



Ministry of Health
& Family Welfare
Government of India



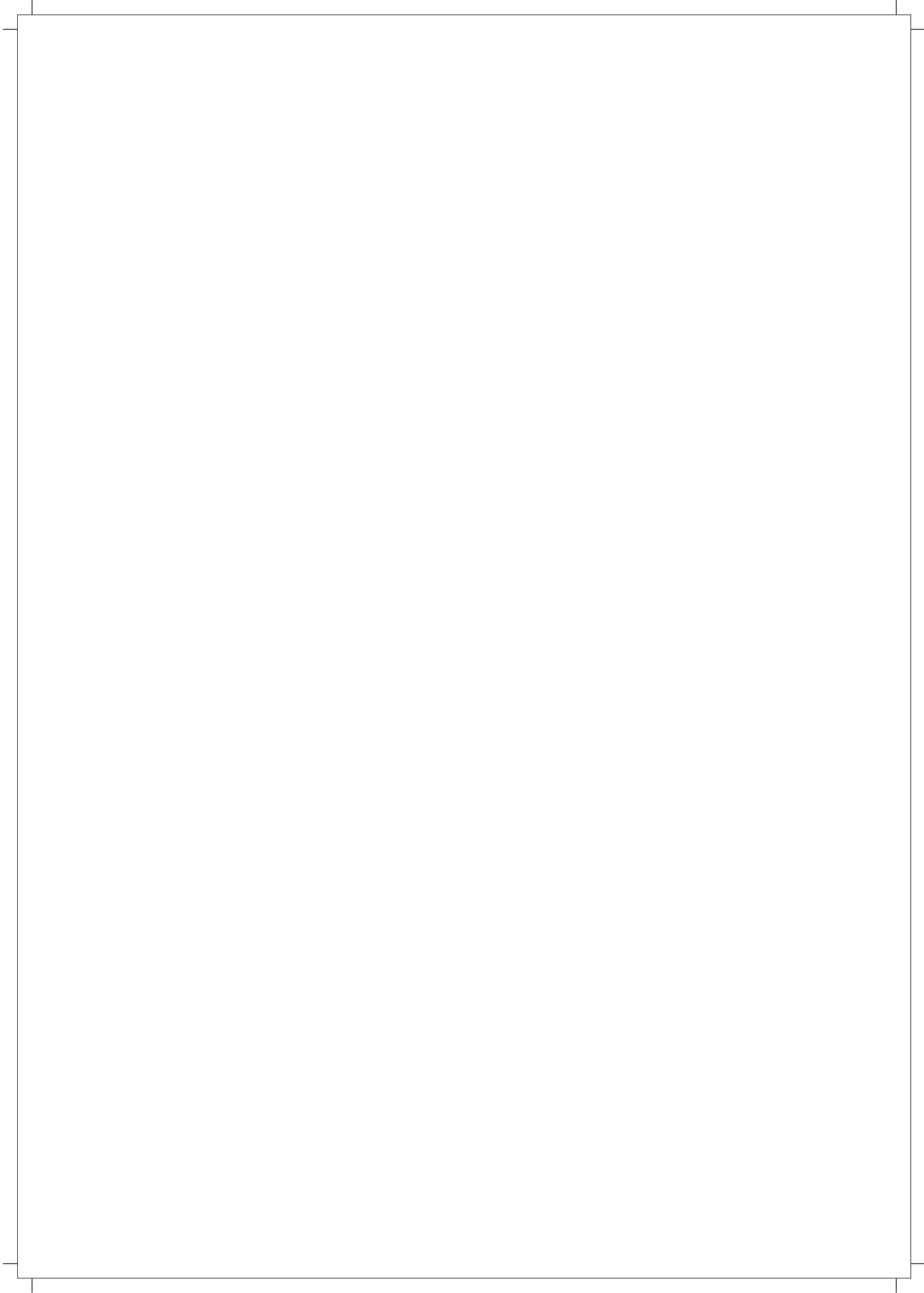
Operational Guidelines

Pentavalent Vaccine Introduction

(DPT+HepB+Hib)



भूलनजाना
टीकाकरण
ज़रूर करवाना!





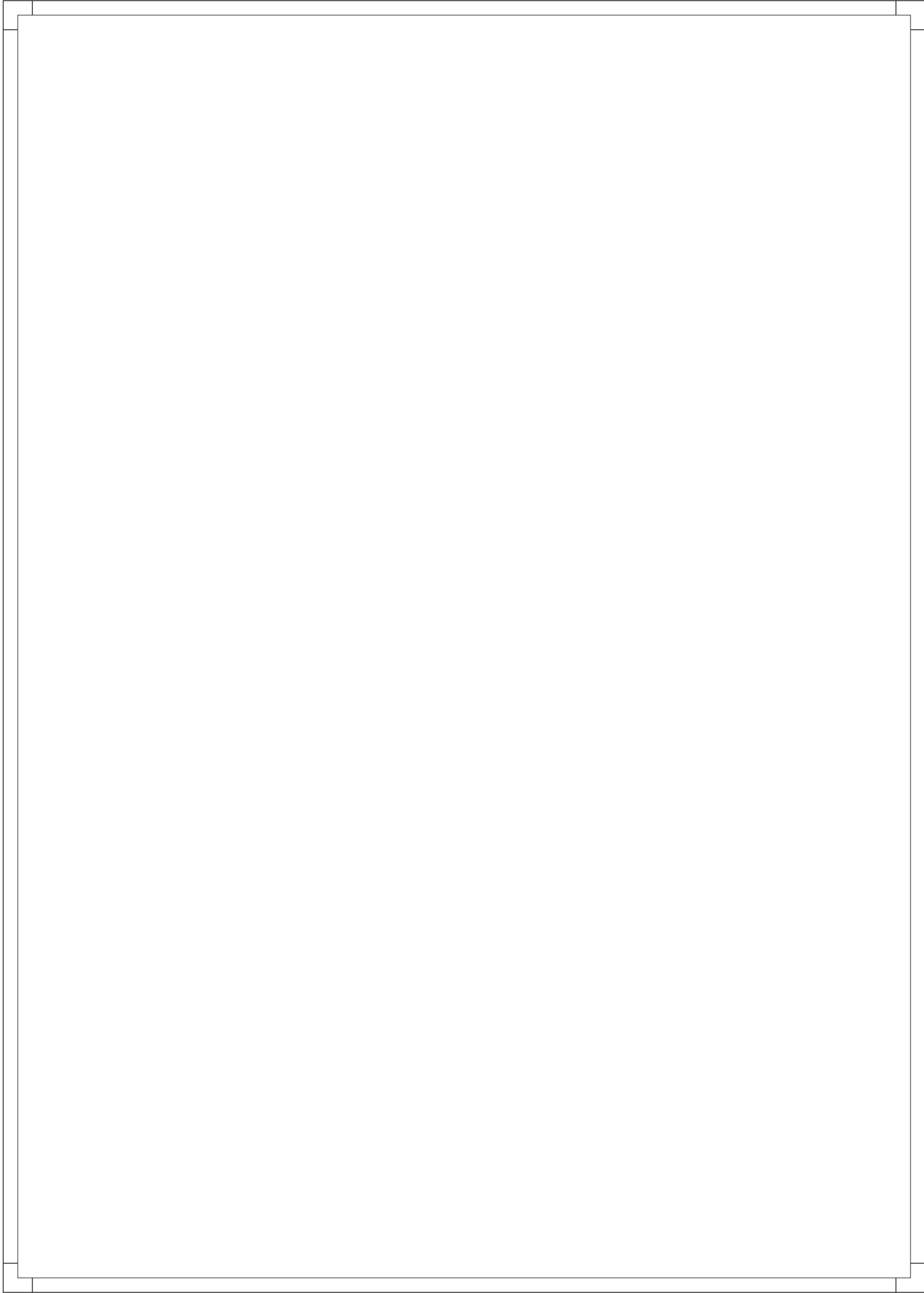
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Operational Guidelines Hib-containing Pentavalent Vaccine in the Universal Immunization Programme 2014



Operational guidelines developed by the WHO Country Office for India for Ministry of Health & Family Welfare, Government of India



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ACRONYMS

AD	auto-disable
AEFI	adverse event following immunization
ALRI	acute lower respiratory tract infection
ANM	auxiliary nurse midwife
ASHA	accredited social health activist
AVD	alternate vaccine delivery
AWW	anganwadi worker
BCG	<i>Bacillus Calmette-Guerin</i>
CCH	cold chain handler
CDPO	child development project officer
CHC	community health centre
CMO	chief medical officer
CSF	cerebrospinal fluid
DHS	District Health Society
DIO	district immunization officer
DPT	diphtheria–pertussis–tetanus
DTFI	district task force for immunization
FHW	female health worker
GAVI	Global Alliance for Vaccines and Immunization
Gol	Government of India
HMIS	health management information system
Hib	<i>Haemophilus influenzae</i> type b
IAP	Indian Academy of Pediatrics
IAPSM	Indian Association of Preventive and Social Medicine
ICDS	Integrated Child Development Scheme
IEC	information, education and communication
ILR	ice-lined refrigerator
IMA	Indian Medical Association

IPHA	Indian Public Health Association
JE	Japanese Encephalitis
LHV	lady health visitor
MCH	maternal and child health
MCP	mother–child protection (card)
MCTS	mother and child tracking system
MCV-2	measles-containing vaccine second dose
MD,NHM	Mission Director, National Health Mission
MO	medical officer
MoHFW	Ministry of Health and Family Welfare
MR	measles and rubella
NHM	National Health Mission
NTAGI	National Technical Advisory Group on Immunization
OPV	oral polio vaccine
OVP	open vial policy
PHC	primary health centre
PIE	post-introduction evaluation
RI	routine immunization
RMNCH+A	reproductive, maternal, newborn, child health and adolescent health
SHG	self help group
SHS	State Health Society
SIO	state immunization officer
STFI	state task force for immunization
TOT	training of trainers
TT	tetanus toxoid
UIP	Universal Immunization Programme
UNICEF	United Nations Children's Fund
U5MR	under-5 mortality rate
URI	upper respiratory infection
VPD	vaccine-preventable disease
VVM	vaccine vial monitor
WHO	World Health Organization



1. BACKGROUND

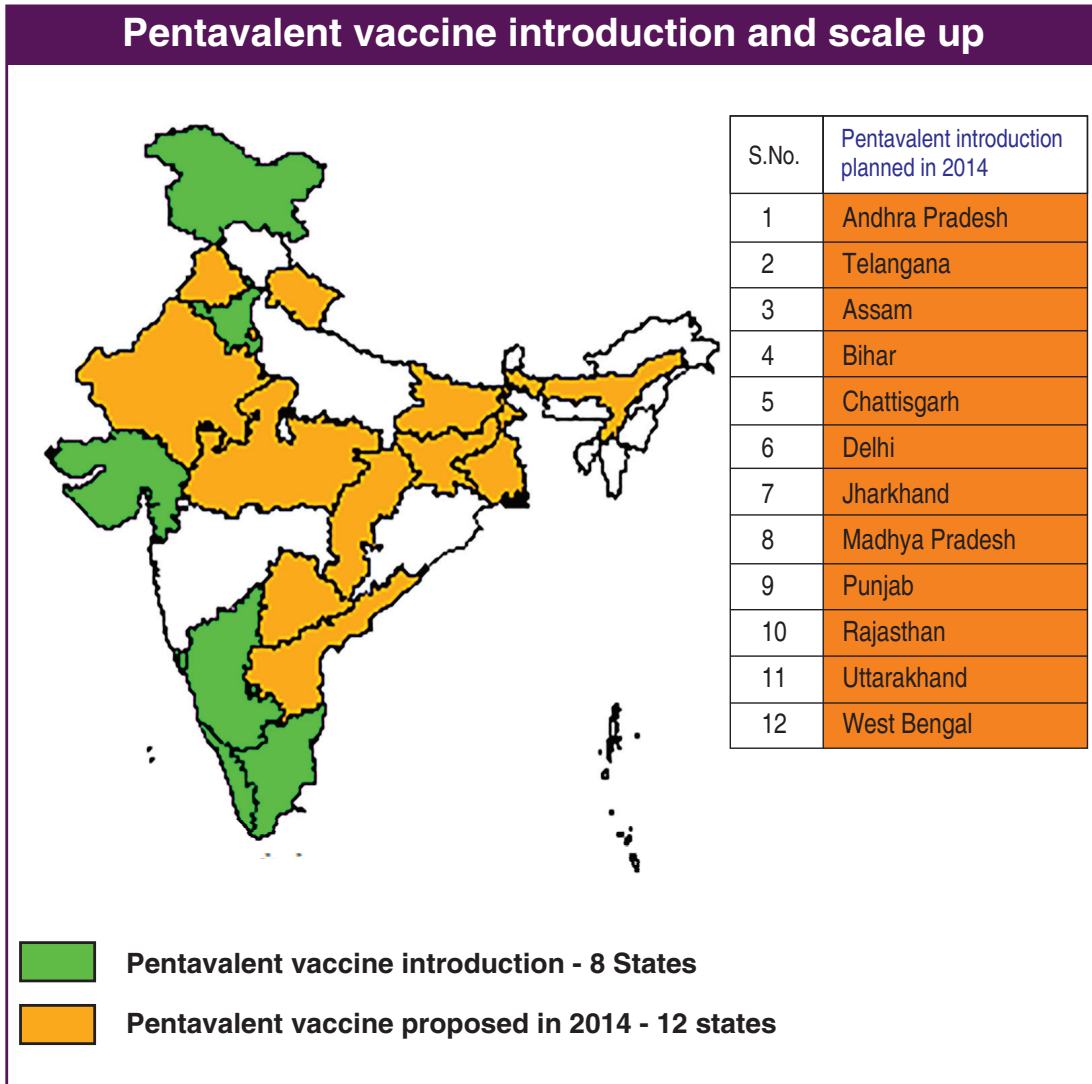
India has achieved truly impressive milestones through immunization and continues with its efforts to achieve comprehensive immunization coverage through the Universal Immunization Programme (UIP). Immunization is considered to be one of the most cost-effective public health interventions that has delivered excellent results in providing direct and effective protection against preventable childhood diseases such as measles, hepatitis B, diphtheria, poliomyelitis, tetanus and pertussis. Under the UIP programme, significant achievements have been made in preventing and controlling vaccine-preventable diseases.

