating regional hepatitis B control. With this, Dr Shin expressed his support of the panel and assured that it would have the range of expertise needed to address the diverse needs of countries in the Region. It is expected that ERP will provide guidance and expert opinion on how to best support countries that need to increase vaccination coverage and prevent on-going chronic infection of infants and children. Several countries in the Region will likely require a renewed commitment and awareness of hepatitis B control, which may have a positive effect on other health programmes, especially maternal and newborn care.

In the process of determining which countries have met the regional goal, the panel will provide a better picture of the progress made thus far in the Region. As the Western Pacific Region is the first to adopt a regional hepatitis B control goal, ERP will provide the international community with evidence of feasibility that will benefit global hepatitis B control. Within the Region, ERP will provide the momentum and motivation needed to reach or continue to the next stages of hepatitis B prevention.

Guidance on the vision for the future of hepatitis B control in the Western Pacific Region will be valuable to ensure that we are prepared to support and continue with the Region's tremendous progress. Dr Shin thanked the panel members for their dedication to the health of the children in this Region and wished them a successful and fruitful meeting.

## 1.3 Session 2: Consultation overview, objectives and outcomes

Dr Karen Hennessey provided an overview for the outcome-oriented consultation and noted that the agenda was based on the 2010 TAG recommendations.

The 2010 TAG recommendations were reviewed and served as the basis for building this consultation agenda. In brief, the TAG recommended the following: the ERP proposal for facilitating regional hepatitis B control should be endorsed; countries should initiate the certification process if serosurvey data indicate they have achieved the regional goal; ERP and WHO should develop regional guidance for prevalence surveys (certification and monitoring); Cambodia, the Lao People's Democratic Republic and Papua New Guinea should develop action plans for increasing vaccination

coverage; and the 2012 target year was clarified to ensure the meaning is consistent with the 2005 Regional Committee resolution, meaning that prevalence is less 2% among 5-year-old children and countries should not be provisionally certified based on immunization coverage.

## 2. PROCEEDINGS

### 2.1 Session 3: Status of hepatitis B control in the Western Pacific Region

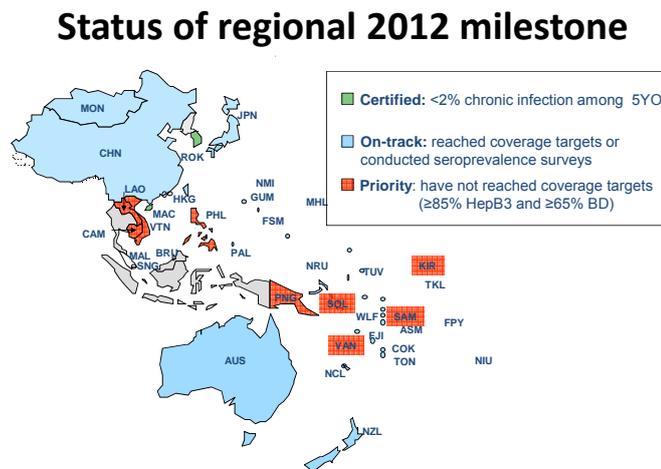
Presenter: Dr Karen Hennessey

Chair: Dr Takaji Wakita

Rapporteur: Dr Yoshihiro Takashima

This session provided an overview of the regional status towards hepatitis B control, including the status of each country and how they would be addressed during this meeting. Specifically, countries would be reviewed in terms of whether they were a country with low vaccination coverage, high vaccination coverage and high seroprevalence data, and high vaccination coverage and no or little seroprevalence data (as shown in Figure 1).

Figure 1:



Hepatitis B birth dose and three-dose (HepB3) coverage was shown for each country. The nine priority countries, comprising five non-Pacific countries (Cambodia, the Lao People's Democratic Republic, Papua New Guinea, the Philippines and Viet Nam) and four Pacific island countries (Kiribati, Solomon Islands, Samoa and Vanuatu), all reported less than 85% HepB3 coverage and/or less than 65% birth dose coverage in 2009.

Seroprevalence data from Hong Kong (China), Malaysia and Mongolia have been submitted to the Regional Office for consideration for certification. Certification panels will be convened and the process may begin as soon as official letters requesting certification are received from the Governments.

This session also included a discussion of the term "certification". Certification has a distinct meaning in the field of vaccine preventable diseases; it is usually reserved for disease eradication initiatives such as smallpox and poliomyelitis. At the country level, certification translates as an

intensive and final process (i.e. polio certification took years for most countries) and some countries fear that being considered "certified" would decrease support for unfinished work. "Validation" or "verification" would better allow the communication of the continuum of hepatitis B control. The downside to changing terminology is that the process has been extensively referred to as certification and may cause confusion.

ERP members questioned whether the drawbacks to the term certification were theoretical or real. It was clarified that it is real problem with at least one concrete example coming from China. China has a tremendous burden of chronic infection among adults and would like to expand its control programme to incorporate this important public health problem. There is real concern that becoming certified would decrease future support for hepatitis B control strategies beyond immunization.

The advantages of changing the terminology were recognized and there was consensus in the value of changing the terminology from certification to verification.

## 2.2 Session 4: Review of the certification process

Presenter: Dr Minal Patel  
Chair: Dr Andrew James Hall  
Rapporteur: Dr Yvan Hutin

A review of the certification process for the Republic of Korea and Macau (China) indicated that the process took around three to four weeks and that there was no standardized approach. The reports covered a very broad range of topics. Clarifications requested by the certification panels to the countries included not only essential queries (e.g. survey sampling, analytic details, potential biases) but also supplemental queries (e.g. surveillance system) that are not the main focus of the exercise.

**Simplification.** The presentation covered the need to simplify the process. This phase of assessing hepatitis B control does not need the same rigor as certification of polio eradication. In addition, many countries publish or have existing reports on hepatitis B serosurveys; these reports can be used as part of the certification application rather than requiring an additional report. The proposed approach to simplify the process is to ask countries to complete a cover sheet that summarizes key information (Annex 3) and to provide documentation on hepatitis B serosurveys and other supporting documents as needed. Documentation on hepatitis B serosurveys can be a published article or report. The cover sheet has four sections covering vaccine programme history, coverage data, seroprevalence data and an open section where the country could pose questions to the certification panel on strategies for hepatitis B control.

