

My No: EPI/81/VII/2007

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Provincial /Regional Directors of Health Services,  
Directors of Teaching Hospitals/Specialized Campaigns,  
M. SS /D.M.OO of Provincial /Base Hospitals,  
Heads of Decentralized Units and,  
Medical Officers of Health

### **Introduction of combined pentavalent (DTP-Hep B- Hib) Vaccine into the EPI**

A decision has been taken to introduce Hib (*Haemophilus Influenzae B*) vaccine into the EPI programme in Sri Lanka from year 2008. This decision is based on the recommendation by the National Advisory Committee on Communicable Diseases. The Hib vaccine will be in the form of a combined pentavalent (DTP-HepB-Hib) vaccine, which would include DTP and Hep B and therefore would replace both DTP and Hepatitis B in the present schedule.

#### **Background**

The bacterium, *Haemophilus influenzae type B* (Hib), is an important cause of infections in infants and young children; severe disease in adults due to Hib is uncommon.

Where it has been studied carefully, Hib is the leading cause of acute bacterial meningitis in infants and children less than five years old, accounting for one-third to one-half of all cases of bacterial meningitis in this age group. Bacterial meningitis is fatal unless treated immediately with antibiotics. Even with proper treatment 3-25% of affected children may die. Permanent disability with sequelae that include deafness, learning disabilities, and difficulties in movement is not uncommon among those who survive the infection.

Studies have also shown that Hib accounts for up to one-quarter of the severe pneumonia cases in young children. WHO estimates that without vaccination 400,000 children die each year of Hib disease.

The disease burden study on 'Haemophilus Influenzae B' carried out in 2004 has indicated that it is an emerging public health issue in Sri Lanka. The study has revealed that Hib meningitis incidence under

5 years population in the Colombo district is 20.1 per 100,000, and it estimated all Hib disease incidence to be 124.5 cases per 100,000 under 5 years. This rate is the highest incidence reported in the south Asian region.

### **Hib Vaccine**

Safe and effective vaccines against Hib infections exist. These vaccines have been routinely used to vaccinate infants in many countries for over 10 years. The experience with these vaccines has shown that they are very safe and highly effective in preventing severe Hib disease, including meningitis and pneumonia. Studies have shown that vaccination reduces the risk of invasive Hib disease in young children by >90%, and in some cases, has even led to protection of unimmunized populations by 'herd immunity'. WHO has recommended that Hib conjugate vaccine be included in routine infant immunization programmes in all countries where the resources permit its use and the burden of disease is established.

Hib conjugate vaccines are available in several different formulations. They can be obtained as a liquid or freeze-dried powder (lyophilized), in single or multi-dose vials, and as monovalent vaccines (Hib conjugate vaccine only) or in combination with other routine vaccines (e.g., DTP, DTP- hepatitis B).

Pentavalent (DTP-Hep B-Hib) vaccines are available in both liquid and freeze-dried forms. However in the freeze-dried form combined DTP-Hep B is available in liquid form and Hib component as freeze-dried and therefore the latter should be reconstituted (mixed) before use.

It has been decided to use liquid form Pentavalent (DTP-HepB-Hib)vaccine in the national EPI programme considering the convenience of using liquid form of Pentavalent (DTP-HepB-Hib)vaccine at busy immunization clinics,. At present, only single dose liquid form Pentavalent (DTP-HepB-Hib) vaccine is available.

### **Donor support for introduction of Pentavalent (DTP-HepB-Hib) vaccine**

With the support of the GAVI Alliance combined pentavalent (DTP-HepB-Hib) vaccine will be introduced into the national EPI programme in 2008 in all districts of the country. During Phase I GAVI support (2003-2007), all countries were supported to introduce new vaccines as a donation. Hence Sri Lanka received Hep B vaccine for 5 years as a donation. However, in Phase II GAVI support is based on co-finance policy, where both the recipient country and GAVI share the vaccine cost.

Initially the contribution from the country will be minimal. Subsequently it will be increased and by 2015 each country will have to bear the total expenditure.

