**Nation-wide scale-up of**

***Haemophilus influenzae type b* (Hib) as Pentavalent vaccine**

**in Universal Immunization Program of India:**

**Introduction Plan**

Ministry of Health and Family Welfare,

Government of India

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**Executive Summary**

Pentavalent vaccine (DPT+ Hep B+ Hib) was introduced in the Universal Immunization Program (UIP) of two states of India in December 2011. By mid- 2013, this vaccine was a part of UIP in eight states of India. The decision on the introduction of the Hib vaccine as pentavalent vaccine in the country was based on the recommendations of National Technical Advisory Group on Immunization (NTAGI) following a meeting of the group held in June 2008 at the Ministry of Health and Family Welfare, New Delhi. The introduction of the vaccine was supported by the GAVI following an approval in June 2009 of a proposal submitted in September 2008.

A post-introduction evaluation of the pentavalent vaccine was conducted in Tamil Nadu and Kerala in 2012 and a number of lessons have been learned as a part of this evaluation.

The Ministry of Health and Family Welfare, Government of India is committed to strengthening UIP in India, including health system strengthening and the introduction of new vaccines as a priority. The UIP in India was guided by the strategic Multi Year Plan (2005-10) for Universal Immunization program in India, which had 6 goals and 20 objectives. The introduction of newer vaccines is one of the goals(goal 5) in the Multi-Year Plan (MYP). An addendum to MYP was prepared in 2008, which provided additional strategies for introducing pentavalent vaccine in UIP, incorporating the findings of National Cold Chain Assessment and realigning the costing and financing for immunization program in India. A revised comprehensive Multi-Year Plan (cMYP) of India for the period 2013-17 has been prepared and is in the final stage of approval. A country wide scale-up of pentavalent vaccine in UIP is a part of this plan. (cMYP of India along with costing and financing document is being shared separately).

The introduction of new vaccine provides additional opportunities for the strengthening of immunization program in any country. India recognizes pentavalent vaccine introduction in additional states of India as an opportunity to strengthen UIP in the states in which it is introduced. India has also received a grant from GAVI for immunization related health system strengthening in India for the period of 2014-16.

The NTAGI has recommended a nationwide scale-up of pentavalent vaccine during its meeting held in New Delhi on 23rd September, 2013. The recommendation has been endorsed by the Mission Steering Group meeting held on 6th December, 2013.

The country is approaching the GAVI Alliance to provide financial support for the introduction of the Hib as pentavalent (DPT +Hep B + Hib) vaccine in a 10 dose vial in the states that have yet to introduce the vaccine. This document aims to facilitate the application for GAVI support for introduction of the pentavalent vaccine in UIP in these states of India.

This introduction plan is an update on previous introduction plan prepared in 2011. It outlines the guiding principles, strategies and indicators for monitoring the successful introduction of Hib as pentavalent vaccine in UIP in all states of India by applying the lessons learnt from the previous introduction of the vaccine in eight states.

Additionally, India is also deliberating on the options of introducing the Inactivated Polio Vaccine as a part of the polio end-game strategy and the combined Measles and Rubella vaccine as a part of its goal of eliminating measles and controlling rubella by 2020. India is also looking at the possibility of a pilot introduction of Pneumococcal conjugate and Rotavirus vaccine in a selected state. This introduction plan proposes to support the introduction of pentavalent vaccine and also facilitate the process for future introduction of other newer vaccines.

**Background:**

With GAVI support of US$ 165 million in the form of commodity assistance of vaccine supply under the GAVI new vaccines support window (2008), India introduced Hib vaccine as pentavalent vaccine in Universal Immunization Programme (UIP) at two states namely Tamil Nadu and Kerala, in December 2011. Subsequently, it was introduced in a phased manner in 6 additional states (Goa, Gujarat, Haryana, Jammu & Kashmir, Karnataka, and Puducherry) by early 2013. The state of Delhi has also introduced Hib containing pentavalent vaccine from their own state budget in 2013. The present plan proposes to expand the vaccination program to all states of the country by late 2014/ early 2015.

The Ministry of Health and Family Welfare, Government of India intends to utilize the opportunity to introduce new vaccine for a further strengthening of the health systems and UIP in India. The effect of pentavalent vaccine on health system was assessed as a part of post introduction evaluation conducted in Tamil Nadu and Kerala states in 2012. The evaluation highlighted that the introduction of the new vaccine benefitted the immunization related health system components and thus boosted the confidence to further scale-up and introduce new and underutilized vaccines in UIP.

The UIP is fully funded central governments to the state government. The state governments implement the program using the existing infrastructure in the state. There is inbuilt mechanism to review and monitor the program, which is done through already well-defined mechanisms. The linkage between Union and State government interaction are provided in cMYP (2013-17) of India, being provided separately.

**Evaluation of Pentavalent Introduction in India**

Following introduction of Pentavalent vaccine in Tamil Nadu and Kerala, a Post Introduction Evaluation (PIE) of pentavalent vaccine was conducted by WHO India along with other partner institutions and various government organizations in July-August 2012.

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

The **major positive findings** observed during the evaluation were:

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

Major **areas identified for strengthening**:

* The **recording and reporting formats** had not been updated to incorporate pentavalent vaccine yet.
* There was a need to further **strengthen AEFI monitoring and reporting system**. The measures such as printing of job aids for AEFI surveillance and reporting protocols and additional sensitization of health staff was required.
* There appeared to be limited **local use of data for action**. Training of staff was required in calculating coverage rates, wastage and drop-out rates etc. and how to use information for corrective programmatic measures.
* **There was a need for streamlining the** Open Vial Policy for **birth dose of hepatitis B vaccine and the zero dose of OPV.**
* **Strengthening of immunization waste disposal system**, specifically in the rural health facilities.

**Application of PIE findings**

The lessons learned from PIE were utilized in the following ways:

1. The PIE field visits were followed by a debriefing to the state level officials in both Tamil Nadu and Kerala. The major findings and observations and key recommendations were shared during these debriefings with state officials. They initiated appropriate corrective measures.
2. The findings of this PIE were shared with national government and immunization program officials of 15 states of India during a ‘National workshop for communication in Routine Immunization in India’ held at New Delhi on 06-07 September 2012. Amongst this, six programme managers were from states where Pentavalent was introduced.
3. The findings were utilized to update operational guidelines for pentavalent vaccine introduction in India and revision of training material for pentavalent vaccine scale up in India.
4. The state level workshops for pentavalent vaccine introduction were used for dissemination of these findings in Jammu & Kashmir, Haryana, Gujarat, Goa, Puducherry and Karnataka. Approx. 18,000 copies of revised guidelines were distributed to 6 states which introduced pentavalent vaccine in late 2012 and early 2013.
5. The findings were shared through various immunization partners meetings in India and shared at WHO/SEARO Regional Review Meeting held at Bangkok, Thailand in October 2012.
6. The report of PIE was also shared with the program managers of states where scale up was undertaken in 2012-13.

**Rationale for national scale-up of Hib vaccine in India**

Pneumonia and diarrhoea, respectively, are responsible for 17% and 9% of global child deaths, together claiming the lives of more than 1.7 million under-five children in 2012 alone. India has the highest morbidity & mortality burden due to these two causes. An estimated 436,000 pneumonia & diarrhoea deaths have occurred in India in 2013.

Pneumonia continues to be a common cause of mortality in under-five children in India, accounting for 24% deaths as reported by Child Health Epidemiology Research Group (CHERG) in 2010 (Liu, et al. 2012 Lancet 379:2151-61).A review of studies conducted in India between 1987 to 2007, reported an incidence of acute lower respiratory infection (ALRI) between 290-536 per 1000 child-years and of severe ALRI in 27-96 per 1000 child-years. The burden of disease in terms of episodes per child per year ranges from 0.03 to 0.52. (Mathew JL et al. Indian Pediatr 2011, 48: 191-218).

Results from several Indian studies from 1991 to 2013 report that Hib is responsible for pneumonia in 15-19% of under five children and for meningitis in 24-70% children < 2 years and 20-44 % children <5 years (Kabra SK et al. 1991; Bahl R et al. 1995; Patwari AK et al. 1996; Sahai S et al. 2001; Chinchankar N et al. 2002; Minz S et al. 2008; Gupta M et al. 2010; Ramchandran P et al 2013; Fitzwater SA, et al. 2013).

The integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) proposes a cohesive approach to ending preventable pneumonia and diarrhoea deaths by 2025. In 2012, the call to action “Committing to Child Survival: A Promise Renewed” challenged the global community to reduce child mortality to 20 or fewer child deaths per 1000 live births in every country by 2035. The Global Vaccine Action Plan sets out a strategy for preventing childhood disease through vaccination by reaching 90% national coverage and 80% coverage in all districts for all relevant antigens including Hib which is being administered in 173 countries.

In alignment of these global goals, India reaffirmed its commitment to child survival at a national event, “India’s Call to Action Summit for Child Survival and Development” in February 2013. But because of limited sub-national implementation of Hib and delay in introducing Pneumococcal & Rotaviral vaccines, India ranks second lowest with 33% score just ahead of Nigeria (22%) among 15 high-burden countries where 75% pneumonia and diarrhoea deaths occur. Pan-India introduction of pentavalent has thus become an urgent programmatic necessity.

The scale up of pentavalent vaccine in states with large birth cohort and consequent, high disease burden will have a significant epidemiological impact in terms of reduction of disease and death burden and realization of MDGs. Since some of the states being included for scale up are large states with poor immunization coverage, introduction of pentavalent will give them an opportunity to re-energize their immunization delivery system. The national scale-up of pentavalent will also pave the way for introduction of IPV, pneumococcal and rotaviral vaccines as mandated by WHO in near future.