**Communications.** To communicate this new process and encourage certification, a one-page country circular was proposed. This circular would set forth the certification requirements, explain how to initiate the process and outline the steps along the way.

**Standardization.** The certification process itself requires standardization to increase consistency and transparency. The process could also be used to ensure that relevant aspects of hepatitis B control are covered by communicating on strategies that could be impactful in the country. To address these issues, an evaluation tool was drafted that frames country reviews around three components (schedule, coverage, survey) and suggests reference points or milestones that are not rigid (Annex 4).

Overall, the process required substantial EPR input to ensure that the proposed changes reflect external expert opinion. Key discussion points included the following:

- (1) Cover sheet. It was mentioned that reported coverage figures may not be accurate and they may fluctuate from year to year. Hence, it would be helpful if countries provided a time

horizon that was longer than the five years allotted in the cover sheet, and if WHO provided comments on the quality of data if possible. It was requested to include district-level coverage when available. While ERP members pointed out that a vague birth-dose definition is not useful, others referred to the fact that the birth dose is effective beyond 24 hours, and that if countries had data beyond 24 hours, they should be used. It was suggested that data from the WHO/UNICEF Joint Reporting Form (JRF) should be included. The WHO hepatitis B country profiles include key JRF data and these would be included in the certification package.

The cover sheet could also ask about hepatitis B surface antigen (HBsAg) screening practices and use hepatitis B immunoglobulin (HBIG). It was suggested to include a section on longer-term plans for sustaining hepatitis B control gains. It was noted that if a country had more than one serosurvey, then multiple coversheets could be used to complete section 3 for each serosurvey. Only serosurveys that meet certification requirements as described in the 2007 guidelines or serosurveys that provide supplemental evidence need to be included. It is not necessary to report on an exhaustive list of seroprevalence studies conducted in the country, especially given the multitude of convenience samples in subpopulations that are frequently conducted.

(2) Supplemental documentation. Other supplemental documentation that could be useful would be reports from a cold chain review or an Effective Vaccine Management assessment. Experience from one Pacific island country suggested that despite high coverage, seroprevalence was higher than expected because of vaccine freezing.

(3) Evaluation tool and reference points. ERP and WHO shared appreciation for steps towards standardizing the certification process. It was recognized that the evaluation tool provides a framework to systematically review country data, but it does not replace the judgement needed by ERP to assess the unique country situations. While some experts questioned the need for three-level assessments (weak, acceptable, strong), others pointed out that the intermediate level may be helpful to compare strong and weak areas. It was noted that some criteria may not need three tiers and it would be better not to force them into three tiers. ERP decided this was an important tool and that they should spend more time going through it in detail. ERP would test the tool during the session on country reviews and would report back specific feedback at that time.

Another opportunity for piloting the cover sheet and evaluation tool would be during possible certification opportunities with Hong Kong (China), Malaysia and Mongolia.

There was no clear consensus on whether the evaluation tool should be given to countries to promote transparency and to maximize feedback to countries. However, it was mentioned that the Eastern Mediterranean Regional Office has had success with similar tools during a peer-review process and that they have helped to build capacity in countries by illustrating the evaluation standards.

### 2.3 Session 5: Country reviews to determine certification readiness

Presenter: Dr Karen Hennessey

Chair: Dr Eric Mast

Rapporteur: Dr Minal Patel

The purpose of the session was to seek recommendations on which countries can proceed with certification, which ones require more seroprevalence data, and which ones require clarification to decide. All countries for consideration had at least 65% birth dose coverage and 85% HepB3 coverage (except Japan and Australia) and seroprevalence data that may indicate they have met the regional

goal. An additional purpose of the session was to pilot and fine-tune the proposed certification evaluation tool.

The process went as follows:

- (1) ERP members agreed that no review was necessary to recommend that the following countries start the certification process: Australia, China and New Zealand.
- (2) Dr Wakita had data from Japan that he presented separately on the second day of the meeting.
- (3) ERP members split into two groups to evaluate the status of eight countries and areas:

Group 1: Dr Jong-Hyun Kim, Dr Mark Kane, Dr John Ward and Dr Andrew James Hall reviewed American Samoa, Fiji, the Commonwealth of the Northern Marina Islands and Singapore.

Group 2: Dr Takaji Wakita, Dr Eric Mast, Dr Tilman Ruff and Dr Hui Zhuang reviewed the Marshall Islands, New Caledonia, Palau and Tonga.

- (4) The two groups presented their country/area recommendations and input on the evaluation process.

Group presentations yielded the following decisions:

<b>Proceed with verification</b>	<b>Clarification before proceeding</b>	<b>Seroprevalence study recommended</b>
Australia	Japan	New Caledonia
China	Singapore	
New Zealand	Northern Mariana Islands, Commonwealth of the	
American Samoa	Marshall Islands	
Fiji	Palau	
Tonga		

A review of the country/area data brought up the following issues.

(1) Should ERP consider seroprevalence studies of children under 5 years old? The group decided that the decision would be made on a case-by-case basis but would lower the seroprevalence threshold for younger cohorts as per guidelines.

(2) How recent should the seroprevalence data be? It was decided that older data would be acceptable but that ERP could request newer information on a country-by-country basis. Additionally, the country must have high hepatitis B coverage since the time of the seroprevalence survey.

(3) Are convenience samples acceptable? In general, convenience samples would not be acceptable but exceptions could be made, as with Tonga, where there is good evidence that the convenience sample is representative of the population. Convenience sample point prevalence should be held to the same standard as those from a cluster survey and include confidence intervals even though most of these will incorrectly be based on the assumption of simple random sampling.

Comments on the evaluation tool and reference points. Many detailed comments were made on fine-tuning the evaluation tool and reference points. These comments will be incorporated in the next version of the tool and will be piloted during the next country certification.

