सत्यमेव जयते

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन
(2005-2012)

OPERATIONAL GUIDELINES

for Hepatitis B Vaccine introduction in the Universal Immunization Program

Ministry of Health & Family Welfare
Government of India

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Suggestions for improving or enhancing the Operational Guidelines for Hepatitis B vaccine in the Universal Immunization Programme are always welcome and encouraged.

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Abbreviations

ADS	Auto Disable Syringe
AEFI	Adverse Events Following Immunization
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
CHC	Community Health Centre
DNA	Deoxyribonucleic acid
DPT	Diphtheria, Pertussis, Tetanus Vaccine
EPI	Expanded Program on Immunization
GAVI Alliance	Global Alliance for Vaccines and Immunization
GoI	Government of India
HBcAg	Hepatitis B Core Antigen
HBeAg	Hepatitis B *e* Antigen
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
Hib Vaccine	Haemophilus Influenzae type b Vaccine
HIV	Human Immunodeficiency Virus
ILR	Ice Lined Refrigerator
IPC	Interpersonal Communication
MOI/c	Medical Officer In charge
NGO	Non Governmental Organization
OPV	Oral Polio Vaccine
Pentavalent	Pentavalent (DPT+HepB+ Hib) vaccine
PHC	Primary Health Centre
TT	Tetanus Toxoid
UIP	Universal Immunization Programme
UNICEF	United Nations' Children's Fund
VVM	Vaccine Vial Monitor
WHO	World Health Organization

Target Audience

These guidelines are meant to assist immunization programme managers at state, district and sub-district levels in introducing hepatitis B vaccine into immunization programmes. The intention is to provide information that is practical as well as technically and operationally sound.

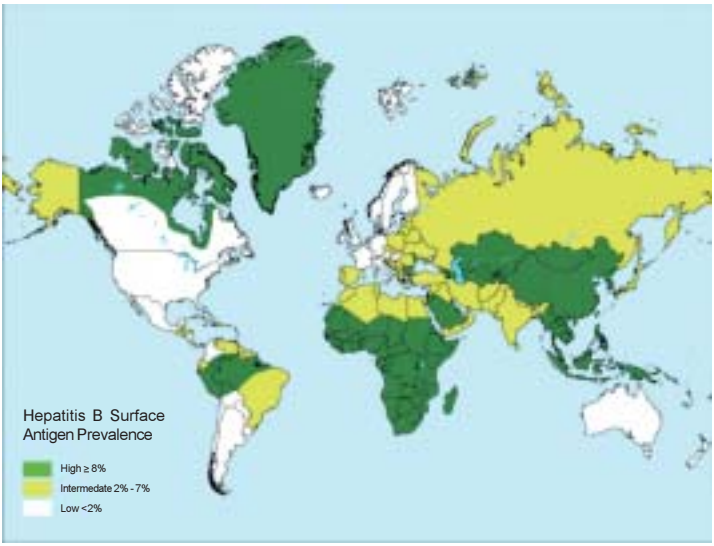
HEPATITIS B DISEASE AND VACCINE

Background

Hepatitis B is a major public health problem worldwide. Approximately 30% of the world's population, or about 200 Crore (2 billion) persons, are estimated to be infected with Hepatitis B Virus (HBV). Of these, an estimated 36 crore (360 million) have chronic HBV infection and are at the risk of serious illness and death from liver cirrhosis and Hepato Cellular Carcinoma (liver cancer); diseases that are estimated to cause about 5,00,000 - 7,00,000 deaths each year worldwide.

Safe and effective vaccine is available against hepatitis B since 1982. The World Health Organization (WHO) recommends that routine vaccination of all infants against HBV infection should become an integral part of national immunization schedules worldwide. High coverage with the primary vaccine series among infants has the greatest impact on the prevalence of chronic HBV infection in children.

In the fourteenth meeting of Global Advisory Group (GAG) on Expanded Program on Immunization (EPI) 1991, it was recommended that hepatitis B vaccine should be an integral part of national immunization programmes worldwide by 1997 and this decision was reaffirmed in the 45th World Health Assembly (1992). As of end of 2008, 177 countries have fully included and 2 countries have partially included this vaccine in their national immunization programmes. In countries that have implemented universal childhood hepatitis B vaccination, chronic HBV infection and incidence rates of long-term complications like liver cancer have declined markedly.



Prevalence of chronic infection with hepatitis B virus, by country, 2006 (CDC)

In India, the available data indicate that the country has intermediate endemicity of hepatitis B, with prevalence of Hepatitis B Surface Antigen (HBsAg) between 2% and 10% among several populations studied. The number of HBsAg carriers in India has been estimated to be over 4 crore (40 million). About 15-25% of HBsAg carriers are likely to suffer from cirrhosis and liver cancer and may die prematurely. Infections occurring during infancy and childhood have the greatest risk of becoming chronic. Of the 2.6 crore (26 million) infants born every year in India, approximately 10 lakh (1 million) run the life-time risk of developing chronic HBV infection. The hepatitis B vaccine, as part of the Universal Immunization Programme (UIP), would prevent these chronic infections, and hence Government of India is including the vaccine in the UIP.

Hepatitis B Virus

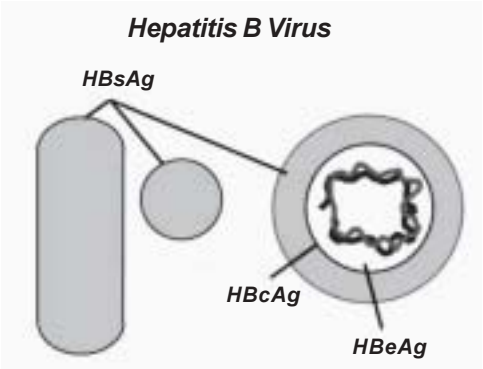


Diagram showing empty non infectious surface antigen particles and infectious HBV particle with core

HBV is a 42nm partially double stranded DNA virus, belonging to family Hepadnaviridae, and is composed of a nucleocapsid core (core antigen or HBcAg), surrounded by an outer lipoprotein coat (surface antigen or HBsAg). Surface antigen (HBsAg) is produced in vast excess and is found in the blood of the infected person as filamentous or spherical particles (without core) having a mean diameter of 22nm. During rapid replication a core related protein(*e* antigen or HBeAg) is produced not incorporated into the virion but secreted out into the serum. HBV is found in all body fluids. HBV-related acute and chronic liver disease is one of the major causes of infectious disease-related mortality worldwide.

Humans are the only known natural host for HBV, although some non-human primates have been infected in laboratory conditions. HBV is relatively resilient and, in some instances, has been shown to remain infectious on environmental surfaces for about a week at room temperature.

HBV contains numerous antigenic components, including surface antigen on the lipoprotein coat (HBsAg), Hepatitis B core antigen (HBcAg), and Hepatitis B *e* antigen (HBeAg).

Several well-defined antigen-antibody systems are associated with HBV infection as shown in the table below.

Antigen or Antibody	Presence in serum	Inference
HBsAg (Australia antigen, Surface antigen on the outer lipoprotein coat)	Yes, 30-60 days after exposure	Infection and infectivity
HBcAg (Core antigen)	Difficult to detect. Detected in the liver tissue with acute or chronic infection	Infection
HBeAg (Core related protein that is secreted out into serum)	Yes, with high virus titres and during rapid replication of virus	High infectivity
Anti-HBs	Yes, during convalescence after Acute infection or following HepB vaccination	Immunity to HBV
IgM anti- HBc	Yes	Recent infection
Total Anti-HBc	Yes	Infection in undefined past
Anti-HBe	Yes	Low infectivity

Modes of Transmission

HBV is transmitted through contact with infected blood or body fluids across breakages in skin/mucous membranes and unprotected sexual intercourse. HBV is 100 times more infectious than Human Immunodeficiency Virus (HIV). Unlike HIV, HBV is able to remain active on surfaces (e.g. table tops, razor blades, blood stains etc) for about a week without losing infectivity. The primary routes of transmission are:

Child to child (also adult to child): Infected children and most chronically infected adults look healthy. Transmission occurs during play through cuts, bites, scrapes, scratches or contact with wounds

(Most common mode of transmission in India.)

Peri-natal transmission: from mother to baby, usually at the time of birth

through unsafe blood transfusions and organ transplant

through drug users sharing needles, or through unsafe injections or other unsafe medical procedures

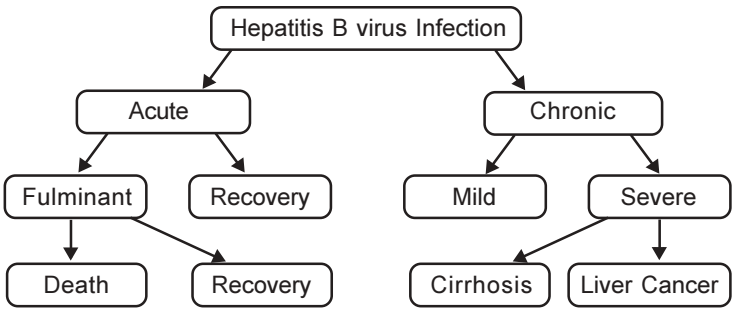
through unprotected sexual contact

Clinical Features

Outcomes of HBV Infection

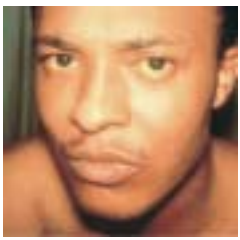
Hepatitis B disease is the inflammation of the liver cells caused by HBV. The outcomes of HBV infection are age dependent and include acute (short term and clinically apparent) hepatitis B and chronic (long- term and mostly unapparent) disease. The infecting dose of virus and the age of the person infected are important factors that correlate with the severity of acute or chronic hepatitis B. Only a small proportion of acute HBV are actually recognized clinically.

Spectrum of liver diseases following HBV infection



Acute hepatitis B infection

Acute hepatitis B occurs in approximately 1% of perinatal, 10% of early childhood (1-5 years old) and about 30% late (> 5 years old) HBV infections. The course of acute hepatitis B is extremely variable and the incubation period ranges from 2 to 5 months (average 3 months). Common symptoms include:



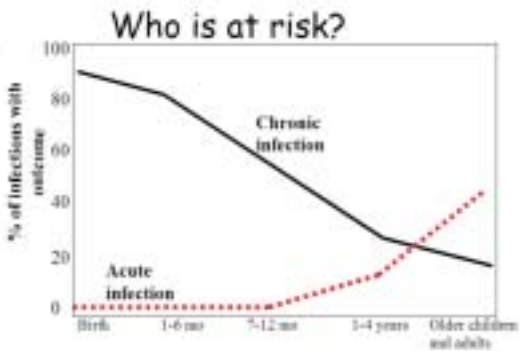
- Fever (mild or absent)

- Loss of appetite
- Tiredness
- Pain in muscles, joints
- Nausea, diarrhoea and vomiting
- Pain abdomen
- Headache
- Dark urine
- Pale stools
- Jaundice

Most acute hepatitis cases result in recovery except about 1% of them, progressing to fulminant hepatitis. Fulminant hepatitis has a very high mortality at about 70%.

Chronic hepatitis B infection

Chronic HBV infection is one of the most common and persistent viral infections in humans. If infection occurs in infancy, 99% remain asymptomatic.



90% of these become chronic carriers. In contrast, 30% of those infected during childhood (1-5 yrs) and 6% of those infected during adulthood become chronic carriers. Persons with chronic HBV infection have a 15-25% risk of dying prematurely due to HBV related liver cirrhosis and cancer. The example in the table below demonstrates, out of 100 persons infected at different ages, the number of persons at the risk of developing chronic HBV infection and complications.

Type	IF Infected	THEN chronic HBV infection	AND Cirrhosis/ Carcinoma*
Infant	100	90% = 90	15% of 90 = 14
Child(1-5yrs)	100	30% = 30	15% of 30 = 5
Adult	100	6% = 6	15% of 6 = 1

**assuming the lower rate of 15% complications*

In Africa and Asia, liver cancer is second only to tobacco as the most frequent cause of cancer deaths among adult males, most of which are attributed to HBV infection.

