Consultation on Improving and Monitoring Hepatitis B Birth Dose Vaccination

13–15 June 2012
Manila, Philippines
REPORT

CONSULTATION ON IMPROVING AND MONITORING HEPATITIS B BIRTH DOSE VACCINATION

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NOTE

The views expressed in this report are those of the participants in the Consultation on Improving and Monitoring Hepatitis B Birth Dose Vaccination held from 13 to 15 June 2012, and do not necessarily reflect the policies of the World Health Organization.
### LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AEFI</td>
<td>Adverse events following immunization</td>
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<tr>
<td>ANC</td>
<td>Antenatal care</td>
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<td>BD</td>
<td>Birth dose</td>
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<tr>
<td>CDC</td>
<td>Center for Disease Control and Prevention</td>
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<td>CHW</td>
<td>Community health worker</td>
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<td>CTC</td>
<td>Controlled temperature chain</td>
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<tr>
<td>EINC</td>
<td>Essential intrapartum newborn care</td>
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<td>EPI</td>
<td>Expanded programme on immunization</td>
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<tr>
<td>FHS</td>
<td>Family health service</td>
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<tr>
<td>GAVI</td>
<td>The GAVI Alliance</td>
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<tr>
<td>Hib</td>
<td><em>Haemophilus influenzae</em> Type B</td>
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<tr>
<td>HB</td>
<td>Hepatitis B</td>
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<tr>
<td>HBIG</td>
<td>Hepatitis B immune globulin</td>
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<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
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<td>HBV</td>
<td>Hepatitis B virus</td>
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<td>HB3</td>
<td>Third dose of hepatitis B vaccine</td>
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<tr>
<td>HCW</td>
<td>Health care worker</td>
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<tr>
<td>HSS</td>
<td>Health systems strengthening</td>
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<tr>
<td>IEC</td>
<td>Information education communication</td>
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<tr>
<td>JRF</td>
<td>Joint Reporting Form</td>
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<td>MCH</td>
<td>Mother and child health</td>
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<td>MCN</td>
<td>Maternal, child health and nutrition</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
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<tr>
<td>MNCH</td>
<td>Maternal neonatal child health</td>
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<tr>
<td>NIP</td>
<td>National Immunization Programme</td>
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<tr>
<td>OB/Peds</td>
<td>Obstetrics and paediatrics</td>
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<tr>
<td>OB/GYN</td>
<td>Obstetrics and gynecology</td>
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<tr>
<td>SBA</td>
<td>Skilled birth attendant</td>
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<tr>
<td>UNICEF</td>
<td>United Nation’s Children’s Fund</td>
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<tr>
<td>VHV</td>
<td>Village health volunteer</td>
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<tr>
<td>VVM</td>
<td>Vaccine vial monitor</td>
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SUMMARY

On 13-15 June 2012, five Member States were hosted at the WHO Western Pacific Regional Office, Manila, the Philippines, to discuss implementation strategies and monitoring of hepatitis B birth dose vaccination. Participating countries were Cambodia, the Lao People’s Democratic Republic, Papua New Guinea, the Philippines and Viet Nam, with support from China Center for Disease Control and partner organizations including: the Burnet Institute (Australia), the United States Centers for Disease Control and Prevention (USA), the Asian Liver Center (USA), the Coalition to Eradicate Viral Hepatitis in Asia Pacific (Singapore), Path Viet Nam, UNICEF, the Victorian Infectious Disease Reference Laboratory (Australia), and the Zeshan Foundation (Hong Kong, China). Dr Tilman Ruff of the University of Melbourne and member of the WHO Regional Hepatitis B Expert Resource Panel, served as Chairperson.

The meeting provided an opportunity for countries facing similar challenges to share experiences and successes. Participants focused on improving timely hepatitis B birth dose vaccination via coordination between maternal and child health and immunization programmes. The need to increase skilled birth attendant access for women in poorly resourced settings remains a critical issue. Strategies to strengthen in-country collaboration were discussed, with the use of BD as a driver for increasing postnatal care access.

Ensuring babies born in health facilities receive BD is important, whilst innovative approaches, such as specific home-visit programmes and controlled-temperature-chain (CTC) vaccine use, were highlighted as effective options for reaching home births. The importance of high-level governmental support and a policy framework to enable new approaches was emphasized.

Additionally, a session reviewing data management was particularly appreciated in providing insights into the vaccination coverage estimation process. Several opportunities to improve and clarify data recording and reporting practices were identified.

Participating countries identified barriers and responses to improving timely BD vaccination within their specific national contexts. These ranged from strengthening policy, guidance, training opportunities and data recording and reporting practices. Ongoing progress and support for in-country and international collaboration is vital as the Western Pacific Region moves towards the goal of reducing chronic hepatitis B prevalence to less than 1%.
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ANNEX 5 - ACTIVITIES TO INCREASE BIRTH DOSE COVERAGE DISCUSSED
DURING WORK GROUPS

Keywords:

Hepatitis B/ Birth Dose
1. INTRODUCTION

Hepatitis B is a major public health concern in the WHO Western Pacific Region, with over half of the chronic hepatitis B infections worldwide yet only 28% of the world’s population. This substantial disease burden led to the adoption of the 2005 Regional Committee resolution WPR/RC56.R8, which states that the Region should reduce chronic hepatitis B infections in five-year-old children to less than 2% by 2012 as an interim milestone towards the final goal of less than 1%. The implementation and monitoring of hepatitis B birth dose (BD) vaccination are key strategies for reducing chronic hepatitis B infection rates in children. Vaccinating newborn infants against hepatitis B within 24 hours of birth, followed by at least two more timely doses, prevents 95% of mother-to-child transmission of the hepatitis B virus.

It has been estimated that vaccination coverage should reach at least 65% timely hepatitis B BD coverage and 85% three-dose coverage to reduce chronic infection prevalence to less than 2%. In 2010, eight countries did not meet coverage targets for timely hepatitis B BD: Cambodia (57%), Kiribati (63%), the Lao People’s Democratic Republic (<28%), Papua New Guinea (35%), the Philippines (37%), Solomon Islands (62%), Vanuatu (63%) and Viet Nam (21%). These countries face significant challenges in reaching newborns with timely vaccination due to: (1) the high proportion of babies born at home without a skilled birth attendant; (2) obstetricians, midwives or birth attendants generally not being accustomed to providing expanded programme on immunization (EPI) vaccines and reporting data for monitoring; (3) a lack of understanding of the safety and indications of newborn hepatitis B vaccination; (4) a lack of funds to fully implement and monitor BD vaccination programmes; and (5) an inadequate cold chain.

There are many opportunities to increase BD coverage, including vaccinating all newborn babies delivered by a skilled birth attendants (SBA). Several countries have a higher proportion of SBA-delivered births than the proportion of births receiving BD vaccination including Cambodia (71%), the Philippines (62%), Papua New Guinea (53%), and Viet Nam (88%).

To support some of the above-mentioned priority countries, it was proposed to convene a consultation to review country strategies and the status of BD vaccination, monitoring of vaccination coverage, and options for delivering hepatitis B vaccination as part of postnatal care services. The meeting covered topics related to options for improving access to vaccination, strengthening collaboration between EPI and maternal health programmes, and best practices in monitoring. Similar topics will be covered during the Pacific Island Programme Strengthening (PIPS) Workshop planned for the first quarter of 2013; therefore, the three priority Pacific island countries did not participate in this consultation.

1.1 Objectives

This meeting was conducted with the following objectives:

(1) To review country situations for improving hepatitis B BD coverage and integration with postnatal care services.

(2) To discuss monitoring and new methodology for calculating WHO/UNICEF estimates for hepatitis B BD coverage and other EPI vaccinations.

(3) To draft country-specific action plans for improving hepatitis B BD coverage, postnatal-care integration, and resource gaps and opportunities.
1.2 **Participants**

National EPI managers and maternal-neonatal health programme managers from the ministries of health of Cambodia, the Lao People’s Democratic Republic, Papua New Guinea, the Philippines and Viet Nam attended the consultation. In addition, China participated in sharing experiences of its successful hepatitis B control programme.

The temporary advisers who facilitated the meeting were Dr Tilman Ruff, Nossal Institute for Global Health; Dr Chris Morgan, Burnet Institute; and Dr Francisco Averhoff and Dr Minal Patel of the United States Centers for Disease Control and Prevention (US CDC).