#### 2.4 Session 6: Proposal for certification of Pacific island countries

Presenter: Dr Frank Mahoney

Chair: Dr Hui Zhuang

Rapporteur: Dr Kathleen Wannemuehler

All Pacific island countries have introduced a birth dose and a three- or four-dose schedule for multiple years; all but one country introduced hepatitis B vaccination more than 10 years ago. Implementing seroprevalence studies in Pacific island countries is uniquely difficult because of small population sizes, widely dispersed populations, difficult access to some populations, limited technical capacity and limited financial resources.

The draft protocol presented could be used by Pacific island countries to implement serosurveys simultaneously or independently; either way, each country would be evaluated separately. Surveys measuring surface antigen with rapid test kits would be accepted. ERP might consider flexibility with regards to precision estimates for Pacific island countries. The method of lot quality assurance sampling (LQAS) might be considered for some countries. The four priority countries (Kiribati, Solomon Islands, Samoa, Vanuatu) are not ready to proceed with certification.

The following points were discussed.

##### (1) Maximizing efficiency

ERP was asked whether the draft protocol was recommending pooling the serosurveys of Pacific island countries to have a single estimate. The answer was "No". The protocol provides a single framework so that results would be consistent; however, each country would complete its own survey. Surveys could be implemented simultaneously to save costs, gain efficiency and provide potential for standardization. There was agreement that each country would be evaluated separately.

ERP was asked whether Pacific island countries could have more flexibility regarding the required precision of 0.5%. No clear consensus was gained; however, it was felt by some that flexibility by the panel might be appropriate.

It would be advantageous to combine hepatitis B seroprevalence surveys with surveys measuring seroprevalence of other infections such as HIV, measles or polio. Advantages to this approach would be shared costs and collaboration.

The relevance of conducting serosurveys for small countries, e.g. those with birth cohorts of less than 200, was mentioned. It was suggested that studies should be designed to provide useful information to the country and survey among the highest risk populations to ensure

uniformly low prevalence, especially among different ethnic groups. There was consensus that not all Pacific island countries were ready for certification.

(2) Rapid tests

The participants discussed the acceptability of using rapid tests. It was mentioned that different types of kits are available on the market, but comprehensive guidance was lacking on which kits meet minimum standards. It was also noted that a drawback to rapid tests was the absence of a blood sample for testing of other markers, genotypes and infections. One type of protocol to consider would be to obtain a serum sample from those with positive rapid test results. WHO Headquarters is in the final stages of clearing guidelines for conducting national hepatitis B seroprevalence surveys; the proposed protocol for Pacific island countries should be consistent with and refer to this document.

In terms of the sensitivity of rapid tests, a study proposed to be conducted in Bangladesh will compare the sensitivity of a rapid test to that of a serum ELISA test. Dr Kim mentioned that he is in the process of comparing the sensitivity of eight different rapid kits. It was concluded that the sensitivity for detecting HBsAg with a rapid test was good and that studies using rapid tests with verified high sensitivity would be accepted.

A safety concern regarding the possible re-use or inadequate disposal of the lancet was raised. It was pointed out that with proper training, experience has shown safe practices.

(3) Lot quality assurance sampling.

The applicability of using LQAS methods in Pacific island countries was discussed. It was voiced that LQAS was a possible option, but no decision was made regarding which country(s) might benefit from this approach. This can be addressed on a case-by-case basis.

## 2.5 Session 7: Seroprevalence survey options for programme monitoring

Presenter: Dr Kathleen Wannemuehler

Chair: Dr Hui Zhuang

Rapporteur: Dr Frank Mahoney

This session described options for seroprevalence survey methods for hepatitis B control programme assessment and monitoring.

Currently, WHO is developing global guidelines for conducting national seroprevalence surveys. However, some countries in this Region have interest in conducting smaller-scale surveys for programme monitoring. These include countries that have not yet reached high immunization coverage rates and are not ready to conduct a large national survey for certification purposes but are interested in monitoring progress towards the goal and identifying geographical or demographic areas of concern. In addition, it will be of interest to conduct post-certification monitoring to insure seroprevalence rates continue to be less than 1%.

The following points were discussed.

(1) LQAS versus traditional cluster sampling methods. It was mentioned that LQAS makes the most sense for countries or areas with low prevalence, meaning they could be relevant for certification or post-certification monitoring. As the prevalence increases, the sample size requirements for LQAS approach that of traditional sampling methods. LQAS does not take

into account a cluster effect, the impact of which is not clear. LQAS is not ideal for populations that have varying infection prevalences.

(2) Convenience sampling. In general, convenience samples were not favoured. Blood donors were often screened and hospital patients were not representative of the general population.

(3) Options for reducing the sample size of traditional cluster surveys. Sample size calculations could reasonably be based on one-sided hypotheses since we can safely assume that the impact of vaccination is to decrease infection rates; we have no reason to think they would increase rates. There may be exceptions to the standard use of adjusting sample size by a factor of two to accommodate the sampling design effect; there may be some cases where heterogeneity is known to be low and a smaller design effect would be acceptable. Surveys in Africa have shown design effects of 1.3–1.5. In China, the design effect was less than 2 for children under 5 years and greater than 2 for children older than 5 years. For countries that are interested in interim or baseline prevalence such as Cambodia and Papua New Guinea, precision as low as 0.5% may not be necessary.

(4) Lessons learnt from national surveys. A review of national surveys highlighted the need to ensure that data were analysed to reflect sampling weights and cluster design. It was not clear—based on the description of methods—if these were addressed. During the certification process, the certification panels should request clarification if these analytic features are not clear.

## 2.6 Session 8A: Priority country status and challenges

Presenter: Dr Yoshihiro Takashima

Chair: Dr Mark Kane

Rapporteur: Dr Yvan Hutin

In 2007, WHO in the Western Pacific Region defined eight strategies for hepatitis B control. The presentation reviewed strategy one (routine services) and two (birth dose) for the priority countries, including Cambodia, the Lao People's Democratic Republic and Papua New Guinea.

