World Health Organization

Preventing Perinatal Hepatitis B Virus Transmission:

A Guide for Introducing and Strengthening Hepatitis B Birth Dose Vaccination

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About this guide

This document is intended for use by national immunization programme managers, maternal neonatal and child health (MNCH) professionals, and immunization partners involved with operationalizing hepatitis B birth dose (HepB-BD) introduction or strengthening an existing HepB-BD programme. The document also provides information on the practicality of HepB-BD, to help policy-makers, partners and managers who are considering introduction of HepB-BD into an immunization schedule.

General guidance about planning the introduction of a vaccine into a national immunization programme is provided in the document *Principles and considerations for adding a vaccine to a national immunization programme: from decision to implementation and monitoring* published by WHO in 2014 and available at http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/.

However, as hepatitis B birth dose is not an entirely new vaccine, but rather a new delivery strategy for a vaccine already included in the routine schedule, this guide will focus on the unique aspects and programmatic features of administering hepatitis B vaccine as a birth dose.

The specific objectives of this guide are:

→ to provide an overview of WHO recommendations, best practices, technical justification and strategic approaches relating to providing hepatitis B birth dose to newborns.

→ to highlight the unique operational requirements for introducing a vaccination that should be delivered as soon after birth as possible, preferably within 24 hours.

→ to inform the policy discussions and operational strategies for the introduction of hepatitis B birth dose vaccination into a national immunization programme.

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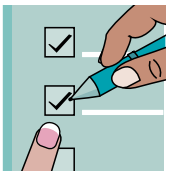

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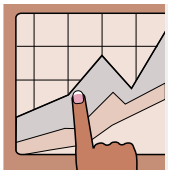

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Abbreviations & acronyms

AEFI	adverse event following immunization
BCG	Bacille Calmette-Guérin
CHEW	community health extension worker
cMYP	comprehensive multi-year plan
CPAD	compact pre-filled auto-disable device
CTC	controlled temperature chain
DHS	demographic and health survey
DTP	diphtheria-tetanus-pertussis vaccine
EPI	Expanded Programme on Immunization
Gavi	Gavi, the Vaccine Alliance
HBsAg	hepatitis B surface antigen
HBeAg	hepatitis B 'e' antigen
HBV	hepatitis B virus
HepB	hepatitis B vaccine
HepB3	hepatitis B vaccine third dose
HepB-BD	hepatitis B vaccine birth dose
HEW	health extension worker
Hib	*haemophilus influenzae* type B
HIV	human immunodeficiency virus
IEC	information, education and communication
JRF	Joint Reporting Form
MICS	multiple indicator cluster survey
MNCH	maternal neonatal and child health
MDVP	multi-dose vial policy
NITAG	national immunization technical advisory group
NGO	non-governmental organization
OCC	out-of-cold-chain
OPV	oral polio vaccine
PIE	post-introduction evaluation
SBA	skilled birth attendant
SMS	Short Message Service
TBA	traditional birth attendant
UNICEF	United Nations Children's Fund
VVM	vaccine vial monitor
WHO	World Health Organization

Glossary

Adverse event following immunization (AEFI). Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Cirrhosis. Chronic scarring of the liver as a result of chronic inflammation of liver cells due, among other causes, to chronic hepatitis B infection.

Chronic HBV infection. Long-term HBV infection, defined as persistence of HBsAg in the blood for more than six months.

Controlled temperature chain (CTC). A specific set of conditions allowing the transport and storage of a WHO-prequalified vaccine at temperatures outside of the traditional +2 °C to +8 °C cold chain, for a single excursion into ambient temperatures of up to 40 °C, for a limited period of time just prior to administration.

Obstetric staff. A health-care worker responsible for delivering a newborn or providing postnatal care (e.g. midwives, skilled birth attendant, postnatal care staff).

Hepatitis B infection. A liver infection caused by the hepatitis B virus; clinically indistinguishable from other causes of viral hepatitis.

HBeAg. Hepatitis B 'e' antigen; serves as a marker of viral replication/infectiousness.

HBsAg. Hepatitis B surface antigen; serves as a marker of current infection.

Home births. Used throughout this document as a proxy to refer to births taking place outside of health facilities (including in the home, or any designated dwelling or hut, etc.).

Low birth weight. Weight of less than 2500g irrespective of gestational age.

Perinatal HBV transmission. HBV transmission from mother-to-child during birth.

Seroprevalence. Proportion of members of a population whose sera are positive for a specific antibody (e.g. AntiHBs or antiHBc) or antigen (e.g. HBsAg or HBeAg).

Skilled birth attendant (SBA). An accredited health professional – such as a midwife, doctor or nurse – who has been educated and trained to proficiency in the skills needed to manage uncomplicated pregnancies, childbirth, and the immediate postnatal period.

Timely HepB-BD. The global standard for measuring vaccination coverage with HepB-BD, defined as HepB-BD given within 24 hours after birth.

Total HepB-BD. Total number of HepB-BD administered including timely and late administration.

Traditional birth attendant (TBA). The term TBA usually refers only to traditional, independent (of the health system), non-formally trained and community-based providers of care during pregnancy, childbirth and the postnatal period.

Vaccine vial monitor (VVM). A chemical-indicator label which records cumulative heat exposure through a gradual change in colour and indicates when the vaccine has exceeded its heat exposure limit and should be discarded.

Overview

Worldwide, over 240 million people are chronically infected with hepatitis B virus (HBV), which can lead to premature death from liver cirrhosis or cancer.[1] HBV is the second most important known human carcinogen, after tobacco. However, HBV infection can be prevented by one of the safest and most effective vaccines available. The hepatitis B (HepB) vaccine not only protects children and adults from HBV infection, but clinical trials have established that if given within 24 hours after birth and followed by at least two subsequent doses, the vaccine is approximately 90% effective at preventing perinatal HBV infection.[2] This means the vaccine can prevent HBV infection in newborns even after they have been exposed to the virus from their mother. Protecting newborns is important because infection at this point in the life-cycle is much more likely to persist as chronic HBV infection and lead to premature death.

In 1992, the World Health Organization (WHO) recommended that countries introduce hepatitis B vaccine into their national immunization schedules to prevent HBV-related disease and death. In 2009, WHO emphasized prevention of mother-to-child HBV transmission by recommending that all countries, even those with low HBV prevalence, introduce universal hepatitis B birth dose (HepB-BD) vaccination.[3] Unfortunately, many countries have not yet introduced HepB-BD, or have difficulty reaching high and timely HepB-BD coverage. In 2014, less than 38% of newborns worldwide received HepB-BD within 24 hours after birth.[4]

HepB-BD introduction has unique features with important programmatic implications. For example, HepB-BD must be administered as soon as possible after birth to prevent mother-to-child transmission, with best efficacy if given within 24 hours after birth. This has important operational implications because maternal and MNCH workers are often better positioned to administer HepB-BD quickly after birth, as compared to immunization staff. This document focuses on what is unique to HepB-BD introduction and builds on other key immunization references available from WHO.[5,6,7,8]

1 Ott JJ, Stevens GA, Groeger J, Wiersma ST (2012). Global epidemiology of hepatitis B virus infection: new estimates of age-specific HBsAg seroprevalence and endemicity. Vaccine 2012;30:2212–19.
2 Plotkin, SA, Orenstein W, Offit PA. Vaccines. 2013;6:206.
3 WHO position paper on hepatitis B vaccines. Geneva, World Health Organization, 2009 (http://www.who.int/wer/2009/wer8440.pdf).
4 http://apps.who.int/immunization_monitoring/globalsummary.
5 Immunization training resources (http://www.who.int/immunization/documents/training/en/).
6 *Principles and considerations for adding a vaccine to a national immunization programme*. Geneva, World Health Organization, 2014 (www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/).
7 *Practices to improve coverage of the hepatitis B birth dose vaccine.* Geneva, World Health Organization, 2013 (WHO/IVB/12.11) (http://www.who.int/immunization/documents/control/who_ivb_12.11/en/index.html).
8 *Introduction of hepatitis B vaccine into childhood immunization services*. Geneva, World Health Organization, 2001 (WHO/V&B/01.31) (http://whqlibdoc.who.int/hq/2001/WHO_V&B_01.31.pdf).

TABLE 1.
UNIQUE CONSIDERATIONS FOR HEPB-BD INTRODUCTION EMPHASIZED IN THIS DOCUMENT

TOPIC	CHAPTER	UNIQUE CONSIDERATIONS FOR HEPB-BD INTRODUCTION
Vaccine administration	2	→ Newborn injection → Critical timing (within 24 hours after birth)
Service delivery – facility births	3	→ Obstetric, maternal and postnatal care staff to vaccinate → Engagement of hospital sector, encourage facility standing orders
Service delivery – home births	4	→ Use of both existing and innovative strategies to access births outside of health facilities, including postnatal care contacts
Vaccine characteristics	5	→ Must use monovalent vaccine for birth dose → Option of compact pre-filled auto-disable device (CPAD) presentation
Vaccine handling and logistics	5	→ Vaccine is heat stable but highly freeze sensitive → Vaccine security – avoid diverting monovalent vaccine for use with older age groups
Policy and targets	6	→ Regional, country disease reduction targets → Consideration of existing EPI and MNCH policies
Planning	7	→ Situational analysis (know where births take place and newborn care practices) → Joint planning between EPI and MNCH → Opportunities to strengthen immunization programmes and postnatal care → Cost and logistics of including non-EPI settings (births in maternity units or in the community)
Training	8	→ Expansion of training to obstetric and newborn care cadres
Supervision	8	→ Expanded supervision of obstetric and newborn staff by EPI or MNCH
Monitoring coverage and measuring impact	9	→ Expansion of recording and reporting by obstetric staff → Coverage indicator includes timeliness (24h) → Seroprevalence instead of surveillance
Adverse events following immunization (AEFI)	9	→ Must anticipate coincidental neonatal deaths
Advocacy, communication, social mobilization	10	→ World Health Assembly resolution, regional goals → Engagement of non-communicable disease control programmes regarding cancer prevention

CHAPTER 1

The importance of hepatitis B birth dose vaccination

A The virus—newborns have a high risk of infection

Globally, more than 240 million people have chronic hepatitis B virus (HBV) infections and it is estimated that more than 686 000 deaths per year are due to the acute or chronic consequences of HBV.[9] HBV infects the liver and if the infection becomes chronic, it can lead to cirrhosis and liver cancer, one of the most common causes of cancer-related death.

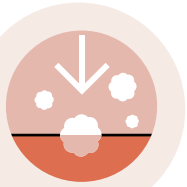
HBV is transmitted by exposure to infected blood and other body fluids, such as semen and vaginal fluid; therefore, the virus can be transmitted at all stages of life (**Box 1**).

In highly endemic countries, HBV infection is commonly transmitted from mother-to-child at birth or during early childhood. Key facts about mother-to-child transmission of HBV include:

- it occurs primarily at birth through infected blood;
- the risk of transmission from an infected mother to her newborn is up to 90%;
- in utero transmission is rare;
- the virus is not transmitted by breastfeeding;
- caesarean section will not prevent transmission.

Newborns and young children have the highest risk of acquiring chronic HBV infection. The risk for developing chronic HBV infection varies inversely with age; if exposed, newborns have up to 90% risk of chronic infection with the risk dropping but remaining high during infancy, children between one and five years have approximately 30% risk, and those older than five years have a risk of 5-10% (**Figure 1**).[2]

9 Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet. 2015;385(9963):117-171



BOX 1.

ROUTES OF HBV TRANSMISSION

→ **Vertical transmission**
—Newborns: mother-to-child or perinatal transmission due to exposure to blood during labor; in utero transmission is rare

→ **Horizontal transmission**
—Early childhood: likely from breaks in skin (scratches, dermatitis), likely through infected close contacts
—Adult transmission: sexual contact, injection drug use

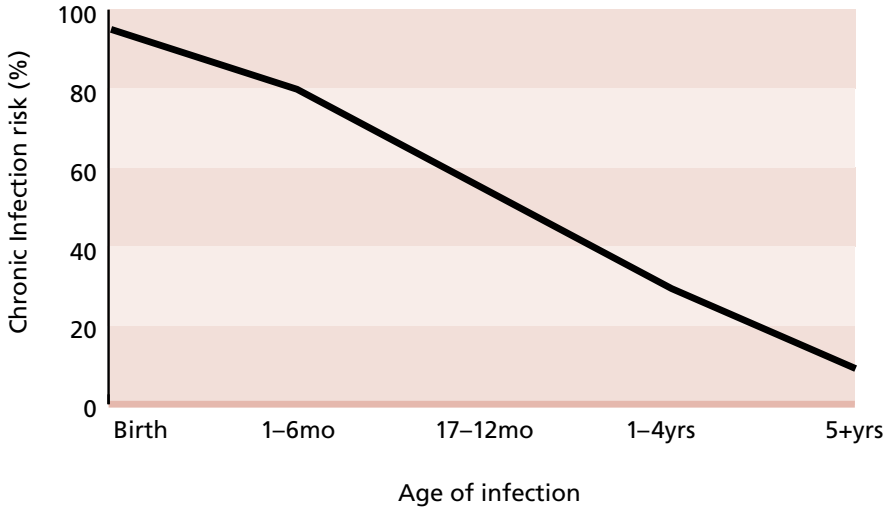
→ **Nosocomial transmission**
—All ages: unsafe injections, medical procedures, blood transfusions

Up to 25% of adults who acquired their HBV infection during childhood die from HBV-related liver cancer or cirrhosis. The best way to prevent chronic disease that leads to death is by preventing infection as early in life as possible. The most important prevention points are soon after birth, to interrupt mother-to-child transmission, and in early childhood, to interrupt other routes of transmission at that age.

B The vaccine – safe, effective and affordable

Hepatitis B vaccination is the most effective way to prevent HBV infection. Clinical trials have established that vaccine given within 24 hours after birth, followed by at least two more doses, is effective at preventing perinatal HBV infection and inducing immunity to HBV. Details of the vaccine will be provided in later chapters; however, as an overview, hepatitis B vaccine is one of the safest and most effective vaccines available. The vaccine contains non-infectious material and cannot cause HBV infection. When first introduced, hepatitis B vaccine was expensive, deterring its use in immunization programmes. Current prices of HepB vaccine are significantly lower, making it highly cost-effective to include in national immunization programmes. It is considered as one of the top ten "best buys" in the field of non-communicable disease.

FIGURE 1.
RISK OF CHRONIC HBV INFECTION BY AGE OF INFECTION

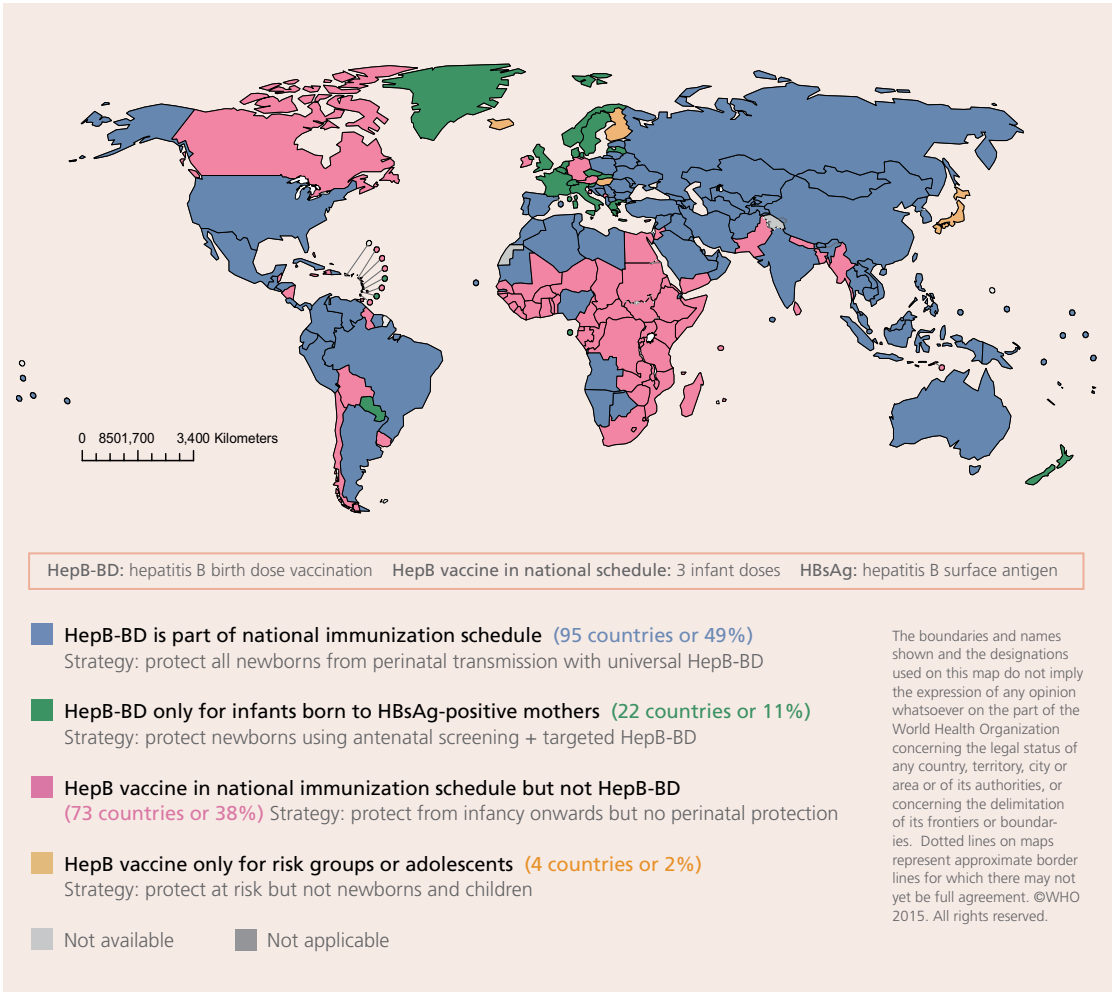


▼ If exposed to the virus during birth, newborns have up to 90% risk of acquiring chronic HBV infection

C Global status of hepatitis B birth dose vaccination

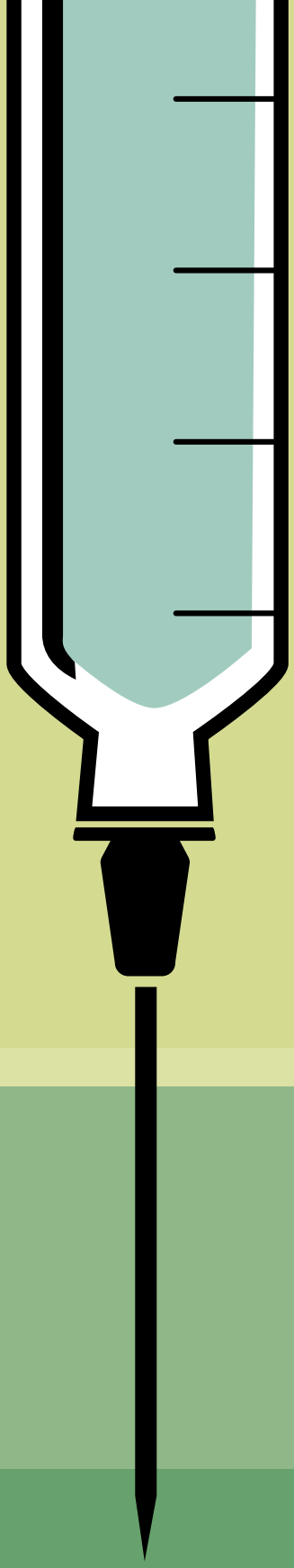
Significant progress has been made in providing hepatitis B vaccination as part of an infant vaccination schedule; however, global coverage of HepB-BD remains low. Despite WHO recommendations, in 2014 only 96 (49%) out of 194 countries reported offering HepB-BD as part of their national immunization programme (**Figure 2**) and less than 38% of babies born worldwide received HepB-BD within 24 hours after birth. In order to support progress in preventing perinatal-HBV transmission WHO recommends that all regions adopt hepatitis B control goals.[3] By 2014, the African, Eastern Mediterranean and Western Pacific WHO regions had established goals to prevent hepatitis B through vaccination. These Regions are using control goals to increase awareness about the burden of HBV and to encourage member countries to improve their vaccination coverage.

FIGURE 2.
COUNTRIES PROVIDING HEPB-BD IN 2014



Data source: WHO/UNICEF Joint Reporting Form 2014, as at 05 November 2015 and ECDC published data at http://vaccine-schedule.ecdc.europa.eu/Pages/Scheduler.aspx
194 WHO Member States; Map production Immunization Vaccines and Biologicals (IVB),WHO; Date of slide: 05 November 2015

YOUR NOTES



CHAPTER 2

Vaccine administration essentials

A Vaccine formulation, dosage, route and site of vaccination

HepB vaccines are available in monovalent and combination formulations such as DTP-Hib-HepB (see Chapter 5). **MONOVALENT HEPATITIS B VACCINE MUST BE USED FOR THE BIRTH DOSE**. This is because combination vaccines contain multiple antigens, such as DTP-HepB-Hib, that should be given at a later age to maximize their immunogenicity.

HepB-BD is administered by intramuscular injection with a needle at a 90 degree angle in the anterolateral aspect of the thigh. The standard dose for a newborn is 0.5 mL.

B Timing of administering the birth dose

WHO recommends that all infants receive the first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours, to prevent mother-to-child (perinatal) HBV transmission. This should be followed by at least two subsequent doses.[3] As the mother's HBV status may be unknown, every newborn should be vaccinated.

HepB vaccine is most effective if given within 24 hours after birth; however, in some circumstances, delayed vaccination is unavoidable. Evidence from observational studies shows that birth dose vaccination can still be effective against perinatal transmission, even if given later than 24 hours after birth. However, as more time passes, the vaccine becomes less effective in preventing perinatal transmission (although it will still interrupt other routes of transmission).

It is important for programmes to have a clear policy on how many days after birth the HepB-BD can be administered. This policy should be clearly stated in training and instruction materials to ensure that HepB-BD will be given even if the 24 hour window

▲ Site of HepB-BD vaccination:
anterolateral aspect of the thigh

has passed. This information is important for programme managers and vaccinators so that they know how late they can vaccinate and how to record this information. The message to communities and pregnant women remains that HepB-BD should be given within 24 hours after birth or as soon as possible.

