Operational Guidelines

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

Ministry of Health & Family Welfare
Government of India
New Delhi
2011

सत्यमेव जयते

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन
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The Suggestions to improve or enhance the content of this 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) 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 routine immunization programmes of all countries (WHO, 2006). The Hib vaccine has been included in routine childhood vaccination programmes in more than 150 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 some parts of the developing world.

In India, available data on Hib diseases indicates that Hib is a leading cause of meningitis and pneumonia in children aged less than 5 years. The WHO has estimated that annually 2.4

to 3.0 million cases of Hib disease occurs in India, with total deaths estimated to be at 72,000 (Watt et al, 2009; NTAGI Sub-committee, 2009). Hospital based studies in India indicate 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 streptococcal pneumonae) 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 sequalae (NTAGI Sub-committee, 2009).

The introduction of Hib vaccine in UIP in India would prevent the morbidity and mortality associated with Hib disease and will reduce the infant mortality rate (IMR) in India. It has been estimated that control of Hib related diseases will reduce IMR by 4 percentage points[1]. The reduction in IMR 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, and Millennium Development Goal 4).

[1]According to the National Technical Advisory Group of India (NTAGI) subcommittee on Hib, there were an estimated 72,000 deaths attributable to Hib disease in 2009. Under 5 mortality figures (UNICEF, 2010) estimate that 1,726,000 children die before reaching their 5th birthday. Using these two figures, Hib associated deaths are 4% [(72,000 / 1,726,000)*100] of all under 5 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 in the nose and throat area.

NOTE: *In spite of its name, Haemophilus influenzae type b does not cause influenza (i.e., the "flu") or the common cold. Similarly, Hib is not the same as 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 via droplets of saliva 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 the child reaches 2 or 3 months of age, the level of maternal antibodies decreases and the risk of Hib infection 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 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 infection, ALRI) in children. It has been found that up to 20% of the severe bacterial pneumonia cases are caused by Hib.

2.4.3. Other Hib infections include:

- Septicaemia: Presence of pathogenic bacteria in the blood.
- Septic arthritis: Inflammation of the joints.
- Osteomyelitis: Inflammation of the bones
- Epiglottitis: Inflammation of the larynx and

pharynx. In the absence of appropriate and immediate treatment, 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 culture needs to be done on sterile fluids like CSF or blood. For CSF, a delicate procedure called a lumber puncture (LP) must be done. The samples collected need to be stored and transported in appropriate media while maintaining appropriate cold chain to have any chances of culturing 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 for disease 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 (mono-valent) and combination (DPT+Hib, DPT+HepB+Hib) forms. The formulation which will be provided in Universal Immunization Programme (UIP) in India will be 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 in 10 dose presentation.

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 pentavalent vaccine.

3.4. Storage temperature

Pentavalent vaccine should be stored at temperature of 2-8 degree Celsius, in the basket of 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 is indicated in children from the age of 6 weeks up to 12 months.

3.6. Vaccination schedule

Three dose primary series will be considered routine. The first dose is given to children at six weeks of age or older. The vaccine may be given at the same time as DTP, 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-Birth Dose**	BCG, OPV-0, **Hep B-Birth Dose**
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 year	**DPT-B2**	**DPT-B2**

Phasing In:- *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., DPT/HepB 1 or DPT/HepB 2) will complete the schedule with DPT & Hep B only.*

3.7. Dosage and route:

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

vaccine. Pentavalent vaccine 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 also be provided within 24 hours of birth.*

3.8. Inter-changeability of the vaccines

Liquid pentavalent vaccines 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, such as with pentavalent vaccine, the rate of AEFI is not any higher than when DPT is given alone. However, the introduction of pentavalent vaccine (or any other new vaccine) may coincide with the increased reporting of AEFIs in the 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 contraindication for administration of pentavalent vaccine:

1.10.1. Severe allergic reactions

Although rare, an individual may have had 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.

1.10.2. 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 on 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 the 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 vaccine. **A booster dose is not recommended**.