*Cambodia.* In Cambodia, 44% of births occurred in health centres in 2009 (22% in 2005). The Government provides a US\$ 15 incentive to midwives for facility delivery. Populations that are challenging to reach for routine immunization include migrants, rural hard-to-reach populations, ethnic minorities, and urban poor. Reasons for not being immunized included being too busy (28%), mobile (23%), fear of vaccination (22%) and lack of knowledge (12%). There is an ingrained attachment to the concept of being born at home. In 2009, timely birth dose coverage was under 60%, with most districts under 50% in 2008, and HepB3 coverage was around 90%. An action plan proposed during the national EPI review in 2010 included reaching the underserved as identified by health centres, introducing community support systems, and microplanning by operational districts and provincial health departments.

*Lao People's Democratic Republic.* In the Lao People's Democratic Republic, 80% of births occur without attendants. The routine immunization strategy includes fixed sites (15%), outreach (35%) and mobile (50%). Issues include lack of public demand, inaccurate targeting, vaccine stock-outs and lack of funds. In 2008, birth dose coverage was still under 20%, and HepB3 coverage was still under 70%. Birth dose coverage by district is concerning, apart for one district that exceeds 90%. Solutions considered for increasing birth dose coverage included introduction of a fee exemption for facility-based deliveries in certain areas, training of traditional birth attendants, provision of birth certificates to mothers, and procurement of Uniject™ for use in the hardest-to-reach areas.

*Papua New Guinea.* In Papua New Guinea, the coverage of timely birth dose was just above 20% while HepB3 was 69%. A small number of districts have coverage above 80%. Challenges include high percentage of births occurring at home (48%), absence of hospital birth dose coverage, missed opportunities for vaccination, and absence of advocacy. The strategies proposed by the National Immunization Programme (NIP) included providing incentives for facility deliveries, promoting birth dose for hospital births, promoting coverage for home births and helping low performance districts increase HepB3 coverage.

Few countries use Uniject™. Major common challenges include weak routine immunization systems, high proportion of districts with chronic low coverage, ineffective Reaching Every District (RED) strategies, and high proportion of home deliveries. Other issues include weak political commitment, insufficient community demand, lack of optimal strategies and lack of funds.

The following discussion points were covered during this session.

(1) Three-dose coverage

Strengthening routine EPI is a priority. It should be emphasized that hepatitis B control is dependant on strengthening the EPI system as a whole. This approach should be addressed on a country-by-country basis. Polio eradication showed that children are reachable, physically and programmatically. Countries were able to eradicate polio and maintained their polio-free status. The difference is that hepatitis B control will require strengthening routine systems. In the Eastern Mediterranean Region, the approach was to bring partners together to make a plan.

It was mentioned that RED had weak management and that it was not addressed. RED did not fail, but it was not completely implemented. Each country needs an in-depth EPI review followed by a partners' meeting.

(2) Birth-dose coverage

Most people who deliver babies do not work for EPI. Hence, it is difficult to get them to give vaccines. However, with coordination, education and collaboration, especially between the Maternal and Child Health programme and EPI, it can ultimately happen. Several primary health care initiatives can be used as models.

In Papua New Guinea, a project in a remote province introduced a system to support the village health workers. The neonatal package included Uniject™ out of the cold chain. Timely birth dose coverage increased to 74% for home births and 93% for facility births. Success was notable, but the cost was high and feasibility for scale-up and sustainability are unclear.

Increasing facility-based birth dose coverage is low-hanging fruit. Some funding is available to document coverage in facilities initially. However, it is unclear how secure that funding line is.

(3) About advocacy

Donor funding is an important catalyst. Vaccination week and World Hepatitis Day could be used. Public and government awareness must be ensured. ERP can also help with advocacy.

(4) Technical support

ERP could set up teams to provide technical assistance to countries. For example, ERP could have a Mekong team and a Pacific island team. Many countries know what to do, but they lack

high-level support and/or funding. The plans have to be more comprehensive and involve partners.

## 2.7 Session 8B: Challenges and the future for birth dose

Presenter: Dr Tilman Ruff  
Chair: Dr Mark Kane  
Rapporteur: Dr Yvan Hutin

A meeting was convened in Melbourne to review birth dose issues. A product of that meeting was the "Melbourne Declaration". Recommendations included integrating with the integrated package for neonatal care, promoting use of the controlled temperature chain within the context of a possible heterogeneity in terms of thermostability, researching and developing solutions that could be used for home births, increasing demand in the population and addressing residual concerns among health care workers. Funds must be secured (particularly in the current GAVI context) and the Decade of Vaccine could be an opportunity.

The key discussion point was that it could be highly beneficial if GAVI support would be available for monovalent hepatitis B vaccine and for some cases, Uniject™.

## 2.8 Session 9: Status and challenges on the 1% control goal

Chair: Dr John Ward  
Rapporteur: Dr Minal Patel

Proposing a timeline for the <1% goal was discussed in this session.

One of the main purposes for establishing a goal is to help motivate countries to improve programmes and have a unified regional position; establishing a timeline for the <1% goal might help maintain momentum. Many countries are estimated to have met the <1% goal; however, one of the disadvantages of setting a goal now would mean that hepatitis B control would have simultaneous target dates being 2012 and another target year further in the future.

In addition to measuring the number of countries in the Region that have achieved the goal, it is also important to analyse and communicate the impact that vaccination programmes have had on decreasing prevalence rates in the Region's population as a whole.

We have not done well in communicating that the actual goal is <1% and that <2% is an interim milestone. Communicating to countries the change in terminology from certification to verification will provide an opportunity to remind countries of this distinction. Additionally, we could improve our communication on the tremendous achievement this Region has had on hepatitis B control. This is particularly important as we approach 2012 and not all countries will have met the goal. We have a chance to highlight achievements in an upcoming article on the status of hepatitis B control in the Western Pacific Region scheduled for publication in the *WHO Weekly Epidemiological Record* in May 2011.

