Introduction of Hepatitis B Vaccine In the Universal Immunization Programme

Operations Guide for Program Managers

Child Health Division

Department of Family Welfare

Ministry of Health & Family Welfare

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1. Magnitude of Problem

1.1 Hepatitis B: The World Scenario

Hepatitis B is a major public health problem worldwide. Approximately 30 percent of the world's population, i.e. about 2 billion persons, have serologic evidence of current or past HBV infection. Of these, an estimated 350 million have chronic HBV infection and at least one million persons die annually from HBV-related chronic liver disease, including cirrhosis and liver cancer.

Hepatitis B vaccine is safe and is highly effective in preventing HBV infection and its serious consequences. Protection afforded by this vaccine is long lasting. Numerous studies have shown that adding Hepatitis B vaccine into the Expanded Program of Immunization is highly cost-effective, even in areas with low HBV endemicity. In 1991, the Global Advisory Group of the Expanded Program on Immunization of WHO recommended that Hepatitis B vaccine should be introduced into national immunization programs in all countries by the year 1997. The World Health Assembly approved this in 1992. More than 100 countries have already included this vaccine in their national immunization programs. In countries that have implemented universal childhood Hepatitis B immunization, HBV carrier rates have declined markedly and incidence rates of long-term consequences like liver cancer have shown a decrease.

1.2 Hepatitis B in India

Based on the prevalence of Hepatitis B carrier state in the general population, countries are classified as having high (8% or more), intermediate (2-7%), or low (less than 2%) HBV endemicity. India has intermediate endemicity of Hepatitis B; with Hepatitis B surface antigen (HBsAg) prevalence between 2% and 10% among populations studied. The prevalence does not vary significantly by region in the country. The number of HBsAg carriers in India has been estimated to be over 40 million (*4 crore*). In India of the 25 million infants born every year, over one million run the lifetime risk of developing chronic HBV infection.

Estimates indicate that annually over 100,000 Indians die due to illness related with HBV infection.

Hepatitis B e Antigen (HbeAg) prevalence among pregnant women, who are HBsAg positive ranges between 8% and 47%, with most studies showing rates of 18% or less. Therefore, perinatal transmission is unlikely to be a major route of acquisition of HBV infection in India.

HBV infection and its long-term consequences can be prevented with the use of a safe vaccine. World Health Organization (WHO) recommends that Hepatitis B vaccine should be given to all infants.

Several cost-effectiveness analyses of inclusion of Hepatitis B vaccine in India's national immunization program have been performed. These indicate that universal childhood Hepatitis B immunization in India will be highly cost-effective. It is thus, desirable that the vaccine be included in India's national immunization program at an early date.

1.3 Experience with Hepatitis B Vaccination in India

During the last few years, Hepatitis B vaccine has been available in the private sector in urban areas for those who can afford it. The Indian Academy of Paediatrics, which is the highest professional body of paediatricians in the country, has advocated Hepatitis B vaccine as part of the routine immunization schedule. Many doctors therefore, administer Hepatitis B vaccine to patients and children under their care. In addition, schools and non-governmental voluntary organizations have been organising Hepatitis B vaccination drives based on payment by the recipients. Though these drives possibly reflect public acceptance and demand for Hepatitis B vaccine, the vaccine has not reached the rural population and the urban poor. It is important to note that close to 90% of immunization in India is provided by the public sector.

The Government of India is also supporting planned state programs for introduction of new vaccines as part of routine immunization. These include the Government of Andhra Pradesh's Partnership Project for Hepatitis B vaccine and strengthening of routine immunization with the Children's Vaccine Program at PATH. This project is expected to (i) help in development of IEC resource material and (ii) provide experience with training of staff, planning of cold chain and other vaccine logistics planning. These will prove useful when the national-level program is launched.

The other states to initiate introduction of Hepatitis B vaccination in a limited way in the U.I.P. (Universal Immunization Program) are Delhi, Kerala and Haryana.

The Government of India is now working towards a planned phasing-in of Hepatitis B vaccine, based on programmatic capacity of the states and districts and sustainable funding.

2. Objectives & Strategy for Introducing Hepatitis B Immunization as part of UIP

2.1 Goals and Objectives of Hepatitis B Immunization

The ultimate goal of Hepatitis B vaccination is to reduce morbidity and mortality associated with chronic HBV infection, including cirrhosis and liver cancer. However, because the long-term consequences of HBV infection occur several years after infection, this goal will take a long time to attain. Therefore, the following short-term goals and objectives have been defined:

- Phased introduction of Hepatitis B vaccine into the UIP.
- Delivery of Hepatitis B vaccine and all other EPI 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 & action on improving the monitoring of cold chain, Injection safety & proper disposal of medical waste including the A.D. syringes.

3. Strategy for Hepatitis B Immunization

3.1 Approach to Introduce the Vaccine in Phased Manner

The Government of India has decided to include Hepatitis B vaccine in its National Immunization Program. However, in view of the country's vast size, financial and logistic constraints, and other factors, it is proposed to phase in the vaccine gradually.

Initially during the year 2002, urban slums in 15 cities would be covered by this immunization. In the next year, *(2003)* 32 rural districts will be included. Thereafter, the Govt. of India plans to expand the coverage with Hepatitis B vaccine to additional districts in a phased manner. Districts that demonstrate a high vaccination coverage rate (fully immunized children above 80 percent) will be included. Other districts will be encouraged to improve routine program performance, before they are considered for this additional vaccine.

4. Management Issues related with Hepatitis B Immunization

4.1 Starting with most needy & with due attention for Quality

Though children rarely develop acute illness after infection, children run the highest risk of developing chronic Hepatitis B disease, which may cause liver complications including the liver cancer later in life. These complications can be prevented if children are immunized in early childhood with Hepatitis B vaccine before they contract the infection. According to the strategy decided by the Government of India, children below the age of one year in only the slums of the selected cities and all the infants in selected districts will be offered free Hepatitis B vaccination. Each child will receive three doses, simultaneously with the three doses of DPT. In areas where Hepatitis B vaccine is introduced, all vaccinations for children will be administered using auto-disable (AD) syringes.

4.2 Vaccine Preparation

Monovalent Hepatitis B vaccine in 10-dose vials will be used. Vaccine requirements for the next few years have been worked out. Several companies now manufacture Hepatitis B vaccine indigenously in India.

Before the introduction of this new vaccine, cold chain requirements may need to be reviewed. Administrative forms and immunization cards will also need revision to allow for the new vaccine. Training of UIP staff on technical and practical aspects of Hepatitis B disease, Hepatitis B vaccine, and how to record administration of the new vaccine will be required. Providing information to the public and to key decision-makers will be beneficial. Evaluation of introduction of Hepatitis B vaccine will be accomplished through regular monitoring, and through review of reported coverage data. Sero-surveys, conducted a few years after the introduction of the vaccine, will further help in determining the effectiveness of the program.

Table 1: Phasing-in of Hepatitis B Vaccine in Selected Urban Slums and Rural Districts

Phase I A (July 2002-July 2003) Metro cities					Phase 1 B (Aug 2003- Aug 2004)				
Slum	Total Popn 2001 (millions)	Surviving infants 2002	Target popn 2002	F. I.* (%)	District	Total Popn (millions)	Surviving Infants	Target popn	F. I.* (%)
Greater Mumbai	19.9	131805	118361	90	Madurai	5.6	75487	75110	99.5
Kolkata	6.6	94233	78685	84	Nilgiri	1.7	15608	15483	99
Chennai	6.11	36562	36014	98	Virudhnagar	3.8	71407	68908	97
Delhi	19.9	67973	57641	85	Ramanathapuram	2.6	25502	24814	97
Hyderabad	5.3	26866	22809	85	Alapuzzha	4.6	40804	39009	96
Bangalore	9.5	17372	13498	78	Erakulum	6.7	58146	54366	94
Ahmedabad	8.4	21715	16330	75	Pathamithan	2.7	40804	37376	92
Kanpur	5.9	17170	10731	62	Kodagu	1.2	51005	48404	95
Pune	11.9	13029	9433	72	Shimoga	3.5	51005	47231	93
Lucknow	5.3	11211	8218	73	Mysore	5.7	45905	42645	93
Vadodra	5.3	104030	63458	61	Chittoor	8.1	77528	67759	87
Jaipur	7.6	19190	8060	42	Vizianagaram	0.5	54065	45253	84
Indore	3.7	67670	46287	68	Goa	2.9	10201	9038	87
Patna	6.8	28280	4016	14	Ratnagiri	3.7	38764	36012	93
Bhopal	2.7	70700	55782	79	Chandrapur	4.5	45905	28966	63
					Satara	6.1	45905	42508	93
					Balaghat	3.1	23462	21210	90
					Sundergarh	1.8	45905	36861	80
					Rupnagar	2.2	23462	21984	93
					Hoshiarpur	3.2	36724	34226	93
					Panchkula	1.0	14281	12796	90
					Ambala	2.2	36724	31913	87
					Hamirpur	1.0	11221	10380	93
					Solan	1.1	20402	18566	91
					Nainital	1.6	30603	25309	83
					Pondicherry	1.6	20402	19606	96
					Lakshdweep	0.1	20402	19280	95
					Jorhat	2.1	30603	29073	95
					Sibsagar	2.3	30603	25400	83
					Rajouri	1.0	30603	30328	99
					Udhampur	1.6	28563	25450	89
					Surat	4.9		19600	80
Total Phase IA		**727806**	**549321**						
Phase IB districts							1164240	1055018	
Phase IB cities							735084	554815	
Total for Phase IB							**1899324**	**1609833**	

*** F.I. = Percentage of fully immunized children with 1dose of BCG & Measles vaccine & 3 doses of DPT & Oral Polio Vaccine within first year of life.**

4.3 Reducing Vaccine Wastage

Vaccine wastage has been currently estimated at approximately 25%, i.e. five percent higher than that for DPT. This allows accounting for wastage due to availability of lesser children at times and some leakages during the phasing-in period. However, prior to the introduction of Hepatitis B vaccine, a study will be undertaken to determine baseline wastage rates and reasons. This will help evolve strategies to reduce vaccine wastage. Vaccine manufacturers are soon likely to start attaching Vaccine Vial Monitors (VVMs) to all Hepatitis B vaccine vials to indicate whether the vaccine has been damaged by heat.

Once VVMs become commonplace, an open vial policy will be encouraged to reduce vaccine wastage. ***Special attention will need to be given to prevention of use in non-targeted populations*.**

According to the WHO multidose vial policy (WHO/V&B/00.09), opened, multidose vials of Hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks ***in Fixed Health Facilities if all the following conditions are met:***

- *The expiry date has not passed.*
- *The vial has been stored under appropriate cold chain conditions (i.e. refrigerated between 2^o C and 8^o C).*
- *The vaccine vial septum (where the needle is put in to withdraw doses) has not been submerged in water (to prevent this from happening, well-sealed ice packs should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored).*
- *An aseptic technique has been used to withdraw all doses.*
- *The Vaccine Vial Monitor (VVM), if attached, has not reached the discard point.*

In Outreach Sessions, opened multi-dose vials of Hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks if:

- *All the above conditions for reuse of multi-dose vials in fixed health facilities are met; and*
- *A VVM is attached to the vial.*

4.4 Vaccine Requirements

The estimated number of doses of monovalent Hepatitis B vaccine that will be required over the next two years (2002-2003) are being estimated based on the population of infants for each city and district as shown in Table 1 above. These estimates were produced using the assumption of 25% vaccine wastage rate in 2002 and 20% in 2003.