**Proposed scale-up of pentavalent vaccine in UIP**

The Government of India proposes to introduce Hib as pentavalent vaccine in the remaining states of the country in a phased manner with the next phase starting in October 2014. It is proposed that by April 2015, all 35 states and Union Territories of India should be providing pentavalent vaccine as part of UIP in the country. Table 1 provides information on the proposed plan for pentavalent vaccine scale-up in India

Table1: Proposed scale-up plan for pentavalent vaccine in India

|  |  |  |
| --- | --- | --- |
| Start Month | Oct 2014 | Apr 2015 |
| No. of states/UTs | 11 | 16 |
| Names of the states/UTs | AssamBiharMadhya PradeshRajasthanAndhra PradeshChhattisgarhJharkhandPunjabWest BengalDelhiUttrakhand | MaharashtraOrissaUttar PradeshArunachal PradeshHimachal PradeshManipurMeghalayaMizoramNagalandSikkimTripuraA&N IslandsChandigarhD&N HaveliDaman & DiuLakshadweep |

**Rationale for selection of states for phased introduction**

The initial selection of states for introduction of Hib containing pentavalent vaccine (Tamil Nadu and Kerala) was based on the immunization program performance and ability of the health system to handle a new intervention. The subsequent 6 states were selected based on the demand from the states and geographic, demographic and health systems diversity- which would help the government to understand the implementation challenges in varied settings of this large and complex country.

The states proposed for scale-up in October 2014 collectively have the highest burden of disease, and have requested the Government of India for inclusion of pentavalent vaccine in their UIP.

The remaining states constitute of two groups- UP, Maharashtra and Odisha have high disease burden and diverse health system challenges while the other states are having small, scattered populations on hilly terrains. For a smoother implementation of the programme, these states are proposed to introduce pentavalent vaccine in April 2015.

**State Preparedness & Monitoring**

Under the National Health Mission (NHM), state consultations occur twice a year and states are required to develop program implementation plans. The Ministry of Health and Family Welfare, Government of India will have special consultations with these states (as done in the past) to discuss the implementation of the pentavalent vaccine and identify state specific needs. The program implementation plans (PIPs) will include the introduction of the pentavalent vaccine.

In the run-up to the introduction of the vaccine in each state, the Ministry of Health and Family Welfare will track the preparedness of states on a regular basis before the pentavalent vaccine is introduced. The tracking will specifically focus on the plans put in place by the state for supply management, training of district/block programme managers and frontline workers, implementation of Open Vial Policy, actions for injection safety, strengthening AEFI management and creating appropriate awareness among the community. This tracking will be done through desk reviews of reports prepared by the state governments as well as through field visits to the states by government and partner agencies, especially the National Polio Surveillance Project of WHO that has a strong field presence and is highly experienced with monitoring such activities.

After introduction of the vaccine, the coverage of pentavalent vaccine will be tracked facility-wise through monthly HMIS (Health Management Information System) reporting. The age-appropriate status of vaccination will be monitored through immunization registry in Mother & Child Tracking system (MCTS). Adequacy of cold chain and vaccine supply chain management will also be monitored through existing National Cold Chain Management Information System (NCCMIS) and proposed National Vaccine & Logistic Management Information system (NVLIMS).

In addition to monitoring the administrative reports of coverage, the national and state governments will monitor the progress and quality of implementation of pentavalent roll-out through monitoring of sessions, community, block/ PHC and district level functioning of immunization delivery system using standard checklists with the help of partners’ support and a trained cadre of Immunization Field Volunteers (IFV) under NHM.

All these data on coverage and quality in terms of supply management, training, social mobilization, Open Vial Policy, injection safety, AEFI management etc. will be regularly reviewed at district and state level task forces to identify gaps and take appropriate interventions in time.

**Implementation Plan**

Choice of the Vaccine:

India is currently using 10 dose liquid pentavalent vaccine vials in UIP and proposes to use the same in the additional states in which the scale-up is proposed. The implementation of the 10 dose vial will not have any impact on the cold chain capacity in the stores at all levels. In fact, there will be a space saving if the 10 dose liquid formulation is used (two vials of DPT and Hep B replaced by single vial of Pentavalent).

The revised Vaccine Schedule

The pentavalent vaccine will replace the current DPT schedule in the UIP and the Hepatitis B program in these states (Table 2). In addition, an alternative schedule will be in place for institutional deliveries, where children will be given one dose of monovalent Hepatitis B vaccine.

Table 2: The following will be the revised routine immunization schedule in these states

|  |  |
| --- | --- |
| **Vaccine** | **Schedule** |
| BCG | Birth |
| OPV | 6 weeks, 10 weeks, and 14 weeks |
| Pentavalent (DPT + Hep B + Hib) | 6 weeks, 10 weeks and 14 weeks |
| Measles | 9 months |

Note: a birth dose of mono-valent Hepatitis B vaccine will be offered to children born in institutions (approximately 80%) of children in India.

The procurement mechanism

All vaccines being used in India under UIP currently, except the pentavalent vaccine, are indigenously manufactured and procured by Government of India, directly from the manufacturers. There are a numbers of vaccines manufacturing units in the private or sector, which are the major supplier of the vaccines for the UIP. The vaccines are supplied to the four General Medical Stores depots (GMSDs) in the country, from where, these are further transported to regional and district vaccine stores maintaining the cold chain.

The pentavalent vaccine is being procured through the UNICEF supply mechanism, using GAVI funding in all 8 states where pentavalent vaccine is part of UIP. The same mechanism would be followed for the states introducing vaccine in 2014-15.

The Government of India will self-finance procurement of the pentavalent vaccine beyond GAVI funding period.

Vaccine price and cost of vaccine introduction

The price of the 10 dose liquid pentavalent vaccine through GAVI mechanism will be US $2.1 per dose. This is much less than the cost of US$ 3.60 per dose for the single dose and 2 dose vials. The NTAGI has recommended the use of 10 dose vials for introduction of pentavalent vaccine in India. India has a birth cohort of approximately 22 million in the remaining states for vaccine introduction. The birth cohort, the vaccine requirement, and the cost sharing for the vaccine introduction is given in the table 3 below:

Table 3: Summary Table of Infant cohort targeted for pentavalent vaccination in India2014-2016

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   | Year | **2014** | **2015** | **2016** |
| 1 | ***Target infant cohort*** |
| 1.1 | Cohort already being covered as on Jan 01 of the year (a) | 5,037,000 | 18,300,000 | 27,394,000 |
| 1.2 | Additional targeted cohort to start in the year (b) | 13,053,000 | 9,094,000 | 0 |
| 2 | ***Vaccine doses requirement***  |
| 2.1 | For the cohort already being covered for entire year (= a\*3 doses\*15% Wastage) (c ) | 17,830,980 | 64,782,000 | 96,974,760 |
| 2.2 | For the additional cohort starting in the year (d) | 11,551,905 | 24,144,570 | 0 |
| 2.3 | Buffer stock needed for the cohort starting in the year (equal to 25% of annual cohort being targetted or =(b\*25%\*3\*1.18) (e) | 11,551,905 | 8,048,190 | 0 |
| 3 | **Total vaccine doses requirement in the year (=c+d+e)** | **40,934,790** | **96,974,760** | **96,974,760** |
| Remarks: 1. In the year 2014, the additional cohort will start in Oct 2014 and therefore vaccine supply for this additional cohort has been calculated for 3 months only. Thus, for 2014, the calculation has been done as (equal to 3 months of supply or one fourth of annual cohort or =(b/4)\*3\*15% wastage rate)
2. In the year 2015, the additional cohort will start in Apr 2015 and thus additional supply has been calculated for 9 month period. Thus, for 2015, the calculation has been done as (equal to 9 months of supply or three fourth of annual cohort or =(b\*3/4)\*3\*15% wastage rate)
3. The buffer stock has been calculated for additional birth cohort starting in that year and equivalent of 25% requirement for annual cohort.
4. Wastage rate for vaccine has been calculated at 15% and wastage multiplication factor is 1.18.
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National Regulatory Authority

India has a functional National Regulatory authority. The vaccines in India are considered under the category of drugs and needs licensing for the marketing in India from the office of the Drug Control General of India, known as The Central Drug Standard Control Organization (CDSCO). Besides, there is strict quality control mechanism and every lot of vaccine in India is tested by Central Drug Laboratory, Kasauli, before it is sent for the use in the field. There are currently a number of manufacturers, which have been licensed for liquid/lyophilized pentavalent vaccine in India and a few more are in the pipeline.

Cold Chain system and capacity

The country finished the National Cold Chain Assessment in 2008 and Effective Vaccine Management (EVM) assessments have been done in 2013. The cold chain capacity, areas for strengthening have been identified and effective actions are being taken to ensure that gaps, if any are addressed, prior to the vaccine introduction. *(Detailed draft report of EVM assessment is being appended).*

The HSS proposal, approved for GAVI funding also aims to strengthen cold chain capacity in majority of the states of India, where pentavalent vaccine is proposed to be introduced in this stage. The EVM have already been done in majority of the states proposed in this scale up.

Each state and regional store is expected to maintain a stock of 3 months of required vaccine. These stores supply to the district stores, which in turn maintain 2-3 months of vaccine supply. Hence, the space requirement at state and regional level is at least for a six month stock of vaccines.

The cold chain action plan prepared by the Govt. of India, as part of this strategy is also enclosed as Annex 1 in this plan.