Diagnosis

It is not possible, on clinical grounds, to differentiate hepatitis B from hepatitis caused by other viral agents. Diagnosis of hepatitis B is confirmed by demonstration of specific antigens and/or antibodies in the patient's serum.

Acute HBV infection:

- Presence of HBsAg (surface antigen) and IgM antibody against core antigen (IgM anti-HBc)
- Presence of HBeAg (hepatitis B *e* antigen) during the initial, highly replicative phase of infection. HBeAg indicates high infectivity.
- Appearance of Antibody (after several weeks of infection) to HBsAg (Anti-HBs) and disappearance of HBsAg signals recovery.

Chronic HBV Infection:

- Persistence of HBsAg for more than 6 months is characteristic
- with or without HBeAg (Presence of HBeAg infers high infectivity)

Marker of HBV infection:

Total Anti-HBc in serum indicates HBV infection current, or past.

Hepatitis B Vaccine

The hepatitis B vaccine is the **first vaccine against a cancer** (primary liver cancer). Safe and effective, the vaccine has been available commercially since 1982. Hepatitis B vaccines are available as:

- Monovalent, or stand alone and
- Combination (DPT-HepB, DPT-HepB+ Hib, and HepB-Hib etc)

The currently used hepatitis B vaccines in UIP are prepared by using the HBsAg grown in yeast cells by DNA recombinant technology. The vaccine contains only the 22nm non infectious surface antigen (HBsAg) particles and not the entire virus. It does not contain any live components, reducing chances of vaccine-induced complications. It however contains alum as adjuvant and may contain thiomersal used as a preservative in multi-dose preparations.

The completed vaccination series induces protective antibody levels in about 95% of vaccinee, in a variety of vaccination schedules.

When countries include hepatitis B vaccine as part of routine childhood immunization programmes, following sustained high coverage, HBV infection in children is essentially eliminated in 10 to 15 years resulting in significant reduction in long term complications of HBV infection such as cirrhosis and liver cancer later.

Vaccination Schedule

Hepatitis B vaccine schedule

The hepatitis B vaccination schedule in UIP includes Birth dose within 24 hour of delivery, followed by 3 more doses of HepB vaccine along with DPT. Birth dose should be provided for all institutional deliveries, within 24 hrs of birth. Subsequently, 3 doses should be provided at 6, 10 and 14 weeks age along with three doses of DPT and OPV. Prospective of birth dose.

Vaccination Schedule:

Age	Vaccines		
Birth	HepB birth dose	BCG	OPV0 zero dose
6 weeks	HepB1	DPT1	OPV1
10 weeks	HepB2	DPT2	OPV2
14 weeks	HepB3	DPT3	OPV3

Target Age Group & Phasing In

Infants run the highest risk of developing chronic hepatitis B (90%) disease following infection by HBV. This risk decreases significantly with increasing age. Therefore, infants should be immunized before they are exposed to HBV infection starting at birth. Accordingly, the Government of India (GoI) has decided to adopt the strategy to administer a dose of

hepatitis B vaccine immediately after birth and three doses along with DPT in the prospective birth cohort[1] of children below the age of one year. ***In the initial stage of the introduction of hepatitis B vaccine, the vaccine will be administered to new cohort and only those children, who are coming for the first dose of DPT will be started with the hepatitis B vaccination*** **(Phasing in).**

Dosage

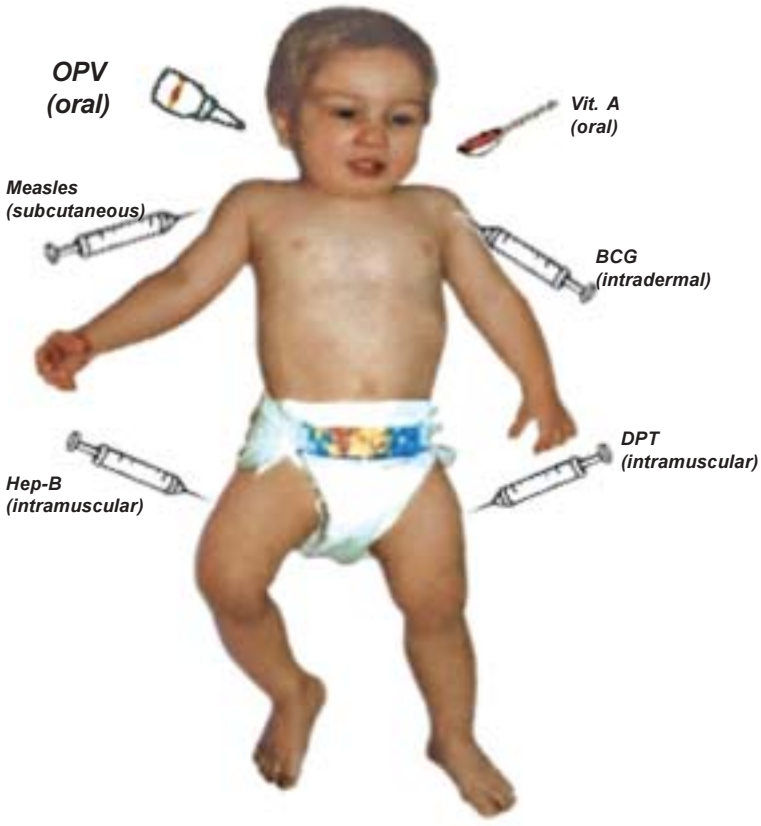
The standard paediatric dose of the hepatitis B vaccines (Monovalent hepatitis B vaccine and combinations) is 0.5ml. It is a cloudy liquid that is available in a 10 dose vial and does not require reconstitution. If the vaccine is allowed to stand for a long time, it separates from the liquid and looks like fine sand at the bottom of the vial. The vaccine must be mixed by rolling the vial gently between the hands.

Long-Term Protection and Booster Doses

Based upon the current scientific evidences, the protection afforded by hepatitis B vaccine lasts for lifelong. Even if the antibodies wane in the serum, long-term protection relies on immunological memory, allowing a protective memory response of the body to produce antibodies with the help of memory B cells and memory T4 cells, after exposure to HBV or vaccine. **Booster doses are, therefore, not recommended.**

1. The new birth cohort who presents for first dose of DPT.

Remember



All due vaccines can be given at same time but in different sites e.g. it is safe and effective to give BCG, OPV, DPT, HepB, Measles & VitA at same time to a 9 month completed child who has never been immunized.

Storage Temperatrue

The storage temperature for hepatitis B vaccine is the same as for DPT vaccine, i.e. between +2 °C and +8 °C. The vaccine is generally heat-stable but is highly freeze-sensitive and **MUST NEVER BE FROZEN. The freezing point of hepatitis B vaccine is about -0.5 °C.** The freezing of the vaccine causes the HBsAg protein to dissociate from alum adjuvant and thus to lose its immunogenicity/potency.

Safety of Hepatitis B Vaccine

Hepatitis B vaccine is a very safe vaccine with proven efficacy. Since 1982, over 120 crore (1.2 billion) doses of hepatitis B vaccine have been used worldwide. The rates of mild fever and/or irritability following simultaneous vaccination of children by hepatitis B and DPT vaccines is similar as when DPT vaccine is administered alone.

Mild transient side effects:

Most common side effect is pain at the injection site. Mild systemic complaints like fatigue, headache, irritability and fever higher than 37.7 °C which may usually start within a day after the vaccination and may last for one to two days.

Serious allergic (anaphylactic) reactions:

Serious allergic reactions to the vaccine are rare at about 1-2 per 10 lakh (1 million) doses and may include: generalized urticaria, difficulty in breathing, swelling of the mouth and throat, hypotension, shock

Contraindications

The only two contraindications to withhold or postpone the administration of hepatitis B vaccine are:

- **A severe allergic reaction to a vaccine component or following a prior dose of hepatitis B vaccine.** Such allergic reactions are rare. Further doses are

contraindicated if there is a history of anaphylaxis to a previous dose.

- **Persons with moderate or severe acute illness** should not be vaccinated until their condition improves. However, a minor illness, such as an upper respiratory infection, is not a contraindication to vaccination

The following are NOT contraindications

- Minor illness, such as respiratory tract infection or diarrhoea with temperature be low 38.5 °C
- Asthma
- Prematurity or low birth weight
- History of jaundice at birth
- Treatment with antibiotics
- Infection with HIV
- History of seizures (convulsions, fits)
- Diseases of the heart, lung, kidney or liver
- Congenital anomalies
- Neurological conditions such as cerebral palsy and Down's syndrome

Injection Technique and Safety

Hepatitis B vaccine, like DPT vaccine, is given intramuscularly on antero-lateral aspect of mid-thigh (vastus lateralis muscle). Both vaccines can be administered simultaneously, though on different thighs i.e. if DPT is injected in left thigh of an infant, then hepatitis B vaccine can be given on right side, at the same time.

Stretch skin flat between finger and thumb on both sides at outer Mid-thigh (Antero-lateral aspect) keeping needle at 90^0 to surface

Administering vaccine: DOs

- Divide the thigh into three equal parts from knee to hip.
- Clean the skin, if dirty, with a clean water swab and let it dry.
- Place your thumb and index finger on each side of the place where you intend to inject and stretch skin slightly.
- Push the needle at a 90^0 angle deep into the muscle.
- Press the top of the plunger with your thumb to inject the vaccine and withdraw the needle.

Administering vaccine: DON'Ts

- DO NOT give hepatitis B vaccine in buttock as this route of administration has been associated with decreased protective antibody levels, because of injection into subcutaneous fat. In addition there may be a risk of injury to the sciatic nerve.
- DO NOT administer hepatitis B vaccine intra-dermally because this route of administration does not produce an adequate antibody response in children.
- DO NOT mix hepatitis B vaccine in the same syringe with other vaccines.

Follow safe injection and Waste Disposal practices

Injection safety should be followed meticulously for each injection given and waste should be disposed carefully to prevent damage to self and others.

Auto Disable Syringe

- Use Auto Disable Syringes (ADS) supplied by Government of India and not any other Disposable syringes/ needles or Glass syringes

- Follow GOI guidelines (Central Pollution Control Board or CPCB) guidelines for safe disposal of immunization waste disposal
- **Keep hands clean before giving injections**

  - Wash or disinfect hands prior to preparing injection material.
  - Cover any small cuts on the service provider's skin. Wear sterile gloves to cover if pos sible.
- **Use sterile injection equipment, every time**
- **Prevent the contamination of vaccine and injec tion equipment**

  - Prepare each injection in a designated clean area where contamination from blood or body fluid is unlikely.
  - If injection site is dirty, wash with clean water swab
  - Always pierce the rubber cap of a vial with a sterile needle.
  - Do not leave needle in the stopper of a vial.
  - Follow product-specific recommendations for use, storage, and handling of a vaccine.
  - Discard any needle that has touched any non-sterile surface.
- **Assume all used equipment is contaminated**
  - Always cut an used syringe at hub immediately after use using the hub cutter provided for the purpose.

- Do not keep used syringes lying on the table or don't throw carelessly into a dust bin
- Never try to recap or bend needle of a syringe

- **Practice safe disposal of all medical sharps waste**
  - Used sharps (needles) are cut and deposited in a hub cutter and then carried to the PHC for safe disposal.
  - At PHC disinfect sharps by boiling in water for at least 10 minutes or by chemical method (1% hypochlorite solution for 30 min)
  - Treated sharps are to be disposed in safety pit
  - Disinfect plastic portion of a syringe and send the collected material for recycling
  - Alternately send all collected material for safe disposal at a Common Biomedical Waste Treatment Facility (CBWTF), if such facility is available
- **Prevent needle-stick injuries**
  - Do not recap.
  - Collect sharps in a puncture proof container (Hub cutter).
  - Anticipate sudden movement of the child.

Safe immunization practices	
	**Do not racap the needle**
	**Do not leave the needle inside the vial**
	**Do not touch the needle**

Adverse Events Following Immunization (AEFI) Surveillance

An AEFI is 'a medical incident that takes place after an immunization, causes concern and is believed to be caused by the immunization'. Hepatitis B vaccine is a very safe vaccine and AEFIs are extremely rare. Nonetheless, any suspected AEFIs must be reported as per GoI's national AEFI surveillance guidelines, 2010. The standard reporting formats need to be filled for serious AEFIs.