With 2012 approaching, we should be extolling the positive, demonstrating success, engaging needs and building commitments. New maps should be created that show the changing epidemiology of chronic childhood infection in the Western Pacific Region, similar to the hallmark polio maps. Additionally, it was mentioned that the International Agency for Research on Cancer (IARC) could be available to assist with modelling the number of lives saved in the Region based on cancer registry data. It was also strongly suggested to use World Hepatitis Day to advocate for hepatitis B control in the Region.

The final decision was to not set a target year for the 1% goal at this time. More data on infection rates in key priority countries (Cambodia, the Lao People's Democratic Republic and Papua New Guinea) should be available in 2011 or early 2012. This will provide information on the feasibility of attaining the regional 1% goal. It was noted that the goal should not necessarily be paced on the most challenged country; it will be important to balance aspiration with feasibility. The ideal plan will be to recommend the target year in 2012 in time for both the TAG and Regional Committee meetings.

## 2.9 Session 10A: Lessons learnt from China

Presenter: Dr Yvan Hutin

Chair: Dr Jong-Hyun Kim

Rapporteur: Dr Karen Hennessey

China has met its national targets of reducing chronic infection among children under 5 years of age through the remarkable increase in hepatitis B vaccination coverage and equity in access to vaccination. Nationwide catch-up vaccination campaigns among people up to the age of 15 years have been conducted; however, the burden of chronic infection remains unchanged for older cohorts. With this, China is looking towards expanding its strategies for hepatitis control.

Areas of continued work in vaccination and expanding strategies were presented and discussed as summarized below.

- (1) Certification of achieving regional goals. Although China has published data to indicate it has achieved regional goals, there is reluctance to become certified as this may be interpreted as the work in hepatitis B control is finished. Changing the terminology from certification to verification and an increased emphasis on the continuum of hepatitis B control may help China provide the rationale for initiating the process of documenting achievement of regional goals.
- (2) Hepatitis B vaccination. Although China's vaccination programme has reached its targets and resulted in remarkable disease reduction, there remains potential to further prevent perinatal and childhood transmission through vaccination efforts. ERP guidance in this area included: (a) investigating the reasons for the 1% perinatal infections that continue to occur despite extremely high coverage, including distinguishing between vaccine failure and failure to vaccinate, and (b) consider establishing subnational disease reduction targets (e.g. province or district level targets); this could lay the groundwork for a regional strategy. One tool that could be used is the WHO Western Pacific Region model to estimate the number of persisting perinatal infections on the basis of the input parameters generated by the final evaluation of the GAVI project.
- (3) Screening pregnant women. China could generate more evidence to constitute a more solid basis to guide screening of pregnant women and use of HBIG (e.g. retrospective study to see what happened to children born to women who screened HBsAg-positive, as discussed during recent GAVI missions).
- (4) Serologic survey among adults. China could maximize the plans to collect serum specimens among adults through the serosurvey to provide an opportunity to plan a national programme to manage hepatitis B treatment, e.g. estimate the proportion of persons with chronic infection who are eligible for treatment. Tests that could be done in adults include HBeAg, hepatitis B virus, DNA, indicator of fibrosis using a portable fibroscan, enzymes and anti-hepatitis C virus.

(5) Hepatitis B treatment. The case management consultation in 2009 focused on evaluation of clinical practices, access to quality treatment, and equitable insurance coverage. ERP provided the following guidance: (a) the serosurvey among adults could offer an opportunity to estimate the magnitude and cost of a national programme to manage hepatitis B treatment; (b) portable fibroscans could be used among a subset of the survey population to estimate the proportion of persons eligible for treatment among those with chronic infection; and (c) a public policy document on treatment indications should be prepared to ensure that the treatment agenda is driven by public health priorities and equity.

(6) Hepatitis A vaccination. Key areas for improvement include strengthening vaccination coverage monitoring and evaluation including distinguishing between the impacts of vaccine and the improvements in socioeconomic factors.

(7) Hepatitis E vaccination. Basic information on hepatitis E burden of disease will inform the most effective strategies for vaccination when the vaccine becomes available.

(8) Hepatitis C screening and response. National hepatitis C virus prevalence is estimated to be 0.4%. The identification of a positive hepatitis C test could be used as signal to harm reduction activities among injection drug users. Organizing efforts for hepatitis C virus screening and response is challenging because it does not fall under the purview of the vaccination programme.

#### 2.10 Session 10B: Future of hepatitis B control in the Western Pacific Region

Presenter: Dr Andrew James Hall

Chair: Dr Jong-Hyun Kim

Rapporteur: Dr Karen Hennessey

This session presented experiences and advancements in hepatitis B control. Experience from the United Kingdom found that investigations of contacts and follow-up of persons with hepatitis B infection have not been cost-beneficial as most close contacts have already been infected and follow-up is expensive and time-consuming.

Experience with vaccination of high-risk adults has not been successful in most settings around the globe. Health care worker vaccination programmes would be the one exception and a regional strategy and published guidance could be important. The United Kingdom has the practice of training HBsAg-positive health care workers in low-risk specialities. There was no consensus in the group of the effectiveness of this practice.

Survey data on providing Lamivudine during pregnancy and administering HBIG and vaccine at birth increases the prevention of perinatal transmission to 98%–99%. The major obstacles are logistics, costs and drug resistance with Lamivudine (about 12%). The United Kingdom recommends the use of Tenofovir; however, there are safety concerns for its use during pregnancy.

The major benefits for considering hepatitis B treatment are that it reduces viral load, reduces the risk of liver cancer for the patient and reduces the risk of transmission to others. Its drawbacks are costs and unknown treatment effectiveness among the genotypes of the Western Pacific Region.

High-risk strategies have failed in general and treatment is costly and logistically demanding. It would be reasonable to have permissive language to allow high-risk strategies, but not to recommend the investment.

Regarding treatment, liver cancer is the most common cancer in China. Population screening and treatment is important for a large population in China. Cost-effectiveness will not be along the lines of that of vaccination but may help define its position in public health priorities.