Vaccine wastage and Open Vial Policy

Currently, the acceptable vaccine wastage rate for routine immunization vaccines of 10 dose vial in India is 25%. The Government of India plans to conduct vaccine management assessment on regular basis and intends to reduce the vaccine wastage rate over a period of time. Under the UIP, the vaccines are supplied from PHC (last cold chain point) to the outreach session site through vaccine carrier. The open vial policy for Hep B birth dose and OPV zero dose was implemented in India in 2011. Subsequently, following field reviews and findings of pentavalent PIE in India, which reported successful use of this policy, the open vial policy was further scaled up to all liquid vaccines under UIP including the pentavalent vaccine.

Injection Safety

The Ministry of Health and Family Welfare, Government of India has already implemented a policy regarding administration of all injectable vaccines under UIP through AD syringes. The costs of the AD syringes and waste management are borne by the government. The implementation of the pentavalent vaccine will adhere to the same policies. The government will provide AD syringes and the hub cutters for the implementation. The post-introduction evaluation in Tamil Nadu and Kerala has shown that injection safety and waste disposal practices also get additional attention and make improvements following new vaccine introduction.

Adverse Events Following Immunization (AEFI) monitoring

Surveillance for adverse events following immunization (AEFI) was established in India in 1986 as a component of the Universal Immunization Programme (UIP) and the National AEFI Guidelines were published in 2005. A National AEFI Committee was established in 2008 to provide technical, policy and strategic guidance for AEFI surveillance in India and revisions were made to the national guidelines in 2010. In December 2012, an assessment of the National Regulatory Authority (NRA) and affiliated institutions in India by a team of international experts led by WHO declared India functional against the entire core functions. Following this assessment, a detailed institutional development plan has been drawn up to further strengthen the regulatory capacity in India during 2013-2015. Strengthening AEFI surveillance is an integral part of the institutional development plan.

A series of important activities have been carried out during the last two years in the country to further strengthen AEFI surveillance.

An AEFI Secretariat was set up in India in 2012 with technical and operational support of WHO Country Office for India (WCO India). The main objective of the AEFI Secretariat is to coordinate AEFI surveillance/vaccine safety surveillance with Central Drugs Standard Control Organization (CDSCO), National Centre for Disease Control (NCDC), Integrated Disease Surveillance Project (IDSP), WHO and other partner agencies.

The National AEFI Committee has been reconstituted in 2013 to include specialists from a broader range of expertise, including pharmacology, forensic medicine and pathology. Causality Assessment meetings have been conducted on a quarterly basis at national level to enable timely causality assessment of serious AEFI cases, explore safety signals and share findings with other vaccine pharmaco-vigilance stakeholders.

As a part of the efforts to strengthen AEFI detection and reporting, the AEFI module has been included in the training curriculum for the intensified training of the frontline health workers in nine highest priority states of India. The training is currently in progress with support from WHO-NPSP. More than 45% of the 157,366 auxiliary nurse midwives (ANMs), 35% of the 490,358 Accredited Social Health Activists (ASHAs) and 31% of the 606,342 anganwadi workers (AWWs) have undergone this training in 2013.

The Indian Academy of Paediatrics (IAP) created a special portal (idsurv.org) in 2012 to encourage timely reporting of AEFI by pediatricians, both in the public and private sector. A partnership between the AEFI Program and academia has been institutionalized by establishing an AEFI Technical Collaborating Centre at one of the leading medical institutions of the country for technical support and oversight.

In addition to AEFI reporting through the program, vaccine safety reports are also obtained by the national regulator from the vaccine manufacturers and from the Pharmaco-vigilance Programme of India (PvPI) at the Indian Pharmacopoeia Commission (IPC) for reporting of adverse drug reactions including AEFI. The AEFI Secretariat has established a data sharing arrangement with IPC for ensuring convergence in vaccine safety reports and their adequate investigation.

WHO introduced a new causality assessment methodology and a pool of national and state level experts have been trained on this new methodology in June and July 2013 with technical and financial support of WHO. The state level experts invited belonged to states that have recently included pentavalent vaccine in their UIP schedule, namely Goa, Gujarat, Haryana, Jammu & Kashmir, Tamil Nadu, Kerala, Karnataka and Puducherry. International experts from WHO HQ and other agencies participated in these workshops. Besides trainings of state AEFI Committees and medical college experts were conducted for states of Bihar, Andhra Pradesh, Orissa and Madhya Pradesh that are among the states planned to introduce Hib containing pentavalent vaccine in future.

Communication guidelines for handling AEFI have also been developed to enable health workers to respond in a timely and appropriate manner to a vaccine adverse event and undertake crisis management, if required. In addition, autopsy protocols and verbal autopsy protocols are being specifically developed to be a part of the revised National AEFI Guidelines to improve investigation of AEFI deaths.

AEFI reports from the state of Maharashtra are currently being uploaded on the Vigiflow system, the global vaccine safety database at WHO collaborating centre for ADR monitoring at Uppsala, Sweden.

As India expands the use of Hib containing pentavalent vaccine in the country, the National Technical Advisory Group on Immunization (NTAGI), the apex immunization advisory body, has recognized the vaccine safety concerns and has supported an extensive research study to characterize events that are categorized as serious AEFI (including death and hospitalization) in 6-24 week old infants in the context of Universal Immunization Programme (UIP).

A detailed action plan for AEFI surveillance strengthening is provided as annex 2 of this plan.

Revision of records and tools

A major activity before the introduction of pentavalent vaccine in UIP is to revise the immunization cards, reporting formats and of the other monitoring tools. The section on DPT and Hep B vaccines in these tools will be replaced by the column for pentavalent vaccine. There are good experiences from states which have introduced pentavalent vaccine till now and with sustained focus, the revised recording and reporting tools start working well.

Staff training

The introduction of the vaccine will require training of the health care providers at various levels. The training guidelines for pentavalent vaccine will be added as an addendum to the existing training materials. The topics to be covered include: Hib infections and burden of disease; vaccine efficacy and safety; schedule and administration; AEFI and waste management; and vaccine procurement.

The development partners and the National Institute of Health and Family Welfare, New Delhi, which is a nodal agency for training health professionals in the country, have already developed the standard operating procedures and training material for pentavalent introduction in the past. These materials will be adapted and utilized by the states that are proposed to be included in the scale-up of pentavalent vaccine. The trainings will be cascaded from the state down to the block level. Training of trainers will be conducted at state and district level with the support of partner organizations. The trainers will conduct a half day intensified and focused training of the front line workers at the block level before the introduction of the vaccine. The quality of trainings and their progress will be monitored with the support of partners like WHO-NPSP.

The supervised trainings will also be an opportunity to improve the quality of services provided by the participants. These existing health training mechanisms will support the introduction of the new vaccine. The umbrella funds under NRHM, allocated for RCH, will be utilized for the same.

Cold Chain handlers:

Vaccine and Cold Chain Handler Handbook was developed, printed and widely disseminated.

Training started during 2010. Around 24000 (67.5%) of the 35000 cold chain handlers were trained by the end of 2012.An evaluation of Cold chain training was conducted jointly by NIHFW, WHO and UNICEF along with the Medical Officer training evaluation. A total of 12 districts (in 12 states) were covered in this detailed evaluation, which was conducted between February to May 2012.

National Cold Chain Training Centre (NCCTC) at State Health Transport Organization, Pune has been established and is presently functioning as a collaborative centre of NIHFW for cold chain trainings since 2012. This training will restart the trainings for cold chain technicians and officers with financial support of GoI through NIHFW with technical support of UNICEF. EVM Assessments has been conducted in total 10 states of India till 2012. The EVM assessment in 2012 were done Tamil Nadu state.

Social mobilization/IEC

An IEC plan will be developed with key partners i.e. WHO/ NPSP, UNICEF, USAID, CARE and PATH etc. The target groups will include politicians, media, medical community and parents and guardians.

Advocacy efforts will focus upon the program managers and implementers in the community to increase their awareness about the new vaccine, the cost effectiveness, and the need for proper vaccine management. The political decision makers will be sensitized to raise awareness of the need to increase government financing for immunization, specifically, to secure co-financing of new vaccines.

Advocacy will also be done with clinicians to obtain their support for the introduction of the new vaccine, disease surveillance and AEFI surveillance etc. The communication material will be developed for parents, clinicians, and the media.

The information and awareness-raising campaigns will be organized prior to, and during, the introduction of the new vaccine using the maximum number of channels of communication available throughout the country. Various partners like WHO, NPSP, UNICEF, NIPI and others will be requested to assist in these efforts. The goal is to obtain agreement by decision makers and acceptance of the new vaccine by health care workers and the community, particularly parents. The Indian Public Health standards for the Immunization are being finalized. The GoI will work with its partners and the national experts such as WHO, WHO-NPSP, UNICEF, PATH, Indian Academy of Pediatrics, and, NGOs to engage all levels of stakeholders for the advocacy of the immunization system strengthening and increase community awareness about introduction of new vaccines.

**Overcoming barriers to immunization**

The National Rural Health Mission (NRHM) (2005-12) in India was launched with the goals to strengthen the health system and improve the program performance. The NRHM in India has made a major impact on the immunization program. The Ministry of Health and Family Welfare, Government of India has launched the National Urban Health Mission (NUHM) as a sub-mission in 2013. The NUHM seeks to improve the health status of the urban population particularly slum dwellers and other vulnerable sections by facilitating their access to quality health care. The NUHM is expected to cover all state capitals, district headquarters and other cities with population of 50,000 and above in a phased manner. Cities and towns with population below 50,000 will be covered under NRHM.

