Operational Guidelines

Introduction of *Haemophilus influenzae b* (Hib) as Pentavalent Vaccine in Universal Immunization Program of India

सत्यमेव जयते

World Health Organization
COUNTRY OFFICE FOR India

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Suggestions for improvement of these Operational Guidelines are encouraged & welcome.

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TARGET AUDIENCE

These guidelines are meant to assist immunization program managers at state, district and sub-district levels to introduce *Haemophilus influenzae* type b (Hib) vaccine as pentavalent (DPT+ HepB+ Hib) vaccine in the immunization program. The intention is to provide information that is practical as well as technically and operationally sound.

1

BACKGROUND

Haemophilus influenzae type b (Hib), a bacterium, is estimated to cause approximately 8.1 million cases of serious Hib diseases, and an estimated 371,000 deaths globally in the year 2000 (Watt et al, 2009). The most important manifestations of Hib infection – namely pneumonia, meningitis and other invasive diseases – occur primarily in children aged < 2 years, particularly in infants. Vaccines are the only public health tool, capable of preventing the majority of cases of serious Hib disease. In view of their demonstrated safety and efficacy, World Health Organization (WHO) recommended in 2006 that Hib vaccines be included in all routine infant immunization programmes (WHO, 2006). The Hib vaccine has been included in routine childhood vaccination programmes in nearly 180 countries, in all regions of the world. As a consequence, invasive Hib disease has been practically eliminated in many industrialized countries, and its incidence has been dramatically reduced in those parts of the developing world, where vaccine has been introduced.

In India, available data on Hib diseases indicates that Hib is one of the leading causes of meningitis and pneumonia in children less than 5 years old. According to WHO estimates, 2.4 to 3.0 million cases of Hib disease occur annually in the country with total deaths estimated to be at 72,000 (Watt et al,

2009; NTAGI Sub-committee, 2009). Hospital based studies in India show that Hib contributes 40-50% of all meningitis and 25-30% of all pneumonia cases. Hib is the most common cause of meningitis and the second largest cause of pneumonia (after *Streptococcus pneumoniae*) in India. The case fatality ratio for the Hib meningitis and pneumonia is in the range of 10-30%. In addition to mortality, Hib causes a substantial morbidity burden with 25-30% of Hib meningitis survivors suffering from long term neurological sequelae (NTAGI Sub-committee, 2009).

The introduction of Hib vaccine in the Universal Immunization Programme (UIP) in India would prevent the morbidity and mortality associated with Hib disease and will bring down the infant and Under 5 mortality rate (U5MR) in India. It has been estimated that control of Hib related diseases would reduce U5MR by 4 percentage points[1]. The reduction in child mortality will play a vital role for India to achieve its national and international child-health related goals (National Health Policy 2002, National Rural Health Mission Goals and Millennium Development Goal 4).

The Hib as pentavalent (DPT+HepB+Hib) vaccine has already been introduced in Tamil Nadu and Kerala states of India in December 2011. Now, the pentavalent vaccine is being introduced in a few additional states of the country. This is an updated version of operational guidelines published in the year 2011. The update has been done to incorporate experience, lessons learnt, and best practices from pentavalent vaccine introduction in 2 states. The findings from Post Introduction Evaluation (PIE) of pentavalent vaccination in Kerala and Tamil Nadu, conducted in August 2012, has been used to update these operational guidelines and summarised in Annexure 1.

[1]According to the National Technical Advisory Group on Immunization (NTAGI) subcommittee on Hib, there were an estimated 72,000 deaths attributable to Hib diseases. Under-five mortality figures (UNICEF, 2010) estimate that in India, 1,726,000 children die before reaching their fifth birthday in 2009. Using these two estimates, Hib associated deaths are 4% [(72,000 / 1,726,000)*100] of all under-five mortality.

2

THE DISEASE

2.1. What is *Haemophilus influenzae* ?

Haemophilus influenzae is a Gram-negative coccobacillus that affects only humans. There are six types of *Haemophilus influenzae* (a, b, c, d, e, and f), but *Haemophilus influenzae* type b (Hib) bacteria accounts for over 90% of serious *Haemophilus influenzae* infections in children. Hib bacteria live as commensals in the upper respiratory tract.

NOTE: *In spite of its name, 'Haemophilus influenzae' does not cause influenza (i.e., the "flu") or the common cold. Similarly, Hib should not be confused with HIV or Human Immunodeficiency Virus, the virus that causes AIDS.*

2.2. Modes of transmission

Like measles, Hib is passed from an infected person to an uninfected person via droplets of saliva/respiratory secretions, when an infected individual coughs or sneezes. Hib can also be spread when children share toys and other objects that they have put in their mouth. The probability of transmission increases when children spend prolonged periods of time together in settings such as day-care or crèches. Children are often asymptomatic carriers of the Hib bacteria showing no signs or symptoms but still can infect others.