India has attained another milestone with the introduction of *Haemophilus influenzae* type b (Hib) vaccine into the UIP as a pentavalent vaccine (containing diphtheria–pertussis–tetanus [DPT], hepatitis B and Hib antigens). The introduction of pentavalent vaccine will reduce the number of injections required for vaccinating children at 6, 10 and 14 weeks of age. At these age intervals, the infant currently receives six injections (three doses of DPT and three doses of hepatitis B); however, with the introduction of pentavalent vaccine, the infants will now receive only three injections instead of the six as mentioned earlier. This is expected to have a positive impact on acceptance in the community.

Pentavalent Vaccine in UIP
(5 antigens)
DPT + Hepatitis B + Hib
The force of five in one

Following the recommendations of the National Technical Advisory Group on Immunization (NTAGI), Hib-containing pentavalent vaccine was introduced in the states of Kerala and Tamil Nadu in December 2011. The vaccine was subsequently introduced in late 2012 and early 2013 in a phased manner in six other states and union territories – Goa, Gujarat, Haryana, Jammu and Kashmir, Karnataka and Puducherry. The states of Andhra Pradesh, Assam, Bihar, Chhattisgarh, Delhi, Jharkhand, Madhya Pradesh, Punjab, Telangana, Uttarakhand and West Bengal have planned to introduce the pentavalent vaccine in the latter part of 2014. The remaining states are scheduled to introduce this vaccine by mid-2015. Since DPT and hepatitis B vaccines are already an integral part of the UIP programme in the country, these guidelines focus on the introduction of Hib-containing pentavalent vaccine into the UIP.

Fig. 1. Pentavalent vaccine introduction in states with support from Gol



The introduction of any new vaccine into the immunization programme is an opportunity to strengthen health systems and improve the reach of immunization services to disadvantaged populations. World Health Organization (WHO) recommends that a post-introduction evaluation (PIE) of a new vaccine be conducted within 6–12 months to assess community acceptance and its impact on the existing immunization system. Although a PIE is done in the context of a new vaccine introduction, the exercise provides a broad overview of the immunization programme performance and thus boosts confidence to further scale up and introduce new and underutilized vaccines in the programme. The effect of pentavalent vaccine on the health system was assessed as part of the PIE conducted in Tamil Nadu and Kerala in 2012, while the recently conducted PIE in March 2014 included assessment of both pentavalent vaccine and MCV-2 in the six states and union territories.



This is an updated version of operational guidelines published in the year 2011. The findings and recommendations of the two previously conducted PIEs of pentavalent vaccine have been used to update these operational guidelines. The update has incorporated experiences, lessons learnt and best practices from the pentavalent vaccine introduction in the eight states where the vaccine has already been introduced (Annexure 1). These guidelines will be helpful in pentavalent vaccine introduction in the remaining states.



2. THE DISEASE

HAEMOPHILUS INFLUENZAE TYPE B (Hib)

In 2000, *Haemophilus influenzae* bacterium was estimated to cause approximately 8.1 million cases of serious Hib disease and an estimated 371 000 deaths globally (Watt et al., 2009). The most important manifestations of Hib infection—pneumonia, meningitis and other invasive diseases—occur primarily in children aged less than 2 years, particularly in infants. Vaccines are the only public-health tool capable of preventing a majority of cases of serious Hib disease. In view of their demonstrated safety and efficacy, WHO recommended in 2006 that Hib vaccines be included in all routine infant immunization programmes (WHO, 2006). The Hib vaccine has since been included in routine childhood vaccination programmes of nearly 180 countries across 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 this vaccine has been introduced.

In India, available data on Hib disease indicates that it is one of the leading causes of meningitis and pneumonia in children aged less than 5 years. Hospital-based studies in India show that Hib contributes 40–50% of all meningitis and 25–30% of all pneumonia cases. The case fatality rate for 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).

According to WHO estimates, 2.4–3.0 million cases of Hib disease occur annually in the country, with an estimated 72 000 deaths due to the disease (Watt et al., 2009; NTAGI sub-committee, 2009). As per UNICEF estimates on under-5 mortality figures in India for 2009 (UNICEF, 2010), 1 726 000 children died before reaching their fifth birthday. Going by these two estimates, Hib-associated deaths comprise 4% $[(72\,000/1\,726\,000)*100]$ of all under-five deaths in India.

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 introduction of Hib-containing pentavalent vaccine in the UIP will 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 disease would reduce U5MR by four percentage points.



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 Hib accounts for more than 90% of serious *Haemophilus influenzae* infections in children. *Haemophilus influenzae* bacteria live as commensals in the upper respiratory tract.

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 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-cares or crèches. Children are often asymptomatic carriers of the Hib bacteria, showing no signs or symptoms, but can still infect others.

2.3 Risk groups for Hib disease

Hib disease most commonly occurs in children aged less than 5 years (4–18 months age group is at the highest risk [WHO, 2006]). It is important to immunize children and prevent disease very early in life. At birth, maternal antibodies protect most infants. At 2 to 3 months of age, the level of maternal antibodies decreases and the risk of Hib disease increases for the child. By the age of 5 years, most children would already have developed immunity against Hib. For this reason, Hib disease is considered rare after the age of 5 years.

2.4 Signs and symptoms of Hib

Hib disease should be suspected in the case of any child with signs and symptoms of the following:

2.4.1 Bacterial meningitis

Bacterial meningitis is the inflammation of 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, 40% of Hib meningitis cases result in death. Further, 15–35% 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).

Remember

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



2.4.2 Pneumonia (inflammation of the lungs)

In developing countries, Hib is a major cause of pneumonia or acute lower respiratory tract infection (ALRI) in children, accounting for 20% of severe bacterial pneumonia cases.

2.4.3 Other Hib diseases include

- septicaemia: infection of the bloodstream,
- septic arthritis: infection in the joints,
- osteomyelitis: infection of the bones, and
- epiglottitis: infection of the larynx and pharynx.

In the absence of appropriate and immediate treatment, up to 50% of such cases are fatal.

2.5 Diagnosis of Hib disease

Diagnosis of Hib disease can be made by bacterial culture, latex agglutination test or by polymerase chain reaction. In actuality, it is difficult to identify Hib in poor resource settings. The bacterial culture of sterile fluids such as cerebrospinal fluid (CSF) or blood is needed. Lumbar puncture, which is an invasive procedure, should be done for CSF. To culture Hib bacteria, 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).

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 is a cost-effective strategy for the prevention of Hib disease.

Frequently asked questions – *Haemophilus influenzae* type b

1. *What is Hib? What diseases does it cause?*

Hib is the abbreviation for *Haemophilus influenzae* type b, a bacterium that causes severe diseases, as listed below:

- Bacterial meningitis – inflammation of the membranes that cover and protect the spinal cord and brain. It is a serious infection
- Pneumonia – inflammation of the lungs
- Septicaemia – presence of pathogenic bacteria in the blood
- Septic arthritis – inflammation of the joints
- osteomyelitis: infection of the bones, and
- Epiglottitis – inflammation of the area around the vocal cords and obstruction of the airway.

Hib disease is not the same as hepatitis B, which is a viral disease that affects the liver.

2. *Why is Hib disease a public health problem?*

Hib disease is a public health problem because it causes serious infections that can result in hospitalization or death from diseases such as pneumonia (one of the major causes of death in children) and meningitis.



3. How does the Hib infection spread?

Hib bacteria are passed from child to child through droplets of saliva expelled when an infected child coughs or sneezes. Hib also spreads among children when they share toys and other things that they have put in their mouths.

4. Who can get Hib infections? Who is most at risk?

Hib mostly affects children under five years of age; children between four months and 18 months of age are most at risk. By the age of five years, most children have developed antibodies against the disease; hence serious diseases from Hib are uncommon in older children and adults.

5. Do antibiotics work against Hib infections?

Antibiotics are used for treatment of Hib disease, but they are not always effective. Even with antibiotics and the best medical care, 3–5% of meningitis patients die. Some strains of Hib are now resistant to antibiotics, making treatment even more difficult.

6. How can Hib infections be prevented?

Most Hib infections can only be prevented by the Hib containing pentavalent vaccine. A small proportion of cases can be averted by giving antibiotics to members of households where children have been infected, but at best this amounts to only 1–2% of all cases.

7. What are the limitations of Hib vaccine?

Hib vaccine protects only against diseases caused by the Hib bacterium. After Hib immunization, a child may still get pneumonia, meningitis or flu caused by other bacteria and viruses.

8. Who should be immunized with Hib vaccine?

Generally, all children aged up to 1 year (after 6 weeks and less than 1 year of age) should receive Hib vaccine as part of RI.

9. Why is Hib given as a pentavalent vaccine and not separately?

The schedule for DPT, hepatitis B and Hib is the same at 6, 10 and 14 weeks. Therefore, if these three vaccines are given separately, a child gets three injections at the same time. Giving a pentavalent vaccine will reduce the number of injections.



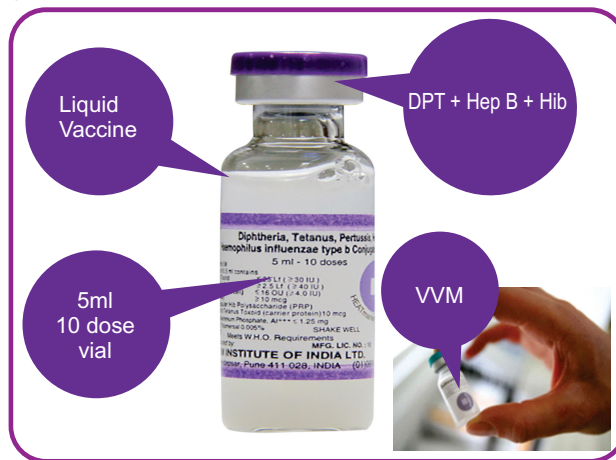
3. Hib-CONTAINING PENTAVALENT VACCINE

Hib vaccines (either alone or in combination) only provide protection against Haemophilus influenzae type b. It is important to note that the above-mentioned illnesses may also be caused by other etiological agents. Hence, administration of Hib-containing vaccines will only prevent infections due to Hib but not due to other etiological agents.

3.1 Formulation

Hib vaccines are available in different formulations of liquid or lyophilized (dried powder), stand-alone (monovalent) and as a combination (DPT + Hib, or DPT + hepatitis B + Hib). Hib vaccines (in various formulations) are being licensed in India since almost a decade and are widely used in the private sector.

Hib-containing pentavalent vaccine is provided in the UIP as a liquid pentavalent vaccine. Hence, it does not require any reconstitution of vaccine. The pentavalent vaccine contains five antigens (DPT + hepatitis B + Hib) in a single formulation.



3.2 Presentation

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

3.3 Storage volume

The storage volume of Hib-containing pentavalent vaccine in 10-dose vials is approximately the same as currently used DPT or hepatitis B vaccine in a similar presentation. Hence, less cold chain space would be required while introducing the pentavalent vaccine.

3.4 Storage temperature

The Hib-containing pentavalent vaccine is freeze sensitive and hence, it should be stored at temperatures ranging between +2°C and +8°C, in the basket of an ice-lined refrigerator (ILR). It is important to use conditioned ice packs to prevent freezing during transportation.

3.5 Age group for vaccination

The Hib-containing pentavalent vaccine in India is recommended for infants from 6 weeks (1½ months) to less than 1 year of age.

Remember

- Pentavalent vaccine is freeze sensitive and should never be stored at the base of an ice-lined refrigerator (ILR).
- It should be placed in the basket just below the hepatitis B vaccine and preferably above/with DPT vaccine.

3.6 Vaccination schedule

A primary series of three doses have been included as part of the RI schedule. The first dose is given to children at 6 weeks (1 ½ months) or more in age. Table 1 describes the current immunization schedule (i.e. prior to pentavalent introduction) and immunization schedule post Hib-containing pentavalent introduction.

Table 1. Immunization schedule—current and post-pentavalent introduction

Age	Current immunization schedule (Prior to pentavalent introduction)	Immunization schedule (post pentavalent introduction)	Remarks
At birth	Hepatitis B (birth dose)	BCG, OPV (0 dose), hepatitis B (birth dose)	(1) BCG vaccine can be given up to 1 year of age (2) DPT vaccine can be given up to 5–6 years (not beyond 7 years) of age (3) Measles vaccine can be given up to 5 years of age (4) JE vaccine can be given up to 15 years of age.
6 weeks (1 ½ months)	OPV-1, DPT-1, hepatitis B-1	OPV-1, pentavalent-1	
10 weeks (2 ½ months)	OPV-2, DPT-2, hepatitis B-2	OPV-2, pentavalent -2	
14 weeks (3 ½ months)	OPV-3, DPT-3, hepatitis B-3	OPV-3, pentavalent -3	
9 months	Measles first dose, JE-1 (where applicable)	Measles first dose, JE-1 (where applicable)	
16–24 months	DPT-booster first dose, measles second dose, OPV booster dose, JE second dose (where applicable)	DPT-booster first dose, measles second dose, OPV booster dose, JE second dose (where applicable)	
5–6 years	DPT-booster second dose	DPT-booster second dose	
10 years	TT first booster dose	TT first booster dose	
16 years	TT second booster dose	TT second booster dose	

BCG: *Bacillus Calmette-Guerin*; DPT: diphtheria-pertussis-tetanus; Hib: *Haemophilus influenzae* type b; JE: Japanese Encephalitis; OPV: oral polio vaccine; TT: tetanus toxoid



3.7 Phasing in of pentavalent vaccine in UIP

During the initial months of pentavalent vaccine introduction, only those children who are coming for the first dose of DPT and hepatitis B will be administered pentavalent vaccine. Infants who have already received either their first or second doses of DPT and hepatitis B (i.e. DPT 1/hepatitis B1 or DPT 2/hepatitis B2) will complete the schedule with DPT and hepatitis B only. This is called 'phasing-in' of pentavalent vaccine in UIP.