The policy on how late to vaccinate is straightforward for programmes using monovalent HepB vaccine; HepB-BD should be given as soon as possible after birth and the next dose should be given four weeks later. Countries using a hepatitis B-containing combination vaccine (e.g. DTP-Hib-HepB) often adopt a 4-dose schedule by simply adding HepB-BD to the combination vaccine schedule (see **Table 2**). These countries will need to decide when to stop giving HepB-BD, keeping in mind that the subsequent dose is fixed according to the combination vaccine schedule. Some counties stop providing HepB-BD beyond 2 weeks after birth to have a consistent message regarding a four week gap between doses. However, with a 4-dose schedule, it is not necessary to have a four week gap between the HepB-BD and subsequent dose because the combination schedule meets the dosing requirements. Therefore, HepB-BD can be given up until the day before the combination vaccine is due. Both options are acceptable. The first option may be easier to understand as vaccinators may hesitate to have minimal spacing between vaccine administration; while the second option takes advantage of giving HepB vaccine at any encounter before the combination vaccine is due.

The hepatitis B vaccine does not interfere with the immune response to any other vaccine, and vice versa. Thus, HepB-BD, bacillus Calmette–Guérin (BCG), and oral polio vaccine (OPV) can all be administered during the same visit.

It is also important to consider the best timing of HepB-BD in relation to other newborn care interventions. HepB-BD should not interfere with life-saving interventions. Coordination with newborn care is discussed in more detail in Chapter 3.

TIMING OF THE SUBSEQUENT HEPATITIS B VACCINE DOSES

HepB-BD alone will not prevent mother-to-child infection; it must be followed by at least two subsequent doses that are given on-time. A study from Thailand found that late administration of the second dose of HepB vaccine resulted in a higher rate of mother-to-child HBV transmission compared with infants who received the second dose on-time (**Country Example 1**).

A complete HepB vaccination series can be made up of either three or four doses (**Table 2**). Countries should decide which schedule is best suited to their programme. The 3-dose schedule may be less expensive, but is more complicated to administer because infants receive different vaccines at the second immunization visit than at the first and third visits. Moreover, it may be difficult to achieve a high-level of completion of the three doses of HepB vaccine with this schedule in countries where a high percentage of children are born outside of health facilities. A comprehensive summary of WHO-recommended immunization schedules for children can be found online.[10]

TABLE 2.
RECOMMENDED HEPATITIS B VACCINATION SCHEDULES

NAME OF DOSE	TIMING OF ADMINISTRATION OF DOSE	
	3-DOSE SCHEDULE	4-DOSE SCHEDULE**
HepB-BD	As soon as possible after birth (≤24 h)	As soon as possible after birth (≤24 h)
HepB1	HepB1 is not given (i.e. not counted*)	As per combination vaccine schedule
HepB2	4 weeks minimum after HepB-BD	As per combination vaccine schedule
HepB3	4 weeks minimum after HepB2	As per combination vaccine schedule

* Not counting HepB1 is recommended as a standard to allow for reporting coverage of HepB-BD and HepB3 when using a 3-dose schedule.
** In the 4-dose schedule, the second dose is still called HepB1 in order to avoid confusion with DTP1/Pentavalent1.

10 WHO recommendations for routine immunization (http://www.who.int/immunization/policy/immunization_tables/en/).

C Side-effects

Hepatitis B vaccine is very safe. Mild transient side-effects may occur after immunization, including soreness at the injection site, irritability and fever. These transient effects may start within a day after the vaccine has been given and last from one to three days. Serious allergic reactions are very rare; see Chapter 10 for more details on adverse events following immunization.

D Contraindications

The only contraindication to HepB vaccine administration is anaphylactic reaction to a previous dose; however, newborns will not have received a previous dose, and thus there are no true contraindications to birth dose. However, birth dose vaccination is often delayed due to conditions falsely believed to be contraindications (**Box 2**).

Pre-term infants should be vaccinated at birth and their dose recorded and reported.

Low birth weight is not a contraindication to vaccination. However, if a newborn's birth weight is <2000g, vaccine effectiveness is reduced. This vaccine dose should not be counted towards the primary series and three additional doses should be given according to the national vaccination schedule.[3]

Some health-care workers are concerned when it comes to vaccinating unstable newborns, as parents might erroneously associate negative outcomes with the birth dose. Birth dose vaccination may be delayed for newborns who are unstable, at the discretion of the health-care worker. Instability is not a medical contraindication to vaccination; however, birth dose vaccination may be delayed for newborns who are unstable at the discretion of the healthcare worker.

BOX 2.

THE FOLLOWING ARE NOT CONTRAINDICATIONS TO HEPB-BD VACCINATION:

- → prematurity
- → low birth weight
- → small for gestational age
- → HIV infection of mother or infant
- → jaundice

THAILAND

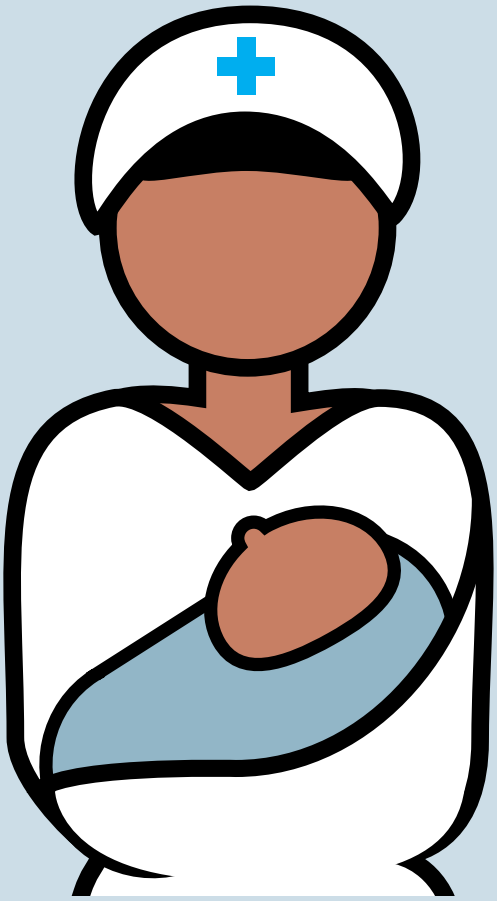
COUNTRY EXAMPLE 1:

IMPORTANCE OF TIMELY SUBSEQUENT HEPB DOSES IN PREVENTING PERINATAL TRANSMISSION

To study the effects of delayed second dose of HepB vaccine, a study in Thailand assessed the risk of developing chronic HBV infection in infants born to chronically HBV-infected mothers. The risk of an infant becoming chronically infected, despite receipt of HepB-BD, was 3.74 times higher if the interval between the first and the second dose exceeded 10 weeks. While more studies are needed, these findings suggest that immunization programmes should ensure timely second-dose vaccination to infants born to mothers with chronic HBV infection.

Tharmaphornpilas P et al. Increased risk of developing chronic HBV infection in infants born to chronically HBV infected mothers as a result of delayed second dose of hepatitis B vaccination. Vaccine. 2009;27:6110–6115.

YOUR NOTES



CHAPTER 3

Service delivery – health-facility births

Births take place in two main settings: in health facilities or in the 'home', meaning any community setting outside of a formal health facility. Different strategies will be needed for reaching newborns in each of these settings. This chapter covers establishing HepB-BD vaccination in health facilities that offer care during childbirth and the postnatal period. In health facilities, many requirements are already in place, including skilled health staff and, in many cases, cold-chain and injection equipment. Programmes to establish HepB-BD in health facilities share common goals with broader MNCH improvement programmes. Both programmes recognize the importance of reaching every woman and every newborn with quality care around the time of childbirth. Both aim for increased skilled birth attendance in health facilities, as well as the provision of the first postnatal care within 24 hours after birth, wherever a baby is born.[11,12]

HepB-BD introduction in health facilities providing childbirth and postnatal care is an efficient strategy, and may initially appear to be relatively simple to implement. However, it will require planning, resources and, most importantly, engaging a new sector to take on immunization responsibilities. Considerations for HepB-BD implementation in health facilities are listed in **Box 3**.

A Integrate birth dose vaccination with newborn care policies and practice

Policy and procedure documentation for health facilities should clearly specify administration of HepB-BD within the first 24 hours after birth as an essential component of good quality childbirth care. This is likely to need a standing order that requires and

11 WHO, UNICEF. Every newborn: an action plan to end preventable deaths. Geneva, World Health Organization, 2014 (http://www.everynewborn.org/every-newborn-action-plan/).

12 WHO recommendations on postnatal care of the mother and newborn. Geneva, World Health Organization, 2013 (http://www.who.int/maternal_child_adolescent/documents/postnatal-care-recommendations/en/).

BOX 3.
KEY CONSIDERATIONS FOR INTRODUCING HEPB-BD IN HEALTH FACILITIES

- → **Develop high-level political commitment** to mandate vaccination in delivery rooms or postnatal care wards
- → **Establish technical policies** and standing orders to implement the practice
- → **Assign responsibility** for administering vaccine in health facilities
- → **Integrate** birth dose with current newborn care practices
- → **Build capacity** for vaccine handling, administration, reporting and recording
- → **Equip** with cold-chain capacity if needed
- → **Monitor implementation**: a health facility supervisory checklist is discussed in Chapter 8 and an example provided in ANNEX 5.
- → **Include the private sector** in HepB-BD programme, where appropriate
- → **Engage** professional societies, communities: communication, advocacy and partnership

▼ Example of a potential barrier to HepB-BD vaccination: Father must carry newborn from the hospital to the EPI clinic across the street for vaccination.

authorizes appropriate staff (see below) to provide the HepB-BD vaccination in a timely way. Instituting such practices may also require national policy support (see Chapter 6).

It will be important for EPI and MNCH programmes to work together to ensure that HepB-BD administration is coordinated with current newborn care practices, and does not interfere with essential life-saving interventions.[13,14,15] For example, certain newborn care activities take absolute priority before vaccine administration, such as drying and breathing assessment, resuscitation where required, skin-to-skin contact, cord clamping and breastfeeding initiation. **Country Example 2** provides an example of integrating birth dose vaccination as part of essential newborn care.

Vaccination for newborns needing resuscitation or other immediate care may be justifiably delayed at the discretion of the health-care staff in order to implement life-saving interventions. However, a clear directive should be in place to vaccinate as soon as the newborn is stabilized. For example, the designated provider in charge of HepB-BD administration should track unvaccinated newborns and ensure they are vaccinated once stable. For newborns that are transferred to another health facility, vaccination status should be verified prior to transfer if the newborn is not critically ill. As part of the transfer report, it should be noted whether HepB-BD has been given or not. The receiving institution should ensure that the transferred newborn receives HepB-BD as soon as possible.

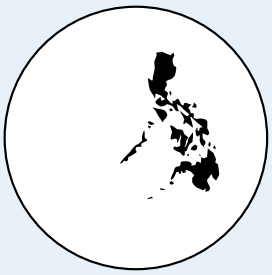
Many medications may be administered to both mother and newborn during delivery. Guidance should be developed, and practices monitored, to ensure that medicines intended for the mother, such as oxytocin, are not confused with HepB-BD vaccine for the baby.

B Assign responsibility for administering the birth dose

The critical and brief window to protect against mother-to-child HepB transmission means that both vaccine and vaccinator should be available at all times. A designated provider should be assigned to administer HepB-BD; preferably the skilled birth attendant at the delivery. It is tempting to assign HepB-BD vaccination responsibilities to EPI clinic staff; however, this arrangement can lead to late or missed vaccinations if vaccinations are not offered at all times or if the clinic is not conveniently located (photo left).

13 WHO guidelines on maternal, newborn, child and adolescent health: recommendations on newborn health. Geneva, World Health Organization. (http://who.int/maternal_child_adolescent/documents/guidelines-recommendations-newborn-health.pdf)
14 Essential interventions, commodities and guidelines for reproductive, maternal, newborn and child health. Geneva, World Health Organization, 2011 (http://www.who.int/pmnch/topics/part_publications/essential_interventions_18_01_2012.pdf).
15 Pregnancy, childbirth, postpartum and newborn care: a guide for essential practice (3rd edition). Geneva, World Health Organization, 2015 (http://www.who.int/maternal_child_adolescent/documents/imca-essential-practice-guide/en/).

THE PHILIPPINES



COUNTRY EXAMPLE 2:

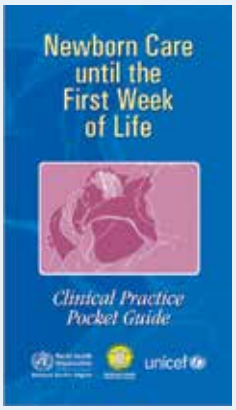
INTEGRATING HEPB-BD INTO AN ESSENTIAL NEWBORN CARE PROTOCOL

In response to an outbreak of sepsis in newborns in a Philippines hospital, an observational time-series study of newborn care practices was conducted in hospitals across the country. The minute-by-minute recording of newborn care used in this study resulted in the development of a national essential newborn care protocol describing the series of time-bound, chronologically-ordered, standard procedures that a baby should receive at birth.

The protocol specifies dividing early newborn care procedures into chronological phases. IMMEDIATE NEWBORN CARE includes actions to take place immediately after birth, such as immediate drying and breathing assessment, skin-to-skin contact, cord clamping and breastfeeding initiation. ESSENTIAL NEWBORN CARE includes interventions to take place as soon as possible after immediate newborn care, and starts with hepatitis B birth dose vaccination and recording.

Sobel HL et al. Immediate newborn care practices delay thermoregulation and breastfeeding initiation. Acta Paediatrica. 2011:100:1127–33.

Newborn care until the first week of life. Clinical Practice Pocket Guide. Manila, World Health Organization, Regional Office for the Western Pacific, 2009 (www.wpro.who.int/immunization/documents/newborncare_final.pdf).



Designating responsibility is necessary to eliminate potential gaps or duplication resulting from confusion about which staff member (e.g. obstetrician, paediatrician, midwife or immunization staff) is responsible for administering HepB-BD.

Staff assigned responsibility for vaccination should be available after working hours, because many babies are born at night; this is another reason why it may be most helpful to assign this role to the birth attendant. Ensuring staff are available to vaccinate at all times is especially important in health facilities where a new mother and baby may be rapidly discharged home within the first 24 hours after birth.

In some settings, junior staff may not be allowed to administer medications without prior approval. Studies have shown that health facilities with standing orders for HepB-BD have higher coverage.[7] The standing orders established as part of a health-facility policy should clearly authorize who is responsible and what type of staff is eligible to provide HepB-BD vaccination. Designated vaccinators could come from any staff competent to administer injections, including staff attending the delivery and/or working in the postnatal care area.

▼ HepB-BD administration should be integrated with essential newborn protocol, so that it is a step in a series of essential newborn care activities; for example immediately following skin-to-skin contact and breast feeding initiation.

C Keep a stock of vaccine near delivery ward

Place and time requirements for HepB-BD are different from other vaccines, so special arrangements are needed to ensure the vaccine is available at the time and place of delivery. This will have implications for the physical location of a vaccine refrigerator. At the service-delivery level, HepB-BD will preferably be stored in the delivery room or postnatal ward. If the refrigerator is located elsewhere in the facility, it may create a barrier to timely vaccination, especially if inconvenient or if the storage point requires special permission to access. If the refrigerator is not physically located in the maternity unit, it may be feasible to arrange to have a regular vaccine supply by storing the vaccine in a vaccine carrier kept in the delivery or postnatal room.

If using a refrigerator that is not dedicated solely for vaccines, it is essential that vaccines are clearly marked as such, and placed alone on one shelf of the refrigerator, as other biologic materials may easily be mistaken for vaccines.

D Explore options for health facilities lacking cold chain

In some settings, a substantial proportion of births take place in health facilities lacking access to a cold chain. Some of these facilities may have an immunization clinic nearby where vaccine can be brought and stored in a vaccine carrier onsite. Vaccines stored in this way should be replenished at regular frequent intervals, because temperature control is likely to be more reliable at the immunization clinic. Sufficient stock should always be available to anticipate births.

Other facilities may be too remote to rely on supplies obtained from nearby clinics and in these settings strategies for vaccination would be similar to those reaching home births – this is covered in the next chapter.

E Include private sector in birth dose vaccination

Experience from other countries has shown that HepB-BD coverage is lower in private delivery facilities compared to public facilities. If government policy provides free universal vaccination, vaccines should be made available to private facilities on the condition that vaccination is provided free-of-charge to newborns. Many countries have demonstrated success in providing free vaccine to private health providers in exchange for data on vaccine administration and access to facilities for supervision. **Country Example 3** provides an example of engaging participation in the private sector in the Philippines.

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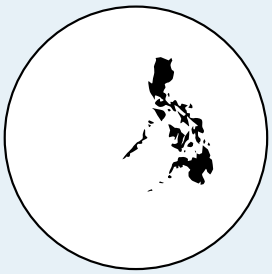
COUNTRY EXAMPLE 3:

FREE VACCINE FOR PRIVATE PROVIDERS



In the Philippines, 20% of deliveries take place in the private sector, where families are frequently charged for the cost of HepB-BD. In order to decrease this financial barrier, a programme was developed which allows for private providers to obtain routine infant vaccines free from EPI, since EPI was already procuring vaccine for the national birth cohort, not just those served in the public sector. In exchange for free vaccine, the private sector reports their doses administered to EPI. A HepB-BD assessment found that many private providers were not aware of this programme and so EPI has made an effort to increase awareness among private providers. This type of public-private partnership can result in protecting more newborns.

Patel MK et al. Findings from a hepatitis B birth dose assessment in health facilities in the Philippines: opportunities to engage the private sector. Vaccine. 2014; 32(39):51404.

YOUR NOTES

CHAPTER 4

Service delivery – home births

Accessing births outside a health facility, referred to in this text as 'home births', brings challenges for newborn health programmes. The ultimate solution and priority should be to facilitate delivery of newborns in health facilities. In the meantime, WHO recommends providing the first postnatal contact to a home birth as early as possible within 24 hours after birth; this representing an important synergy between efforts to provide newborn care and prevent perinatal HBV transmission.[12] As part of the situation analysis (see Chapter 7), opportunities for linking HepB-BD with early postnatal services provided for mothers and newborns, should be identified and leveraged.

There are two options for vaccinating a newborn delivered at home: either the newborn must be brought to a health facility to receive HepB-BD, or the vaccine must be taken to the newborn through a home or community visit.

A Bringing the newborn to a health facility

General strategies that can be used to encourage bringing newborns born at home for HepB-BD vaccination include the following.

EDUCATING FAMILIES

Educating mothers and other caregivers, during the antenatal period, about the importance and timing of HepB-BD may motivate them to ensure their baby receives timely HepB-BD. Antenatal visits are a key opportunity for education; for example, 74% of pregnant women in the WHO African Region had at least one antenatal care contact.[16] Community health workers and other antenatal care providers should be trained to include HepB-BD in counselling.

16 http://apps.who.int/gho/data/view.main.1610?lang=en

SUPPORTING COMMUNITIES

Community-based staff also play a role in reminding families to seek HepB-BD within 24 hours, or as soon after delivery as possible. Programmes that fund or supplement transportation to bring women and babies to a health facility can facilitate access.

B Reaching the newborn at home

Outreach may refer to a scheduled immunization session in a community or to a home visit for delivery or postnatal care. The likelihood of administering a timely birth dose is greater when vaccination is integrated with delivery or postnatal care contacts. It is important to clarify that administration of vaccine within 24 hours after birth is preferable, but if not possible, vaccination after 24 hours should still take place. General strategies for reaching newborns through outreach include the following.

SEEKING SYNERGIES WITH INTERVENTIONS BEING DELIVERED AT BIRTH OR DURING THE POSTNATAL PERIOD

WHO and the United Nations Children's Fund (UNICEF) recommend home visits for postnatal care of mother and newborn, with demonstrated improvement in newborn survival.[17] This referenced guideline, together with other evidence, suggests that the first postnatal assessment should be conducted within 24 hours of birth. As part of the situation analysis (see Chapter 7), opportunities for linking HepB-BD with early postnatal services provided for the mother and newborn should be identified and leveraged.

TRAINING AND SUPERVISION OF SKILLED BIRTH ATTENDANTS (SBAS) OR OTHER CADRES WHO ARE ABLE TO ADMINISTER VACCINES

With proper training and access to vaccine, SBAs can administer HepB vaccine if they attend a birth in a home or other community setting. The immunization and MNCH programmes should collaborate to ensure HepB-BD is part of the standard duties of SBAs and ensure that they are trained, supervised and equipped for vaccination. This is especially important in settings where community visits by SBAs, at the time of birth, are part of national or subnational policy. Key considerations for preparing SBAs for vaccination are provided in **Box 4**.

17 WHO/UNICEF. Home visits for the newborn child: a strategy to improve survival. Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/hq/2009/WHO_FCH_CAH_09.02_eng.pdf).

▲ Reaching home births within 24 hours after birth can be challenging; it is better to vaccinate late than to wait until the 1st dose of the infant series (usually scheduled at 6 weeks).

ASSESSING AND INCREASING CAPACITY FOR AUXILIARY HEALTH WORKERS OR COMMUNITY HEALTH WORKERS TO ADMINISTER VACCINES

In settings where there is a policy in place to allow them to give injections, these cadres may be trained to administer HepB-BD. This practice will vary considerably depending on the regulations and policies in each particular country, but studies undertaken in countries, including China, Indonesia and Papua New Guinea, have shown that it is feasible to administer HepB-BD to infants born at home through this strategy.[18,19,20] Some countries may have an intermediate cadre of community health workers known as "health extension workers" (HEWs) or "community health extension workers" (CHEWs), or schemes in place where community health workers receive a more extensive or enhanced set of training and skill development. In some settings, these workers are able to administer injections such as oxytocin or Depo-Provera®,[21] and it may be possible to train them to also administer HepB vaccine to births that take place within their communities.

18 Wang L et al. Hepatitis B vaccination of newborn infants in rural China: evaluation of a village-based, out-of-cold-chain delivery strategy. Bull World Health Organ. 2007;85(9):688–94.

19 Creati M, Saleh A, Ruff TA, Stewart T, Otto B, Sutanto A et al. Implementing the birth dose of hepatitis B vaccine in rural Indonesia. Vaccine. 2007;25:5985–93.

20 Morgan C et al. Improving immunization and newborn survival at the aid post level in Papua New Guinea. In: Internal Evaluation Report, Melbourne, Macfarlane Burnet Institute, 2010.

21 Expanding community-based access to injectables, 2011. (https://www.k4health.org/sites/default/files/Summary_of_Country_Programs_20June2011_Final-1.pdf).