Since the Government is committed to share a significant amount of the cost in introduction of Pentavalent (DTP-HepB-Hib) vaccine, it is important to give due consideration to the accountability. Therefore, the Ministry of Health will take necessary measures to ensure accountability at national, district (RDHS) and divisional (MOH) levels.

### **Schedule**

The Pentavalent (DTP-HepB-Hib) vaccine will be introduced into the current EPI schedule at completion of 2, 4 and 6 months of age. First three doses of OPV also will also be given with the Pentavalent (DTP-HepB-Hib) vaccine at the same time as done in the past with DTP and Hep B vaccines at the completion of 2, 4 and 6 months of age.

Please note that no pentavalent fourth dose will be given at the age of 18 months but the fourth dose of DTP given at this age will be continued.

If any dose of Pentavalent (DTP-Hep B-Hib) vaccine is missed or delayed, it should be given at the next earliest available opportunity for immunization. The immunization regime should not be restarted if a dose is missed.

### **Eligible children for Pentavalent (DTP-HepB-Hib) vaccine**

All children presenting to immunization clinics for DPT1 and Hepatitis B 1 on or after the 1<sup>st</sup> January 2008 will be eligible to receive the Pentavalent (DTP-HepB –Hib) vaccine.

Children who have received their first or/and second dose(s) of DPT and Hepatitis B before the 1<sup>st</sup> January 2008 will not be eligible for Pentavalent (DTP-HepB –Hib) vaccine as their subsequent DTP and Hep B vaccination.

### **Dosage**

The standard dose for infants and children is 0.5 ml.

### **Route and site of administration of the Pentavalent (DTP-Hep B-Hib) vaccine**

Pentavalent (DTP-Hep B-Hib) vaccine should be given as an INTRAMUSCULAR (IM) injection to the anterolateral aspect of the thigh in infants.

Pentavalent (DTP-Hep B-Hib) vaccine SHOULD NOT be given in the buttock or administered intradermally because this route of administration does not produce an adequate antibody response. In addition there may be a risk of injury to the sciatic nerve, if it is given in the buttock.

Unlike the present practice of administering two injectable vaccines (DPT and Hep.B) in the same clinic session, where it is advised that the two injections are administered in different sites/thighs, in Pentavalent (DTP-HepB-Hib) there is no special concern of which side/site to be used. However, it is advisable to use the left thigh/deltoid muscle to maintain an uniform practice.

### **Contra-indications**

There are very few reasons to withhold or postpone administration of Pentavalent (DTP-Hep B-Hib) vaccine.

It should be avoided only for children with:

- A history of a severe allergic reaction (e.g. generalized urticaria, difficulty in breathing, swelling of mouth and throat, shock) to a previous dose of Pentavalent DTP- Hep B - Hib vaccine or with known hypersensitivity to any vaccine component
- A history of an encephalopathy of unknown aetiology after a previous immunization with a vaccine containing pertussis.

In these circumstances, the vaccination course should be continued with DT and Hepatitis B, which are available in all government immunization clinics. Since the monovalent Hib vaccine is not available in the government clinics, these children may not be able to receive the Hib vaccine in the routine immunization clinics.

- A severe acute illness with temperature above 38.5°C. As with other vaccines, vaccination should be postponed in children suffering from acute febrile illness
- A progressive neurological disease.

### **The following are NOT contra indications;**

- Minor illnesses such as respiratory tract infection or diarrhoea with temperature below 38.5°C
- Allergy or asthma

- Family history of convulsions
- Treatment with antibiotics
- Treatment with topical corticosteroids or systemic use of corticosteroids at low dosage (<0.5 mg/kg of prednisone or equivalent) in case of skin diseases like dermatitis, eczema, or other localised skin disorders
- Infection with HIV
- Breast feeding
- History of seizures (Convulsions, fits)
- Chronic illnesses such as those of heart, lung, kidney or liver
- Stable neurological conditions e.g. cerebral palsy, Down syndrome
- Prematurity or low birth weight
- History of jaundice at birth.

### **Precautions for Use**

Precautions should be taken to avoid undesirable reactions before administering the vaccine. These precautions include review of the child's medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine and the child's history of recent health problems.