The National Health Mission (NHM) now subsumes NRHM and NUHM which have been designated as sub-missions. NHM envisages “Attainment of Universal Access to equitable, affordable and quality health services, accountable and responsive to people’s needs with effective inter-sectoral convergent action to address wider social determinant of health”. To attain this vision NHM would seek strengthening of UIP through Health System Strengthening, overcoming equity issues and improving programme management.

The development of the Multi Year Strategic Plan 2005-2010 paved the path for the improvement of the UIP in India.

An addendum to MYP of India (2005-2010) was prepared to extend its period till 2012. Now, work on new cMYP for the period 2013-17 has been prepared and being shared separately.

A Health system strengthening proposal submitted by Govt of India to GAVI Alliance has also received funding approval and will be implemented by WHO, UNICEF and UNDP in India for the period of 2014-16. The proposal aims at strengthening immunization related health system in India and will support the following areas:

1. Strengthen vaccine logistics and cold chain management in poor performing states through public-private partnerships and through improved human resources capacity, institutional strengthening and supportive supervision
2. Design and implement an electronic vaccine intelligence network (eVIN) that will enable real-time information on cold chain temperatures and vaccine stocks and flows
3. Increase in demand for routine immunization (RI) through innovations in behavior change communication (BCC) Strategies
4. Strengthen the evidence base for improved policymaking (at all levels) on programmatic areas like procurement and vaccine delivery and on sequencing and adoption of new antigens
5. Leverage the success of the National Polio Surveillance Project (NPSP) to strengthen RI service delivery in 8 priority states.

Broad areas of involvement of polio network for RI strengthening

India has now been polio free for more than 35 months and is likely to be certified polio free in early 2014 along with other countries of South East Region. With the eradication of polio there has been a strategic shift in priorities. The technical support structures established for polio eradication, both at the national and sub-national levels, by WHO, UNICEF and other partners are now ‘transitioning’ to provide support to intensification of routine immunization from 2012 onwards, based on the lessons learnt from polio. This feeds into the overall goal of strengthening health systems in the country. The following broad thematic areas have been identified for strengthening routine immunization:

* The polio programme has identified more than 400 000 high risk areas. These areas are at high risk of all vaccine preventable diseases due to low population immunity and other risk factors. These sites are being incorporated into routine immunization micro plans across all states. As of 01 December 2013 more than 91% HRAs have been tagged with RI micro plans across the country.
* Similar to the polio task forces the government has issued guidelines to set up state and district level task forces for routine immunization. The task forces will regularly review data on programme performance, ensure accountability and improve inter-sectoral coordination. 32 out of the 35 states have constituted state task forces. 621 out of 667 districts have constituted district task forces as of December 2013
* WHO NPSP has been supporting national and state governments in RI monitoring. GoI has issued instructions to all states in December 2013 to expand monitoring. RI monitoring will generate actionable data on critical aspects such as involvement of local governments, missed areas for RI, reasons for partial RI coverage, quality of mobilization activities etc. and will be used by the task forces to review the programme on a regular basis.
* It has been noted that the progress of ongoing health workers’ training is too slow to produce any change in their practices. In view of this, WHO-India (NPSP) has developed a training module in consultation with government and partners to conduct intensified and focused training of frontline health workers. The objective and focus of these trainings will be on building the interpersonal skills of these frontline workers and to equip them with the information and skills required to address the queries of the parents so that they can undertake better mobilization and reduce drop outs.
* Linking of acute flaccid paralysis (AFP) surveillance and UIP reviews: regular and high quality AFP surveillance reviews useful data, which was utilised for the further programmatic corrections and follow up reviews. Programmatic information related to RI will be collected during all AFP surveillance reviews coordinated by WHO and provided to state governments for appropriate corrective actions in UIP
* Social mobilization strategies used in polio to mobilize communities are being adapted to create demand generation for RI. A new communication campaign with a new logo and tag line has been launched. SM net approaches and staff are assisting mobilization of communities and building confidence for RI.

Special Immunization Weeks for high risk areas

GoI observed four rounds of special immunization weeks (SIW) in 2013. These SIWs targeted children aged <2 years and pregnant women in nearly 400,000 high risk areas (HRAs) identified through polio eradication program. On an average, more than 120,000 immunization sessions were organized during each round of SIW in the country. As per the reports received, more than 9.2 million vaccinations were given to children aged <2 years and more than 1.1 million pregnant women were vaccinated during the four rounds of SIWs. WHO-India monitored 20,000 immunization sessions and >48,000 children during each SIW. Monitoring of the SIWs showed that early 40% of the identified HRAs were targeted during each round of SIW. Nearly 18% of all vaccinated children in the high priority states received vaccine for the first time and 45% of left-out children in the monitored high risk areas were reached through the SIWs. GoI has decided to continue with SIWs to strengthen RI.

**Post Introduction activities**

Surveillance

The surveillance of vaccine preventable diseases is done by passive surveillance and hospital based surveillance system. There is a case based surveillance system in India for AFP surveillance. The Integrated Disease Surveillance Project (IDSP) provides data on measles cases, besides, an outbreak based surveillance system for measles is operational in 23states of the country.

The Indian Council of Medical Research is the nodal agency for the health research in India. Two bacterial meningitis surveillance sites have been started in Chennai and Vellore with some more sites under development in northern India (One in Delhi and other in Lucknow). The government of India and ICMR has already set up bacterial meningitis sentinel surveillance sites 11 places in 6 states of India, which has started functioning in mid-2011.

Strengthening supervision, Follow-Up and Evaluation

Periodic evaluations and supervision will enable in identifying the problems inherent in the introduction of pentavalent vaccine in UIP in India. The supervision and monitoring is in-built with the routine immunization program and will be further strengthened and intensified. The post introduction evaluation will be conducted within 6-12 months of the introduction of the pentavalent vaccine, to take the lessons learned on the awareness of health care personnel and the community on the importance and acceptance of pentavalent vaccine and the effect of new vaccine introduction on health systems.

The routine monitoring visits will be made by the Government of India and partners (WHO, NPSP, UNICEF etc.) to the pentavalent introducing states. These visits will ensure the appropriate functioning of the program and will help in taking corrective measures for the strengthening of the immunization efforts. The mechanism for the regular coverage evaluation for the different antigens will be streamlined.

Post introduction evaluations (PIE):

The countries introducing any new vaccine usually conduct the post introduction evaluations to assess the performance of the health systems and service delivery 6 to 12 months after the introduction of the new vaccine. India will also conduct an impact evaluation after the introduction of pentavalent vaccine in UIP, as per W.H.O. recommendations with involvement of all stakeholders. The report from these consultations would be used for appropriate corrective measures.

Effective Vaccine Management Assessment

India will be conducting additional EVM assessment in these states and would implement the action plan already prepared, based upon the existing assessments (annex 1). The program will make the utilization of freezing indicators routine in order to ensure the quality of freeze sensitive vaccines, including pentavalent vaccine.

## **Financial Sustainability beyond GAVI support**

The GoI has started the process of financing the vaccine introduction in UIP. The efforts focus on mobilizing appropriate resources, facilitating access to funds, improving reliability and the efficiency of the programme. A detailed costing and financing analysis for UIP in India has been finished recently. (Annex 3). The GoI will fund vaccination with pentavalent once GAVI Alliance support is over.

**Improving Reliability**

The decision by GoI to procure the pentavalent vaccines through UNICEF for the medium term is to ensure a sustainable supply of reliable vaccines for the UIP, and until the supply through direct procurement can be better assured.

**Improving Program Efficiency**

There are a number of areas where UIP shall work to ensure improved efficiency of the programme. Poor vaccine management practices and high vaccine wastage can lead to poor utilization of resources. The EVM assessments are already being done in India and will be planned on the regular basis to be able to determine programme inefficiencies and more importantly implement corrective strategies to work towards limiting these inefficiencies.

The overall objective for programme efficiency will focus on wastage reduction through better vaccine management practices, cold chain improvements in line with the recent cold chain assessment recommendations and enhanced monitoring and supervision. The GoI will ensure that all activities related to the implementation of the pentavalent vaccine are monitored. A post introduction evaluation will be conducted 6-12 months after the introduction.

The details and timelines of these activities is provided in Annex 4.

**Annexes:**

**Annex 1:**

**Cold Chain Expansion Plan for India**

India is having the biggest immunization program in the world with birth cohort of 27 million and 30 million pregnancies every year. The programme has evolved with multiple milestones since 1978.Considerable progress needs to be made in effective coverage of immunization in order to reduce the morbidity and mortality due to vaccine preventable diseases. However, coverage of vaccination services show disparities in multiple variants. The progress depends on the Equity being given the priority, Health system strengthening to effective vaccine delivery, Community mobilization & increasing demand and Inter-linkage with maternal and child health interventions. These four components are key drivers of Immunization in India in achieving effective immunization coverage in near future.

Cold chain and vaccine logistics is a key driver of immunization programme.Strengthening the cold chain system (equipment, infrastructure, human resource,) and improving vaccine delivery through alternate vaccine delivery system, implementation of open vial policy and National Cold Chain MIS, along with national Effective Vaccine management assessment are some of the few initiatives which are seen to have positive impact on immunization supply chain (ISC)system. National Cold Chain Training Center (NCCTC) at SHTO, Pune and National Cold Chain and Vaccine Management Resource Center (NCCVMRC) at NIHFW, Delhi have been established to support MOHFW and states in planning, monitoring and capacity building initiatives for cold chain and vaccine management . These initiatives are important as key component of health system strengthening for immunization programme. Issues in cold chain are mostly management, however technology helps a lot in improving the management function of the ISC system .Policies, practices, process along with technology are the integral part of the ISC, however, in India we are in process of strengthening these 3 Ps and in recently approved HSS proposal through GAVI assistance, Cold Chain and Vaccine Logistics management is one of the key objective. National EVM, 2013 is the first systematic assessment which has assessed all five levels of supply chain of the country since the inception of UIP in 1985. The improvement plan and cold chain action plan is being developed for improving the Cold Chain and Vaccine Logistics management along with long term policies on cold chain.