In many countries, traditional birth attendants (TBAs) represent a resource that can be developed with appropriate support, education and training, but it cannot replace the need for all women to have care from a skilled attendant. However, if properly linked to the health-care system, TBAs have a role in increasing access to skilled care and birth dose vaccination.[22]

INCREASING ACCESS TO VACCINATION WITH OPTIMAL VACCINE PRESENTATION

Single-dose vials or compact pre-filled auto-disable devices (CPADs) (**Country Example 4**) may be preferable, especially if a large proportion of births occur in the home. CPADs are desirable as ready-to-use pre-filled vaccine delivery devices that are easier to use, require less training and can be clearly distinguished from other types of injectable medicines. This may be beneficial for reaching home births; for example, if lay health workers providing post-natal care are authorized and trained to use CPADs. CPADs cannot be reused and are equipped with a vaccine-vial monitor (VVM) ensuring that excessive heat exposure can be monitored.

Opened multi-dose vials of HepB vaccine may be returned to the cold chain the next day for subsequent use if all conditions of the WHO multi-dose vial policy (MDVP)[23] are met (see **Box 6** in Chapter 5 for details).

▼ CPADs are small, light, and easy to use, and can help increase HepB-BD coverage for home-births.

22 For more on incorporating TBAs into strategies for increasing access to skilled birth attendants, see Making pregnancy safer: the critical role of the skilled attendant: A joint statement by WHO, ICM and FIGO. Geneva, World Health Organization, 2004 (http://whqlibdoc.who.int/publications/2004/9241591692.pdf).

23 WHO policy statement: multi-dose vial policy (MDVP), revised 2014 (WHO/IVB/14.07) (http://apps.who.int/iris/bitstream/10665/135972/1/WHO_IVB_14.07_eng.pdf).

INDONESIA

COUNTRY EXAMPLE 4:
BD COVERAGE IMPROVED BY USING CPADS

In the 1990s, a series of projects to identify optimal strategies for achieving high HepB-BD coverage was undertaken in Indonesia, where >90% of births occur in the home. A programme was created training village midwives in the use of CPADs. They were allowed to store these CPADs out of the cold chain (see Chapter 5) in their homes. Thus, HepB-BD was available immediately when a midwife was called to a delivery, and was available even when midwives did not have access to a conventional cold chain. Both village midwives and mothers preferred the use of CPADs. The successful use of CPADs was expanded nationwide, and even though facility delivery rates are still low, coverage with HepB BD is now 84%.

Creati M et al. Implementing the birth dose of hepatitis B vaccine in rural Indonesia. Vaccine. 2007;25(32):5985–93.

VIETNAM

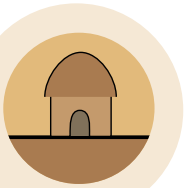
COUNTRY EXAMPLE 5:
PREGNANCY TRACKING TO IMPROVE HEPB-BD COVERAGE

Vietnam has established a strategy for tracking pregnant women in order to increase timely HepB-BD coverage. In two districts where 20%–36% of newborns were born at home, community health workers tracked pregnancies by recording names, addresses and expected delivery dates of pregnant women. Village health workers informed community health workers of births to further ensure that HepB-BD was administered; this system helped the districts to achieve 90%–97% coverage with HepB-BD.

Murakami H et al. Implementation of and costs associated with providing a birth dose of hepatitis B vaccine in Viet Nam. Vaccine. 2008;26(11):1411–19.

ESTABLISHING OR STRENGTHENING BIRTH NOTIFICATION SYSTEMS

One of the obstacles to timely vaccination after a home birth is that health-care staff might not be informed that these births have occurred. Careful tracking of all pregnancies is vital to ensuring newborns delivered at home receive timely access to all essential newborn services, including HepB-BD. Community health workers can be instrumental in assisting with tracking pregnancies in their community and notifying the skilled/facility health worker, through Short Message Service (SMS) or other mobile phone services, should a birth occur at home. **Country Example 5** highlights Vietnam's successful implementation of a pregnancy tracking system and the resultant improvement in HepB-BD coverage. Programmes promoting timely birth notification will not only increase HepB-BD, but can also help to strengthen other aspects of routine immunization, and maternal and newborn care.



BOX 4.

KEY CONSIDERATIONS WHEN PREPARING SBAS TO ADMINISTER HEPB-BD DURING A HOME BIRTH

Training:

- Training should include vaccine handling, administration, recording and reporting to the coordinating EPI clinic/office.
- It should be stressed that oxytocin and HepB-BD should be separated in storage and transport, and very clearly labelled to avoid confusing products and erroneous administration.

Supervision:

- Existing supervision of SBA's work should include checks to ensure that proper vaccination practices are being followed.

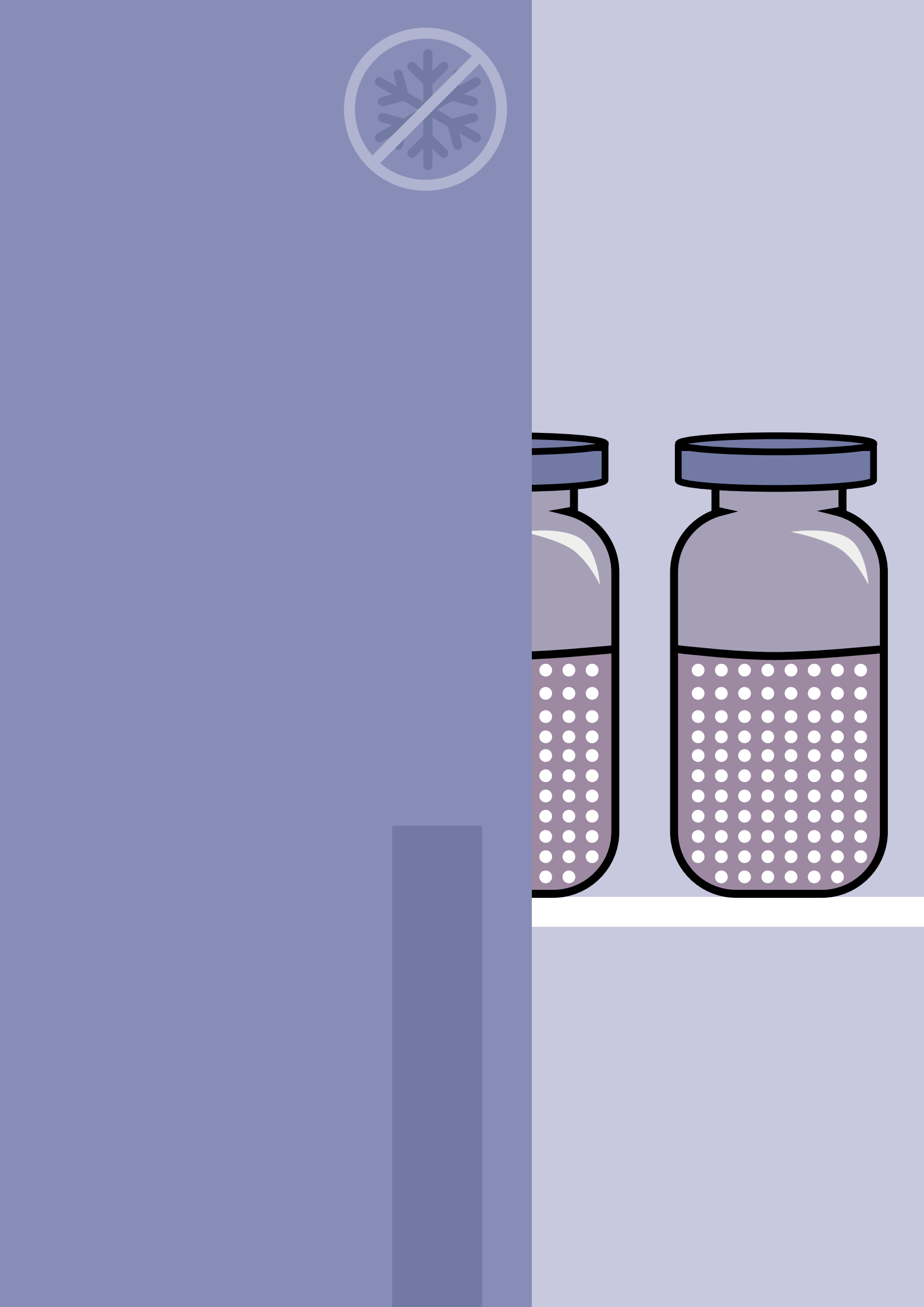
Access to vaccine:

- The following supplies should become a standard part of the SBA kit and brought to all deliveries: HepB-BD vaccine; an auto-disable syringe; a safety box, and a home-based record (vaccination card).
- SBAs should have access to the vaccine 24 hours a day and 7 days a week.
- The immunization programme should supply HepB-BD to SBAs at no cost and SBAs should not charge families for the vaccine or its administration.

Optimal vaccine presentation:

- Single-dose vials or CPADs may be preferable.

YOUR NOTES



CHAPTER 5

Vaccine products and logistics

Vaccine supply chain and logistics is the backbone of immunization services. There are many WHO resources available online, including the *Effective Vaccine Management Initiative*,[24] *Immunization in Practice* modules,[5] and supply chain and logistics management tools.[25] The six key areas of vaccine supply chain and logistics to consider are **product, quantity, place, time, quality and cost**.

A Products

There are several HepB vaccine product options. WHO prequalified vaccine options can be found online.[26] As emphasized in Chapter 2, only monovalent vaccine should be used for the HepB-BD, but either monovalent or combination vaccines can be used for subsequent doses.

WHO prequalified monovalent HepB vaccine is available in various vial sizes (single-dose, 2-dose, 6-dose, 10-dose and 20-dose vials). Single-dose presentations are available in ampoules or in a CPAD, i.e. Uniject™. Monovalent HepB vaccine, and some combination vaccines with HepB, come in liquid form and do not require reconstitution.

Some factors to be considered when choosing a presentation of HepB vaccine for HepB-BD introduction are provided in **Box 5**. Deciding on the number of doses per vial is very different for HepB-BD, compared with other vaccines. This is because the need to reach newborns within 24 hours after birth means that HepB-BD cannot be batched into routine immunization sessions. The average number of births in a health facility or catchment area will influence decisions on vial size. Some countries may consider a combination of single-dose and multi-dose vials to facilitate service delivery in various

24 Effective Vaccine Management (EVM) Initiative, (http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/).
25 Supply chain and logistics management resources can be found online here: http://www.who.int/rhem/supplychain/en/ and here: http://www.who.int/immunization/programmes_systems/supply_chain/en/.
26 WHO prequalified vaccines (http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/).

settings. Multi-dose vials are generally used for vaccinating newborns delivered in larger health facilities with more frequent births. Single-dose vials may be appropriate in health facilities handling fewer births and for vaccinating infants delivered at home. In these situations, single-dose vials reduce wastage and avoid health-care providers' reluctance to open multi-dose vials for only a few newborns.

If multi-dose vials are in use, health workers should be trained on the application of the WHO multi-dose vial policy for HepB vaccine (**Box 6**).

BOX 5.
FACTORS AFFECTING CHOICE OF VACCINE PRESENTATION

- → **Cost** per dose
- → Average **number of births** in catchment areas
- → **Skills of delivery staff**
  (i.e. would single dose vials or CPAD be easier to implement?)
- → **Cold-chain** capacity requirements (see **Table 3**)
- → **Waste-disposal** requirements
- → Policies and practices on **number of children present** before opening a vial

The cold-chain capacity required will vary depending on the vial sizes chosen (see **Table 3**).

B Cost

Cost per dose of vaccine, after accounting for likely wastage, is an important factor in choosing a vaccine product. Based on UNICEF's published costs from selected manufacturers in 2015, the cost of monovalent HepB vaccine ranged from US$0.16 per dose in a 10-dose vial to US$0.38 per dose in a single dose vial.[27] The limited information available on vaccine price for countries that procure vaccines independently (i.e. not through UNICEF Supply Division or the PAHO Revolving Fund) suggests that published price data vary considerably; from US$0.80 to US$7.50 per dose for single dose-vials in 2014.[28] The cost of HepB in the Uniject™ CPAD is approximately US$1.50 per dose.

27 UNICEF price data, HepB vaccine (http://www.unicef.org/supply/files/HepB.pdf).

TABLE 3.
COLD CHAIN CAPACITY REQUIREMENTS FOR VARIOUS HEPATITIS B VACCINE PRESENTATIONS

MONOVALENT HEPB PRESENTATION	APPROXIMATE* PACKED VOLUME PER DOSE
Standard vial (single dose)	14.4 cm3/dose
Uniject™ (single dose only)	12 cm3/dose
2-dose vials	7.6 cm3/dose
6-dose vials	4.2 cm3/dose
10-dose vials	2.8 cm3/dose
20-dose vials	2.6 cm3/dose

* Packed volume/dose varies by manufacturer. Figures here are based on median values for each presentation.

BOX 6.
MULTI-DOSE VIAL POLICY (MDVP)[22] FOR HEPB VACCINE

In health facilities, opened multi-dose vials of HepB vaccine may be kept and used for up to four weeks (28 days) if all the following conditions are met:

- → the expiry date has not passed;
- → the vaccine vial monitor (VVM) has not reached the discard point;
- → the vial has been kept at recommended temperatures (between 2 °C– 8 °C);
- → the part of the vaccine vial where the needle is inserted to withdraw doses has not been submerged under water (to prevent this from happening, well-sealed ice packs should be used in vaccine carriers, and water should not be allowed to accumulate where the vials are stored);
- → an aseptic technique has been used to withdraw all doses.

In outreach sessions, opened multi-dose vials of HepB vaccine may be kept and used for up to four weeks (28 days) if:

- → all the conditions for reuse of multi-dose vials in fixed health facilities are met;
- → a VVM is attached to the vial.

In some cases, a country may choose a more expensive presentation of HepB vaccine (e.g. single-dose vials versus multi-dose vials or use of CPADs) because it facilitates achieving greater HepB-BD coverage. This extra investment may result in overall immunization programme-savings due to reduced vaccine wastage and overall health-system savings by reducing the prevalence of chronic hepatitis B infection.

C Forecasting and supply

Like other vaccines in any national immunization programme, forecasting, procuring and distributing adequate vaccine supplies requires accurate estimates of the target population and strong stock management mechanisms. Forecasting quantity should be based on the size of the target population, the estimated vaccine coverage and the wastage factor. The target population for HepB-BD is the number of live births. Supply chain and distribution systems may require upgrading or expansion to ensure that vaccine and supplies reach delivery wards and/or postnatal care sites. There may also be opportunities for an integrated supply chain with other MNCH medicines.

▼ Example of storing vaccine in a cold box so that it is conveniently located near delivery and recovery wards.

Estimated wastage should be based on actual wastage of an existing vaccine with the greatest similarity in presentation and formulation. WHO has developed a vaccine forecasting tool to assist national immunization programmes in conducting multi-year forecasts of vaccine and injection supply needs. This Excel® tool also helps calculate vaccine and supply costs, as well as storage-capacity needs and costs.[29]

In an effort to reduce wastage, some countries may opt to use a combination of both single- and multi-use vials to accommodate settings with less frequent births. However, this will add to the complexity of forecasting, procuring and supplying vaccine.

Monovalent HepB vaccine is of value to older age groups but is vulnerable to theft, or administration to individuals outside the target age range; hence, special precautions may be needed to ensure stocks of vaccine are secure.

D Handling and storage

Procuring WHO pre-qualified vaccine, ensuring potency through proper temperature control and preventing contamination through adherence to multi-dose vial policy (MDVP) are all part of ensuring vaccine quality. WHO prequalified products are attached with VVMs.

The WHO recommended storage temperature for HepB vaccine is the same as for diphtheria-tetanus-pertussis (DTP) vaccine i.e. between +2 °C and +8 °C. If stored in this temperature range, the vaccine is generally stable for at least four years from the date of manufacture.

HepB vaccine has unique considerations in terms of temperature control, since HepB vaccine is one of the most freeze-sensitive and heat-stable vaccines available (**Figure 3**).

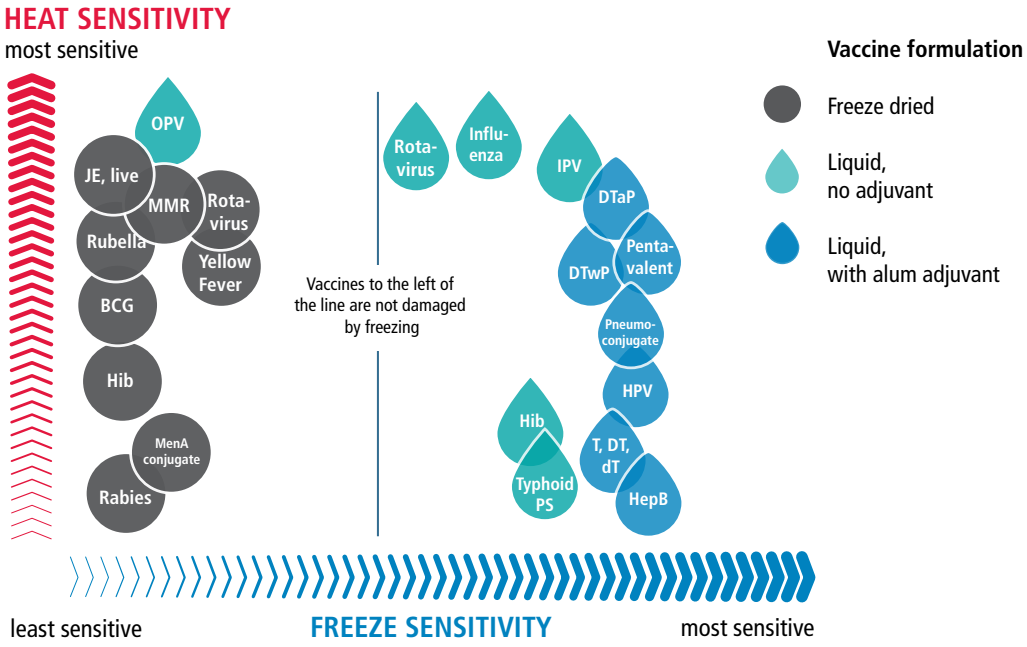
FREEZING

HepB vaccine **MUST NEVER BE FROZEN** or it will lose its potency and administration may result in discomfort, pain or ulcer formation at the injection site. Many temperature-monitoring studies have indicated that vaccines are more at risk of freezing damage during transportation than while in storage at a health facility. Temperature of the vaccine must be consistently monitored for potential freezing during transport, including when received at national level and at all levels of storage. Temperature loggers and freeze

28 WHO vaccine product, price and procurement (V3P) web platform (http://who.int/immunization/programmes_systems/procurement/v3p/platform/database/en/).

29 WHO vaccine forecasting tool, as well as additional information on vaccine forecasting can be found online (www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/index2.html).

FIGURE 3.
RELATIVE TEMPERATURE SENSITIVITY OF VACCINES



indicators are recommended for transport of all freeze-sensitive vaccines. When using cold boxes or vaccine carriers, it is recommended to use cool water packs or conditioned ice packs (kept at room temperature until they begin to melt before packing the carrier), and/or to ensure vaccines do not come into direct contact with ice packs. More detail can be found in the WHO Vaccine Management Handbook.[30]

If freezing is suspected, the **SHAKE TEST** should be conducted to determine whether the vaccine has been damaged by freezing; **ANNEX 1** provides the protocol for a shake test.[31] If the vaccine fails the shake test, it must be discarded.

Additional information on preventing freeze damage to vaccines, including best practices, is outlined in a WHO aide-memoire on the topic.[32]

30 How to monitor temperatures in the vaccine supply chain. WHO vaccine management handbook. Geneva, World Health Organization (WHO Module VMH-E2.01.1) (http://www.who.int/immunization/documents/financing/who_ivb_15.04/en/)
31 Shake test protocol. Temperature sensitivity of vaccines. Geneva, World Health Organization, 2006 (WHO/IVB/06.10) (http://apps.who.int/iris/bitstream/10665/69387/1/WHO_IVB_06.10_eng.pdf). See also ANNEX 1.
32 Aide-memoire for prevention of freeze damage to vaccines. Geneva, World Health Organization, 2009 (WHO/IVB/07.09) (http://www.who.int/immunization/documents/WHO_IVB_07.09/en/).
33 Hepatitis B. Immunization in practice, Module 1: Target diseases and vaccines. Geneva, World Health Organization (http://www.who.int/immunization/documents/training/en/)

REMEMBER:
HepB vaccine must never be frozen
If freezing is suspected, the SHAKE TEST should be conducted to determine whether the vaccine has been damaged by freezing.

HEAT STABILITY

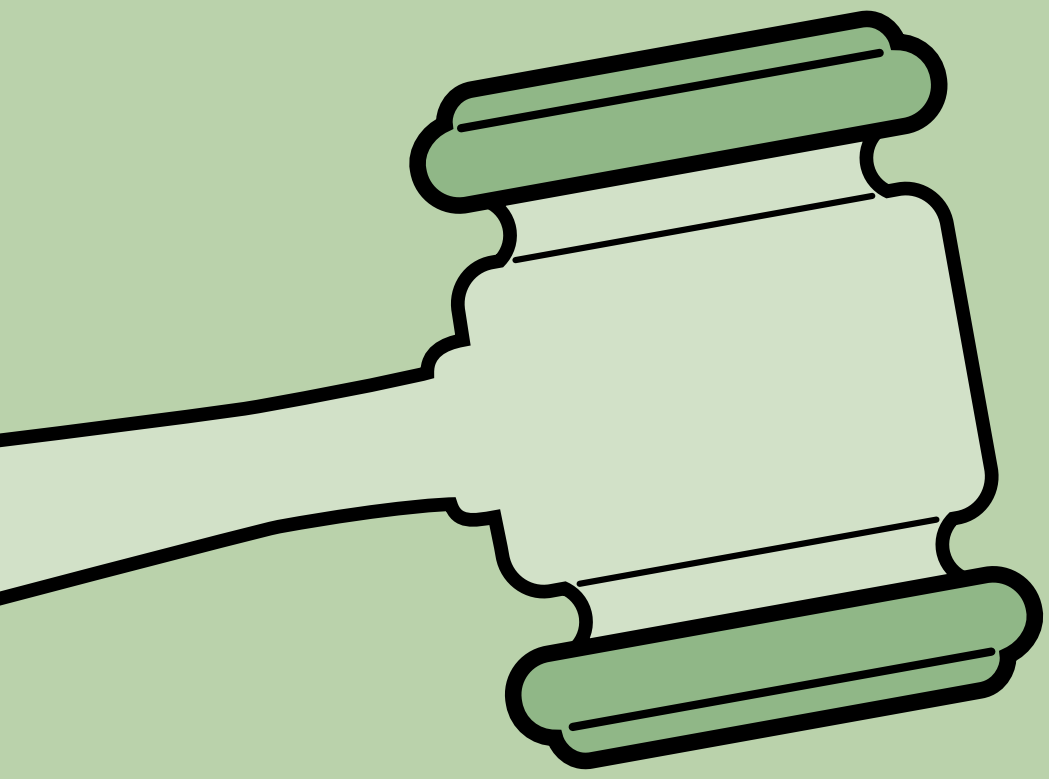
Most HepB vaccines are heat stable and have been found to maintain immunogenicity after exposure to temperatures of up to +45 °C for one week and temperatures up to +37 °C for one month.[3] For this reason, several field trials have been conducted to study programmatic advantages (e.g. increase vaccination coverage, decrease freezing vaccine, decrease cold-chain capacity requirements) of keeping HepB vaccine in ambient temperatures at service-delivery points. These studies have been reviewed and found to lead to increases in birth dose vaccination coverage, especially as a strategy for reaching home births.[7]

These studies referred to maintaining vaccine at ambient temperatures as 'out of the cold chain'. This should be distinguished from a **controlled temperature chain (CTC)** which has been formally defined as a specific set of conditions allowing for a vaccine to be stored and transported outside of the traditional +2 °C to +8 °C cold chain, including a single excursion into ambient temperatures not exceeding +40 °C and for a duration of a specific number of days just before administration.[30] The vaccine must be licensed and pre-qualified by the appropriate regulatory authorities for use in a CTC and with a label that specifies the conditions; see **ANNEX 2** for more detailed description of CTC.