2.3. Risk groups for Hib disease

Hib disease is most common in children under five years of age. Children between the ages of 4 to 18 months of age are most at risk (WHO, 2006). It is important to immunize children and prevent disease very early in life. At birth, antibodies from the mother sufficiently protect most infants. When a child reaches 2 or 3 months of age, the level of maternal antibodies decreases and the risk of Hib infections increases. By the age 5 years, most children will have already developed their own immunity against Hib. For this reason, Hib disease after the age of five years is considered rare.

2.4. Diseases caused by Hib infection

2.4.1. Bacterial meningitis:

Bacterial meningitis is the inflammation of the membranes that cover and protect the spinal cord and brain, known collectively as the meninges. In the absence of vaccination, bacterial meningitis in children is most often caused by Hib. In developing countries, as many as 40% of Hib cases result in death. Furthermore, 15% to 35% of children who survive Hib meningitis are left with permanent neurological disabilities such as mental retardation, developmental delay and hearing loss (NTAGI sub-committee, 2009).

2.4.2. Inflammation of the lungs:

In developing countries, Hib is a major cause of pneumonia (or acute lower respiratory tract infection, ALRI) in children. Up to 20% of the severe bacterial pneumonia cases are caused by Hib.

2.4.3. Other Hib infections include:

- Septicaemia: Infection of the blood-stream.
- Septic arthritis: Infection in the joints.
- Osteomyelitis: Infection of the bones.
- Epiglottitis: Infection of the larynx and pharynx.

In the absence of appropriate and immediate treatment, upto 50% of cases are fatal.

2.5. Diagnosis of Hib infection

The diagnosis of Hib disease can be made by bacterial culture, latex agglutination test or by polymerase chain reaction (PCR). In reality, it is very difficult to identify Hib in resource poor settings. The bacterial culture of sterile fluids like CSF or blood is needed. For CSF, an invasive procedure called a lumber puncture (LP) must be done. The samples collected need to be stored and transported, within a short period of time, in suitable media, while maintaining the appropriate temperature (between 20°C and 35°C) to be able to culture Hib bacteria.

2.6. Treatment

Treatment for Hib disease is not always effective because some strains of Hib may be resistant to antibiotics. Antibiotic resistance is a serious problem, which is continuously increasing in developing countries, including India. Immunization against Hib is a cost effective strategy of prevention.

3

HIB CONTAINING PENTAVALENT VACCINE

Hib vaccines, either alone or in combination, protect against *Haemophilus influenzae* type b. It is important to note that Hib containing vaccines do not prevent meningitis and pneumonia caused by other etiologic agents.

3.1. Formulation

Hib vaccines are available in different formulations of liquid or lyophilised (dried powder), stand-alone (monovalent) and combination (DPT+Hib, DPT+HepB+Hib). The Hib vaccines in various formulation are licensed in India for almost a decade and widely used in the private sector. The formulation that shall be provided in the National Immunization Programme will be the liquid pentavalent vaccine (LPV). The vaccine will have 5 antigens (DPT+HepB+Hib) in a single formulation.

3.2. Presentation

The liquid pentavalent vaccine (LPV) in the UIP will be available as a multi-dose vial (10 doses).

3.3. Storage volume

The storage volume of Hib vaccine in 10 dose vials is approximately the same as currently used DPT or HepB vaccine in similar presentation. Hence, there would not be any additional cold chain space requirement, while introducing the pentavalent vaccine.

3.4. Storage temperature

Pentavalent vaccine should be stored at temperature of 2-8 degree Celsius, in the basket of Ice-Lined Refrigerator (ILR) and should never be frozen. Conditioned ice packs should be used during transportation to prevent freezing.

3.5. Age group for vaccination

Hib containing pentavalent vaccine in India is recommended for infants from 6 weeks to less than 1 year of age.

3.6. Vaccination schedule and 'Phasing in'

Three dose primary series will be considered routine. The first dose is given to children at six weeks of age or older. The vaccine to be given at the same time as DPT, OPV, and HepB vaccines, as shown, for example, in the schedule below.

