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# Hepatitis B Vaccine Introduction

## Lessons Learned in Advocacy, Communication, and Training

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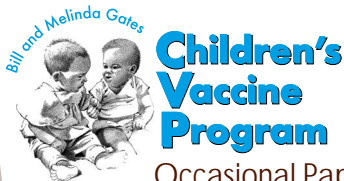
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Hepatitis B is a killer, taking the lives of 900,000 people each year.<sup>2</sup> This disease is especially dangerous for infants, since those who are infected when young may carry the infection for the rest of their lives, often without knowing it. Chronic carriers can infect others and are themselves at risk of serious liver disease later in life, including cirrhosis and liver cancer.<sup>2</sup>

Fortunately hepatitis B vaccine, if provided to infants, helps protect them against these problems. In effect, it is the world's first anticancer vaccine. Due to the seriousness of hepatitis B disease, and because of the high effectiveness and safety of the vaccine, the World Health Organization (WHO) recommends that it be given to all children worldwide.<sup>4</sup> A recent WHO "aide-memoire" on hepatitis B is included at the end of this paper.

The hepatitis B vaccine has been available for decades, but introduction into the developing world only began in the late 1980s. Currently more than 100 countries routinely provide the vaccine, but many still cannot afford to do so. The partner agencies of the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund for Children's Vaccines are working to change this situation.<sup>5</sup>

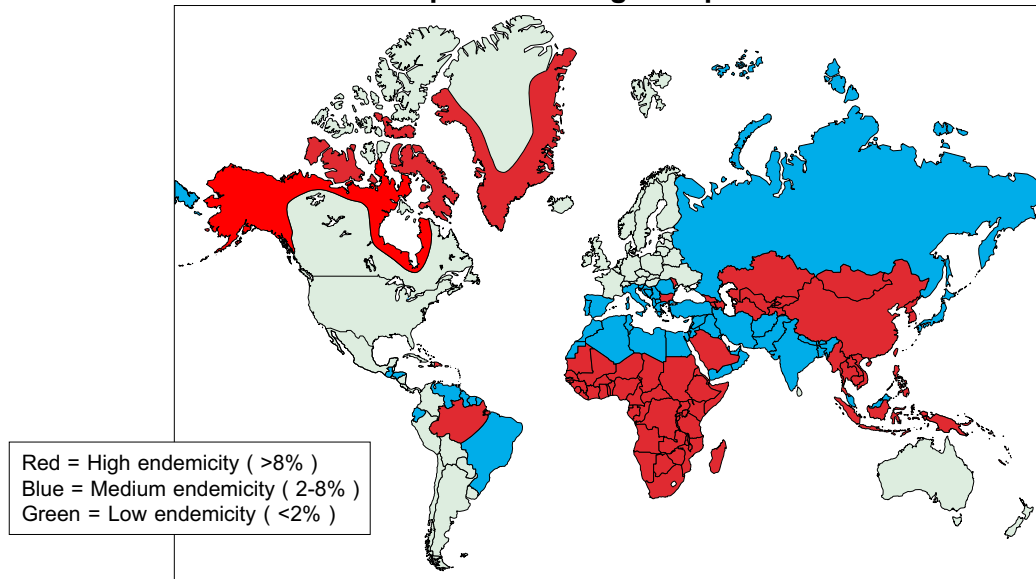
The lessons shared in this paper are the result of over ten years of experience in hepatitis B vaccine introduction worldwide. PATH (Program for Appropriate Technology in Health) worked on some of the earliest introduction programs in Asia and Africa under the aegis of the International Task Force on Hepatitis B Immunization. One key result of the first developing-world programs was a significant reduction in the cost of hepatitis B vaccine, from \$20 to \$30 per pediatric dose to less than \$1 per dose. Another benefit was experience gained in the best ways to introduce hepatitis B vaccine into national immunization programs. This paper focuses on lessons learned about effective advocacy with decision makers, communication with parents and caretakers, and training health staff regarding hepatitis B.