Currently, no hepatitis B vaccines have been pre-qualified for CTC use. The 2009 WHO recommendation of distributing and storing vaccine in a +2 °C to +8 °C cold chain should be maintained until a vaccine product is licensed and labelled for CTC.[3] WHO recognizes the programmatic advantages of CTC for increasing access to birth dose vaccination and is encouraging development and labelling of products for CTC. Several HepB vaccine manufacturers may have products that meet the CTC criteria and could offer a product that is licensed and labelled for CTC use in the near future.

SEPARATION

After a period with no disturbance, a separation of vaccine components may be observed in the vial, i.e. a fine precipitate appears at the bottom of the vial.[33] In such cases the vaccine is safe to use; the vial should be shaken to mix the contents before using the vaccine.



CHAPTER 6

Policy and guidance

Policies mandating or guiding HepB-BD vaccination reflect a national commitment and help ensure that standards are being applied consistently. This chapter presents considerations for HepB-BD policy and guidance.

A Deciding to introduce birth dose

As with any new vaccine introduction, it is important to have a systematic and transparent process for making a decision about introducing HepB-BD into a national immunization programme. Ideally, the national immunization technical advisory group (NITAG),[34] or an equivalent independent body, should be requested to undertake a rigorous review of the evidence and make an independent recommendation to the national government. This review may consider seroprevalence of hepatitis B infection (HBsAg positive) and overall capacity and performance of the routine immunization system.

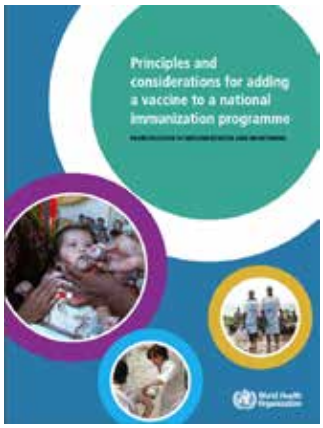
A briefing note presenting issues, goals, strategies and recommended actions may help concisely advocate for political support for HepB-BD introduction, as well as for establishing a universal birth dose policy (see below). An example of such a briefing is provided in **ANNEX 3**. More information on how to engage decision-makers and opinion leaders can be found in Chapter 10.

As with other decisions regarding a national immunization schedule, the national government takes the decision regarding introduction of HepB-BD. Subsequently, the interagency coordinating committee (ICC),[35] or equivalent group, will serve to coordinate partner activities and funding, as well as the roll-out and evaluation of the vaccine introduction.

34 NITAGs should consist of national experts in a broad range of disciplines – such as senior paediatricians, immunization and vaccine experts, epidemiologists, public-health experts, health economists, health systems experts and social scientists – who are capable of analysing the different types of scientific evidence, and issues, that should be considered in making an informed decision.

35 A committee made up of representatives of the Ministry of Health (MOH), WHO, UNICEF, and other domestic and external partners to improve coordination among partners for the support of the national immunization programme.

For more information on the stakeholders, sequence of tasks and issues to be considered in the decision-making process for vaccine introduction, please see *Principles and considerations for adding a vaccine to a national immunization programme*.[6]



▶ WHO document: Principles and considerations for adding a vaccine to a national immunization programme[6]

B National birth dose policies

Once the decision to introduce HepB-BD is taken, it is recommended that a clear national policy is established mandating universal HepB-BD vaccination **within 24 hours** after birth, followed by at least two additional routine doses.[7] In some countries, such policies should also exist at subnational levels.

In order to generate commitment to establish a national HepB-BD immunization policy, it is important to involve decision-makers and opinion leaders early on in the process. When drafting a national birth dose policy, potential decision-makers and opinion leaders to include are:

- health-ministry officials;
- other government officials (e.g. finance-ministry officials);
- professional societies, medical associations and leaders in the private-health sector;
- donor agencies and non-governmental organizations;
- community and religious leaders.

Note that this will include officials, professionals and partner agencies with interests in cancer prevention, chronic disease prevention, safe motherhood and essential newborn care, as well as those with interests in immunization.

Key aspects of a national policy could include important messages on the benefits of timely HepB-BD for interruption of perinatal transmission and reduction in chronic disease. Policy elements that are important for effective implementation should define timely HepB-BD as within 24 hours of birth and mandate separate reporting of administration and timing of HepB-BD. Broader policy positions adopted by many countries, that benefit coverage, may also include making vaccination services universal and providing vaccinations for free.[36]

▲ In the Philippines, HepB-BD is part of an essential newborn care package that is covered under their national health insurance.

C Local policies and procedures

Country experiences shed light on a number of ways in which local policy and procedures can support HepB-BD introduction or lead to an increase in vaccination coverage. Some examples are provided below.

NATIONAL OR LOCAL POLICIES TO INCREASE ACCESS TO SKILLED CARE AT THE TIME OF BIRTH

Countries that have succeeded in increasing the proportion of births that take place in health facilities, have simultaneously experienced an increase in HepB-BD vaccination coverage (**Country Example 6**). Such policies or initiatives include: decreasing costs of childbirth in a health facility; improving service quality in facilities providing care during pregnancy and childbirth, and providing incentives to families or health workers to encourage referral to health facilities.

36 Cui et al. Preventing hepatitis B though universal vaccination: reduction of inequalities through the GAVI China project. Vaccine. 2013;31(S9): J29–J35.

POLICIES TASKING DELIVERY ROOM OR POSTNATAL CARE STAFF WITH VACCINATION RESPONSIBILITIES

Policies that expand the categories of staff permitted to provide vaccination services may be needed, specifically with regard to obstetric, maternal or newborn care staff. For example, in some countries, hospital staff are considered part of a curative health sector and do not administer vaccine; instead they refer mothers and their newborns to an immunization clinic. This practice has been often found to delay vaccination beyond 24 hours, even in the best of circumstances, such as where the immunization clinic is nearby and operates daily. In settings such as this, it is helpful to have an overarching policy or guideline expanding HepB-BD vaccination responsibilities to curative health professionals.

HEALTH-FACILITY POLICIES

Delegation of authority through facility-based standing orders, or establishing vaccination protocols, has been shown to increase HepB-BD coverage in health facilities. For example, standing orders may specify that staff are authorized to vaccinate or may outline specific steps for HepB-BD vaccination, reinforcing vaccination as a standard part of routine childbirth or postnatal care.

EXPANDING MATERNAL AND NEWBORN POLICES AND BENEFITS

If a maternal and newborn package is available as part of national health benefits or insurance, inclusion of HepB-BD can help ensure that newborns are vaccinated. In the Philippines, HepB-BD is part of an essential newborn care package that is covered under their national health insurance. Administration of HepB-BD for each newborn is required in order for the hospital to be reimbursed for delivering the baby.

D Developing or adapting standards and guidance

HepB-BD implementation will require developing or adapting existing national standards and guidance. This will usually require a survey of the range of documents used by obstetric, maternal and newborn care staff, to identify where there is a need to revise guidance on care at childbirth or in the early newborn period. Examples may include:

- → service delivery manuals, standard treatment guidelines, textbooks, handbooks, newborn care protocols for MNCH and immunization staff;
- → job aids or posters displayed in delivery rooms or postnatal wards;
- → supervisory checklists (refer to Chapter 8);
- → training materials and job aids (refer to Chapter 8).

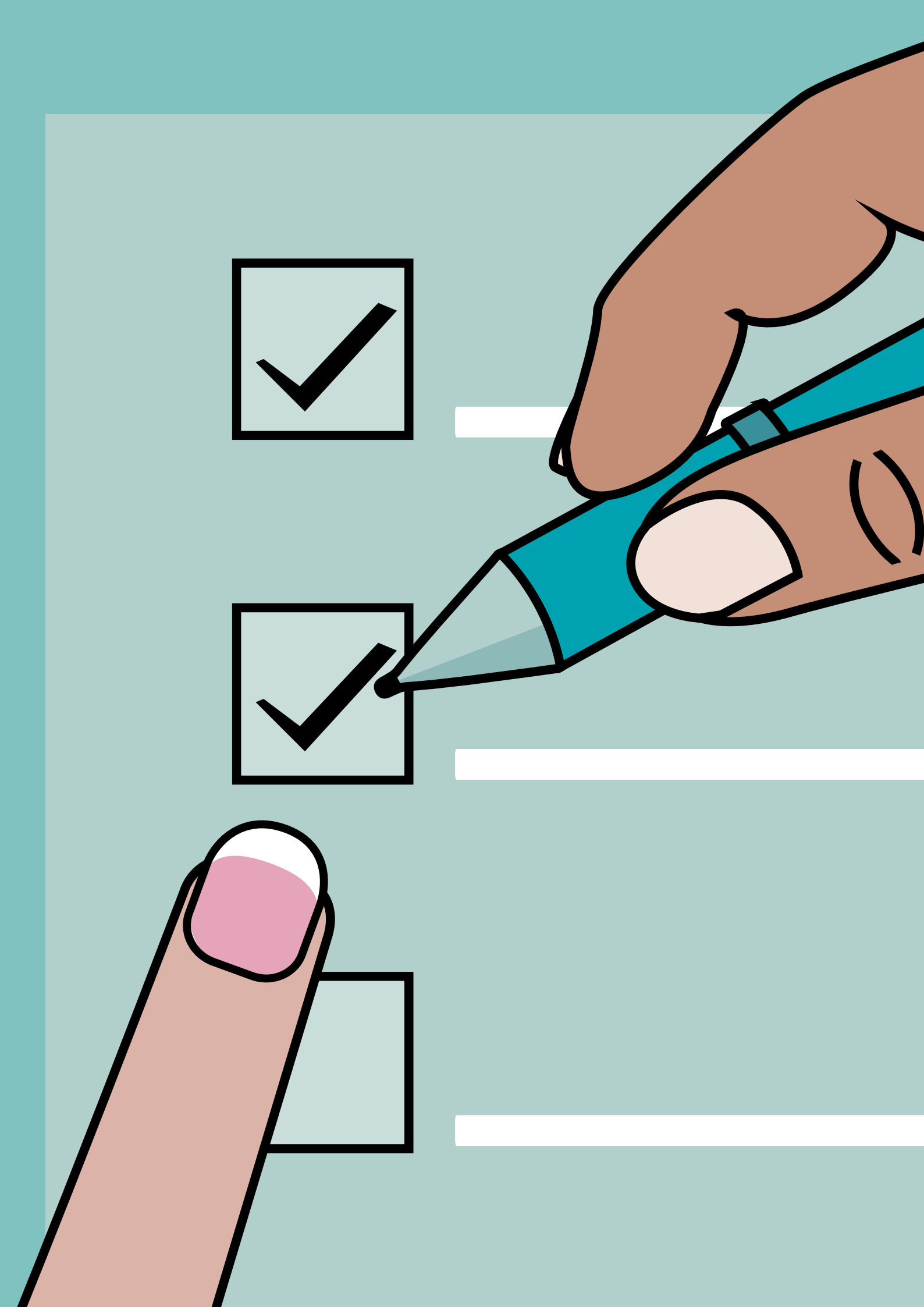
CHINA

COUNTRY EXAMPLE 6:
INCREASING HEALTH FACILITY-BASED DELIVERIES

In 2002, China's hospital delivery rate was 78% and timely birth dose coverage was 60%. In order to decrease maternal and neonatal mortality, eliminate maternal and neonatal tetanus and improve timely delivery of HepB-BD, incentives were instituted to increase hospital delivery rates, such as providing pregnant women with subsidies to deliver in hospitals. By 2009, the hospital delivery rate was 96% and timely birth dose coverage was 91%.

Cui F et al. Evaluation of policies and practices to prevent mother to child transmission of hepatitis B virus in China: results from China GAVI project final evaluation. Vaccine. 2013:31(S9):J36–J42.

YOUR NOTES



CHAPTER 7

Planning

As most countries already include three doses of HepB vaccine in their national immunization schedules, it is true that the addition of a birth dose does not technically constitute a new vaccine introduction per se, but rather the launch of a new strategy to deliver an existing vaccine. However, the unique time and place of administration and involvement of a new cadre to administer vaccine soon after birth, merits following the same planning considerations as any new vaccine introduction. In general, the planning process for introducing new vaccines into a national immunization programme consists of information gathering, gaining consensus on strategies, translating strategies into a detailed action plan and, finally, integrating plans with comprehensive multi-year plans (cMYP) for immunization (**Box 7**).

A Situation analysis

Given the many unique aspects of HepB-BD immunization, a situation analysis for HepB-BD introduction will be essential for developing strategies and planning. For example, if almost all deliveries occur in health facilities, then developing effective strategies for facility-based implementation should be prioritized. The checklist in **ANNEX 4** outlines elements of a situation analysis. Global evidence on best practices for achieving high HepB-BD coverage should also be considered (**ANNEX 5**).[7] Methods for the analysis should include reviewing immunization and MNCH policies, practices and data, as well as interviewing stakeholders.

B Coordination between EPI and MNCH

Planning for HepB-BD introduction will be similar to other new vaccine introductions, with the addition that, in this case, it is even more important to conduct planning jointly between EPI and MNCH. This is essential for obstetric staff to be prepared and responsible

for administering HepB-BD. Joint planning and implementation will likely involve topics such as policy amendments, training, supervision, and vaccine supply.

Other areas to coordinate include building on existing MNCH initiatives such as pregnancy tracking and strategies for reaching infants born outside of health facilities, for skilled delivery and postnatal care. Opportunities may also exist to integrate the supply chain with that of other essential MNCH medicines, like oxytocics, for distribution to delivery facilities and postnatal care settings. In addition, knowledge of national and subnational management structures for MNCH and immunization services may guide how best to designate vaccination and monitoring responsibilities.

C Detailed vaccine introduction plan

A detailed HepB-BD introduction plan will be critical for ensuring that the actions required are followed through to each level. This plan should include activities, timelines, budgets and persons or agencies responsible. Suggested components of a detailed action plan are summarized in **Box 8**. In addition, a WHO vaccine introduction plan template, as well as a checklist, activity list and timeline tool for general vaccine introduction, has been made available on the internet.[6]

It is critical that enough time be allowed to plan and implement the many activities involved so that introduction of HepB-BD is not rushed. For example, developing materials and training staff throughout the country can take months and will need planning with adequate lead time. Similarly, if the cold-chain system requires expansion or repair, the time to procure and install new equipment needs to be planned well in advance.

▼ Dr Shin Young-soo, the World Health Organization's Regional Director for the Western Pacific, addressing audience during an advocacy event on World Hepatitis Day 2012, Philippines.

BOX 7.

KEY ACTIVITIES OR OUTCOMES TO CONSIDER FOR HEPB-BD VACCINATION

- ☐ **Situation analysis** (**ANNEX 4**)
- ☐ **National policies** support timely HepB-BD vaccination and, where appropriate, link to regional targets for HepB control
- ☐ **Health-facility policies** and procedures require and authorize appropriate staff to give HepB-BD
- ☐ **Private sector** provides HepB-BD and has access to vaccine supply
- ☐ HepB-BD vaccination **integrated with newborn care** for both facility births and home births
- ☐ Innovative **outreach strategies** where home births are common
- ☐ Monovalent HepB vaccine **integrated fully into vaccine supply chain**
- ☐ Health facility, cold chain and **strategic placement** of vaccine in delivery room or postnatal care ward
- ☐ **Train** all appropriate staff working in immunizations and maternal and newborn health
- ☐ **Supervise and monitor** at national, subnational and facility level in all settings where births take place (public-health facility, private facility, community)
- ☐ **Immunization coverage reporting** distinguishing HepB-BD given within 24 hours after birth
- ☐ **Community education and advocacy** includes messages on the long-term prevention benefits of HepB-BD

BOX 8.
COMPONENTS OF A DETAILED VACCINE INTRODUCTION PLAN

- → **Background** and country context
- → **Goals, objectives, expected impacts and challenges**
- → **Strategies and policies** (choice of vaccine product, service-delivery strategies, opportunities for integrating activities with other health interventions, phased or nationwide introduction)
- → **Resources, costs, financing and sustainability**
- → **Implementation activities and timelines**
  - Coordination, monitoring, evaluation of implementation
  - Planning for vaccine procurement and distribution
  - Cold chain, logistics, vaccine management, waste management and injection safety
  - Updating recording and reporting forms and systems
  - Training
  - Social mobilization, communication and advocacy

Given the many diverse programme components and technical areas involved, some countries may choose to establish technical sub-committees for such areas as: advocacy and communications; cold chain, logistics and vaccine management; training and supervision; AEFI surveillance, etc.

PHASED VERSUS SIMULTANEOUS INTRODUCTION

A national roll-out has advantages; broader coverage will lead to a faster impact, as well as allow for nationwide promotion of the birth dose vaccine. However, in some circumstances, countries may consider a phased approach to introduction. For example:

- → a pilot implementation is needed to identify and address programmatic and logistical challenges, such as the ability of health-care workers to adjust to a new vaccine delivery strategy;
- → the capacity to train and supervise staff is limited and national staff can only support a certain number of provinces/districts at a time;
- → introduction in certain parts of the country will present programmatic and logistical challenges that need to be addressed (e.g. limited cold-chain capacity in certain areas).

D Costing

Activities within the plan should be costed to determine the amount of funds that will be required for HepB-BD introduction. A WHO tool is available to help estimate costs: *Immunization costing and financing: A tool and user guide for comprehensive multi-year plan (cMYP).*[37] **Box 9** summarizes the costs to consider. Once a detailed action plan has been drafted, activities and costs should be incorporated in the country's cMYP for immunization.

BOX 9.
POTENTIAL COSTS ASSOCIATED WITH HEPB-BD INTRODUCTION

- Vaccine, injection equipment
- Additional cold chain and dry storage needs
- Expansion of vaccine distribution sites (i.e. delivery facilities)
- Distribution costs
- New delivery strategies (delivery rooms, postnatal wards, outreach for home births)
- Personnel and training
- Expansion of waste management
- Development of communication strategy and roll-out of information, education and communication (IEC) media and materials
- Revision, printing home-based records, registries, forms
- AEFI monitoring and response

E Strengthening routine immunization and MNCH services

Introducing a new vaccination strategy offers opportunities to focus on specific elements of routine immunization services that need to be improved. In addition, because of the

37 WHO cMYP Guidelines, and cMYP costing and financing tool and user guide, online: http://www.who.int/immunization/programmes_systems/financing/tools/cmyp/en/.

close coordination required, introduction of HepB-BD, in particular, also offers opportunities for strengthening aspects of MNCH programmes. This most effectively happens when identifying opportunities in advance and incorporating activities in planning and costing processes. A few examples of system-strengthening opportunities unique to HepB-BD introduction are listed below.

LEVERAGING TRAINING FOR HEPB-BD TO BENEFIT ROUTINE IMMUNIZATION AND IMPROVED QUALITY OF ESSENTIAL NEWBORN CARE

Most new strategy introductions offer the opportunity to add refresher concepts to the vaccine introduction trainings or to improve on guidance and forms – see more in Chapter 8.

HEPB-BD AS AN ADDED IMPETUS FOR EARLY POSTNATAL CARE CONTACT

Principally in home births or settings where women are discharged very soon after delivery, motivation for timely HepB-BD can increase the energy and resources put into ensuring postnatal care.

HEPB-BD AS ENTRY POINT TO THE IMMUNIZATION PROGRAMME

As one of the first vaccines to be administered, along with OPV0 and BCG, HepB-BD provides an opportunity to educate the mother on the benefits of vaccination during antenatal care visits or as part of early postnatal care.

ADDITIONAL INCENTIVE FOR TIMELY VACCINATIONS

HepB-BD alone will not prevent mother-to-child transmission; 2–3 subsequent routine doses are required and these doses should be given on time to maximize the vaccine's effectiveness. Emphasizing to caregivers the importance of adherence to the routine immunization HepB schedule, will help timely vaccination with other antigens.