There is urgent need for feedback from State EPI officers of the concerned states and District Immunization Officers about the actual number of infants living in slums of cities and districts stated above. The source of this information also needs to be specified. This will help the concerned officers from Government of India to review the requirement of vaccine more accurately.

4.5 Injection Safety

Currently, reusable glass syringes and needles and sterilization equipment like autoclaves/double rack steam sterilizers are used throughout India. There is evidence that in some areas the quality and safety of injection techniques and sterilization is uncertain. The Government desires to improve injection safety and is planning to conduct a comprehensive injection safety assessment and use the findings to outline a national policy on the injection safety. In the project cities and districts, through this initiative, the UIP is assessing the feasibility & benefits of moving away from the currently used reusable / sterilizable syringes and needles to auto-disable (AD) syringes in accordance with the WHO-UNICEF-UNFPA policy statement on injection safety. **It is planned that in all the 15 cities and 32 districts listed above, AD syringes will be used for all routine immunization of infants, including Hepatitis B vaccines.**

4.6 Cold Chain Logistics

Introduction of monovalent Hepatitis B vaccine will require an assessment of cold-chain capacity. The Hepatitis B vaccine is relatively heat stable but is easily destroyed by freezing. Therefore, storage and shipping procedures to prevent freezing of vaccines at all levels of the cold chain will need attention. Under the Immunization Strengthening Project (World Bank), a major effort to not only replace but also to expand the cold chain, has been undertaken over the last two years. Several states (Andhra Pradesh 2001, Madhya Pradesh 2000, Orissa 2000 and Uttar Pradesh 1999) have conducted assessments of their cold chain requirements. In these states, it has been shown that the need for cold chain space can be addressed by moving equipment form some districts with excess refrigerators to those that are deficient. This fact was proved to be true when these districts successfully conducted national immunization days for polio immunization, without any cold chain capacity constraints. Some ongoing activities of the Government of India regarding the cold chain are:

1. Procurement of additional cold chain equipment and vaccine vans, which would be required in the next three years through the Immunization Strengthening Project.

2. Assistance from KfW for cold chain equipment procurement is already in progress and the equipment is being installed in priority districts.

3. Solar refrigerators provided by JICA are also being installed in Eastern India.

4. Funds from the Immunization Strengthening Project are available for maintenance of the existing cold chain equipment.

Even though the government is convinced that cold chain will not be a major problem in the target districts, the Government of India will conduct further district-specific cold chain capacity assessment. As a first step in this process, the Government of India has approached the WHO/SEARO cold-chain expert to conduct a brief review of the cold chain space requirement in these districts. The cold-chain expert has calculated the extra cold chain space required *(see Table below)*.

District Program Officers have been requested through letter No. T 220020/2/ 2000- CH (Pt) dated 6th March 2002 from Joint Secretary MOHFW, Govt. of India, to review the cold chain system prior to introduction of Hepatitis B vaccine in all districts, in order to ensure sufficient cold storage capacity. -

4.7 Administrative Aspects

All UIP forms, administrative and reporting formats will need to be revised/updated by the concerned State & District authorities (Director Family Welfare, SEPIO, CMHOs & DIOs) to include Hepatitis B vaccine. These include:

- *Immunization schedule*
- *Immunization card*
- *Daily tally sheet*
- *Vaccine inventory register*
- *Vaccination register*
- *Monthly report forms*

5. Training of Trainers, Doctors & Health Workers:

The initial training of selected Master Trainers deputed by states for introduction of Hepatitis B vaccine will be conducted by PATH. This will be followed by the training of doctors, supervisors and vaccinators by the Master Trainers in all the selected cities and districts participating in the Program. In coming years, gradually the training for introduction of Hepatitis B vaccine will be integrated with the ongoing training for Universal Immunization Program (UIP). The India UIP will use funding made available through the World Bank for these training activities. Children's Vaccine Program at PATH has also been approached and has agreed to provide the required training materials.

5.1 Training of Master Trainers:

Four Master Trainers from each of the 15 first phase cities will be trained in 2 batches of 30 participants each. These 2 batches will be trained at New Delhi in June 2002. The training duration for each batch will be two-three days.

5.2 Training of Trainers

The **Trainers** selected from each city will be responsible to train the Vaccinators, Supervisors and Medical Officers / Program Managers in his/her city/district. Five Regional Training Programs will be organized to train the trainers in July 2002. The duration of this training will also be 2-3 days.

5.3 Training of Vaccinators, Supervisors, Medical Officers & Program Managers

In cities, the training program will be organized for vaccinators with the help of the Trainers as well as the Master Trainers referred above. It is expected that training of Medical Officers & Program Managers will be completed by August 2002. The training of vaccinators is to be completed by September 2002.

5.4 Cold Chain training

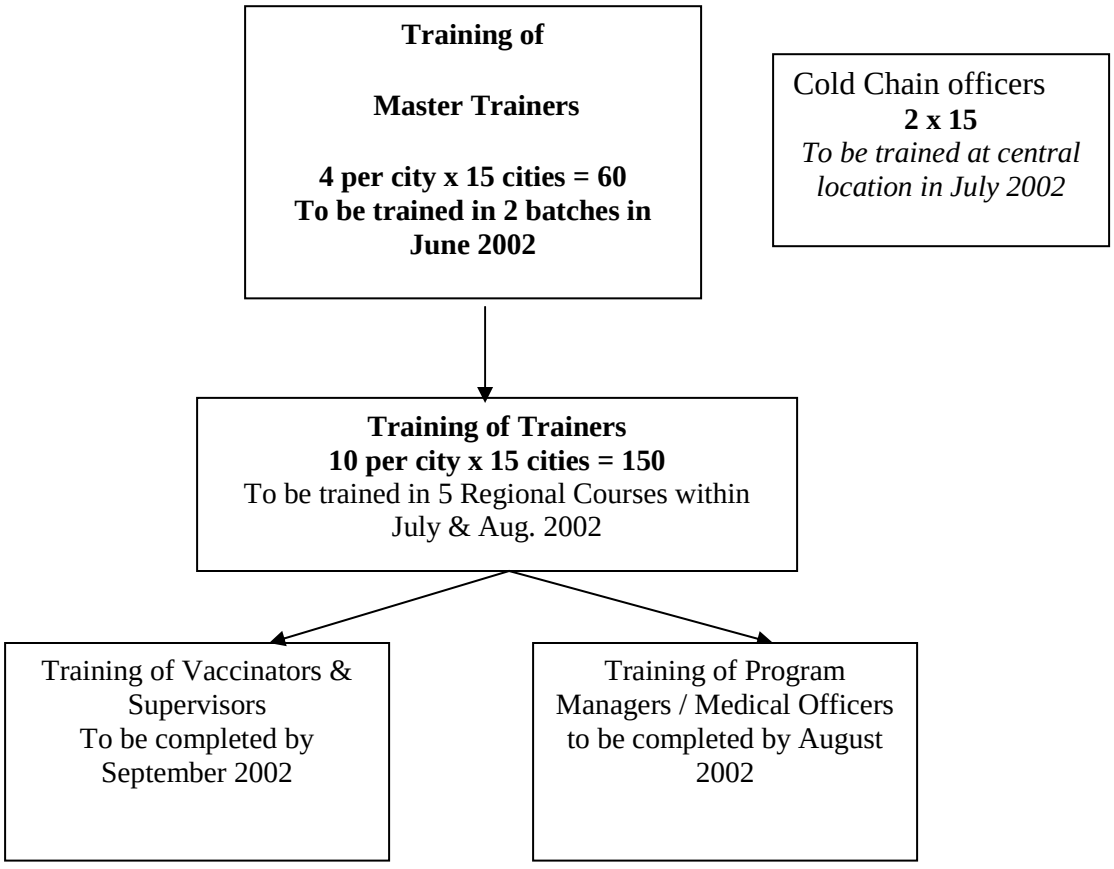
Two cold chain officials from each of the 15 first phase cities will be trained. This training will be organized at a central location in July 2002.

5.5 The contents of training will include:

Micro planning for assessment of Beneficiaries, Vaccine, Cold Chain, Manpower & Scheduling of Vaccination Sessions

All the concerned medical officers, supervisors & vaccinators will be trained by the Trainers and Master Trainers in their city/district about use of Hepatitis B vaccine, use and safe disposal of AD syringes, maintaining the cold chain, monitoring /treating any adverse reaction effectively, monitoring through field visits and reports, progress and constraints in the implementation and possible solutions to implementation challenges.

The Flow Chart of Training Plan



6. Practical Information on Administration of Vaccine

6.1 Vaccination Schedule

The proposed new schedule for childhood immunization using monovalent Hepatitis B vaccine is given in Table 2 below:

Table 2: Proposed Childhood Vaccination Schedule, India

Vaccine	***Schedule***
BCG	Birth
OPV	6 weeks, 10 weeks, 14 weeks
DPT	6 weeks, 10 weeks, 14 weeks
Hepatitis B	6 weeks, 10 weeks, 14 weeks
Measles	9 months

The Hepatitis B & DPT vaccines can be given on the same day on different limbs. That is, if DPT is injected in the left lower limb of the infant, Hepatitis B vaccine can be given in the right lower limb at the same time. Further, the recommended age of receiving DPT, Hepatitis B & Oral Polio immunization is the same as stated above The mild fever observed in some children receiving Hepatitis B vaccine & DPT vaccine on the same day is the same in intensity as observed when DPT vaccine alone is administered.

6.2 Birth Dose of Hepatitis B Vaccine

As a result of the low rate of HBeAg-positivity among persons with chronic HBV infection in India, perinatal HBV transmission probably accounts for a minor proportion of HBV transmission. Further, only about 25% of all births in India take place in hospitals. Therefore, a birth dose of Hepatitis B vaccine is not being incorporated in the UIP schedule. The feasibility of providing a birth dose to neonates of women who deliver in hospitals may be considered at a future date.

6.3 Contraindications

There are very few reasons to withhold or postpone the administration of Hepatitis B vaccine. Immunizations are too often delayed or denied because of conditions falsely believed by health care workers to be contraindications for the administration of vaccine.

A child with a history of a severe allergic reaction (e.g. generalized urticaria, difficulty in breathing, swelling of the mouth and throat, hypertension, shock) to a previous dose of Hepatitis B vaccine should not receive another dose.

6.4 Safety of Hepatitis B Vaccine:

Hepatitis B vaccine is a very safe and proven vaccine, with over a 100 countries administering it as part of their routine immunization programmes. Hepatitis B vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of Hepatitis B vaccine have been used worldwide.