Administration of any subsequent dose of Pentavalent (DTP-HepB-Hib) should be carefully considered if, in connection with the administration of vaccine, one or more of the following effects have been observed: 40°C temperature within 48 hours following vaccination (not due to other identifiable causes); collapse or shock (hypotonic hyporesponsive episodes) within 48 hours following vaccination; persistent crying lasting more than 3 hours during the 48 hours following vaccination; convulsions, with or without fever, within 3 days following vaccination.

Pentavalent (DTP-HepB-Hib) vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration of the vaccine to these subjects.

### **Storage temperature and shelf-life**

Penta valent (DTP-Hep B-Hib) vaccine should be stored and transported between 2°C. 8°C. IT SHOULD NOT BE FROZEN. Hence this vaccine should **NEVER** be stored in the freezer

compartment and should preferably be kept in the middle shelf of the main compartment of the refrigerator in all places storing the vaccine including MOH offices.

While transporting the vaccine vials should **NOT** be kept in contact with ice in vaccine carriers/flasks and during clinic sessions Penta valent (DTP-Hep B-Hib) vials should **NOT** be kept in contact with ice.

### **Injection Safety**

At present only auto- disable (AD) syringes are used in the national EPI in the country. Therefore, administration of Pentavalent (DTP-HepB-Hib) vaccine will be carried out using AD syringes. AD syringes and safety boxes for the national EPI will be provided by the Medical Supplies Division in coordination with the Epidemiology Unit and the RDHS, MOH and head of medical institutions will be responsible to ensure the availability and use of injection safety items at all immunization clinics in their respective areas. Further it is emphasized that appropriate and safe disposal of sharps waste should be ensured in all aspects of the programme .

### **Role of MOH in introduction of Pentavalent (DTP-HepB- Hib) vaccine into EPI**

- Training of MOH staff on Introduction of Pentavalent (DTP-Hep B-Hib) vaccination
- Creating public awareness regarding new additions to EPI by organizing public education programmes
- Timely request of adequate vaccine stocks for the area, supervision of storage and transport of vaccines and maintenance of cold chain
- Timely request of adequate stocks of AD syringes for the area, identifying mechanisms for disposal of AD syringes and sharps waste for the area and monitoring the implementation and sustenance of the activity.
- Monitoring and supervision of immunization coverage, vaccine wastage and reporting of AEFI at MOH level with regard to Pentavalent (DTP-Hep B-Hib) vaccine quarterly, according to the quarterly EPI Return for the area and taking corrective measures when required
- Monitoring of dropouts from immunization with regard to Pentavalent (DTP-Hep B-Hib) vaccination.
- Monitoring of record keeping at clinic level and MOH level
- Monitoring timeliness of EPI returns sent from MOH Office to RDHS/RE
- MOH is responsible for vaccine management accountability: More than 1% vaccine wastage should not be allowed since single dose liquid pentavalent vaccine is used. Each vial of vaccine is accountable and any significant wastage should be clearly documented and should be reported to

both Epidemiology Unit and RDHS. Any losses due to unacceptable reasons will be recovered from the responsible officer.

### **Role of Public Health Nursing Sister in introduction of Pentavalent vaccine into EPI**

- Training of PHMM on Pentavalent (DTP-Hep B-Hib) vaccination
- Education of public regarding the new addition to the EPI
- Monitoring and supervision of maintenance of cold chain and proper storage of vaccine stocks
- Supervision of organization of immunization clinics to facilitate administration of Pentavalent (DTP-Hep B-Hib) vaccine.
- Supervision of disposal of sharps waste in the area with regard to AD syringes and other injection material
- Monitoring of immunization coverage, vaccine wastage, AEFI and dropout from immunization with regard to Pentavalent (DTP-Hep B-Hib) vaccination at Clinic/PHM level and MOH level.
- Monitoring and supervision of record keeping at clinic level and MOH level.
- Accurate, timely compilation of EPI data at MOH level