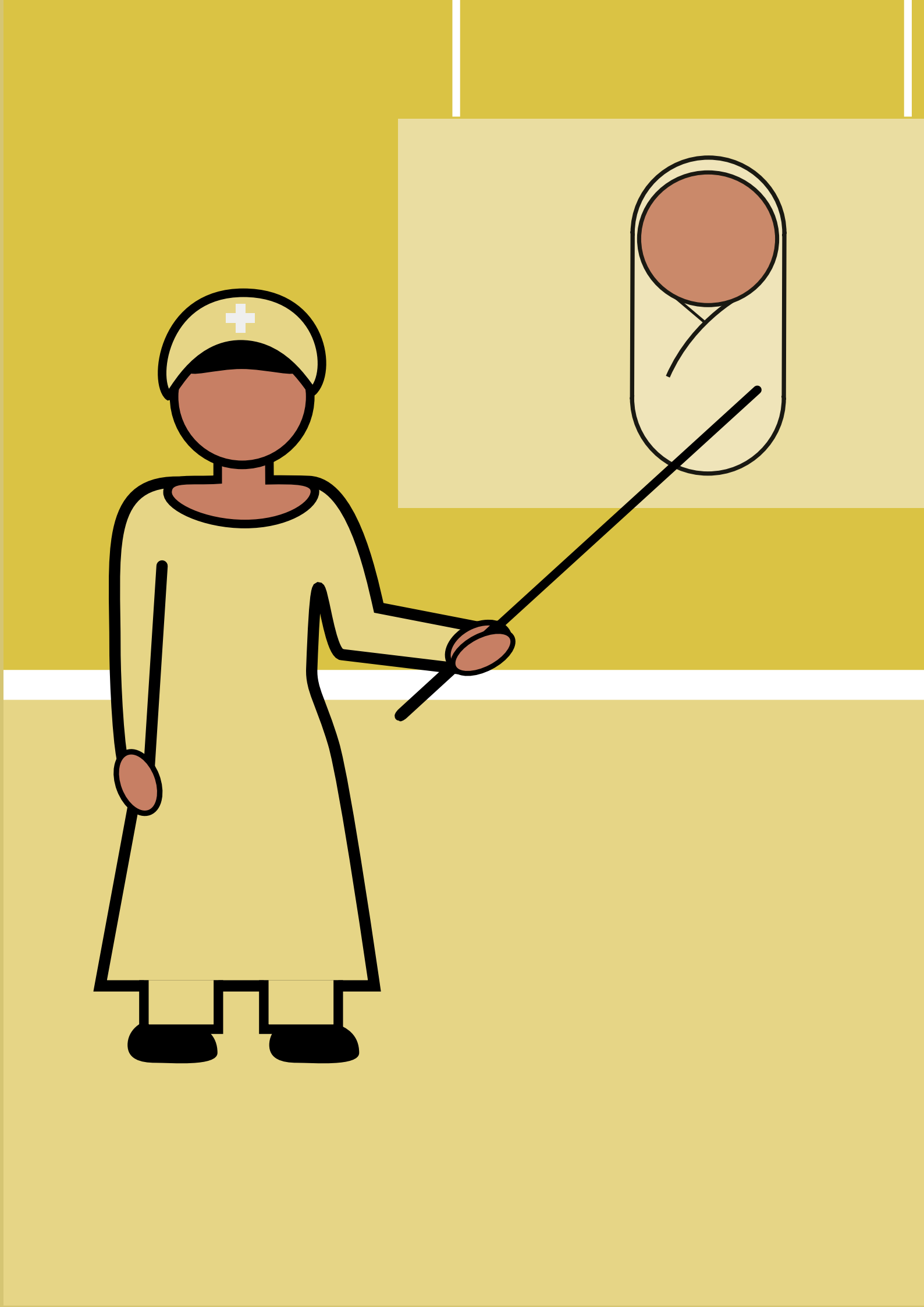
IMPROVING TARGET POPULATION ESTIMATES

Efforts to link pregnancy tracking, birth notification, or birth registration systems with immunization registries, will provide additional data sources for estimating a more accurate picture of a catchment area's target population. This is important for planning and evaluating service delivery, as well as for calculating population-based health indicators. Improving knowledge of live births also helps with service planning and monitoring across the whole spectrum of newborn and child-care programmes.

IMPROVING SUPPLY CHAIN AND DISTRIBUTION

Upgrading or expansion of the supply chain, distribution and storage systems to enable HepB vaccine availability at point-of-delivery, can also benefit availability of essential MNCH medicines, such as oxytocics, if supply chains are integrated.

YOUR NOTES



CHAPTER 8

Training and supervision

A Who to train?

HepB vaccine will not be new to most immunization programmes; however, the birth dose has many unique programme characteristics making it essential to conduct training among immunization staff (immunization managers, cold chain and supply focal points and data managers), health workers (delivery and postnatal care staff) and supervisors. Ideally, training should be conducted in both the public and private sectors.

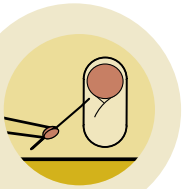
An important distinction to make regarding HepB-BD training is that the vaccination strategy will probably involve new cadres of delivery staff who may not have experience with immunization programmes. Some may have experience with providing a birth dose of OPV or BCG. However, timing for these vaccines is not as critical as it is for HepB-BD, hence newborns are often referred to the immunization clinic for these vaccinations.

B Training topics and resources

In general, HepB-BD training should cover the same topics presented in this document, with emphasis on the unique features of the birth dose as highlighted above. Some country experiences suggest that coverage with HepB-BD is increased when health staff are better informed on the scientific rationale behind the 24-hour timing to interrupt perinatal transmission.[38] **Box 10** provides suggested topics and *Principles and considerations for adding a vaccine to a national immunization programme*[6] provides an overview of training considerations for any new vaccine introduction.

HepB-BD training topics and emphasis will vary depending on national polices and health-care worker practices. For example, some delivery staff may have experience with

38 Downing SG et al. Barriers to the delivery of hepatitis B birth dose: a study of five Papua New Guinean hospitals in 2007. Papua & New Guinea Med J. 2008;51(1–2):47–55.



BOX 10.
SUGGESTED TRAINING TOPICS FOR HEALTH-CARE STAFF ON HEPB-BD

- **Hepatitis B virus** and its consequences
- Modes of hepatitis B **transmission** (with a focus on perinatal transmission) and risk of infection
- **Composition, safety, efficacy and side-effects** of HepB vaccine
- **Why and how** the HepB-BD is being added to national immunization schedules
- Importance of administering HepB-BD **as soon as possible after birth** to prevent perinatal HBV transmission
- The **revised immunization schedule**, emphasizing the importance of completing the entire HepB vaccine series in order to provide long-term protection
- How to use the addition of HepB-BD to strengthen national immunization and postnatal care services
- How to handle the vaccine, including **cold-chain requirements**
- How to **administer the vaccine** and safe injection practices
- **Record keeping** and reporting of birth dose using new forms
- **Educating parents** and how to respond to questions about the vaccine
- Methods for **monitoring and evaluating** the impact of hepatitis B immunization
- Links between HepB-BD and the need for **skilled attendance at birth**, and timely early essential newborn care

providing routine injections to newborns (e.g. vitamin K injection at birth) and delivery staff in rural settings may have experience with immunization practices as childhood immunization may already be one of their responsibilities.

Training for HepB-BD introduction is also an opportunity to include refresher training to health workers and supervisors on other major aspects of the immunization programme, especially in areas where previous programme assessments have identified weaknesses. Suggested refresher topics include areas such as: vaccine forecasting and ordering; cold-chain management (including multi-dose vial policy and interpreting VVMs; safe injection and waste-disposal practices; AEFI surveillance and reporting, and data collection and analysis (including estimating denominators to calculate coverage

rates and estimating drop-out rates). Training, especially if coordinated with MNCH programmes, may also be an opportunity to integrate other aspects of essential newborn care, especially the life-saving interventions required immediately after birth and in the first 24 hours of life.

If HepB-BD is being newly introduced to a country, then it is likely that resources (including course guide, trainer's manual, lesson plans and participant's guides) will be developed specifically for HepB-BD. It will also be important to examine all other immunization and MNCH training materials, including Standard Treatment Manuals or Standard Operating Procedures, to ensure that HepB-BD is included as a standard element of routine immunization and childbirth and/or postnatal care.

C Planning your training

General principles for planning training are summarized in **Box 11**. Specific to HepB-BD, planning training will require coordination with MNCH to ensure that delivery and postnatal care staff are included. It will also be important to explore opportunities to add HepB-BD introduction training to continuing MNCH training, in both pre-service and in-service programmes.

BOX 11.
NEW VACCINE TRAINING – PLANNING CONSIDERATIONS

- **Assessment** of health-worker knowledge and skills should take place to guide training content
- Training schedule and timing should **minimize health-service disruptions**
- Training should take place **soon before birth dose introduction**; if too much time passes, skills and knowledge will be lost without application
- **Quality of training should be monitored** at all levels
- In addition to specific HepB-BD training, information should be added to medical, nursing and midwifery **student curriculums** and training materials

SENEGAL

COUNTRY EXAMPLE 7:
TRAINING HEALTH WORKERS FOR EFFECTIVE HEPB-BD INTRODUCTION

In 2005, Senegal introduced HepB vaccine (as component of a pentavalent vaccine) into its routine immunization schedule at 6, 10 and 14 weeks of age. Senegal plans to introduce HepB-BD in January 2016 and will train over 2000 health workers from both EPI and MNCH (medical doctors, midwives, and nurses). To prepare for the training, a one-week workshop was convened involving 20 national EPI and MNCH staff, and immunization and training experts (WHO and USAID). The main purpose of this workshop was to develop communication materials, revise monitoring and reporting tools, and design a training program for introducing HepB-BD. The workshop proposed the following training program for training health staff.

Learning content: The training program includes eight modules:

1. HBV Infection and importance of HepB-BD
2. HepB vaccine attributes and storage conditions
3. HepB-BD eligibility
4. HepB-BD immunization strategy
5. Administering HepB-BD within 24h
6. Immunization data management
7. AEFI notification and case management
8. Communicating about HepB-BD to community and health workers

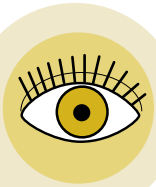
Training materials: A training package composed of a training guide, a slideshow desk, a case-study, a pre and post-test, a simplified job-aid, and an aide-memoire.

Cascade training: A training-of-trainers approach was used to enable knowledge to be passed to all levels of the health system. This will also establish a pool of trainers at regional (14 regions) and district levels (76 districts) before the introduction of the HepB-BD in Senegal. District trainers will then train health workers in the 1300 health stations. In addition to cascade training, supportive supervision will be provided to support health staff.

▲ Train front line healthcare workers and midwives to explain that in addition to the birth dose, a total of 3 doses will be needed for full protection against hepatitis B.

BOX 12.

POTENTIAL AREAS TO CHECK DURING SUPERVISORY VISIT.



YES	NO	
☐	☐	Do delivery staff members have sufficient knowledge related to HepB-BD administration (timing of vaccination, contraindication, site of vaccination)?
☐	☐	Is HepB-BD vaccine easily available (nearby refrigerator, cold box in delivery room or postnatal ward)?
☐	☐	– Is temperature monitored and found to be in the appropriate range?
☐	☐	– Do staff members know how to perform a shake test to check for freezing?
☐	☐	Is there a stock management system in place to avoid stock outs?
☐	☐	Are all recording and reporting forms updated and available?
☐	☐	Is the date of HepB-BD being recorded on the home-based record (vaccination card) for the caregiver and in the register?
☐	☐	Is timely HepB-BD being recorded and reported (i.e. within 24 hours after birth)?
☐	☐	Is the mother receiving key information (purpose of HepB vaccine, potential side-effects and when and where to take her child for subsequent doses)?
☐	☐	Is a monthly HepB-BD monitoring chart available in the facility?
☐	☐	Is vaccination coverage reaching the target for the catchment area?
☐	☐	If applicable, is the proportion of newborns receiving HepB-BD being tracked by location of birth (health facility versus home)?
☐	☐	Are opportunities to vaccinate newborns delivered at home being maximized (e.g. SBA brings vaccine to home births, HepB-BD provided at postnatal care visits)?

D Supervision

Supportive supervision is a necessary component of successful immunization programmes; several resources exist, including *Training for mid-level managers (MLM), module 4*[39] and *Reaching every district*.[40] Supportive supervision, in general, emphasizes mentoring, on-the-job training and joint problem solving. In addition, it offers an opportunity to gain insight into the status of new vaccine introduction knowledge and implementation. Like any change to vaccination strategy, intensified supervision is needed to ensure that implementation goes as planned.

When first introducing HepB-BD, it is important to plan supervision of staff, in delivery rooms or postnatal care wards, that may be responsible for HepB-BD administration; this includes facility staff and individuals supporting home births.

There are several practices that may be unfamiliar to them, such as:

- dealing with products that require cold chain, and reading VVMs;
- providing injections to a newborn;
- educating mothers on the importance of HepB-BD and receiving additional vaccines;
- providing documentation on the vaccination to the mother and the immunization programme.

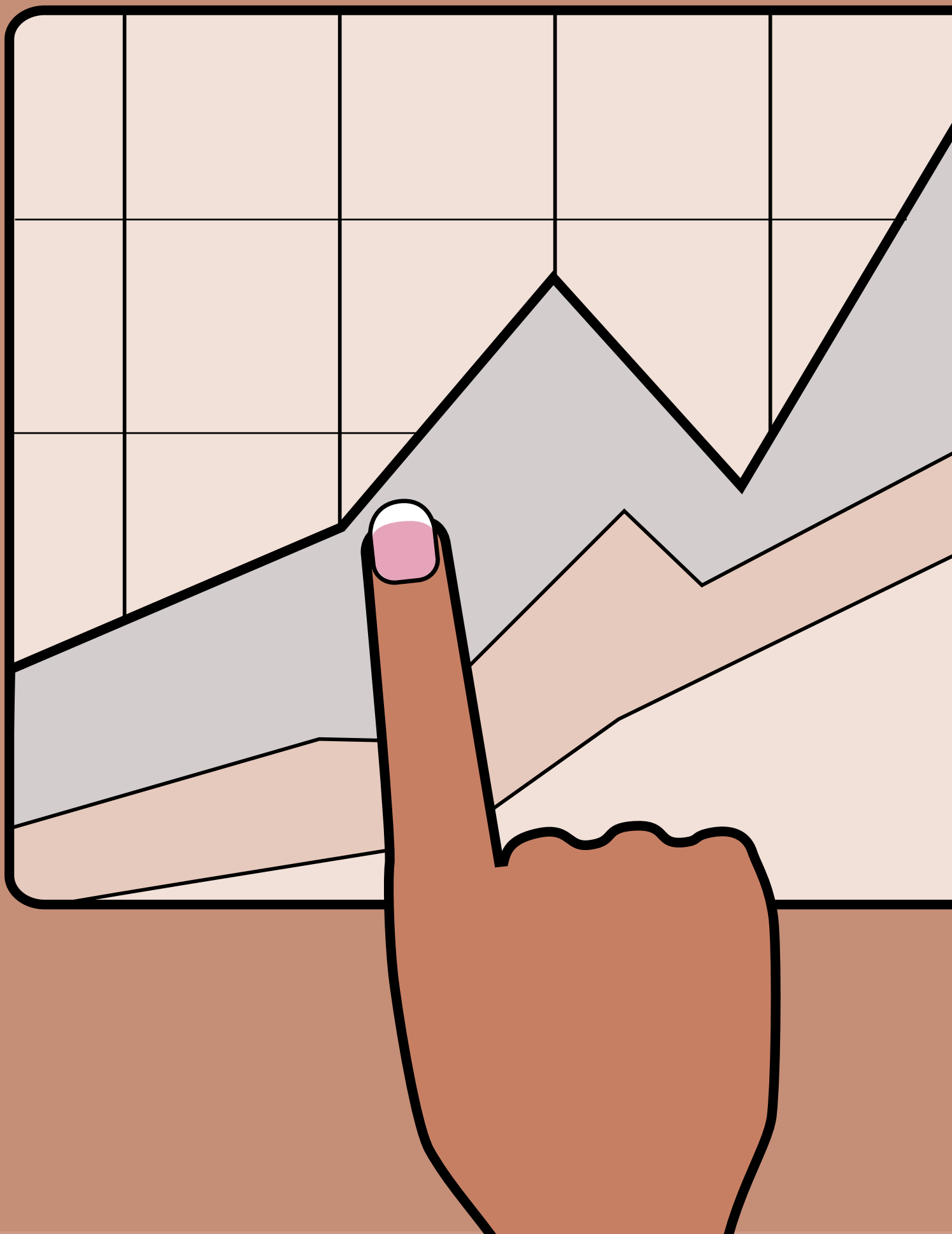
The introduction of new vaccination sites (e.g. delivery settings) will require additional resources to allow for the expansion of the immunization programme's supervisory schedules and the modification of supervisory tools to include HepB-BD vaccination (**Box 12**). A comprehensive supportive supervisory checklist for HepB-BD in health facilities is provided in **ANNEX 6**.

Some countries may have opportunities to integrate HepB-BD supervision with other established supervisory platforms, such as maternal health supervisory visits, or including a HepB-BD element as part of national hospital accreditation, or through programmes such as the Baby-Friendly Hospital Initiative. For example, in the Philippines, periodic hospital-accreditation visits include a review of HepB-BD.

39 Training for mid-level managers (MLM), Module 4: Supportive supervision. Geneva, World Health Organization, 2008 (WHO/IVB/08.04), (http://www.who.int/immunization/documents/mlm/en/)

40 Microplanning for immunization service delivery using the Reaching Every District (RED) strategy. Geneva, World Health Organization, 2009 (WHO/IVB/09.11) (http://www.who.int/immunization/documents/RED-strategy-document.pdf)

41 WHO, UNICEF. Baby-friendly hospital initiative, revised 2009 (http://www.who.int/nutrition/topics/bfhi/en/)



CHAPTER 9

Monitoring vaccine coverage, impact and AEFI

Like other vaccines in EPI, HepB-BD coverage must be monitored and reported at all administrative levels (i.e. district, provincial and national) and appropriate programmatic action taken where coverage is below expected levels. Unlike other antigens, HepB-BD is administered outside the traditional EPI setting; therefore, mechanisms must be established allowing for monitoring to be conducted by MNCH and EPI. HepB-BD monitoring has other unique aspects, including: 1) the denominator for calculating coverage is live births instead of surviving infants; 2) it is the only antigen which has a coverage indicator containing a time component, defined as within 24 hours after birth.

Definitions commonly used include the following.

- **Timely birth dose coverage**: the proportion of live births who receive a HepB-BD within 24 hours after birth. All doses given on day 0 or 1 of life meet this definition (i.e. the date of delivery and the day following delivery). This is the global standard for monitoring HepB-BD coverage.[42]
- **Total birth dose coverage**: the proportion of live births who receive any HepB-BD, defined as those vaccinated any time up until the first dose is due, or as per country guidance on upper age range.
- **Health facility birth dose coverage:** the proportion of live births in a health facility who receive HepB-BD. This may be tracked separately if there are different coverage targets for facility births, especially regarding timely birth dose administration.
- **Home birth dose coverage:** the proportion of live home births who receive HepB-BD.

This section outlines the methods for monitoring and evaluating a HepB-BD vaccination programme.

42 WHO/UNICEF Joint Reporting Process (http://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/).

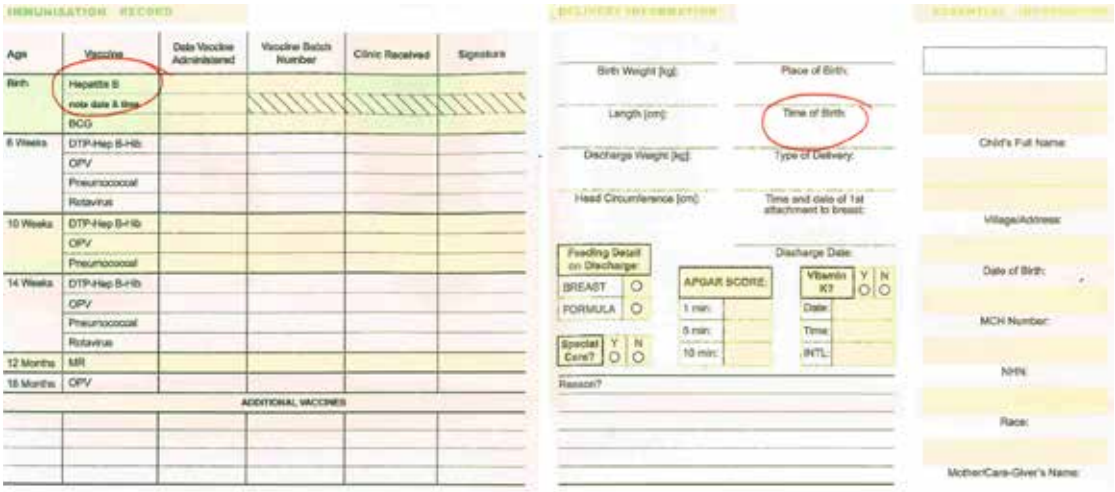
A Recording, reporting and monitoring coverage

The main recording tools[43] used for immunization-related activities should be adapted to include HepB-BD. The format for immunization records should be modified to include a designated column for entering the date of HepB-BD administration. If a country uses electronic vaccine registries for recording, or electronic or web-based databases for reporting, it will be important to update these to reflect HepB-BD. Ideally, this should be integrated with any other new vaccine introductions planned so that revisions can include all new antigens planned for introduction.

Birth dose coverage should be recorded and reported separately for timely birth dose (within 24 hours) and for birth dose given after 24 hours but prior to the next scheduled HepB vaccination. In areas with a high percentage of home deliveries, it can be useful, for programmatic reasons, to monitor birth dose coverage separately for health-facility deliveries and for home deliveries.

43 For further information on immunization monitoring, see Training for mid-level managers (MLM) Module 5: Monitoring the immunization system. Geneva, World Health Organization, 2008 (WHO/IVB/08.05) (http://www.who.int/immunization/documents/mlm/en/) and Immunization in practice, Module 6: Monitoring and surveillance. Geneva, World Health Organization (http://www.who.int/immunization/documents/training/en/)

FIGURE 4.
HOME-BASED RECORD WITH HEPB-BD



This immunization record from Fiji illustrates a 4-dose HepB schedule (birth dose + 3 doses of Pentavalent). The record also provides an indication if HepB-BD was TIMELY: the time and date of the HepB given at "Birth" should be same day or day after the "Time of Birth" on the card.

The following are details about common tools and forms used.

Home-based records (vaccination cards, child health books, etc.).[44] The home-based record documents the child's immunization history and status. This record will need to be adapted to include HepB-BD. The date of HepB-BD administration should be entered and the card should be returned to the parent. **Figure 4** gives an example of a home-based record that includes both the date-of-birth and the date of administration of HepB-BD.

A mechanism to provide a record of the HepB-BD administration in non-traditional EPI settings should be established. The easiest way of doing this is to integrate the EPI's home-based record in these non-traditional EPI settings (e.g. health facilities delivering babies, private clinics, outreach postnatal care contacts) so that they may be given to parents at the time of HepB-BD administration (**Country Example 8**). If this cannot be done, a separate durable record can be created and provided to the family; the date of HepB-BD should then be transferred to the EPI home-based record at the first EPI visit. Tips for good practices are found in **Box 13**.[45]

44 Home-based records exist in various and continuously evolving forms, and terminology may vary considerably across countries (e.g. well baby books, immunization cards, child health passports, etc.).

45 Practical guide for the design, use and promotion of home-based records in immunization programmes. Geneva, World Health Organization, 2015 (WHO/IVB/15.05) (http://apps.who.int/iris/bitstream/10665/175905/2/WHO_IVB_15.05_eng.pdf)

Tally sheets. The purpose of a tally sheet is to track how many doses are given during an immunization session; this data is incorporated into monthly reports (covered in the section below). Since HepB-BD should be provided as births occur, and not in group immunization sessions, tally sheets serve to provide a running count of the doses given over a period of time. An example of a tally sheet is provided in **ANNEX 7**.