**India will be implementing HSS project during 2014 to 2017** which envisages lots of activities pertaining to strengthen and improve Cold chain and vaccine logistics. Some of these are as listed below:

1. Improve Human resources to improve Cold Chain performance: It will include human resources for National Cold Chain Training Centre (NCCTC) and National Cold Chain & Vaccine Management Resource Centre (NCCVMRC)
2. Develop National Cold Chain Action Plan
3. Capacity building which include development of training modules, TOTs, other trainings
4. Supportive supervision and monitoring
5. EVM assessments and development of improvement plans
6. Vaccine Logistics management Information System
7. Roll out of National Cold Chain Management Information System (NCCMIS) across country: At present data of 563 districts out of 643 districts is available on NCCMIS
8. Enhancing national Cold Chain capacity through procurement of Cold chain equipment at national stores
9. SMS enabled real time monitoring of storage temperature of the vaccines
10. Developing PPP models for Cold chain and vaccine logistics management in select states

**However, as long term perspective, Country has identified following broad areas of cold chain and Vaccine Logistics Management for developing** comprehensive system approach with defined objectives and time frame to reach the vision of a *Reliable, Affordable and Efficient supply chain system for quality immunization .*To achieve this, the following will be considered

1. Management and Policy

* Introduce VAR for Vaccine stores up to Sub National level
* Real time Vaccine Logistic Management Information system (VLMIS) for 5 levels of supply chain. NCCMIS need to be integrated to VLMIS
* National Cold Chain action Plan

2. Human Resource and capacity building

* Define staffs for CCL at all levels
* Each GMSD and SVSs should have services of Vaccine Logistics Manager (VLM) and access to prompt repair and maintenance of cold chain equipment storing vaccines.
* Develop Training package for the VLMs and also for the Immunization programme managers and house them in the institution to overcome attrition
* Review of Knowledge (Training) to skills transformation barriers
* Regular Orientation, at least every 3 years for all staffs

3. Infrastructure

**A. Building**

* Dedicated stores for State, Division, District and Health Facilities(PHC),
* Consider the future need, national standard
* Greater collaboration with PWD, Electricity and Municipal corporation/bodies for regular maintenance

**B. Equipment**

* Standardized equipment specification as per acceptable standards
* Minimize variety of equipment to reduce no of spare parts
* All WIC/WIF with working hooters
* Mapping of spare parts to repair nonfunctioning equipment (Solar, Haier, Blue star, others)

**C. Transport**

* Use only conditioned icepacks during transportation of vaccine
* Promote use of refrigerated vaccine van at districts and above

**D. Temperature monitoring**

* Develop national temperature monitoring policy for different level of vaccine stores
* Undertake calibration of temp monitoring devices
* Undertake temp mapping of cold rooms
* Initiate use of Freeze markers during transportation of vaccines
* Wireless/SMS based temperature monitoring devices for all cold rooms and initiate the same for cold chain points

4. **Planning, Documentation and MIS**

* Define **realistic stock level** in months at five supply chain level
* Define , print and distribute **standard vaccine stock registers**
* Vaccine indent and distribution plans based on the required peak stocks.
* Preventive maintenance plan for technicians
* **Regular data uploading in NCCMIS** for performance assessment of CC at all level
* Establish a system for recording wastage in vaccine registers

5. **Improvement in Practice and Supportive Supervision**

* Manual temperature monitoring and recording to be carried out 2 times daily, for all 7 days including holidays
* Maintain a service log sheet for each of the equipment. This can be done as part of the Temperature monitoring booklet.
* Diluents MUST be marked in supply voucher and should be recorded just like the vaccines in stock registers.
* At CHC and PHC the DF must be used exclusively to prepare ice packs. Vaccines must never be stored in the same unit. All vaccines should be kept in ILRs at the CHC and PHC.
* Always use standardized Ice Packs after conditioning

To achieve this, a National Cold chain and Vaccine logistics Action plan (NCCVLAP) will be developed which shall provide directions, strategies, guidelines and standards for Immunization Supply Chain strengthening.

**Key component of NCCVLAP are:**

1. National standards for **:**

*Vaccine stores at all levels*

*Cold Chain point expansion guidelines*

*Cold Chain Equipment plan for different level of vaccine stores*

*Quality maintenance of vaccine*

*Temperature Monitoring of cold chain system*

*Human resource for* Cold Chain and VM

1. Procurement Policy for CCE(Types of equipment , specifications ,rate contract and procurement)
2. Establishment of CCL centers and strengthening capacity of NCCTC and NCCVMRC for CCVLM and moving beyond capacity building
3. Review Mechanism of CCVLM in the districts, states and National
4. Capacity building of HR engaged for Cold Chain and VM
5. Standard documentation system, data generation and MIS ( NCCMIS, VLMIS ,Temp monitoring MIS )
6. Supportive supervision and Improvement of management skills of programme managers
7. Research and technology up gradation of ISC
8. Assessment and studies ( EVM, vaccine wastage , temp monitoring , AVDS and others )
9. Establish CCE Testing Lab for regular performance assessment of CCE and provides feedback to MOHFW for future CCE procurement

**Time line for development of NCCVLAP**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sr.No | Activity | Time line (2014) | Participating Agency /Individuals | Responsible Agency  |
| 1 | Activation National Cold Chain Sub group  | Immediate, by end January | ALL | MOHFW/UNICEF |
| 2 | Formation of core group for development NCCVLAP | 1st week of Feb | UNICEF, WHO, UNDP, B&GF,NCCVMRC and NCCTC | MOHFW/NCCVMRC/UNICEF |
| 3 | 2 days Consultation meeting and thematic group work  | 3rd week of March  | UNICEF, WHO, UNDP, B&GF,NCCVMRC , NCCTC, national and international experts |  NCCVMRC/UNICEF |
| 4 | Thematic groups to develop respective document through series of consultation meeting  | 3rd week of May  | Members of the Thematic group  | NCCVMRC/UNICEF |
| 5 | Draft NCCVLAP developed through consolidation of all the thematic group work | 3rd week of June  | Members of the Thematic group  | NCCVMRC/UNICEF |
| 6 | Presentation of draft NCCVLAP to IAG | Mid July  | IAG members  | NCCVMRC/UNICEF |
| 7 | Inputs of IAG members included in the NCCVLAP and final version ready  | Mid-August  | Core group  | NCCVMRC/UNICEF |

**Annex 2:**

# **Plans for strengthening AEFI surveillance in India in context of the pentavalent vaccine expansion**

**Introduction**

The Expanded Programme of Immunization (EPI), launched in 1978 in India became the Universal Immunization Programme (UIP) in 1985 with the inclusion of vaccines targeting six vaccine preventable diseases (Tetanus, Diphtheria, Pertussis, Poliomyelitis, Measles and Tuberculosis).

The JE vaccine was introduced in 2006 and is given in 112 JE endemic districts in 15 states. Hepatitis B vaccine was introduced in 2007-08 in 10 states which was subsequently expanded to cover the entire country in 2011. Pentavalent vaccine (a single shot vaccine containing DPT, Hepatitis B and *Haemophilus influenza b* vaccines) was introduced in 2011 in Kerala and Tamil Nadu. Six more states are using this vaccine in 2013. The second dose of Measles is now part of National Immunization Schedule since 201. Second dose of JE vaccine was introduced from 1st April 2013 in endemic districts.

**Milestones in Adverse Events Following Immunization (AEFI) Surveillance Program**

AEFI surveillance in India started in 1986 as part of the Universal Immunization Program (UIP) to detect and report AEFIs. The National AEFI guidelines were developed in 2005 and revised further in 2010. To enable AEFI reporting and investigation at district and state level, state and district AEFI committees were mandated by the National AEFI Program in 2007. The National AEFI committee was set up in 2008. A National AEFI Secretariat was established in 2012 at the Immunization Technical Support Unit (ITSU) with WHO country office support.

**Current status of the AEFI program in India**

As per the National AEFI Guidelines of 2010, all serious and non-serious AEFIs need to be reported. Non- serious AEFIs need to be reported routinely through the monthly HMIS report. Serious AEFIs (death, hospitalization, prolongation of hospitalization, persistent or significant disability/incapacity, or is life threatening) are to be reported immediately through the First Information Report (FIR) within 24 hours of the case notification, followed by a Preliminary Information Report (PIR) within 7 days and Detailed Investigation Report (DIR) within 90 days of submission of the FIR.

AEFI Committees have been set up in each district and at the State level. The District Immunization Officer (DIO) and the State EPI Officer (SEPIO) are the member secretaries. The role of the AEFI Committees is to strengthen AEFI reporting at all levels, ensure maintenance of national policy and standards and ensure prompt and thorough investigation of serious AEFIs.

Regular training programs are held for sensitization of State and district level officials. In the training modules on RI for Medical Officers and Health Workers, there are designed sessions on AEFI Program and this in service training imparts knowledge about every aspect of the program. Since 2006-07, a series of campaigns were conducted across the country to introduce JE vaccine and 2nd dose of Measles vaccine in routine immunization. In the preparation for these campaigns, capacity building of health workers and medical officers has been done to sensitize them on reporting and managing AEFIs. Specific AEFI kits were developed and used during the campaigns to manage AEFIs. All health workers have been trained in managing life threatening situations. Special media sensitization workshops were also held to prepare for the pentavalent introduction in past in 8 states of the country so far.