Other areas of work such as injection safety and nosocomial transmission need to also be on the prevention agenda. Education of health care workers has a role for helping them understand their personal risk of becoming infected as well as protecting their patients from infection.

### 3. CONCLUSIONS AND RECOMMENDATIONS

#### 3.1 Conclusions

##### 3.1.1 Status of hepatitis B control in the Western Pacific Region

After clarifying the rationale for changing "certification" to "verification", it was concluded that changing the terminology would provide an opportunity to present the process in terms of the continuum of control, which is important to China and other countries that have successfully implemented childhood vaccination programmes. "Verification" is also consistent with terminology used with other vaccine-preventable disease control initiatives.

##### 3.1.2 Review of the certification process

After reviewing the certification experience of Macao (China) and the Republic of Korea, it was concluded that the current verification process should be made more efficient and country reviews should be more standardized. Using existing reports or published papers as supplementary documents would decrease the redundancy and workload on country staff. Having evaluation criteria would improve the consistency and transparency of the country review process. Tools discussed during the consultation would require more input and fine-tuning before they should be considered final.

##### 3.1.3 Country reviews to determine verification readiness

Country reviews led to the decision that six countries were ready for verification and five countries could be ready but need clarification or supplemental data (countries listed in the recommendation section). The country review process highlighted a few clarifications regarding acceptability of serologic data including: convenience surveys are generally not acceptable unless they are representative (e.g. Tonga); and rapid tests are acceptable if they have been verified to have sensitivity in the range of laboratory-based ELISA tests. ERP is available to review protocols for serologic surveys prior to implementation to ensure they meet verification requirements.

##### 3.1.4 Proposal for verification of Pacific islands countries

The protocol would serve as guidance for Pacific island countries, but each country could implement separately and would be evaluated separately. Simultaneous or coordinated implementation would be supported due to its potential for cost savings and standardization. The proposed protocol for Pacific island countries should be consistent with and refer to the WHO Headquarters' guidance for conducting national hepatitis B seroprevalence surveys.

### 3.1.5 Seroprevalence survey options for programme monitoring

LQAS makes the most sense for countries or areas with low prevalence; meaning they could be relevant for verification or post-verification monitoring. In general, convenience samples were not favoured, but they could be acceptable if the population is well-defined and representative to the age groups or geographic areas from where they are sampled. Sample size calculations could reasonably be based on one-sided hypotheses since it can be assumed that vaccination will decrease infection rates and not increase them. For countries that are interested in interim or baseline prevalence such as Cambodia and Papua New Guinea, precision as low as 0.5% may not be necessary.

### 3.1.6 Priority country status and challenges

The three priority countries presented (Cambodia, the Lao People's Democratic Republic and Papua New Guinea) have substantial challenges for reaching regional milestones and goals. Strengthening routine EPI is a priority and it should be emphasized that hepatitis B control is dependant on strengthening the EPI system as a whole. Increasing facility-based birth dose coverage is low-hanging fruit. Each country needs an in-depth EPI review followed by partners' meeting. Donor funding is an important catalyst. ERP could create teams to provide countries with technical assistance advocacy.

### 3.1.7 Challenges and the future for hepatitis B birth dose

The "Melbourne Declaration", a product of a WHO Headquarters' consultation on preventing perinatal HBV transmission, is useful for bringing together and communicating the multiple strategies for increasing birth dose. ERP voiced that GAVI support for the cost-effective and impactful hepatitis B birth dose would complement their current support for hepatitis B-containing combination vaccines and would build on their historic support for preventing chronic hepatitis B infection in children.

### 3.1.8 Status and guidance on the 1% control goal

ERP decided not to set a target year for the 1% goal at this time. More data on chronic infection rates in key priority countries (Cambodia, the Lao People's Democratic Republic and Papua New Guinea) should be available in 2011 or early 2012. This information will help to determine the feasibility of attaining the regional 1% goal. Although it was noted that the goal should not necessarily be paced on the most challenged country, it will be important to balance aspiration with feasibility. The ideal plan would be to recommend the target year in 2012 in time for both the TAG and Regional Committee meetings.

### 3.1.9 Lessons learnt from China

China has made tremendous progress and serves as an example for the Region. Although China has published data to indicate it has achieved regional goals, there is reluctance to become certified as this may be interpreted as the work in hepatitis B control being finished. Changing terms from certification to verification and placing an increased emphasis on the continuum of hepatitis B control may help China provide the rationale for initiating the process of documenting achievement of regional goals.

### 3.1.10 Future of hepatitis B control in the Western Pacific Region

Vaccination of health care workers is the most successful vaccination programme targeting high-risk adults. ERP concluded that providing permission language could be useful, but it did not recommend vaccination of high-risk groups in general.

There are promising advances and evidence for providing antiviral treatment during pregnancy to prevent perinatal transmission and treatment of adults with chronic hepatitis B infection to prevent liver disease. However, costs and logistics prohibit ERP from making a treatment recommendation for the Region in general.

### 3.2 Recommendations

Key ERP recommendations include the following:

- (1) To better reflect the continuum of hepatitis B control and to be consistent with other vaccine-preventable disease control initiatives, the process for determining if countries have achieved the regional milestone or goal should be referred to as "verification" rather than "certification".
- (2) Six countries and areas have data suggesting they have met the regional milestone and should begin the verification process (American Samoa, Australia, China, Fiji, New Zealand and Tonga); five countries need further clarification to decide if they are ready for verification (Japan, the Marshall Islands, the Commonwealth of the Northern Mariana Islands, Palau and Singapore);
- (3) Tools to standardize and increase transparency of the verification process should be piloted and finalized for use.
- (4) The WHO Regional Office for the Western Pacific should establish regular communications with ERP on the verification progress and with countries and other partners as appropriate.
- (5) A communications strategy should be developed to inform countries of the changes in the verification process, encourage verification for those countries that are ready, emphasize the tremendous progress, highlight the needs of the few countries that will not make the milestone, and begin to shift attention to the 1% goal. Communications should take advantage of the upcoming World Hepatitis Day to highlight this initiative.
- (6) The WHO Regional Office for the Western Pacific should support the design and implementation of serologic surveys among the 10 to 13 Pacific island countries and areas that have had high immunization coverage for more than five years (Cook Islands, French Polynesia, Guam, the Marshall Islands\*, the Federated States of Micronesia, New Caledonia, Niue, the Commonwealth of the Northern Mariana Islands\*, Nauru, Palau\*, Tokelau, Tuvalu, Wallis and Futuna); the three countries noted with "\*" may not need further data on chronic infection rates if ERP finds them ready for verification after clarification (#2 countries above).
- (7) The WHO Regional Office for the Western Pacific should finalize guidance on serologic survey options for countries such as Papua New Guinea and Cambodia that are interested in data for assessment and advocacy. Such survey options could also be useful for monitoring hepatitis B control after verification. Guidance should be consistent with WHO Headquarters' guidelines for national seroprevalence surveys.
- (8) The WHO Regional Office for the Western Pacific should engage ERP to support countries to increase immunization coverage; areas of support could include advocacy, technical assistance, and resource mobilization. Such support will vary depending on individual ERP members' expertise and areas of interest.
- (9) The target year for the 1% goal should be established in 2012, preferably prior to the 2012 TAG and Regional Committee meetings. Waiting until 2012 has advantages: (a) it allows more time for progress; (b) chronic infection rates may be available from three priority countries allowing better

prediction of achievement of the goal; and (3) there will not be simultaneous target years for hepatitis B control.

(10) The WHO Regional Office for the Western Pacific should develop regional guidelines for national programmes to vaccinate health care workers.

(11) Although not suitable for general regional recommendations, the WHO Regional Office for the Western Pacific could provide case-by-case recommendations on strategies to strengthen perinatal hepatitis B prevention including HBsAg screening of pregnant women, HBIG for newborn infants and antivirals for mothers at highest risk for transmission.

(12) Similarly, treatment for chronic hepatitis B offers important opportunities to prevent transmission and liver cancer, but costs and logistics prohibit a regional recommendation at this time. Recommendations being drafted by WHO Headquarters on hepatitis B treatment in resource-constrained settings could be a useful resource for the Region.

#### 4. ACKNOWLEDGEMENTS

The WHO Western Pacific Regional Office gratefully acknowledges the commitment and dedication of the members of the hepatitis B Expert Resource Panel to the cause of reducing hepatitis B infection and disease in this Region. We would like to give special recognition to the resource persons for preparing high-quality working documents that provided a starting point for this highly productive and informative consultation. The active participation and open discussion of all participants were greatly appreciated and have led to thoughtful and relevant guidance. We would like to thank all the chairpersons and rapporteurs for their meeting and reporting contributions.

**TIMETABLE**

Time	Monday, 21 February	Time	Tuesday, 22 February
0800-0830	<b>REGISTRATION</b>	0830-0900	<b>Country reviews – Wrap-up and summary (continuation)</b>
0830-0850	1. <b>Opening</b> <ul style="list-style-type: none"> <li>• Speech</li> <li>• Introductions</li> <li>• Administrative announcements</li> </ul>	0900-0920	<b>8A. Status and challenges of priority countries</b>
0850-0910	2. <b>Meeting overview, objectives, outcomes</b>	0920-0940	<b>8B. Birth dose vaccination challenges and future</b>
0910-0930	3A. <b>Status of hepatitis B control in the Western Pacific Region</b>	0940-1030	<b>8C. Discussion and recommendations</b>
0930-1000	3B. <b>Discussion and recommendations</b>		
1000-1020	<b>COFFEE BREAK</b>	1030-1100	<b>COFFEE BREAK</b>
1020-1040	4A. <b>Review of certification process</b>	1100-1230	<b>9. Status of and guidance on 1% goal: Discussion and recommendations</b>
1040-1100	4B. <b>Discussion and recommendations</b>		
1100-1230	5. <b>Country reviews to determine readiness for certification</b>		
1230-1330	<b>LUNCH BREAK</b>	1230-1330	<b>LUNCH BREAK</b>
1330-1430	<b>Continuation of country reviews</b>	1330-1350	<b>10A. China experience and regional communication strategy</b>
1430-1450	6A. <b>Proposal for Pacific Island Country certification</b>	1350-1410	<b>10B. Future of hepatitis B control in the Western Pacific Region</b>
1450-1520	6B. <b>Discussion and recommendations</b>	1410-1500	<b>10C. Discussion and recommendations</b>
1520-1540	<b>COFFEE BREAK</b>	1500-1530	<b>COFFEE BREAK</b>
1540-1600	7A. <b>Seroprevalence survey options</b>	1530-1630	<b>11. Expert Resource Panel administration and next agenda topics</b>
1600-1630	7B. <b>Discussion and recommendations</b>	1630-1645	<b>12. Closing</b>

WORLD HEALTH  
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ORGANISATION MONDIALE  
DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC  
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

HEPATITS B EXPERT RESOURCE PANEL  
CONSULTATION

WPR//DCC/EPI(01)/2011/IB/2  
18 February 2011

Tagaytay, Philippines  
21-22 February 2011

ENGLISH ONLY

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**WHO Western Pacific Regional Cover Sheet for Hepatitis B Control Certification**

Country: \_\_\_\_\_ Contact Name: \_\_\_\_\_ Email Address: \_\_\_\_\_ Date: \_\_\_\_\_