Tally sheets should be used for all HepB-BD vaccinations. A child vaccinated in a facility setting should be recorded in the immunization register and tally sheet/log. However, for doses administered in the home and doses administered in other non-traditional EPI settings, a mechanism to capture these doses should be established. For example, a midwife who provides vaccine at the home of a newborn could bring a tally sheet with her (this may require a separate tally sheet per child) or could document the dose provided on the tally sheet stored at the EPI clinic or health facility.

Tally sheets should document whether the dose was given within 24 hours, or more than 24 hours after birth. Even though timely birth dose is the main indicator for coverage, it is important to vaccinate all children, even if more than 24 hours after birth, as the vaccine still has some efficacy. Tracking doses administered more than 24 hours after birth is needed for supply management and will remind health workers to vaccinate even if a child presents later than 24 hours after birth.

To provide information for improving coverage, it is useful to monitor HepB-BD coverage by location of birth, as HepB-BD coverage should be universally high among babies born in health facilities. In order to monitor this, tally sheets and monthly reports can be amended to include columns for birth dose administration by location. See **ANNEX 8** for an example of how to modify a tally sheet to include information on location of birth.

It is worthwhile for supervisors to spend time reviewing tally sheets with staff, to improve the quality of reporting.

Immunization registers. While tally sheets record the doses given for each session, the immunization register records doses given to each individual to ensure that they receive all the vaccines, and allows health workers to track defaulters. The register should be revised to include a column for documenting the date of HepB-BD, as well as the child's date-of-birth. Refer to WHO's Immunization in Practice[43] for more information to include in the register and how to use the register on subsequent visits by the mother and infant.

NAMIBIA

COUNTRY EXAMPLE 8: EARLY INITIATION OF THE HOME-BASED RECORD

In Namibia, the Child Health Passport, which documents not only the child's vaccination history but also a complete range of health, growth and development indicators, is initiated as early as possible after delivery. These yellow cards are given to mothers upon discharge from the maternity wards, and are required to be brought to the Home Affairs Office in order to register the baby's birth and to issue the birth certificate. In large hospitals, the Home Affairs Office may actually be located within the hospital grounds, facilitating the entire registration process. Linking the birth registration to the home-based record not only reinforces the importance of the Child Health Passport as a key health record for the child, but also ensures that newborns are not discharged before being vaccinated.

▲ Early initiation of the home-based record can help ensure that newborns are not discharged before being vaccinated.

BOX 13.
TIPS FOR HOME-BASED RECORDS

Reason for home-based records

- Keeps track of immunizations the child has received
- Reminds parents of the next date of vaccination
- Helps health workers know what services the child needs

Information to tell the parent

- Record should be brought to every visit at the health facility, even if the child is not coming in for vaccination services

How to store the card

- Must be kept in good condition
- Must be kept in a dry place

Ask to see the home-based record for both mothers and children every time they visit a health facility or health services session. Check whether they are eligible for any vaccine or other child health service.

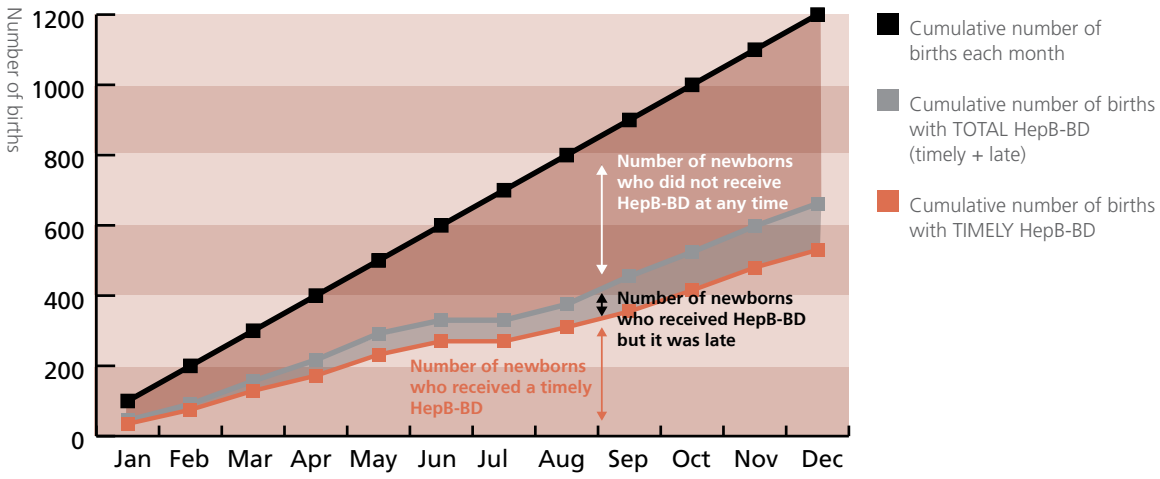
DO NOT MISS AN OPPORTUNITY TO VACCINATE!

A good practice for maximizing HepB-BD vaccination is to review the birth register and immunization register weekly. If a newborn is missing from the immunization register, the name and relevant information should be copied into it. These unvaccinated newborns should then be sought out for HepB-BD vaccination and for the other vaccines that local immunization policy requires should be given at birth.

Birth registers. Birth registers are used by health facilities to document details on the mother and child, including name, date and time of birth, birth weight, residence and any complications. These are sometimes called obstetric registers and are usually maintained in the delivery room of a health facility that provides childbirth care. Vaccines administered at birth are not often included on the birth register. One option for monitoring HepB-BD coverage in health facilities is to add a column for recording the date of HepB-BD administration; this helps establish HepB-BD as a routine part of childbirth care. Another option is to create a separate HepB-BD register listing the name of the child, the date-of-birth and the date of HepB-BD vaccination. This practice may also be extended for other vaccines that local immunization policy requires should be given at birth.

Coverage monitoring charts. A coverage monitoring chart is a simple and effective tool for visually monitoring the progress towards immunization coverage targets in a catchment area. Coverage monitoring charts should be adapted to monitor timely HepB-BD and can include tracking of total HepB-BD (see **Figure 5**).

FIGURE 5.
MONTHLY MONITORING CHART TRACKING BOTH TIMELY AND TOTAL HEPB-BD



Integrated monthly reports. Traditionally, immunization data are collated at each level into a monthly report. When HepB-BD is added to the immunization schedule, the monthly report should also be adapted to include doses given ≤24 hours and those given >24 hours after birth.

Monthly reports should be submitted by all health facilities providing HepB-BD (even if that is the only vaccine they are administering). EPI facilities will follow their normal reporting structure; non-traditional EPI settings will need to be integrated into the existing structure.

The monthly report should contain the following elements with regard to HepB-BD:
- → the number of HepB-BD doses administered in the month (those administered within and more than 24 hours after birth) and number of live births;
- → stocks received and used, including vaccines and injection equipment;
- → the number of adverse events following immunization (AEFI) identified.

For an example of a monthly integrated report adapted to include HepB-BD, see **ANNEX 9.**

Stock records. Stock records are used to manage the number of vaccine vials available at all administrative levels. These forms/databases should be modified to include information about monovalent hepatitis B vaccine vials.

Annual WHO/UNICEF Joint Reporting Form. As part of their annual WHO/UNICEF Joint Reporting Form (JRF), national immunization programmes should report the number of timely HepB-BD administered. This also requires reporting of numbers of live births to allow for calculation of coverage of HepB-BD.

B Recording and reporting in specific circumstances

Recording and reporting HepB-BD for home births. HepB-BD given in the home must be recorded and reported. Special mechanisms might be necessary to ensure that these doses are recorded in the home-based record, vaccination register and monthly tally sheet.

Private facilities. Private health facilities should routinely report HepB-BD, and its timing, administered in their facility. This allows the immunization programme to better estimate coverage and vaccine supply needs.

C Assessing programme implementation

Coverage surveys. Periodic immunization coverage surveys, demographic and health surveys (DHS), and multiple indicator cluster surveys (MICS), are all opportunities to include an assessment of timely HepB-BD once it has been introduced into the national immunization schedule. It is important to ensure that the questionnaire is modified to include all relevant questions related to HepB-BD, including time after birth that the vaccine was given.

EPI programme reviews and post-introduction evaluations (PIEs). EPI programme reviews are undertaken every three to five years and should be adapted to include HepB-BD once it has been introduced. Similarly, countries which have recently introduced additional vaccines and are conducting a post-introduction evaluation (PIE), may wish to include some core HepB-BD related questions. These assessments are a good way to evaluate the impact of introduction on the country's immunization programme and to rapidly identify problems, needing correction, that are the result of the introduction of HepB-BD, or that predated it. The New vaccine post-introduction evaluation (PIE) tool[46] contains guidance and templates for conducting these assessments.

Health-facility assessments. Programmes should be able to vaccinate every birth that takes place in a health facility; however, this does not always happen. In order to identify specific potential barriers, countries may wish to conduct a HepB-BD health-facility

NIGERIA

COUNTRY EXAMPLE 9: ASSESSING HEPB-BD IMPLEMENTATION

In 2004, Nigeria introduced HepB vaccine to be given as soon as possible after birth and up to 2 weeks after birth. In 2014 the national HepB-BD coverage was estimated to be 32%.

In September 2015 an assessment was conducted to evaluate the knowledge, practices and implementation of HepB-BD and to identify ways to improve coverage. The assessment included structured interviews with key informants in three States, six Local Government Authorities, and 26 health facilities that offer newborn delivery services.

The assessment found that HepB-BD was a priority for the national EPI program and they are committed to improving coverage. An example of actions identified to improve coverage included:

- → clarify that HepB-BD should be given even up until 2 weeks after birth — as it was observed in some settings that newborns older than 24 hours were not vaccinated,
- → continue to scale-up HepB-BD in facilities — as the assessment found that 50% of facilities do not provide Hep-BD in delivery or post-natal wards,
- → update forms so that both timely and 'late' HepB-BD (given 24 hours after birth) can be recorded and monitored,
- → continue to sensitize community health workers — as they were the most common way caregiver's learned to bring a home-birth to a health facility for HepB-BD vaccination.

Provided here are references from other countries that have conducted similar assessments:

Seoung SC et al. Using Data to Guide Policy: Next Steps for Preventing Perinatal Hepatitis B Virus Transmission in Cambodia. Vaccine 2012; Dec 17;31(1):149-53.
Xeuatvongsa A et al. Hepatitis B Vaccine Birthdose Practices in a Country Where Hepatitis B is Endemic — Laos, December 2011–February 2012. Morb Mort Wkly Rep July 26, 2013 / 62(29);587-590.
Hutin Y et al. Improving hepatitis B vaccine timely birth dose coverage: lessons from five demonstration projects in China, 2005-2009. Vaccine. 2013 Dec 27;31 Suppl 9:J49-55.
Patel MK et al. Findings from a hepatitis B birth dose assessment in health facilities in the Philippines: Opportunities to engage the private sector. Vaccine. 2014 Sep 3;32(39):5140-4.

assessment following introduction. This type of assessment is more specific and in-depth at the health-facility delivery level, and can help identify issues such as health-care worker misconceptions, stock-outs, failures to designate responsibility, lack of knowledge and lack of cold chain (see **Country Example 9**). If possible, include an assessment of linking birth dose vaccination with home deliveries or post-natal care home visits.

D Assessing programme impact (seroprevalence surveys)

Vaccine-preventable disease surveillance is traditionally used to inform the impact of immunization programmes. However, most HBV-related complications do not develop until later in life; hence, another method is needed to monitor HepB vaccine impact in children. WHO recommends measuring the impact of HepB vaccination by assessing the prevalence of chronic HBV infections among children through a serosurvey. Details of how to do this serosurvey are found in *Documenting the impact of hepatitis B immunization: best practices for conducting a serosurvey*[47] and *Sample design and procedures for hepatitis B immunization surveys: A companion to the WHO cluster survey reference manual.*[48]

The purpose of a serologic survey will usually be to measure the overall impact of the HepB vaccination programme as a whole, and cannot distinguish the impact of birth dose vaccination in isolation.

E Monitoring and investigating AEFI

HepB-BD is one of the safest vaccines available. Severe reactions are rare and are believed to occur in about 1.1 per million vaccine doses.[49] However, since HepB-BD administration takes place at a time of highest risk of neonatal death from unrelated causes, it is essential that programme managers be prepared for a coincidental neonatal death following HepB-BD vaccination. Neonatal deaths suspected of being related to vaccination, can decrease public confidence in the vaccine and the immunization programme as a whole (see **Country Example 10**). This highlights the importance of monitoring AEFI, being prepared to respond rapidly and having a communication strategy in place to inform the public, address their concerns and correct misinformation.

46 New vaccine post-introduction evaluation (PIE) tool. Geneva, World Health Organization, 2010 (WHO/IVB/10/03), http://whqlibdoc.who.int/hq/2010/WHO_IVB_10.03_eng.pdf.

47 Documenting the impact of hepatitis B immunization: best practices for conducting a serosurvey. Geneva, World Health Organization, 2011 (WHO/IVB/11.08), http://whqlibdoc.who.int/hq/2011/WHO_IVB_11.08_eng.pdf.

48 Sample design and procedures for hepatitis B immunization surveys: A companion to the WHO cluster survey reference manual. Geneva, World Health Organization, 2011 (WHO/IVB/11.12), http://whqlibdoc.who.int/hq/2011/WHO_IVB_11.12_eng.pdf.

49 Bohlke K, Davis RL, Marcy SM, et al. Risk of anaphylaxis after vaccination of children and adolescents. Pediatrics 2003;112:815–20.

Immunization programmes should have an AEFI monitoring system in place for all vaccines; however, this system will be new for MNCH programmes. MNCH and immunization staff must be trained on potential AEFI following HepB-BD and supervised to ensure AEFI monitoring and reporting. Detailed procedures for reporting and investigating AEFI are described in the Global manual on surveillance of adverse events following immunization.[50]

All serious AEFI should be investigated quickly in order to identify potential causes. While AEFI can be due to a rare reaction to the vaccine itself – with most reactions being mild and short-term – they can also be due to programme errors, such as contamination of the vaccine, use of non-sterile techniques, or administering the vaccine at the wrong site or through the wrong route. AEFI surveillance can therefore be an effective way to detect problems with the handling and administration of vaccines and to correct these mistakes through training and supervision of health workers. All investigations should be reported to an AEFI committee that is able to meet immediately to discuss potential causality, and steps to be taken.

AEFI response preparedness and communication. Countries should have a general AEFI response plan in place; the basic elements of such a plan are highlighted in **Box 14**. Along with HepB-BD introduction, consider adding expertise in neonatal care to existing AEFI committees.

The national communication strategy should be updated to allow for a rapid and effective response to AEFI, anti-vaccine movements and any allegation that can have a negative effect on public acceptance of the HepB-BD and trust in the immunization programme. The communication strategy should include facts about vaccine safety, expected side-effects and the concept of coincidental timing of HepB-BD administration and the highest risk period for neonatal deaths. A proactive approach with the media, for example, conducting technical briefings and media workshops, can facilitate balanced coverage if and when AEFI do occur, and timely communication of the results of AEFI investigations is important to counter rumours and incorrect information in the media.

Finally, educating parents, health workers and communities on the benefits and safety profile of HepB-BD will facilitate confidence in the vaccine and immunization programmes overall, and is an important pre-emptive measure in AEFI management.

Additional materials on the detection, investigation and communication of AEFI, are available on the WHO Global Vaccine Safety website, including an e-learning course on vaccine safety basics which contains a module on communication.[51]

50 Global manual on surveillance of adverse events following immunization. Geneva, World Health Organization, 2014 (http://www.who.int/vaccine_safety/publications/aefi_surveillance/en/)

51 Global vaccine safety. Reference documents and publications. Geneva, World Health Organization (www.who.int/vaccine_safety/publications/en/);
WHO E-learning course on vaccine safety basics (www.who.int/vaccine_safety/initiative/tech_support/ebasic/en/).

VIETNAM

COUNTRY EXAMPLE 10: THE IMPORTANCE OF AEFI PREPAREDNESS

Between 2006 and 2008, 11 neonatal deaths were reported to be related to HepB-BD in Vietnam. An external investigation found no association between the AEFI and HepB-BD. However, these reports received widespread media attention which led to decreased parental and health-care worker confidence in the vaccine and decreased HepB-BD vaccination; coverage dropped from 64% in 2006 to 25% in 2008.

After intensive training, education and communication campaigns, coverage of HepB-BD increased to 76% by 2012. Vietnam's experience with AEFI demonstrates the critical need for early risk communication and education of health workers and parents, particularly in countries with high neonatal death rates from other causes.

Proceedings of the WHO third Expert Working Group meeting on hepatitis B, Tokyo, 6–7 March 2007. WHO Regional Office for the Western Pacific, Manila, Philippines (http://www.wpro.who.int/immunization/documents/docs/MTGRPT_HepBExpert3.pdf).

BOX 14. AEFI RESPONSE PLAN

An AEFI response plan should include:

- actions with specific roles for the immunization programme and its partners;
- list of AEFI committees at various levels, including the names of experts who can meet immediately to assess potential causality and next steps;
- a communications strategy, including channels of engagement with various types of media and identified, well-respected spokespersons at all levels;
- mechanisms to engage health workers about communicating with the public on AEFI and safety concerns;
- information packages for media, including FAQs and key messages on immunization, in general, and those specific to HepB-BD.

▲ Serosurveys can be conducted to monitor the impact of newborn and infant vaccination program by measuring chronic infection prevalence in young children.

YOUR NOTES

CHAPTER 10

Advocacy, communication, social mobilization

Creating demand for HepB vaccine, in general, can often be challenging, since HBV infection in children is usually silent and there may be low awareness that HBV causes liver disease and premature death. A comprehensive and coordinated set of advocacy, communications and social mobilization activities that focus on the benefits of HepB vaccination and the importance of timely birth dose delivery is critical to create and sustain the support of policy-makers and opinion leaders, as well as community acceptance of, and demand for, HepB-BD. A good practice is to develop an advocacy and communications plan for HepB-BD introduction, aligned with the overall national health promotion and communications strategy. Establishing a technical sub-committee on advocacy and communications can be helpful in developing and implementing the plan. To ensure the activities are effective in reaching all key target audiences, and that messages are clear and appropriate for each audience, it is important that the sub-committee include representation from different sectors of society, as well as experts in immunization, maternal and child health, and health promotion.

Topics for key messages and tips for advocacy are summarized in **Boxes 15–17**, and sample information points provided in **ANNEX 10**.

DECISION-MAKERS

Advocacy efforts among decision-makers and opinion leaders are important in generating commitment for adding HepB-BD to national immunization schedules. The decision-makers and opinion leaders who should be considered in this connection include those below.

- Health-ministry officials
- Other government officials (e.g. finance)
- Partner and donor agencies
- Nongovernmental organizations (NGOs)
- Community leaders
- Religious leaders
- Pharmacists
- Clinicians in the private sector
- Professional associations
- Teachers

Note that this will include decision-makers and opinion leaders with interests in cancer prevention, chronic disease prevention, safe motherhood and essential newborn care, as well as those with interests in immunization.

PARENTS AND COMMUNITIES

Communication and social mobilization efforts for parents and the general public should aim to raise awareness and improve understanding of the disease burden associated with HBV (liver cancer and cirrhosis) and how to protect their children against the disease. Antenatal care visits are important opportunities to educate mothers about HepB-BD vaccination and can be discussed in the context of maternal vaccinations, such as tetanus or influenza vaccination.

Fear of adverse events or harm, in particular, has been documented as a barrier to birth dose vaccination.[7] In addition to broader community concerns that may be raised against vaccination in general, the timing of HepB-BD increases the possibility of coincidental newborn deaths or illnesses being blamed on HepB-BD. As discussed in Chapter 9, this further emphasizes the need for hepatitis B immunization programmes to prepare communications in advance in order to respond in a timely manner to any adverse events or perceptions.

OPPORTUNITIES TO RAISE AWARENESS

Global awareness campaigns such as World Hepatitis Day, World Immunization Week, and World Health Day, among others, offer opportunities to boost the profile of hepatitis B virus, the importance of birth dose, and other routine immunization messages.

▼ Raising awareness: the 2014 theme for Immunization Week in the Western Pacific Region was "Stop Hepatitis B and liver cancer. Vaccinate at birth."

BOX 15.
KEY MESSAGES FOR DECISION-MAKERS

- Disease burden and health-system costs associated with HBV-related cirrhosis and liver cancer
- Modes of HBV transmission (with focus on mother-to-child transmission) and risk of infection
- The safety and efficacy of HepB vaccines
- The cost-effectiveness of HepB-BD immunization
- The need for financial support to ensure the sustainability of HepB-BD
- Opportunities for synergy between HepB-BD and other initiatives to promote newborn survival
- The importance of their role as advocates for the successful introduction of HepB-BD

BOX 16.
KEY MESSAGES FOR PARENTS AND THE GENERAL PUBLIC

- Hepatitis B virus and its consequences, especially when infection happens at birth
- Modes of HBV transmission and who is at risk of becoming infected
- Efficacy and safety of HepB-BD
- Potential side-effects of HepB vaccine
- Why the vaccine is being added to the national immunization programme
- Importance of timing of the HepB-BD (within 24 hours after birth)
- Importance of taking a child to receive remaining vaccines, including subsequent HepB doses

BOX 17.
TIPS FOR ADVOCACY, COMMUNICATIONS AND SOCIAL MOBILIZATION ACTIVITIES[6]

- **Establish a sub-committee** to help plan and implement advocacy, communications and social mobilization activities and to sensitize its members about HepB-BD
- **Conduct research** on knowledge, attitudes, beliefs and practices (KABP) around HepB-BD, hepatitis B virus and other vaccines, plus immunization in general to inform communications around HepB-BD and to pre-empt potentially negative public reactions to the vaccine
- **Educate and inform the media** about viral hepatitis B and HepB-BD well in advance
- **Educate and mobilize a broad range of stakeholders** (e.g. community and religious leaders, the private sector, NGOs and universities) to promote HepB-BD and routine immunization
- **Train health workers** in how to communicate with parents and the community about hepatitis B virus, ways to prevent infection and benefits of HepB-BD, as well as in effective communication methods. Develop job aids to assist them in conveying these messages
- **Include messages about prevention measures** for HBV in communications about HepB-BD
- **Include the promotion of all childhood vaccines** in IEC activities, messages and materials
- In communications to parents and the community, and in the training of health workers, **include information about possible side-effects** and what to do if a child has an adverse reaction
- Before vaccine introduction, **establish a crisis communication plan** to be able to rapidly respond to reports of severe adverse events or other potential crises
- **Assess the need** for, and value of, starting HepB-BD introduction with a well-publicized launch
- **Disseminate regular information** on the progress of HepB-BD introduction, its impact on HBV burden and performance of the overall immunization programme, to policymakers and the media

YOUR NOTES

Annex 1:
How to perform a shake test

When to conduct a shake test. The test procedure described below should be conducted on all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot. Hepatitis B vaccine should never be frozen; freezing ldamages the vaccine. The shake test is used to test a vial that has been suspected of freezing, to see if the vaccine has been damaged by freezing.