Mild transient side effects that may occur after immunization include soreness at the injection site (3−9%); fatigue, headache and irritability (8−18%); and fever higher than 37.7°C (0.4−8%). These transient side effects usually start within a day after the vaccine has been given and last from one to three days. When Hepatitis B vaccine is given at the same time as DTP vaccine, the rate of fever and/or irritability is no higher than when DTP is given alone.

Serious allergic reactions to the vaccine, i.e. hives, difficulty in breathing and shock are rare, affecting about one child per 600 000 vaccinated. **(***Reference: Vaccine Safety Committee, Institute of Medicine,* Hepatitis B Vaccines, in Stratton KR, Howe CJ, Johnston RB, eds. *Adverse events associated with childhood vaccines: evidence bearing on causality.* Washington DC, National Academy Press, 1994: 211−235.**)**

Serious side effects reported after receiving Hepatitis B vaccine are very uncommon *(Andre, 1989; CDC, 1991 a; Greenberg, 1993; Niu, 1996)*. While reported, there is no confirmed scientific evidence that Hepatitis B vaccine causes chronic illness, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, or autoimmune disorders. There is no risk of HBV infection from the vaccine.

Large-scale Hepatitis B immunization programs in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events. Furthermore, surveillance of adverse events in the United States after Hepatitis B vaccination have not shown a clear association between Hepatitis B vaccine and the occurrence of serious adverse events including Guillain-Barre' syndrome, transverse myelitis, optic neuritis, and seizures *(Shaw, 1988; CDC, 1991 a; Niu, 1996; Niu 1998 CDC, unpublished data)*. Additional evaluations are ongoing. A recent study suggested persons developing rheumatoid arthritis after Hepatitis B vaccination were genetically at-risk for rheumatoid arthritis (*Pope, 1998*).

Any presumed risk of adverse events associated with Hepatitis B vaccination must be balanced with the expected 4,000 to 5,000 HBV-related liver disease deaths that would occur without immunization, assuming a 5 percent lifetime risk of HBV infection.

6.5 The following are NOT contraindications

- *Minor illness, such as respiratory tract infection or diarrhoea with temperature below 38.5 °C;*
- *Allergy or asthma;*
- *Family history of convulsions;*
- *Treatment with antibiotics;*
- *Infection with HIV;*
- *Breastfeeding;*
- *History of seizures (convulsions, fits);*
- *Chronic illnesses such as chronic diseases of the heart, lung, kidney or liver;*
- *Stable neurological conditions such as cerebral palsy and Down syndrome;*
- *Prematurity or low birth weight;*
- *History of jaundice at birth*
-

6.6 Limitations

Hepatitis B vaccine protects only against Hepatitis B; it does not protect against other types of hepatitis or jaundice.

More than 95% of infants develop protective antibodies after three doses of Hepatitis B vaccine. However, small percentages are not protected after vaccination.

7. Management of Adverse Events Following Immunization (AEFIs)

Although extremely rare, the health system has to be prepared for managing adverse events following immunization.

7.1 Suggested Actions for Managing AEFIs

1. When parents bring a child with complaints after the immunization, please listen patiently. Do not ignore them.

2. Do not panic and please attend the patient immediately. Keeping the child under observation for the next 24 hours is recommended. The suggested guidelines for clinical management are stated below.

A. *Fever & pain at the site of injection*

Give Paracetamol, 10-15mgm/Kg Body Weight.
Child aged 6months to 1 year - 1/4th Tab. (Standard Tablet of 500mg)
Child aged 1 year to 3 years - 1/2 Tab.
Child aged 3 years to 5 years - 1/2 Tab.
(The paracetamol syrup contains 125mg/5ml & in case of the children not able to swallow the tablet the syrup can be prescribed)

B. Anaphylactic Reaction

Symptoms: Pruritus, Erythema, Urticaria, Angio Neuritic Oedema, Cold clammy skin, cyanosis, feeble pulse & Hypotension. Angioedema may present as hoarseness of voice & stridor (noisy laboured breathing).

Treatment: Adrenalin: 0.015 ml/Kg Body Weight of 1:1000 dilutions injected subcutaneously.

This can be repeated after 15 minutes. In case of severe reaction1:000 dilution can be given intravenous immediately.

Hydrocortisone: 100 mg intravenous stat & repeat if required.

Intravenous Fluids: Start Ringers lactate or ½ strength isotonic saline & maintain intravenous line for administration of i/v drugs.
Inj. Aminophylline: 4 to 6 mg./Kg. diluted with 20 ml of saline is given i/v in case of broncho spasm. It can be repeated every 4 to 6 hours if required.

Maintain clear airway. In case of respiratory failure Cardiopulmonary Resuscitation may be required. Depending on the place of action & facilities available it can be done by – Mouth-to-Mouth Breathing, Bag & Mask, Intubation if facilities & trained personnel are available.

Antibiotics: are ordinarily not indicated. In case there is an associated systemic infection & toxic shock syndrome the combination of Inj. Ampicillin 100mg./Kg Body Weight in 4 divided doses along with Gentamycin 5mg./Kg divided in 3 doses can be given.

3. If the patient is not responding to the treatment provided refer him quickly to the nearest hospital with better clinical facilities & more trained staff.

4. Note down the detailed address of the child, history of any previous illness the child may be having, details of sign symptoms of adverse reaction observed, any other treatment/ vaccine taken along with the Hepatitis B vaccine, treatment provided for adverse reaction and detailed address of the hospital where the child is being referred.

5. Inform your senior district and state authorities with stated details about the adverse reaction observed.

6. As a standard practice keep an Adverse Reaction Kit ready for use by medical officer at all the vaccination sessions containing Injection Adrenalin, Hydrocortisone, Aminophylline & Tablet Paracetamol to deal with adverse reaction due to any vaccine.

8. Preparations for Launching the Program in your City/ District:

Hepatitis B vaccination is being introduced in the first phase in selected 15 cities and 32 districts in the country. The main consideration for selecting these locations is coverage of more than 80 percent eligible children through routine immunization, based on coverage evaluation surveys.

According to the strategy decided by the Government of India, children below the age of one year in only the slums of the selected cities and ALL the infants in selected districts will be offered free Hepatitis B vaccination.

- Basic information on the umber and location of slums in your city/district & approximate number of infants (children below the age of one year), as per the latest census should be obtained. A working map of the city/district showing important landmarks, location of slums and health care facilities (government, private, & NGO) also needs to be procured, if not already available.

- The nearest cold storage facility available in working order, where the delivery of Hepatitis B vaccine would be most appropriate should also be communicated to the central cell at the Ministry of Health.

- A list of organizations/ NGOs that can help in motivating the slum community to utilize immunization services should be prepared to ensure the success and sustainability of this initiative.

- An assessment of any additional cold chain capacity that may be required, repair & maintenance needs to be fulfilled should also be assessed and addressed, This will ensure that existing vaccines and the new Hepatitis B vaccine to be received from July 2002 onwards will be stored safely.

- Selection and nomination of capable and committed officers and other experienced trainers for master trainer training under this project should be done. These master trainers will then take the responsibility of training all the medical officers, supervisors and vaccinators in their city/district about use of Hepatitis B vaccine, use and safe disposal of AD syringes, maintaining the cold chain, and monitoring /treating any adverse reaction effectively. Hence it is extremely important that no compromise is done in selection of good trainers.

- A checklist for the above requirements is enclosed as Enclosure 1, for ready reference by program managers.

- The overall time schedule of major activities at the national and state level under this initiative is enclosed as Enclosure 7.

- ***The Chronogram of activities to be initiated at each level for introducing Hepatitis B vaccination in selected cities & districts is summarized below. This can be used as a checklist of the responsibilities for all the partners of the program.***

Table 3: Chronogram of Activities at Each Level for introduction of Hepatitis B in 15 Cities in year 2002-03

	Activities	Sub Activity	Sub Activity	Sub Activity	Sub Activity	Sub Activity
Jan.-March 2002	Initiating Preparatory Activities at National Level Informing concerned states/ cities through formal letter about the program.	Finalising Plans for study on Cold Chain Assessment & assigning to suitable Organization	Finalising Plans for study on Proper disposal of AD syringes, Sharps & assigning to suitable Organization	Development of Training Material for Introducing Hep. B vaccination	Initiating National Injection Safety Coalition	Development of Operations Guide for Program Managers
Person Responsible	GOI	UNICEF & GOI	WHO, GOI & UNICEF	PATH, GOI, WHO & UNICEF	PATH, GOI, WHO, UNICEF, WORLD BANK, IAP & Rep. Of Industry.	WHO, GOI, PATH & UNICEF
April- June 2002	Developing City Action Plans Selecting Master Trainers National Launching ceremony	National Workshop for Program Managers of 15 cities to brief about the Program & Action Plan May 2002	Development of Action Plan by each city & submission to G.O.I. June 2002	- Nominate Master Trainers for Training - Send list to GOI by May 30th 2002. -Implement IEC Activities in June & July 2002	Training of Master Trainers In June 2002	National Launching ceremony for Hepatitis B in June 2002
Person/ Organization Responsible		Govt. of India assisted by WHO, PATH & UNICEF	CMHO & Dist. Imm Officer under supervision of SEPIO, Director & Secy. F.W.	CMHO & Dist. Immunization Officer under supervision of SEPIO, Director & Secy. F.W.	GOI assisted by PATH, WHO & UNICEF	GOI

	Activities	Sub Activity	Sub Activity	Sub Activity	Sub Activity	Sub Activity
July-Sept 2002	IEC Activities for introducing Hepatitis B vaccination Training of functionaries by Master Trainers Procurement & Supply of Hepatitis B vaccine & AD syringes Start providing Hep B vaccination with DPT from Sept.2002	Trainings of Trainers to be completed within July-Aug.2002	Training of Cold Chain Officers in July 2002.	Trainings of concerned Medical Officers, Vaccinators, MPW & Supervisors by Master Trainers & Trainers to be completed within Aug.-Oct. 2002	Procurement & Supply of Hepatitis B vaccine & AD syringes at Regional Vaccine Storage facility at Chennai, Kolkotta Mumbai & Karnal in July 2002	Procurement & Supply of Hepatitis B vaccine & AD syringes from Regional Stores to 15 selected cities in Aug. 2002. Start providing Hep B vaccination with dose 1,2 & 3 of DPT from Sept.2002
Person Responsible		G.O.I.,W.H.O.,UNICEF, PATH,Master Trainers SEPIO, SIHFW & Medical College	GOI assisted by PATH, WHO & UNICEF	Master Trainers & Trainers under supervision of SEPIO, SIHFW & Medical College	GAVI, UNICEF & GOI	GOI & SEPIO/Director F.W of concerned States along with CMHO& cold chain officer of concerned cities.