Occasional Paper #4  
January 2001

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## Hepatitis B is a global problem



### Communication strategies for effective vaccine introduction

Before addressing issues specific to hepatitis B, we would like to share some suggestions for general approaches to new vaccine introduction:

- **Bring in the experts.** Strategic use of local and global hepatitis B experts can make a world of difference when educating decision makers about the need for hepatitis B immunization. GAVI can help you identify the right people for the job.
- **Plan ahead.** Introduction of a new vaccine affects many aspects of the health care system, including service delivery policies and vaccine procurement and logistics. Changes in any of these areas can impact communication and training strategies and messages, so begin thinking about communication issues early on, and be sure to coordinate with colleagues focusing on other aspects of the program.
- **Anticipate misinformation, confusion, and negative reactions** whenever introducing something new. People often are resistant to change—it will take time to win over the “late acceptors” and to respond to the questions and concerns of all relevant staff.
- **Coordinate messages and materials for key audiences: decision makers, health care providers, and parents.** Advocacy, communication, and training activities benefit from a consistent and coordinated approach.
- **Always use “best communications practices”** when designing and implementing your program. This includes incorporating strategic

communications planning from the first stages of the program, always using audience research to guide message and product design, and always pretesting materials prior to production and distribution. Try using qualitative research methods to better understand, and influence, provider and consumer knowledge, beliefs, and behaviors.

- **Focus on improving communication between providers and consumers first**, then use other media to support those interpersonal efforts. Parents report that their most reliable source of information about immunization is their health care provider<sup>6</sup>, so it is important that providers be able to accurately describe hepatitis B, the vaccine, and the importance of immunizing children.

## Lessons specific to hepatitis B advocacy, communication, and training

Through the years PATH has learned a number of lessons specific to communication aspects of hepatitis B introduction. By being alert to these issues, we have been able to avoid some potential pitfalls and make the overall advocacy, communication, and training process more effective.

### 1. Hepatitis B can be a confusing subject for decision makers, providers, and the public.

- People are often confused about the differences between hepatitis B and other forms of hepatitis.
- They are also confused about jaundice. It is important to avoid implying that jaundice is caused only by hepatitis B. For example, it is misleading to say, “Hepatitis B vaccination prevents jaundice,” when, in fact, hepatitis B vaccination only prevents jaundice caused by hepatitis B.
- Hepatitis B can cause liver cancer many years after the child is infected; for this reason it sometimes is not considered a disease of children. This situation can make it more difficult for parents to see the benefits of infant immunization.
- Hepatitis B is transmitted in different ways in different places. In some countries, hepatitis B usually is transmitted to children when they are very young. But in other countries infection more often occurs later in life, causing parents to question the necessity of immunizing a young child.



Coordinated training and educational materials and messages for vaccinators, outreach workers, and parents, can dramatically increase program impact.

When resources are limited, concentrate on providing high-quality reference materials and training for doctors, nurses, vaccinators, and outreach workers.

- There can be confusion about whether adults need to be immunized in addition to children. The answer depends on evaluation of specific risk in the area—adult immunization makes sense in some countries, but not in others.
- Rumors abound related to the safety and efficacy of various hepatitis B vaccines. Sometimes misinformation is spread by those who may profit from it.
- Some health care providers are not aware that WHO currently recommends that all infants receive hepatitis B vaccine.

**2. Use every opportunity to educate providers about hepatitis B.** How to most effectively do that depends on your situation.

- In Lombok, Indonesia, the government experimented with new systems for birth reporting and for delivery of hepatitis B vaccine within the first week of life. Due to changes in the roles and responsibilities of various staff, special training was required throughout the project area.
- But in the Philippines, fewer systemic changes were envisioned, so extra training sessions were not needed. Instead, the Department of Health made sure that hepatitis B information was disseminated through in-house publications, and that it was discussed at staff meetings and regional and national conferences. Staff training curricula were updated as well.

**3. Design materials based on audience needs.**

- In Lombok, audience research revealed that parents tended to have lower levels of education and that they held many traditional (non-medical) beliefs about disease causation. Taking this into account, the introduction team decided to keep educational messages simple and to focus primarily on parental behavior (such as how many times to take the child for immunization) more than on scientific information about the disease or vaccine. In general this strategy worked well since all parents learned how to get their children immunized. Parents who had more complicated questions could get additional information from their doctors.
- In Thailand, parents were more knowledgeable, so materials were designed to address more sophisticated questions. One special situation: many providers and consumers in Thailand were confused about the

need for adult vaccination. Because most teenagers and adults in that country have already been exposed to the hepatitis B virus, adult and teen vaccination does not provide much benefit. Helping parents and providers understand this became a key communication goal for the program.

**4. Evaluations in Indonesia and Thailand showed that mass distribution of expensive printed materials for parents was not cost-effective.**

- When resources are limited, concentrate on providing high-quality reference materials and training for doctors, nurses, vaccinators, and outreach workers.
- If you find that give-away materials for parents are necessary, try to develop good quality flyers instead of colorful booklets. They are less expensive to print and distribute.