3.8 Dosage and route

The dose of pentavalent vaccine is 0.5 ml. The route of administration is the same as DPT vaccine, i.e. by intramuscular injection in the antero-lateral aspect of mid-thigh.

3.9 Interchangeability of the vaccine manufacturers

In the UIP, pentavalent vaccine from different manufacturers can be used to complete the immunization schedule of an infant.

3.10 Adverse events following immunization

Hib-containing pentavalent vaccine has not been associated with any serious adverse effects. However, redness, swelling and pain at the site of injection may occur in 25% of vaccinated children. Less commonly, children may develop fever or become irritable for a short period. Additionally, introduction of pentavalent vaccine (or any other new vaccine) may coincide with an increased reporting of adverse events following immunization

(AEFIs) in the states and districts. Such AEFI cases, including those following administration of pentavalent vaccine, if any, should be reported as per the Government of India's (GoI) revised "AEFI Surveillance and Response Operational Guidelines".

Remember

- Even after the introduction of pentavalent vaccine, DPT and hepatitis B will continue to be in the national immunization schedule.
- Birth dose of hepatitis B will continue to be administered in institutional delivery cases and must be provided within 24 hours of birth.
- Children will continue to receive DPT boosters at the age of 16–24 months and 5–6 years (not beyond 7 years) of age.
- In case where child has not received any dose of pentavalent vaccine before his/her first birthday then the child must be given DPT vaccine doses as per guidelines.



3.11 Contraindications

There are two major contraindications for the administration of pentavalent vaccine:

3.11.1 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.

3.11.2 Children with moderate or severe acute illness.

Such children should not be administered pentavalent vaccine until their condition improves. Minor illnesses, such as upper respiratory tract infections are not a contraindication to vaccination.

Remember

- As per AEFI guidelines, the child should be observed for at least 30 minutes after the vaccination
- The auxiliary nurse midwife (ANM) /vaccinator must ensure that the reasons for any dose missed are entered in the immunization counterfoil (MCP Card) and followed up subsequently. Reasons due to AEFIs, if any, must be addressed and reported on priority basis (refer to Figure 5: Revised immunization component in MCP card)

3.12 Immunogenicity, efficacy and effectiveness

All Hib-containing vaccines including pentavalent vaccines are safe and efficacious. They provide 85–95% 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.

3.13 Long-term protection and booster dose

In general, the Hib vaccine provides protection for at least 15 years. Current scientific evidence suggests that the vaccine provides lifelong protection. In cases 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.

3.14 Open vial policy

The Govt has adopted the open vial policy for pentavalent vaccine in UIP. The policy guideline was issued in October 2011. In February 2013, the Ministry of Health and

Remember

Open Vial Policy not applicable to





Family Welfare (MoHFW) issued revised guidelines for the open vial policy for vaccines under the UIP. The current open vial policy is applicable to only multi-dose vials—DPT, tetanus toxoid, pentavalent vaccine, hepatitis B and oral polio vaccine (OPV).

The guideline, when followed correctly, ensures effective utilization of vaccines and minimizes wastage. This policy is being followed in the eight states where Hib-containing pentavalent vaccine has been introduced into the UIP. The open vial policy will be applicable to all states introducing Hib-containing pentavalent vaccine. The post-introduction evaluation (PIE) of pentavalent vaccine in the eight states that have introduced this vaccine shows that the open vial policy for multi-dose vials has had a positive impact on the overall vaccine wastage. The states need to have a robust alternate vaccine delivery mechanism to ensure effective implementation of the open vial policy.

3.15 Open vial policy guidelines

Vaccines opened in a fixed or outreach session can be used at more than one immunization session for up to four weeks provided:

- the expiry date has not been reached;
- the vaccine vial monitor (VVM) has not reached the discard point;
- vaccines are stored in appropriate cold chain conditions, both during transportation and in the cold chain storage point;
- vaccine septum has not been submerged in water or contaminated in any way; and
- no case of AEFI has been reported.



4. PROGRAMME-LEVEL ACTIONS AND DECISIONS TO BE TAKEN

4.1 Estimating vaccine and syringes needed

The auto-disabled (AD) syringes (0.5 ml) available under the UIP are to be used to administer pentavalent vaccine as well.

Currently, DPT and hepatitis B vaccines provided under the UIP require two separate injections. With the inclusion of pentavalent vaccine, a single injection will deliver five antigens (DPT + hepatitis B + Hib), thus reducing the requirement of AD syringes.

Remember

Hepatitis B and DPT vaccines will continue to be given in the UIP programme as hepatitis B birth dose and DPT booster doses. Do not forget these doses while calculating the auto disabled (AD) syringe requirements.

Every beneficiary will require three doses of pentavalent vaccine. Considering the standard vaccine wastage rate of 15% 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 wastage multiplication factor (1.18) X 1.25

Primary health centers (PHCs) and districts need to forecast their vaccine needs for the stipulated time period to ensure that the right amount of vaccines, logistics 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 stock of vaccine and syringes in order to assess the lead time and re-ordering levels.

Requirement for AD syringes related to introduction of pentavalent vaccine

- Less requirement of AD syringes (0.5 ml) at state, district and sub-district levels with the introduction of 3 injections of pentavalent vaccine (which will replace 6 injections of DPT and hepatitis B)
- Each AD syringe is packed separately, hence, maximum permissible wastage rate for AD syringes is 10% (Wastage multiplication factor is 1.11).

4.2 Wastage rate and buffer stock

The open vial policy is recommended for pentavalent vaccine to significantly reduce vaccine wastage. The buffer stock is meant for managing sudden and unexpected shortages. The amount of buffer stock recommended is generally 25% of the annual requirement. Buffer stock is supplied only in the first year of vaccine introduction.

Remember

A maximum of 15 % wastage is acceptable for Pentavalent and all other vaccines that are eligible for reuse as per open vial policy guidelines.

The maximum acceptable wastage for vaccines eligible for reuse under the open vial policy (such as pentavalent vaccine, OPV, hepatitis B, DPT, TT vaccine) is 15%. The wastage multiplication factor for calculations is 1.18.

For other vaccines such as measles and JE, the maximum acceptable wastage is 25% and the wastage multiplication factor is 1.33. For BCG, the maximum acceptable wastage is 50% and the wastage multiplication factor is 2.0.

4.3 Managing DPT and hepatitis B 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. The vaccine will be administered to only those infants who will come for their first doses of DPT and hepatitis B. The phasing in of pentavalent vaccine requires several considerations by district and sub-district officials in order to properly manage the existing stock balances:

- Children who have already received DPT1 + hepatitis B1 or DPT2 + hepatitis B2 should complete vaccination as per the earlier recommended schedule.
- Two booster doses of DPT vaccine will still be required in the programme at 16–24 months and 5–6 years (not beyond 7 years) of age.
- Hepatitis B vaccine stock will be required for administration of birth dose at those facilities where deliveries are conducted.

Precise local level planning is necessary to manage existing stocks of DPT and hepatitis B vaccines and minimize vaccine wastage, taking into account vaccines' VVM status and expiry date. After introduction of pentavalent vaccine, DPT vaccine dose for every child would be reduced from five doses (three in the first year of life and two booster doses) to two doses only (for booster doses). Similarly, only one hepatitis B dose at birth would be required for each infant, reducing the requirement from the previous four doses per child. Stocks of hepatitis B vaccine need to be shifted from health facilities which are 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 hepatitis B vaccines immediately after pentavalent vaccine introduction. Medical officers in charge should ensure that the guidelines are followed by vaccine and cold chain handlers.



4.4 Estimating cold chain storage needs and managing the cold chain

There will not be any additional cold chain space requirement for pentavalent vaccine since two vials of vaccines (one DPT and one hepatitis B) will be replaced by a single vial of Hib containing pentavalent vaccine. However, a small quantity of DPT vaccine (for booster doses) and hepatitis B vaccine (for birth dose) will still need to be stored.

4.5 Updating recording and reporting formats

All recording and reporting formats should be revised to include pentavalent vaccine and be distributed before introduction. Forms that will need revision include: vaccine stock forms, immunization cards, due lists, tally sheets, monthly progress reports at all levels, maternal and child health (MCH)/immunization register, coverage monitoring charts, supervisory checklists, computer databases, immunization coverage surveys and evaluation formats.

The reporting of pentavalent vaccination will be done through existing reporting mechanisms such as the health management information system (HMIS) and the mother and child tracking system (MCTS). The HMIS and MCTS portals have been updated to include pentavalent vaccine. Figures 2 and 3 reflect the uploaded pentavalent vaccine coverage in the HMIS and the MCTS.

Fig. 2. Reporting pentavalent vaccine coverage in the HMIS

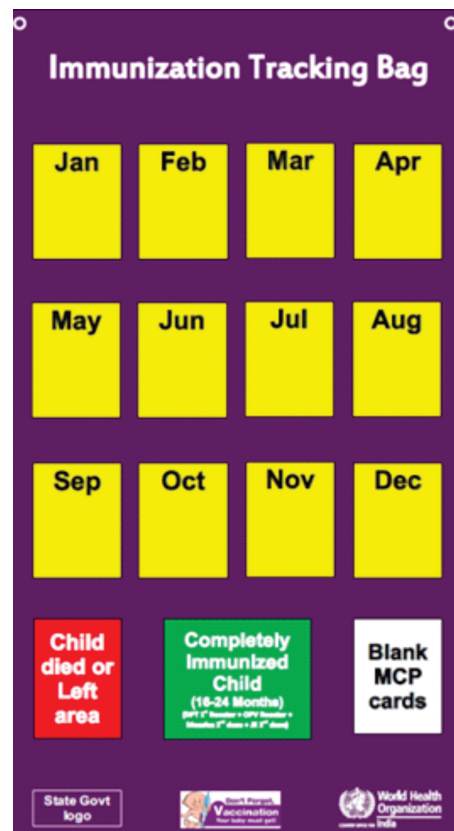
M6	CHILD IMMUNIZATION	M10
22	Number of Infants 0 to 11 months old who received the following	10.1
22.1	BCG	10.1.01
22.2	DPT1	10.1.02
22.3	DPT2	10.1.03
22.4	DPT3	10.1.04
22.4A	Pentavalent 1	10.1.04A
22.4B	Pentavalent 2	10.1.04B
22.4C	Pentavalent 3	10.1.04C
22.5	OPV 0 (Birth Dose)	10.1.05
22.6	OPV 1	10.1.06
22.7	OPV 2	10.1.07
22.8	OPV 3	10.1.08

Fig. 3. Reporting pentavalent vaccine coverage in the MCTS

4.6 Communication, reporting and tracking

It is important to revise and distribute information, education and communication (IEC) materials for creating awareness among the community and caregivers before the vaccine is introduced in the programme. Materials that must be revised include posted immunization schedules (tin plates, posters, wall paintings and billboards), immunization cards and counterfoils and training material for health workers. The prototypes of IEC material are available from the GoI and have been shared with the states. The states can adapt these IEC materials as per their requirements.

Figure 4 shows a prototype of a tracking bag used to keep track of immunizations using immunization counterfoils (MCP Card). Figure 5 reflects prototypes of immunization component that need to be replaced in mother-child protection (MCP) cards. All MCP cards should have a counterfoil as per the prototype and should be used to track beneficiaries using the tracking bag.



4.7 Prepare and train health-care staff

The successful introduction of pentavalent vaccine will largely depend upon the training conducted for all levels of health functionaries. Health-care providers are not only responsible for handling and administering the vaccine but are also a major source of information for parents and the community.

Health-care personnel who require training include district immunization officers (DIOs), medical officers (MOs), cold chain handlers, supervisors, data managers and frontline health workers. The officials and staff of the Department of Women and Child Development such as child development project officers (CDPOs), integrated child development services (ICDS) workers and *anganwadi* workers also need to be trained. In addition, plans should be drawn up to train the faculty of paediatrics and preventive and social medicine departments in medical colleges as well as private practitioners involved in immunization service delivery.

4.8 Training approach

As mentioned earlier, training activities should commence at the state level. Each state where pentavalent vaccine is to be introduced is expected to conduct five training workshops (of one day duration each). This includes the pentavalent advocacy and launch workshop.

It is important to ensure sensitization of pediatricians/medical practitioners through involvement of Indian Medical Association (IMA), the Indian Academy of Pediatrics (IAP) and the Indian Public Health Association (IPHA).



Every opportunity should be utilized for sensitization to the new vaccine introduction (pentavalent vaccine). State/district task force meetings and medical officers' training sessions are ideal fora for discussing pentavalent vaccine introduction. The state, district and sub-district programme managers should remember that training should be held strictly as per the timelines recommended in this guideline.

Training materials should include standardized PowerPoint presentations from these operational guidelines and immunization handbooks for MOs and health workers. The materials include FAQs on Hib-containing pentavalent vaccine. These materials should be translated into the local language and used appropriately.

Remember

Pentavalent introduction sensitization training should be conducted as recommended. Ensure that these are not clubbed/tagged with other ongoing training or review meetings. However, it is encouraged to share key messages at appropriate platforms.

4.9 Launch of vaccination programme

The launch of pentavalent vaccine provides states with an 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 should be planned for pentavalent vaccine introduction to improve general awareness about UIP and specific knowledge related to pentavalent vaccine. A successful launch of pentavalent vaccine will include mass media components as well as capacity building of health workers in interpersonal communication to respond to queries posed by the community. Other related government departments, local media and NGOs should also be briefed and brought on board, so that they may also spread the message and motivate the community to benefit from immunization. The state and district task forces on immunization should steer the planning, coordination, implementation and monitoring of the programme.

Operational guidelines, tools and appropriate communication materials should 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.