Management of AEFI

Although extremely rare, the health system has to be prepared for managing these serious AEFI. AEFI management for hepatitis B vaccine is similar to that of other vaccines in the immunization schedule.

When parents bring a child with complaints after the immunization,

- Please listen patiently.
- Do not ignore them.
- Do not panic and please attend to the patient immediately
- Keep the child under observation

Initiate action as per suggested guidelines stated below:

A. Redness and swelling at the site of injection

cold compress

B. Fever and pain at the site of injection

Give Paracetamol, 10-15mg/Kg body weight.

(The Paracetamol syrup contains 125mg per 5ml and can also be prescribed for infants)

C. Anaphylactic Reaction

Refer to annexure 8 of this handbook for recognition and management of anaphylaxis

The risk of serious adverse events associated with Hepatitis B vaccine is very low (1-2 / 1,000,000). This must be balanced with an expected 4,000 to 5,000 HBV-related serious liver diseases such as cirrhosis and cancer that would occur in the same population without immunization, assuming a 5% lifetime risk of HBV infection and a 15% long term serious liver diseases among the chronically infected.

Limitations

Hepatitis B vaccine is highly efficacious with more than 95% infants developing antibodies with complete course of vaccination. However, in order to maintain public trust in the vaccine, it needs to be clarified that a small percentage of vaccinee, who may not develop antibodies and still remain vulnerable to hepatitis B. Furthermore, it is important to clarify that hepatitis B vaccine protects against hepatitis B virus only. It does not protect against other types of hepatitis or jaundice. Hence, Jaundice may still occur due to infection from other hepatitis viruses or other causes such as haemolysis and obstruction to the bile flow.

HEPATITIS B VACCINATION IN INDIA

Introduction and Progress

Several analyses indicate that the inclusion of hepatitis B vaccine in the universal immunization programme is highly cost-effective intervention. India has intermediate endemicity of hepatitis B with prevalence of HBsAg between 2% and 10% among several populations studied.

The vaccine has been available in the private sector in India for last few years. The GoI introduced hepatitis B vaccine in 2002 - 03, as a pilot in 33 districts and 14 cities across the country. The success of this pilot programme led to the further expansion of vaccination to 10 selected states of India in 2007-08.(i.e. Jammu & Kashmir, Himachal Pradesh, Punjab, Madhya Pradesh, Maharashtra, West Bengal, Andhra Pradesh, Karnataka, Kerala and Tamilnadu) These states were selected on the basis of better UIP performance as in CES 2002. These states have been shown in shade in the figure on next page. The states, which are not shaded will be introducing hepatitis B vaccination in 2011.

Hep B Vaccination in India

States which introduced HepB Vaccine in 2007-2008
Introducing in 2011

Objectives and Strategies

The long term goal of including hepatitis B vaccination in UIP in India is to reduce morbidity and mortality associated with chronic HBV infection, including cirrhosis and liver cancer. The short-term goals and objectives are as follows:

- Delivery of hepatitis B vaccine along with all other UIP vaccines according to safe injection practices.
- Training of health care workers, and sensitisation of policy makers and the community about HBV infection and hepatitis B vaccine.
- Utilising introduction of hepatitis B vaccine as an opportunity to increase attention and action on improving the monitoring of cold chain, injection safety and proper disposal of medical waste including AD syringes.

STEPS FOR THE INCLUSION OF HEPATITIS B VACCINE IN THE UIP

Steps for the Inclusion of Hepatitis B Vaccine in the UIP

The inclusion of hepatitis B vaccine into the routine immunization schedule requires careful planning at all levels. This initially involves top-down macro-planning at the state level. Later on, with micro-planning, precise logistics and financial needs for each district and sub-district levels are calculated bottom-up, i.e., starting from the more peripheral levels and moving towards the higher levels. These activities need to be started at least 3-6 months prior to the vaccine introduction. The new vaccine introduction planning should be seen as an opportunity to strengthen RI service delivery.

Planning at State / Regional Level

This includes the following elements:

- seek commitment and support for introduction of hepatitis B from various departments and stakeholders
- develop advocacy and social mobilization activities plan
- prepare a training plan
- develop and disseminate immunization guidelines (e.g. injection safety, cold chain, AEFI surveillance etc.)
- develop plans for supervision, monitoring and evaluation, including plan for providing feedback.

Planning at District / Sub-district levels

This includes the following elements:

- **Revise micro-plans:** use prescribed formats for UIP at each level

- **Estimate:** Calculate vaccine and logistics requirement at each level
- **Cold chain:** evaluate the availability and adequacy at all levels
- **Indenting and delivery:** ensure availability of required vaccine and other logistics needed to introduce the vaccine
- **Modify and disseminate revised formats:** reporting, recording and immunization card etc
- **Trainings:** health workers and staff at all levels
- **Advocacy and social mobilization** activities around the introduction of the new vaccine.

More generally, programme managers at all levels need to undertake the following activities, which will be described in some detail in the following sections.

1. estimate beneficiaries and sessions
2. estimate vaccine and syringe needs
3. estimate storage needs
4. manage cold chain
5. update recording and reporting systems
6. prepare and train staff
7. plan advocacy and social mobilization
8. supervise, monitor, evaluate and provide feedback

1. Estimate Beneficiaries and Sessions

The inclusion of hepatitis B vaccine into UIP will result in increase in the number of injections and the workload at an immunization sessions. In this section, we learn to calculate the additional number of injections, with the introduction of this new vaccine in UIP schedule.

There will not be any change in the process of estimated number of beneficiaries. To estimate the beneficiaries *(actual surveyed as per Community Need Assessment-CNA or if that is not available, estimation based on population and indicators such as birth rate and Infant Mortality Rate-IMR)* using the same figures as used in the UIP. Calculate the total number of injections required to be given under UIP, including hepatitis B vaccine for the estimated number of beneficiaries.

The introduction of hep B vaccine in UIP will lead to additional 4 injections per beneficiaries in the immunization program (1 injection for birth dose and 3 for primary schedule of 6, 10 and 14 weeks). It may be noted that in those areas, where institutional deliveries are low, the actual requirement of birth dose would be less i.e. if only 50% deliveries are taking place in institutional set up then 3 doses and 0.5 for birth dose should be used for estimating the number of beneficiaries.

While the beneficiaries remain the same, the actual injection load will increase. This will have effect on the sessions planned. You can now calculate the number of sessions required based on the injection load, according to the guidelines (as given below). Then make the resultant changes

in the existing micro-plans, considering the additional injection load of hepatitis B vaccine. Make a workable micro-plan suitable to local conditions and staff availability.

Outreach sites

- If less than 25 injections are expected, then plan a ses sion for every alternate month or once in three months.
- For every 25-50 injections, plan one session a month.
- If more than 50 injections are expected, then plan two ses sions a month.
- However, ensure that a minimum of 4 sessions are held in a year.

Fixed sites (PHC/CHC/Referral Hospitals)

- Number of sessions at fixed sites (PHC/CHC/Referral Hospitals) should be planned based on workload to suit local conditions. Avoid overcrowding and plan daily sessions at busy sites if needed.

2. Estimate vaccine and syringe Need

Why forecast?

- Accurate forecasting is essential to ensure that a right amount of vaccines, injection and cold chain equipment are available to vaccinate all eligible infants at a given time in a given area.
- Efficient forecasting allows for efficient management of logistics, proper schedule of delivery in manageable quantities, and efficient immunization services.
- Furthermore, it ensures an adequate buffer stock to meet unexpected needs.

Wastage rate and wastage factor

- Wastage rate (%) is the proportion of vaccine (and other injection items) that is wasted due to a variety of reasons to that which was appropriately used (i.e. number of infants vac cinated).
- Wastage factor is a mathematical derivative used to ac count for the correct amount needed for an immunization session, taking into account the existing wastage rate.

  e.g. if the wastage rate is 25%, then wastage multiplication factor is 100/(100 - 25) = 1.33
- Therefore, if 50 infants are to be vaccinated with 4 doses of Hepatitis B, then the vaccine requirement is 50 x 4 x 1.33 = 266 doses.

Buffer stock

Buffer stock ensures that there is sufficient stock to tide over sudden and unexpected shortages. This is generally 25% of requirement.

The number of hepatitis B vaccine doses required is estimated using the number of target infants, the number of doses in immunization schedule (i.e. 4), the wastage factor and buffer stock required.

Calculate vaccine requirement

Use following steps to calculate the total number of doses needed to introduce hepatitis B vaccine.

Step 1: Calculate the doses administered per year

Doses administered per year = Target infants x number of doses per infant

Step 2: Calculate the yearly vaccine requirement with wastage

Total vaccine doses used per year = Doses administered per year x wastage multiplication factor (1.33)

Step 3: Calculate the yearly vaccine requirement with buffer stock

Total vaccine doses needed to introduce vaccine in first year = Total vaccine doses used per year x buffer stock factor (1.25)

To combine these 3 steps in one formula:

Total vaccine doses needed to introduce vaccine in first year = Target Infants x 4 x 1.33 x 1.25

Case Study 1

Dr Aniruddh Kumar is District Immunization Officer of Hariyali District in Van Pradesh where Hepatitis B vaccine is to be introduced for the first time. The target infants in his district are 50,000.

He calculates vaccine requirements thus:

Total vaccine doses needed to introduce vaccine in first year

= 50,000 X 4 X 1.33 X 1.25

= 332,500 doses

Calculate syringe requirement

Use the following steps to estimate the number of syringes needed for introduction of the hepatitis B vaccine.

Step 1: Calculate the number of injections administered per year

Injections administered per year = Target infants x Number of doses per infant

Step 2: Calculate the yearly syringe requirement with wastage

Annual number of syringes needed = number of injections administered per year x Wastage factor (1.11)

Step 3: Calculate the yearly syringe requirement with buffer stock

Total syringes needed per year = Annual number of syringes needed x buffer stock factor (1.25)

To combine these 3 steps in one formula for hepatitis B vaccine: There are 4 additional doses (and therefore syringes) needed for hep B vaccine. Therefore, the additional requirement will be as follows:

Total syringes needed per year = Target Infants x 4 x 1.11 x 1.25

Case Study 2

With the introduction of Hepatitis B into the immunization programme, Dr Aniruddh Kumar is now calculating his additional syringe requirements for the target infants of 50,000. He calculates syringe requirements thus:

Total additional syringes needed in the first year = 50,000 X 4 X 1.11 X 1.25 = 277,500 syringes

3. Estimate Storage Needs

Adding hepatitis B vaccine to the UIP requires a re-evaluation of storage capacity at all levels. Since both exposure to heat and freezing destroys the potency of hepatitis B vaccine, it should be stored at temperatures between +2° C and +8° C only. Hence, assess cold chain requirements at all levels and implement plans, to accordingly revise cold chain storage capacity.

Assessing cold chain storage capacity

Inclusion of hepatitis B Vaccine (as a 10 dose vial) into UIP requires additional storage space. Hence, one needs to estimate the total requirement of cold chain space based on the additional hepatitis B vaccine requirement at each level of storage. The table below outlines the storage capacity of various cold chain equipments.