## Hope for the future

In the decade since the first Task Force programs, many countries have found ways to integrate hepatitis B immunization into their national programs. Botswana, China, Egypt, Indonesia, Philippines, Thailand, Tunisia, South Africa, and Zimbabwe are among the developing world nations that now routinely protect their children against hepatitis B.<sup>7</sup> With assistance from the GAVI partner agencies and the Global Fund for Children’s Vaccines, more than 30 additional countries now are beginning introductory efforts.

There is one additional, and crucially important, opportunity that the GAVI partners must not let slip away: now is the time to give the “Polio Troops” a new mission in countries where National Immunization Days are phasing out. No one has been more successful than the Polio Eradication Initiative in mobilizing communities for health. Now that polio eradication efforts are winding down in many areas, staff and volunteers can broaden their efforts, focusing on improving routine immunization and other primary health care programs.

With the attention of so many interested parties focused on improving access to childhood vaccines like hepatitis B and *Haemophilus influenzae* type B (Hib), and with broadened partnership at the country level, it is clear that we can win the battle against these killer diseases.



Keep messages simple when communicating with less-educated audiences. A key message for parents in Lombok was to visit the clinic a total of five times to fully immunize each child.

# World Health Organization

## AIDE-MEMOIRE

### Introducing hepatitis B vaccine into national immunization programmes<sup>8</sup>

## Hepatitis B Immunization

#### Background

Hepatitis B (HepB) is a major public health problem worldwide. Approximately 30% of the world's population, or about 2 billion persons, have serologic evidence of hepatitis B virus (HBV) infection. Of these, an estimated 350 million have chronic HBV infection and at least one million chronically infected persons die each year from liver cancer and cirrhosis. HBV is second only to tobacco as a known human carcinogen.

A safe and effective vaccine against HepB has been available for nearly 20 years. HepB vaccine is effective in preventing HBV infections when it is given either before exposure or shortly after exposure. At least 85%-90% of HBV-associated deaths are vaccine-preventable.

WHO recommends that HepB vaccine be included in routine infant immunization programmes in all countries. This document provides an outline of information needed to implement a national decision to introduce HepB vaccine, with a particular focus on issues relevant to countries applying for support for the introduction of HepB vaccine from the Global Fund for Children's Vaccines (GFCV).

#### Objectives

The primary objective of routine infant HepB immunization is to prevent the early childhood infections which result in chronic liver disease later in life. By preventing chronic HBV infection, this strategy also serves to reduce the major reservoir for transmission of new infections.

#### Immunization Strategies

**Routine Infant Immunization.** Immunization of all infants as an integral part of the national immunization programme is the highest priority in all countries. Additional immunization strategies that should be considered depending on the epidemiology of HBV transmission in a particular country are:

- **Prevention of perinatal HBV transmission.** In order to prevent HBV transmission from mother to infant, the first dose of HepB vaccine needs to be given as soon as possible after birth (preferably within 24 hours). In countries where a high proportion of chronic infections are acquired perinatally (e.g., SE Asia), a birth dose should be given to infants when feasible. It is usually most feasible to give HepB vaccine at birth when infants are born in hospitals. Efforts should also be made in these countries to give HepB vaccine as soon as possible after delivery to infants delivered at home. In countries where a lower proportion of chronic infections is acquired perinatally (e.g., Africa), the highest priority is to achieve high DTP3 and HepB3 vaccine coverage among infants. In these countries, use of a birth dose may also be considered after disease burden, cost-effectiveness, and feasibility are evaluated.
- **Catch-up vaccination of older persons.** (Note: The GFCV does not provide vaccine for catch-up vaccination). In countries with a high endemicity of HBV infection (hepatitis B surface antigen [HBsAg] prevalence  $\geq 8\%$ ), catch-up immunization is not usually recommended because most chronic infections are acquired among children  $< 5$  years of age, and thus, routine infant vaccination will rapidly reduce HBV transmission. In countries with lower HBV endemicity, a higher proportion of chronic infections may be acquired among older children, adolescents and adults; catch-up immunization for these groups may be considered.

#### Vaccine Formulations

HepB vaccine is available in monovalent formulations that protect only against HepB and also in combination formulations that protect against HepB and other diseases.

**Monovalent** HepB vaccines:

- can be used for any dose in the HepB vaccine schedule;
- *must be used* for vaccination at birth.

**Combination** vaccines that include HepB vaccine:

- can be used *any time all of the antigens in the combination vaccine are indicated* by the schedule;
- *cannot be used before 6 weeks of age* (because DTP and Hib immunogenicity are reduced if given before this age); thus, combination vaccines *cannot be used* to administer the birth dose of HepB vaccine.