PROTOCOL FOR CONDUCTING A SHAKE TEST

HOW TO CONDUCT A SHAKE TEST.

This protocol must not be altered. There is only one correct way to conduct a shake test.

1.

Take a vial of vaccine of the **same type and batch numbe**r as the vaccine you want to test, and made by the same manufacturer.

2.

Clearly mark the vial as "**FROZEN**."

3.

Freeze the vial in a freezer or freezing compartment of a refrigerator until the contents are completely solid.

4.

Let it **thaw**. Do NOT heat it!

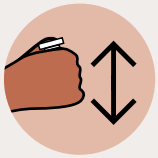
5.

Take your "TEST" vial from the batch that you suspect has been frozen.

6.

Hold the "FROZEN" vial and the "TEST" vial together **in one hand**.

CONTINUED>

7. 

Shake both vials vigorously for 10–15 seconds.

8. 

Place both vials on a flat surface side-by-side and start continuous **observation** of the vials until the test is finished.
(NOTE: If the vials have large labels that conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial).

9. Use an adequate **source of light** to compare the sedimentation rates between vials.

IF...

10. The TEST vial sediments **slower** than the FROZEN vial

Sedimentation is **similar in both vials**

—OR—

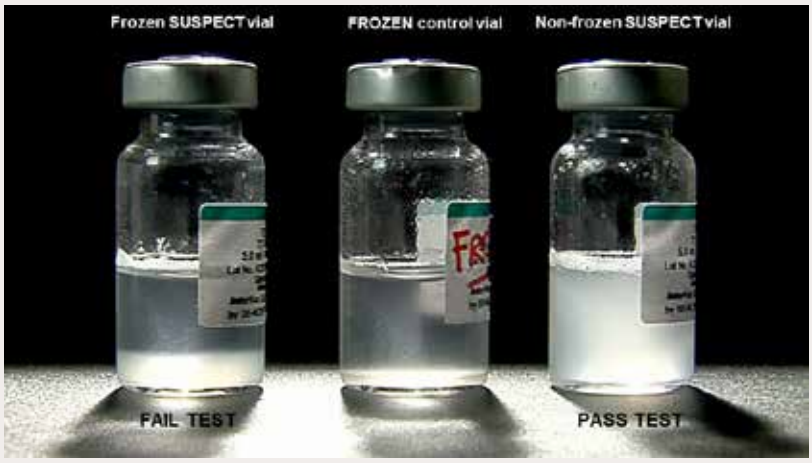
The TEST vial sediments **faster** than the FROZEN vial

THEN...

11. **USE THE VACCINE BATCH.**

VACCINE DAMAGED:
Notify your supervisor. Set aside all affected vaccine in a container marked "**DAMAGED VACCINE FOR DISPOSAL – DO NOT USE**"

Discard all affected vaccine once you have received permission to do so. **Complete/ submit** appropriate form to indicate vaccine loss.

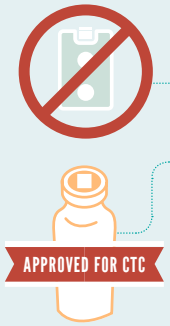


Source: Ümit Kıvanc (http://www.who.int/bulletin/volumes/88/8/08-056879/en/). Step-by-Step Shake test educational video : https://vimeo.com/8389435

Annex 2: CTC Infographic

WHAT IS A CONTROLLED TEMPERATURE CHAIN (CTC)?

A controlled temperature chain is an optional method of transporting and storing vaccines in carriers **WITHOUT ICE PACKS** up to a specific number of days before the vaccines are administered. It is only recommended for vaccines **OFFICIALLY LABELED FOR THIS USE** where a pronounced need is apparent and **TRAINING AND SUPERVISION** are provided. Vaccines carried in a CTC must be monitored using a vaccine vial monitor (VVM) and peak temperature threshold indicator (PTTI) to indicate exposure to heat.



HOW ARE VACCINES APPROVED FOR CTC?

Not all vaccines can be used in a CTC. To be used in a CTC, four conditions should be met:

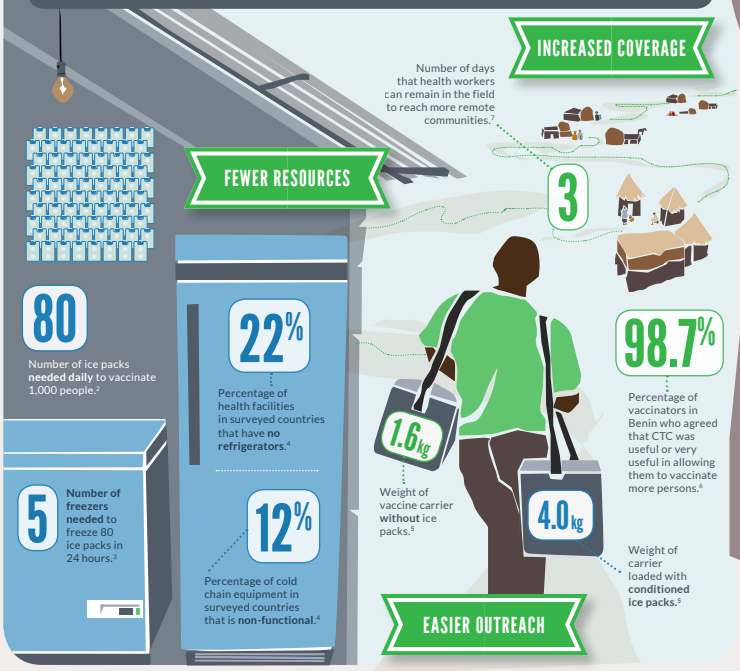
1. **LAB** — The vaccine must undergo and pass stability testing. → THERMOSTABLE
2. **NATIONAL REGULATORY AUTHORITY** — Appropriate regulatory authorities must license the vaccine for CTC use with a label that specifies the conditions of use. → LICENSED
3. **WHO** — The vaccine must be prequalified by the World Health Organization. → PRE-QUALIFIED
4. **COUNTRY** — The government of the country where the vaccine will be used must give its consent in advance. → APPROVED

FOR CTC APPROVED FOR CTC

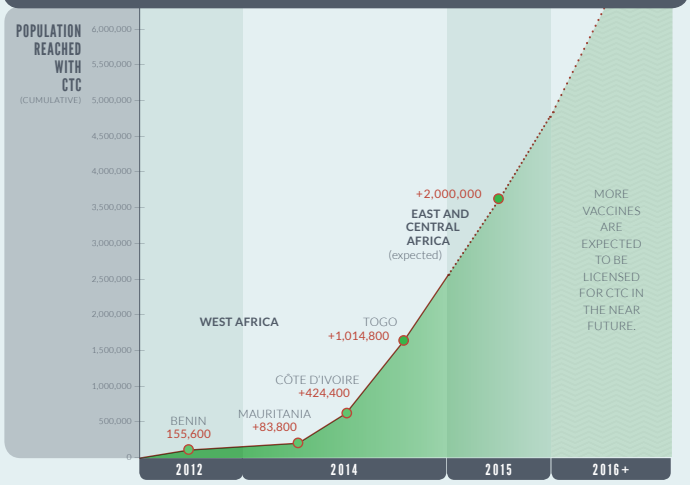
HOW DOES A CTC COMPARE TO A TRADITIONAL COLD CHAIN?

TRADITIONAL COLD CHAIN	CONTROLLED TEMPERATURE CHAIN (CTC)
Vaccine label indicates +2°C to +8°C for **all** storage and transport.	Vaccine label indicates +2°C to +8°C for **initial** storage and transport, and permits up to **40°C** for at least 3 days prior to use.
VVM — Vaccine vial monitors protect potency and quality by monitoring cumulative exposure to heat.	VVM + PTTI — Vaccine vial monitors and peak temperature threshold indicators protect potency and quality by monitoring cumulative and peak exposure to heat.
Conditioned ice packs or cool water packs are required in vaccine carriers.	No ice packs or cool water packs are required in vaccine carriers. Reduced risk of freezing.
No need for additional training, monitoring or supervision.	Health workers need additional training, monitoring and supervision.
When implemented correctly, preserves the safety and potency of the vaccine.	When implemented correctly, preserves the safety and potency of the vaccine.
Requires cooling equipment, transport, and human resources at all levels to maintain cold chain.	Half the cost.[1] Fewer freezers, fewer journeys and less staff time are needed to manage and maintain cold chain requirements.

WHY IS CTC USEFUL?



WHO IS BEING REACHED WITH CTC?



World Health Organization

Want to know more about CTC? Email vaccines@who.int or visit: www.who.int/immunization/programmes_systems/supply_chain/

1 Lydon P, et al. Economic benefits of keeping vaccines at ambient temperature during mass vaccination: the case of meningitis A in Chad. WHO Bulletin. 2014;92:86-92.
2 Assuming each vaccination team requires 8 ice packs per day to vaccinate 100 people. Need 10 teams to vaccinate 1,000 people. Translates to 80 ice packs to vaccinate 1,000 people in a day.
3 A commonly-used WHO pre-qualified freezer can freeze around 7.2 kg of ice packs in 24 hours. Five of these freezers are required to freeze 80 ice packs in 24 hours.
4 WHO EVM Database: data from the most recent EVM assessments in 64 countries across 6 WHO regions, 2010-2014.
5 A commonly-used WHO pre-qualified vaccine carrier with a capacity of 1.7 L weighs 1.6 kg when empty and 4.0 kg when fully loaded with ice packs.
6 Zipursky S, et al. Benefits of using vaccines out of the cold chain: Delivering Meningitis A vaccine in a controlled temperature chain during the mass immunization campaign in Benin, 2014. Vaccine;32:1431-1435.
7 Vaccines for different antigens may allow for excursions of an even higher number of days.

Annex 3:
Example: Policy brief

Executive statement:

Hepatitis B virus (HBV) infection is a major cause of cirrhosis, liver cancer and end-stage liver disease. An effective intervention to prevent HBV infections is completion of the HepB 3-dose vaccination series, including a birth dose of the vaccine to newborns. This brief proposes the addition of the HepB-birth dose into the country's current immunization schedule and strategies for implementation. This policy brief is addressed to senior management in the Ministry of Health (MOH), including individuals responsible for the oversight of programmes involving immunization, maternal and newborn health, cancer prevention or chronic disease prevention.

Statement of issue:

Hepatitis B virus background

HBV infection is a major cause of acute and chronic liver disease (e.g. cirrhosis and primary liver cancer) globally, and is the sixth leading cause of death from infectious disease worldwide with an estimated 686 000 annual deaths.[a] WHO estimates that a third of the world's population (more than two billion people) have been infected with HBV, and that 240 million people are living with chronic HBV infection, placing them at risk for serious illness and death from cirrhosis and hepatocellular carcinoma (HCC).[b,c] Worldwide, 30% of cirrhosis and 53% of all HCC deaths are attributable to HBV infection.[d]

HBV is transmitted by percutaneous and permucosal exposure to infected blood and other body fluids (e.g. semen and vaginal fluid), including transmission from mother-to-child.[e] The likelihood of developing chronic HBV infection is highest if infection occurs at the time of birth; of persons infected during the perinatal period, approximately 70%–90% develop chronic HBV infection.[f,g] Vaccination is the most effective way to prevent HBV infection.

Hepatitis B vaccination and strategies

The HepB vaccine series for children, including a HepB birth dose, plus at least two additional doses in the routine schedule, can prevent most HBV infections and the chronic sequelae of cirrhosis and liver cancer.[e] It is estimated that 85%–90% of HBV-associated deaths are vaccine preventable.[h] WHO recommends that immunization of infants with HepB vaccine be a part of every country's national immunization schedule, and that all infants should receive their first dose as soon as possible, preferably within 24 hours of birth.

Administration of a timely birth dose of HepB, preferably within 24 hours of delivery and followed by at least two subsequent doses, is approximately 90% effective at preventing perinatal HBV infection. Screening of pregnant mothers for chronic HBV infection prior to HBV vaccination of newborns has been shown not to be an effective strategy. Therefore, it is critical that every effort be made to administer the first dose of HepB vaccine to every infant within 24 hours after birth. After receiving a full 3-dose series, the vaccination remains effective for decades and is likely to provide lifelong protection.

a Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet. 2015;385(9963):117-171

b Ott JJ, et al. Global epidemiology of hepatitis B virus infection: new estimates of age-specific HepBsAg seroprevalence and endemicity. Vaccine. 2012;30(12):2212–19.

c Hepatitis B fact sheet. Geneva, World Health Organization (http://www.who.int/mediacentre/factsheets/fs204/en/, accessed 7 August 2015).

d Perz JF, et al. The contributions of hepatitis B virus and hepatitis C virus infections to cirrhosis and primary liver cancer worldwide. J Hepatol, 2006;45(4):529–38.

e Hepatitis B vaccines. WHO position paper. Weekly Epidemiological Record, No. 40 2009;84:405–420,84th year (http://www.who.int/wer/2009/wer8440.pdf).

f Goldstein ST, et al. A mathematical model to estimate global hepatitis B disease burden and vaccination impact. Int J Epidemiol. 2005;34(6):1329–39.

g Van Damme P, Ward J, Shouval D, Wiersma S, Zanetti A. Hepatitis B vaccines In: Plotkin SA, Orenstein W, Offit PA, editors. Vaccines. 6th ed. Philadelphia, Saunders Elsevier, 2012:205–34.

h Hepatitis B immunization: introducing hepatitis B vaccine into national immunization services. Geneva, World Health Organization, 2001 (WHO/V&B/01.28) (http://whqlibdoc.who.int/hq/2001/WHO_V&B_01.28.pdf).

The hepatitis B vaccine is one of the safest and most effective vaccines available. The vaccine contains non-infectious material and cannot cause HBV infection. Mild transient side-effects may occur after immunization, including soreness at the injection site, irritability and fever. These transient effects may start within a day after the vaccine has been given and last from one to three days. Serious allergic reactions are very rare.

[*If applicable:* Hepatitis B vaccine is available and prequalified in a compact pre-filled auto-disable device (CPAD) which can offer certain advantages for birth dose-administration. CPAD technology can facilitate the safe and easy delivery of HepB vaccine outside of traditional EPI settings, or for births that take place at home. CPADs are smaller and faster than using a regular syringe, and make the injection process easier and faster.]

Goals and challenges in the country – example

[If applicable: The WHO Region has set a target for member states to reduce prevalence of chronic HBV infection to xx% among children aged xx years by 20xx]. Hepatitis B 3-dose coverage among one-year-olds now reaches xx% leaving young children susceptible to HBV infection; newborns unvaccinated at birth leave opportunities for mother to child transmission.

In recognition of ongoing transmission of viral hepatitis, the country's MOH seeks assistance from various international organizations to provide advice in the areas of viral hepatitis prevention, treatment, communication, policy and research. Together with national counterparts, this group of experts may propose a goal of ensuring all newborns receive HepB birth dose as soon as possible following birth (within 24 hours). However, reaching newborns with vaccination is not straightforward; despite WHO recommendations, only 96 (49%) of 194 countries report offering birth dose as part of their routine hepatitis B immunization programme, and only 38% of newborns received the vaccine at the recommended time.

Recommendation:

Administration of a birth dose of hepatitis B vaccine currently [is not part of the countries national immunization programme/ needs to be strengthened]. It is feasible to reach a substantial proportion of births by ensuring all newborns born in health-care facilities receive a birth dose of hepatitis B vaccine. Support from the government and international stakeholders in initially implementing routine birth dose vaccination in all MOH facilities will help to reach an estimated xxx out of xxx births that take place in the country each year. We recommend implementing the following practices recommended by WHO in all health facilities providing delivery services in order to improve coverage of timely birth dose vaccination.

- → Include standing orders for hepatitis B vaccination of newborns within 24 hours after birth for all deliveries in health facilities or attended by skilled birth attendants.
- → Ensure hepatitis B vaccine is available in the delivery room or postnatal ward for all facility births.
- → Ensure training of birthing staff on the importance and administration of timely hepatitis B vaccination of newborns (within 24 hours of birth).
- → Ensure that hepatitis B vaccination be included in essential postnatal care training.

i Plotkin, SA, Orenstein W, Offit PA, editors. Vaccines. Philadelphia, Saunders Elsevier, 2013;(6th ed.):206.

j Country specific data on hepatitis B (HepB3) immunization coverage among 1-year-olds (%) can be accessed online from the WHO vaccine-preventable diseases monitoring system: http://apps.who.int/immunization_monitoring/globalsummary/

Other effective policies to improve coverage of HepB birth dose to all newborns include:

- → increasing skilled attendance at birth, preferably in health facilities, in national plans for improved maternal and newborn survival;

- → in settings with low rates of childbirth in health facilities, ensure that a home visit takes place within xx time of a home birth and that HepB birth dose is administered during the visit, or that the newborn is brought to a health facility as soon as possible, preferably within 24 hours.

To prevent perinatal transmission and early childhood infections, the hepatitis B vaccination series should be incorporated into every country's immunization schedule. Providing a birth dose of hepatitis B vaccine for all newborns will help prevent many future chronic HBV infections in the country. The need for timely hepatitis B vaccination will provide additional programmatic drive to provide mothers and newborns with health care within the first 24 hours following birth – a critical period when 45% of maternal deaths and neonatal deaths occur.

Annex 4:
Situation analysis checklist

PARTNERS

- Who is the **key person**(s) to work with at MNCH?

- Which **other partners** can assist with HepB-BD? NGOs? WHO? UNICEF?

- Which **civil service/professional organizations** should be engaged? For example, midwife associations? Paediatric/obstetric professional organizations? Private maternal health-care providers?

DATA TO INFORM VACCINATION STRATEGY

- **Proportion** of births that take place in health facilities versus outside facilities ('home births')?
- **Proportion** of births attended by a skilled birth attendant?
- **Proportion** of home births delivered by skilled birth attendant?
- **Proportion** of deliveries that take place in public versus private health facilities?
- Do delivery staff have the **skills** needed and authorization to administer vaccine?
- How many health facilities currently provide vaccination services onsite?

- How are health-care staff being informed of births within the community?

- Who is authorized to give vaccines (doctors, nurses, midwives, birth attendants)?

- What is the experience and coverage of BCG or OPV vaccination at birth?

Potential integration with other activities

- Proportion of women who have at least one antenatal care visit (ANC1)?
- Proportion of newborns who receive postnatal care? At what age? Who conducts newborn visits? Can vaccination be added?
- Initiatives providing outreach for home deliveries? Who conducts them? What services are provided?
- Other mother or newborn interventions administered after birth (e.g. vitamin A, iron, folic acid, BCG)?
- Is any training being planned that has HepB-BD integrated?
- Is there community-based distribution of contraceptives and community-directed interventions for malaria control that may provide an opportunity for integration?

Supply and cold chain

- How will HepB-BD vaccine be provided to health facilities?
- Percent of health facilities that have a functioning cold chain?
- What presentations of monovalent HepB vaccine are already in use? Consider various vial sizes and novel presentations, such as CPAD.
- Can existing cold chain accommodate monovalent HepB vaccine? Is freeze monitoring in place?

Capacity building, supervision, updating

- Who will train delivery staff on birth dose implementation/ how will they be trained?
- How will monitoring/supervision of health facilities be done?
- How will EPI and MNCH protocols and forms be updated?

Annex 5:
Practices to improve coverage of birth-dose vaccine[7]

Service delivery arrangements

- → Increase 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 delivery room or postnatal ward;
  - clear definition of who is to vaccinate, that includes maternal health providers;
  - positioning birth dose vaccination as part of essential newborn care in a way that does not interrupt urgent interventions;
  - 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
- → Where infants are born outside health facilities, considering options such as:
  - home visits to provide timely vaccination;
  - integration of birth dose with home visits for other postnatal care;
  - vaccine transport and storage outside the standard cold chain in a CTC;
  - use of CPADs (e.g. Uniject®);
  - careful community-based pregnancy tracking.

Health workforce considerations

- → Addressing health-care providers' lack of knowledge and particular attitudes and perceptions towards newborn vaccination
- → Well-structured health-worker training, including education on perinatal transmission, backed up by frequent follow-up and supportive supervision
- → Considering options for task-shifting to reach populations difficult to access

Technologies relevant to birth dose

- → Distribution and storage arrangements that utilize the potential for keeping vaccine outside the standard cold chain, positioning it as close to the birth place as possible
- → The potential use of CPAD/Uniject™ by community-based health-care providers
- → 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
- → Incorporation of birth dose and its timing within vaccination records
- → Accurate definition of timely birth dose in coverage reporting
- → Considering options for serosurveys for establishment of need and for monitoring

Financing arrangements influencing birth dose coverage

- → Adequate funding for birth dose programmes, with consideration of transport efficiencies for distribution to the periphery
- → 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
- → Responding to parental refusal of vaccination

Leadership and governance practices

- → A national policy for universal birth dose vaccination
- → Clear national guidance defining timely birth dose as within 24 hours of birth
- → Removing unnecessarily stringent restrictions contraindicating vaccination
- → Considering options for vaccine use in CTC and accrediting new vaccinators
- → Strong central communications to support public confidence in vaccines

Annex 6:
Health-facility hepatitis B birth dose supervisory checklist

HEALTH-FACILITY HEPATITIS B BIRTH DOSE SUPERVISORY CHECKLIST

Instructions: Use this checklist to optimize hepatitis B vaccine birth dose coverage. It can be a stand-alone assessment or key components can be added to a more comprehensive/existing health-facility supervisory checklist.