3.13 Continuation of HepB birth dose and DPT boosters:

Following the introduction of pentavalent vaccine, at the age of 6, 10 and 14 weeks, the DPT & HepB vaccines will be given as combination pentavalent vaccine However, HepB vaccine will be continued to be used for the birth dose (with in 24hrs).

Similarly, the booster doses of DPT vaccines (at 16-24 months & at 5-6 years)will continue to be given as stand alone formulations.

3.14 Open Vial Policy:

In 2011, the Government of India has adopted policy that open vials of Oral Polio Vaccine (OPV) and Hepatitis B can be reused for Zero dose and birth dose, respectively. These open vials should be kept in proper cold chain and with date of opening of the vial mentioned. This open vial should not be used after one month of its opening.

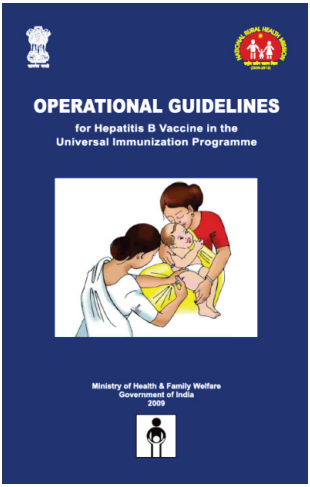
However, with the introduction of pentavalent vaccine, the Open Vial Policy will be further reviewed and the expert group will be consulted before any plan to role out or pilot open vial policy in any district or state of India. The states will be communicated this decision as and when made.

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.



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.

4.1. State-level activities

- Conduct state level advocacy workshop: 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 and Health workers,
- Develop and disseminate immunization guidelines (e.g. injection safety, cold chain, AEFI surveillance etc.),
- Plan advocacy and social mobilization activities,
- Modify and disseminate revised formats: reporting, recording and immunization card etc,
- Indenting and delivery: ensure availability of required vaccine and other logistics needed to introduce the vaccine,
- Utilize activities to introduce Hib vaccine as an opportunity to strengthen RI services and develop plans for supervision, monitoring and evaluation.

4.2. District and Sub-district levels activities

- ***Revise micro-plans:*** use prescribed formats for UIP at each level ,
- ***Estimate:*** Calculate vaccine and logistics

requirement at each level,

- ***Cold chain:*** evaluate the availability and adequacy at all levels,
- ***Indenting and delivery:*** ensure availability of required vaccine and other logistics needed to introduce the vaccine ,
- ***Disseminate revised formats:*** reporting, recording and immunization card etc,
- ***Advocacy and social mobilization*** activities around the introduction of the new vaccine,
- ***Trainings:*** health workers and staff at all levels,
- 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 vaccine are provided in the Universal Immunization Programme requiring 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)

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 lead time and re-ordering levels.

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.*

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. The existence of a 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.

4.4. Management of DPT and HepB stock balances

As previously mentioned pentavalent vaccine will be phased into UIP and eventually replace the need to give separate injections for DPT1+HepB1, DPT2+HepB2 and DPT3+HepB3. The phasing-in of pentavalent vaccine requires several considerations by district and sub-district officials in order to properly manage existing stock balances. First, children who have already received DPT1+HepB1 or DPT2+HepB2 should complete this regimen as per the previous recommended schedule. Second, 2 doses of DPT vaccine will still required in the programme for DPT boosters at 16-24 months and 5-6 years. Finally, Hepatitis B vaccine is still be required for birth dose.

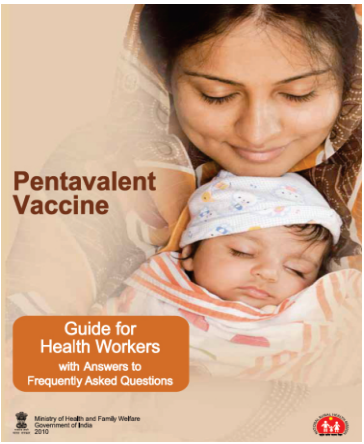
Precise local level planning is necessary to manage existing stock of DPT and HepB vaccine and minimize any vaccine wastage taking into account the considerations and the status the VVM and expiry date of the vaccine.