**Current Status of Serious AEFIs in India including Following Pentavalent Vaccination**

|  |
| --- |
| **Serious AEFIs Data as on 21st Jan 2014)** |
| **Year**  | **Serious AEFIs Pentavalent**  | **Serious AEFIs Other Vaccines**  | **Total Serious AEFIs (Pentavalent and other vaccines)** | **Grand Total**  |
| **Death**  | **Others including Hospitalization**  | **Total**  | **Death**  | **Others including Hospitalization**  | **Total**  | **Death**  | **Others**  |
| 2011 | 1 | 3 | 4 | 135 | 179 | 314 | 136 | 182 | 318 |
| 2012 | 14 | 42 | 56 | 146 | 184 | 330 | 160 | 226 | 386 |
| 2013 | 42 | 96 | 138 | 124 | 288 | 412 | 166 | 384 | 550 |
| 2014 | 1 | 4 | 5 | 5 | 1 | 6 | 6 | 5 | 11 |
| **Total**  | **58** | **145** | **203** | **410** | **652** | **1062** | **468** | **797** | **1265** |

**AEFI surveillance strengthening activities - 2013**

With an annual birth cohort of ~27 million children, till 2012 India had reported ~400 serious AEFI cases (comparatively a small number given the birth cohort). Among the many factors contributing to the under-reporting of AEFI cases in the country are the fear of blame among health workers, poor training and awareness amongst frontline workers, a lack of time bound AEFI investigation and the need for protocols to investigate serious AEFI deaths as and when they are reported. With the establishment of the National AEFI secretariat, in 2013 alone India has recorded 550 serious AEFI cases.

In order to improve AEFI reporting and correctly assessing the cause of AEFIs, workshops on Causality Assessment were conducted in 2013 for all pentavalent states, support was provided to states (especially Kerala, Haryana and Jammu & Kashmir) for the investigation of AEFIs.

During the “Year of Intensification of Routine Immunization” (2012-13), the Government of India initiated an intensified and focused training of frontline workers (ANMs, LHVs, Anganwadi workers and ASHAs) with the objective of enhancing their operational and interpersonal (IPC) skills in the nine priority states of UP, MP, Rajasthan, Bihar, Chhattisgarh, Jharkhand, Haryana, Gujarat and West Bengal. Training tools used included Info-kits for health workers and facilitator guide for trainers developed by WHO-India (NPSP), and IPC skills-development film developed by UNICEF. By end 2013, close to 50% of targeted 1.2 million frontline workers have been trained in these nine states. During these trainings, in addition to AEFI reporting and management, the frontline workers were also trained on using IPC skills to improve communication with parents and the community.

In the past two years, specific steps have been taken for better coordination between various stakeholders in AEFI surveillance system. These are the National, state and district AEFI committees, Central Drugs Laboratory at Kasauli and Kolkata, national and sub national drug authorities, the state forensic laboratories and the Universal Immunization Programme (UIP) coordinate the implementation of the AEFI surveillance system.

**Some of the initiatives taken to improve surveillance of AEFIs in 2013 include:**

1. Successful assessment of Indian National Regulatory Authority as functional including component of AEFI:
2. Establishment of National AEFI Secretariat at ITSU
3. Partnership with Lady Hardinge Medical College as National AEFI Technical Collaborating Centre for technical oversight and support
4. Reorganization of National AEFI committee which has held 2 annual meetings as per meeting calendar.
5. Capacity building for AEFI monitoring and Causality Assessment at national and state level, for 13 states through workshops in Goa and Bangalore (for 8 pentavalent states – Kerala, Karnataka, Tamil Nadu, Goa, Gujarat, Jammu and Kashmir, Puducherry and Haryana), Bhubaneswar (Odisha, Andhra Pradesh, Bihar, Rajasthan and Jharkhand) and Srinagar (for State and Regional AEFI Committees, Medical Colleges, ADR Monitoring Centres, etc).
6. Training of national AEFI committee members and experts on new WHO Causality Assessment methodology in June 2013
7. Regular Causality assessment sub-committee meeting as per the calendar
8. Support to states for AEFI investigation of serious AEFIs including those following pentavalent vaccine in Kerala, Haryana , Delhi and Jammu and Kashmir
9. Development and dissemination of Communication guidelines for AEFI for health workers
10. Coordination with vaccine pharmacovigilance stakeholders with AEFI edition of IPC newsletter
11. Development of autopsy protocols and SOPs for investigation of AEFI deaths
12. Research study to risk of hospitalization and death following administration of UIP vaccines in 2 states
13. Sanction of 4 Zonal AEFI Consultants from NRHM funds to strengthen AEFI investigation, monitoring and feedback & support states in AEFI reporting, investigation and follow up. These consultants would be based at zonal DCGI offices at Ghaziabad, Kolkata, Mumbai and Chennai.
14. ANM and ASHA training on a special immunization curriculum including a module on detecting, reporting and managing AEFIs in the field.
15. AEFI Secretariat collaborates with Indian Pharmacopoeia Commission (IPC) the pharmaco-vigilance centre of CDSCO, which has network of more than 90 regional centres for reporting of adverse drug reactions including AEFIs. Many of these centres are located in private hospitals and private medical colleges.
16. AEFI data from one of the states in the country is uploaded on Vigiflow, a global databases of ADRs including AEFIs at Uppsala, Sweden. This is a web-based AEFI database and at present the state of Maharashtra is contributing cases from India to it.
17. Private sector involvement to improve AEFI reporting has been strengthened by establishment of a web link for reporting AEFIs from private sector-IdServ and inclusion of AEFI in the Basic Vaccinology Course of IAP
18. National AEFI Guidelines are currently being updated to incorporate the needs for causality assessment and timely investigation.

As the NTAGI has approved the countrywide expansion of pentavalent vaccine to additional states, efforts are on to enable a smooth introduction with better surveillance for AEFIs before and after pentavalent expansion.

**Future activities - AEFIs**

A detailed annual AEFI work plan has been developed for strengthening AEFI program. Greater support to the 11 target states for pentavalent expansion by Oct 2014 is planned through orientation workshops for District Immunization Officers on reporting and recording, investigation and analysis of AEFIs. In addition, the state AEFI committees are being revitalized to conduct technical assessment of reported AEFIs. Each state AEFI committee has been requested to partner with a reputable govt. medical college in the state for leveraging the multi-specialty medical technical expertise in the medical colleges.

With the establishment of the National AEFI Secretariat and zonal AEFI consultants, better follow up of reported cases is planned for ensuring case investigation and causality assessment review.

**Some of the activities which are being planned to improve AEFI surveillance are:**

1. Piloting AEFI surveillance system for reporting of all serious and non-serious AEFIs in two districts.
2. Piloting an electronic database and reporting system for AEFIs in two states for further scale up to all states.
3. Improved coordination with pharmacovigilance partners (NRA, CDSCO, IPC, etc.) for sharing of information on AEFIs reported by manufacturers and Adverse Drug Reactions monitoring centres.
4. Increased participation of private sector in AEFI reporting and surveillance.

Annex 3: Costing and Financing of Immunization Program in India

**Report on Costing and Financial Sustainability of the India Immunization Programme**

**I. Introduction**

India is at an important time in the development of its Universal Immunization Programme (UIP). It is planning several improvements such as the addition of many new and underutilized vaccines as well as adding new staff at different administrative levels. It will probably also be graduating from GAVI support since its Gross National Income (GNI) per capita[[1]](#footnote-1) will be too high to be eligible and will need to secure other sources of financing. As a result, information on the costs and sources of financing for the UIP will be particularly important for policy-makers to make informed decisions on phasing-in strategies and timing of these programme improvements.

The report on costing and financial sustainability of the India Immunization Programme was developed during June to December 2013, under the auspices of the Immunization Technical Support Unit (ITSU) in India and assisted by the immunization partners WHO and UNICEF. The team that collected and analyzed the data was led by a research scientist from the Public Health Foundation of India and consisted of Government of India Ministry officials, and experts from the Immunization Technical Support Unit (ITSU-MoHFW) and the immunization partners. Data were collected during June to September 2013. Then meetings were held with the Ministry officials to go over the preliminary findings and assumptions to be made in the analysis. Finally, the data were analyzed and put into a report during September to December 2013.

**2. Summary of Findings on Baseline Expenditures**

The main findings of the cost analysis are the following:

* Total baseline expenditure was INR 3,446 crore ($718 million), including shared personnel costs,[[2]](#footnote-2) and INR 2,131 crore ($444 million) without shared costs.
	+ Expenditures on the routine programme were INR 1,253 crore ($261 million) and, on the supplemental immunization activities (SIAs), were INR 878 crore ($182 million).
* Table 1 shows total baseline expenditures with shared costs and selected indicators on cost per output and programme financing.

**Table 1. Baseline Expenditures and Selected Indicators, 2012.**

|  |  |  |
| --- | --- | --- |
| Baseline Indicators | Total Expenditures USD | Total Expenditures INR |
| Routine Immunization only | 261,089,884 | 12,532,314,431 |
| Campaigns | 182,995,523 | 8,783,785,120 |
| Total immunization specific expenditure (A) | 444,085,407 | 21,316,099,550 |
| Total shared cost (B) | 273,942,919 | 13,149,260,100 |
| Grand Total ( A + B) | 718,028,326 | 34,465,359,650 |
| Per capita | 0.2 | 9.6 |
| Per DTP3 child | 14 | 672 |
| % National funding | 90% | 90% |
| % Total health expenditures | 1% | 1% |
| % Govt. health expenditures | 2% | 2% |
| % GDP | 0.03% | 0.03% |

**3. Details of Baseline Programme Cost and Financing**

The year 2012 is the baseline for the cost and financing projections since it has the most recent complete information. The actual expenses of the government and the immunization partners were taken into account for the baseline cost calculation.