Summary of Country Data							Supporting documents*
<b>Section I. Hepatitis B (HepB) Vaccination Programme</b>							
1. Hepatitis B vaccine schedule history							
Year	Year	Nationwide (Yes/No)	Age 1 <sup>st</sup> dose	Age 2 <sup>nd</sup> dose	Age 3 <sup>rd</sup> dose	Age 4 <sup>th</sup> dose (If applicable)	
Introduction							
Revision 1							
Revision 2							
2. Birth cohort size:							
3. Campaigns to vaccinate cohorts born before national policy ('catch up')?* <input type="checkbox"/> Yes <input type="checkbox"/> No							
4. Policies to vaccinate children >1 year old (school-based, health visit etc)?* <input type="checkbox"/> Yes <input type="checkbox"/> No							
5. High risk group vaccination activities (e.g., health care workers)?* <input type="checkbox"/> Yes <input type="checkbox"/> No							
Group		Year started	Latest coverage data	Year of the latest coverage data			
<b>Section II. Vaccination Coverage Data</b>							
Most Recent Years	1 <sup>st</sup> dose data		HepB3 Administrative	HepB3 WHO-estimate	HepB3 Survey		
	1 <sup>st</sup> dose within ___ hours/days	1 <sup>st</sup> dose within 24 hours					
1. If coverage figures are low for particular year(s), please describe or provide report*:							
2. Do you have known groups of people or geographic areas with low coverage? _____							
<b>Section III. HBsAg seroprevalence estimate among cohorts born after nationwide hepatitis B vaccination (ie, including children at least 5 years of age): SURVEY REPORT REQUIRED</b>							
1. Survey year*: 1998							
2. Survey population: <input type="checkbox"/> National <input type="checkbox"/> Other, specify: _____							
3. Recruitment sites: <input type="checkbox"/> Population <input type="checkbox"/> Schools <input type="checkbox"/> Health care centres <input type="checkbox"/> Other, specify: _____							
4. Survey design: : <input type="checkbox"/> Probability sample, specify _____ <input type="checkbox"/> Other, specify: _____							
5. Test done <input type="checkbox"/> HBsAg only <input type="checkbox"/> HBsAg with other tests: _____ (Provide algorithm*)							
6. Lab technique: <input type="checkbox"/> Commercially available ELISA kit, specify: _____ <input type="checkbox"/> Rapid test, specify: _____ <input type="checkbox"/> Other*, specify: _____							
7. HBsAg prevalence of survey age groups born after routine hepatitis B vaccination: _____							
8. Precision: 95% confidence interval [including cluster effect] : _____							
9. Median age and range of the sample for the above estimate: _____							
10. Sample size of the sample for the above estimate: _____							
11. Study limitations:							
<b>Section IV. Expert Consultation **</b>							
Areas of hepatitis B control that country would like expert panel to provide advice on (e.g, health care worker vaccination, surveillance):							

\*Provide report, data/graphs, or publication; \*\*Responses to Section IV will be provided along with a certification report

Promgramme elements	Evaluation criteria	Weak (1)	Acceptable (2)	Strong (3)	ERP Comments
Vaccination schedules and target groups	Vaccination schedule				
	Timely birth dose				
	Nationwide vaccination for >5 years				
	Optional: Catch up strategies				
	Optional: High risk groups				
	<b>Summary comments on schedule</b>				
Coverage	HepB3 coverage last 5 years				
	Timely birth dose coverage last 5 years				
	Quality of coverage data				
	<b>Summary comments on coverage</b>				
Serologic survey	Conducted after >5y high coverage				
	Relevant age groups targeted				
	Sampling design				
	Representative sample				
	Lab QA and procedures				
	Diagnostic tests				
	HBsAg prevalence =				
	Precision estimate =				
<b>Summary comments on survey</b>					
<b>Overall Comments:</b>					

**Reference points for evaluation criteria – to be further developed by ERP**

Criteria	Weak (1)	Acceptable (2)	Strong (3)
Vaccination schedule	? Intervals between doses shorter than recommended	? $\geq 1m$ between BD and 2 <sup>nd</sup> dose ? $\geq X m$ between BD and 3 <sup>rd</sup> dose ? Other acceptable schedules	? $\geq 1m$ between the BD and 2 <sup>nd</sup> dose ? $\geq X m$ between the BD and 3 <sup>rd</sup> dose (or last dose)
Timely birth dose (BD)	? No policy for timely birth dose	? BD as soon as possible after birth ? BD within 24 hours monitored ? BD in 3d for challenging countries	? BD within 24 hours of birth
Routine vaccination for >5 years	? Acceptable schedule and birth dose for less than 5y	? Acceptable schedule and acceptable BD policy for at least 5y	? Strong schedule and strong BD policy >5y
Optional: Catch up strategies	? N/A	? Strategy including children born when hepB was included into EPI	? Strategy including broad age ranges with monitoring data.
Optional: High risk groups	? N/A	? Vaccination of health care workers	? Vaccination of health care workers with coverage data
HepB3 coverage last 5 years	? Average HepB3 coverage <85% in last 5y	? Average HepB3 coverage 85%-95% in the last 5y	? Average HepB3 >95% for the last 5y
HepB-BD coverage last 5 years	? Average coverage of HepB-BD <65% in last 5y	? Average HepB-BD coverage 65%-85% for last 5y	? Average HepB-BD >85% for the last 5y
Quality of coverage data	? Coverage data unvalidated	? Coverage data validated, inconsistent	? Coverage data validated and consistent
Conducted after >5y high coverage	? Survey before 5 years of acceptable coverage	? Survey after 5y of acceptable coverage	? Survey conducted after >5 years of strong coverage
Relevant age groups targeted	? Children <5y of age	? Children $\geq 5y$ of age	? Survey includes multiple cohorts $\geq 5y$
Sampling design	? Convenience sample ? Population not well defined	? Well defined population ? Statistical sample	? Multi-stage cluster sample
Representative sample	? Special population; not representative	? Special population; representative	? Sampling designed to be nationally representative
Lab QA and procedures	? Lab QA not known ? Procedures not described	? Key procedures described (specimen storage, handling, retesting equivocal..?) ? Known reputable lab?	? Key procedures described (list) ? Confirmatory testing ? Known QA certification (CAP, CLIA, ISO...?)
Diagnostic test	? Unknown sensitivity	? Validated but lower sensitivity (rapid tests, dried blood spots?)	? Used validated tests with high sensitivity
HBsAg prevalence =	? >2%	? 1-2%	? <1%
Precision estimate =	? Upper bound of 95% CI > 2%	? Upper bound of 95% CI < 2%	? Upper bound of 95% CI < 1%