	Activities	Sub Activity	Sub Activity	Sub Activity	Sub Activity	Sub Activity
Oct.-Dec 2002	Start providing Hep B vaccination with DPT Monitoring of introduction and feedback Discussion & Action for Safe Injection Practices & Proper disposal of AD syringes & Sharps	Start providing Hep B vaccination with DPT to infants in slums of selected cities	Monitoring of introduction of Hep. B vaccination with Quality, Proper Management of any adverse reaction & feedback to State & GOI	Monitoring Visits by National Technical Experts along with National & State Program Managers to review Progress & to assist in solving Problems	-National Workshop for Program Managers of 15 cities to review the progress of the program -Discussion & Action for Safe Injection Practices & Proper disposal of AD syringes & Sharps	Action for Safe Injection Practices & Proper disposal of AD syringes & Sharps to be started in each city participating in the Program
Person Responsible		Doctors & vaccinators working with Med. Coll. & District Hospitals, All Govt. Health Care facilities in urban area	Chief of Med. Coll. & Dist. Hospital, Medical Section of Municipal Corp., CMHO, SEPIO, Director & Secy. F.W.	Govt. of India & concerned State Govts. assisted by WHO, PATH & UNICEF	Govt. of India assisted by WHO, PATH & UNICEF	Chief of Med. Coll. & Dist. Hospital, Medical Section of Municipal Corp., CMHO, SEPIO, Director & Secy. F.W.
Jan.-March 2003	Same Activities to be started for 32 dist. as started in April – June 2002 for 15 cities except National Launching Ceremony.					

9. Micro planning for assessment of Beneficiaries, Vaccine, Cold Chain, Manpower & Scheduling of Vaccination Sessions

The method of calculating beneficiaries is quite simple and is similar to the method of calculation for other vaccines being used under the UIP. Detailed calculations of beneficiaries, logistics and personnel requirements are vital to successful planning and implementation. These calculations and planning should be in micro detail, including that for immunization sessions in outreach and or fixed facilities. All constraints should be identified and corrective measures instituted well in advance.

The guidelines for calculating requirements are summarized in the table stated below. The example of calculation shown in this table is an effort to demonstrate that assessing the requirements & constraints in advance is possible. Hence it should be viewed as a guideline. The further fine tuning of the micro plan will be required by local program managers depending on the local circumstances & manpower available.

Table 4: Assessment of Requirements for Micro planning Immunization Sessions

Beneficiaries	Total slum population X birth rate X 0.8 (aiming at coverage of 80% infants
Doses of Vaccine needed for Hepatitis B	No. of Beneficiaries X 3 doses for each child X 1.25 (the multiplication by 1.25 is to include 20% vaccine wastage)
No. of Vaccine Vials	Total doses needed as calculated above / 10 (the division by 10 is done because each vial of Hepatitis B vaccine contains 10 doses)
AD Syringes	• No. of Beneficiaries X 3 AD syringes of 0.5ml for Hepatitis B vaccine for each child X 1.05 (To include 5% wastage) • To add up AD syringes needed for BCG, DPT & Measles for each infant add - No. of Beneficiaries X 5X 1.05 • To add up AD syringes needed for 2 doses of TT for pregnant women add – No. of Pregnant women X 2 X 1.05
Safety Boxes	Total of AD syringes needed for infants & Pregnant women / 90 (the division by 90 is done because each safety Box of standard size can contain 90 syringes)
Cold Chain Capacity	Please compare from row 2 above that is total doses of Hepatitis B vaccine needed with the additional cold storage capacity available with you after storing other vaccines. Storage capacity of different cold chain equipments is stated in the Table shown in Enclosure 2 of Operations Guide.
Manpower	No. of vaccinators needed every month to administer all the vaccines needed for infants & Pregnant women under UIP stated above = No. of infants & pregnant women in your city/ dist. x 7 contacts (3 contacts for 3 doses of Hepatitis B, DPT & OPV as all the three vaccines can be provided simultaneously + 1 contact for BCG + 1 for Measles + 2 for 2 doses of T.T. to each Pregnant Woman) / 12 months / 200 (Please see below the assumption stated as footnote of this table)
No. of Immunization Sessions	No. of vaccination sessions needed per month in the city/dist.= No. of infants & pregnant women in your city/ dist. x 7 contacts X 12 months / 50 children/ pregnant women per vaccination session (by 1 vaccinator) The no. of vaccination sessions worked out above can be reduced based on no. of vaccinators available for providing vaccination.

Assumption: At the rate of 5 minutes per child for vaccination plus advice to parents one vaccinator can immunize approx. 50 children in 4 hours. As per standard guidelines of GOI routine vaccination is performed 1 day per week or for 4 days in a month. Hence @ 50 children per day a vaccinator can immunize 200 children per month.

10. Integrating Hepatitis B with Routine Immunization:

Introduction of Hepatitis B vaccine is not a separate vertical program. It is to be integrated in to the existing routine/ universal immunization programme as part of the regular schedule, in the project cities and districts.

One of the main considerations for selection of specific cities and districts for introducing this new vaccine is the achievement of immunization coverage rates of 80 % or more under the routine immunization programme for infants. This selection was based on data from district level coverage evaluation surveys. This strategy is targeted to encourage more cities and districts to improve their routine immunization coverage as the program is expanded.

The additional inputs being provided in cities/ districts selected for introduction of this new vaccine in the form of AD syringes, renewed emphasis on maintenance of cold chain, training of program managers and vaccinators, safe injection practices and safe disposal of AD syringes are the opportunities to foster improvements in the overall system of universal immunization, using the new initiative of the introduction of Hepatitis B vaccine.

The safe disposal of AD syringes and proper maintenance of cold chain for example is not only going to help proper introduction of Hepatitis B vaccine, but it will also help in addressing the bigger issue of medical waste management and proper maintenance of cold chain for ensuring potency of all vaccines.

11. Roles & Responsibilities at different levels:

11.1 Role of District Administration, Partner U.N. Agencies, Municipal Corporation/ Urban Health Care Agencies, N.G.Os, and Medical Colleges/ State Institutes of Health & Family Welfare.

The prevention of diseases and deaths in children through immunization is one of the most cost effective and feasible interventions in public health available today. The increasing interest and participation of the community is also evident in this area, which made eradication of small pox possible, and currently we see the possibility of eradicating Polio in the foreseeable future. .

Immunization therefore, is a necessary part of all public health partner programs and this initiative will require the active participation of all the agencies and partners cited above. The activities expected and already being done by various agencies involved in this project are listed below:

Table 5: Roles & Responsibilities at different levels

Partner Agency	***Activities Expected***	***Already being done***
State/ City/District Administration	Assist & monitor the micro planning, IEC, administering vaccine & managing the adverse reaction by the city/ district health care system.	In selected districts of Andhra Pradesh including introduction of Hepatitis B vaccine.
Municipal Corporation/ Urban Health Care Agencies	Assist in micro planning, IEC & administering vaccine through available staff, vehicles & Urban Health facilities under the corporation.	In selected districts of Andhra Pradesh including introduction of Hepatitis B vaccine.
GAVI Partner Agencies	To Assist in 1. Micro Planning 2. Monitoring through field observation reports. 3. Implementation through assisting in problem/ constraint identification & suggest solutions. 4. Developing Operations Guide for Program Managers. 5. Developing training material & training of trainers. 6. Procurement of vaccines, AD syringes, 7. Assistance in logistics where supplies are falling short of genuine needs.	Item 1, 2& 3 are to be assisted by W.H.O., UNICEF, PATH and also by World Bank, DIFID & USAID as & when requested. Item 4 is being assisted by W.H.O. Item 5 is planned to be assisted by PATH. Item 6 is being assisted by UNICEF & GAVI. Item 7 is being assisted for AD syringes for vaccines other than Hepatitis B by UNICEF at present. Item 7 is to be assisted by other partners also listed above as & when the need arises.

Partner Agency	***Activities Expected***	***Already being done***
NGOs	1. Can assist a lot in mobilizing the parents of infants to participate in getting the infants immunized. 2. Assist in organizing/ arranging with support of community the logistics for vaccination sessions where required.	In selected districts of Andhra Pradesh including introduction of Hepatitis B vaccine.
Medical Colleges/ State Institutes of Health & F.W.	To Assist in 1. Micro Planning 2. Monitoring through field observation reports. 3. Implementation through assisting in problem/constraint identification & suggest solutions. 4. Conducting training for doctors & vaccinators.	

11.2 Role of Hospitals & Health Centres:

Hospitals and health centers (PHCs, CHCs, Sub-centers, Urban Health Centers, Post Partum Centers and immunization clinics of under the ICDS, municipal corporations, medical college hospitals, district hospitals and other hospitals catering to the slum population, or located near slum populations are important partners for this program. As stated above under Chapter 7 and summarized in Table 3, the CMHO and DIO of each selected City/district are responsible for micro planning of the workload, logistics (vaccine, cold chain etc.). They should also skillfully delegate responsibilities among their staff for conducting and supervising immunization services, including provision of the new Hepatitis B vaccine, to infants residing in the slum populations around them. The concerned doctors, nurses and vaccinators working in thesehospitals and health centers will also need to be deputed for training under this new initiative, as detailed in Chapter 4 above, to orient them about the new vaccine (Hepatitis B) along with proper use and disposal of AD syringes.

The supervision & support of SEPIO, Director F.W. & the Secretary Family Welfare is crucial for the success of the above activities.

As already being done under the routine immunization program, care is needed in maintaining quality records on the cold chain (temperature and power failure record of ILRs/deep freezers/walk-in-coolers and walk-in-freezers), indent (demand note), receipt, issue and use of vaccines. The particulars of beneficiaries receiving the vaccine (Name, Age, Sex, address, dose 1,2 or 3 of the vaccine) reporting on adverse reactions observed following the immunization, and the treatment given in such cases, with outcomes should also be recorded.

Proper maintenance of such records will help project managers assess the accurate coverage of beneficiaries in different slum areas (with the help of address) by each health facility. This will also help to monitor dropout rates; identification of problems related to the cold chain, logistics & supply of the vaccine/ AD syringes and safety boxes.

Targeted IEC activities and mobilization of parents of infants in the slums will also have to be organized regularly by the concerned hospitals/ health centers with the help of State EPI Officer/ District Chief Medical & Health Officer/ District Immunization Officer, local NGOs, schools, press and media and the local administration. In addition to the regular budget available for IEC under the UIP and the pulse polio programme, a small addition is being planned for IEC efforts related to launching of the Hepatitis B vaccine.

Segregating target slum populations from those in the non-slum areas in close proximity may pose operational problems for program managers. In this context, an important role will have to be played by senior authorities of the Health Care Facility as well as by the vaccinators. Parents will have to be carefully explained that free supply of Hepatitis B vaccine is meant for infants whose parents cannot afford to pay the cost of this comparatively costlier vaccine.

The necessary precautionary steps will also have to be taken by the senior authorities of the Health Care Facility as well as by the vaccinators, to safeguard against pilferage/ misuse of Hepatitis B vaccine supplied under this project, especially for vaccinating the adults. Similarly, leakage of AD syringe equipment into the commercial market will have to be strictly controlled.