### **Role of Supervisory Public Health Midwife in introduction of Pentavalent vaccine into EPI**

- Training of PHMM on Pentavalent ( DTP-Hep B-Hib) vaccination
- Education of public regarding the new addition to the EPI
- Monitoring and supervision of maintenance of cold chain and proper storage of vaccine stocks
- Supervision of organization of immunization clinics to facilitate administration of Pentavalent (DTP-Hep B-Hib) vaccine
- Supervision of disposal of sharps waste in the area with regard to AD syringes and other injection material
- Monitoring of immunization coverage, vaccine wastage, AEFI and dropout from immunization with regard to Pentavalent (DTP-Hep B-Hib) vaccination at Clinic/PHM level and MOH level.
- Monitoring and supervision of record keeping at clinic level and MOH level
- Accurate, timely compilation of EPI data at MOH level

### **Role of Public Health Midwife in introduction of Pentavalent vaccine into EPI**

- Education of the public on the new addition to the EPI
- Maintenance of cold chain during transport of vaccines and during clinic sessions

- Enforcing vigilance and providing personal attention to prevent dropouts from immunization and to detect AEFI with regard to Pentavalent DTP-Hep B-Hib vaccine.
- Safety assurance of the sharps waste disposal activity in the immunization clinics
- Maintenance of accurate records regarding all immunization at clinic level especially on Pentavalent (DTP-Hep B-Hib) vaccination: Birth and Immunization Register, Clinic Immunization Register, Clinic AEFI Register, Part A/B of CHDR, Clinic Summary , Quarterly MCH Clinic Return

### **Role of Regional Epidemiologist/MO-MCH in introduction of Pentavalent vaccine into EPI**

- Conduction of district training programme for MOH and hospital staff at district level and active participation, co-ordination and supervision of training programmes at MOH level.
- Close monitoring of vaccine storage and maintenance of cold chain at Regional Drug Stores and at MOH level
- Close supervision of vaccine and AD syringes supply in the region
- Overall supervision of mechanisms developed in the region for disposal of AD syringes and sharp waste.
- Close monitoring and supervision of immunization coverage and vaccine wastage quarterly and reporting of AEFI monthly with regard to Pentavalent (DTP-Hep B-Hib) vaccine

### **Role of Heads of Health Institutions in introduction of Pentavalent vaccine into EPI**

- Timely requisition of adequate vaccine stocks and AD syringes for the immunization clinic
- Close monitoring of vaccine storage and maintenance of cold chain at the institutional level
- Close supervision of vaccine and AD syringe supply to the clinic
- Overall monitoring of immunization coverage, vaccine wastage and AEFI with regard to Pentavalent (DTP-Hep B-Hib) vaccination at hospital level.
- Overall monitoring and supervision of record keeping at hospital level
- Officer Incharge of the EPI clinics is responsible for vaccine management accountability: More than 1% vaccine wastage should not be allowed since single dose liquid pentavalent vaccine is used. Each vial of vaccine is accountable and any significant wastage should be clearly documented and should be reported to both Epidemiology Unit / RDHS. Any losses due to unacceptable reasons will be recovered from the responsible officer.

## **Role of Officer In-charge / Regional Medical Supply Division (RMSD) in introduction of Pentavalent vaccine into EPI**

- Timely request of adequate vaccine stocks and AD syringes for the district
- Timely distribution of vaccines and AD syringe to MOH and medical institutions
- Maintenance of cold chain for vaccine during storage at RMSD and transport
- Preparation of the correct monthly stock return for the district
- OIC RMSD is totally responsible for vaccine management accountability at the RMSD. More than 1% vaccine wastage should not be allowed since single dose liquid pentavalent DTP-HepB-Hib vaccine is stored. Each vial of vaccine is accountable and any significant wastage should be clearly documented, to be reported to both Epidemiology Unit and RDHS. OIC RMSD will be held responsible for any losses due to unaccepted reasons.

### **Training of Health Staff**

Introduction of Pentavalent (DTP –HepB-Hib) vaccine into the routine immunization programme, EPI, requires training and educating of field health staff to provide the knowledge and skills to sustain a successful programme. This training should include the use of AD syringes and methods adopted for safe disposal of used AD syringes and other sharp waste.

Following have been identified as important issues that should be clearly and completely addressed during all training sessions.