Age	Current scheduled vaccines	After introduction of Pentavalent vaccine
At Birth	BCG, OPV-0, **Hep B-0**	BCG, OPV-0, **Hep B-0**
6 weeks	OPV-1, **DPT-1, HepB1**	OPV-1, **Pentavalent-1**
10 weeks	OPV-2, **DPT-2, HepB2**	OPV-2, **Pentavalent -2**
14 weeks	OPV-3, **DPT-3, HepB3**	OPV-3, **Pentavalent -3**
16-24 months	**DPT-B1**, OPV-B	**DPT-B1**, OPV-B
5-6 year	**DPT-B2**	**DPT-B2**

During the initial months of pentavalent vaccine introduction, only those children who are coming for the first dose of DPT will be administered pentavalent vaccine. Infants who have already received either their first or second doses of DPT & Hep B (i.e., DPT1/HepB 1 or DPT2/HepB 2) will complete the schedule with DPT & HepB only. This is called 'Phasing in' of pentavalent vaccine in UIP.

3.7. Dosage and route:

The dose of pentavalent vaccine is 0.5 ml. The route of administration of pentavalent vaccine is the same as DPT

vaccine. This is a liquid vaccine therefore, is used directly from the vial and given by intramuscular injection in the antero-lateral aspect of the mid-thigh in infants.

NOTE: *Children will continue to receive DPT boosters at the age of 16-24 months and 5-6 years of age using DPT vaccine. Similarly, birth dose of HepB using single antigen HepB vaccine will continue and must be provided within 24 hours of birth.*

3.8. Inter-changeability of the vaccines manufacturers

Liquid pentavalent vaccines (LPV) from different manufacturers can be used to complete the immunization schedule of an infant.

3.9. Adverse events following immunization

Hib vaccine has not been associated with any serious adverse effects. However, redness, swelling and pain at the site of injection may occur in as many as 25% of those who have been vaccinated. Such reactions usually start within 1 day after immunization and last for 1–3 days (WHO 2009, Govt. of India, 2010). Less commonly, children may develop fever or can become irritable for a short period. When the Hib vaccine is given at the same time (or as a combination vaccine with DPT i.e.pentavalent vaccine), the rate of adverse events following immunization (AEFI) is not any higher than when DPT vaccine is given alone. However, the introduction of pentavalent vaccine (or any other new vaccine) may coincide with the increased reporting of AEFIs in the states and districts. All these AEFI cases, including those following pentavalent vaccine should be reported as per the Government of India AEFI surveillance and response operational guidelines (Govt. of India, 2010).

3.10. Contraindications:

There are only 2 major contraindications for administration of pentavalent vaccine:

3.10.1. Severe allergic reactions

Although rare, an individual may have a severe allergic reaction to a component of the vaccine following a previous dose of Hib / pentavalent vaccine. In such an event,

subsequent doses are contraindicated and should not be given.

3.10.2. Persons with moderate or severe acute illness

Children with moderate or severe acute illness should not be administered pentavalent vaccine until their condition improves. The minor illnesses, however, such as upper respiratory infections (URI) is not a contraindication to vaccination.

3.11. Immunogenicity, efficacy and effectiveness

All Hib containing vaccines (i.e., pentavalent vaccine) are safe and efficacious. They provide 85% to 95% protection after completion of the schedule. The vaccination reduces nasopharyngeal colonization – or carriage – of the organism, leading to substantially greater reduction in disease transmission and incidence than can be directly attributed to the effects of the vaccine. This indirect effect or 'herd immunity' has been demonstrated in several post-introduction effectiveness studies.

3.12. Long term protection and booster dose

In general, the Hib vaccine provides protection for at least 15 years. Current scientific evidence suggests that protection is life long. In case where serum antibodies wane, an anamnestic response of antibody production triggered by memory B cells and memory T4 cells often occurs following re-exposure to the pathogen. **A booster dose is not recommended in India.**

3.13 Open Vial Policy

The Government of India adopted the Open Vial Policy for pentavalent vaccine in UIP and the policy guideline was issued in October 2011. This policy is being followed for pentavalent vaccine in Kerala and Tamil Nadu. The Open Vial Policy for pentavalent vaccine will be implemented in all other states introducing this vaccine.

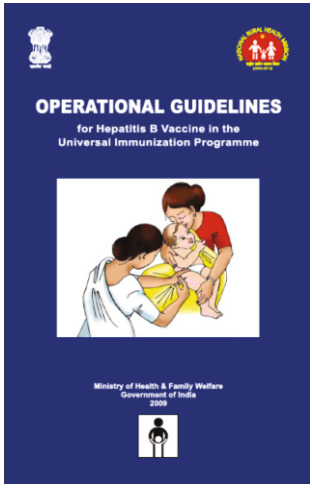
Additionally, Open Vial policy in India is also recommended for institutional set up for Hepatitis B birth dose and Oral Polio Vaccine zero dose (OPV-0) since May 2011.