Equipment	Storage Capacity (mixed antigen)
ILR 300 ltrs	60,000 doses
ILR 140 ltrs	25,000 doses
Cold Box 20 ltrs	6000 doses and 52 Ice Packs
Cold Box 5 ltrs	1500 doses and 20 Ice Packs
Vaccine Carrier	15-20 vials and 4 Ice Packs

State and district cold stores indent vaccines on a quarterly basis. Thus, at the beginning of each quarter, the state/district should have:

- vaccine stock for 3 months (1/4th of the estimated annual requirement).
- additional 25% of quarterly requirement as buffer stock

PHC cold stores, however, indent vaccines every month. Thus, at the beginning of each month, the PHC should have:

- vaccine stock of 1 month (1/12th of the estimated annual requirement).

additional 25% of monthly requirement as buffer stock

Case Study 3

We take an example of a Primary Health Centre (PHC), which caters to a total population of 100,000. Assume annual birth rate of 25/1000, there will be 2500 target beneficiaries. (Since, this is a hypothetical example and for the simplicity of calculations, we are not taking infant mortality rate in consideration). Therefore, a total number of children to be immunised every month i.e. 2500/12=210

Let's calculate vaccine storage space requirement at that PHC:

It has been estimated that for every child to be fully immunised (including Hep B) cold chain space need is 69 cubic cm(ml)*. Thus, total cold chain space needed=

75.7*210/1000*1.25=18.12 litres (less than 1/2 of the small ILR, ie 45 litres)

4. Manage Cold Chain

Effects of heating and freezing on vaccine potency

Hepatitis B vaccine loses its potency upon freezing, so protection from temperatures colder than +2° C is crucial at all levels of cold chain. Vaccine freezing does occur at all levels and there is very limited awareness of this problem among programme managers.

Adjuvants (such as aluminium salts) are included in some vaccines (All TT series vaccines including, DPT, TT and Hepatitis B) to enhance immunogenicity of vaccine antigens. These adjuvant containing vaccines are sensitive to freezing. In hepatitis B vaccine, freezing breaks the bond between hepatitis B surface antigen (HBsAg) and the alum adjuvant. This process is irreversible and Hepatitis B vaccine thus loses its immunological potency, once frozen.

When does the vaccines get Frozen?

Vaccine freezing is commonly found to occur at two levels, during storage in ILRs, and during vaccine transport to the session sites.

Preventing vaccine freezing during storage

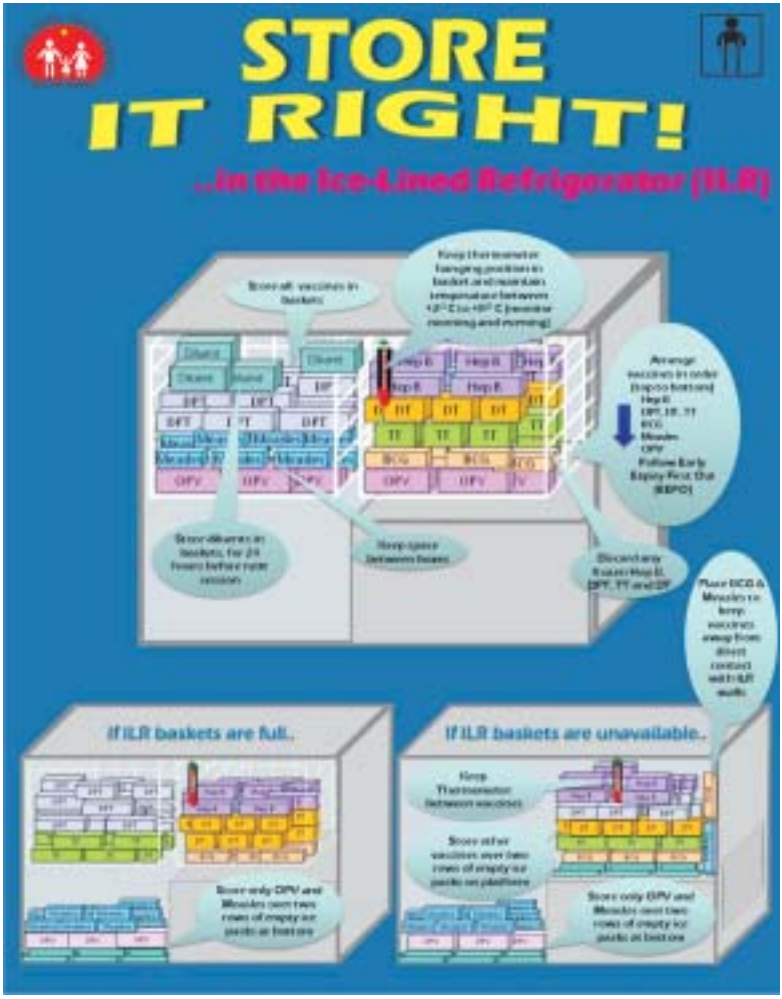
There are various ways to prevent and reduce freezing during storage:

In cold rooms

- store freeze-sensitive vaccines away from evaporator.

In ice-lined refrigerators (ILRs)

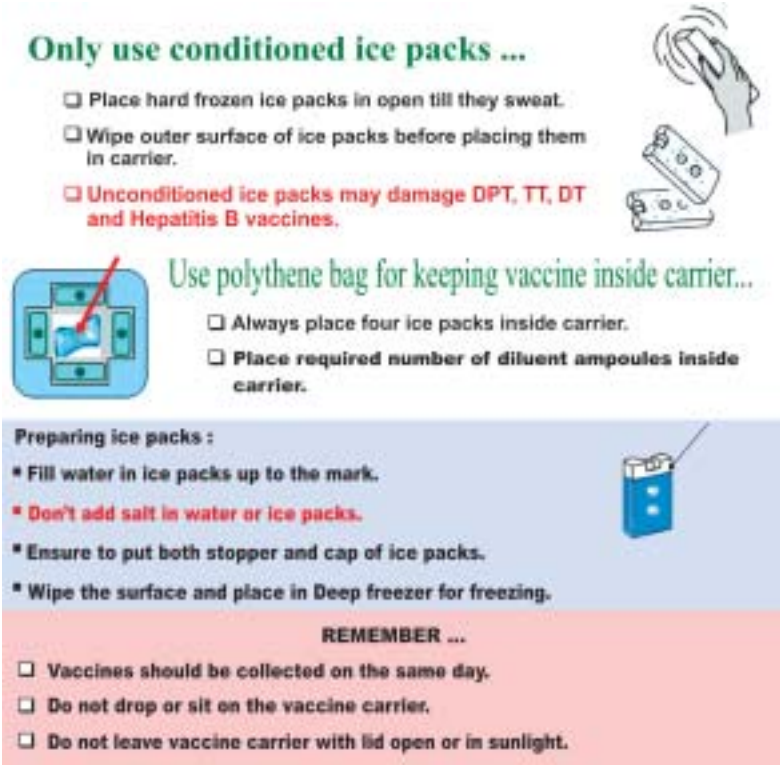
- keep all vaccines, particularly freeze-sensitive vaccines such as hepatitis B and 'T' series vaccines in the baskets in the ILRs,
- set the thermostat to ensure a temperature of +2° C to +8° C.
- do not adjust the thermostat after power cuts or if the temperature occasionally rises above +8° C.
- ALWAYS ensure sufficient gaps for air circulation while storing the vaccine containing boxes



Job-aid 1: Sticker for Ice Lined Refrigerators

Prevent vaccine freezing during transport

Studies show that the maximum instances of vaccine freezing occur during transport of vaccine to the session sites. To prevent this, follow the steps given below for preparing and conditioning ice packs. (This job-aid can be used as a sticker for vaccine carriers)



Job-aid 2: Sticker for Vaccine Carriers

Check for heat damage

Vaccine Vial Monitor (VVM): A VVM is a label that changes colour when the vial has been exposed to heat over a period of time. Before opening a vial, check the status of the VVM, printed on the vial label or cap. The VVM is a square inside a circle. As the vial is exposed to heat, the square becomes darker. Use only vials with inner squares that are lighter than the outside circle.

	Inner square is lighter than outer circle. ***If the expriy date has not been passed, USE the vaccine.***	Usable
	At a later time, inner square is lighter than outer circle. ***If the expiry date has not been passed, USE the vaccine.***	
	**Discard point:** Inner square matches colour of outer circle. ***DO NOT use the vaccine. Inform your supervisor.***	Not usable
	**Beyond the discard point:** Inner square darker than outer circle. ***DO NOT use the vaccine. Inform your supervisor.***	

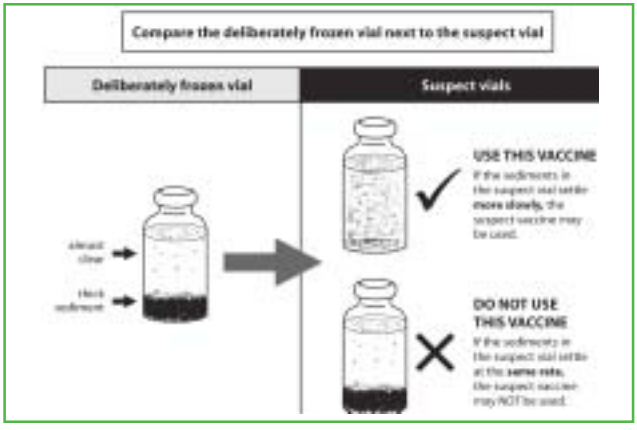
VVM merely indicates the exposure of Hepatitis B vaccine to heat. ***Remember that the vaccine is vulnerable to freezing too***

Check for cold damage (freezing)

Shake test: Shake test determines whether adsorbed vaccines (DPT, DT, TT or HepB) have been frozen at some point in the cold chain. After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes which gradually settle to the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same batch which has never been frozen. **Conduct the test at the storage point when you suspect that a large number of vials have been frozen. If there is obvious flocculation or freezing, then discard the vials.**

Conducting Shake Test

Step 1 - prepare a frozen control sample: Take a vial of vaccine of the same type, batch and manufacturer as the vial you want to test. Freeze the vial until the contents are solid (at least 10 hours at -10°C) and then let it thaw. This vial is the **control sample**. Mark the vial clearly so that it is easily identifiable and will not be used by mistake.



Step 2 - choose a **test sample**: Take a vial(s) of vaccine from the batch(es) that you suspect has been frozen. This is the test sample.

Step 3 - Shake the control and test samples: Hold the control sample and the test sample together in one hand and shake vigorously for 10-15 seconds.

Step 4 - Allow to rest: Leave both vials to rest by placing the vials on a table and not moving them further.

Step 5 - Compare the vials: View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample has most probably not been frozen and can be used. If the sedimentation rate is similar or more than the control, the test vial has probably been damaged by freezing. It should not be used.

Minimize Vaccine Wastage

It is important to minimize wastage of hepatitis B vaccine just as it is important to minimize the wastage of other vaccines too. It must be remembered that all vaccines cost a considerable amount of money.

Strategies to decrease vaccine wastage include:

- Predicting accurate vaccine requirement based on micro-planning and procuring only required quantities
- Ensure stock position is intimated to higher authorities on a regular basis
- Maintenance of the cold chain at all levels including transport
- Prevention from freezing
- Meticulous planning and conduct of sessions
- Raising demand for immunization services by communication with the community
- Use of vaccine vial monitors (VVM)
- Quarterly monitoring of wastage

5. Update Recording and Reporting Systems

Adding any new vaccine in immunization program requires updating the forms and IEC materials that list the vaccines in the immunization programme.

Update Forms

Identify and update all recording and reporting formats to reflect the addition of the new vaccine.

- Vaccine stock forms and
- Immunization cards or Mother and Child Protection (MCP) cards,
- Monthly Progress Report at all levels (*See Annexure 6)*
- MCH/Immunization Register
- Monitoring Chart
- Supervisory checklists (*See Annexure 7*)
- Computer databases
- Immunization coverage surveys and evaluations;

It is preferred to revise these formats to include hepatitis B vaccine and distribute them before introduction. Alternatively, in the initial stage of introduction, the existing forms can be adapted locally (e.g. health workers may add hepatitis B vaccine data by hand to existing forms and use these as long as they last). However, errors and omissions are more likely to occur if the latter course is chosen. This process may be done either at the state level or district level, depending upon the prevailing practices in the state. However, if the

modification is done at the state level and templates are shared further down, it will expedite the entire process.

Update Informational Materials

The informational materials for community and caregivers need to be revised/updated and distributed before the vaccine is introduced. Materials that must be revised include:

- posted immunization schedules, (tin-plates, posters, wall paintings and billboards)
- immunization cards and counterfoils
- materials for parents
- training material for health workers

6. Prepare and Train Staff

Training for health care staff is essential to successfully introduce hepatitis B vaccine into the UIP. The health care providers are responsible for handling and administering the vaccine and they are a major source of information for parents and other members of public. Additional trainings can be minimized if delivery of information on hepatitis B disease and vaccine is integrated into existing training programmes. Health care personnel, who need training include District Immunization Officers (DIO), Medical Officers (MO), cold chain handlers, supervisors, data managers and frontline Health Workers (HW).