General guidelines for more effective dissemination are as follows:

4.9.1 Advocacy

Advocacy is the process of 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 the IMA, IAP, IPHA, Indian Association of Preventive and Social Medicine (IAPSM); community leaders including *panchayati* raj institution members; influencers such as religious leaders, teachers, self-help groups (SHGs) and the media.

Remember

Sensitize ANM/ASHA/AWW regarding revised immunization portion in MCP card including counterfoil

Emphasize the role of ASHA/AWW in tracking beneficiaries by using counterfoil, tracking bag and due list.

4.9.2 Social mobilization

Social mobilization is one of the most important activities in the immunization programme. High quality social mobilization efforts lead to better community awareness and acceptance of the new vaccine. A range of communication media should be used to deliver messages to front line workers such as auxiliary nurse midwives (ANMs), anganwadi workers (AWWs), accredited social health activists (ASHAs) and community volunteers. Health workers, if properly trained and informed, can motivate and generate community interest in the UIP and the new vaccine. They are the main source of information for the general public. It is therefore critical to ensure that all ASHAs, AWWs and link workers are trained on key aspects of pentavalent vaccine, including the four key messages during their half-day training workshop.

Four key messages for caregivers

- What vaccine was given and what diseases it prevents
- When and where to come for the next visit
- What minor adverse events could occur and how to deal with them
- Keep the immunization card safe and bring it along at the next visit.





5. STEPS FOR THE INCLUSION OF PENTAVALENT VACCINE IN THE UIP IN INDIA

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

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

5.1 Assessment of preparedness

The Ministry of Health and Family Welfare (MoHFW), GoI has developed and disseminated state- and district-level checklists with the support of partners. These checklists have been developed to support the state and district programme managers in assessing critical information on 14 key immunization components as given in Table 2. These checklists will help in assessing and identifying strengths and weaknesses at state, district and block levels to take corrective actions for effective and successful introduction of Hib-containing pentavalent vaccine in the UIP in respective states.

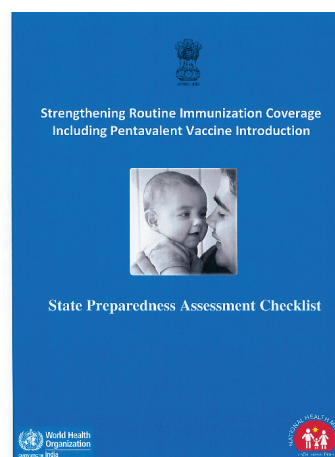
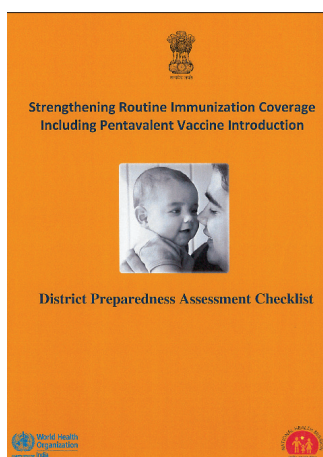


Table 2. Checklist components

1. Human resource vitals	2. Background information	3. Microplanning status	4. Training status
5. Reporting and recording practices	6. Vaccine coverage and wastage	7. Vaccine management, transport and logistics	8. Waste management and injection safety
9. Monitoring and evaluation	10. AEFI	11. Mobilization	12. Advocacy and communication
13. Surveillance	14. Cold chain maintenance	15. General impressions	16. Additional remarks/ comments

5.2 State-level pentavalent vaccine introduction activities

The following activities should be undertaken at the state level for the successful introduction of Hib-containing pentavalent vaccine into the UIP:

5.2.1 State task force for immunization (STFI)

- STFI should be convened periodically to steer all activities for introduction of pentavalent vaccine in the state, including commitment and support from various departments and stakeholders. Issues identified in activities for smooth introduction of the vaccine should be addressed during meetings of the STFI and the State Health Society (SHS).
- States should make best use of lessons learnt from the polio programme to strengthen RI. Use the opportunity that introduction of this new vaccine provides to highlight issues that need attention for corrective action.
- WHO-India's National Polio Surveillance Project (NPSP), UNICEF and other key RI partners involved in immunization at state and district levels are expected to proactively support the authorities in providing quality information/monitoring data at STFI and district task force for immunization (DTFI) levels for appropriate actions.

5.2.2 Assess district preparedness

The state needs to assess the preparedness of districts using standardized checklists. The qualitative and quantitative data should be reviewed, compiled and reflected in the state preparedness checklist. State preparedness assessment checklist should be completed as per timelines and forwarded for review at the national level to the Deputy Commissioner, Immunization Division, Nirman Bhawan, New Delhi.

5.2.3 Track high priority districts

Assign high priority districts identified under reproductive, maternal, newborn, child health and adolescent health strategy (RMNCH+A) and polio emergency preparedness and response plans to state-level health officials. They should visit these districts and provide oversight to activities for introduction of pentavalent vaccine, including participation in DTFI and assessment of district preparedness using checklists.



5.2.4 Strengthening RI micro plans

- All high-risk areas identified in polio microplans should be incorporated into the RI microplans. Ensure all vulnerable sections are provided an equal opportunity to avail services.
- Monitor completeness of all components of microplanning.

5.2.5 Indenting and delivery of vaccine and logistics

Ensure availability of required doses of pentavalent vaccine and other logistics. Ensure that the plans for phasing in and repositioning of hepatitis B vaccine are in place. DPT vaccine stocks would also need attention.

5.2.6 State-level training workshops for training the health workforce

- This is a critical activity and needs timely planning and implementation. Conducting these training of trainers (TOT) workshops will create a pool of master trainers who will in turn ensure that the officials concerned at all levels are sensitized well in time prior to introduction. The state immunization officer will be responsible for planning and conducting state-level training workshops as per timelines. Key development partners such as WHO, UNICEF and others should proactively support the states and districts in planning, sensitization of health officials and monitoring the quality of training.
- Five training workshops should be conducted at the state level. This includes the pentavalent vaccine advocacy and launch workshop. Details are given in Table 3.

Table 3. State-level training workshops/TOTs

S.No.	Trainees	Trainers	Duration	Timeline
1.	Mos: DIO and 2 MOs per district (3 persons per district). Also include SMOs of WHO NPSP, UNICEF district coordinators, and others such as State Programme Manager (NRHM), State IEC Consultant, State ASHA Coordinator, State Cold Chain Officer, State Data Manager, State M and E Coordinator (NRHM), State Finance and Accounts manager (NRHM)	SIO with support from State CCO, HMIS and MCTS coordinators, IEC consultant and partners – WHO NPSP, UNICEF, others	One day for each workshop	Within 3 weeks after completion of national level workshop
2.	Data handlers: District level HMIS and MCTS coordinators, district computer assistant to DIOs, District M and E focal person (NRHM), focal person responsible for immunization reports in CMO office (districts to identify and nominate least 3 persons per district)	State Immunization Officer (SIO), State HMIS and MCTS coordinator, State M and E focal person/coordinator, representatives from partner organizations such as WHO, UNICEF and others		

2.



S.No.	Trainees	Trainers	Duration	Timeline
3.	Vaccine and cold chain handlers: District refrigerator mechanic, vaccine storekeeper in charge of immunization programme at district level (at least 2 persons per district)	State Immunization officer (SIO), State cold chain officer (CCO), representatives from partner organizations such as WHO,	One day for each workshop	After the national level workshop (at least 2 weeks prior to the launch)
4.	IEC/media handling focal persons: Districts to identify and nominate at least 2 persons dealing with media and IEC for sensitization at state level	SIO with support from WHO, UNICEF and other partners, State IEC consultant, media officer, partners		
5.	Pentavalent vaccine advocacy and launch: Workshop for key state/ district officials, development partners including media (print/ electronic)	SIO with support from WHO, UNICEF and other partners, State IEC Consultant, media officer, partners. PS to chair and MD NRHM to co-chair. Directors and all CMOs should be present		

Notes: 1. Refer to Annexures 2, 3 and 4 for agenda and tips for trainers for Serial Nos 1, 2 and 3, respectively. 2. Submit district-wise fortnightly progress on training status to the GoI on the first and fifteenth of each month

5.2.7 Dissemination of guidelines/revised formats/IEC materials

- Disseminate relevant guidelines and training material during training to each category of staff for introduction of pentavalent vaccine
- Ensure printing of IEC materials (as per prototypes) in local languages in adequate numbers
- Ensure that all the updated reporting and recording tools including immunization component in MCP card, registers, due lists, etc. are printed and disseminated in time. Appropriate translation in local languages should be undertaken if required. Ensure use of this updated material in the sensitization workshops at all levels.

5.2.8 Tracking beneficiaries (left outs and drop outs)

- Undertake headcount for estimation of beneficiaries by ANMs/ASHAs/AWWs for improved micro planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure it is a time-bound activity and gets completed in 1–2 weeks
- State health authorities and partners should intensively monitor this activity and share findings at all relevant platforms



- Implementation of immunization tracking bag (one per session site). ASHA or AWW of that area to be made responsible for this. ANM to provide oversight and cross check counterfoils to ascertain reasons for drop outs.

5.2.9 Intensifying monitoring and supervision

- Intensify supervision and monitoring of programme at district, block, session and house-to-house levels through government functionaries and partners. Use standardized RI monitoring formats provided by MoHFW.

5.3 District-level pentavalent vaccine introduction activities

The following activities should be undertaken at the district level for successful introduction of Hib-containing pentavalent vaccine into UIP:

5.3.1 District task force for immunization (DTFI)

- DTFI should be convened periodically to steer all activities for introduction of pentavalent vaccine in the district, including obtaining commitment and support for introduction of this vaccine from various departments and stakeholders. Issues identified in activities essential for smooth introduction of pentavalent vaccine in the district should be addressed during meetings of the DTFI and the District Health Society (DHS).
- Districts should make best use of lessons learnt from the polio programme to strengthen RI. Make best use of the opportunity that introduction of this new vaccine provides to highlight issues that need attention for corrective action.
- WHO, UNICEF and other key RI partners at district level are expected to proactively extend support in providing quality information/monitoring data to DTFI for guiding and taking appropriate actions.

5.3.2 Assess district preparedness

The district needs to assess the preparedness of the blocks using standardized checklists. The qualitative and quantitative block/planning unit data should be compiled and reflected in the district preparedness checklist. The district preparedness checklist with necessary annexures should be completed and submitted to the district oversight team (CMO and DM). Following their approval, the District Immunization Officer (DIO) needs to forward the checklist to the state as per the timeline.

5.3.3 Track high-priority blocks

Senior district health officials have to be identified and deployed to visit and provide oversight to activities for introduction of pentavalent vaccine in high-priority blocks and urban areas, including participation in DTFI and assessment of district preparedness using checklists.

5.3.4 Strengthen RI microplans

- All high-risk areas identified in polio microplans should be incorporated in the RI microplans. Ensure that all vulnerable sections are provided an opportunity to avail of the services.
- For improved microplanning, a head count should be undertaken for estimation of beneficiaries by ANMs/ASHAs/AWWs using standardized tools. This has to be a time bound activity (1–2 weeks) and has to be intensively monitored by government functionaries and partners. DTFI to monitor its completeness.

5.3.5 Indenting and delivery of vaccines and logistics

- Estimate vaccine and logistics requirements at each level for pentavalent vaccine and submit the indent to the state for timely supply of vaccine.
- Ensure timely availability of required doses of pentavalent vaccine and other logistics. Ensure that the plans for phasing in and repositioning of hepatitis B vaccine are in place. DPT vaccine stocks would also need attention.

5.3.6 District-level training workshops for training the health workforce

- Prepare a training calendar to train the health workforce.
- Conduct district-level TOTs to create a pool of trainers at district and block levels. The DIO will be responsible for ensuring timely completion of training as per guidelines. Key development partners such as WHO, UNICEF and others are expected to proactively support the district in planning and sensitization to the workshop activities including monitoring the quality of training.
- The district and block level pool of trainers are expected to follow the cascading approach for sensitizing the health work force at district and block levels. These include training of identified block/urban planning unit MOs, cold chain handlers, data handlers, health workers and supervisors (ANMs, lady health visitors (LHVs) and health supervisors) and community mobilizers (ASHAs, AWWs and link workers).
- Five training workshops need to be conducted at the district level including a district pentavalent vaccine advocacy and launch workshop. Details are given in Table 4.



Table 4. Summary of district training workshops/TOTs

S.No	Trainees	Trainers	Duration	Timeline
1.	Mos: Blocks to identify and nominate the names of at least 2 MOs per block/urban planning unit. Nominations to be forwarded to DIO. Others include District Programme Manager NRHM, District IEC Consultant, District ASHA Coordinator, District Cold Chain Handler, District Data Manager, District M and E Coordinator (NRHM), District Accounts Manager (NRHM)	Master trainers: DIO and 2 MOs trained at state level	One day for each workshop	Within 2 weeks after completion of state-level workshop
2.	Data handlers: Block/planning unit to identify and nominate at least 2 data handlers involved in immunization data entry (HMIS and MCTS data) per block/planning unit. Nomination to be forwarded to DIO	Master trainers: DIO and 2 MOs trained at state level. Include HMIS and MCTS staff trained at state level.		Within 3 weeks after completion of state-level workshop
3.	Vaccine and cold chain handlers: Block/planning unit to identify and nominate at least 2 persons per vaccine storage point. Nominations to be forwarded to DIO	Master trainers: DIO and 2 MOs trained at state level along with district cold chain handler, refrigerator mechanic trained at state level		At least 2 weeks prior to the launch
4.	IEC/media handling focal persons: Blocks to identify and nominate at least one person dealing with media and IEC. Nominations to be forwarded to DIO	DIO with support from WHO, UNICEF and other partners, district IEC consultant, media officer, partners		
5.	Pentavalent advocacy and launch: Workshop for key district/block officials, development partners including media (print/electronic). DIO with support of partners to prepare the agenda and list of invited officials	DIO with support from WHO, UNICEF and other partners, district IEC consultant, media officer. DM to chair		

Notes: 1. Refer to Annexures 2, 3 and 4 for agenda and tips for trainers for Serials 1, 2 and 3 respectively.