Table 2 shows the baseline cost profile. In 2012, the total estimated cost of the UIP was INR 3,446 crore ($718 million), including shared cost. Shared personnel cost (those who spent less than 100% of their time for immunization) contributed the maximum in total expenditure (38%) while all routine recurrent cost contributed 36%. The contribution of SIAs was 25% in total cost. The detailed expenditure on shared personnel cost is provided in Table 3. Vaccines and injection supplies under routine recurrent cost are those used for routine immunization only. The amount spent on vaccines and injection supplies for supplementary immunization has been provided under SIAs. Personnel cost includes salaries and benefits for all who spent 100% of their time for immunization starting from the national level. Transport cost included the operational cost of Teeka express, vaccine handling cost at GMSD and the petrol, oil, lubricant for vaccine transport. It was assumed that there were a total of 700 vaccine vans (250 4WD, 450 2WD) and 120 Teeka express in 2012. Training cost included the actual expenditure of the government on training as well as the training expenses by immunization partners. The components and detailed expenditures under social mobilization, programme management and other routine recurrent cost are shown in Tables 4, 5 and 6 respectively.

**Table 2. Baseline Universal Immunization Program Costs, 2012**

|  |  |  |  |
| --- | --- | --- | --- |
| **Routine Recurrent Costs** | **2012 ($USD millions)** | **2012 (INR crore)**  | **%** |
| Vaccines | 59.92 | 287.60 | 8.3 |
| Injection Supplies | 16.46 | 79.00 | 2.3 |
| Personnel | 11.40 | 54.72 | 1.6 |
| Transport  | 27.09 | 130.02 | 3.8 |
| Cold chain maintenance | 9.24 | 44.34 | 1.3 |
| Training | 5.94 | 28.53 | 0.8 |
| Social mobilization, advocacy, communication activities | 50.23 | 241.10 | 7.0 |
| Disease surveillance | 18.97 | 91.04 | 2.6 |
| Programme management | 9.67 | 46.40 | 1.3 |
| Other routine recurrent costs | 37.91 | 181.96 | 5.3 |
| **Subtotal** | **246.81** | **1,184.71** | **34.4** |
| **Capital Costs**Cold chain equipment | 14.28 | 68.52 | 2.0 |
| **Subtotal** | 14.28 | 68.52 | 2.0 |
| **Total Routine Costs (without shared costs)** | **261.09** | **1,253.23** | **36.4** |
| **Supplemental Immunization Activities (SIAs)** |
| Polio Vaccines and Injection suppliesOperational costsTotal | 95.2253.00**148.21** | 457.04254.37**711.41** | 13.2 7.4 **20.6** |
| MeaslesVaccines and Injection suppliesOperational costsTotal | 15.1413.11**28.25** | 72.6962.91**135.59** | 2.11.8**3.9** |
| JEVaccines and injection suppliesOperational costsTotal | 4.851.68**6.54** | 23.308.08**31.38** | 0.70.2**0.9** |
| **Subtotal SIAs** | **183.00** | **878.38** | **25.5** |
| **Shared personnel costs** | **273.94** | **1,314.93** | **38.1** |
| **GRAND TOTAL** | **718.03** | **3,446.54** | **100.0** |

**Table 3: Details of shared personnel cost in 2012**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Shared personnel | Numbers in 2012\* | Salary per month (INR) | % of time spent on immunization | INR Crore | USD million |
| MO (in charge) at block level  | 4833 | 35,000 | 10% | 20.30 | 4.23 |
| Data entry operators at block level  | 4833 | 8,000 | 5% | 2.32 | 0.48 |
| MO (in charge) at PHC level  | 24049 | 35,000 | 10% | 101.01 | 21.04 |
| ANM  | 207578 | 12,500 | 33% | 1027.51 | 214.06 |
| MPW  | 14648 | 12,500 | 33% | 72.51 | 15.11 |
| LHV  | 16109 | 12,500 | 33% | 79.74 | 16.61 |
| Data entry operators at PHC level  | 24049 | 8,000 | 5% | 11.54 | 2.40 |
| Total | 296,099 |   |   | **1,314.93** | **273.94** |

\* Source: Rural Health Statistics in India, 2012.

**Table 4: Details of expenditure on social mobilization, advocacy and communication activities in 2012**

|  |  |  |
| --- | --- | --- |
| **Cost components** | INR Crore |  USD million |
| ASHA incentives for social mobilizations | 194.62 | 40.55 |
| Printed materials (banners, posters, IEC materials) BCC tool | 24.98 | 5.20 |
| Advocacy and communication (UNICEF) | 5.73 | 1.19 |
| SMNet (UNICEF) | 15.77 | 3.29 |
| **Total** | **241.10** | **50.23** |

**Table 5: Details of programme management expenditure in 2012**

|  |  |  |
| --- | --- | --- |
| **Cost components** | INR Crore |  USD million |
| Evaluations, program reviews and assessment meetings | 10.97 | 2.29 |
| Office supplies and consumables | 0.31 | 0.06 |
| Micro planning | 2.17 | 0.45 |
| Immunization Technical Support Unit (ITSU) | 4.77 | 0.99 |
| Operational cost of polio and other VPDs (UNICEF) | 9.36 | 1.95 |
| Operational cost of polio and other VPDs (WHO) | 18.83 | 3.92 |
| **Total** | **46.40** | **9.67** |

**Table 6: Details of expenditure for other activities under routine immunization in 2012**

|  |  |  |
| --- | --- | --- |
| **Cost components** | INR Crore |  USD million |
| Service provision in underserved and hard to reach areas (including slums) | 18.39 | 3.83 |
| ASHA Incentives | 132.29 | 27.56 |
| Planning, supportive supervision and monitoring  | 6.56 | 1.37 |
| Intensification of Routine Immunization (WHO) | 0.41 | 0.09 |
| Research studies (Govt + WHO) | 4.05 | 0.84 |
| Measles, JE control programme (UNICEF) | 1.92 | 0.40 |
| Other state specific activities | 18.35 | 3.82 |
| **Total** | **181.96** | **37.91** |

Figure 1 shows the detail distribution of baseline routine immunization cost without shared cost. Among the routine recurrent cost, vaccine cost was the highest (23%) followed by social mobilization, advocacy and communication activities (19%), other recurrent cost (15%) and transport (10%).

**Figure 1. Baseline Cost Profile (without shared costs), 2012**

Figure 2 shows the sources of financing in the baseline year for the UIP. The Government of India paid for most of the programme expenditures (90%). Other sources of financing were WHO (4%), UNICEF (3%),[[3]](#footnote-3) and GAVI (3)%.

**Figure 2. Baseline Financing, Indian Immunization Program, 2012**

**4. Recurrent Costs – Structure and analysis**

**4.1 Demographic projections**

The calculation of the birth cohort and other target groups is based on Indian government estimates and on the latest census of India (Table 7). The population growth rate is 1% and the infant mortality rate is assumed to decrease from 44 per 1000 in 2012 to 25 per 1000 in 2017.

**Table 7. Key Demographic Variables for India, 2012 and 2017**

|  |  |  |
| --- | --- | --- |
| Demographic Variable | 2012 | 2017 |
| Birth Cohort | 24,676,883 | 26,323,130 |
| Population Growth Rate | 1% | 1% |
| Infant Mortality Rate | 44 | 25 |
| Childbearing age women | 15% | 15% |

**4.2 Vaccine and injection supplies**

The vaccine prices used for the baseline and projections are shown in Table 8. The costs are a mixture of GAVI prices as well as prices obtainable by the government of India. India is unique since it has many local manufacturers from which it can purchase vaccines for the national programme.

**Table 8. Prices per Dose and Expected start year, and Implementation Strategy for Vaccines**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Vaccines** | **Price per dose** | **Expected start year** | **Implementation strategy** | **Sources of financing** |
| BCG | USD 0.05 | NA | Routine | Govt |
| Hep B (birth dose) | USD 0.05 | NA | Routine | Govt |
| OPV | USD 0.06 | NA | Routine | Govt |
| Measles | USD 0.16 | NA | Routine | Govt |
| DTP | USD 0.04 | NA | Routine | Govt |
| TT | USD 0.02 | NA | Routine | Govt |
| JE | USD 0.18 | NA | Campaign | Govt |
| DTP-Hib-HepB (penta) | USD 2.11 | 2014-15 | Roll out to all states2014- 11 states2015– 16 states | GAVI up to 2015 |
| IPV | USD 1.00 | 2015-16 | Pan India | Govt |
| MR | USD 0.50 \* | 2014-15 | Pending NTAGI endorsement. Start with campaign (1-15 yr olds) in 2014. 2015 onwards under routine at 9 months or 1.5 years old. | Govt |
| Rotavirus | USD 1.00(Bharat) | 2016-17 | Pending NTAGI | Govt |
| Pneumococcal | USD 3.30\*\* | 2017 | Pending NTAGI | Govt |

Sources: \*MR: <http://www.gavialliance.org/library/news/press-releases/2013/over-700-million-children-in-49-countries-to-be-protected-against-measles-and-rubella/>

\*\*Pneumococcal: [http://www.pfizer.com/news/press-release/press-release-detail/pfizer signs new\_ agreement\_with\_unicef\_to\_supply\_a\_total\_of\_up\_to\_740\_million\_doses\_of\_prevenar\_13\_for\_the\_world’s\_poorest\_countries\_through\_2025](http://www.pfizer.com/news/press-release/press-release-detail/pfizer%20signs%20new_%20%20agreement_with_unicef_to_supply_a_total_of_up_to_740_million_doses_of_prevenar_13_for_the_world%27s_poorest_countries_through_2025)

Figure 3 and Table 9 show projected resource requirements for vaccines from 2013 until 2017. The vaccine wastage rates are given in Annex Table A.1. During the first four years, the resource requirements are highest for pentavalent vaccine as it is scaled up in the country. However, by 2017, the larger share of resource requirements will shift to PCV vaccine if the vaccine is introduced nationwide in 2017.