Training Approach

Training activities would commence at the national-level, with an orientation of state officers on hepatitis B vaccine introduction. This would be followed by training of district-level trainers at the State level.

In turn, this should be followed by the training of all Medical Officers at district level. The supervisory staff, cold chain handlers, and Auxiliary Nurse Midwifes (ANMs) also need to be trained in various aspects of Hepatitis B vaccination. This group of staff can be trained by MOs in their respected PHC/CHC areas. Additionally, sensitization of the frontline Health Workers and community level workers including ASHAs may also be conducted.

These orientation training should ideally be conducted before Hep B vaccine is introduced in the program and before public information campaigns are undertaken. It also need to be ensured to update all training materials related to immunization to include information about hepatitis B disease and vaccine. Also, advocate for inclusion of information about hepatitis B disease and vaccine in the curricula for health care staff training programmes and medical/nursing courses.

Training Tips

As the trainings of Medical Officers and Health Workers in Immunization program in India are already ongoing and the content on Hepatitis B vaccination has already been incorporated in those trainings, choosing what to teach is important.

Some points to consider when planning training are:

- Use skill-based training, interactive discussions and hands on approach to teach tasks and procedures.
- Teach in settings that are as close as possible to real work conditions (staff meetings, in-service training workshops and newsletters.)
- Teams that work together should be trained together.
- Ensure follow-up and supervision after training.
- Use every opportunity to reach health care staff, even if this means that some individuals may receive the same information more than once.

Training Content - Broad areas

Training must cover information on hepatitis B vaccine and HBV-related diseases as well as programmatic issues. The main hepatitis B specific topics that should be covered in the training are:

- Types of Hepatitis
- Hepatitis B virus, transmission and disease,
- Importance of infant vaccination
- Hepatitis B vaccine and schedule
- Vaccine and logistics management
- Vaccine administration
- Injection safety, and waste disposal,
- AEFI surveillance
- Reports and records
- Advocacy and communication

The attention need to be paid that how and when the vaccine will be administered and which children should receive the vaccine.

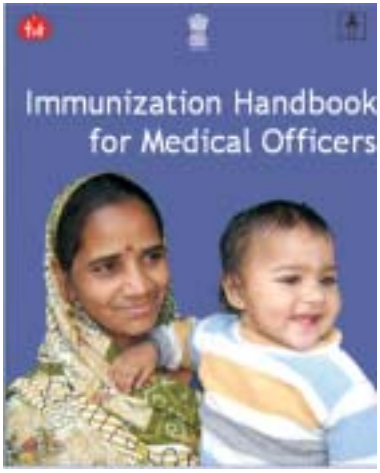
The content

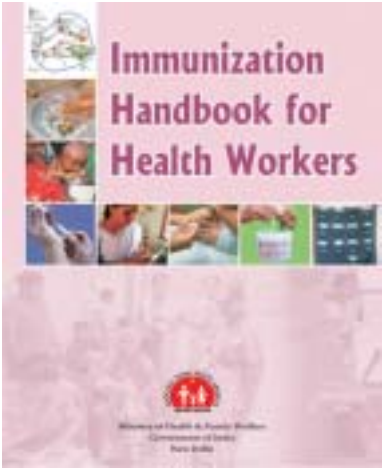
The content should focus on practical aspects, which trainee will be able to put to use immediately after return rather than teach mere theory. For the training of Medical officers in Hepatitis B vaccine and disease, this operational guidelines can be utilised. There are standardised agenda and power point presentations, based upon these modules, which can be utilised for training purpose. Besides, this standard

information on Hepatitis B from various sources including FAQ can be utilised for this purpose.

For the training of health workers, the Frequently Asked Questions (FAQs) given in Immunization Handbook for Medical officers and health workers should be utilised as training content. Besides this the two key resources to develop training content are:

- Immunization Handbook for Health Workers
- Immunization Handbook for Medical Officers





Suggested Agenda and topics to be covered In the training Of Medical Officers

- Review objectives/expectations (10 min)
- Routine Immunization recap and Introduction to New Vaccines (30 min)
- Hepatitis B Disease and Vaccine, schedule, route of administration, storage and care of vaccine (60 min)
- Inclusion of Hepatitis B Vaccine under UIP – Steps in introduction - planning vaccine requirements, assessing cold chain space, session planning (60 min)
- Conduct of Immunization session with Hepatitis B vaccine packing the VC, injection technique and safety, recording reporting, (30 min)
- Tips for HW training and development of training plan (10 min)
- Frequently Asked Questions (20 Min)
- Open discussion

Suggested agenda and topics for half- day training of Health Workers

- Registration (10 min)
- Pre-test (see Annex 5A) (10 min)
- Review objectives/expectations (5 min)
- Routine immunization recap and discussion on schedules (10 min)
- Hepatitis B disease and importance of infant immunization (20 min)
- Hepatitis B vaccine and its schedule (10 min)
- Cold chain maintenance, conditioning of icepacks and packing of vaccine carrier (20 min)
- Injection technique and waste management (20 min) (demonstration)
- AEFI surveillance (10 min)

Some of the materials that could be used and disseminated during training session are:

- Job aids on vaccine freezing (stickers for ILRs and vaccine carriers)
- CDs with presentation for training (Supplied separately. State and District Trainers to use it)
- Flipbooks for training by MOs (Supplied separately. District and Block trainers to use it)

7. Advocacy and Social Mobilization

The introduction of hepatitis B vaccine in the UIP, advocacy and social mobilization are important in order:

- to generate support and commitment for the new vaccine; and
- to dispel misconceptions about the disease and the vaccine that could undermine public confidence

Advocacy with stakeholders/key decision makers/opinion leaders is essential to ensure that the vaccine is offered to all eligible infants in every district. **Social mobilization** is needed to ensure that the general public, including caregivers accept the vaccine. These activities are necessary because hepatitis B disease has:

- no external manifestation for most infections;
- an insidious onset and a very long interval before onset of complications;
- an impression of NOT being responsible for these complications; and
- no directly recognizable deaths in most cases

Advocacy

Advocacy is a process for raising awareness, especially among decision-makers and service providers, to ensure that (hepatitis B immunization) is available for all children. Increasing awareness in the community of the importance of HBV as a cause of disease and death is a key activity and requires sound scientific data on the current and future

disease burden. Another critical aspect is to show the impact of immunization in preventing that disease burden. As nearly all disease prevention will occur several decades after delivery of immunization in that cohort, special advocacy efforts are needed.

The **decision-makers and opinion leaders** who should be considered for advocacy efforts include:

- health department officials
- other government officials (ICDS, Dept. of Education)
- elected representatives at state, district and panchayat evels
- clinicians in the private sector
- nongovernmental organizations
- community leaders and decision-makers
- media
- religious leaders, and
- teachers

The **key messages** for these groups could include:

- Disease burden associated with HBV-related cirrhosis and liver cancer in India or in the state;
- modes of HBV transmission;
- importance of infant immunization in preventing chronic hepatitis B;
- efficacy and cost-effectiveness of hepatitis B immunization;
- safety of hepatitis B vaccine;

- importance of the addition of hepatitis B vaccine to strengthen immunization services;
- importance of their role as advocates for the successful introduction of hepatitis B vaccine

Possible key messages for policy-makers

- Infant immunization for hepatitis B will prevent large number of chronic liver diseases decades later.
- Of the 2.6 crore infants born every year in the country, around 10 lakh run the life-time risk of developing chronic HBV infection of whom 1-2 lakh may suffer serious liver disease including liver cirrhosis and cancer.
- Infant Immunization is highly cost effective in preventing liver cirrhosis and cancer
- There is no cure for hepatitis B. Prevention is better!
- Sustained high coverage with hepatitis B vaccine can virtually eliminate hepatitis B infections in 10-15 years

Launching of Hepatitis B vaccination

Introduce the vaccine into the programme with a well publicised launch at various level. This launch should be attended by all the stakeholders and general public. The opportunity should be utilised to educate public and policy makers alike about the disease, its prevention and how the immunization benefits the individual and the nation.

For a successful launch apart from the mass media event

one to one contact with people (Interpersonal Communication- IPC) is equally important. In this, take help of other government departments, local media and NGOs that can spread the message and motivate the community to utilize immunization.

Social Mobilization

Social mobilization is targeted towards the community and caregivers and is focused on getting children to the immunization session. A range of media should be used to deliver the messages, including health workers, Anganwadi workers (AWWs), Accredited Social Health Activists (ASHA), community volunteers and mass media.

Health workers, in particular, can be motivated to generate interest in the hep B vaccine as this can improve coverage of other vaccines too. They are the main source of information to the general public.

All these opportunities should be utilised for spread messages about routine immunization and traditional antigens in RI.

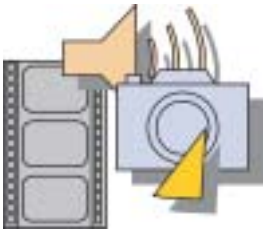
Possible **key messages** for the parents and general public are:

- Hepatitis B and its consequences
- modes of HBV transmission
- importance of infant immunization
- target group for immunization, and an explanation of why older children are not being immunized with hepatitis B vaccine
- how many times and when infants should be

immunized make sure that the baby is immunized at birth t the hospital and later three times with DPT and OPV at 6, 10 and 14 weeks age

- Importance of all other vaccines of UIP in addition to hepatitis B vaccine
- limitations of hepatitis B vaccine

Social Mobilization Channels



Surveys show that the best channels for increasing demand for immunization are health workers, AWWs, local leaders and local groups. Generally, parents perceive health workers as a credible source of information about health. Inter-personal communication is the best way to give parents information about the hepatitis B vaccine and when and where to bring their child for the vaccination.

Mass communication media, involving radio, TV and print materials, can complement the basic channel of IPC, but it is not a substitute for it and is inadequate by itself. In summary, for social mobilization:

- Used handouts and pamphlets for awareness generation
- Use FAQ on HepB for HWs
- Use training material for all category of health staffs

Prepare to respond in a timely manner to misconceptions about hepatitis B disease and vaccine that could undermine public confidence in the programme. Misconceptions about the safety of hepatitis B vaccine may also occur because of case reports of AEFIs.

Activities/ Materials for Introducing Hepatitis B Vaccine		
Materials	**Intended Use**	**Main Messages**
Inter Personal Communication (IPC) (ANM, AWW, ASHA, etc.)	To initiate discussions with small groups of parents as part of RI sessions and on other occasions	• Basic facts about hepatitis B disease and vaccine • When and where to bring children for immunization • Bring RI card for every visit. • Treating side effects
Info-kit for health workers (Annexure 1 and 2)	A reference for health workers helping them respond to parents' questions and listing their duties	• Basic facts about hepatitis B disease and vaccine • What health workers have to do to while adding hepatitis B vaccine
Pamphlet for parents (Annexure 3)	A reference for parents to clarify doubts regarding the vaccine and the schedule	• Basic facts about hepatitis B disease and vaccine • Ages at which children should get vaccines • Importance of immunization
Pamphlet for community leaders (Annexure 4)	A reference for community leaders to help plan support activities and respond to public's questions	• Basic facts about hepatitis B disease and vaccine • What leaders can do to provide support
Posters, hoardings, banners, wall painting	To raise public awareness and provide information about the immunization schedule	• Vaccines in the UIP, including hepatitis B • Ages at which children should get vaccines • Importance of immunization
Print, Radio and television spots	To raise awareness among the public, community leaders, and health workers	• Increased protection to the public through hepatitis B vaccine • No additional visits needed for getting the vaccine • Caregivers should bring children for all vaccines

Dissemination Strategy

Ensure timely dissemination of guidelines, tools, and other communication materials to the appropriate audiences. Failures in communication commonly occur because the disseminated materials sometimes do not reach and or the formats are not appropriate for the intended audience. The materials often end up at warehouses at some intermediate point. A few general guidelines for more effective dissemination are the following:

Design a **dissemination plan** that specifies:

- who is supposed to use and therefore receive the materials
- in what quantity end-users need them
- by what means they will be sent to the intended users
- who is responsible for sending them
- the budget needed.