#### Schedule

HepB vaccine schedules are very flexible; thus, there are multiple options for adding the vaccine to existing national immunization schedules without requiring additional visits for vaccination.

#### Options for Adding Hepatitis B Vaccine to Immunization Schedules

Age	EPI Visit	Hepatitis B Vaccine Options						
		Other Antigens		No Birth Dose			With Birth Dose	
Birth	0	BCG	OPV0	I	II	III	HepB†	HepB†
6 weeks	1	OPV1	DTP1	HepB*			HepB†	HepB‡
10 weeks	2	OPV2	DTP2	HepB*				HepB‡
14 weeks	3	OPV3	DTP3	HepB*			HepB†	HepB‡
9-12 months	4	Measles						

\*monovalent or combination vaccine

†monovalent vaccine

‡combination vaccine

Programmatically, it is easiest if the 3 doses HepB vaccine are given at the same time as the 3 doses of DTP (Option 1). This schedule will prevent infections acquired during early childhood, which account for most of the HBV-related disease burden in high endemic countries, and also will prevent infections acquired later in life. However, this schedule will not prevent perinatal HBV infections because it does not include a dose of HepB vaccine at birth. Two schedule options can be used to prevent perinatal HBV infections: a 3-dose schedule of monovalent HepB vaccine, with the 1<sup>st</sup> dose given at birth and the 2<sup>nd</sup> and 3<sup>rd</sup> doses given at the same time as the 1<sup>st</sup> and 3<sup>rd</sup> doses of DTP vaccine (Option 2); and a 4-dose schedule in which a birth dose of monovalent HepB vaccine is followed by 3 doses of a combination vaccine (e.g., DTP-HepB)(Option 3). The 3-dose schedule (Option 2) is less expensive, but is more complicated to administer, because infants receive different vaccines at the 2<sup>nd</sup> EPI visit than at the 1<sup>st</sup> and 3<sup>rd</sup> visits. The 4-dose schedule (Option 3) is easier to administer programmatically, but is more costly, and vaccine supply issues may make it unfeasible.

#### Administration

HepB vaccine is given by intramuscular injection in the anterolateral aspect of the thigh (infants) or deltoid muscle (older children). It can safely be given at the same time as other vaccines, such as DTP, Hib, measles, OPV, BCG, and yellow fever vaccines. If more than one injection is given at the same time, separate injection sites should be used.

# World Health Organization

## Injection Equipment

The injection equipment for HepB vaccine is the same type as that for DTP or Hib:

- 0.5 ml (if AD), 1.0 ml or 2.0 ml syringe
- 25 mm, 22 or 23 gauge needle

Sterile autodisable (AD) injection devices are recommended.

## Dosage

The standard pediatric dose is 0.5 ml.

## Vaccine Procurement

In most countries, GFCV-funded HepB vaccine will be supplied through the UNICEF procurement mechanism. The number of HepB vaccine doses required is estimated using the size of the birth cohort, the coverage rate for DTP and the number of doses in the immunization schedule. These calculations should also include wastage and the size of the reserve stock.

## Presentation

HepB vaccines are generally available as a liquid in single-dose and multi-dose glass vials. Multi-dose vials of monovalent HepB vaccines generally contain 2, 6, or 10 doses. Multi-dose vials of DTP-HepB vaccine contain 2 doses.

## Storage and Shipping Volume

The total storage volume for other EPI vaccines (BCG, DTP, measles, OPV, TT) is about 11.0 cm<sup>3</sup> per dose. Storage volumes (vial plus packet containing vial plus other packaging) for HepB vaccines supplied through UNICEF are:

Vaccine	Packed volume per dose cm <sup>3</sup>			
	1 dose vials	2 dose vials	6 dose vials	10 dose vials
HepB monovalent	9.7	4.8	3.2	3.0
HepB + DTP (packaged together)	—	41.2	—	8.2
DTP-HepB (combined)	—	—	—	3.0
DTP-HepB-Hib	—	9.7	—	—

## Cold Chain Issues

The storage temperature for HepB vaccine is the same as for DTP vaccine, from 2 °C to 8 °C. *HepB vaccine should never be frozen.* If frozen, HepB vaccine loses its potency.

Adding HepB vaccine to the national immunization programme will require cold chain assessments at all administrative levels:

- to assure adequate storage capacity is available, and
- to assure policies and procedures are in place to prevent freezing of HepB vaccine.