Partner organizations represented included: the Asian Liver Centre; the Coalition to Eradicate Viral Hepatitis in Asia Pacific; PATH Viet Nam; the United Nations Children’s Fund (UNICEF) East Asia and Pacific Regional Office and Philippines Office; US CDC, Victorian Infectious Diseases Reference Laboratory, Australia; and the Zeshan Foundation.

1.3 **Opening remarks**

Dr Hans Troedsson, Acting Regional Director, WHO Western Pacific Region, welcomed participates and partners to the meeting. He highlighted that the world has watched the Region make a bold commitment and substantial progress in combating chronic hepatitis B infection. Through strong vaccination efforts, chronic infection rates among children in the Region have dropped dramatically from a staggering 8%-10% to less than 2% regionwide and in most countries. A decrease in prevalence to 2% means over one and a half million children in the Region have been spared lifelong chronic hepatitis B infection, 25% of whom would have died prematurely due to liver disease.

Dr Troedsson remarked on the significant public health achievement this represents and congratulated country participants and partners for their success. Such an achievement also means that most countries in the Region have met the Region’s 2012 hepatitis B control milestone to reduce chronic hepatitis B infection rates in children to less than 2%. With this success, the EPI Technical Advisory Group has recommended that the target year to reach the regional goal of less than 1% infection rates should be set. Reaching that goal will require high coverage with at least three doses of hepatitis B vaccine — including a BD given within 24 hours birth. Vaccinating a newborn baby within 24 hours of birth presents a challenge for many countries as it requires having a skilled birth attendant and vaccine present at the time of birth. The purpose of the consultation was to share experiences on the opportunities to reach newborn infants to deliver essential newborn care and give them hepatitis B vaccine before lifelong infection with the virus can take hold.

Dr Troedsson commented that the consultation would begin with sharing of country and expert experiences and end with country presentations on feasible activities to increase access to hepatitis B vaccine. He looked forward to hearing the actions proposed and the support that may be needed from WHO and partners. Dr Troedsson concluded by thanking everyone for their dedication to the health of the children in the Region and extended wishes for a successful and fruitful meeting.

1.4 **Appointment of officers of the meeting**

Dr Tilman Ruff was appointed as Chairperson of the meeting. Dr Francisco Averhoff, Ms Amy Kolwaite, Dr Minal Patel and Dr Melanie Thompson were appointed as rapporteurs.
2. PROCEEDINGS

2.1 Regional perspectives on immunization and maternal and child health (MCH)

2.1.1 Overview of BD vaccination and hepatitis B control in the Region

Presenter: Dr Karen Hennessey, WHO Technical Officer, EPI

An overview of hepatitis B infection, vaccination and control in the Region was provided. In settings with highly endemic hepatitis B virus transmission, such as the WHO Western Pacific Region, both the perinatal period and early childhood are high-risk periods for acquiring chronic hepatitis B infections. Timely BD vaccination followed by at least two subsequent timely doses can prevent up to 95% of chronic hepatitis B infections.

Eight countries in the Region have been designated as priorities for increasing timely hepatitis B BD coverage, including Cambodia, Kiribati, the Lao People’s Democratic Republic, Papua New Guinea, the Philippines, Solomon Islands, Vanuatu and Viet Nam. The importance of timely BD vaccination was stressed: it provides, not only protection against exposure that may have already occurred during birth, but also begins protection against early childhood acquisition of chronic infection. It is often forgotten that this mode of transmission accounts for up to 50% of HBV-related deaths in the Region.

The first priority in preventing perinatal HBV infection should be to ensure that all newborn infants born in health facilities are vaccinated. In such a setting, skilled birth attendants should be available to administer vaccine. For those not born in health facilities, effort should be taken to ensure that newborns have contact with a health professional within two days of birth, but also begins protection against early childhood acquisition of chronic infection. It is often forgotten that this mode of transmission accounts for up to 50% of HBV-related deaths in the Region.

Dr Kaptiningsih started by highlighting the major causes of maternal and neonatal mortality in the Region. Although the Region has made good progress, some countries, such as Cambodia, the Lao People’s Democratic Republic, Papua New Guinea and the Philippines, still have high maternal and neonatal mortality rates. Antenatal care coverage and deliveries assisted by SBA are still low in the Lao People’s Democratic Republic and Papua New Guinea, which limits the opportunity for promoting hepatitis B BD vaccination in those countries. There are also inequities between SBA-attended births and the mother’s education level, wealth quintile and place of residence. Therefore, it is important that countries address this issue, even if they have achieved a high coverage rate nationally.

Two approaches were presented to improve the coverage of hepatitis B vaccination. In countries with a high proportion of deliveries assisted by SBA or high coverage of postnatal care, the direct approach is to implement hepatitis B BD vaccination within 24 hours after delivery in the health facility or within two days of a home birth during the postnatal care visit. For those countries with low coverage, the indirect approach involves increasing the coverage of maternal and newborn health services through registration of all pregnant women in highly populated areas and provision of
antenatal care, as well as counselling to encourage a facility birth or a home birth assisted by an SBA. In some countries, a combination of the two approaches will be best.

Dr Kaptiningsih concluded it is critical to increase the availability of hepatitis B vaccine and to improve the cold chain in health facilities and arrangements for vaccinations for newborn babies delivered at home. It is also important to ensure that MCH providers have adequate knowledge and skills to deliver hepatitis B vaccinations. A close collaboration between EPI and MCH programmes at all levels is necessary to create a common agreement on roles and functions, but also to address possible challenges, such as traditional beliefs or possible adverse effects, as well as to monitor progress —both in coverage and quality of service.

2.1.3 Strengthening routine immunization in collaboration with MCH: opportunities and challenges

Presenter: Dr Yoshihiro Takashima, WHO Technical Officer, EPI

Successful country experiences in addressing timely hepatitis B BD were presented. Dr Takashima first described the Philippines’ Essential Newborn Care Protocol, which defines a time period for each intervention, with BD included from 90 min to six hours after birth, resulting in higher rates of timely hepatitis B BD.

In three provinces in China, collaboration between EPI and obstetric departments has allowed the development of a common guideline, joint recording form and joint training, including false contraindications, with a designated supervisor for the whole process. The venture has led to an overall increase in timely hepatitis B BD in all provinces in just one year. The second part of the collaboration deals with on-time hepatitis B BD for home-delivered newborns. Previously, China’s Hangnan prefecture had a high proportion of home births, with separate EPI and MCH systems, resulting in very low coverage for hepatitis B BD. A collaborative plan, with joint antenatal registration, active identification/registration/monitoring of pregnant women, regular joint EPI and MCH meetings, BD planning and midwife coordination has increased coverage from 20% to 60%.

In 2009, an integrated maternal neonatal child health (MNCH) outreach programme that includes hepatitis B BD outreach was developed in the Lao People’s Democratic Republic by the Government and donors to accelerate progress towards the MDG goal of reducing maternal and child mortality. An international EPI review found that this undertaking has had both positive and negative effects on EPI. On one side, there has been an increase in both outreach funding and access to life-saving preventive interventions, other than vaccines, as well as increased satisfaction with MNCH services among caretakers. However, with the outreach programme, there is a perception that EPI is a lower priority, and EPI staff are not always included in MNCH planning activities and supervisory visits. Additionally the planning and management of outreach services has become complicated, increasing the workload with little increase in resources, causing delays in EPI activities. Consideration was given to further strengthening EPI so that it also serves as a system to deliver MNCH services. EPI should coordinate in the planning, management and implementation of MNCH outreach since EPI already has a system and plans to deliver services to every village.
2.2 Country perspectives on BD implementation

2.2.1 Cambodia

Presenter: Dr Chheng Morn, Deputy Manager, NIP, Cambodia

Cambodia faces special challenges, such as 80% of its population living in rural areas and the majority of its health structure depending on health centres. Despite this, progress has been made in controlling hepatitis B by vaccinating children. Timely hepatitis B BD and HB3 were expanded nationally in 2005, with BD administered up to seven days after birth. BD coverage given within 24 hours increased from 25% in 2007 to 68% in 2011 (Figure 1). At least part of these gains can be attributed to the large increase in facility deliveries in recent years from 10% in 2000 to 54% in 2010. A serosurvey in 2006 revealed the hepatitis B surface antigen (HBsAg) rate to be 3.4% at five years of age. A follow-up subnational survey was conducted, with preliminary data indicating that HBsAg prevalence has been reduced.

Figure 1.