4

STEPS FOR THE INCLUSION OF Hib AS PENTAVALENT VACCINE IN UIP IN INDIA

The inclusion of Hib as pentavalent vaccine into the UIP schedule requires careful planning at all levels. This initially involves top-down macro-planning at the state level, followed by bottom-up micro-planning, detailing precise logistics and financial needs for each district and sub-district levels, starting from the more peripheral levels and moving towards the higher levels.

It is recommended that planning activities start 3-6 months prior to scheduled introduction of the vaccine. Moreover, the introduction of pentavalent vaccine should be viewed as an opportunity to strengthen overall routine immunization service delivery in the states and districts.



The broad steps involved for the introduction of pentavalent vaccine are similar to those employed for the introduction of Hepatitis B vaccination in UIP in India (Govt. of India, 2009). Therefore, the operational guidelines for Hepatitis B vaccine introduction in UIP in India have been consulted and used to develop the subsequent sections of this document that highlight the major activities that should be undertaken

to ensure effective and successful implementation of Hib containing pentavalent vaccine in the UIP. The specific activities conducted for pentavalent vaccine introduction in Kerala and Tamil Nadu states have been documented and may be used for planning by the state officials (Gupta et al, 2012).

4.1. State-level activities

- **Conduct state level training and advocacy workshops,** seek commitment and support for introduction of pentavalent vaccine from various departments. Specifically, the Department of Health and Family Welfare, the Department of Women and Child Development and the Department of Education and other stakeholders
- **Prepare a training plan** for Medical officers, Health workers, ICDS staff and other possible stakeholders i.e. medical college faculty and private practitioners etc.
- **Develop and disseminate immunization guidelines** (e.g. injection safety, cold chain, AEFI and VPD surveillance etc.)
- **Plan advocacy and social mobilization** activities at all levels.
- **Modify and disseminate revised formats:** recording and reporting formats including immunization card etc.
- **Indenting and delivery:** ensure availability of required vaccine and other logistics needed to introduce the vaccine and get cold chain system ready
- **Utilize activities** to introduce Pentavalent vaccine as **an opportunity to strengthen RI services** and develop plans for supervision, monitoring and evaluation
- **Conduct media sensitization workshop** prior to

the vaccine introduction (preferably, a week prior to the launch date)

- A state level pentavalent launch event and wide publicity for awareness generation

4.2. District and Sub-district levels activities

- **Revise micro-plans:** use prescribed formats for UIP at each level
- **Trainings:** health workers and staff at all levels with specific focus on key aspects of pentavalent vaccine and use of Open Vial policy etc.
- **Estimate:** Calculate vaccine and logistic requirements at each level
- **Cold chain: e**valuate availability and adequacy at all levels
- **Indenting and delivery:** ensure availability of required vaccine and other logistics needed to introduce the vaccine
- **Disseminate revised formats:** reporting, recording and immunization card, etc.
- **Advocacy and social mobilization :** activities around the introduction of the new vaccine
- **Develop plans :** for supportive supervision and monitoring

4.3. Program level actions and decisions to be taken

4.3.1. Estimate vaccine and syringes needed

Currently, DPT and Hepatitis B vaccines provided under the Universal Immunization Programme require two separate injections. With the inclusion of pentavalent vaccine, a single injection will deliver 5 antigens (DPT+HepB+Hib), therefore, there will be less requirement of Auto-Disable syringes.

Every beneficiary will require 3 doses of pentavalent vaccine. Considering the standard vaccine wastage rate and

buffer stock of 25%, the annual vaccine requirement in the **first year** can be calculated as follows:

= (Targeted annual beneficiaries) x (3 doses) x (1.33 X 1.25)

Primary Health Centres (PHCs) and districts need to forecast their vaccine needs for the stipulated time period to ensure that the right amount of vaccines, injection and cold chain equipment are available to vaccinate all eligible infants at a given time, in a given area. Each of these levels should monitor the vaccine and syringes stock in order to assess the

NOTE: *Considering that 3 injections of pentavalent vaccine will replace 6 injections of DPT and HepB (3 injections of DPT + 3 injection of HepB), the number of syringes required at state, district and sub-district levels will be reduced. However, injection material requirement will not change for the other vaccine given as per national schedule.*

lead time and re-ordering levels.