## Reducing Vaccine Wastage

Reducing vaccine wastage becomes increasingly important as the costs of vaccines rise. An important strategy to reduce wastage is to monitor wastage rates. Monitoring increases ordering accuracy and reduces wastage by providing reliable data for estimating the number and size of vials to be ordered. It also serves as a tool for improving the practices of health centres when wastage rates are found to be unacceptably high.

Other strategies to reduce vaccine wastage include:

- careful planning of vaccine ordering and distribution;
- implementation of WHO's multi-dose vial policy. (Vaccine vial monitors will be provided on all HepB vaccines supplied through UNICEF, which will facilitate implementing this policy);
- appropriate use of single-dose and multi-dose vials;
- careful maintenance of the cold chain;
- attention to vaccine security; and
- reducing missed opportunities for vaccination.

## Injection Safety

HepB vaccine procured through the GFCV will be supplied together with autodisable (AD) syringes and safety boxes. Managers at each level are responsible for ensuring that adequate supplies are available at all times so that each injection is given with a sterile injection device. Attention should also be given to proper use and disposal of safety boxes to collect these materials.

## Revision of EPI Forms and Materials

An important element of integrating HepB vaccine into national immunization programmes is to revise training and informational materials, forms used to monitor and evaluate the programme, and vaccination cards.

## Information, Education, and Communication Needs

When introducing HepB vaccine into national immunization programmes, information, education and communication (IEC) efforts are important in order to generate support and commitment for the new vaccine and to assure that the vaccine is appropriately handled and administered. The primary target audiences for IEC efforts are decision makers/opinion leaders, health care staff, and the general public (including parents).

## What information is needed to assess HepB disease burden?

Adequate seroprevalence data needed to assess HepB disease burden are generally available in all countries, or from adjacent countries with similar HBV endemicity. Thus, additional seroprevalence studies are usually not needed.

## How should HepB vaccine be phased into the existing infant immunization programme?

A strategy in which HepB vaccine is given to infants who have not yet completed the DTP vaccine series at the time HepB vaccine is introduced is generally the most feasible to implement.

## Which type of HepB vaccine is most suitable?

The following issues should be considered when planning for the procurement of HepB vaccine: the existing immunization schedule and planned HepB vaccine schedule, including whether a birth dose is recommended; impact on cold chain capacity; the proper mix of single/multi-dose vials; the number of injections per visit; vaccine security; impact on local vaccine production; and cost. Use of combination vaccines (e.g., DTP-HepB vaccine) may offer certain programmatic advantages. These include:

- a decrease in the number of injections required per visit (and thus decrease the number of AD needles and syringes required); and
- a decrease in the amount of space required for cold chain storage and transport.

## How can the addition of HepB vaccine be used to strengthen the national immunization programme?

The introduction of HepB vaccine should be used as an opportunity to strengthen the existing national immunization programme. Programme elements that need particular attention include stock management, reducing vaccine wastage, and injection safety.

## Budgeting for HepB vaccine introduction

Capital and recurrent costs related to the introduction of HepB vaccine should be estimated and included in the annual EPI budget. Additional capital costs might include investment in cold chain equipment and information campaigns targeted to the general public. Additional recurrent costs include vaccines, AD syringes, training, cold chain maintenance, safe disposal of waste, and evaluation of program impact.

## Endnotes

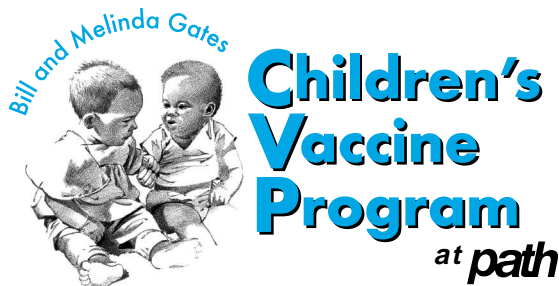
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7. WHO, 2000. A map of countries routinely providing hepatitis B vaccine can be found at [www.who.int/vaccines-surveillance/graphics/htmls/hepb.htm](http://www.who.int/vaccines-surveillance/graphics/htmls/hepb.htm)
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This paper was originally presented at the GAVI Partners' Meeting, Noordwijk, Netherlands, Nov. 21, 2000.

For further information about hepatitis B and immunization programs, visit the "Resource Center" of the Bill and Melinda Gates Children's Vaccine Program at PATH website: [www.ChildrensVaccine.org](http://www.ChildrensVaccine.org)

If you do not have web access, contact the Gates CVP at PATH by mail:  
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