Challenges and solutions:

Several challenges and potential solutions were presented. A particularly important challenge is reaching populations in remote areas, as well as floating and mobile communities. A separate strategy will need to be developed to adequately reach these populations. In addition, a national stock shortage was also noted as an important barrier to vaccination, with possible solutions being to: (1) improve stock management practices, (2) ensure sustainable financial procurement of hepatitis B vaccine, and (3) improve coordination among stakeholders.

A BD assessment conducted in October 2011 revealed that health workers misunderstand hepatitis B BD contraindications and that training for midwives is needed. The same assessment
showed that infants are more likely miss BD vaccination if they are born in a facility that refers vaccination off-site in the EPI clinic rather than vaccinating in the delivery ward. New guidelines and training should be developed to support vaccination at the site of delivery, and refrigerators should be placed in provincial hospitals to support the constant supply of vaccine for babies born in facilities.

2.2.2 Lao People’s Democratic Republic

Presenter: Dr Kongxay Phounphenhack, Deputy Manager, NIP, Lao People’s Democratic Republic

There are limited health facilities in the Lao People’s Democratic Republic, and those that are available are underutilized, with an average bed occupancy rate of 48%. Consequently, home deliveries account for 85% of births and there is less than one midwife per 10,000 population. As a result, the country has only experienced minimal increases in BD coverage, with 2011 coverage reaching only 34% (Figure 2). A serosurvey conducted in 2012 revealed the HBsAg prevalence rate to be 3.0% in mothers and 1.5% in children.

Figure 2.

Challenges and solutions:

One of the main challenges to reaching high BD coverage in the Lao People’s Democratic Republic is the high proportion of home births without SBA. This is due in part to a shortage of midwives, cultural preferences and beliefs, geography and climate. Important responses to these challenges include training midwives to vaccinate when assisting home deliveries. For newborn babies that are delivered in facilities, EPI and MCH departments need to coordinate their efforts to
ensure that all delivery facilities are equipped to vaccinate newborns on-site. Like Cambodia, the Lao People’s Democratic Republic also reports problems with a consistent vaccine supply in the field and stresses the need to ensure proper stock management.

2.2.3 Papua New Guinea

Presenter: Dr William Lagani, Manager, Family Health Services, Department of Health, Papua New Guinea

BD vaccination is usually provided within 24 hours of birth for facility deliveries and after more than 24 hours for deliveries outside of facilities. The subsequent doses are given as part of DTP-HepB-Hib vaccine at one, two and three months of age. Three-dose and BD vaccination coverage has remained fairly stable over the past five years, ranging from 50%-60% for three-dose coverage and 25%-35% for BD coverage (Figure 3).

Figure 3.

A synopsis of a project to reach home births in two health centre catchment areas in Angoram, East Sepik, was provided. In project areas, local village health volunteers were trained to use Unijet devices for hepatitis B vaccine outside the cold chain. Results showed that BD coverage increased overall by 30% and reached 65% among home births and 92% among facility births. Issues identified with scaling up the project include the fact that Unijet is more costly than the currently used 10-vials, and the availability of village health volunteers is not uniform across the country.

Challenges and solutions:

Even among facility births, supervisory visits have revealed missed opportunities for vaccination. A specific focus on increasing BD coverage among institutional births is a feasible and
cost-effective action. This will likely have a differential impact across the country, as the rate of supervised births is not uniform, ranging from 12%-96% across provinces, with a natural average of 40%.

Geographic conditions were stated as an important challenge to achieving high BD coverage. Responses include: (1) increasing the vaccine storage capacity at provincial hospitals; (2) increasing supervisory activities to eight provincial hospitals; (3) incorporating practices and monitoring of BD vaccination into the Reaching Every District to Reach Every Child initiative; and (4) integrating BD vaccination with postnatal care and possible scaling-up of the Uniject project.

Another important challenge is the lack of SBA and health care workers in Papua New Guinea in general. Recommendations from the country’s Maternal Ministerial Task Force include revitalizing midwifery training and including birth vaccination (BCG and hepatitis B) in the midwifery training curriculum. These recommendations should be closely followed for implementation.

2.2.4 The Philippines

Presenter: Dr Joyce Ducusin, Medical Specialist, Department of Health, Philippines

Since the nationwide introduction of hepatitis B BD vaccination in 2007, there has been a slight increase in coverage over time to 40% in 2011 (Figure 4). The barriers associated with the moderately slow start-up include a lack of reliance on external funding and the fact that 40% of newborn babies are hard to reach because they are born at home. Additionally, stock outages have prevented a larger number of infants being reached with vaccine.

Figure 4.

A health facility improvement initiative that includes a community focus on pregnancy and
birth tracking is continuing. Until facility deliveries increase, it is imperative to concentrate on improving home BD coverage. A hepatitis B serosurvey is planned for late 2012, which will require some technical and financial assistance.

Challenges and solutions:

One of the challenges noted was low BD coverage in health facilities. Possible solutions include: (1) increasing implementation services that fall under the Maternal, Newborn, Child Health and Nutrition Package, which dictates BD be given between 90 minutes to six hours after birth; (2) including hepatitis B BD vaccination as one of the indicators for the conditional cash transfer covering an estimated 700,000 infants defined as the poorest of the poor; (3) taking full advantage of the Mandate Republic Act Number 10152, which requires all children less than five years of age to be given basic immunization, including the BD of hepatitis B vaccine within 24 hours; (4) continuing assessment and supervision, including reviewing admitting orders and health centre logbooks; (5) coordinating with the Bureau of Health Facilities to re-include hepatitis B BD in the requirements for health facility licensing; and (6) ensuring that all aspects of providing and monitoring hepatitis B BD are covered as part of the Implementing Rules and Regulations for the Republic Act Number 10152.

BD assessments that were conducted in eight regions of the country in early 2012 proved to be helpful in understanding barriers to vaccination, and continuing assessment will be worthwhile. Partnerships must be formed with private birth attendants, private facilities and other public health providers to ensure the provision of the hepatitis BD.

2.2.5 Viet Nam

Presenter: Dr Nguyen Lien Huong, Medical Officer, National EPI, Viet Nam

Viet Nam introduced BD vaccination on a national scale in 2005. In 2006, coverage reached 64%. However, in 2007, the country experienced a dramatic drop in coverage to 29% due to coincidental AEFI reports and then another drop in 2010 to 21% due to vaccine stock outages (Figure 5). However, hepatitis B BD coverage is showing improvement, with coverage of BD vaccine given within 24 hours reported as 55% in 2011.

To improve coverage, directions on implementation of BD vaccination have been issued by the Ministry of Health, and, in 2010, workshops on hepatitis B BD were held to increase the involvement of leaders from provincial health departments and hospitals. Training sessions on increasing BD vaccination have also been conducted in Hai Duong province. There are also plans to set guidelines for hepatitis B BD, displaying standard operating procedure in the form of posters in health facilities. Additionally, information education communication (IEC) materials and leaflets on hepatitis B vaccination are planned for development and distribution. Finally, low-performing provinces are being examined for opportunities to increase hepatitis B BD coverage, conduct training workshops, and assess local data for missed opportunities and causes of low coverage.
Challenges and solutions:

Supervision has found that not all hospitals administer the hepatitis B BD. Provincial health service and hospital involvement should be strengthened, as well as issuing a circular from the Ministry of Health to ensure provision of hepatitis B BD. There is lingering vaccine hesitancy after the 2006 AEFI reports; distribution of IEC materials and training on vaccine safety should be ongoing. Viet Nam was the fourth country in a series of five country presentations that reported an issue with stock outages. Guidelines should be developed to ensure vaccine supply and good vaccine management.

2.3 Experience and opportunities to improve BD coverage

2.3.1 Practices to improve coverage of the hepatitis B BD vaccine: a review for the WHO EPI/IVB Immunization Practices Advisory Committee (IPAC)

Presenter: Dr Chris Morgan, Principal Fellow, Burnet Institute, Australia

Findings from a comprehensive review of the implementation evidence to guide BD programmes was presented (Annex 4). Sixty-four studies from 13 settings met the inclusion criteria, mostly addressing service delivery, workforce and governance. The study found that variations in definition of BD affected reporting. Additionally, issues in service delivery, reaching babies born outside health facilities, integration with postnatal care, human resources, technological approaches, health information systems, community knowledge and governance were discussed. Approaches to maximize vaccination within health facilities remain a top priority. For babies born outside health facilities, there can be an associated reduction in neonatal mortality with enhanced postnatal care, including through home visits, but the central question remains of where to target programme efforts.
The study concluded that it depends on each country’s pattern of where childbirth takes place.