4.3.2. Wastage rate and Buffer stock

The maximum acceptable wastage for pentavalent vaccine will be 25%. However, it is important to minimize the wastage of pentavalent vaccine just as it is important to minimize the wastage of other vaccines. Open Vial Policy is recommended for pentavalent vaccine, which has likely to reduce the vaccine wastage. The buffer stock ensures that there is sufficient supply to manage sudden and unexpected shortages. The amount of buffer stock recommended is generally 25% of the annual requirement. The buffer stock is supplied only in the first year of vaccine introduction.

4.4. Manage DPT and HepB vaccines stock balances (Phasing in, Phasing out and repositioning)

The pentavalent vaccine will be 'Phased in' under the UIP In the initial months of pentavalent vaccine introduction; it will be administered to only those infants who will be coming for the first doses of DPT and HepB. The '**phasing in'** of

pentavalent vaccine requires several considerations by district and sub-district officials in order to properly manage existing stock balances. :-

- Children who have already received DPT1+HepB1 or DPT2+HepB2 should complete vaccination as per the previous recommended schedule.
- 2 doses of DPT vaccine will still be required in the programme for DPT boosters at 16-24 months and 5-6 years.
- Hepatitis B vaccine stock would be required for birth dose, at those facilities where deliveries are conducted.

Precise local level planning is necessary to manage existing stock of DPT and HepB vaccine and minimize any vaccine wastage, taking into account the considerations and the status the Vaccine Vial Monitor (VVM) and expiry date of the vaccine. As described above, following introduction of pentavalent vaccine DPT vaccine doses for every child would be reduced from 5 doses (3 in first year of life and 2 booster doses) to 2 doses only (for booster doses). Similarly, only one dose of hepatitis B vaccine for birth dose would be required for each infant, reducing requirement from previous 4 doses per child. Hepatitis B vaccine stocks need to be shifted from the health facilities, not conducting deliveries and not offering hepatitis B birth dose. All these factors would require consideration at the time of indenting and re-distribution of DPT and HepB vaccine doses, immediately after Pentavalent vaccine introduction.

4.5. Estimate cold chain storage needs and manage cold chain

There will not be any additional cold chain space requirement for liquid pentavalent vaccine introduction because 2 vials of vaccine (1 DPT and 1 HepB) will be replaced by a single vial of pentavalent vaccine for infant

immunization schedule, leading to space saving. However, small quantity of DPT vaccine (booster doses) and Hepatitis B vaccine (birth dose) need to be stored.

4.6. Update recording and reporting formats

The introduction of pentavalent vaccine will require that all recording and reporting formats be revised to reflect this change in the programme. Forms that will need revision include: vaccine stock forms, immunization cards, tally sheets, monthly progress report at all levels, MCH/Immunization register, coverage monitoring charts, supervisory checklists, computer databases, and immunization coverage surveys and evaluation formats etc.

It is strongly recommended to revise these formats to include pentavalent vaccine and distribute them before introduction. Alternatively, existing forms can be adapted locally with a plan for modification in the formats, at the earliest possible. Health workers may use existing columns for DPT or HepB for entry of pentavalent vaccine data by hand, to the existing forms and use these as long as supplies last. It should be recognized that if existing forms are used, it is more likely that errors and omissions will occur.

The reporting of pentavalent vaccination will be done through existing reporting mechanisms such as HMIS. However, with the pentavalent vaccine introduction, an additional paper report, in suggested format, is to be sent by all levels to the next level on a monthly basis. State Expanded Program of Immunization Officer (SEPIO) would share this report with Immunization division at MoHFW, on monthly basis. The format for additional paper reporting would be shared with the states. This additional paper report should continue until a mechanism for pentavalent vaccine is well settled into the existing reporting channels.

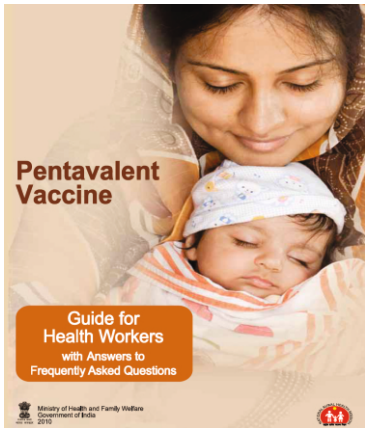
4.7. Update IEC material and FAQs

Officials are expected to revise and distribute information materials for the community and caregivers, before the vaccine is introduced in the program. Materials that must be revised include: posted immunization schedules (tin-plates, posters, wall paintings and billboards), immunization

cards and counterfoils, materials for parents and training material for health workers. The prototypes of IEC material is available from Govt. of India and will be/have already been shared with the states, which can be appropriate adapted for the state and can be used for printing and distribution.