Additionally,

- Use those channels that are most convenient for the audience, not those most easy for the programme managers (e.g. mass media).
- Ask audience members what channels and formats are easiest for them to use.
- Monitor dissemination - that the material is reaching the intended people and that they feel it is appropriate and useful for them.

8. Supervise, Monitor and Evaluate

Supervise planning and implementation

Supervision in the planning phase is focused on checking the infrastructure and human resource capacity, finding challenges and to solve them. After inclusion of hepatitis B vaccine in the schedule, it is focused on checking the adequacy of implementation and on preventing deviations from guidelines. Supervision must focus on the critical aspects of quality, effectiveness and safety and on anticipated weaknesses.

Supervisors have an important role to prevent bad plans and to alter poor implementation. To achieve this, Supervisors must themselves be familiar with what is expected in the programme and what role they are expected to play. A key component of supervision is to encourage and motivate frontline health workers (ANMs, AWWs, ASHAs) and guide them through on the job training, wherever necessary.

Tools for supervision

Supervisors should use a checklist (Annexure 7) as a tool to document the level of implementation of plans, and coverage with the vaccine. Alternatively, the check lists given in Immunization handbook for Medical Officers may also be utilised for supervisory visits. ,The checklists to be used by a state should be developed locally if local specific additional

information is required and if the form is required in local language.

Schedule supervisory visits

Supervising officers should visit a few immunization sessions in action to observe the actual implementation of the programme in field. During the visit, they should try to assess the proper maintenance of cold chain, safe disposal of AD syringes, and actual coverage of beneficiaries with all doses of vaccines under UIP by sample checks in the field and find out any weaknesses or constraints. Supervision should be conducted as per a pre-determined plan at various levels as below:

At state level: Supervisors from the state level should make supervisory visits to all districts before introduction of the vaccine. If that is not possible, visit select districts and blocks, with particular difficulties or questionable preparations.

At district level: Supervisors from district should make planned supervisory visits to all blocks/PHCs, particularly with difficulties or questionable prepara tions for logistics or social mobilization.

At block/PHC level: Supervisors from the block/PHC should make supervisory visits to selected immunization session sites.

At all levels: In addition to the above, supervisory visits may be needed at all levels, depending on the outcome of the scheduled visits.

Monitor implementation

Monitoring of ongoing activities is crucial for effective implementation of Hep B vaccination program. This opportunity should be utilised for strengthening RI monitoring in these states. The monitoring of hep B vaccination should be done to ensure an early uptake and improving coverage with this new antigen in RI program. Incorporate monitoring of hepatitis B vaccine introduction into routine monitoring systems as soon as the vaccine is included in UIP. Staff at all levels should closely monitor progress in vaccine introduction, particularly during the first year. With the addition of hepatitis B vaccine to the UIP, a fully immunized (FI) child is defined as the one completing HepB3, in addition to other traditional vaccines (BCG, 3 doses of OPV, 3 doses of DPT and Measles vaccine) in the UIP schedule by one year of age.

Develop a monitoring plan which could include monitoring of:

- Vaccine and Logistic Supply
- Vaccine utilization (coverage) and wastage
- Cold Chain
- Injection safety and waste disposal
- Vaccination practice at immunization sites
- Coverage monitoring, including birth dose
- Implementation of training, IEC and social mobilization.

Monitor vaccines and logistics supply

Examine available records for supply, utilization and balance of vaccines and AD syringes and physically verify whether there is a logical association between vaccines and AD syringes supplied and used. Explore and address reasons if the following are found:

- utilization of vaccine and AD syringes shows a pattern of rapid increase or decrease week after week; or
- doses consumed for vaccines to be provided at the same time (DPT, HepB and OPV) differ widely from each other for the same period.

If there is any mismatch between the reported number of doses and AD syringes used, consult the concerned vaccinators, doctors, store in charge and supervising authorities to find out the reason for the variance/mismatch. If their reply is found convincing and realistic appreciate and thank them. If the reply points towards problems or irregularity in work/ management, discuss solutions with the concerned persons and also inform the senior authorities.

Monitor vaccine utilization (coverage)

Hepatitis B vaccine coverage can be monitored using both reported and evaluated coverage data.

Use reported coverage data

In general, coverage data of UIP, is reported by all levels. Analyze HepB3 and DPT3 immunization coverage data at every level on at least a quarterly basis. This will help in planning, to correct problems and to monitor programme

impact. Using reported data to estimate coverage has its advantages. The information is timely, the method makes use of numbers that are already routinely gathered and data can point out problems in service delivery.

However, coverage estimates based on such data may be biased when the size of the target population is wrong or, more commonly, when reports on the number of doses administered are incomplete. This can lead to overestimation or underestimation of coverage. To ensure completeness and accuracy, state and district immunization managers should audit reported data from districts and blocks periodically, preferably on a quarterly basis, particularly, in the first year after inclusion of hepatitis B vaccine. The following are examples of reported data that can be used to monitor hepatitis B immunization.

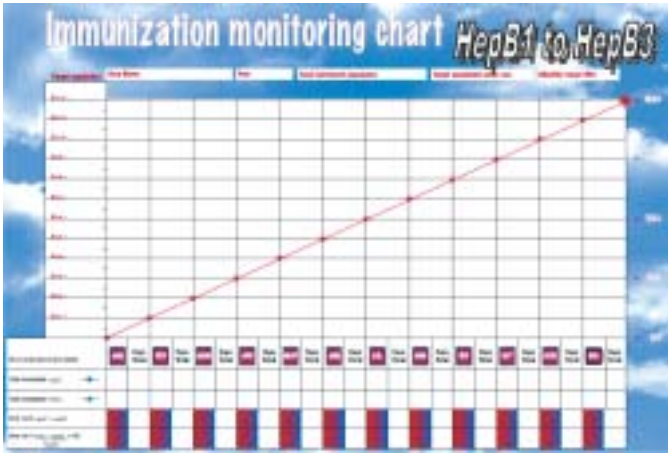
HepB3 Coverage: This measures the proportion of infants who complete the hepatitis B immunization series.

$$\frac{\text{Children immunized with HepB3 by 1 yr of age}}{\text{Target population (children under 1 yr of age)}} \times 100$$

HepB1 vs. HepB3: This monitors the drop-out rate (the proportion of children that are incompletely vaccinated) for HepB

$$\frac{\text{(HepB1 - HepB3)}}{\text{HepB1}} \times 100$$

The dropout rates for hepatitis B vaccine should not be higher



than drop-out rates for DPT and OPV. Use the WHO vaccine coverage monitoring chart to monitor these indicators graphically and provide feedback to lower administrative levels.

HepB3 vs. DPT3: This monitors completion of hepatitis B vaccine series in comparison with that of the DPT series. By the time the child has completed DPT series it should have received the last (third or fourth) dose of hepatitis B vaccine.

$$\frac{(\text{DPT3} - \text{HepB3})}{\text{HepB3}} \times 100$$

If DPT3 coverage exceeds HepB3 coverage by more than 5%, assess missed opportunities for administering hepatitis B vaccine, which may include:

Concern about wasting expensive vaccine leading to:

- Reluctance to open a vial for one child.

- HepB vaccine offered less often than DPT vaccine.
- HepB vaccine not available at all session sites.

Other reasons for missed immunization:

- Hepatitis B vaccine shortages or supply problems.
- False belief that hepatitis B vaccine has excessive contraindications.
- Inadequate staff training to administer new vaccine.
- In the case of monovalent vaccine, reluctance of mothers to accept multiple injections in single visit.

HepB-birth dose coverage:

Hepatitis B vaccine birth dose is given at a set up different than routine immunization program. Special efforts should be made to improve coverage with birth dose, and recording and reporting also. Measuring the percentage of children receiving hepatitis B vaccine within 24 hrs after birth provides an indicator of the success of the programme in preventing peri-natal HBV infections. It is also a good indicator of program efficiency.

There are a few additional activities, which can be done to increase coverage with birth dose of hepatitis B vaccine:

- Labor room and nursery staff have a greater role and they should also be trained
- Obstetricians and to the staff nurses may be given orientation training
- The hepatitis B vaccine may be made available round the clock close to the labor room

- Experience has shown the issues related to the recording and reporting of birth dose. The states and districts have to pay specific attention to this issue and may streamline it.
- The standardized IEC material for use at these institutions may be utilized and prominently displayed.

Use evaluated coverage data for monitoring

Immunization coverage surveys are useful for obtaining additional information relating to any improvement in immunization coverage. They often provide more accurate information than reported data. Standard questionnaires used for EPI surveys have to be modified to include hepatitis B vaccine doses. The important surveys of UIP coverage are:

- UNICEF Coverage Evaluation Survey
- National Family Health Survey (NFHS); and
- District Level Household Surveys (DLHS)

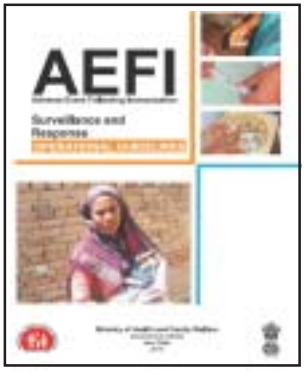
Serological surveys can also be used to provide serologic evidence of receipt of vaccination.

Monitor cold chain

The consequences of failures in cold chain are well known – hepatitis B vaccine gets damaged by higher temperatures as well as by freezing. The system will end up delivering vaccines that are no longer potent and effective if proper cold chain is not maintained. Therefore, strict attention to maintenance of cold chain is essential. The basic information that should be known to a supervisor/programme manager on the cold chain and the capacity and maintenance of various equip-

ments is summarized earlier. The efforts should be directed towards improving cold chain maintenance and temperature monitoring at various level. The posters on freeze sensitivity of RI vaccines and correct placement of vaccines in ILR should be displayed at strategically correct places at different levels.

Monitor immunization safety



Hepatitis B vaccine is very safe. However, any AEFIs suspected by health workers or public to temporally be associated with hepatitis B vaccination should be reported in the prescribed GoI formats, including death, disability, hospitalizations, and any other severe or unusual medical event or event clusters. The minor AEFIs should be reported through monthly reporting formats.

The immunization waste should be disposed off as per standard waste disposal guidelines. Check compliance with safety strategies from existing supervisor checklists (*Annexure 9)* and seek explanations for deviations from safety norms, such as recapping, non-use of hub-cutters and other incorrect practices

Evaluate impact

The ultimate outcomes of hepatitis B immunization (preventing chronic HBV infection and its long-term

consequences -cirrhosis and liver cancer) are difficult to measure. However, serological surveys can provide data on reduction in rates of HBV infection, compared to baseline HBsAg positivity data already available. Thus, a serological survey of 3-5 year old children conducted approximately 5 years after the full implementation of hepatitis B immunization programme and comparison with results from children of similar age in previous surveys can also provide data on programme's effectiveness, as part of a long-term evaluation process.

Post introduction evaluation (PIE)

The national govt or state may plan to conduct the Post Introduction Evaluation (PIE) of Hepatitis B vaccine introduction in the state/s. These PIE are usually done within 6-12 months of vaccine introduction in a state and aims to find out the status of vaccine introduction, its impact on the health system and to derive corrective lessons. The states should be encouraged to conduct such evaluations.

ANNEXURES

Information for Health Workers:

20 Frequently Asked Questions about Hepatitis B Disease and Vaccine

1. What is hepatitis B?

Hepatitis B is a disease due to infection and inflammation (swelling) of liver caused by HBV. Infection with HBV can cause short term (acute) or long- term (chronic) disease.