2. Submit fortnightly progress on training status of each level of functionaries to the State Immunization Officer.

5.3.7 Dissemination of guidelines/revised formats/IEC material

- Disseminate relevant guidelines and training material to the participants in the workshops
- Ensure that the district has an adequate number of printed IEC materials (as per prototypes)
- Ensure that all the updated reporting and recording tools such as MCP cards, registers, due lists, etc. are printed and disseminated to blocks/planning units in time. Ensure that these materials are discussed and used in the sensitization workshops.

5.3.8 Tracking beneficiaries (left outs and drop outs)

Implementation of immunization tracking bag (one per session site).ASHA or AWW of that area to be made responsible. ANM to provide oversight and cross-check counterfoil to identify reasons for drop outs.

5.3.9 Cold chain

Ensure cold chain assessment is undertaken prior to the pentavalent launch. Key issues and gaps identified should be followed up.

5.3.10 Intensifying monitoring and supervision

Based on GoI guidelines intensify supervision and monitoring of RI at district, block, session and house-to-house levels through government functionaries and partners. Use standardized formats provided by MoHFW.

5.4 Block level pentavalent vaccine introduction activities

The following activities should be undertaken at the block level for the successful introduction of Hib-containing pentavalent vaccine into UIP:

5.4.1 Strengthen RI microplans

- All high-risk areas identified in polio microplans should be incorporated in the RI microplans
- Revise microplans. Use prescribed formats for UIP at each level to ensure inclusion of identified high risk areas in session plans.
- Undertake head count for estimation of beneficiaries by ANMs/ASHAs/AWWs for improved microplanning. Use standardized tools. Ensure that this is a time bound activity (1–2 weeks) and that it is intensively monitored by government functionaries and partners. MO in charge to monitor and provide oversight to this activity.
- DTFI to monitor progress.



5.4.2 Indenting and delivery of vaccines and logistics

- Estimate vaccine and logistic requirements at block and sub-center level for pentavalent vaccine and submit the indent to the district for timely supply.
- Ensure timely availability of required doses of pentavalent vaccine and other logistics. Ensure cold chain handlers are trained for phasing in and repositioning of hepatitis B vaccine. DPT vaccine stocks would also need attention.

5.4.3 Block training workshops for training ANMs/ASHAs/AWWs

- ANMs/LHVs/health supervisors: The district may plan to train the ANMs at district or block level. If training is planned at the block level, efforts should be made to conduct high quality training.
- Mobilizers (ASHAs and AWWs) are to be trained at block level by trained block level officials.
- WHO, UNICEF and other partner agencies are expected to support the pentavalent introduction activities at district /block level, including monitoring the quality of training.
- Details of training at block level are given in Table 5.

Table 5. Block-level training workshops/TOTs

S.No	Trainees	Trainers	Duration	Timeline
1.	Health workers (ANMs, LHVs, health Supervisors)	District and block master trainers (DIO and 2 MOs trained at state level + 2 block level MOs trained at district level). They will be supported by other trained officials such as district/block level data handlers, district vaccine and cold chain handler and others	One day for each workshop	Within 3 weeks of completion of the district-level workshop
2.	Mobilizers (ASHAs and AWWs)	District and block master trainers DIO and 2 MOs trained at state level + 2 block level MOs trained at district level. They will be supported by other trained officials such ASHA coordinators at the district level and others		

Notes: 1. Refer to Annexures 5 and 6 for agenda and tips for trainers for Serials 1 and 2, respectively. 2. Submit fortnightly progress on training status of each level of functionary to DIO



5.4.4 Dissemination of guidelines/revised formats/IEC materials

- Disseminate relevant guidelines and training materials to the participants during the training workshop.
- Ensure printed IEC materials are shared with the participants. Ensure appropriate display of IEC materials.
- Ensure that all the updated reporting and recording tools including immunization component in MCP cards, registers, due lists, etc. are shared during the training workshops.

5.4.5 Tracking beneficiaries (left outs and drop outs)

- Emphasize on implementation of the immunization tracking bag (one per session site). ASHA or AWW of that area to be made responsible. ANM to provide oversight and cross-check counterfoil to ascertain reasons for dropouts.
- Share the due list formats and revised immunization component in the MCP card. Demonstrate the use of counterfoil using immunization tracking bag with a focus on “missed dose tracking”.

5.4.6 Intensify monitoring and supervision

Strengthen monitoring and supervision through LHVs and health supervisors. Explain preparation of supervision plan based on priority and use of standardized formats.

Remember

- Dates for task force meetings at state and district levels should be decided on priority.
- All stakeholders and partners should be invited to task force meetings.
- Identified issues should be raised in task force and health society meetings at appropriate levels for solutions.
- Calculate requirement of vaccine and logistics at all levels timely.
- Trainees should be timely intimated.
- Training batch should not exceed 40–50 participants.
- Catch-up training should be planned in case of absenteeism.

State should collate training feedback from all districts and submit progress status







6. SUPERVISION AND MONITORING

6.1 Supervision and monitoring of implementation

Oversight of the implementation activities at all levels is crucial. Supervision should focus on bridging the gaps identified through the state and district preparedness assessment checklists.

6.1.1 At the national level

Review of the state preparedness checklists and assessment of progress achieved in addressing the identified issues at regular intervals will contribute to effective implementation and also have the added benefit of strengthening the RI system in each state.

Field visits by national observers will provide real-time information. The observers must visit the health facilities at all levels to assess the preparedness of states prior to introduction. The observers must share their observations with the district and state level officials for further action (if any).



6.1.2 At the state level

Review of the district preparedness checklists must be reviewed by the SIO. It is recommended that a state team be formed to oversee the implementation process. Officers from various departments can also be involved in the state-level training to enable participation in monitoring.

Field visits by the SIO and state observers (assigned for high-priority districts) must focus on checklist findings and visit the district training sessions. Issues identified must be shared with district and state task forces for corrective actions.

6.1.3 At the district level

In addition to officers of the health department, officials from ICDS department should also be involved in block level monitoring of training. CDPO and local administrative officers should be invited by block MOs to observe training of ASHAs and AWWs at the primary health center (PHC).

6.2 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 immunization session sites and community level coverage of all antigens offered through UIP to detect coverage gaps. The introduction of pentavalent vaccine in the UIP provides an opportunity to strengthen the overall monitoring of RI programme. The GoI mandated intensified RI monitoring strategy should be used for pentavalent vaccine related monitoring as well. Appropriate information may be collected on the status of implementation through all components of RI monitoring.

6.2.1 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.

6.2.2 District and block level monitoring.



This provides information on coverage, vaccine stocks, wastage rates, etc.

6.2.3 Household monitoring.

This uses convenience sampling in the community surrounding RI session sites to assess the coverage of RI antigens in children under 35 months of age.

Remember

- Pentavalent vaccine will replace DPT 1, 2, 3 and hepatitis B 1, 2, 3 doses
- After the launch of pentavalent vaccine, hepatitis B vaccine will continue to be used only as birth dose (within 24 hours) in case of institutional deliveries. The existing DPT and hepatitis B vaccine stocks will need repositioning.
- DPT vaccine will continue to be used in the RI programme as booster dose at 16–24 months and 5–6 years (not beyond 7 years) of age.
- Infants that have already started with DPT vaccination will continue and complete the schedule with DPT vaccine.
- Open vial policy will be followed for Hib-containing pentavalent vaccine. The existing mechanisms such as the task force for immunization and review meetings should be used for feedback and information sharing for appropriate corrective measures and follow-up.

Remember

- Pentavalent vaccine will replace DPT 1, 2, 3 and hepatitis B 1, 2, 3 doses
- After the launch of pentavalent vaccine, hepatitis B vaccine will continue to be used only as birth dose (within 24 hours) in case of institutional deliveries. The existing DPT and hepatitis B vaccine stocks will need repositioning.
- DPT vaccine will continue to be used in the RI programme as booster dose at 16–24 months and 5–6 years (not beyond 7 years) of age.
- Infants that have already started with DPT vaccination will continue and complete the schedule with DPT vaccine.
- Open vial policy will be followed for Hib-containing pentavalent vaccine.

6.3 Monitoring supply of vaccines and logistics

Available records must be examined for supply, utilization and balance of vaccines and AD syringes and verified physically to see whether there is a logical association between vaccines and AD syringes supplied and used.

If the following are found, there is a need to explore and address the reasons:

- The utilization of the vaccine and AD syringes shows a pattern of rapid increase or decrease week after week;

Remember

- Store pentavalent vaccine in ILRs only between +2°C and +8°C.
- In ILRs, place pentavalent vaccine at the top of the basket.
- Pentavalent vaccine should never be frozen
- Perform shake test as per WHO guidelines when there is suspicion of vaccine being frozen.
- Freeze sensitive vaccines including pentavalent vaccine if found frozen should be discarded.



- Doses consumed for vaccines that are provided at the same time (pentavalent vaccine and OPV) differ widely from each other for the same period. Remember
- Store pentavalent vaccine in ILRs only between +2°C and +8°C.
- In ILRs, place pentavalent vaccine at the top of the basket.
- Pentavalent vaccine should never be frozen
- Perform shake test as per WHO guidelines when there is suspicion of vaccine being frozen.
- Freeze sensitive vaccines including pentavalent vaccine if found frozen should be discarded.

If there is any mismatch between the reported number of doses and AD syringes used, the concerned vaccinators, doctors, stores-in-charge and supervising authorities must be consulted to determine the reason for the variation or mismatch. If their reply is found convincing and realistic, no action is required other than appreciating them. If the reply points towards problems or irregularities in work/management, solutions need to be discussed with the persons concerned. The senior authorities should be informed well in time.

6.4 Monitoring the cold chain

Pentavalent vaccine must be stored between +2°C and + 8°C. It is damaged by freezing as well as at higher temperatures. Therefore, strict attention to conditioning of icepacks and the maintenance of cold chain is essential.

6.5 Monitoring immunization safety

Pentavalent vaccine is a safe and effective vaccine; however, as with any new vaccine added to the programme, adequate attention should be paid to ensure that sensitive surveillance for AEFIs is in place. Any suspected AEFI thought to be associated with pentavalent vaccination should be reported in the prescribed Gol formats, including hospitalizations, deaths and any other severe or unusual medical event or event clusters. If an AEFI occurs, measures should be taken to check the compliance with safety strategies from existing supervisory checklists and explanations sought for deviations from safety norms, such as recapping, non-use of hub-cutters and other incorrect practices.

6.6 Monitoring hepatitis B birth dose implementation and DPT boosters

It has been noticed through evaluation surveys and from review meetings that coverage with hepatitis B birth dose has been lower than other antigens in UIP.. This situation requires specific attention, considering that the birth dose needs to be





administered within 24 hours of delivery. It is recommended that in the backdrop of pentavalent vaccine introduction, when hepatitis B vaccine standalone formulation will be withdrawn from the 6, 10 and 14 weeks' schedule, attention needs to be paid to increase coverage with hepatitis B birth dose. Similar attention should be paid to increase coverage with DPT booster doses and second dose of measles-containing vaccine (MCV2).

6.7 Post-introduction evaluation and impact assessment

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

WHO recommends that a post introduction evaluation (PIE) be conducted within 6–12 months of introduction of a new vaccine. The aim of such evaluation is to determine the status of vaccine introduction and its effect on the health system, to derive lessons for necessary corrective measures. A PIE of pentavalent vaccine was conducted in Tamil Nadu and Kerala in 2012 and in Gujarat, Haryana, Jammu and Kashmir, Karnataka, Puducherry and Goa in 2013 (refer to Annexure 1 for key findings and recommendations). The findings of PIE in these eight states have been used to update these guidelines. The national and state governments must plan to conduct PIE of pentavalent vaccine within 6 – 12 months of vaccine introduction.



7. FREQUENTLY ASKED QUESTIONS - Hib - CONTAINING PENTAVALENT VACCINE

1. *What is pentavalent vaccine?*

Pentavalent vaccine is a vaccine that contains five antigens (diphtheria, pertussis, tetanus, hepatitis B and Haemophilus influenzae type b).

2. *What are the advantages of pentavalent vaccine?*

- a. The addition of Hib vaccine provides protection against one more deadly disease.
- b. The number of injections administered under UIP during the first year of life reduces from nine to six.
- c. It does not require reconstitution.

3. *Till what age can pentavalent vaccine be administered?*

As per National Immunization Schedule, pentavalent vaccine should be started for any child aged more than 6 weeks and can be given up to 1 year of age.

4. *What is the schedule for pentavalent vaccine?*

Three doses of pentavalent vaccine are included in UIP. The first dose is given only after a child is 6 weeks old. The second and third doses are given at 10 and 14 weeks of age respectively, also in the form of pentavalent vaccine. There is no booster dose recommended under UIP.

5. *Is there any reason why a child should not be given pentavalent vaccine?*

- a. Age – a child below 6 weeks of age should not be given pentavalent vaccine.
- b. Vaccination history – a child whose vaccination schedule has been initiated with DPT/hepatitis B vaccine will continue to receive subsequent doses of DPT/hepatitis B and not pentavalent vaccine.
- c. Severe allergic reactions—although serious side effects have not been reported, a child who has had a severe reaction to pentavalent vaccine earlier should not be given another dose.
- d. Children with moderate or severe acute illness should not be administered pentavalent vaccine until their condition improves. Minor illnesses, however,

such as upper respiratory infections (URIs) are not a contraindication to vaccination.

Remember

All efforts should be made to mobilize the beneficiary to the session site to receive the primary schedule within the first year of life

- 6. A child who is 10 months old has not received any immunization. What are the vaccines that can be given to this child?**

The child should receive BCG, measles, first dose of pentavalent vaccine and first dose of JE vaccine (if child is living in a Japanese encephalitis (JE) endemic district where routine JE vaccine is being offered) with OPV dose and Vitamin A syrup.