4.8. Prepare and train staff

It has been learnt from the pentavalent vaccine introduction experience in Kerala and Tamil Nadu that successful vaccine introduction largely depends upon the training and sensitization of all levels of health functionaries. Health care providers are responsible for handling and administering the vaccine and they are a major source of information for parents and other members of the public. Training for health care staff is essential to the introduction of any new vaccine (including pentavalent vaccine) into the UIP. The need for additional training will be minimized if the delivery of information on Hib disease and pentavalent vaccine is integrated into existing training activities. Health care personnel who require training include District Immunization Officers (DIO), Medical Officers (MO), cold chain handlers, supervisors, data managers, and frontline Health Workers (HW). The officials and staff of Dept. of Women and Child Development (CDPO, ICDS workers and Anganwadi workers, etc.) shall also be trained. The training of faculty in Paediatrics and Preventive and Social Medicine departments in medical colleges and private practitioners involved in immunization service delivery should also be conducted.



4.8.1. Training Approach

Training activities should commence at the state level, with a one-day orientation of state and district officers on

pentavalent vaccine introduction. Subsequently, district level officials (preferably DIOs) would train the medical officers of the districts. These medical officers will, in-turn, be responsible for training health workers, including ANMs, supervisors and cold chain handlers.

Orientation of ASHAs and AWW is important for successful implementation of the vaccination program and can be done during their monthly meetings.

The Child Development Project Officers, ICDS supervisors, and Anganwadi workers (AWW) will also be sensitized about the introduction pentavalent vaccine. Health department and ICDS will coordinate their efforts to ensure smooth implementation of these trainings, sensitization and further implementation.

Sensitization of paediatricians/medical practitioners through involvement of Indian Medical Association (IMA); Indian Academy of Pediatrics (IAP) & Indian Public Health Association (HPHA) should also be done.

Specific training related to pentavalent vaccine introduction should not preclude that other training opportunities are taken advantage of to convey important pentavalent vaccine messages. For example, district task force meeting and medical officer trainings are ideal fora during which pentavalent vaccine introduction topics should be integrated and discussed.

Training material includes the standardised power-point presentations circulated by Govt of India, Immunization Handbooks for Medical officers and Health workers that include FAQs on pentavalent vaccine and a separate set of published FAQs on pentavalent vaccine. This material can be translated in the local language and be used appropriately.

4.8.2. Training content – broad areas

Training must cover information on Hib related diseases and pentavalent vaccine as well as programmatic issues. The

main topics that should be covered in these trainings are:

- Types of *Haemophilus influenzae* bacteria
- Hib bacteria, transmission and disease
- Importance of infant vaccination
- Pentavalent vaccine and schedule
- Vaccine and logistics planning and management
- Use of Open Vial Policy
- Vaccine administration
- Injection safety and safe waste disposal
- Adverse events following immunization (AEFI) surveillance
- Recording and reporting
- Monitoring and supportive supervision and.
- Communicating with parents.

4.9. Launch of vaccination program

The launch of the pentavalent vaccine provides the States with an ideal opportunity to educate the public and policy makers alike about Hib disease, its prevention and the positive health benefits to individuals and the community. A well-publicized launch ceremony for pentavalent vaccine introduction to improve general awareness about UIP and specific knowledge related to pentavalent vaccine should be planned. A successful launch of pentavalent vaccine will include mass media components as well as one-to-one interpersonal contact with beneficiaries to openly respond to queries that arise. To be able to respond comprehensively, other related government departments, local media and NGOs should be briefed and brought on board, so that they may also spread the message and motivate the community to benefit from immunization.

Operational guidelines, tools and appropriate communication materials must be distributed well in advance in the local language, to target audiences. Failures in communication commonly occur because the disseminated materials do not reach the intended targets and/or the

information is not appropriate for the intended audience. A few general guidelines for more effective dissemination are the following:

4.9.1. Advocacy

Advocacy is a process for raising awareness, especially among decision-makers and service providers, to ensure that pentavalent vaccination is available for all targeted children. Decision-makers and opinion leaders, who should be considered for advocacy efforts, will include health department and government officials, elected representatives at state, district and '*Panchayat*' levels, private sector clinicians, nongovernmental organizations, professional bodies such as Indian Medical Association (IMA), Indian Academy of Pediatrics (IAP), Indian Public Health Association (IPHA), Indian Association of Preventive and Social Medicine (IAPSM) etc., community leaders including '*Panchayati Raj* Institution' members and influencers such as religious leaders and teachers, Self Help Group (SHG) and the media.