12. Launching the program in the community & suggested steps to ensure continued community participation.

Success for the programme lies in the level of awareness created in health care workers, target populations, the general public, decision-makers and community groups. Health workers should also be empowered to generate interest in the programme and successfully implement it. IEC activities are therefore, an important part of implementation of Hepatitis B immunization program.

Addition of Hepatitis B vaccine to the national immunization program can improve coverage of other UIP vaccines. This is related to renewed motivation among health workers to deliver a new vaccine to the population. In addition, inclusion of a new vaccine in the immunization program creates increased awareness among the public and among health care staff about benefits provided by vaccination, leading to an increase in participation rates.

A workshop of program managers and other senior staff from municipal corporations and Health & Family Welfare departments from 15 project cities was held in May 2002. Details on the new initiative to strengthen routine immunization and introduce Hepatitis B vaccine in the Universal Immunization Programme in their cities were discussed.

A national-level workshop including policymakers, NGOs, Ministry of Health staff, and clinicians is planned to be held in June 2002 to disseminate information.

While launching the above program at city/ district level the following experiences gained from the introduction of a similar programme in other states may please be considered:

12.1 ***Launching*** at the national and state level does not rule out the necessity of IEC at the local level and detailed discussions with the relevant local groups, such as doctors in the government and private sector, vaccinators, ICDS (integrated child development scheme), Municipal Corporation and local administration. It is also important to answer all queries and apprehensions that parents of target children may bring up during interactions. . **The common questions/ apprehensions and their answers on Hepatitis B disease and vaccine are enclosed as Enclosures 3 to 5. These can be used by program staff in adequately responding to questions from other health staff, private doctors, and members of the community.**

12.2 ***The program should be started in the beginning in 2 or 3 selected health care facilities*** in the city/ district. This is to ensure adequate arrangements for providing efficient services, foolproof arrangements for immediate reporting and management of any adverse reaction reported after administering the vaccine.

After the program has stabilized in these facilities, it can confidently be expanded to other health facilities catering to the target population. The successful uptake of the vaccine will be guaranteed, once the program is implemented with due care and dependable service from educated and knowledgeable and trained health workers. *What is true for the business world is also true for health care in the public system that there is no better IEC and marketing strategy than having as many as possible satisfied and well served customers, or in our case beneficiaries.*

12.3 The involvement of local health & welfare workers, NGOs, local leaders of community, professional, religious and business groups, volunteers, youth and mothers in mobilizing the parents to get their children vaccinated should be requested and encouraged, with due respect and recognition of their contribution. When these partners of the program visit the health care facility to seek help for any other disease, they should be treated with respect. This will help to develop a good rapport and relationship with these important community influencers and they can become strong advocates for immunization programmes in the communities they represent.

In the initial phase, the emphasis of the program is to immunize infants in selected slum populations. Hence clear message about this focus of programme needs to be communicated by localized IEC campaigns in selected slum areas. A large-scale general IEC campaign may raise the expectations of the community. Therefore, we should be careful not to encourage the demand of vaccination to cover all the age groups. This can be achieved by explaining to the community in simple language the scientific fact that why immunizing the infants is priority and the best use of available resources.

13. Monitoring Quality & Performance of Program

13.1 Monitoring Vaccine Procurement, Balance, Supply & Utilization of Vaccines.

All supervisors/ program managers monitoring this program should try to examine the records available for procurement, balance, supply and utilization of vaccines and AD syringes. The effort should be made to see through records, on the spot observation and physical verification whether there is a logical association between the number of doses and AD syringes procured, supplied and used.

If there is any mismatch found between the reported number of doses and AD syringes used, the concerned vaccinators, doctors, store in charge and supervising authorities should be consulted to find out the reason for the variance/mismatch. If their reply is found convincing and realistic they should be appreciated and thanked. If the reply is found pointing towards problems or irregularity in work / management, the solution for the problem should be discussed with the concerned persons and should be informed also to the senior authorities.

If the utilization of vaccine and AD syringes shows a pattern of rapid increase or decrease week after week, or the doses consumed for vaccines recommended to be provided at the same time (such as DPT, Hepatitis B & OPV 1st, 2nd & 3rd doses of routine immunization) differ widely from each other for the same time period, the reason for the same should be explored and addressed.

13.2 Monitoring quality aspects of the programme and immunization session in action

The scrutiny of records alone will not be sufficient for effective monitoring. All the supervising officers need to visit some of the immunization sessions in action to observe the actual implementation of the programme in the field. The proper maintenance of the cold chain, safe disposal of AD syringes and actual coverage of beneficiaries with all the doses of vaccines under the UIP will have to be assessed by sample checks in the field to find out any weaknesses, constraints and to correct them on time.

13.3 Basics of Cold Chain Management

The consequences of failures in the cold chain are well known – 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/Program Manager on the cold chain and the capacity and maintenance of various equipment is summarized in Enclosure 2.

14. Tracking Progress of the Program in Achieving its Objectives

The ultimate objective of Hepatitis B immunization is to prevent chronic HBV infection and its long-term consequences (cirrhosis and liver cancer). However, these outcomes are difficult to measure. Also, since most HBV infections in children are asymptomatic, disease surveillance cannot be used to evaluate the impact of Hepatitis B immunization. Furthermore, cirrhosis and liver cancer caused by HBV infection generally do not occur until adulthood. Therefore, indirect measures of program impact must be used. In addition to monitoring the introduction process, the following methods can be used to evaluate implementation of Hepatitis B immunization.

14.1 Monitoring Introduction of Hepatitis B Vaccine

Experience of districts where vaccine is introduced in the first phase would be useful to districts where it is introduced later. Close monitoring will therefore be essential in the first phase. It will include visits of the national Hepatitis B vaccine introduction advisor, of the representatives of other partner agencies requested

by Govt. of India and joint site visits of the Hepatitis B vaccine introduction advisor with the national staff to selected cities and districts. These visits will be utilised to review the progress in implementation of the program and to provide assistance to program staff in the project cities and states.

Preparation of Performance Reports by the states will also be required describing their experience, including any problems encountered and suggestions for improvement. Aspects to be reviewed should include acceptability to the public, ease of use and acceptability to health staff, coverage of infants with each dose, and appropriate storage, distribution and use of the Hepatitis B vaccine.

The improvement in the quality issues of the UIP viz. increased attention and action for better maintenance of cold chain, proper injection safety and disposal of AD syringes will also need to be reviewed regularly.

14.2 Evaluating Program Effectiveness

Effectiveness of introduction of Hepatitis B vaccine can be evaluated by measuring coverage through (i) routine reports, and (ii) coverage surveys. For both of these, Hepatitis B vaccine indicators and targets can be the same as those for DPT3. Coverage surveys may provide more accurate information than routine reports.

Serological surveys can be used to provide serologic evidence of receipt of vaccination. Such surveys can also 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 the Hepatitis B immunization program and comparison with results from children of similar age in previous surveys can also provide data on program's effectiveness, as part of a long-term evaluation process.

			Enclosure - 1
Basic Information Required for Starting Hepatitis B Vaccination in the Slum Population of Selected Cities & Districts			
	Name of the City: **State:**		
A	**DEMOGRAPHIC DATA**		
1	- Maps for slum population available	Yes	No
2	- Date of map preparation		
3	***Please bring mapped data of slum population***		
	in your city		
4	**(Please attach as enclosure 1, Names & addresses of the slums selected for introducing Hepatitis B Vaccination in your city/district with general population & child population below the age of 1 year in each slum.)**		
B.	**HEALTH INFRASTRUCTURE SUPPORTING SLUMS**		
		PHCs / UHCs	**PP Units**
1	Number of public health facilities catering to Slum population Immunization **(Please fill up Names & addresses of these facilities in enclosure 1.Please specify against the name of each slum which Health facility will be appropriate to provide Immunization facilities to the particular Slum.**)		
2	Average number of Immunization Sessions per week in each slum		
	- *At health facility*		
	- *Outreach sessions*		
3	***Please Specify any other existing Govt./Public Health Infrastructure which is supporting the slum population***		

		Hospitals	**Clinics**
4	Approximate Number of Private Health Facilities catering to Slum population immunization services **(Please fill in Names & addresses of these facilities also in enclosure 1)**		
5	***Please Specify any other existing Private Health Facilities (NGOs) supporting the slum population***		
C.	**COMMUNITY MOBILIZATION**		
		Numbers	
1	**Number of accredited / recognized NGOs working with slums which can help for motivating the community towards availing immunization services**		
	- *NGOs working in the Health Care Activities*		
2	- *Non Health NGOs*		
	(Please attach Names & addresses of above NGOs also as enclosure 2)		
D.	**IMMUNIZATION TRAINING:**		
1	***Master Trainers:*** *Please provide the names & profiles of 3-4 master trainers from your city to be nominated for attending the" Training of Trainers" workshop. These master trainers will be responsible for further training activities in your city related to this program.*		
	Master Trainee Nominee 1		
	Master Trainee Nominee 2		
	Master Trainee Nominee 3		
	Master Trainee Nominee 4 (Optional)		
2	**Number of health officials to be trained in your city**	**Numbers**	
	- *Medical Officers / EPI Officials*		
	- *Vaccine Administrators / ANMs / Multipurpose Health Workers*		
	Paramedical Supervisors/ Health Assistants		

E.	***COLD CHAIN***		
1	**Cold Chain Capacity: Existing**	**Number**	**Capacity (Ltrs)**
	- ILR –Small		
	- ILR –Large		
2	- Capacity Requirement Estimated for Hepatitis B Vaccine		
3	- Capacity Addition Required before receipt of Hepatitis B Vaccine		
	- ILR Small Required		
	- ILR Large Required		
4	**The Address of cold chain facility & Officer in charge with phone no., where you will like to receive supply of Hepatitis B vaccine for your city / District**		
5	**Status of Cold Chain Infrastructure**		
	Please provide an overview on the		
	Upkeep and maintenance of Cold		
	Chain equipment for immunization in your city		
6	- Average age of cold chain equipment		
7	- Number of trained cold chain handlers		
8	- Availability of spares - (circle appropriately)	**Adequate**	**Inadequate**
9	**Please attach as Enclosure 3, a list of Names & No. of essential cold chain equipments which are waiting for repair for more than 4 weeks after the request for repair has been sent**		

Enclosure 1

	Name of City/District selected for Introducing Hepatitis B Vaccination in Slum Children					
	Name of State					
					Nearest & Appropriate Health	
	Name of Slum	**Address**	**Total Population**	**Children < 1 year**	**Care Facility**	
					Govt.	**Private / NGO**
Slum1						
Slum2						
Slum3						
Slum4						
Slum5						

Enclosure 2

Basic Features of Cold Chain System:

The cold chain is a system of storing and transporting vaccines at recommended temperatures from the point of manufacturing to the point of its use.

Three vital components of the cold chain are:

- ✓ Equipment
- ✓ Power
- ✓ Maintenance

Equipment

Electrical			
WIF	WIC	DF	ILR

- Walk-in-Freezer (WIF): Prefabricated freezer rooms set up at State HQ & Regional levels to bulk store oral polio vaccines and measles vaccines at temperature around -20 °C. Bulk quantities of ice packs are also frozen and stored.