- 7. What vaccine will be given to a child who has received at least one dose of pentavalent vaccine before his/her first birthday?**

If a child has received at least one dose of pentavalent vaccine before his/her first birthday then the child should be administered the due pentavalent doses at a minimum interval of four weeks, at the earliest available opportunity.

- 8. If a child comes unimmunized after completing 12 months of age, what vaccines would you give?**

Three doses of DPT and OPV at intervals of four weeks and a booster dose of DPT after six months are to be administered. Also, measles vaccine and Vitamin A solution should be given with the first dose of DPT. Such a child will not receive BCG, hepatitis B and pentavalent vaccines.

- 9. Should pentavalent vaccine be given to a child coming from a state which has not yet introduced pentavalent vaccine in its UIP schedule?**

Yes, pentavalent vaccine should be given to a child irrespective of the state he/she comes from, provided the child is less than 1 year of age and has not yet received any dose of DPT vaccine.

- 10. What are the side effects of pentavalent vaccine?**

Pentavalent vaccine has not been associated with any serious side effects. However, redness, swelling and pain may occur at the site where the injection was given. These symptoms usually appear the day after the injection has been given and last from 1 to 3 days. Less commonly, children may develop fever for a short time after immunization.



ANNEXURE 1

KEY FINDINGS AND RECOMMENDATIONS OF POST-INTRODUCTION EVALUATION (PIE) OF PENTAVALENT VACCINE IN INDIA

The introduction of any new vaccine into the immunization programme is an opportunity to strengthen health systems and improve the reach of immunization services to disadvantaged populations.

WHO recommends that a post-introduction evaluation (PIE) of new vaccines be conducted within 6–12 months to assess community acceptance and their impact on the existing immunization system. Although a PIE is done in the context of new vaccine introduction, the exercise provides a broad overview of the performance of the immunization programme and thus boosts the confidence to further scale up and



introduce new and underutilized vaccines in the programme. The effect of pentavalent vaccine on the health system was assessed as part of the PIE conducted in Tamil Nadu and Kerala in 2012, while the recently conducted PIE in March 2014 included assessment of both pentavalent vaccine and MCV-2 in six states and union territories.

The major objectives of PIEs conducted in eight states and union territories were to understand the vaccine introduction process from policy to implementation, map critical success factors and challenges, identify lessons learnt for future introduction of new vaccines, and assess whether lessons learnt from the polio programme are being applied to strengthen RI.

India is planning to introduce a number of new vaccines such as IPV, rotavirus, rubella and pneumococcal vaccines in the near future. The lessons learnt and recommendations from the two PIEs would be useful for national and state governments to strengthen components of the immunization-related health systems as they plan to roll out pentavalent vaccine and other new vaccines in the country.

Key lessons learnt from the two PIEs :

- Preparations for roll-out of a new vaccine should begin early, at least three to four months in advance of the actual vaccine launch. An operational plan should be prepared with detailed activities and timelines.
- Standard checklists should be used by review teams in each state and district to review their preparedness. Only after the review has determined the preparedness to be satisfactory should the state be allowed to introduce any new vaccine.
- A state-level official launch ceremony should be organized under strong political leadership, with the engagement of media, to increase programme visibility and boost confidence among public about the new vaccine.
- Districts should also organize launches for greater public awareness and ownership at local levels.
- State and district task forces for immunization should regularly review performance of the immunization programme and monitor RI activities. The task forces should also review preparedness for vaccine introduction.
- Staff vacancies at all levels, particularly in high-risk areas, should be filled up.
- Existing RI microplans should be revised to include high-risk areas and migratory/non-migratory settlements identified under the polio programme. New microplans should be prepared using a bottom-up approach to ensure inclusion of all components.
- State and district level planning workshops should be organized prior to the launch to orient all stakeholders about the pentavalent vaccine.
- Prior to the introduction of new vaccine, good quality training should be provided to the health staff (including data managers and cold chain handlers) on all aspects of vaccine delivery, from operations to appropriate use of communication channels. Training should also cover topics such as open vial policy, injection safety and waste management, due list preparation, four key messages, beneficiary mobilization to session sites and use of data for actions.
- Reporting and recording tools such as mother–child protection (MCP) cards, registers, tally sheets, etc. must be revised and printed in adequate numbers well in time before pentavalent vaccine introduction.



- Encourage use of immunization tracking tools such as tracking bag, MCP card, immunization counterfoil, etc.
- Cold chain management and vaccine management should be strengthened to avoid vaccine stock-outs and wastage. Waste disposal practices should be reviewed and strengthened at all facilities. Outsourced models of waste management work well and may be adopted.
- Adequate numbers of hub-cutters and black and red bags should be available at immunization sites.
- AEFI surveillance should be strengthened through capacity building of medical officers and health workers. All serious and severe AEFIs should be promptly investigated to establish causality and build trust within the community. AEFI kits should be available at session sites.
- National and state level officials should undertake field visits for supportive supervision with appropriate and timely feedback for corrective actions.
- IEC materials should be made available in ample quantities before the launch of the vaccine to raise awareness in the community. IEC materials (both written and pictorial) should be clear, attractive and easy to read. They should provide focused messages and contain adequate information about the vaccine. If necessary, they should be translated into the local language for wider dissemination.
- All communication channels should be harnessed – FM radio, television, print and social media – for wide publicity and increased vaccine acceptance among the public. Engagement with the media should be sustained in the post-introduction phase for dispelling myths and motivating and educating communities. It should be highlighted that pentavalent vaccine, which was earlier available only in the private sector, is now available free of charge in government institutions. This will help increase immunization coverage.
- It is recommended that advocacy be conducted both before the launch of a new vaccine and periodically thereafter to highlight the benefits of the vaccine and increase awareness. Stakeholders at all levels, including the community and caregivers, need to be engaged, educated and mobilized.
- States should ensure that ASHAs and other health workers are paid their incentives and other dues on time.



ANNEXURE 2

PENTAVALENT VACCINE TRAINING WORKSHOP FOR MEDICAL OFFICERS AT STATE/DISTRICT LEVEL

Table 1. Pentavalent vaccine training workshop for medical officers

Agenda for pentavalent vaccine training workshop for medical officers		
Total time: 6 hours		
Time	Activity	Person/s responsible
	Registration	
15 min	Objectives of the workshop and opening remarks	
15 min	Basic facts about pentavalent vaccine	
20 min	Current and revised vaccination schedule	
20 min	Concept of “phasing in”, “phasing out” and repositioning of vaccine	
15 min	Introduction to the immunization component of the MCP card /counterfoil and its use through tracking bag	
20 min	Understanding “full immunization” and “complete immunization”	
30 min	Use of coverage monitoring chart, including demonstration of the tool.	
30 min	Update on revised data entry tools and logistic requirements (MCP cards, tally sheets, MCH registers, HMIS/MCTS formats)	
15 min	Entry of pentavalent vaccine in HMIS and MCTS portals	
20 min	Coverage trends after pentavalent vaccine Introduction, and actions required	
20 min	National Cold Chain Management Information System(NCCMIS) status	
20 min	FAQs on pentavalent vaccine	
20 min	Vaccine safety (AEFI) and immunization waste management	
30 min	What to do after this workshop: role in sensitizing the health workforce	
15 min	Interaction about way forward	
	Wrap up	

Note: Person/s responsible for conducting training to be decided at the local level



Tips for trainers

Make the participants feel special and important since they are master trainers for introduction of a new vaccine in the state. They must understand that they are playing a key role in strengthening of the health system, particularly the immunization programme in the state. All sessions must be interactive. Methods to be used are PowerPoint presentations, role plays, exercises and interactive discussions. Trainers should be patient listeners to any feedback from the trainees.

What should be discussed?

- Explain the objectives of the workshop to participants(why they have been called and what is expected from them).
- Inform them about the basic facts of pentavalent vaccine.
Key messages: vaccination saves lives; pentavalent vaccine is safe and effective; it has already been introduced in eight states of India; 1.7 crore (17 million) doses of vaccine have been administered to target beneficiaries since its introduction; it is available as a liquid formulation in 10-dose vial.
- Let participants know that pentavalent vaccine is expensive. The cost of each vial is approximately INR 1300. Participants should understand the implications of reporting inflated/incorrect coverage.
- Discuss the existing vaccination schedule (with DPT1, 2, 3 and hepatitis B 1,2,3) and then make them understand the revised schedule (3 doses of pentavalent vaccine will replace DPT1,2,3 and hepatitis B 1,2,3). Following pentavalent vaccine introduction, hepatitis B (birth dose) will continue to be given in institutional delivery cases and DPT vaccination will continue in the programme only as booster doses (DPT first booster at 16–24 months and DPT second booster at 5–6years [not beyond 7 years] of age), and in cases when an unimmunized child comes up for immunization after his/her first birthday.
- Reporting of coverage : Do not forget to explain that all children younger than one year of age who have already received any dose of DPT and hepatitis B (other than hepatitis B birth dose) will continue to receive DPT and hepatitis B until they complete their schedule (phasing in and repositioning of vaccine).
- Introduce them to the revised MCP cards with emphasis on counterfoil use. Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, tools, etc.).
- Emphasize the usefulness of tracking tools: estimation of beneficiaries, due list registers, tally sheets, tracking bags and counterfoils, etc.
- Provide clarity on the terms “full immunization” and “complete immunization”. In the context of ASHA incentives for tracking the left outs, dropouts and mobilization of beneficiaries, compare the physical achievements with the financial utilization (INR 150 per session for mobilization to session site, INR 100 for each fully immunized child, and INR 50 per for each completely immunized child).
- Coverage trends after pentavalent vaccine introduction: explain that in the initial months following pentavalent vaccine introduction, the coverage of both

standalone DPT and hepatitis B vaccines will continue to be reported and recorded along with infants covered for pentavalent vaccination, i.e. infants that have started with pentavalent first dose. As more and more infants start getting pentavalent vaccine as 1, 2, and 3 doses, this trend will soon change and data will start showing the coverage of standalone DPT and hepatitis B vaccine going down and coverage of pentavalent vaccine going up. This trend will finally lead to showing only pentavalent vaccine (1, 2, and 3) coverage reporting.

- Understanding importance of session-wise coverage reports: this will help programme managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc.
- Use of coverage monitoring chart: explain how to make it, what data to use, importance of monthly and cumulative coverage data, etc. This is to be prepared every month for monitoring left outs and dropouts, especially in reference to pentavalent first dose to pentavalent third dose. MOs should fix responsibility of the person who will be required to update and display the same every month.
- Demonstrate to participants where to report pentavalent vaccine coverage in HMIS and MCTS. Also, make them understand the fields in HMIS where AEFI data and vaccine stock positions are to be entered.
- Are they aware of the National Cold Chain Management Information System (NCCMIS) software? Explain to them the value of this tool and indicators generated. Review the status of NCCMIS and provide the password if required.
- Review monitoring and supervision mechanism at state/district (who are involved in RI monitoring in the districts/block?). Are they aware of standardized RI monitoring formats approved by the GoI? Is monitoring happening as per these formats? Has there been any data entry for monitored sessions? Is any analysis available, and shared with district or block?).
- Reiterate the “Remember” messages.
- Ask them to bring out possible issues that they visualize that they might face during the new vaccine introduction.
- Explain to them what they have to do when they go back to their districts. These officials should know that as master trainers they need to further conduct training at block/planning unit level. The master trainers will have to take the help of other officials that have been trained at the state level such as HMIS and MCTS coordinators, district computer assistants to DIOs, district M and E focal person/coordinators (NRHM), focal person responsible for immunization reports in CMO office, district vaccine store keeper, district cold chain handlers and district IEC focal persons.
- The master trainers must ensure that a timeline is prepared and followed for training the health workforce involved in the immunization programme.
- Remember: all training will have some common and some cadre-specific messages.
- Each batch should not have more than 40 participants. In large states/districts more than one batch may have to be planned.



ANNEXURE 3

PENTAVALENT VACCINE TRAINING WORKSHOP FOR DATA HANDLERS AT STATE/DISTRICT LEVEL

Table 2. Pentavalent vaccine training workshop for data handlers

Agenda for pentavalent vaccine training workshop for data handlers		
Total time: 6 hours		
Time	Activity	Person/s responsible
	Registration	
15 min	Objective of the workshop and opening remarks	
15 min	Basic facts about pentavalent vaccine	
20 min	Current and revised vaccination schedule	
20 min	Concept of “phasing in”, “phasing out” and repositioning of vaccine	
20 min	Understanding “full immunization” and “complete immunization”	
30 min	Use of coverage monitoring chart. Demonstrate tool for analysis	
30 min	Update on revised data entry tools and logistic requirements (MCP cards, tally sheet, MCH registers, HMIS / MCTS formats)	
15 min	Entry of pentavalent vaccination in HMIS and MCTS portals	
20 min	Coverage trends after pentavalent vaccine introduction, and actions required	
15 min	Assessing immunization performance: physical and financial	
15 min	NCCMIS status 15 minFAQs on pentavalent vaccine	
30 min	What to do after this workshop: role in training the data handlers	
	Wrap up	

Note: Person/s responsible for conducting training to be decided at the local level

Tips for trainers

Make the participants feel special and important since they are master trainers for a new vaccine introduction in the state. They must understand that they are playing a key role in strengthening of health system, particularly the immunization programme in the state. All sessions must be interactive. Methods to be used include PowerPoint presentations, role plays, exercises and interactive discussions. Trainers should be patient listeners to any feedback from the trainees.

What should be discussed?