During discussions, it was noted that provision of postnatal visits is significantly affected by limitations in staffing levels and funding. Community-level access to populations has an effect on neonatal death reduction, but the effect depends on local regulations. Consequently, special policies may be required for hard-to-reach areas. The full review is currently being processed within WHO for publication as a technical resource later in 2012.

2.3.2 The China experience in increasing BD coverage

Presenter: Dr Cui Fuqiang, Deputy Director, NIP, CDC, China

China has historically had high chronic hepatitis B infection prevalence; estimated prevalence among adults was 9.8% in 1992. In 1992, hepatitis B vaccine was recommended for routine infant immunization, at which time families were required to pay for vaccination. This was likely a contributing factor to low coverage in poor and remote areas. In 2002, hepatitis B vaccine was fully integrated into EPI, and vaccine was provided free. Following a national immunization regulation in 2005, all EPI vaccines were made available at no cost.

Perinatal transmission is an important route of transmission; therefore, preventing mother-to-child transmission is a high priority. Because of this, improving coverage for BD vaccine given within 24 hours is a key strategy for reducing infection rates in China. The general approaches include building bridges between the delivery services of MCH and EPI; increasing hospital delivery rates; training health care workers; increasing awareness among parents of the importance of timely BD; and developing microplans to increase coverage among home births, including providing subsidies to providers.

For children born in hospitals, one of the strategies to improve the availability of vaccine is to designate staff responsible for administering the BD according to the guidance “Who delivers the infant should give the immunization” policy. For children born at home, the interventions include education of health workers, pre-registration of pregnant women to anticipate the delivery and vaccination date, timely notification of births by the birth attendant, ensuring availability of vaccine in the village and providing subsidies to village doctors for administration of BD vaccine.

Survey data indicate a marked increase in coverage after implementation of universal vaccination. Coverage of BD given within 24 hours increased from 29% in 1992 to 91% in 2009. Additionally, the prevalence of HBsAg among children under five is now less than 1%.

Lessons learnt in improving coverage of BD given within 24 hours include: (1) Demonstration projects allowed identification of an effective strategy. (2) Collaboration with MCH is key: Increasing hospital deliveries generated benefits as regards timely BD, but also for maternal mortality and tetanus elimination. (3) A standard training package for health care workers helps, while IEC in the population creates a demand. (4) For home birth, pre-registration, with microplanning, raises coverage, even in the absence of out-of-cold-chain approaches. In addition, GAVI support in Western Provinces played a role in increasing coverage in previously low-performing provinces and countries. The country also supported actions to increase the rate of institutional births. With this increase, BD coverage also increased.

Targeting high-risk populations with additional training, funding and subsidies has been important. A recently published paper from China suggests a lower BD effectiveness among
newborns vaccinated in less than 24 hours compared with those vaccinated during days 1-7, contradictory to expectations. Potential causes could be: an information bias in group allocation; that the immune response is better 1-7 days after birth compared with less than one day; or that known positive mothers may be more likely to vaccinate early even though newborns that received hepatitis B immune globulin (HBIG) were excluded from the analysis.

2.3.3 Progress with the controlled temperature chain

Presenter: Ms Diana Chang-Blanc, on behalf of the Optimize WHO/PATH collaboration

The controlled temperature chain (CTC) approach takes advantage of the fact that many vaccines are more stable than their current licenses indicate. The key thrust is to enable the use of certain vaccines outside the standard +2° to +8°C range, via endorsement through a regulatory process, without requiring any reformulation. The regulatory approval will allow for ‘on-license’ use and is important for ensuring the vaccines remain potent and safe throughout their life cycle. Furthermore, regulatory precedent for reflecting stability in vaccine licenses currently exists in Canada, the United States of America and the European Union.

Many countries have already begun using certain antigens outside the cold chain for limited periods of time, relying on the vaccine vial monitor (VVM). Although field studies have confirmed the potency of vaccines used in this way, this is considered ‘off-license’ use, which is not condoned by manufacturers and regulators.

CTC work initially started using hepatitis B vaccine as a pathfinder. However, in-vitro potency data are not completely predictive of hepatitis B vaccine integrity, thus there is no direct correlation with clinical efficacy. Further data, in addition to in-vitro data, would be needed to demonstrate the integrity of the vaccine after high temperature exposure before a license variation could be considered. Work on hepatitis B vaccine continues, and a re-licensed hepatitis B vaccine will not be available before 2014. In the interim, the CTC pathway is being charted using the meningococcal A vaccine (MenAfriVac) in a campaign setting.

2.3.4 Reaching home births: design considerations for two projects in the Lao People’s Democratic Republic

Presenter: Dr Minal Patel, Medical Epidemiologist, US CDC

In the Lao People’s Democratic Republic, approximately 80% of deliveries occur at home without the assistance of an SBA. The repercussions of this can be seen in high neonatal and maternal mortality rates and low hepatitis B BD coverage. Creative solutions are needed to increase BD coverage.

To improve the awareness of health care providers of impending births, the US CDC will be piloting a project in one province that will give village health volunteers (VHVs) cellphones. They will be instructed to call the health care provider when a child is born or a mother/child has danger signs, as well as to report cases of neonatal tetanus and maternal/neonatal deaths. Additionally, they will educate pregnant women about antenatal care (ANC), delivery in a health facility and

breastfeeding. Finally, the health staff will be given a cellphone and money for transportation in order to: (1) attempt to provide SBA services; (2) evaluate the mother/child; (3) provide maternal education; (4) provide maternal vitamin A and iron supplementation; (5) vaccinate newborns (BCG, BD, plus vitamin K); (6) provide a birth certificate and immunization card; and (7) provide vaccinations to other eligible children. Evaluation of the programme will include a coverage survey, comparing children born before and after the pilot test.

Use of the Uniject device addresses barriers posed by remote births, as well as a lack of trained staff and a cold chain. A total of 21,000 doses of Uniject have been donated to the Lao People’s Democratic Republic, but decisions still need to be made as to how and where they will be provided. VHVs could administer the dose and store the vaccine using CTC, or the vaccine could be given to health facilities without cold chain capacity. Another option could be to provide it to health facilities with the most remote births in their catchment area. Logistics, training curricula, supervision and data reporting plans need to be piloted to ensure that doses are used where they will have the greatest impact. After the pilot test runs for one to two months, it will be evaluated and possibly scaled up.

After the presentation, it was noted that WHO Headquarters is supportive of the WHO Regional Office’s recommendation to use CTC as part of the field guidelines for BD implementation. However, ongoing research is needed for 28-day limitation compared with relying on VVMs. The use of VVMs may extend storage life and reduce wastage significantly.

2.3.5 Tools and resources for increasing BD coverage

Presenter: Dr Francisco Averhoff, Medical Epidemiologist, US CDC

The WHO Western Pacific Region has been a leader in controlling the hepatitis B virus, and there have been many lessons learnt that are valuable for other regions. A good example is the field guidelines for implementation of BD vaccination. The presentation described tools that are being developed to serve as resources for immunization programmes to strengthen hepatitis B perinatal prevention programmes through BD vaccination. These are global tools that together will make a programme manager’s guide that can be adapted to regional or country contexts. The tools recommended for inclusion in the guide include a policy brief, job-aids, and problem-solving guides for senior- and mid-level managers addressing low BD coverage in facilities or homes.

The group discussed the need to include audience-specific issues, such as use of HBIG and mention of BCG in the global tools. Documents should direct readers to appropriate information. The WHO South-East Asia Regional Office manual for helping countries with health systems analysis does include some high-resource strategies, so it may serve as a useful resource for gap analysis. There is potential for global tools to assist with development of advocacy pieces to mobilize high-level government support.

2.3.6 Health systems strengthening support to immunization

Presenter: Dr Momoe Takeuchi, WHO Technical Officer, Health Services Development

This presentation highlighted how some countries in the Region have been able to strengthen their health systems through GAVI support. Through the increased funding, countries have increased facility-based service delivery and outreach activities. In some countries, HSS support has provided an opportunity to increase the use of SBA, the provision of antenatal and postnatal care, and
implementation of a comprehensive MNCH package, including immunization. Some HSS support has also focused on issues such as increasing microplanning, strengthening the capacity of health managers and reducing inequities in service coverage. A potential way to utilize such HSS support for improving hepatitis B BD coverage was discussed, with potential for use of BD as a global indicator.