4.5. Estimate storage 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 vaccines (1 DPT and 1 HepB each) will be replaced by a single vial of pentavalent vaccine, leading to space saving. However, small quantity of DPT vaccine (booster doses) and Hepatitis B vaccine (birth dose) need to be stored.

4.6. Updating 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.



It is preferable to revise these formats to include pentavalent vaccine and distribute them before introduction. Alternatively, existing forms can be adapted locally. 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.

It is also suggested that at the time of revision of formals, attention should be paid to included a column for birth due of HepB vaccine also.

4.7. Update IEC material and FAQs

Revise and distribute informational 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.

4.8. Prepare and train staff

The successful introduction of pentavalent vaccine will largely depend 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 will 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.) will also be trained.

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 on pentavalent vaccine introduction.

Orientation of ASHAs and AWW during their monthly meetings at block level is important for successful implementation of the vaccination program.

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

Involvement/ and sensitization of pediatricians/ medical practitioners through IMA/ IAP should also be included in the training plan.

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 forums during which pentavalent vaccine introduction topics should be integrated and discussed.

Training materials include Immunization Handbook for Medical officers, and Health workers that includes FAQs on pentavalent vaccine and a separate set of published FAQs on pentavalent vaccine.

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 the training are:

- Types of Haemophilus influenzae bacterium
- Hib bacteria, transmission and disease,
- Importance of infant vaccination
- pentavalent vaccine and schedule
- Vaccine and logistics planning and management
- Vaccine administration
- Injection safety, and waste disposal
- Adverse Events Following immunization (AEFI) surveillance
- Recording and reporting
- Monitoring and supportive supervision
- Communicating with parents.

4.9. Launching of vaccination program

The launching of pentavalent vaccine provide States with an ideal opportunity to educate & inform the public and policy makers alike about Hib disease, its prevention and the positive health benefits to individuals and the community. A well publicized launching 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 will surely 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 utilize 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 the service (Hib/pentavalent vaccination) is available for all 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 like 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 and influencers such as religious leaders and teachers, and the media.

4.9.2. Social Mobilization

Social mobilization is similar to advocacy, but has different target audiences (caregivers) and is focused on getting children to the immunization session. 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 messages adapted to suit the audience are:

- Hib diseases and its consequences
- Modes of transmission of Hib diseases
- Importance of infant immunization
- The target group for immunization and an explanation of why older children are not being immunized with Hib/ 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 LP vaccine.
- Limitations of LP vaccine.

4.9.3. Supervision and monitoring of implementation:

Supervision in the planning phase is focused on checking the infrastructure, financial needs and 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. These supervision visits will be done by the officials and supervisory staff of both health dept. and ICDS.

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 the state should be developed locally, if local specific additional information is required and if the form is required in local language. The 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 RI monitoring strategy has two components:

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

(ii) **Household monitoring:** uses convenience sampling in the community surrounding RI session sites to assess the coverage of RI antigens of children <36 months old.

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 the 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, weeks after weeks; 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 variance 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 higher temperatures as well as by freezing. 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 program, adequate attention should paid to ensuring 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 abscesses, hospitalizations, deaths and any other severe or unusual medical event or event clusters. If an AEFI does occur, measures should be take to check the compliance with safety strategies from existing supervisor checklists and seek explanations for deviations from safety norms, such as recapping, non-use of hub-cutters and other incorrect practices.

4.10. Disease surveillance & Post Introduction Evaluation

Disease surveillance for bacterial meningitis and invasive bacterial disease will be strengthened in order to track the epidemiology of Hib disease and burden of disease. As per the recommendations of the NTAGI, a surveillance for Bacterial meningitis has been initiated in a few tertiary hospitals, in selected states jointly with the Immunization Division, Indian Council of Medical Research (ICMR), and development partners.

National or state governments are encouraged to plan and conduct post introduction evaluation of liquid pentavalent vaccine within 6-12 months of vaccine introduction. The aim of the assessments would be to determine the status of vaccine introduction, its impact on the health system, and to derive lessons for necessary corrective action.

5

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