- Walk-in-Coolers (WIC): Prefabricated cold room used for bulk storage of vaccine at state and regional stores. Vaccines in the temperature range of +2°C to +8°C are stored here.

- Deep Freezer (DF): Freezer unit with temperature range between -18°C to 20°C are used for storing oral polio vaccines and measles and for freezing ice packs. The holdover time is 18 to 26 hours. Presently, in use are two model 300/304 liters and 140/144 liters. 300-type store 90,000 doses and freezes 35-40 ice packs, and 140 model stores 65,000 doses and freezes 20-25 ice packs.

- Ice Lined Refrigerators (ILRs): Units used for storing vaccine in temperature ranges +2°C to +8°C. Sizes available are 300/304 & 144/140 liters. Capacity of around 90000 & 65000 doses of T series & BCG vaccines respectively can safely be stored in the basket section, which maintains the desired temperature. This unit has an improved holdover time of 50 hours, a temperature retaining feature, which is maintained by the frozen water containers concealed in the sides of the unit. To activate the ice lining thermostat feature, switch on the yellow light when the ambient temperature is between 25°C & above.

Non-Electrical		
Cold Box	Vaccine carrier	Ice Packs

- Cold Boxes: Big insulated boxes of size 5 ltrs & 20 ltrs used for transporting about 1500 & 6000 vaccine doses respectively. Fully frozen ice packs are placed all around the vaccine before placing the vaccine in the cold box. To protect the labels on the vials, place the vaccine in cartons or polythene bags. In an emergency, the cold box can also be used to store vaccine as well as frozen ice packs. The vials of Hepatitis B, DPT, DT & TT vaccines should not be placed in direct contact with frozen ice packs and should be surrounded by OPV or carton cutting spacers.

- Vaccine Carriers: These are insulated boxes used for carrying small quantities of (16-20 vials) to the sub-centres or villages by health workers. Four ice packs are laid in the vaccine carrier to maintain the temperature inside. The vaccine should be kept clear of direct touch with the ice pack. When packing the vaccine carrier, the ice packs should be put in after due time for “sweating” to avoid accidental freezing of freeze-sensitive vaccines such as Hepatitis B, DPT, DT & TT.

- Ice Packs: Water filled plastic containers frozen and used in the cold chain to lower the temperature range for safe vaccine storage. In ILRs, the sidelining feature of ice packs improves and maintains the holdover time during failure of electricity. In cold boxes and vaccine carriers they lower and maintain the temperature inside the box while the vaccine is being transported.

- Ice packs can be frozen in Walk-in-freezers, deep freezers and ice factories. A large deep freezer can freeze around 42 icepacks and a small one 20-25 ice packs in 24 hours. To supplement the freezing capacity during NID/Mop-ups, ice packs are also frozen in ice factories and stored in cold boxes to last the activity days. Proper outside wash of these packs after freezing cleans the salt stuck to it, which otherwise is damaging to the cold boxes and vaccine carriers.

Power Factor

Generators	Automatic Voltage Stabilizers	Servo Stabilizer

- Generator: To save the vaccine from damage due to extended mains power failure, a standby diesel generator of suitable capacity, i.e., 7.5-10 kVA is a must. All States, Regional, Districts and Block-level sites storing the vaccine should have a reliable standby power supply. The set should be located in a separate /weatherproof enclosure. The generator should be run at least once a week. The fuel tank should be kept full at all time, plus a reserve fuel stock for 2-3 days.

- Automatic Voltage stabilizers: No electrical cold chain equipment should be installed/operated without a Voltage stabilizer. The compressor operations of freezers & ILRs are always secured if the units are connected through a voltage stabilizer. This reduces the range of fluctuation in the main voltage of 155-280 volts to a smaller range of 220± 10 volts. The stabilizer switches-off the supply to your refrigerator if mains are either above 280V or below 155V.

- Servo Stabilizer: To combat the unstable power supply, all Walk-in-freezers & Walk-in-coolers are supplied with servo stabilizers that control voltage fluctuations. The result is a smooth & operational compressor & all the other electrical components attached to it. ***Never Bypass the Servo Stabilizer.***

Maintenance of Cold Chain Equipment & Monitoring:

As indicated in the chart below, DPT, TT, and Hepatitis B vaccines will lose their potency if frozen. Hepatitis B, in particular, freezes at only –0.5°C. If these vaccines freeze, they should be discarded. Their potency cannot be recovered by warming the vaccines. Conversely, BCG, OPV, and measles vaccines will lose their potency when exposed to too much heat or light. The damage of heat and light is cumulative and cannot be reversed by re-freezing the vaccine. It is important, therefore, to maintain the proper temperature for all vaccines during all phases of transport and storage from manufacturer to the beneficiaries.

The following chart shows the correct storage temperature (and storage location) for each vaccine at the PHC. Once the vaccines move from the PHC to the sub-center and outreach session, they can be kept in vaccine carriers at a temperature range between 2°C to 8°C.

Vaccine	Characteristics	Recommended storage temperature at PHC	Storage at PHC
BCG	Sensitive to heat and ultraviolet light. Stable at 2°C to 8°C for maximum five weeks.	-15°C to -20°C	Deep freezer
OPV	Sensitive to heat. Stable at 2°C to 8°C for maximum five weeks.	-15°C to -20°C	Deep freezer
Measles	Sensitive to heat and ultraviolet light. Stable at 2°C to 8°C for maximum five weeks.	-15°C to -20°C	Deep freezer
DPT	Relatively heat-stable vaccine. Freezes at –3°C. Discard if frozen.	+2°C to +8°C	Ice-lined refrigerator
Hepatitis B	Relatively heat-stable vaccine. Freezes at –0.5°C. Discard if frozen.	+2°C to +8°C	Ice-lined refrigerator
TT	Relatively heat-stable vaccine. Freezes at –3°C. Discard if frozen.	+2°C to +8°C	Ice-lined refrigerator

Many people believe that monitoring the cold chain only requires that refrigerators are functioning; however even if the refrigerators work, vaccines can be damaged by:

- Freezing DPT, TT, or Hepatitis B vaccine
- Opening the door of the ice-lined refrigerator (ILR) or deep freezer too often
- Overstuffing the refrigerator or freezer and preventing cold air from circulating
- Not using vaccines on a first-in, first-out basis
- Fluctuating temperatures in the ILRs, or deep freezers, because of irregular functioning

Following is a list of steps a cold chain technician/ officer, Supervisor/ Medical Officer can follow to make sure the cold chain is functioning properly. Your monthly check should follow each of the steps in sequence. However, when monitoring the cold chain on a regular basis, you can use your judgment to determine which steps need daily or weekly monitoring.

Step 1: Check that cold chain supplies are adequate

Most Primary Health Centers (PHCs) are now equipped with ice-lined refrigerators and deep freezers of 140-liter capacity for storage of vaccines. PHCs should also have at least one cold box of 5-liter capacity to store vaccines in case of emergencies or during a breakdown of the cold chain equipment. The PHC should also have enough vaccine carriers and icepacks to equip all the sub-centers managed by the PHC, with an additional buffer of 10 percent. If supplies are low or if equipment breaks down, notify the district headquarters immediately.

Step 2: Check the maintenance of the cold room

Cold rooms will vary from place to place, but all cold rooms should follow the most basic principles of good cold-chain maintenance. If any of the items listed below are not followed in a PHC, take steps to implement them as soon as possible.

- ILRs and deep-freezers should be installed in a room that is not directly exposed to sunlight or any other source of heat.
- The room should also be well ventilated and protected from rain or flooding.
- ILR and deep-freezers should be sitting level, on wooden blocks to avoid dampness
- The plugs should be permanently fixed to the power socket through voltage stabilizers labeled “DO NOT REMOVE”
- The ILR and deep-freezers should be kept at least 10 cm away from the wall.
- Equipment should be locked and opened only if necessary

Step 3: Check the temperature log of the ILR

The ice-lined refrigerator (ILR) should maintain a temperature range between +2°C and +8°C, even during continuous power cuts of up to 48 hours. Check the temperature log and make sure it is completely and regularly filled out and that the temperature has not dropped below +2°C or above +8°C in the past month.

IF:	THEN:	
The temperature has fallen below 0°C	Conduct a shake test to determine whether the vaccines were frozen	
	If the shake test shows that the vaccines were frozen	Then discard the vaccines and order a fresh batch from the district stores.
The temperature has risen above +8°C	Check that there is not a thick layer of ice along the walls or bottom of the ILR.	
	If layer of ice exists	Then the ILR needs to be defrosted and cleaned
	If a layer of ice does not exist	Then adjust the temperature to a lower range.

Step 4: Open the ILR and check the vaccines

A routine check of the ILR should include the following components. If anything is not functioning properly, alert the proper health staff and discuss ways they can ensure that the situation is improved. Check that:

- The thermometer is functioning.
- The vaccines are stacked with at least 2 cm between them so air can circulate.
- OPV and Measles vaccines are kept at the bottom of the ILR.
- Make a routine check of some batches of OPV and see if the VVMs are valid. This is a good indicator of any heat exposure to that lot of vaccines.
- BCG, Hepatitis B, DPT, TT, DT, and JE vaccines are kept in the top basket of the ILR.
- No other drugs or food are stored in the ILR.
- There are no expired vaccines in the ILR (discard if expired).

Step 5: Check the temperature record of the deep-freezer

Deep freezers should maintain a temperature range between –15°C to –20°C. A deep freezer has no ice lining, so in a power cut the temperature can exceed +8°C within 12 hours.

- Check the voltage stabilizer. If the green lamp is on and red lamp is off, then the temperature should be within the safe range of –15°C to –20°C.
- Check the temperature log and make sure it is completely filled out and that the temperature has remained in the safe range.

<table>
<tr><th>IF:</th><th colspan="2">THEN:</th></tr>
<tr><td>The temperature has fallen below –20°C</td><td colspan="2">Adjust the temperature of the deep freezer to a range between –15°C and –20°C.</td></tr>
<tr><td rowspan="3">The temperature has risen above -15°C</td><td colspan="2">Check that there is not a thick layer of ice along the walls or bottom of the deep freezer.</td></tr>
<tr><td>If layer of ice exists</td><td>Then the ILR needs to be defrosted and cleaned</td></tr>
<tr><td>If a layer of ice does not exist</td><td>Adjust temperature to a lower range and plan to use vaccines within three months.</td></tr>
<tr><th>IF:</th><th colspan="2">THEN:</th></tr>
<tr><td>The temperature log does not exist or is not regularly filled out</td><td colspan="2">Designate a person to monitor the temperature twice daily and record the temperature in a logbook that can be easily read and accessed by the medical officer and other supervisors from the district.</td></tr>
</table>

Step 6: Open the deep-freezer and check the vaccines (weekly)

A routine check of the deep-freezer should include the following components. If anything is not functioning properly, alert the proper health staff and discuss ways they can ensure that the situation is improved. Check that:

- The thermometer is functioning.
- The vaccines are stacked with at least 2 cm between them so air can circulate.
- No vials of DPT, TT, DT, Hepatitis B, or JE are stored in the deep freezer (if so, discard the vaccines).
- No other drugs or food are stored in the deep-freezer.
- There are no expired vaccines in the deep-freezer (discard if expired).