2.4 BD recording, reporting and coverage estimates

2.4.1 Regional process of vaccination coverage monitoring

Presenter: Dr Jorge Mendoza, WHO Technical Officer, EPI

The session provided an overview of the WHO/UNICEF Joint Reporting Form (JRF), which was initiated in the 1990s to provide consistency in reporting vaccination coverage across countries and between international agencies. Data on hepatitis B vaccination has been included as part of the JRF since the early 2000s. BD vaccination coverage is reported as vaccine administered within 24 hours of birth, which is a global indicator of timely BD; countries in the WHO Western Pacific Region also report total BD coverage, which includes vaccine administered 24 hours after birth. The JRF also includes country queries on whether systems are in place to monitor the delivery of BD vaccine in a timely manner. WHO uses the information from the JRF to assess if regions are meeting their coverage goals. Data are disseminated through several methods, including published immunization summaries and on-line country profiles. This is the only tool that collects extensive data on vaccination programmes and coverage and it is reviewed and modified every two years.

After the presentation, several countries noted confusion regarding the indicator of timely BD, especially concerning whether a dose given on the second day of life is considered valid. It was noted that the JRF instructions specify that vaccine given on the second day of life is valid; however, data collected in the field may be only considering vaccination given within 24 hours, since that is how the indicator of timely BD is defined. The current method of recording BD vaccination in terms of days instead of hours is reasonable; reporting should be clarified so ensure that vaccination on day two of life is considered timely. It was suggested that the global indicator of timely BD should be clarified to reflect the valid period of vaccination after birth; for example, a valid timely BD is within 48 hours and not 24 hours.

2.4.2 Immunization coverage and BD coverage estimation

Presenter: Ms Marta Gacic-Dobo, WHO Technical Officer, EPI/Headquarters

Methods used to measure immunization coverage and the advantages and disadvantages of administrative and survey methods were discussed. Both systems are important, and ideally a country would have a strong administrative method that could be verified through survey methods. Estimates of routine infant immunization coverage are a joint effort between WHO and UNICEF that started in 1999 and has been updated annually since 2001. The system reflects routine immunization system performance, but does not include campaign or non-routine doses. The existing coverage estimates are updated each year incorporating new information.

An annual review of coverage data is done using national JRF reports and published and grey literature, as well as additional information such as stock-out information, data quality audit results and expert opinion. Coverage is determined through a four-phase process that includes data cleaning and then making estimates using anchor points. These immunization coverage estimates are used in several ways, including publications to report progress on immunization and monitoring of progress.
towards international goals, as well as to assist agencies in directing funding and in disease burden models. To address the question of data accuracy, a grade of confidence has been added to the estimates in order to provide a grade (high, medium, low) for the quality of the immunization coverage data.

In 2012, BD was added to the national immunization coverage estimates, starting with the Western Pacific Region. There are challenges due to the limited amount of information currently available. Coverage estimates are done once a year and are finalized in early June. Examples of how to calculate coverage estimation were given. This is the first attempt to apply the methods to hepatitis B BD and produce estimates of BD coverage for Member States in Region.

Retrospective adjustment of coverage estimates was found to be useful since it takes advantage of all available data, for example, coverage surveys and vaccine stock-outs. It is important to communicate explanatory data, such as history of interruptions of programme implementation and coverage surveys. Lack of an accurate denominator is an issue in many countries. Guidelines are being developed on how to assess the accuracy of denominator data; these guidelines will hopefully be available in 2013.

The timeline for the JRF was discussed and summarized as follows:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 15</td>
<td>JRF is sent to WHO Regional Office</td>
</tr>
<tr>
<td>April 15</td>
<td>Regional Office sends the reports to WHO Headquarters</td>
</tr>
<tr>
<td>Early May</td>
<td>Estimates are generated and sent to countries for feedback</td>
</tr>
<tr>
<td>End of June</td>
<td>Country feedback is collected</td>
</tr>
<tr>
<td>Mid July</td>
<td>Coverage estimates are released</td>
</tr>
</tbody>
</table>

2.4.3 Country-specific review of BD estimates

The presentation illustrated the estimation methods using country data. Data from selected countries in the Western Pacific Region were reviewed and estimates of BD coverage presented. Countries were asked to identify additional data sources to help in validating hepatitis B BD coverage.

During the session, it was noted that the definition of HB3 for reporting purposes is unclear. For example, should HB3 be considered the second combination dose or the third dose? Regarding this question, JRF instructions specify that for countries using monovalent vaccine for all doses, HB3 refers to the third dose of hepatitis B vaccine, including the BD, if such a dose is included in the national schedule. For countries using monovalent vaccine for the BD and combination vaccine for subsequent doses, HB3 refers to the third dose of the combination vaccine in addition to the BD.

It was requested that countries share in-country denominator adjustments with WHO so that coverage estimates can be adjusted. WHO/UNICEF estimates only deviate from reported data when reliable data are available to make adjustments.

2.5 Hepatitis B technical questions and answers

This session posed hepatitis B questions to country representatives to gain input from the country perspective.
Question 1: At what age do countries stop giving BD (i.e. after seven days)? Secondly, does specifying vaccination within 24 hours create confusion that leads to not vaccinating after 24 hours?

During outreach in the Lao People’s Democratic Republic, BD vaccine is not provided to newborn babies older than seven days. In a recent health facility assessment of BD practices, it was found that facilities do not usually vaccinate after 24 hours. In the Philippines, a recent health facility assessment of BD found that 44% of facilities reported the maximum age for BD vaccination as one day of age. In Papua New Guinea, the advice is to vaccinate up until seven days of age, since the next dose is at one month of age and there are concerns that proximate dosing could lead to vaccine interference and decreased immunogenicity.

It was clarified that vaccination after seven days could have a benefit in preventing perinatal transmission and also begins protection against horizontal transmission. Furthermore, hepatitis B vaccine will not interfere with the other antigens in the combination vaccines. Because of this, the Regional Operational Field Guidelines for Delivery of the Birth Dose of Hepatitis B Vaccine note that monovalent hepatitis B vaccine can be given up to the day before a combination vaccine is scheduled. This differs from the 2009 WHO position paper on hepatitis B vaccines, which recommends spacing the hepatitis B doses with a minimum interval of four weeks. There is a need for a clear national policy and guideline, as well as an engagement by national societies to ensure clear understanding. The WHO Western Pacific Regional Office will work with the Region’s hepatitis B Expert Resource Panel (ERP) to increase consistency and support countries with best practices and to develop clear messaging.

Question 2: What do countries think of target year 2017 for the 1% goal? Is it reasonable?

In 2011, the EPI Technical Advisory Group recommended that the Region set the target year for the regional goal to reduce chronic infection prevalence in children to less than 1%. The ERP has recommended 2017 as the target year, given that the target year should be in the near future to build on the progress made as well as mobilize attention and interest. Additionally, the target year should be feasible for all or most countries. It was noted that vaccination coverage in 2012 will drive the prevalence rates among five-year-olds in 2017. Coverage levels needed to reach the prevalence goal of less than 1% need to be updated based on what has been learnt from seroprevalence surveys conducted over the last few years. Papua New Guinea and the Philippines reported that they will know more about the feasibility of their meeting the 2017 target after results are available from seroprevalence surveys planned for this year. Viet Nam estimates that, based on current coverage levels, they may have a 1.5% prevalence rate among children in 2017. All agreed that BD coverage is improving but must be increased further to achieve the goal.

Question 3: How does EPI receive BD reports from private facilities?

The Philippines reported receiving vaccination coverage data from the private sector and were interested in hearing experiences from other countries. Cambodia reported that some private clinics in selected provinces have an agreement with the Ministry of Health via a memorandum of understanding. The Ministry of Health provides vaccine and a refrigerator at no cost and in turn these private clinics report data to the district level. However, other private facility data are unknown. Similarly, in Viet Nam, private facilities that receive vaccine from the EPI programme report BD vaccination data to EPI. However, private facilities that procure vaccine on their own do not report coverage data. In Papua New Guinea, private facilities do not report coverage, although efforts to change this have been discussed at advisory committee meetings. They are currently discussing how to work with private providers to supply them with vaccine in exchange for data-reporting. Faith-based organizations are better at reporting, but it is not consistent.
Question 4: Are there guidelines on screening adults for chronic infection including how to manage persons with infection?