4.9.2. Social Mobilization

Social mobilization is aimed at caregivers and is focussed on getting children to the immunization sessions. A range of communication media should be used to deliver messages to vaccinators (ANMs), Anganwadi workers (AWWs), Accredited Social Health Activists (ASHA) and community volunteers. Health workers, if properly trained and informed, can be important conduits of information to motivate and generate community interest in UIP and the new vaccine. They are the main source of information to the general public.

Possible key areas: (to be adapted to suit the audience):

- Hib diseases and its consequences
- Modes of transmission of Hib diseases
- Importance of infant immunization
- Target group for immunization and an

explanation of why older children are not being immunized with pentavalent vaccines

- ❖ How many times and when infants should be immunized? Make sure that the baby is immunized three times with pentavalent vaccine at 6, 10 and 14 weeks
- ❖ Importance of all other vaccines of UIP, in addition to pentavalent vaccine.
- ❖ Limitations of pentavalent vaccine.

4.9.3. Supervision and monitoring of implementation:

Supervision in the planning phase is focused on checking the infrastructure, financial needs, available human resource capacity, detecting challenges and finding appropriate solutions. Supervisors have an important role to prevent poor implementation by ensuring that introduction plans are correct and complete. To achieve this, supervisors must themselves be familiar with what is expected in the programme and what role they are expected to play. A key component of supervision is to encourage and motivate frontline health workers (ANMs, AWWs, ASHAs) and guide them through on-the-job training, whenever necessary. The officials and supervisory staff, of both the health department and ICDS, shall do the supervisory visits.

A detailed supportive supervision plan should be prepared at every level. Supportive supervision must focus on the critical aspects of quality, effectiveness and safety related to programmatic issues. Supervisors should use the checklist provided in the Immunization Handbook for Medical Officers or the most recent updated supervisory checklist as a tool to document the level of implementation of plans, and coverage with the vaccine. The checklists to be used by your state should be developed locally, if local specific additional information is required and if the form is required in local language. Sufficient quantity of forms need to be printed and should be made available at different levels for the supervision efforts.

4.9.4. Monitoring the process of pentavalent vaccine implementation

Standardized data collection formats and operating procedures have been developed by the GoI to monitor the provision of RI services at the point of delivery (immunization session sites) and community level coverage of all antigens offered through UIP to detect coverage gaps. The introduction of pentavalent vaccine in UIP provides an opportunity to strengthen the overall monitoring of the routine immunization programme. The GoI mandated intensified RI monitoring strategy should be used for pentavalent vaccine related monitoring also. The appropriate information may be collected on the status of implementation through all components of RI monitoring

(i) **Session site monitoring:** This captures information on vaccine supply and the availability of logistics, functioning of Alternate Vaccine Delivery (AVD) system, injection practices of ANMs, injection safety and waste disposal, record keeping, and inter-personal communication of service providers.

(ii) **Household monitoring:** It uses convenience sampling in the community surrounding RI session sites, to assess the coverage of RI antigens of children <35 months old.

(iii) **PHC and district level monitoring:** This provides information on coverage, vaccine stocks, wastage rates etc.

The existing mechanisms such as the task force for immunization, other interactions and review meetings should be used for feedback and information sharing for appropriate corrective measures and follow up.

4.9.5. Monitor vaccines and logistics supply

Examine available records for supply, utilization and balance of vaccines and AD syringes and physically verify

whether there is a logical association between vaccines and AD syringes supplied and used. Explore and address reasons if the following are found:

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

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

4.9.6. Monitor cold chain

Pentavalent vaccine must be stored between 2-8°Celsius and is damaged by freezing as well as by higher temperatures. Therefore, strict attention to the maintenance of cold chain is essential.

4.9.7. Monitor immunization safety

Pentavalent vaccine is a safe and effective vaccine, however, as with any new vaccine added to the programme, adequate attention should paid to ensure that sensitive surveillance for adverse events following immunization (AEFI) is in place. Any suspected AEFI thought to be associated with pentavalent vaccination should be reported in the prescribed GoI formats, including hospitalizations, deaths and any other severe or unusual medical event or event clusters. If an AEFI occurs, measures should be take to check the compliance

with safety strategies from existing supervisory checklists and seek explanations for deviations from safety norms, such as recapping, non-use of hub-cutters and other incorrect practices.