Step 7: Develop (and communicate) a contingency plan for equipment Malfunction

If an ILR or deep freezer malfunctions, contact the DIO and DMHO immediately. You can reach the DMHO and DIO by telephone, telegram, or messenger to replace faulty equipment or to get a mechanic to make repairs. Meanwhile, make arrangements to shift the vaccines into the cold box.

Sample contingency plan for equipment malfunction
If an ILR or deep freezer malfunctions, vaccines may be kept for up to 90 hours (if the lid remains closed) in a cold box. The cold box can maintain a temperature between +2°C and +8°C and can hold 1,500 doses of vaccine.

To safely transfer vaccines to cold box:
a. Freeze enough ice packs to use the cold box properly. If the deep-freezer is not functioning, transfer the vaccines to a nearby PHC or get ice packs frozen at a nearby ice factory.
b. Check that the cold box is clean and dry, and that hinges are lubricated.
c. Once ice packs are frozen, let them sit for 10 minutes until they begin to sweat
d. Arrange ice packs on the floor and sidewalls of the cold box.
e. Stack vaccines and diluents in the box. Wrap TT, DPT, DT, and Hepatitis B and JE vaccines in plastic or paper to protect them from direct contact with ice packs.
f. Place a stem thermometer inside the cold box.
g. Place a piece of plastic or paper over the vaccines and arrange ice packs on top.
h. Secure lid of cold box tightly.

Step 8: Make sure all MPHWs maintain the cold chain in outreach sessions

The final link in the cold chain takes place when the health worker carries the vaccine from the PHC to the sub-center and outreach session. The Medical Officer is responsible for making sure the MPHW knows the correct procedure and implements it every time she leaves the PHC.

If answer by the Health Workers is “no” or “I don’t know” to any of the following questions, you may need to work with them to improve the knowledge and implementation of the cold chain.

A. Does she pack the vaccine carrier correctly (see instructions above for packing the cold box)?
B. Does she understand the temperature requirements of each vaccine?
C. Does she know how to read a vaccine-vial monitor?
D. Does she know how to conduct a shake test?
E. Does she collect the vaccines on the day of use? If yes, does she return vaccines within 24 hours.
F. Does she know that reconstituted vaccines should be thrown away after 3 hours?

Table- A

Basic Features of Cold Chain Equipments

Name of Equipment	Usual Place of Installation	Temperature	Utilization	Hold over time in case of Power Failure	Vaccine Storage Capacity
Walk in Cooler	State H.Q & Regional Stores	+2 to +8°	BCG, DPT, TT, Hep-B Vaccine.	4hours	1,200,000-1,500,000 doses
Ice Lined Refrigerator (ILR) 300 Litres	Dist. H.Q & Regional Stores	+2 to +8°C	BCG, DPT, TT, Hep-B Vaccine.	At 43°C 62hrs after 8 hrs of continuous power supply	60,000 doses (mixed antigen) & 20,000 doses of OPV
ILR 140 Litres	PHC	+2 to +8°C	Same as above	Same as above	25,000 doses (mixed antigen) & 18000 doses of OPV
Walk In Freezer	State H. Q.	- 20°C	Preparation of ice packs, OPV & Measles Vaccine.	4 hrs	1,500,000-2,000,000 doses
Deep Freezer 300 Litres	State Region & Dist. H. Q.	- 20°C	Same as above	At 43°C 18hrs after 8 hrs of continuous power supply	Approx. 35 Ice Packs, 60,000 doses of mixed antigen & 30,000 of OPV

Name of Equipment	Usual Place of Installation	Temperature	Utilization	Hold over time in case of Power Failure	Vaccine Storage Capacity
Deep Freezer 140 Litres	PHC	- 20°C	Preparation of Ice Packs	At 43°C 18hrs after 8 hrs of continuous power supply	Approx. 20 Ice Packs,
Cold Box 20 Litres	State, Region & Dist. H.Q.	+2 to +8°C	All vaccines can be stored for transportation or in case of Power failure	5 days	52 Ice Packs & 6000 doses of mixed antigens.
Cold Box 5 Litres	Dist. H.Q. & PHC	+2 to +8°C	All vaccines can be stored for transportation or in case of Power failure	3 days	20 Ice Packs & 1500 doses of mixed antigens.
Vaccine Carrier (1.7 Litre)	Sub Centre	+2 to +8°C	All vaccines can be carried in small quantity for vaccination sessions	24- 36 hrs	4 Ice Packs & 15 to 20 vials of mixed antigens
Day Carrier (0.85 Litre)	Sub Centre	+2 to +8°C	All vaccines can be carried in small quantity for vaccination sessions	6- 8 hrs	2 Ice Packs & 6 to 8 vials of mixed antigens

Enclosure 3.

Apprehensions about Hepatitis B Disease & Vaccine:

1. ***Statement:*** *Hepatitis B is not a killer disease.*

Facts: Hepatitis B is a major disease and is a serious global public health problem. Of the 2 billion people who have been infected with the Hepatitis B virus (HBV), more than 350 million have chronic (lifelong) infections. These chronically infected persons are at high risk of death from cirrhosis of the liver and liver cancer, diseases that kill about one million persons each year.

2. **Statement:** Chronic carrier rate in general population is between 1.62 to 4%.

Facts: In much of the developing world, (sub-Saharan Africa, most of Asia, and the Pacific), most people become infected with HBV during childhood, and 8% to 10% of people in the general population become chronically infected. In these regions liver cancer caused by HBV figures among the first three causes death by cancer in men.

3. **Statement:** It is not necessary to vaccinate all the children. Only children born to Hbs Ag positive mothers need to be given the vaccination.

Facts: Young children who become infected with HBV are the most likely to develop chronic infection. About 90% of infants infected during the first year of life and 30% to 50% of children infected between 1 to 4 years of age develop chronic infection. The risk of death from HBV-related liver cancer or cirrhosis is approximately 25% for persons who become chronically infected during childhood.

In developing countries like India the facilities for blood test of pregnant women for Hbs Ag are available only in a few hospitals and even when available are not being used as a routine test. In India most of the births in rural areas are being conducted at home, which makes conducting any routine blood tests very difficult. In such circumstances for an infection, which affects 8 to 10% of general population and most of them getting it during childhood d it may not be realistic to provide Hepatitis B vaccination only after testing the mothers for presence of Hbs Ag.

4. Statement: Hepatitis B vaccine is not safe and can cause adverse reactions.

Facts: Hepatitis B vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of Hepatitis B vaccine have been used worldwide.

Serious side effects reported after receiving Hepatitis B vaccine are very uncommon (Andre, 1989; CDC, 1991 a; Greenberg, 1993; Niu, 1996). While reported, there is no confirmed scientific evidence that Hepatitis B vaccine causes chronic illness, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, or autoimmune disorders. There is no risk of HBV infection from the vaccine.

Large-scale Hepatitis B Immunization Programs in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events. Furthermore, surveillance of adverse events in the United States after Hepatitis B vaccination have not shown a clear association between Hepatitis B vaccine and the occurrence of serious adverse events including Guillain-Barre' syndrome, transverse myelitis, optic neuritis, and seizures (Shaw, 1988; CDC, 1991 a; Niu, 1996; Niu 1998 CDC, unpublished data). Additional evaluations are ongoing. A recent study suggested persons developing rheumatoid arthritis after Hepatitis B vaccination were genetically at-risk for rheumatoid arthritis (Pope, 1998).

Any presumed risk of adverse events associated with Hepatitis-B vaccination must be balanced with the expected 4,000 to 5,000 HBV related liver disease deaths that would occur without immunization, assuming a 5 percent lifetime risk of HBV infection.

5. Statement: 10% of the patients who receive vaccine fail to develop adequate immunity.

Facts: Studies have shown that the vaccine is 95% effective in preventing children and adults from developing chronic infection if they have not yet been infected. In many countries where 8% to 15% of children used to become chronically infected with HBV, the rate of chronic infection has been reduced to less than 1% in immunized groups of children.

Hence the above facts again reinforce the logic of extending the benefit of prevention by vaccinating larger population groups without waiting till they get infected or become the carriers.

Enclosure 4.

Quick Facts about Hepatitis B for IEC Messages

Hepatitis B Disease

- Hepatitis B virus (HBV) is a major cause of hepatitis, an infection of the liver that can lead to death.
- Infection in adults usually is self-limiting and often results in acute disease with jaundice (yellowing of the eyes and skin), dark urine, loss of appetite, and extreme fatigue lasting weeks or months.
- Infected children rarely develop acute disease, but 25-90% become chronic carriers of the virus, which can lead to death from cirrhosis and liver cancer.
- More than 2 billion people worldwide have been infected with HBV and 350 million are chronic Hepatitis B carriers. Hepatitis B kills about 1 million people (chronic carriers) each year.
- HBV causes 60-80% of the world's primary liver cancer, the number one cause of cancer deaths in males in sub-Saharan Africa and much of Asia, and an important cause of cancer deaths in women.
- Infants and young children are most at risk of HBV. The virus is spread perinatally from an infected mother to her infant at birth, from child to child, from unsafe injections and transfusions, and through sexual contact. Although this is similar to the AIDS-causing virus, HIV, the Hepatitis B virus is 40-100 times more infectious than HIV.

Hepatitis B Vaccine

- Available since 1982, the Hepatitis B vaccine is the first vaccine against a major human cancer. The vaccine is produced from plasma or by recombinant DNA technology and is safe and effective. To date, more than 1 billion doses have been used.
- Vaccination requires three doses of vaccine; the first two doses are usually given one month apart, with the third dose 1 to 12 months later.
- When administered properly the vaccine is about 95% effective against Hepatitis B disease.
- Hepatitis B vaccine can be given concurrently with other vaccines such as measles, diphtheria/tetanus/pertussis (DTP), polio, BCG and yellow fever.
- In 1991 the World Health Organization recommended that all countries add Hepatitis B vaccine into their national immunization programs. So far 100 countries have done so and Hepatitis B vaccine is the prototype of introducing new vaccines into immunization programs in developing countries.
- Because Hepatitis B vaccines cost more than traditional vaccines, children in the poorest developing countries are not getting Hepatitis B vaccine. There are efforts being done by GAVI (Global Alliance for Vaccines & Immunization), U.N. Agencies, NGOs and national governments to develop new and innovative financing mechanisms to help the most needy countries to obtain Hepatitis B vaccine and other important newer vaccines relevant to the developing world.

Enclosure 5.

Frequently Asked Questions about Hepatitis B Disease & Vaccine

What is Hepatitis B?
Hepatitis B is a serious disease of the liver that is caused by the Hepatitis B virus. The virus can be found in the blood and body fluids of an infected person. The virus attacks the liver, and over many years can eventually cause severe illness or death.