- Explain the objectives of the workshop to the participants (why they have been nominated and what is expected from them)
- Inform them about the basic facts of pentavalent vaccine.
Key messages: vaccination saves lives; pentavalent vaccine is safe and effective; it has already been introduced in eight states of India; 1.7 crore (17 million) doses of vaccine have already been administered to target beneficiaries since its introduction; it is available as liquid formulation in a 10-dose vial.
- Let participants know that pentavalent vaccine is expensive. The cost of each vial is approximately INR 1300. Participants should understand the implications of reporting inflated/incorrect coverage.
- Discuss the existing vaccination schedule (with DPT1, 2, 3 and hepatitis B 1,2,3) and then make them understand the revised schedule (3 doses of pentavalent vaccine will replace DPT 1,2,3 and hepatitis B 1,2,3). Following pentavalent introduction, they should know that hepatitis B (birth dose) will continue to be given in institutional delivery cases and DPT vaccination will continue in the programme only as booster doses (DPT first booster at 16–24 months and DPT second booster at 5–6 years [not beyond 7 years] of age), and in cases where an unimmunized child comes up for immunization after his/her first birthday.
- Introduce them to the revised MCP cards with emphasis on counterfoil use. Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, tools, etc.).
- Emphasize the usefulness of tracking tools: estimation of beneficiaries due list registers, tally sheets, tracking bags.
- Provide clarity on the terms “full immunization” and “complete immunization”. In the context of ASHA incentives for tracking the left outs, dropouts and mobilization of beneficiaries, compare the physical achievements with the financial utilization (INR 150 per session for mobilization to session site, INR 100 for each fully immunized child, and INR 50 per for each completely immunized child).
- Reporting of coverage: Do not forget to explain that all children younger than one year of age who have already received any dose of DPT and hepatitis B (other than hepatitis B birth dose) will continue to receive DPT and hepatitis B until they complete their schedule (phasing in and repositioning of vaccine).
- Coverage trends after pentavalent introduction: explain that in the initial months following pentavalent introduction, the coverage of both stand-alone DPT and



hepatitis B vaccines will continue to be reported and recorded along with infants covered for pentavalent vaccination (i.e. infants that have started with pentavalent first dose). As more and more infants start getting pentavalent vaccine as 1, 2, and 3 doses, this trend will soon change and data will start showing the coverage of standalone DPT and hepatitis B vaccine going down and coverage of pentavalent vaccine going up. This trend will finally lead to showing only pentavalent vaccine (1, 2, and 3) coverage reporting.

- Understanding the importance of session-wise coverage reports: this will help programme managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc.
- Use of coverage monitoring chart: explain how to make it, what data to use, importance of monthly and cumulative coverage data, etc. This is to be prepared every month for monitoring left outs and dropouts, especially in reference to pentavalent first dose to pentavalent third dose. MOs should fix responsibility of the person who will be required to update and display the same every month.
- Demonstrate to participants where to report pentavalent coverage in the HMIS and the MCTS. Also, make them understand the fields in the HMIS where the AEFI data and vaccine stock positions are entered.
- Are they aware of NCCMIS software? Explain to them the value of this tool and the indicators generated. Review the status of NCCMIS and provide the password if required.
- Review the mechanism of intensive monitoring and supervision at state/district level. Who in the districts/blocks have monitored RI? Are they aware of standardized RI monitoring formats approved by the GoI? Is monitoring happening as per these formats? Has there been any data entry for monitored sessions? Is there any analysis available that has been shared with the district or block?
- Reiterate the “remember” messages.
- Ask them to bring out possible issues that they might face during the new vaccine introduction.
- Explain to them what they have to do when they go back to their districts. These officials should know that as master trainers they need to further conduct training at block/planning unit level. The master trainers will have to take the help of other officials that have been trained at the state level such as the HMIS and the MCTS coordinators, district computer assistants to DIOs, district M and E focal person (NRHM), focal person responsible for immunization reports in CMO office, district vaccine store keeper, district cold chain handlers and district IEC focal persons.
- The master trainers must ensure that a timeline is prepared and followed for training the health workforce involved in the immunization programme.
- Remember: all training will have some common and some cadre-specific messages.
- Each batch should not have more than 40 participants. In large states/districts, more than one batch may have to be planned.



ANNEXURE 4

PENTAVALENT VACCINE TRAINING WORKSHOP FOR VACCINE AND COLD CHAIN HANDLERS AT STATE/DISTRICT LEVEL

Table 3. Pentavalent vaccine training workshop for vaccine and cold chain handlers

Agenda for pentavalent vaccine training workshop vaccine and cold chain handlers		
Total time: 6 hours		
Time	Activity	Person/s responsible
	Registration	
15 min	Objectives of the workshop	
15 min	Opening remarks	
30 min	Basic facts about pentavalent vaccine	
15 min	Current and revised vaccination schedule	
30 min	“Phasing in” and “phasing out” of vaccine	
30 min	Storage of vaccines in ILRs and repositioning of vaccines (DPT and hepatitis B); explain freeze sensitivity of pentavalent vaccine	
30 min	Update on revised data entry tools and logistic requirements (MCP cards/counterfoil, tally sheets, MCH registers, HMIS/MCTS formats)	
15 min	How to calculate vaccine wastage, emphasizing on pentavalent vaccine?	
20 min	Preventive maintenance mechanism and responding to chain equipment complaints	
15 min	Strengthening reporting and recording of vaccine and cold chain equipment (NCCMIS)	
15 min	Initiatives taken by state to strengthen cold chain supervision and monitoring	
15 min	Reiterate “remember” messages	
15 min	Role of participants as trainers in sensitization training Wrap up	

Note: Person/s responsible for conducting training to be decided at the local level



Tips for trainers

Make the participants feel special and important. They should understand their responsibilities and accountability in respect of the pentavalent vaccine introduction. Let them know that the quality of vaccines being delivered to the beneficiaries depends on them. Their contribution can mitigate AEFI occurrences in the field. Methodology will include PowerPoint presentations/ interactions/ discussions/ patient listening/exercises.

What should be discussed?

- Explain the objectives of the workshop to the participants
- Inform them about the basic facts of pentavalent vaccine
Key messages: vaccination saves lives; pentavalent vaccine is safe/effective; it has already been introduced in eight states of India; 1.7 crore (17 million) doses of vaccine have already been administered to target beneficiaries since its introduction; it is available in the programme as a 10-dose vial.
- Let participants know that pentavalent vaccine is expensive. The cost of each vial is approximately INR 1300. Participants should understand the implications of reporting inflated/ incorrect coverage.
- Discuss the existing vaccination schedule (with DPT1, 2, 3 and hepatitis B 1,2,3) and then make them understand the revised schedule (3 doses of pentavalent vaccine will replace 3 doses of DPT 1,2,3 and hepatitis B 1,2,3). Following pentavalent vaccine introduction, they should know that hepatitis B (birth dose) will continue to be given in institutional delivery cases and DPT vaccination will continue in the programme only as booster doses (DPT first booster at 16–24 months and DPT second booster dose at 5–6 years [not beyond 7 years] of age) and in cases where an unimmunized child comes up for immunization after his/her first birthday.
- Storage of vaccine in ILRs should be between +2°C to + 8°C. Explain how the space required in ILRs will be less when pentavalent vaccine is introduced. Provide insight into repositioning of vaccines (hepatitis B and DPT). Explain about the freeze sensitive nature of the pentavalent vaccine.
- Do not forget to explain that all children younger than 1 year who have already received any dose of DPT and hepatitis B (other than hepatitis B birth dose) will continue to receive DPT and hepatitis B until they complete their schedule (phasing in and phasing out of vaccine).
- Sensitize them on revisions done in the reporting tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers, etc.).
- Emphasize the need for the open vial policy. This will not be possible without the back up of a strong alternate vaccine delivery (AVD) plan.
- Emphasize on minimizing vaccine wastage. Explain to them that the state should review vaccine wastage on a monthly basis and districts should review wastage session wise/on a monthly basis.



- Review the existing alternate vaccine delivery mechanism. Participants should bring the AVD microplan of their district. Two well-performing and two poor-performing districts should share the AVD plans with their SWOT (strengths, weakness, opportunities and threats) analysis.
- This is a freeze-sensitive vaccine. Explain to the participants about the shake test. Play the 10 minute step-by-step shake test film. After the film, let one or two district vaccine handlers/DIOs explain what they understood (how to do and what to infer).
- Review the status of the NCCMIS.
- Explain where the coverage of Hib containing pentavalent vaccine gets uploaded in the HMIS.
- Review the maintenance system of existing cold chain equipment. Is the preventive maintenance model in place and are they aware of it? Review breakdown status and efforts put in by districts. Check with them regarding condemnation of irreparable cold chain equipment at district/block level.
- They should understand the appropriate time to reorder vaccines (lead time).
- The “five mantra” details for all vaccines/diluents including pentavalent vaccine must be written and displayed at all points of vaccine distribution—state/district/regional/zonal/PHC/CHC/ANM.
These are: 1.Name of the manufacturing company 2. Batch number 3. Expiry date 4. Manufacturing date 5. VVM status.
- Ask participants what are the anticipated possible issues that they might experience during vaccine introduction.
- Review mechanism of monitoring and supervision at state and district levels (who will monitor, how these will be done and what tools are to be used). Monitor the training.
- Ensure that vaccine handlers in the district are aware of the contact details of the refrigerator mechanic/person/agency responsible for cold chain repair and preventive maintenance. Details of visit and job undertaken related to cold chain equipment must be documented in the temperature logbook for that particular equipment (when visited – date and time, what was found, what was repaired, outcome of visit and any other instructions given to the vaccine handler of that cold chain point).
- Reiterate the “remember” messages.
- Explain to them what they have to do when they go back to their districts. They will have to provide training on pentavalent vaccination along with the DIO/RCHO/identified MOs to all vaccine and cold chain handlers working at vaccine storage points at block/planning unit level.
- Each batch should not have more than 40 participants. In large districts/ blocks, we should plan to conduct training for more than one batch.



ANNEXURE 5 PENTAVALENT VACCINE TRAINING WORKSHOP FOR ANMS, LHVS AND HEALTH SUPERVISORS AT BLOCK LEVEL

Table 4. Pentavalent vaccine training workshop for ANMs, LHVs and health supervisors

Agenda for pentavalent vaccine training workshop for ANMs, LHVs and health supervisors		
Total time: 6 hours		
Time	Activity	Person/s responsible
	Registration	
10 min	Objectives of workshop and opening remarks	
20 min	Basic facts about pentavalent vaccine	
20 min	Current and revised vaccination schedule	
20 min	FAQs on pentavalent vaccine	
30 min	Introduction to the immunization component of the MCP card. Filling and use of counterfoil and its use through tracking bag Understanding “full immunization” and “complete immunization”	
20 min	Improving microplanning. Emphasize on including polio HRA as part of the microplan and estimation of beneficiaries concept	
30 min	Use of immunization tracking bag and due list for tracking	
30 min	Learning to make sub-centre level coverage monitoring chart. Ask participants to bring their annual target of infants and month-wise DPT 1 and DPT 3 dose coverage for the past 6 months	
30 min	Revised logistics update (registers/MCP cards/tally sheets, MCH registers, HMIS / MCTS formats/ IEC material)	
15 min	Where does an ANM enter data for pentavalent vaccination in the HMIS and MCTS registers/formats?	
20 min	Discuss about how coverage of DPT, hepatitis B and pentavalent vaccine will change when pentavalent vaccine is introduced	

15 min	Importance of ensuring open vial policy for DPT,TT, hepatitis B and pentavalent vaccine is in place through alternate vaccine delivery	
10 min	Explain how monitoring will intensify for vaccines distribution and return of unused/partial vaccines on the day of immunization	
20 min	Vaccine safety (AEFI) and immunization waste management. Explain reporting/management guidelines	
30 min	What to do after this workshop: their role in sensitizing the social mobilizers: ASHAs and AWWs	
15 min	Interaction about way forward Wrap up	

Note: Person/s responsible for conduct of training to be decided at the local level

Tips for trainers

Make the trainees feel special and important. They should understand that it is because of them that we were able to eradicate polio from India and also that they are contributing in a big way in reducing mortality and morbidity related to vaccine-preventable diseases the country. They should realize the value of the faith that the community reposes in them for immunization. It is because of them that we know what progress is being made in the immunization programme. Explain to them that it is important to measure progress in public health. They should understand the value of timely tracking of beneficiaries using tracking tools such as tracking bags, counterfoils and due lists. Make them feel accountable for the vaccine used and vaccine wasted at their level. Focus on introduction of pentavalent vaccine and the expectation in regard to recording and reporting of immunization coverage related to all vaccines, with emphasis on pentavalent vaccine. The methodology will include PowerPoint presentations/interactions/discussions/patient listening/stall methodology.

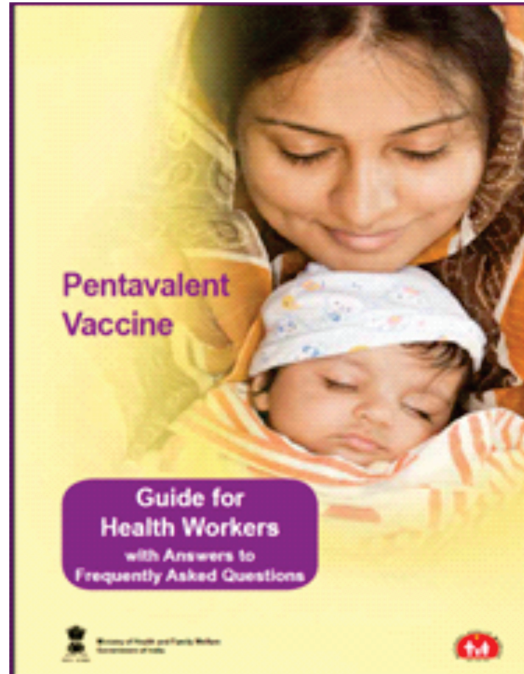
What should be discussed?

- Explain to them the objective of the workshop, why they have been called and what is expected of them.
- Inform the trainees about the basic facts of pentavalent vaccine.
Key messages: vaccination saves lives; pentavalent vaccine is safe and effective; it has already been introduced in eight states of India; 1.7 crore (17 million) doses of vaccine have already been administered to target beneficiaries since its introduction; it is available as liquid formulation in a 10-dose vial.
- Let participants know that pentavalent vaccine is expensive. Cost of each vial is approximately INR 1300. Participants should understand the implications of reporting inflated/incorrect coverage.
- Discuss the existing vaccination schedule (with DPT1, 2, 3 and hepatitis B 1,2,3)



and then make them understand the revised schedule (3 doses of pentavalent vaccine will replace DPT 1,2,3 and hepatitis B 1,2,3). Following pentavalent introduction, they should know that hepatitis B (birth dose) will continue to be given in institutional delivery cases and DPT vaccination will continue in the programme only as booster doses (DPT first booster at 16–24 months and DPT second booster at 5–6 years [not beyond 7 years] of age), and in cases where an unimmunized child comes up for immunization after his/her first birthday.