Countries, for the most part, do not have guidelines or routine HBV screening policies. The WHO Western Pacific Regional Office is working to scale up efforts to create a more comprehensive viral hepatitis programme that covers screening and treatment of chronic infection. There was interest in having more guidance on antenatal screening of women, HBIG, and the use of antivirals. Activities are contingent on the health care capacity in a given country. With regards to health care providers with chronic hepatitis B infection, a variety of policies exists, including steering such staff towards specialities with a minimal risk of HBV transmission or monitoring viral load to assess the risk of transmission. However, this has implications in countries with a high HBV burden, where removing people from the workforce can have severe implications. In terms of vaccination, data show the benefits of vaccinating older ages and high-risk persons, such as health care workers and household contacts of persons with chronic hepatitis B infection.

2.6 Group work: Country activities to improve BD coverage

Work group topics: Groups were asked to identify three to five actions to improve access to BD vaccination. These actions should be feasible for implementation in their respective country contexts, possibly within the next 12 months. In addition, groups were specifically tasked to discuss opportunities to strengthen immunization and MCH integration and coordination of activities.

Work group composition: Two sessions of country work groups were convened. The country teams comprised the following members.

Cambodia: Dr Chheng Morn, Mrs Taing Sokun Phala, Mr Richard Duncan, Ms Chrissy Cheung, and Dr Melanie Thompson. The facilitator was Dr Ben Cowie.

Lao People’s Democratic Republic: Dr Kongxay Phounphenghack, Dr Khampiou Syhakhang, Mr Alejandro Ramirez Gonzalez, Dr Minal Patel, and Dr Amy Kolwaite. The facilitator was Ms Diana Change Blanc.

Papua New Guinea: Dr William Lagani, Dr Ligo Augerea, Dr Siddhartha Datta, Mr Jack Wallace, and Ms Marta Gacic-Dobo. The facilitator was Dr Chris Morgan.

Philippines: Dr Joyce Ducusin, Dr Juanita Basilio, Dr Mariella Castillo, Dr Maricel Castro, Dr Annette Tan, and Dr Lailani Mangulabnan. The facilitator was Dr Paolo Froes.

Viet Nam: Dr Nguyen Lien Huong, Dr Vu Minh Huong, Dr Nguyen Mai Huong, Ms Yan Chan, Dr Kohei Toda, Dr Fuqiang Cui, and Dr Miyuki Tsuruoka. The facilitator was Dr Francisco Averhoff.

Country-specific group discussions follow. An overview of country activities towards increasing BD coverage presented by groups is provided below in Figure 6; a more detailed summary is provided in Annex 5.
2.6.1 Cambodia

Cambodia’s key challenges in increasing BD coverage, as outlined in Section 2.2.1, include reaching hard-to-reach communities, preventing stock-outs and increasing BD coverage in health facilities. Specific activities proposed to increase BD coverage are presented in Annex 5.

The workgroup noted that coordination of EPI and MCH could be improved, with monthly meetings at central and provincial levels. Areas of joint work include: (1) increasing rates for BD vaccination of home births by developing a specific outreach strategy; (2) harmonizing roles and responsibilities; (3) clarifying data reporting and reporting practices; and (4) ensuring BD vaccination is part of curricula for midwife training. Progress in these areas could be incorporated into the NIP guidelines. It was also suggested that these topics could be discussed by placing them on the agenda of the existing national level EPI and MCH meetings.

NIP financing was discussed as an important consideration in preventing hepatitis B vaccine supply shortages. This requires coordinating with the Ministry of Finance and increasing their awareness of the impact of vaccination shortages. Information on the need and rationale for incentives for postnatal care visits and BD vaccination can also be shared with the Ministry of Finance.

To share their experience with other counties, the Cambodia workgroup provided an overview of the strategies used to increase birth facility rates from 20% in 2007 to 55% in 2011. The Government supports a programme to provide a US$ 15 incentive to a midwife who delivers a baby at a health centre and US$ 10 for a delivery at a hospital. It is reported that the practice of providing a share of the incentive to traditional birth attendants for referrals has been adopted, extending the reach of the initiative. Other factors relating to the success of the initiative is the high-level political engagement by the Prime Minister and his wife, as well as good community education and awareness. In terms of sustainability, the programme is fully funded by the national Government.
2.6.2 Lao People’s Democratic Republic

The main challenge to increasing BD coverage in the Lao People’s Democratic Republic is reaching home births; improving BD coverage among facility births was also identified as an important potential way of increasing BD coverage. Specific activities proposed to increase BD coverage are presented in Annex 5.

A significant barrier to vaccinating home births is limited staff and funding for outreach visits. Joint advocacy is needed to increase the workforce of midwives and conduct postnatal care visits. The link between VHV's and health care staff could be strengthened to increase home visits and ensure that BD vaccination takes place during outreach.

In delivery facilities, there is no clear process or delineation of who is responsible for administering and recording BD vaccinations. Developing a general hospital protocol, including clear policy on roles and responsibilities, would be helpful, but would require a Ministry of Health decree. There is a need to update existing forms and birth logbooks to include BD and to develop job-aids or MNCH booklets targeting delivery facility staff.

The group summarized possible areas of work to improve BD coverage. First, develop a ministerial decree on BD implementation to help garner political support for increasing access to postnatal care and BD vaccination. A high-level advocacy regional meeting, including central, provincial and district hospital directors could help to increase health-facility BD coverage. Implementation guidelines for health care workers to ensure best immunization practices should also be developed. Finally, innovative strategies for service delivery, including the use of Uniject in a controlled-temperature chain and cellphones to increase communication, will be explored.

2.6.3 Papua New Guinea

Papua New Guinea’s challenges to increasing BD coverage include both reaching home births and strengthening efforts to vaccinate facility births. Specific activities proposed to increase BD coverage are presented in Annex 5.

Vaccinations are seen as solely an EPI responsibility by many midwives, resulting in delayed vaccination. Consequently, including BD in the midwife training curriculum is important. General health system barriers include internal inefficiencies, provincial autonomy and weak intersectoral coordination. Additional issues are poor reporting and limited community understanding of chronic liver disease. Options to address these challenges include leadership actions from paediatric and obstetric societies, integration with family health services planning, inclusion of BD in the national health standards, support for health system reforms and scaling-up of health-worker training. Uniject use and an increase in cold-chain capacity could also potentially increase BD access. Ensuring that reporting and monitoring activities are actually occurring is important. Data evaluating community-level strategies, such as scaling-up the VHV system, creating community health posts and providing public education, would be useful.

Findings from the pilot test for delivery of vaccine in Uniject and in a CTC showed potential for increasing BD coverage, and there are ongoing discussions about whether to scale up this project. An important aspect of using vaccine in a CTC is to ensure awareness of potential coincidental neonatal deaths. It was noted that countries have difficulty in implementing CTC due to regulatory issues regarding vaccine storage in the cold chain and who can administer injections.
Possible activities to increase BD coverage presented by the group included: (1) improving information for planning, advocacy and public education; (2) providing BD education and training as part of joint obstetric or paediatric supervisory visits and improving reporting from enhanced supportive supervision; (3) conducting a hepatitis B serosurvey; and (4) analysing existing cancer and other hepatitis B-related disease registries. Data on chronic liver disease and cancer treatment costs would be useful for developing public and political education materials that include the economic impact and the cancer-protection effects of vaccinating. A desk review of current knowledge on the root causes and possible barriers to BD vaccinations may help guide a national hepatitis strategy.

2.6.4 Philippines

The Philippines aims to increase BD coverage in facilities while recognizing that home births represent a significant proportion of their birth cohort. Specific activities proposed to increase BD coverage are presented in Annex 5.

Barriers between EPI and MCH have been reduced, with the two programmes now integrated into one office and joint activities related to essential newborn care. The challenge lies in a lack of coordination between health systems, such as public and private health providers, as well as between hospitals and regional offices with higher-level health offices. A standard reporting system is lacking, especially regarding disaggregation of BD administered in under 24 hours, and there is no formal agreement with private sectors supplying the vaccine free of cost. Strategies can be improved by frequent coordination meetings between EPI and MCH. Additionally, hospital and public health implementation must include integrated reporting, joint advocacy and joint monitoring of visits. Ongoing support for existing strategies is required to promote health facility deliveries, training in essential intrapartum newborn care (EINC), and continued assessment of BD practices in health facilities.

EPI has the opportunity to integrate hepatitis B BD into the regulatory structure by providing guidelines for an upcoming law on mandatory vaccination and inclusion in forward planning in the comprehensive multiyear plan to ensure funding security. Increasing awareness and demand among mothers and service providers was discussed as a possible EPI and MCH cross-cutting activity.