2. What are the clinical features of acute and chronic hepatitis B?

About 10% of infants and up-to 30% adults infected by HBV develop a short-term (acute) illness with the following clinical features:

- Fever
- Loss of appetite
- Tiredness
- Pain in muscles and joints
- Nausea, diarrhoea and vomiting
- Pain abdomen
- Headache
- Dark urine
- Pale stools
- Jaundice

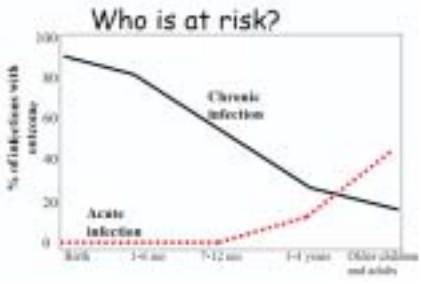
The incubation period is usually 2 to 5 months. Although most acute infections resolve normally, a few (about 1% of acute infections) can lead to fulminant hepatitis and can result in death.

In contrast, **90% of infants,** 30% of children of 1-5 yr and about 6% adults infected with HBV develop chronic infections. Chronic infections remain sub-clinical for a long time without symptoms. Persons with chronic infection have a 15- 25% risk of dying prematurely due to HBV related liver cirrhosis and cancer. Most of the chronic carriers of HBV look healthy but are capable of spreading the disease to others.

3. Why is hepatitis B a public health problem?

HBV infection is a major cause of acute and chronic liver disease. About one-third of the world's population i.e. about 200 crore (two billion) persons, are estimated to be infected with HBV. Of these 35 crore (350 million) suffer from chronic infection. The majority of the serious consequences of in fection with hepatitis B virus occur in people who develop the chronic infection. Worldwide about 5,00,000 -7,00,000 die annually from hepatitis B related complications.

4. Who is at risk of getting hepatitis B?



Anyone who has not been vaccinated can get HBV. Infants and children are particularly vulnerable for chronic infections. Children contract the disease from their mother at birth, or simply from another child while playing. Chronic infections from infancy are dangerous because of the liver damage and cancer.

5. How is hepatitis B spread?

HBV is transmitted through contact with infected blood or body fluids across skin/mucous membrane and unprotected sexual intercourse. HBV is 100 times more infectious than Human Immunodeficiency Virus (HIV). Unlike HIV, HBV is able to remain active on surfaces (e.g. table tops, razor blades, blood stains etc) for about a week.

The primary ways HBV can be spread are described below.

Child-to-child transmission: This (including adult to child) is one of the common modes of transmission. Infants and children frequently have no symptoms following hepatitis B infection. The infected child may look perfectly healthy. Child-to-child transmission usually happens during play, mock fights, scratching, biting etc. as a result of contact through skin sores, small breaks in the skin, or mucous membranes with blood, sores or saliva. Spread from inanimate objects, such as sharing of toys, towels or toothbrushes may also occur because HBV can survive for at least 7 days outside the body.

Mother to baby (peri-natal) transmission: Transmission from an infected mother to her baby usually happens at the time the baby is born.

Injection transmission: Unsafe injection practices such as sharing of needles by drug users or other unsafe medical procedures are a major source of HBV transmission

Sexual transmission: HBV spreads through unprotected sexual intercourse. It is 100 times more infectious than HIV.

6. How big a health problem is hepatitis B in India?

Hepatitis B is a major health problem in India. India falls under intermediate prevalence rate of HBV, with about 4 crore (40 million) HBsAg carriers in India. Of the 2 crore 60 lakhs (26 million) infants born every year in India, around 10 Lakh (1 million) run life-time risk of developing chronic hepatitis B infection.

7. Are there any other types of hepatitis virus?

Yes, in addition to Hepatitis B, there are Hepatitis A, Hepatitis C, Hepatitis D and Hepatitis E viruses. However, Hepatitis B is the most common cause of serious illness and death among all types of hepatitis.

8. Is there a cure against hepatitis B?

There is no known cure for hepatitis B; this is why prevention with hepatitis B vaccine is so important.

9. How can hepatitis B be prevented?

Hepatitis B can be prevented by a full series of hepatitis B vaccination. Hepatitis B vaccine is effective in preventing HBV infections if given either before or shortly after exposure (within 7 days). The vaccine has a high protective efficacy rate, particularly in children.

10. How effective is the vaccine?

The hepatitis B vaccine is 95 percent effective and can be given safely to infants, children and adults.

11. What are the limitations of hepatitis B vaccine?

HBV is one of five viruses known to cause hepatitis in humans. Hepatitis B vaccine only protects against hepatitis B and not other diseases that cause jaundice.

12. How safe is the hepatitis B vaccine? What are its side-effects?

Hepatitis B vaccine is a very safe vaccine with proven efficacy. Since 1982, over 100 crore (1 billion) doses of hepatitis B vaccine have been used worldwide.

Mild transient side effects:

Most common side effect is pain at the injection site. Mild systemic complaints like fatigue, headache, irritability and fever higher than 37.7°C which may usually start within a day after the vaccination and may last for one to two days.

Serious allergic (anaphylactic) reactions:

Serious allergic reactions to the vaccine are rare at about 1-2 per 10 lakh (1 million) doses and may include: generalized urticaria, difficulty in breathing, swelling of the mouth and throat, hypotension, shock

13. Who should get the hepatitis B vaccine?

All infants should receive hepatitis B vaccine.

14. How many doses are needed? When should they be given?

Apart from Birth dose three doses of hepatitis B vaccine should be given. All the doses must be given to ensure long-term protection. The doses are usually given at the same time as DPT and OPV vaccines (at 6, 10 and 14 weeks). 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.

15. Are there any contraindications to the hepatitis B vaccine?

The only two absolute contraindications to withhold or postpone the administration of the hepatitis B vaccine are:

- **A severe allergic reaction to a vaccine component or following a prior dose of hepatitis B vaccine**. Such allergic reactions are rare. Further doses are contraindicated if there is a history of anaphylaxis to a previous dose.
- **Persons with moderate or severe acute illness** should not be vaccinated until their condition improves. However, a minor illness, uch as an upper respiratory infection, is not a contraindication to vaccination

16. How is the vaccine presented?

It is a cloudy liquid that comes in a 10 dose vial and does not require reconstitution. If the vaccine is allowed to stand for a long time, it separates from liquid and looks like fine sand at the bottom of the vial. The vaccine must be mixed by shaking.

17. How is the vaccine stored?

The storage temperature for hepatitis B vaccine is the same as for all other T series (DPT, DT, TT) vaccines in the UIP, between 2°C and 8°C. Hepatitis B vaccine should never be frozen. Freezing the vaccine causes it to lose potency.

18. What are the safety measures to be followed at the time of vaccine administration?

Ensure that the following safety measures at the time of vaccine administration:

- Check the expiry date
- Check VVM to ensure that the vaccine is usable
- Do not use any frozen vaccine.
- Do not use any vial without label
- Use only AD syringes supplied for the purpose

Follow the waste disposal guidelines

19. What is the dosage and site of administration of the vaccine?

The standard paediatric dose of hepatitis B vaccine is 0.5ml. Hepatitis B vaccine is administered by intra muscular injection in the antero-lateral aspect of the thigh. It should NOT be given in buttock. It can safely be given at the same time as DPT and OPV vaccines. When hepatitis B vaccine is administered on the same day as DPT, the vaccines should be given in opposite limbs.

20. How will the reports of hepatitis B vaccine be submitted?

Reports will be sent in the UIP format to the PHC from Health worker and from PHC upwards up to National level consolidated on a monthly basis.

Annexure-2

Roles of Health Workers in the Introduction of Hepatitis B Vaccine

The introduction of the hepatitis B vaccine in the UIP is an important advancement for public health in India. You can help by:

1. Informing families about this new vaccine and its benefits.
2. Giving clear answers in simple language in response to questions from the public.
3. Conducting meetings with community leaders to orient them to the introduction of this new vaccine and about how they can better support the immunization programme.
4. Checking the immunization cards of children to see if any of them need vaccines or more doses of vaccines. Administer the vaccines as needed.
5. Treating the mothers or guardians with respect. Remember, in order to protect the health of children, it is essential to have collaboration between health workers and mothers or guardians of the children.
6. Assuring that each mother or guardian of the vaccinated child knows 4 key messages:
   - which vaccines the child received,
   - the possibility of side effects and what to do in the case of these effects
   - when to return for next dose or vaccination
   - to keep immunization card safe and bring it along for next visit.
7. Reminding parents about the dates and sites of immunization sessions
8. Following all instructions for storage and use of the vaccines.
9. Providing vaccine to all eligible infants following injection safety measures meticulously
10. Report all AEFIs immediately to MO, provide first aid and referral services in case of any serious AEFI.

11. Team up with AWW and ASHA to ensure success of the programme
12. Engage village elders and Panchayat members and obtain community support to the programme.
13. Utilize opportunity of Village Health Day to provide key messages to the community

Information for parents - 10 Frequently Asked Questions about Hepatitis B Disease and Vaccine

1. What is hepatitis B?

Hepatitis B is a serious liver disease caused by HBV, which occurs in the blood and body fluids of infected individuals. When persons are infected with HBV they may have features of acute infection:

- Fever
- Loss of appetite
- Tiredness
- Pain in muscles, joints
- Nausea, diarrhoea and vomiting
- Pain abdomen
- Headache
- Dark urine
- Pale stools
- Jaundice

More seriously, HBV infections during infancy and childhood frequently cause chronic (long-term) infection that can stay undetected without any symptoms in the body for decades before it leads to:

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

2. Who can get hepatitis B? Who is most at risk?

Anyone can get hepatitis B, but infants and young children are most at risk. Although infants and young children rarely become sick on acquiring the in fection, they are at high risk of developing chronic infection with HBV. Chronically infected persons are at high risk of dying from cirrhosis and liver cancer.

3. How is hepatitis B virus spread?

The main ways in which it spreads are:

a. from child to child and adult to child;

b. from mother to baby at birth;

c. through unsafe injections and transfusions;

d. through unprotected sex with an infected person.

The hepatitis B virus is found in the blood and body fluids of an infected person. It spreads to others when they come into contact with the blood or body fluids of infected person through small breaks in the skin and mucus membrane.

4. Can hepatitis B be prevented?

Yes. A safe and effective vaccine has been available since 1982. About 95% of infants who get at least 3 doses of the vaccine will be protected.

5. Who should get hepatitis B vaccine?

All infants should get hepatitis B Vaccine.

6. How many doses are needed? When should they be given?

Usually, hepatitis B vaccine is given at birth for all institutional deliveries as soon as possible but definitely within 24 hr. Then further three doses are given at 6, 10 and 14 weeks age (along with DPT injection and Oral Polio Drops). All the doses must be given to ensure that your child is protected. If a dose is missed it should be given as soon as possible. There is no need to start the schedule again.

7. How is hepatitis B vaccine given?

Hepatitis B vaccine is given by intramuscular injection in the mid-thigh (front and outer part of mid thigh). It can safely be given at the same time as other vaccines, such as DPT, OPV, Measles and BCG vaccines but at different sites by different syringes for each vaccine. In the UIP, hepatitis B vaccine is being offered to the children less than a year of age (infants only).

8. Does it cost anything to get the hepatitis B vaccine?

No. All vaccines under routine immunization including hepatitis B are given free of cost at all at government health facilities.

9. What are the side-effects of hepatitis B vaccine?

Hepatitis B vaccine is very safe. A few infants may suffer side-effects such as redness, swelling and pain at the injection site and mild fever that may last one or two days. Severe allergic reactions are extremely rare.

10. Is there any situation when a child should not be given hepatitis B vaccine?

A child who has had a severe reaction to a previous dose of hepatitis B vaccine should not be given another dose. If a child has a high fever the vaccine may be given at a later visit.

"Hepatitis B vaccine given early in life protects and saves the child from suffering some of the serious liver diseases later in life and also reduces spread of hepatitis B in the community"

Annexure-4

Information for Community Leaders

Government of India is including hepatitis B vaccination for infants in your State under Universal Immunization Programme. The vaccine will be given as an injection along with other vaccines already being given under the programme such as Oral Polio Vaccine (OPV) and DPT. This will help the infants fight one more killer disease hepatitis B, apart from the earlier 6 diseases.