- Introduce them to the revised MCP cards with emphasis on counterfoil use. Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, etc.).
- Emphasize on tracking tools (estimation of beneficiaries/due list registers/tally sheets/use of tracking bags). Provide clarity on the terms “full immunization” and “complete immunization”. In the context of ASHAs, explain the incentives for tracking the left outs and dropouts and mobilization of beneficiaries to session site (INR 150 per session), for each fully immunized child (INR 100 per child) and for each completely immunized child (INR 50 per child). The trainer should explain the importance of comparing physical achievements with financial utilization.
- Reporting of coverage: do not forget to explain that all children younger than one year of age who have already received any dose of DPT and hepatitis B (other than hepatitis B birth dose) will continue to receive DPT and hepatitis B until they complete their schedule (phasing in and repositioning of vaccine).
- Coverage trends after pentavalent introduction: explain that in the initial few months following pentavalent introduction, the coverage of both stand-alone DPT and hepatitis B vaccines will continue to be reported and recorded along with infants covered for pentavalent vaccination (i.e. infants that have started with pentavalent first dose). As more and more infants start getting pentavalent as 1, 2, and 3 doses, this trend will soon change and data will start showing the coverage of stand-alone DPT and hepatitis B vaccines going down and coverage of pentavalent vaccine going up. This trend will finally lead to showing only pentavalent vaccine (1, 2, and 3) coverage reporting.
- Understanding the importance of session-wise coverage reports: this will help the health workers at all levels and also vaccine and data handlers at vaccine





storage points to understand vaccine coverage, utilization, wastage, etc.

- Use of coverage monitoring chart: explain how to make it, what data to use, importance of monthly and cumulative coverage data, etc. This is to be prepared every month for monitoring left outs and dropouts, especially in reference to pentavalent first to pentavalent third dose. MOIC should ensure that each sub-centre displays the updated coverage monitoring chart every month.
- Demonstrate to participants regarding where to report pentavalent coverage in HMIS and MCTS registers.
- Explain to them about the mechanism of intensive monitoring and supervision at session site and block level/vaccine storage point, as well as house-to-house monitoring activity.
- Reiterate the “remember” messages.
- Ask them about the possible issues that they visualize that they might experience in new vaccine introduction.
- Explain to them what they have to do when they go back to their sub-centres, especially sensitizing ASHAs and AWWs in terms of tracking beneficiaries, updating microplans through estimation of beneficiaries using standardized formats, counterfoil updating, tracking ASHA incentives through counterfoils, IEC displays, etc.
- Each batch should not have more than 40 participants. In large districts/ blocks, training for more than one batch may need to be planned.

ANNEXURE 6 PENTAVALENT VACCINE TRAINING WORKSHOP FOR ASHAS/AWWS/LINK WORKERS AT BLOCK LEVEL

Table 5. Pentavalent vaccine training workshop for ASHAs/AWWS/link workers

Agenda for pentavalent vaccine training workshop ASHA, AWW and link workers		
Total time: 6 hours		
Time	Activity	Person/s responsible
	Registration	
10 min	Objectives of the workshop and opening remarks	
10 min	Basic facts about pentavalent vaccine	
10 min	Current and revised vaccination schedules	
30 min	Introduction to the immunization component of the MCP card; filling and using the counterfoil and its use through tracking bag; understanding “full immunization” and “complete immunization”	
10 min	Improving microplanning, emphasizing on estimation of beneficiaries by ASHAs/AWWS in their catchment area	
30 min	Use of immunization tracking bag and helping to prepare due lists for tracking	
10 min	New IEC materials related to pentavalent vaccine and how to display them.	
10 min	Explain to them as to how coverage of DPT, hepatitis B and pentavalent vaccine will change once pentavalent vaccine is introduced	
30 min	Key messages regarding pentavalent vaccine that ASHAs/AWWS must understand for improving vaccine coverage in the field. Emphasize on pentavalent vaccine messages (less pricks, more antigens – force of five in one)	
15 min	Interaction about way forward	
	Wrap up	

Note: Person/s responsible for conducting training to be decided at the local level

Tips for trainers

What training methods will be used? Make the mobilizers feel special and important. They should understand that it is because of them that the country has made progress in both polio eradication and reduction of morbidity and mortality due to other vaccine preventable diseases. Explain to them that immense progress has been made in RI, but to reach the beneficiaries who have



not yet been reached will require special efforts and initiatives. Make them feel accountable for their area of work. Inform them about the pentavalent vaccine introduction in their state and the expectation from them to improve coverage related to all vaccines, with emphasis on pentavalent vaccine. The methodologies to be used are PowerPoint presentations/flip charts/interactions/discussions/patient listening/stall methodology.

What should be informed/discussed?

- Explain the objectives of the workshop, why they have been called and what is expected from them.
- Inform trainees about the basic facts of pentavalent vaccine.
Key messages: vaccination saves lives; pentavalent vaccine is safe and effective; it has already been introduced in eight states of India; 1.7 crore (17million) doses of vaccine have already been administered to target beneficiaries since its introduction; it is available in the programme as a 10-dose vial.
- Let them know that pentavalent vaccine is expensive. The cost of each vial is approximately INR 1300. Three doses to each child will cost approximately INR 400. They should be motivated to get this advantage for children in their area of work.
- Discuss the existing vaccination schedule (with DPT1, 2, 3 and hepatitis B 1,2,3) and then make them understand the revised schedule (3 doses of pentavalent vaccine will replace DPT 1,2,3 and hepatitis B 1,2,3). Following pentavalent introduction, they should know that hepatitis B (birth dose) will continue to be given in institutional delivery cases and DPT vaccination will continue in the programme only as booster doses (DPT first booster at 16–24 months and DPT second booster at 5–6 years [not beyond 7 years] of age), and in cases where an unimmunized child comes up for immunization after his/her first birthday.





- Do not forget to explain that all children younger than one year of age that have already received any dose of DPT and hepatitis B (other than hepatitis B birth dose) will continue to receive DPT and hepatitis B until they complete their schedule (phasing in and phasing out of vaccine).
- Introduce them to the revised MCP cards, especially the counterfoil and train them on utilization of tracking bags.
- Make them understand the terms “full immunization” and “complete immunization”. Also make them understand about the ASHA incentives for social mobilization (INR 150 per session), for each fully immunized child (INR 100 per child) and for each completely immunized child (INR 50 per child).
- Let them know that they have to undertake a very important and critical survey related to estimation of beneficiaries for improving the microplans. Ask them about the possible issues that they visualize that they might experience in the estimation of beneficiaries (survey).
- Critical messages related to pentavalent vaccine should be provided in addition to the four key messages.
- Explain to them their role in case any minor event or an AEFI case is reported.
- Reiterate the “remember” messages.
- Explain to them what they have to do when they go back to their village/area of work.

ANNEXURE 7

PENTAVALENT VACCINE TRAINING WORKSHOP FOR IEC/MEDIA HANDLING FOCAL PERSONS

Table 6. Pentavalent vaccine training workshop for IEC/media handling focal persons

Pentavalent vaccine training workshop IEC/media handling focal persons		
Total time: 6 hours		
Time	Activity	Person/s responsible
	Registration	
10 min	Objectives of the workshop and opening remarks Expected role of the participants in the programme	
30 min	Understanding immunization status at national, state and district levels Explain “full immunization” and “complete immunization” Situational analysis: - Current status (evaluated coverage : Annual Health Survey (AHS) or District Level Household Survey (DLHS); compare with the previous evaluated coverage; explain the progress with focus on districts - Status of high priority districts (RMNCH+A), blocks and groups (polio HRAs) - Current strengths and challenges in immunization program at state and district level - Understanding the issues and efforts related to the unreached. Tagging of polio HRAs in RI microplan - Mobilization efforts, incentives available for ASHA	
20 min	Status of state and district preparedness for pentavalent vaccine introduction (are districts/blocks ready?) Key findings and state efforts to improve the gaps	
20 min	Basic facts about pentavalent vaccine How would current vaccination schedule change after introduction of pentavalent introduction?	

20 min	Key FAQs (refer to operational guidelines): - Hib disease - Pentavalent vaccine	
20 min	Additional questions that media/participants are likely to raise. (Participants should be encouraged to ask questions; facilitator to note these questions on the flip chart and then address them one by one).	
20 min	Increasing visibility of the RI program in state with a focus on pentavalent vaccine introduction. Demonstrate the new IEC prototypes along with state instructions	
20 min	Role of media, (print, electronic and social) in pentavalent vaccine introduction. Disseminate state specific instructions	
30 min	Risk communication (basics for handling an AEFI crisis – refer MoH communication guidelines for building vaccine confidence around AEFI)	
45 min	How to write a press release Essentials of a press conference Key points to remember for conducting a press conference including essential documents needed during the conference	
30 min	Existing mechanism to monitor RI programme in states. State-specific efforts to monitor the visibility of RI in states. Discuss about any evaluation data (if available) Monitoring state IEC/ behavior change communication (BCC) efforts. Discuss and disseminate relevant formats and process of data entry, if any. If it does not exist, plan to institutionalize the same	
20 min	IEC/BCC: Issues/challenges that participants foresee in new vaccine introduction and practical solutions at their level	
15 min	Based on pentavalent operational guidelines: - Activities (training) planned to be completed before vaccine introduction (who trains whom and at what level) Explain the role of participants in: - training the IEC/media handling officials (at least 2 per block/planning unit) - planning the launch of the workshop including the media briefing, press release, etc. Wrap up	

Note: Person/s responsible for training to be decided at the local level.

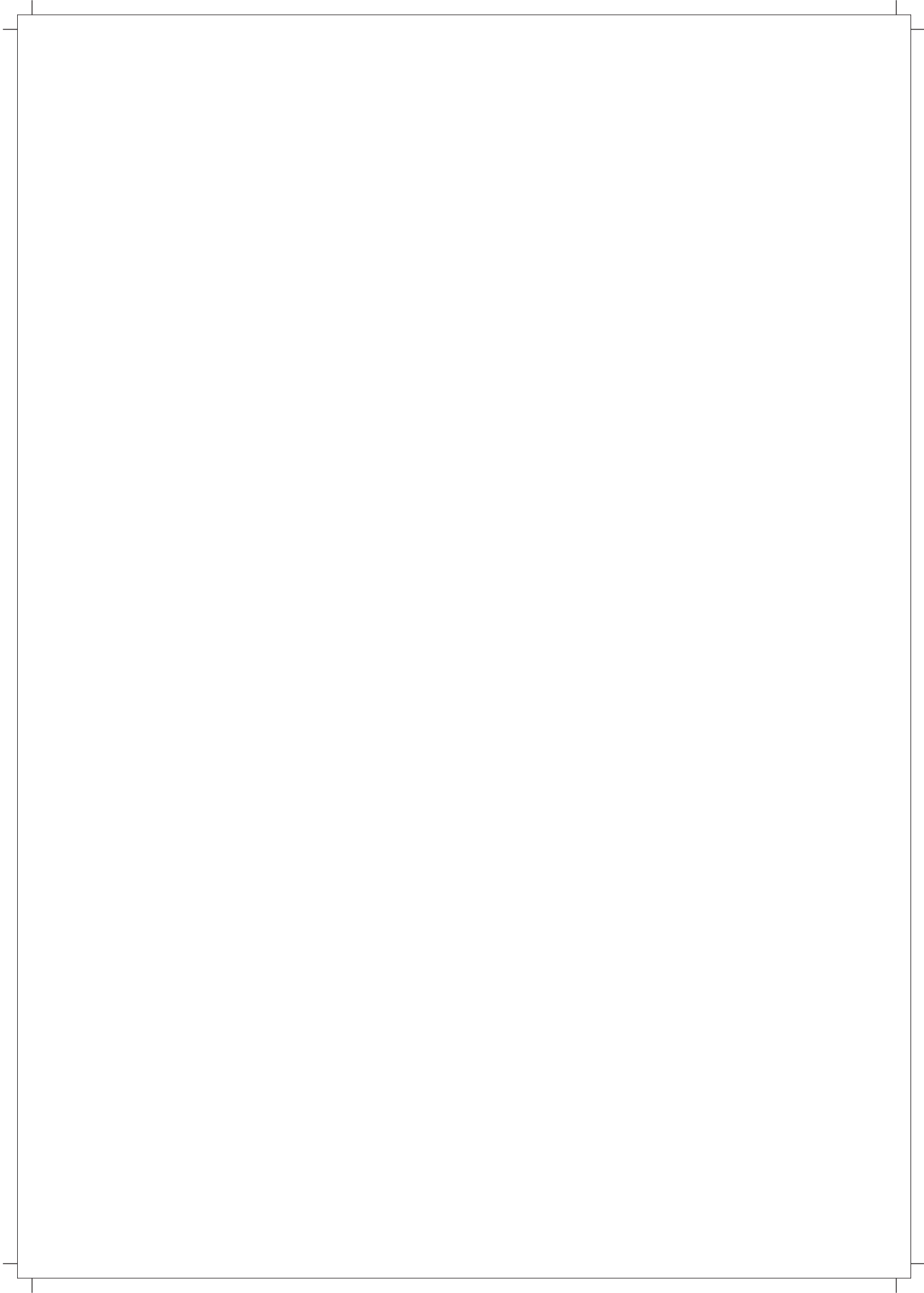


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Suggestions for improvement of these operational guidelines are encouraged. The same may be forwarded to the Immunization Division, MoHFW at riindia2008@gmail.com.







Operational guidelines developed by the WHO Country Office for India
for Ministry of Health & Family Welfare, Governments of India