To address BD reporting gaps with private providers, standard reporting and recording forms and training will be considered. This would include a flowchart to instruct reporting from private facilities to provincial health offices where inventory is monitored. Reporting in public facilities also requires action, such as improved monitoring and supervision of health facilities by EPI, MCH and hospital coordinators.

2.6.5 Viet Nam

Viet Nam has the advantage of having a high proportion of births born in health facilities. However, several opportunities to increase BD coverage in facilities still exist; specific activities proposed to increase BD coverage are presented in Annex 5.

Particular activities to increase BD coverage include coordinating meetings of three sectors (MCH, EPI and hospitals) to review existing policies and developing national BD guidelines, responsibilities for each programme and joint indicators for monitoring. To facilitate collaboration, a Ministerial Directive could mobilize resources, and a plan of action could be facilitated and developed by a steering committee and technical working group. Training may be cascaded from
national down to district level, and IEC materials have already been developed. Ongoing operational research should be dedicated to exploring the barriers and risk factors contributing to newborns not receiving hepatitis B BD. Joint annual reporting from EPI, MCH and hospitals should also be coordinated, and a feedback mechanism could be created.

The group discussed addressing the fear among health care workers regarding coincidental AEFI. Viet Nam has a system in place for protecting health care workers if AEFI do occur. Local vaccine procurement aids in preventing stock outages of vaccine.

In summary, Viet Nam envisions a multifaceted approach to increasing their BD coverage. Support for EPI and MCH coordination could be garnered through a programme policy brief or advocacy by partners. A technical working group under the Working Group on Health and a plan of action on BD implementation could play an important role in strengthening the hepatitis B prevention programme. Rapid assessment of the BD programme and a meeting of stakeholders to discuss BD implementation are other potential activities. Thirdly, a national joint plan of action on BD with EPI and MCH and medical services must be created for effective implementation.

2.7 Partner statements

Presenters:

Chrissy Cheung, Asian Liver Centre  
Jack Wallace, CEVHAP  
Paolo Froes, UNICEF  
Ben Cowie, VIDRL  
Chris Morgan, Burnet Institute  
Vu Minh Huong, PATH Vietnam  
Francisco Averhoff, US-CDC  
Yan Chan, ZeShan Foundation

The above partners made presentations or statements on the type of assistance they can provide to the five priority countries attending the workshop. Partners generally indicated interest in providing financial or technical assistance in a wide range of areas in BD vaccination and hepatitis B control. These include, but are not limited to: policy development, advocacy, education and capacity-building. The development of partnerships was discussed as important for future progress, especially developing partnerships on the ground with affected communities and other relevant stakeholders.

3. CONCLUSIONS

Hepatitis B BD vaccination is an essential part of newborn care that can save lives now by being a driver for increasing access to maternal and newborn care and in the future by protecting newborn infants from acquiring life-long hepatitis B infection. The consultation reached the following conclusions on specific areas of preventing perinatal HBV transmission through vaccination.

(1) Ensure collaboration between maternal and immunization programmes: Coordination and collaboration are central to implementing a successful vaccination programme aimed at preventing mother-to-child transmission of the HBV virus. Key areas of coordination include: (a) integrating BD vaccination as part of essential newborn care; (b) including BD vaccination as part of the postnatal care visit for home births; (c) ensuring SBAs give BD vaccine as part of home delivery assistance; (d) training SBA, midwives and OB/GYN staff to handle and administer vaccine.
Maximize BD coverage among facility births: Addressing missed opportunities for giving timely BD to babies born in health facilities is likely to be the simplest, fastest and cheapest way to increase coverage. Activities to consider for increased coverage include: (a) creating specific policies and guidelines; (b) establishing standing orders in facilities for newborn vaccination; (c) assigning clear responsibility for BD administration; (d) including BD vaccination as part of the OB/GYN and midwifery training curriculum; and (e) engaging relevant professional societies.

Implement innovative strategies for reaching home births: Special ‘interim’ approaches to reach home births may be needed until such a time as facility births becomes the norm. Such approaches include home visits by health staff to mothers and newborns for postnatal care and use of vaccine in Unject or in a controlled temperature chain.

Prevent breaks in vaccine supply: Four out of five priority countries reported hepatitis B vaccine stock-outs. Assessment and actions to prevent stock-outs should be undertaken by all priority countries.

Technical issues related to BD administration:

(a) Timing: The BD should be given as soon as possible after birth, preferably within 24 hours. Clear messaging is required to ensure that vaccination after 24 hours happens. During the consultation, countries reported situations where a BD was not given after 24 hours (mainly in delivery settings) or after seven days.

(b) Spacing: The Regional Operational Field Guidelines for Delivery of the Birth Dose of Hepatitis B Vaccine note that monovalent BD can be given up until the day before a combination vaccine is scheduled, even although the 2009 WHO position paper on hepatitis B vaccine specifies that hepatitis B vaccination should be spaced by four weeks. The Region has made this recommendation based on the following: (i) the combination schedule accommodates appropriate three-dose spacing; (ii) monovalent vaccine will not decrease the immunogenicity of antigens in the combination vaccine; and (iii) BD vaccination prevents, not only mother-to-child transmission, but also childhood transmission, which represents a substantial risk. Updating the WHO position should be considered, given the increasing number of countries using monovalent and combination vaccine.

(c) Monitoring: The global indicator for timely BD vaccination is provision of hepatitis B vaccine within 24 hours of birth. Two issues came up during the consultation related to this global indicator: (i) it should be reinforced to vaccinate after 24 hours; and (ii) what is reported by countries and acceptable on WHO/UNICEF joint reporting form is actually vaccination up to 48 hours of birth (vaccine administered the day after birth). Careful training and messaging is needed to ensure that vaccine provided within 48 hours is included as a “timely BD” and that vaccine is given even if not considered “timely” per the monitoring standards.

Actions to increase access to BD vaccine: Many actions to increase access to BD vaccine were identified (Annex 5). These actions should be discussed in the context of other immunization priorities and the need for technical or financial assistance should be communicated to the WHO Western Pacific Regional Office or partners.
CONSULTATION ON IMPROVING AND MONITORING HEPATITIS B BIRTH DOSE VACCINATION
13-15 June 2012

AGENDA

SESSION 1  OPENING
SESSION 2  REGIONAL PERSPECTIVES ON HEPATITIS B CONTROL
SESSION 3  COUNTRY BD STATUS, CHALLENGES, APPROACHES
SESSION 4  GROUP WORK I: STRENGTHENING EPI/MCH COORDINATION
SESSION 5  GROUP WORK REPORTS
SESSION 6  OTHER EXPERIENCES AND OPPORTUNITIES TO INCREASE BD COVERAGE
SESSION 7  COUNTRY QUESTIONS AND ANSWERS
SESSION 8  GROUP WORK II: COUNTRY ACTIONS TO IMPROVE BD COVERAGE
SESSION 9  GROUP WORK II REPORTS
SESSION 10  PARTNERS SESSION
SESSION 11  SUMMARY OF FIRST TWO DAYS
SESSION 12  DATA RECORDING AND REPORTING AND COVERAGE ESTIMATION
SESSION 13  COUNTRY-SPECIFIC REVIEW OF BD ESTIMATES
SESSION 14  COUNTRY QUESTIONS AND ANSWERS
SESSION 15  SUMMARY AND CLOSE
<table>
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<tr>
<th>Session 1</th>
<th>Opening session</th>
<th>Session 6</th>
<th>Other experiences and opportunities to increase BD coverage</th>
<th>Session 12</th>
<th>Data recording and reporting and coverage estimation</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.00-8.30</td>
<td>Registration</td>
<td>8.00-8.30</td>
<td>BD best practices - a review for the WHO Immunization Practices Advisory Group (C Morgan)</td>
<td>8.30-10.00</td>
<td>Regional process of monitoring (J Aldana-Mendoza) Immunization coverage and BD coverage estimation (M Gacic-Dobo)</td>
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<tr>
<td>8.30-9.15</td>
<td>Opening remarks</td>
<td>8.30-9.15</td>
<td>The China experience on increasing BD coverage (F Cui)</td>
<td>10.30-12.00</td>
<td>Country reviews of routine coverage estimates and estimation of birth dose: (Philippines, Vietnam, PNG, Lao PDR, Cambodia)</td>
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<td></td>
<td>Introduction/Election of meeting officials/Group photo</td>
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<td>1. Have you had any recent coverage surveys or data quality assessments? Please, describe. 2. Have you had any recent estimates for vaccine-preventable disease burden? Please describe.</td>
<td>1.00-2.00</td>
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<td></td>
<td>Regional perspectives on EPI, HB control and MCH</td>
<td>10.00-1.00</td>
<td>Country questions and answers</td>
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<td>COFFEE BREAK</td>
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<td>9.15-10.00</td>
<td>BD vaccination and HB control in WPR (K Hennessey) Maternal and newborn health in WPR (A Kaptiningah) Strengthening routine immunization in collaboration with MCH: opportunities and challenges (Y Takashima)</td>
<td>10.00-10.30</td>
<td>COFFEE BREAK</td>
<td>3.00-3.30</td>
<td>COFFEE BREAK</td>
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<td>10.00-10.15</td>
<td>Discussion</td>
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<td>Country questions and answers</td>
<td>3.30-4.15</td>
<td>12.30-1.30 LUNCH BREAK</td>
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<td>10.15-10.30</td>
<td>COFFEE BREAK</td>
<td>11.00-12.00</td>
<td>1. At what age do countries stop giving BD (i.e., after 7d)? 2. What do countries think of 2017 for &lt;1% goal? 3. How to receive BD reports from private facilities?</td>
<td>4.15-5.00</td>
<td>Partners statements or presentations</td>
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<td>Country BD status, challenges, approaches</td>
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<td>1. Have you had any recent coverage surveys or data quality assessments? Please, describe. 2. Have you had any recent estimates for vaccine-preventable disease burden? Please describe.</td>
<td>3.00-3.30</td>
<td>2.00-2.30 COFFEE BREAK</td>
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<td>Cambodia (Cheng Morn); Vietnam (Nguyen Lien Huong); Philippines (Joyce Ducusin)</td>
<td>11.15-11.35</td>
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<td>11.35-12.05</td>
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<td>12.05-12.30</td>
<td>Group Work II Reports</td>
<td>12.05-12.30</td>
<td>2.30-2.45 Meeting summary (T Ruff)</td>
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<td>12.30-1.30</td>
<td>LUNCH BREAK</td>
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<td>Summary of First Two Days</td>
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<td>3.00-3.30 Summary of First Two Days</td>
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<td>14.00-14.30</td>
<td>Summary and next steps (T Ruff)</td>
<td>14.00-14.30</td>
<td>3.00-3.30 Summary of First Two Days</td>
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**TIMETABLE**