This represents a n important advance for public health because it will help reduce a major public health burden in India. At present it is estimated that annually, out of the 2crore 60 Lakh (26 million) infants born every year in the country, around 10 Lakh (1 million) run the life-time risk of developing chronic hepatitis B Virus infection. Of these about 1.5 Lakh are likely to develop serious liver diseases such as cirrhosis, and cancer causing suffering and premature death at their peak productive age (30-50 yr). The vaccine given during infancy, helps prevent the hepatitis B virus infection and associated chronic complications later in life. The success of introduction of this vaccine in your community depends on your collaboration.

How can you help your community receive the hepatitis B vaccine?

- Inform families about the inclusion of hepatitis B vaccine in the routine immunization. All vaccines under routine immunization are provided free of cost.
- Explain to families the benefits of the vaccine which are: more protection without additional effort
- Be sure that each family knows that their child needs to get all the doses of vaccine as per the schedule (At birth for all institutional deliveries and later at 6, 10 and 14 weeks age along with 3 doses of DPT Injection and Oral Polio drops)
- Motivate families to complete vaccination of the child during its first year of life.
- Remind mothers to check immunization cards for the date of the next vaccination.

By Supporting the Immunization Programme, you are taking care of the health of your community. **Congratulations!**

Health Worker Training Pre-Test

1. Please fill in the blank cells in the Infant Immunization Schedule

Vaccine	Disease(s) prevented	Number of Dose(s)	Route	Site	Vaccine damaged by freezing
BCG					
DPT					
OPV					
Hep B					
Measles					

2. By what age should a child be fully immunized?
3. A 2-year-old has a card that shows only these vaccines given: BCG, DPT, OPV and HepB given at age 3 months and DPT, OPV and Hep B at age 6 months. Which vaccines would you recommend for today?
4. Is the hepatitis B vaccine effective against all forms of jaundice?

Score: For questions score 1 point for each correct answer.

Health Worker Training Pre-Test Answer key

1. Please fill in the blank cells in the Infant Immunization Schedule

Vaccine	Disease(s) prevented	Number of Dose(s)	Route	Site	Vaccine damaged by freezing
BCG	(TB)	(1)	(ID)	(Lt upper arm)	(No)
DPT	(Diphtheria Pertussis Tetanus)	(3)	(IM)	Antero Leteral aspect of mid-Thigh	(Yes)
OPV	(Polio)	(4)	Oral	(Mouth)	(No)
Hep B	(Hep B)	(4)	(IM)	(Antero Leteral aspect of mid-Thigh) not on the same thigh as DPT	(Yes)
Measles	(Measles)	(1)	(SC)	(Right upper arm)	(No)

2. By what age should a child be fully immunized? (Ans: 1 year)
3. A 2-year-old has a card that shows only these vaccines given: BCG, DPT, OPV and Hep B given at age 3 months and DPT, OPV and Hep B at age 6 months. Which vaccines would you recommend for today? (Ans: DPT and Measles)
4. Is the hepatitis B vaccine effective against all forms of jaundice? (Ans: No)

Score: For questions score 1 point for each correct one.

Annexure-6

REPORTING FORM OF IMMUNIZATION SESSION SITE (Tally Sheet)

Name of PHC/ Sub Centre	Name of village/Mohalla	Date of session:	Place of session

Children	Less than 1 year				More than 1 year			
Vaccine	*Tally*		*Total*		*Tally*		*Total*	
	Male	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*
BCG								
DPT1								
DPT2								
DPT3								
DPT Booster 1								
OPV 0								
OPV1								
OPV2								
OPV3								
OPV Booster								
Measles 1ST 1dose Measles 2nd 1dose								
Vit. A1								
Vit. A2								
Vit A3								
Vit. A4								
VIt. A5								
Vit. A6								
Vit. A7								
Vit. A8								
Vit. A9								
HepB0								
HepB1								
HepB2								
HepB3								
DPT Booster 2								

Women	Pregnant women		Others	
	Tally	Total	Tally	Total
TT1				
TT2				
TT Booster				

	Issued	*Consumed*	
AD SYRINGES 0. 5 ml 0.1 ml			
DISPOSABLE SYRINGES 5 ml			Names of staff
HepB VIALS			1. ANM. :
BCG VIALS			2. Superviser :
DPT VIALS			
OPV VIALS			Signature of ANM:
MEASLES VIALS			
TT VIALS			

Annexure-7

Supervision Checklist at Immunization Session site

Sl. No _____Date of Visit___/___/_____Supervisor_____PHC _____Name of Sub-centre_____ Location(PHC /SC/AWC/ Panchayat/UHC)_____

Adherence to Micro plan	
1. Session held in the village/mohalla specified in micro plan (date AND place)	Yes ☐ No ☐
Cold Chain and Logistics	
2. Collection of vaccines on same day/ vaccine delivered at session site	Yes ☐ No ☐
3. Use of vaccine carriers with 4 ice packs	Yes ☐ No ☐
4. Ice packs are properly conditioned	Yes ☐ No ☐
5. Use of polythene bag for all vaccines	Yes ☐ No ☐
6. All vaccines along with diluents available at session	Yes ☐ No ☐
7. Vitamin A available at session	Yes ☐ No ☐
8. Any frozen DPT, TT or HepB vial found?	Yes ☐ No ☐
9. VVM stage "usable" on OPV and HepB	Yes ☐ No ☐
10. All the vaccines at session are within expiry date	Yes ☐ No ☐
11. All vaccines have readable labels	Yes ☐ No ☐
Service delivery and Injection Safety	
12. Clean place available for immunization	Yes ☐ No ☐
13. Washes hands before beginning the immunization session	Yes ☐ No ☐
14. Vaccine is reconstituted correctly just before immunization session	Yes ☐ No ☐
15. Time of reconstitution written on vial	Yes ☐ No ☐
16. Use of correct diluents for BCG and measles	Yes ☐ No ☐
17. Reconstituted vaccines used within four hours of reconstitution	Yes ☐ No ☐
18. Use of 0.5 ml AD syringes for all vaccines except BCG	Yes ☐ No ☐
19. Use of AD syringes 0.1 ml for BCG	Yes ☐ No ☐
20. Correct selection of injection site	Yes ☐ No ☐
21. Correct selection of injection route	Yes ☐ No ☐
22. Correct technique of giving vaccines (angle of the needle for giving I/D, I/M and S/C injections)	Yes ☐ No ☐
23. Correct dose of vaccine given	Yes ☐ No ☐
24. Injection surface (if dirty) is cleaned with clean water swab before injecting	Yes ☐ No ☐
25. Needle NOT touched with swab or finger before injection	Yes ☐ No ☐
26. Correct age of administration of measles vaccine (9-12 months) and up to 5 years to missed children	Yes ☐ No ☐
27. Absence of recapping AND bending used syringes	Yes ☐ No ☐
28. Hub cutters in use for containing used needles after cutting plastic hub of the used syringes	Yes ☐ No ☐ NA ☐
29. Use of separate needle and syringe for each injection (including reconstitution syringes for each vaccine vial)	Yes ☐ No ☐
30. Evidence of maintaining at least 28 days gap between DPT doses	Yes ☐ No ☐
31. Correct method of waste collection for disposal	Yes ☐ No ☐ NA ☐
No needle stick injuries to ANM during last 3 months	Yes ☐ No ☐

Recognition and Treatment of Anaphylaxis

Anaphylaxis is a very rare (estimated as once every million doses of vaccine given) but severe and potentially fatal allergic reaction. ***When anaphylaxis does occur, the patient must be diagnosed properly, treated and managed urgently by trained staff and transferred to a hospital setting.***

Recognition of anaphylaxis

Anaphylaxis is a severe reaction of rapid onset (usually 5-30 minutes after the injection) characterized by circulatory collapse. The early signs of anaphylaxis are generalized erythema and urticaria with upper and/or lower respiratory tract obstruction. In more severe cases, limpness, pallor, loss of consciousness and hypotension become evident in addition. Vaccinators should be able to recognize the signs and symptoms of anaphylaxis in the box below. In general, the more severe the reaction, the more rapid the onset. Most life-threatening reactions begin within 10 minutes of immunization. ***Keep the vaccinee under observation for at least 20 minutes after the injection.***

Unconsciousness is rarely the sole manifestation of anaphylaxis - it only occurs as a late event in severe cases. A strong central pulse (e.g. carotid) is maintained during a faint, but not in anaphylaxis. Anaphylaxis usually involves multiple body systems. However, symptoms limited to only one body system (e.g., skin itching) can occur, leading to delay in diagnosis. Occasional reports have described reactions where symptoms recur 8 to 12 hours after onset of the original attack and prolonged attacks lasting up to 48 hours.

Clinical Progression	Signs and symptoms of anaphylaxis
Mild, Early Warning Signs	Itching of the skin, rash and swelling around injection site. Dizziness, general feeling of warmth
	Painless swellings in part of the body e.g., face or mouth. Flushed, itching skin, nasal congestion, sneezing, tears.
	Hoarseness, nausea, vomiting
	Swelling in the throat, difficulty breathing, abdominal pain
Late, Life-threatening Symptoms blood	Wheezing, noisy, difficulty breathing, collapse, low pressure, irregular weak pulse

Treatment of anaphylaxis

Once the diagnosis is made, **consider the patient as being in a potentially fatal condition, regardless of the severity of the current symptoms.** Begin treatment immediately and, at the same time, make plans to transfer the patient swiftly to hospital (if not already in a hospital setting). Adrenaline (epinephrine) stimulates the heart and reverses the spasm in the lung passages, and reduces edema

and urticaria, thus countering the anaphylaxis. But this very potent agent can cause irregular heartbeat, heart failure, severe hypertension, and tissue necrosis if used in inappropriate doses.

Each vaccinator who is trained in the treatment of anaphylaxis should have rapid access to an emergency kit with adrenaline, and be familiar with its dosage and administration. The expiry date of the adrenaline should be written on the outside of the emergency kit and the whole kit should be checked three or four times a year. Adrenaline that has a brown tinge must be discarded.

Steps in initial management

If already unconscious, place the patient in the recovery position and ensure the airway is clear.

Assess heart rate and respiratory rate (if the patient has a strong carotid pulse, he/she is probably not suffering from anaphylaxis).

If appropriate, begin cardiopulmonary resuscitation.

Give 1:1000 adrenaline (see below for correct dose for age or weight) *by deep intramuscular injection* into the opposite limb to that in which the vaccine was given. (Subcutaneous administration is acceptable in mild cases).

And *give an additional half dose around the injection site* (to delay antigen absorption).

I*f the patient is conscious after the adrenaline is given, place his/her head lower than the feet and keep the patient warm.*

Give *oxygen* by face mask, if available.

Call for professional assistance but never leave the patient alone. Call an ambulance (or arrange other means of transport, ***after*** the first injection of adrenaline, or sooner if there are sufficient people available to help you.

If there is no improvement in the patient's condition within 10-20 minutes, of the first injection, repeat the dose of adrenaline up to a maximum of three doses in total. Recovery from anaphylactic shock is usually rapid after adrenaline.

Record, or get someone to record, vital signs (pulse rate, respiratory rate and blood pressure), as well as time and exact dose of any medication given. Make sure the details accompany the patient when he is transferred. Mark the immunization card clearly so the individual **never** gets a repeat dose of the offending vaccine. At a suitable moment, explain to parents or relatives the importance of avoiding the vaccine in the future.

Report the occurrence of anaphylaxis to the appropriate officer in the ministry of health by fax or phone when the clinical situation is dealt with.

Adrenaline dosage: 1:1000 adrenaline (epinephrine) at a dose of 0.01ml/kg up to a maximum of 0.5 ml injected intramuscularly (or subcutaneously in very mild cases) If the weight of the patient is unknown, an approximate guide is:

Less than 2 years	0.0625 ml (1/16th of a ml)
2-5 years	0.125 ml (1/8th of a ml)
6-11 years	0.25 ml (1/4 of a ml)
11+ years	0.5 ml (1/2 of a ml)

Acknowledgement

These operational guidelines is the result of team work and collaboration between Immunization Division within Ministry of Health and Family Welfare, Govt of India and a development partners supporting routine immunization in India:

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- US Agency for International Development (USAID)/ MCHIP
- United Nations Children's Fund (UNICEF)