- Hib diseases
- Hib Vaccine (contraindications, vaccine administration, storage)
- Use of Injection safety items (AD syringes, safety boxes)
- Vaccine logistics ( vaccine wastage, accountability, maintaining adequate stocks)
- Record Keeping: maintenance of records & registers, completeness, accuracy and timeliness of returns
- Vaccine Safety: Adverse Events Following Immunization

Training programmes at the national level will be conducted for Regional Epidemiologists and MO (MCH) who will be the trainers for their respective health staff. They will be responsible for training MOOH and hospital staff who conduct EPI clinics in their respective districts/ medical institutions.

MOOH will be responsible for training their own staff and this activity should be assisted and monitored by RE and MO/MCH of the district.

### Schedule for training of field/hospital health staff

Level	Target	Responsibility	Supervision	Time
National	RE,MO/MCH	Epidemiology Unit/FHB		By mid October
District	MOH, Staff of EPI clinic at TH, GH, BH	RE, MO/MCH	Epidemiology Unit/FHB	Before end of October
Divisional	PHNS,PHM, PHI Staff of CD, PU, DH, RH	MOH	RE MO/MCH	Before end of November

This guideline on introduction of Pentavalent DTP-Hep B\_Hib vaccine into the EPI may be used as the training material and this will be available in all 3 official languages. Further, electronic version of training material will be developed by the Epidemiology Unit and will be given to each district. It is the responsibility of REE and MOO (MCH) to share this with all MOOH and Hospitals staff during the district level training.

This document contains the background of the programme, implementation strategies, information on Haemophilus Influenza B infection, details of the vaccine and AD syringes.

### Records and Returns

With a new addition to the present immunization schedule it is important to monitor the programme very closely. This should be done with records and returns presently in use in the EPI.

#### *Child Health Development Record (CHDR) –*

Three doses of Pentavalent (DTP- Hep B-Hib) immunization should be recorded in the 3 empty rows provided under corresponding rows for Hepatitis B vaccines. The name of the vaccine ( ‘Pentavalent’) and does should be clearly written in the first column followed by the date, and batch number. AEFI from previous dose should be entered in the corresponding space provided in the same row. It is mandatory to fill the same information in both A and B parts of the CHDR.

### ***Clinic Immunization Register –***

All immunizations carried out in the clinic should be entered in this register. The 3 columns provided for ‘Other’ vaccines should be used to enter 03 doses of Pentavalent (DTP-Hep B-Hib) vaccine.

### ***Clinic Summary –***

As there are no columns available in this register for other vaccines, the columns allocated for the Pre School DPT 1, DPT2 and DPT 3 should be used for entering 3 doses of Pentavalent vaccine. Pre School fourth dose of DPT should be entered in the 4<sup>th</sup> column.

Similarly, 3 columns allocated for the preschool OPV 1, OPV2, and OPV3 should be used for entering Hep B1, HepB2 and HepB3 vaccine and two preschool OPV doses (4<sup>th</sup> and 5<sup>th</sup>) should be entered in the 4<sup>th</sup> and 5<sup>th</sup> columns of the Preschool polio spaces.

This procedure will be followed until such time that the new formats are printed with relevant changes. Even though originally the pre school DPT (1, 2 and 3) and OPV (1, 2 and 3) columns were allocated for the entering of delayed DPT and OPV immunizations, this information is not readily available from the source document (clinic immunization register). Hence these spaces are often kept redundant and using these columns for Pentavalent vaccines will not effect the Medical Information System.

It is important to record this clearly because only a group of infants would receive Pentavalent vaccine in an immunization clinic while many others will receive DTP and Hep B separately.

<i>Date</i>	<i>BCG</i>	<i>Pre schoolers (1-5 years)</i>								
		<i>Pentavelant /DTP</i>				<i>Hep B /OPV</i>				
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
27/01/08										

### ***Clinic AEFI Register-***

A register should be maintained at each clinic to record all adverse events reported following immunizations. The name of the child, the type of adverse event and the vaccine following which the adverse event appeared, should all be entered in the register against the date of the clinic in which it is reported.