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<td>Opening</td>
<td>Other experiences and opportunities to increase BD coverage</td>
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<tr>
<td>BD vaccination and HB control in WPR (K Hennessey) Maternal and newborn health in WPR (A Kaptiningah) Strengthening routine immunization in collaboration with MCH: opportunities and challenges (Y Takashima)</td>
<td>8.45-9.15 Progress with controlled temperature chain: strategy and update (D Chang-Blanc) Reaching home births - design considerations for 2 projects in Lao PDR (M Patel)</td>
<td>10.30-12.00 Country reviews of routine coverage estimates and estimation of birth dose: (Philippines, Vietnam, PNG, Lao PDR, Cambodia)</td>
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<td>(Nguyen Lien Huong); Philippines (Joyce Ducusin)</td>
<td>10.30-11.00 Discussion</td>
<td>1. Have you had any recent coverage surveys or data quality assessments? Please, describe. 2. Have you had any recent estimates for vaccine-preventable disease burden? Please describe.</td>
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<td>(Nguyen Lien Huong); Philippines (Joyce Ducusin)</td>
<td>11.00-12.00</td>
<td>1. At what age do countries stop giving BD (i.e., after 7d)? 2. What do countries think of 2017 for &lt;1% goal? 3. How to receive BD reports from private facilities?</td>
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<td>Strengthening EPI/MCH coordination</td>
<td>12.00-1.00 LUNCH BREAK</td>
<td>1. Have you had any recent coverage surveys or data quality assessments? Please, describe. 2. Have you had any recent estimates for vaccine-preventable disease burden? Please describe.</td>
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<td>Vietnam, Cambodia, Lao PDR PNG, Philippines</td>
<td>5.15-5.30</td>
<td>Discussion</td>
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</table>
ANNEX 3

LIST OF PARTICIPANTS, TEMPORARY ADVISERS, PARTNERS/OBSERVERS/REPRESENTATIVES AND SECRETARIAT

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EFFECTIVE PRACTICES FOR IMPROVING BIRTH DOSE COVERAGE;
Slide presented by Dr Chris Morgan During Session 2.3.1

Box 2: Effective practices for improving coverage with hepatitis B birth dose vaccine

**Service delivery arrangements:**
- Increasing access to skilled care at the time of childbirth;
- Integration of birth dose with maternal and newborn care in health facilities by:
  - A local health facility policy specifying birth dose vaccination;
  - Standing orders for administration of birth dose in delivery room or postnatal ward;
  - Ensuring vaccine is available in the delivery room or postnatal ward
  - Clear delineation of who is to vaccinate that includes maternal health providers;
  - Appropriately positioning birth dose vaccination within essential newborn care; and
  - Coordinated planning between immunization and maternal health staff in health facilities and in districts, including supportive health facility assessments.
- Linkages between immunization and private services providing childbirth care;
- Reaching infants born outside health facilities by:
  - Home visits to provide timely vaccination;
  - Integration of birth dose with home visits for other postnatal care;
  - Vaccine storage outside the cold chain;
  - Careful pregnancy tracking.

**Health Workforce considerations:**
- Addressing health care providers’ lack of knowledge and particular attitudes and perceptions towards newborn vaccination;
- Clear impact from well-structured health worker training backed up by frequent follow-up and supportive supervision; and
- Consideration of task-shifting to reach populations difficult to access.

**Medical technologies relevant to birth dose:**
- Vaccine distribution and storage that utilize the potential for outside the cold chain usage, and position it as close to the birth place as possible;
- The use of 
  - Liquid by community-based health care providers; and
  - Ensuring monovalent hepatitis B vaccine in single-dose or multi-dose presentations.

**Health information system strengthening practices:**
- Birth registries and community birth notification, including tracking home births;
- Integration with vaccination records;
- Accurate definition of birth dose in coverage reporting;
- The use of 
  - Surveys for establishment of need and for monitoring.

**Financing arrangements influencing birth dose coverage:**
- Adequate funding for birth dose programs, with consideration of transport efficiencies for distribution to the periphery; and
- Minimizing costs to families.

**Addressing community concerns or lack of knowledge regarding birth dose**
- Responding to low awareness of the birth dose vaccine and its importance;
- Considering traditional practices of sequestering newborns;
- Addressing fear of adverse events, including planning for the risk of coincidental newborn death or disease; and
- Responding to parental refusal of vaccination.

**Leadership and governance practices:**
- A national policy for universal newborn vaccination;
- Clear national guidance defining timely birth dose as within 24 hours of birth;
- Removing unnecessarily stringent restrictions contraindicating vaccination;
- Endorsing vaccine use outside the cold chain and accreditng new vaccinators;
- Strong central communications to support public confidence in vaccines.
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<th>Cambodia</th>
<th>Lao PDR</th>
<th>Papua New Guinea</th>
<th>Philippines</th>
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<td>EPI and MCH Coordination</td>
<td>Monthly meetings at national and province level</td>
<td>Joint advocacy for awareness and funding of post-natal care/BD home visits</td>
<td>Use BD to reinforce scale-up midwives</td>
<td>Regular meetings to harmonize strategies</td>
<td>EPI and MCH plan of action to increase BD</td>
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<td>Guideline, Training</td>
<td>Central/Province-level training of midwives</td>
<td>Develop generic hospital protocol for BD</td>
<td>Province-level BD training for delivery facilities</td>
<td>Standardize reporting and reporting of BD from facilities</td>
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<td>Implementation, Supervision, Monitoring, Feedback</td>
<td>Expand GAVI BD incentive to other areas</td>
<td>Strengthen VHV and HC links for BD at home</td>
<td>BD as part OB/paeds supervisory visits</td>
<td>Improve coordination with hospitals</td>
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<td>Policy, Research</td>
<td>Clear policy on responsibility of BD</td>
<td>BD as part of outreach</td>
<td>Continue BD assessments in delivery facilities in low performing areas</td>
<td>Gather evidence for policy makers (rapid assessment; risk factors for missing BD)</td>
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<td>Advocacy, Awareness</td>
<td>High level advocacy meeting to implement home and facility BD vaccination</td>
<td>Include BD in vaccination week –engage OB/paeds</td>
<td>Increase demand from mothers and service providers</td>
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<td>Form HB subgroup under Working Group on Health</td>
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