4.9.8. Monitor HepB birth dose implementation and DPT boosters

It has been noticed through evaluation surveys and from review meetings that the coverage with HepB birth dose has been lower than other antigens in UIP in India. This situation requires specific attention considering that birth dose needs to be administered within 24 hours of delivery. It is recommended that in the backdrop of pentavalent vaccine introduction, when HepB vaccine standalone formulation will be withdrawn from 6, 10 and 14 weeks schedule, attention needs to be paid to increase coverage with Hep B birth dose. Similar attention should be paid to increase coverage with DPT booster doses and second dose of Measles Containing Vaccine (MCV2).

4.10. Post-introduction evaluation and impact assessment

Disease surveillance for bacterial meningitis and invasive bacterial disease is being strengthened in India. As per the recommendations of the NTAGI, a hospital based Bacterial meningitis surveillance network has been initiated at 11 sites in 6 states of India. This bacterial meningitis surveillance is being conducted jointly by the Immunization Division, Ministry of Health and Family Welfare (MoHFW), and Indian Council of Medical Research (ICMR). There is a plan for further expansion of this surveillance network.

The World Health Organization recommends that, a Post Introduction Evaluation (PIE) should be conducted within 6-12 months of a new vaccine introduction. The aim of such evaluation is to determine the status of vaccine introduction, its effect on the health system, and to derive

lessons for necessary corrective measures. A Post Introduction Evaluation (PIE) of pentavalent vaccine in Tamil Nadu and Kerala states was conducted in July/August 2012 (summary in Annexure 1). The findings of PIE in these 2 states have been used to update these guidelines and appropriate corrective measures in the states.

The national and state governments are encouraged to plan to conduct Post Introduction Evaluation of pentavalent vaccine within 6 – 12 months of vaccine introduction.

5

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Annexure 1

Post Introduction Evaluation of pentavalent vaccine in Tamil Nadu and Kerala, India, 2012:

The Government of India (GoI) introduced Hib as pentavalent vaccine in Tamil Nadu and Kerala states, starting December 2011. Subsequently, the GoI requested the World Health Organization Country Office for India to conduct a Post Introduction Evaluation (PIE) in these states.

WHO planned, led, coordinated and conducted a PIE of pentavalent vaccine in July/August 2012. The standard WHO PIE tools were adapted for India specific requirements. A standard protocol was prepared in consultation with experts from Indian Council of Medical Research, National Institute of Health and Family Welfare, National Centre for Disease Control, National institute of Epidemiology, UNICEF, USAID, WHO (Country Office, Regional Office for South-East Asia and Headquarters). A desk review was followed by field visits by 15 national and international experts to seven selected districts in 2 states. The districts visited were Thiruvallur, Erode, Virudhunagar and Trichy in Tamil Nadu and Trivandrum, Ernakulam and Mallapuram in Kerala. The evaluation teams visited and interacted with national, state, district and facility level health staff and documented field observations. Additionally, exit interviews were conducted with the caregivers at the session sites. A few private practitioners providing immunization were also contacted in the evaluation. 200 health officials & other staff at various levels and around 180 caregivers were interviewed.

Major findings:

- There was a **good leadership** at various levels, which helped in bringing focus on implementation and increasing the visibility of the program.
- **Proactive engagement with relevant stakeholders** by the state governments and seeking support of the subject matter experts on immunization helped in addressing misinformation and misconceptions prior and during the introduction period.
- **The widely publicised launch events** at all levels increased visibility to the program and helped in increasing community acceptance of the vaccination.
- The **well trained health staff at all levels** and majority of these trainings were conducted before the launch dates.
- The introduction coincided with the use of **Open Vial policy** for pentavalent vaccine for outreach sessions. This has been **effectively implemented** in both states and has contributed in the reduction of vaccine wastage.
- There was **high a acceptance amongst community and health staff** for pentavalent vaccine in both states.

Major recommendations:

- **Update recording and reporting formats** to incorporate pentavalent vaccine.
- Further **strengthen AEFI monitoring and reporting system:** The measures such as printing of 'job-aids' for 'AEFI surveillance; 'for reporting protocols' and by additional sensitization of health staff suggested.
- **Use local data for action:** The staff may be trained in calculating coverage rates, Wastage and drop-out rates etc. and the information may be utilised for corrective programmatic measures.
- **Streamline HepB Birth dose and OPV zero dose** and use of Open Vial Policy for these vaccines.
- **Strengthen immunization waste disposal system,** specifically in the rural health facilities.

In summary, the Hib as pentavalent vaccine had been successfully incorporated in the immunization program in two states. This shows that states in India are ready and prepared for introduction of additional and new antigens in UIP. There is high acceptance for the vaccine amongst both community and health workers. The lessons and experience from the introduction in these two states may help in pentavalent vaccination scale up in other states of India.

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