Abbreviations:
BD=(hepatitis B) birth dose;
HF=health facility;
HCW=health-care worker
SBA=skilled birth attendant

Name of health facility:

Name of supervisor:

Date of visit:

No.	Evaluation Topic	Answer		Potential Actions
HOSPITAL POLICIES AND STANDARD OPERATING PROCEDURES				
1.	Does HF have a policy specifically stating that BD should be given as soon as possible after birth, ideally within 24 hrs?	N	Y	Policy should be created and disseminated to all staff
2.	Does HF have standard operating procedure detailing who is responsible for BD administration, when it should be given, who it should be given to?	N	Y	Standard operating procedure should be created to help clarify roles and responsibilities to staff
3.	If applicable, have BD standing orders been implemented?	N	Y	Standing orders can ensure every newborn is vaccinated
BD ADMINISTRATION				
4.	WHO is responsible for providing BD (e.g. midwife, postpartum nurse, doctor, EPI nurse)?	NA		Responsibility should be clearly assigned, and should be someone who works in the maternity/postnatal unit
5.	Is the HCW responsible for providing BD always available, including evenings/ weekends?	N	Y	The type of HCW should be available all the time to ensure no children are missed
6.	WHEN: Is vaccine given to all newborns within 24 hours of birth?	N	Y	If not, explore reasons
7.	WHEN: Is BD administered at all times, including evenings/weekends?	N	Y	Vaccine should be available all the time
8.	WHERE: Is BD administered (delivery room, nursery, postpartum unit)?			BD should be given in delivery room or postnatal ward
FALSE CONTRAINDICATIONS				
9.	Are premature newborns vaccinated?	N	Y	Educate HCWs that there are no contraindications to vaccination; HCWs may choose to delay vaccination of unstable newborns until they are stable
10.	Are low birth-weight newborns vaccinated?	N	Y	
11.	Do the HCWs believe there are contraindications to vaccination?	N	Y	

No.	Evaluation Topic	Answer		Potential Actions
VACCINE HANDLING, STORAGE, MANAGEMENT				
12.	Is vaccine stored close to the location of administration (e.g. delivery ward, nursery)?	N	Y	Vaccine should be stored as close to the maternity/ newborn ward as possible. If cold chain is not available, consider using a cold box with daily replenishment
13.	Is vaccine accessible at all times (e.g. some health facilities are only accessible when EPI is open)?	N	Y	If vaccine is stored in a room that is only open at certain times, consider storing vaccine in a cold box in the delivery room
14.	Are vaccine stocks sufficient for the target population?	N	Y	Review vaccination ordering
15.	Is the multi-dose vial policy properly followed?	N	Y	Educate staff
16.	Is vaccine stored to avoid freezing (not on top shelf)?	N	Y	Correct placement in fridge
17.	Do staff know how to perform a shake test?	N	Y	If no, educate staff
18.	Is the vaccine stored in a properly working cold chain?	N	Y	Cold chain should be fixed immediately
19.	Is cold-chain temperature properly monitored at least two times daily?	N	Y	Implement temperature monitoring at least twice a day
20.	Are any VVMs in stage 3 or 4, or are any vaccines expired?	N	Y	Remove vials in stage 3/4 or expired vials. Educate HCWs
DATA RECORDING/REPORTING				
21.	Are home-based records (e.g. vaccination cards, mother-child books) given to mothers after receiving BD?	N	Y	Find out reasons why it is not given and stress importance of starting home-based records at birth, and need for mother to keep home-based record (not HCW)
22.	Is BD administration recorded in a registry (e.g. birth registry, EPI registry, hepatitis B log)?	N	Y	Add column to birth registry/provide updated registry
23.	Is date of BD administration recorded?	N	Y	Date should be written. Check marks should not be used
24.	Are all tally sheets/recording/reporting forms updated to contain a column for BD ≤24 hours and BD >24 hours?	N	Y	Provide updated forms, remove old forms
25.	Is data analyzed in each health facility (e.g. monthly coverage chart, monthly report)?	N	Y	Educate HCW on need to review logs monthly to optimize coverage and analyze data by timing of BD
26.	Is data reported monthly to the appropriate person?	N	Y	Ascertain barriers. Educate on proper reporting
27.	What percentage of births in the past month received a BD in ≤24 hours?			Explore reasons why children were not vaccinated and implement corrective action if needed
HOME BIRTHS				
28.	Do SBAs bring BD with them to home deliveries they attend?	N	Y	Educate on importance of timing, need to carry vaccine to home births to avoid missed opportunities
29.	Is BD provided at postnatal care visits for newborns who have not received the vaccine?	N	Y	Educate on importance of timing and need to avoid missed opportunities

No.	Evaluation Topic	Answer		Potential Actions
AEFI				
30.	Does the HF monitor for AEFI?	**N**	**Y**	Educate on AEFI surveillance
31.	Does the HF have a protocol for responding to AEFI?	**N**	**Y**	Protocol should be developed and posted where BD is administered

HEALTH-FACILITY HEPATITIS B BIRTH DOSE SUPERVISORY COMMENTS

Instructions: Use this space to write your overall impressions and specific corrective actions for the health facility to implement based on the findings from your BD supervisory checklist. This form, or these notes, should be left with the health facility.

What are your overall impressions of the hepatitis B birth dose vaccination programme?

What corrective actions do you recommend be implemented?

Annex 7:
Example tally sheet with timely and total birth dose

TALLY SHEET

Region: **Delivery facility:** **Health district:** **Dates covered:**

Vaccines	Vaccination of children			Number of vials opened
	0–11 months	12–23 months	Total	
HepB-BD				
Timely HepB-BD (≤24 hrs)				
>24 hrs *				
BCG				
OPV0				
OPV1				
OPV2				
OPV3				
Rotavirus1				
Rotavirus2				
PCV1				
PCV2				
PCV3				
DTP-HepB-Hib1				
DTP-HepB-Hib2				
DTP-HepB-Hib3				
Measles/Rubella 1				
Measles/Rubella 2				
Yellow Fever				
Completely vaccinated				

* Total birth dose coverage can be calculated by adding doses given ≤24 hours and >24 hours after birth.

Name of Vaccinators

Signature, Date

Annex 8:
Example tally sheet with location of birth

TALLY SHEET

Region: **Delivery facility:** **Health district:** **Dates covered:**

Vaccines	Vaccination of children			Number of vials opened
	Born in a delivery facility	Born at home	Total	
HepB-BD				
Timely HepB-BD (≤24 hrs)				
>24 hrs *				

Vaccines	Vaccination of children			Number of vials opened
	0–11 months	12–23 months	Total	
BCG				
OPV0				
OPV1				
OPV2				
OPV3				
Rotavirus1				
Rotavirus2				
PCV1				
PCV2				
PCV3				
DTP-HepB-Hib1				
DTP-HepB-Hib2				
DTP-HepB-Hib3				
Measles/Rubella 1				
Measles/Rubella 2				
Yellow Fever				
Completely vaccinated				

* Total birth dose coverage can be calculated by adding doses given ≤24 hours and >24 hours after birth.

Name of Vaccinators

Signature, Date

Annex 9:
Example reporting form with number of vaccinated by location

Region:	Month:	District:	Year:	Reporting facility:

1. Demographic Data		
Total Population		A
Infants 0-11 months: annual target		B
Infants 0-11 months: monthly target		C (=B/12)
Expected Pregnancy		D
Expected deliveries: monthly target		E (=D/12)
Children 12-23 months: annual target		
Children 12-23 months: monthly target		

2. Completeness and Timeliness of Reporting	
No. of health facilities in the District	
No. of vaccination posts (Fixed and outreach)	
No. of reports received during the month	
No. of reports received on time during the month	

3. Vaccination Coverage	Delivery Facility Births		Home Births		# of live births this month							
	HepB-BD ≤24 hours	HepB-BD >24 hours	HepB-BD ≤24 hours	HepB-BD ≤24 hours	HepB-BD ≤24 hours	HepB-BD ≤24 hours	BCG	Penta1	Penta3	MCV1	TT2+	PCV3
Monthly Coverage (%)												
Cumulative Coverage (%)												

Drop Out (%) $\frac{\text{Cum (Penta1-Penta3) * 100}}{\text{Penta 1}}$ ☐ $\frac{\text{Cum (BCG-MCV1)* 100}}{\text{Penta 1}}$ ☐

4. Monthly Vaccinations Given by Strategy		Number Given (By age group)			
Vaccine doses		0 - 11 months	12 - 23 months	> 24 months	Total Administered
	BCG				
Delivery Facility Births	HepB-BD ≤24 hours HepB-BD >24 hours				
Home Births	HepB-BD ≤24 hours HepB-BD >24 hours				
	OPV-0				
	OPV-1				
	OPV-2				
	OPV-3				
	Rotavirus - 1				
	Rotavirus - 2				
	Penta-1				
	Penta-2				
	Penta-3				
	PCV-1				
	PCV-2				
	PCV-3				
	Measles - 1				
	Measles - 2				
	LLIN - Children				
	YF				
	Fully Immunized				
		Pregnant Women	Non-Pregnant Women		Others
	TT-1				
	TT-2				
	TT-3				
	TT-4				
	TT-5				
	TT-5+ (Not vaccinated)				
	LLIN - Pregnant Women				
		6-11 months	≥12 months	Post-Partum	
	Vitamin A				

5. Information Education and Communication	
No. of IEC sessions conducted	
No. of participants at sessions	
No. of radio/TV spots conducted	
No. of home visit sessions conducted	

6.AEFI	
No. of cases reported	

7. Waste management
No. of safety boxes used during the month
No. of safety boxes disposed during the month
No. of hub-cutters used during the month
No. of hub-cutters disposed during the month

8. Cold chain temperatures at Health Facilities	
No. of facilities that have reported temp. status	
No. of health facilities with temperature <+2°C	
No. health facilities with temperature >+8°C	
Minimum temperature recorded	
Maximum temperature recorded	

9. Stocks of safe injection equipment	Stock Level		
Safe injection equipment	Beginning	Received	at end
ADS_0.05ml			
ADS_0.5ml			
Sdilution_2ml			
Sdilution_5ml			
Safety boxes			
Hub-cutters			

(aligned with Annex 8 Tally Sheet).

10. Status and utilisation of vaccine stocks and other logistics							
	Stock at district store				Losses due to		No. of vials opened
	Beginning	Received	Issued	stock at end	VVM status (stage 3/4)	Expired	
BCG							
Hepatitis B							
OPV							
Rotavirus							
Penta							
PCV							
Measles/MR							
YF							
TT							
LLIN							
Vit.A (Blue)							
Vit.A (Red)							
Home Based Records							

11. Disease Surveillance								
		AFP	Measles	NNT	Diarrhoea	Yellow fever	Meningitis	Pneumonia
0-11 months	cases							
	deaths							
12-59 months	cases							
	deaths							
5-15 years	cases							
	deaths							
>15 years	cases							
	deaths							
Vaccination status	No. vaccinated							
	No. not vaccinated							
	No. with vacc status unknown							

Remarks

COMPILED BY:

Name:

Designation:

Date:

APPROVED BY:

Name:

Designation:

Date:

Annex 10:
Key information on hepatitis B and HepB vaccine

The following information may be helpful in adapting country-specific HepB information sheets and other communications and training materials for health-care workers.

What is hepatitis B?
Hepatitis B is a serious liver disease caused by the hepatitis B virus (HBV), which is present in the blood and body fluids of infected individuals. After a person is first infected, HBV can cause a short-term (acute) illness that leads to:

- → loss of appetite;
- → nausea;
- → tiredness;
- → pain in muscles, joints or stomach;
- → diarrhoea and vomiting;
- → jaundice (yellow skin or eyes);
- → dark urine.

HBV can cause a long-term (chronic) infection that can be undetected for decades before it leads to:

- → permanent liver damage (cirrhosis);
- → liver cancer;
- → death.

HEPATITIS B INFECTION IS NOT THE SAME AS HIB DISEASE

Why is hepatitis B a public-health problem?
HBV infection is a major cause of acute and chronic liver disease. Most of the serious consequences of HBV infection occur among persons who develop chronic infection – an estimated 240 million people worldwide have chronic HBV infection. About a million persons with chronic HBV infection die each year from liver damage (cirrhosis) and liver cancer. HBV is second only to tobacco as a cause of cancer in humans.

Who can get hepatitis B? Who is most at risk?
Anyone can get hepatitis B but newborns, infants and young children are most at risk. Infants and young children do not usually become sick when they first become infected but they often develop long-term (chronic) infection with HBV. Chronically-infected persons are at high risk of dying from cirrhosis and liver cancer.

How is HBV spread?

HBV is a bloodborne virus that is up to 100 times more infectious than HIV. It is spread efficiently by both skin puncture and mucous membrane contact with blood and other infectious body fluids (e.g. skin sore secretions, semen, vaginal fluid).
HBV is NOT spread through the air or by food or water.
The main ways in which HBV is spread are:

- → from mother to baby at birth;
- → through close contact with an infected person – including child-to-child or adult-to-child.
- → through unsafe injections and transfusions;
- → through unprotected sex with an infected person.

Is there a cure for hepatitis B?
There is no cure for hepatitis B; this is why prevention is so important. Hepatitis B vaccine is the best protection against HBV infection.

How can hepatitis B be prevented?
Universal childhood immunization with at least three doses of hepatitis B vaccine is the most effective way to prevent HBV infection. Clinical trials have established that vaccine given within 24 hours after birth, followed by at least two more doses, is effective at preventing perinatal HBV infection and inducing immunity to HBV. Hepatitis B vaccine is effective in preventing HBV infections if given either before, or shortly after, exposure to the virus.

Who should get hepatitis B vaccine?
All newborn infants should receive HepB vaccine, ideally within 24 hours after birth, to prevent perinatal transmission of hepatitis B. Adults at high-risk for HBV infection (such as health-care workers, sex workers, injection drug users, frequent recipients of blood/plasma transfusions and any other groups coming in regular contact with blood and blood products) could also benefit from vaccination.

How many doses of HepB are needed? When should they be given?
WHO recommends a hepatitis B vaccination schedule of a birth dose within 24 hours of delivery, followed by two or three subsequent doses with a minimum interval of four weeks between doses. All the doses must be given to ensure long-term protection.

- → To prevent the spread of HBV from an infected mother to her baby, the first dose must be given as close as possible to birth, preferably within 24 hours.
- → HepB birth dose should still be given on first possible contact, even if more than 24 hours after birth.
- → After birth, doses are usually given at the same time as DTP, polio and Hib vaccines.
- → If a dose is missed it should be given as soon as possible. There is no need to start the schedule again.
- → Booster doses are not needed.

Why is timing of the HepB birth dose so important?
Administration of a timely birth dose (within 24 hours after birth) is critical to prevent mother-to-child transmission of HBV. For children born to infected mothers, post-exposure prevention with hepatitis B vaccine within 24 hours of birth dramatically reduces the risk of infection for the infant.

The birth dose should ideally be given within 24 hours of birth, as the earlier the vaccine is given the more likely it is that infection will be prevented. However, if not given at birth, the birth dose should be administered on first possible postnatal contact and recorded as a BD >24 hours.

How is HepB vaccine given? What is the size of a dose?
- → Hepatitis B vaccine is given by injection in the thigh (infants) or arm (older children).
- → It should NOT be given in the buttock.
- → Each dose is 0.5 ml.
- → It can be given safely at the same time as all other vaccines.

If hepatitis B vaccine is given on the same day as another injectable vaccine, it should be administered at another injection site. If more than one injection must be given in the same limb, the thigh is the preferred site of injection because of the greater muscle mass, and the injections should be separated by 2.5–5 cm so that any local reactions are unlikely to overlap. Ask your supervisor what the recommended injection site is for each vaccine.

What are the side-effects of hepatitis B vaccine?
Hepatitis B vaccine is very safe. The most common side-effects are redness, swelling or pain where the injection has been given. About one in every 11 children vaccinated is affected by such side-effects. These usually start within a day after the vaccine has been given and last for between one and three days. Less commonly, fever may occur for a short time after the vaccine has been administered – about one in every 14 vaccinated children is affected.

Serious allergic reactions to the vaccine (hives, difficulty in breathing, shock) are rare (about one in every 600 000 vaccinated children).

Data do not indicate a causal association between hepatitis B vaccine and Guillain– Barré syndrome or demyelinating disorders, including multiple sclerosis, nor are there any epidemiological data to support a causal association between hepatitis B vaccination and chronic fatigue syndrome, arthritis, autoimmune disorders, asthma, sudden infant death syndrome or diabetes. WHO's Global Advisory Committee on Vaccine Safety (GACVS) has confirmed the excellent safety profile of hepatitis B vaccine.

The early postnatal period is a fragile time and, in many developing countries, neonatal mortality remains high for various reasons. Over half of neonatal deaths occur within the first 24 hours of life, increasing the likelihood of a coincidental association between birth dose vaccination and neonatal complications, or death due to other causes. It is effective to train health-care providers to be able to answer questions about vaccine safety and address concerns about coincidental AEFIs.

Is there any reason why a child should not be given hepatitis B vaccine?
There are no contraindications for timely hepatitis B birth dose vaccination.

The ONLY contraindication for hepatitis B vaccination is for individuals that have had a severe reaction to a previous dose of hepatitis B vaccine or those with a history of allergic reactions to any of the vaccine's components (particularly to yeast).

Low birth weight, premature delivery, Caesarean sections and HIV infection are NOT contraindications for the administration of the vaccine. However, the timing of vaccine administration should not interfere with treatment of any urgent neonatal care, and should be given only after the baby is stable.

Do older children need hepatitis B vaccine?
In countries where chronic HBV infection is highly endemic, almost all chronic HBV infections are acquired among infants

and young children. In these countries, vaccination of older children is not generally needed. In countries of lower endemicity, the majority of chronic HBV infections are in adolescents and adults, and catch-up vaccination for older age-groups could be considered, depending on when HepB was introduced into the routine immunization programme.

How should hepatitis B vaccine be stored?
Hepatitis B vaccine should be stored between +2 ˚C and +8 ˚C.

> **DO NOT FREEZE the vaccine.**
> **If hepatitis B vaccine is frozen, discard it.**

How does the multi-dose vial policy apply?
In fixed health facilities, opened multi-dose vials of hepatitis B vaccine may be reused, in the next immunization sessions, for up to four weeks (28 days) if all the following conditions are met:

- → the expiry date has not passed;
- → the vial has been kept at recommended temperatures (between +2 ˚C and +8 ˚C);
- → the part of the vaccine vial where the needle is put in to withdraw doses has not been put under water (note: to prevent this from happening, well-sealed ice packs should be used in vaccine carriers and water should not be allowed to accumulate where vials are stored);
- → an aseptic technique has been used to withdraw all doses;
- → the VVM, if attached, has not reached the discard point.

For home births or in outreach sessions, opened multi-dose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks, if:

- → all the conditions for reuse of multi-dose vials in fixed health facilities are met;
- → a VVM is attached to the vial.

What injection equipment is needed?
The injection equipment used for hepatitis B vaccine is of the same type as that used for all other EPI vaccines (except BCG vaccine).

- → Sterile injection equipment is essential for all injections.
- → 0.5 ml auto-disable (AD) injection devices are recommended as the first choice (see WHO/V&B/99.25).

Whichever type of syringe is used, a 25 mm, 22- or 23-gauge needle is recommended.

Used needles and syringes must be sterilized, or disposed of, in accordance with national policy.

Can HepB in a CPAD (e.g. Uniject™) be used to improve the coverage of HepB-BD?
Yes. In comparison to the traditional use of a mono-dose vial and syringe, a CPAD or Uniject™ can offer a number of advantages in certain settings. A range of qualitative studies with health workers and parents consistently report that the device is easy to use, and that there is a high level of confidence in it, as communicated by both the user and recipient (or caretaker).

Designed specifically for low-resource settings, including places where children are born at home rather than in a hospital, CPAD technology can facilitate the safe and easy delivery of HepB vaccine in these settings. In addition, CPAD is smaller and faster than using a regular syringe, and makes the injection process easier, faster, and safer for the vaccinator. In certain countries, HepB-BD is delivered in CPAD by trained community health workers. For example, HepB-BD has been provided in Indonesia in CPAD since 1995, and has delivered millions of doses since its introduction.

YOUR NOTES

YOUR NOTES

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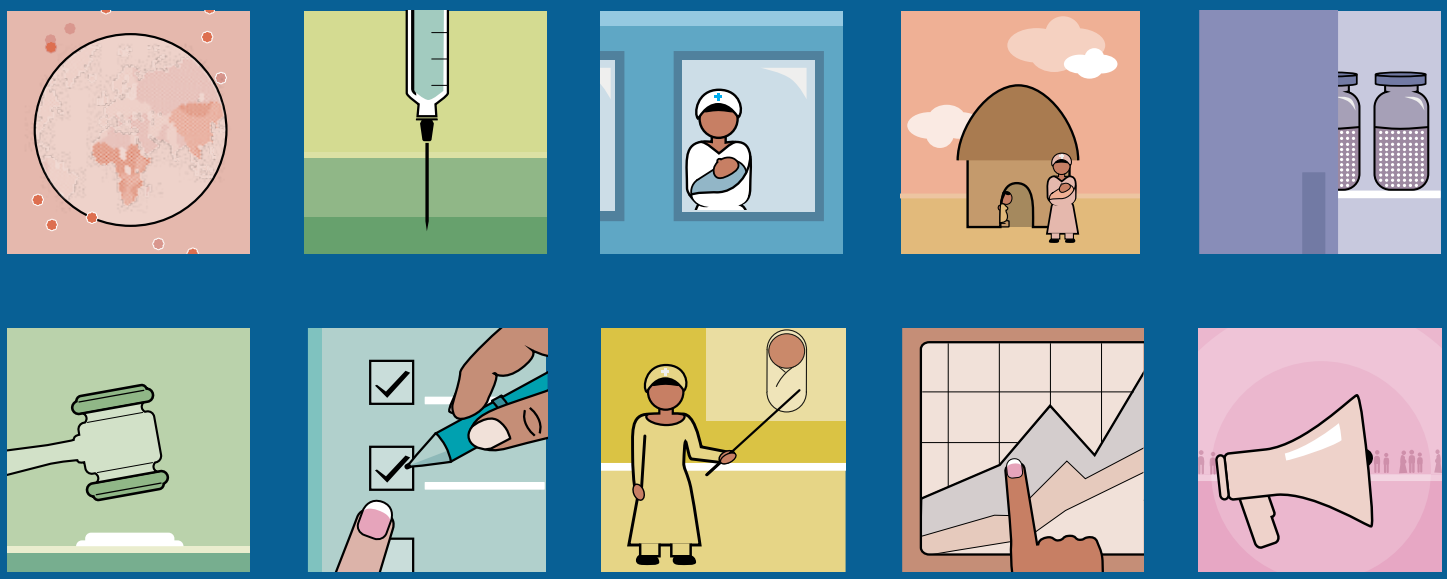

This document is intended for use by national immunization programme managers, maternal neonatal and child health (MNCH) professionals, and immunization partners involved with operationalizing hepatitis B birth dose (HepB-BD) introduction or strengthening an existing HepB-BD programme. It highlights considerations and approaches for providing universal HepB-BD vaccination as part of a national immunization schedule.

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