<i>Date</i>	<i>Name of child</i>	<i>Address</i>	<i>Name of vaccine</i>	<i>Date of immunization</i>	<i>Type of adverse event</i>	<i>Remarks</i>

**Birth and Immunization Register – Form EPI/3/79 –**

Date of Pentavalent (DTP-Hep B-Hib) immunization should be recorded on column 7d, in sub columns 1, 2, 3 provided to record HepB<sub>1</sub>, HepB<sub>2</sub> and Hep B<sub>3</sub>.

<b>7 Date of immunization</b>													
<b>a</b>		<b>b Triple</b>				<b>c Polio</b>				<b>d Hepatitis B/Penta</b>			<b>e Measles</b>
<b>BCG</b>	<b>Scar</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>1</b>	<b>2</b>	<b>3</b>	

**Quarterly MCH Clinic Return –**

At the end of every month, entries in the clinic summary should be added up (totaled) and immunizations performed during the whole month should be recorded in this return monthly. This return should be sent to the MOH office by each PHM at the end of each quarter before the 5<sup>th</sup> of the following month.

As in the case of the clinic summary the corresponding spaces (rows) available for the entering preschool DPT 1 to DPT3 will be used for entering 3 doses of Pentavalent (DTP-HepB-Hib) immunization. It is important to note that in this return the spaces are horizontally aligned in contrast to the vertically aligned columns in the clinic return.

Triple (DPT) preschoolers	1 <sup>st</sup> dose (Penta 1)	
	2 <sup>nd</sup> dose (Penta 2)	
	3 <sup>rd</sup> dose (Penta 3)	
	4 <sup>th</sup> dose (DPT 4)	

**Monthly AEFI Return –**

All adverse events reported from the area following immunizations should be summarized into this return by MOH and copies of the return should be sent to RE and the Epidemiological Unit. Adverse

events from Pentavalent (DTP-HepB-Hib) vaccine should be entered in the column “Other” and it should be named so.

**Monthly Stock Return of Vaccines and ORS –**

The number of Pentavalent (DTP-Hep B-Hib) doses required for the institution for the month should be requisitioned under the column “Other” in the monthly return and it should be named so.

**Vaccine Movement Register -**

This register should be maintained at the MOH office and used for each immunization clinic session held in the area. The number of doses of immunizations used at the clinic and the number of immunizations performed at the clinic should be entered under each clinic session in this register. An extra column should be added to enter Pentavalent (DTP-HepB-Hib) immunization for the purpose. This register is vital in compiling vaccine wastages.

**Quarterly EPI Return (EPID/EPI/2/98) –**

Entries in all Quarterly MCH Clinic Returns received at the MOH office and data on immunization activities carried out in schools, estates and, hospitals in the area should be summarized on to this return. The number of Pentavalent (DTP-HepB-Hib) immunizations for the quarter should be entered under the heading 1- 4 year DPT 1<sup>st</sup> to 3<sup>rd</sup> dose of the return. This arrangement is similar to that of the Quarterly MCH clinic return.

<b>Triple vaccine (DPT)</b>					
1-4 year	1 <sup>st</sup> dose (Penta 1)				
	2 <sup>nd</sup> dose (Penta 2)				
	3 <sup>rd</sup> dose (Penta 3)				
	4 <sup>th</sup> dose (DPT 4)				

Calculation of Pentavalent (DTP-Hep B-Hib) coverage should be done as for other EPI antigens.

	Total number of Pentavalent immunizations from Health Unit, Hospitals and, Estates of the area for the quarter	
Coverage	= _____	x 100
	Estimated number of infants for the quarter	

Vaccine wastage for Pentavalent (DTP-Hep B-Hib) vaccine should be entered in page 3 of the quarterly EPI Return in the table provided. It should be entered on the row marked as ‘other’. Name of the antigen – ‘Pentavalent’ should be clearly written on the first column (A) of the row.

Calculation of Pentavalent (DTP-Hep B-Hib) vaccine wastage should be done similar to other EPI antigens.