What are the symptoms of Hepatitis B?
Infection with HBV can cause both short-term (acute) disease and long-term (chronic) disease.

> ***Acute HBV:*** When symptoms occur, they include loss of appetite, weakness, nausea, vomiting, abdominal pain, jaundice (yellow skin or eyes), dark urine, skin rashes and joint pain. The incubation period is usually 3 to 4 months. The case-fatality rate is about 1 to 2 percent.
>
> ***Chronic HBV infection:*** Persons with chronic HBV infection often do not feel sick for decades after infection, but between 15 and 25 percent will die of liver cancer or cirrhosis—scarring of the liver (*Margolis, et al, 1995*). Chronic carriers of HBV are also capable of spreading the disease to others.

Who is at risk of getting Hepatitis B?
Anyone who has not been vaccinated can get HBV. Small children and adolescents are particularly vulnerable. Children contract the disease from their mother at birth, or simply from another child while playing. Though children rarely develop acute illness after infection, children run the highest risk of developing chronic Hepatitis B, which may cause liver complications later in life.

How is Hepatitis B spread?
Hepatitis B virus is spread by mucous membrane contact with blood or other infectious body fluids such as saliva, semen, and vaginal fluid. Hepatitis B virus is not spread by air, food, or water.

The primary ways HBV can be spread are described below.

Child-to-child transmission.
Most HBV infections worldwide are spread from child-to-child (*Franks et al, 1989; Hurie et al, 1992; Pon et al, 1993; Mahoney et al, 1995*). Child-to-child transmission most likely happens as a result of contact of skin sores, small breaks in the skin, or mucous membranes with blood, sores, or perhaps saliva. Spread from inanimate objects, such as sharing of towels or toothbrushes, may also occur because HBV can survive for at least 7 days outside the body (*Martinson, et al, 1998*).

***Mother to baby (perinatal) transmission*.**
Transmission from an infected mother to her baby usually happens at the time the baby is born.

Injection transmission.
Unsafe injection practices are a major source of HBV transmission (*Simonsen et al, 1999; Kane et al, 1999*). Blood transfusion can also be a major source of HBV transmission in countries where the blood supply is not routinely screened for HBsAg.

Sexual transmission.
HBV is transmitted by sexual contact, which can account for a high proportion of Hepatitis B cases among adolescents and adults in countries with low and intermediate prevalence of HBV infection. In countries with a high prevalence of HBV infection, sexual transmission does not account for a high percentage of cases because most persons are already infected during childhood.

How big a health problem is Hepatitis B in India?
Hepatitis B is a major health problem in India. Though India is an area with a moderate prevalence of HBV, 2.5 to 4.7 percent of the population—about 4 crore people—are HBsAg-positive. As a result, infections will occur in all age groups; however, high rates of chronic infection are maintained mostly by infections occurring in infants and children.

Are there other types of hepatitis?
Yes, in addition to Hepatitis B, there is Hepatitis A, Hepatitis C and Hepatitis E.

No vaccine is available for protection against Hepatitis C and E.

Is there a cure?
Acute jaundice due to Hepatitis B is a self-limiting illness. There is no known cure for chronic Hepatitis B infection. The drugs like ***Phyllanthus amarus, Lamivudine and Alpha interferon*** are being evaluated by Indian scientists.

The trials with interferon & the antiviral Lamivudine indicate that not only is the duration of therapy long (about 2 years) but it costs about Rs.175,000 to 200,000 per patient. Even with this regimen the efficacy of therapy is about 20-40%.

How effective is the vaccine?
The Hepatitis B vaccine is 95 percent effective and can be given safely to infants, children and adults. The vaccine can prevent infection even when it is applied before or within 7 days after exposure to infection.

Studies have shown that the Hepatitis B vaccine can significantly lower the carrier prevalence in a country. In China, the vaccine has lowered the percentage of chronic carriers among children from 14 percent to less than 2 percent. Routine use of the vaccine can change the endemicity from “high” to “low” (e.g. China, Gambia, Indonesia, Thailand, Alaska). In countries with low endemicity, we can expect routine immunization with HB vaccine to essentially eliminate HBV infection. A reduction in incidence of liver cancer in immunized children has also been demonstrated in Taiwan.

How safe is the vaccine?

Hepatitis B vaccine is very safe. Mild transient side effects that may occur after vaccination include:

- Soreness at the injection site (3 to 9 percent)
- Fatigue, headache, and irritability (8 to 18 percent)
- Fever higher than 37.7 °C (0.4 to 8 percent)

These transient signs/symptoms usually start within 1 day after the vaccine is given and last from 1 to 3 days. When given at the same time as DTP vaccine, the rate of fever and/or irritability is no higher than when DTP vaccine is given alone.

Serious allergic reactions to the vaccine (hives, difficulty in breathing, shock) are rare.

Are there any contraindications to the Hepatitis B vaccine?

There are only two reasons to withhold or postpone administration of Hepatitis B vaccine. These are:

- *Severe allergic reaction to a previous dose of Hepatitis B vaccine*. A child with a history of a severe allergic reaction (e.g. generalized urticaria, difficulty breathing, swelling of the mouth and throat, hypo tension, shock) to a prior dose of Hepatitis B vaccine should not receive another dose.
- *Severe allergic reaction to baker’s yeast (the kind used in making bread).* Children with a history of a severe allergic reaction to baker’s yeast should not receive formulations of Hepatitis B vaccine prepared in yeast cells. *These children may safely receive plasma-derived vaccine.*

How is the vaccine presented?

The government has procured a plasma derived recombinant vaccine through UNICEF from a WHO-qualified producer. It is a cloudy liquid that comes in a ten-dose vial and does not require reconstitution. If HB 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 shaking.

How is the vaccine stored?

The storage temperature for Hepatitis B vaccine is the same as for DPT vaccine, between 2°C and 8°C. The vaccine is stable for at least 4 years from the date of manufacture if it is stored at this temperature. ***Hepatitis B vaccine should never be frozen*.** Freezing the vaccine causes it to lose its potency **irreversibly**.

What is the dosage and administration of the vaccine?

The standard pediatric 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 (infants) or the deltoid muscle (adults). It can safely be given at the same time as DPT and polio vaccines. . When Hepatitis B vaccine is administered on the same day as another vaccine, the vaccines should be given in opposite limbs.

Enclosure 6.

FREQUENTLY ASKED QUESTIONS ABOUT AD SYRINGES:

How AD Syringes are different from other syringes?
The full form of AD syringes is Auto Disable Syringes. These syringes get locked after using them once, thus preventing the possibility of reuse.

Why doesn't the AD Syringe allow me to aspirate for blood?
The World Health Organization no longer recommends aspiration. Even though the AD syringe can be pulled back just enough to do a small aspiration, the practice is not recommended. If you do see a small amount of blood at the injection site, it is most likely from disrupting the capillaries.

Can we use AD syringes for all 0.5ml immunization injections?
Yes! The Government has purchased enough AD syringes to allow every 0.5ml immunization injection to be given with an AD syringe. This includes injections of TT for pregnant women, DPT, Hepatitis B, and measles vaccine.

Will AD syringes create a waste problem?
The use of AD syringes should not significantly impact the already large medical waste volume in India. Immunization sharps account for only 5 to 6 percent of medical waste produced in the country. However, all health programs must responsibly manage waste and minimize negative health impacts to the community and the environment. Currently, it is suggested that in outreach immunization sessions, Sub center & PHC (in rural areas) where number of AD syringes used per day are not in large quantity, these can be collected in a safety container/ box (a card board box for safe disposal of AD syringes & needles) and the filled up safety boxes can be buried in a large pit prepared for disposal of other waste also from the clinics of the institution. This pit should be located in a safe area earmarked for this purpose within, or close to the campus of Sub center/ PHC where access by rag pickers and the community can be controlled. .

In urban clinics and hospitals where the number of AD syringes and other medical waste used per day are comparatively larger, their needs to be a more stringent protocol for waste disposal. This involves arrangements for safe collection, segregation by method of disposal required, dis-infection and then ultimate disposal in compliance with available guidelines for medical waste. Different solutions are being tested now and may be available in the coming years.

When will AD syringes be available for BCG injections?

Manufacturers are currently in the process of developing an AD syringe for 0.1ml BCG injections. As soon as these injection devices are available from UNICEF, the UIP will purchase them for the program.

How long will AD syringes be supplied to the UIP?

The Government of India is committed to safe injections for all immunization. As of now, the GOI has funds for 2 years for supply of the vaccine and AD syringes in the pilot districts and cities. It is expected that this will be phased in gradually over the entire country in the regular UIP, as the government expands the introduction of the new Hepatitis B vaccine in the country.

Enclosure 7

Over all Time Schedule of Major Activities

Activities	Jan-June 2002	July-Dec 2002	2003	2004-2006	Person Responsible	Under Supervision of
Developing Action Plan	In15 cities	In 32 dist.	In additional Cities/Dist.	In additional Cities/Dist.	CMHO & Dist. Immunization Officer	SEPIO, Director F.W. & Secy. F.W.
Assessment of cold chain, beneficiaries & Health care facilities to be geared up	In15 cities	In 32 dist.	In additional Cities/Dist.	In additional Cities/Dist.	CMHO & Dist. Immunization Officer	SEPIO, Director F.W. & Secy. F.W.
Training of EPI staff	In15 cities	In 32 dist.	In additional Cities/Dist.	In additional Cities/Dist.	SIHFW, Medical College, CMHO & DIO	SEPIO, Director F.W. & Secy. F.W.
Ongoing training			X	X	SIHFW, Medical College, CMHO & DIO	SEPIO & Director F.W.
IEC campaign for Hepatitis B vaccine introduction	In15 cities	In 32 dist.	In additional Cities/Dist.	In additional Cities/Dist.	CMHO & Dist. Immunization Officer	SEPIO & Director F.W.
Procurement of Hepatitis B vaccine		X	X	X	CMHO & Dist. Immunization Officer	SEPIO, Director F.W. & Secy. F.W.
Introduction of Hepatitis B vaccine		In15 cities	In 32 dist.	In additional Cities/Dist.	CMHO, DIO & Medical section of Municipal Corp., Medical College & Dist. Hospital	SEPIO, Officer in charge of Municipal Corp., Medical College, Dist. Hospital, Director F.W. & Secy. F.W.
Monitoring of introduction and feedback		X	X	X	State EPI Officer, Director Medical, Health, F.W. & Med. Education	Secy. F.W.

Activities	Jan-June 2002	July-Dec 2002	2003	2004-2006	Person Responsible	Under Supervision of
Review of reported Hepatitis B vaccine coverage data			X	X	State EPI Officer, Director Medical, Health, F.W. & Med. Education	Secy. F.W.
National coverage survey				X	Institutes & Officers nominated by Govt. of India	Secy. F.W. from concerned State & Govt. of India

Note: IEC = information, education, communication, DIO = District Immunization Officer.