$\text{Wastage} = 100 - \text{usage}^*$
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Usage*	=	$\frac{\text{Number of DTP-Hep. B-Hib immunizations performed during the quarter}}{\text{Number of DTP-Hep. B-Hib doses used in all clinics during the quarter}} \times 100$
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**Monitoring and Evaluation**

Close monitoring and evaluation of the introduction of Pentavalent (DTP-HepB-Hib) vaccine into the national immunization programme from its initiation is important for sustenance of the programme. Presently used EPI indicators: i.e. vaccine coverage, vaccine wastage and rate of AEFI will be used for this purpose.

Monitoring of Pentavalent (DTP-HepB-Hib) immunization coverage, vaccine wastage and adverse events reported following Pentavalent (DTP-HepB-Hib) immunization should be done at MOH level by MOH and PHNS and at district level by RE and MO/MCH. Epidemiological Unit will be responsible for monitoring at national level as for other EPI antigens.

Monitoring of Pentavalent (DTP-Hep B-Hib) Immunization Coverage

Monitoring of Pentavalent (DTP-Hep B-Hib) vaccine coverage will be incorporated into the routine immunization monitoring mechanism, the Quarterly EPI Return as soon as the vaccine is introduced. Special inputs to improve coverage have to be provided by responsible monitoring authorities for areas with poor coverage of Pentavalent (DTP-Hep B-Hib) immunization. It is also very important that data are recorded in the return accurately and clearly. MOH should be responsible for sending a timely,

accurately recorded return and should not hesitate to take necessary action to sustain the practice. At national level, analysis of Pentavalent (DTP-HepB-Hib) immunization coverage will be dealt with separately to monitor the progress of the activity in its early years.

A completely immunized child for Triple, Hepatitis B and Hib will be defined as a child immunized with all 3 doses within his/her first year and this indicator will be important to assess the progress of the programme.

#### Monitoring of Pentavalent (DTP-Hep B-Hib) Vaccine Wastage

Since DTP-Hep B-Hib single dose liquid pentavalent vaccine is more expensive than other EPI vaccines, it is important to monitor the wastage and to implement strategies to minimize it, at all levels concerned. Also since the Government of Sri Lanka is committed to co finance the Pentavalent (DTP-Hep B-Hib) Immunization Programme from the beginning of introduction, minimizing vaccine wastage is crucial.

The routine immunization monitoring tool of EPI, the Quarterly EPI Return will be used to monitor the wastage of Pentavalent (DTP-Hep B-Hib) vaccine. It is therefore important that reliable and accurate data is provided through the Quarterly EPI Return.

Assessment of causes for vaccine wastage at each MOH level is important as these vary widely between different settings. Strategies for reducing wastage could then be designed accordingly.

#### *Possible causes for high vaccine wastage:*

- Breakdown of cold chain or inadequacy of cold chain maintenance system
- Freezing of vaccines
- Poor monitoring of proper vaccine movement between MOH office and immunization clinics

#### *Strategies that could be designed:*

- Careful planning in vaccine indentation and distribution
- Strict maintenance of cold chain
- Careful planning of immunization clinic locations
- Monitoring of proper vaccine movement at MOH level
- Maintenance of accurate records and utilization of these to minimize inadequacies of vaccine stocks at MOH level
- Improvement of safe vaccine storage

### **Minimizing Vaccine Wastage at Outreach Immunization Clinics**

- MOH should identify an officer at each individual outreach immunization clinic to be responsible for proper vaccine movement at individual clinic level
- Vaccine Movement Register should be rigidly maintained to monitor the flow of vaccines in each outreach immunization clinic
- Only correct amounts of vaccine stocks should be sent to the outreach clinics based on the expected and estimated number of children to be vaccinated

Note: Pentavalent DTP-HepB-Hib vaccine should not be provided to the private sector immunization services.

### **Monitoring of Immunization Safety**

Pentavalent (DTP- Hep B-Hib) vaccine is safe. A list of possible minor adverse events that could occur following immunization of this vaccine has been mentioned above.

All adverse events associated with Pentavalent (DTP-Hep B-Hib) vaccine that are reported by mothers and public should be reported by field health workers using the Monthly AEFI Return. All field health officers should specifically inquire about AEFI following the previous immunization from mothers at the next immunization session.

Please bring the contents of these guidelines to the notice of all officers concerned in your Province/ District/ Institution/Unit.

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