Introduction of IPV and MR in 2015 will increase vaccine resource requirements from INR 633 crore in 2014 to INR 1,455 crore in 2015 (Table 9). Adding rotavirus vaccine in 2016 will increase resource requirements for vaccines by INR 315 crore while introducing PCV vaccine in 2017 will double the requirements for vaccines. It should be noted, though, that the estimate of resource requirements in 2017 is probably an over-estimate since it assumes that PCV will be introduced nationwide although the vaccine will probably be phased-in over time.

Another factor that will affect the impact of the total resource requirements for India is that it will likely be graduating from GAVI support during the period of the cMYP. Thus, it will have to secure a larger proportion of funding for new vaccines as well as for pentavalent.

**Figure 3. Resource requirements for Vaccines, Routine Immunization, 2013-2017**

Table 9 also shows pentavalent vaccine will be gradually scaled-up until it is provided nationwide in 2015. As pentavalent vaccine is scaled-up, DTP and Hepatitis B (primary schedule) vaccines will be phased out while the birth dose of Hepatitis B vaccine will continue. Resource requirements for pentavalent vaccine are projected to decrease in 2016 as the price per dose is assumed to decline from $2.11 to $1.54. Annex Table A.2 provides the resource requirements for vaccines in USD.

**Table 9. Vaccine Resource Requirements for Routine Immunization by Type and Year, INR Crore, 2013-2017**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Vaccines** | **2013** | **2014** | **2015** | **2016** | **2017** |
| BCG  | 14.9 | 15.9 | 15.9 | 16.1 | 16.3 |
| Hep B (Birth dose) | 6.5 | 6.1 | 7.1 | 8.2 | 9.3 |
| OPV | 37.4 | 33.8 | 35.6 | 37.7 | 40.7 |
| DTP-HepB-Hib (pentavalent) | 312.7 | 459.9 | 858.1 | 807.4 | 773.8 |
| DTP | 21.0 | 12.7 | 8.0 | NA | NA |
| Measles | 53.4 | 54.2 | 59.6 | 64.2 | 68.8 |
| TT | 7.6 | 6.6 | 6.7 | 7.1 | 7.1 |
| JE | 37.4 | 30.5 | 31.1 | 31.7 | 32.2 |
| Hep B (primary schedule) | 19.7 | 13.2 | 7.5 | NA | NA |
| IPV | NA | NA | 230.3 | 203.1 | 203.4 |
| MR | NA | NA | 195.1 | 184.0 | 223.0 |
| Rotavirus | NA | NA | NA | 410.4 | 474.0 |
| PCV | NA | NA | NA | NA | 1738.8 |
| **Total** | **510.6** | **632.8** | **1,455.1** | **1,769.9** | **3,587.1** |

Table 10 shows the resource requirements for vaccines for SIAs by antigen and year in INR crore (see Annex Table A.3 for US$). Polio SIAs are assumed to take place every year while measles (monovalent) SIAs end in 2013. Starting in 2015, as part of the commitments to reach the target of measles elimination in the region by 2020, UIP will introduce the measles-rubella vaccine through SIAs phased between 2015 and 2016. As JE campaign will depend on the epidemiological situation, we couldn’t project any cost for the same.

**Table 10. Vaccine Resource Requirements for Supplementary Immunization Activities by Type and Year, INR crore, 2013-2017**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Vaccine** | **2013** | **2014** | **2015** | **2016** | **2017** |
| OPV | 315.4 | 279.2 | 279.2 | 242.4 | 242.4 |
| Measles | 39.7 | NA | NA | NA | NA |
| MR | NA | NA | 704.1 | 704.1 |  NA |
| **Total** | **355.2** | **279.2** | **983.2** | **946.5** | **242.4** |

**4.3 Personnel Costs**

Resource requirements for health care staff are projected based on assumptions about salary ranges, the percentage of time spent on immunization, increase in number of staff per year and annual increases in salary levels. The assumptions on staffing are shown in annex Tables A.4 to A.6. The assumptions about the need for new staffing are based on the findings and recommendations of the 2011 HR Needs Assessment Study (GoI 2011). The study found inadequacies in staffing for the UIP at the national and state levels. Thus, the estimates include recommended additional staff at MOH level  (three deputy commissioners and 12 assistant commissioners) and at State level (two programme officers; one MIS officer; one administrative and finance officers; one data analyst; two cold chain / vaccine handler and vaccine store technicians in each state). At the state levels, the estimates also include some new immunization staff such as cold chain / vaccine handler and vaccine store technicians.

Apart from full time staff, there are shared personnel who work for immunization. Figure 4 shows that resource requirements on shared personnel are much higher than those of full-time staff and are increasing due to annual salary increments and additions to the number of total staff. The amount spent on full time personnel will increase from INR 55 crore in 2012 to INR 101 crore in 2017 if all new staff are hired as per assumptions given in annex tables. On the other hand, the shared personnel cost will increase from INR 1,315 crore in 2012 to INR 2,509 crore in 2017 (Tables 2 and 11).

**Figure 4. Personnel Costs, 2012-2017, INR Crore**

**4.4 Training, Programme Management, Disease Surveillance, Social Mobilization, Advocacy and Communication**

***Training:*** The government is the main source of funding for trainings (Figure 5). However, the immunization partners such as WHO and UNICEF also implement some training programmes on immunization. The amount spent by the government on training will increase from INR 21 crore in 2012 to INR 42 crore in 2017. The resource requirements are projected to double by 2017 because of the increased need for trainings due to recruitment of health workers, new vaccine introduction and planned SIAs.

**Figure 5. Training Costs, 2012 -2017, INR Crore**

***Programme management:*** Expenditure under this category includes evaluations and meeting related expenses, micro planning, office supplies and consumables, operational cost of immunization technical support unit (ITSU) and operational cost of different vaccine preventable diseases. Much of the programme management is supported through the ITSU. The Ministry of Health and Family Welfare (MoHFW) and the Public Health Foundation of India (PHFI) established ITSU in April 2012 with support from the Bill & Melinda Gates Foundation (BMGF). The primary mandate of ITSU has been to strengthen human resource capacity for the UIP and to provide technical and managerial support to MoHFW for revitalizing, and successfully implementing India’s UIP. ITSU is currently focusing its efforts towards improving immunization coverage in four states of India: Bihar, Madhya Pradesh, Rajasthan and Uttar Pradesh, which have been identified as high priority states with low immunization coverage.

Figure 6 shows the baseline costs for programme management in 2012 as well as the projected resource requirements for 2013-2017. The projected resource requirements for programme management increase rapidly from 2013-2016 due to increased funding under GAVI HSS. The GAVI HSS grant which has been channelled to UNDP from 2013-14 is projected to be taken over by the government in 2017. This will result an increase in government spending on programme management from INR 12 crore in 2012 to INR 183 crore in 2017.

**Figure 6. Programme Management Costs, 2012-2017, INR Crore**

***Disease Surveillance:*** WHO is the implementer of the disease surveillance activities. Resource requirements for disease surveillance activities are expected to more than double by 2017, due to introduction of new vaccines. The requirements for surveillance will increase from INR 132 crore in 2013 to INR 259 crore in 2017 and will be fully financed by WHO (2013-2016 as “secure” funding; whereas 2017 is set as “probable” funding). Donor funding in this area will be phasing out and the government will need to increase its investment in disease surveillance.

***Social Mobilization, Advocacy and Communication Activities:*** Under this category, we considered ASHA incentives for social mobilization, government expenditure for printing materials such as banners, posters etc., and advocacy, communication activities and SMNet cost for UNICEF. Government is the main source of financing for social mobilization activities and is projected to double its spending by 2017 (Figure 7). In 2012, the actual expenditure of the government under this head was INR 220 crore which is projected to be INR 451 crore in 2017.

**Figure 7. Social Mobilization, Advocacy and Communication Activities Costs, 2012-2017, INR Crore**

***Other Routine Recurrent Cost:*** We considered service provision in underserved / hard to reach areas (including slums), ASHA incentives for complete immunization, planning, supportive supervision and monitoring activities, intensification of routine immunization, research related expenses and different state specific activities under this category. Government is the main source of funding for these activities while WHO and UNICEF also support some of these (Figure 8). Government expenditure under this category will increase from INR 173 crore in 2012 to INR 270 crore in 2017.

**Figure 8: Other Routine Recurrent Costs, 2012-2017, INR Crore**

**4.5 Cold Chain**

The cold chain related projections are based on the current assessment of cold chain situation in India and future needs. The assumptions are shown in Annex Table A.7. It should be noted that the number of existing cold chain equipment includes both the government purchases as well as purchased through partner support (UNICEF). It should also be noted that KFW is providing 180 crore for cold chain equipment in 2014-15. We present the cold chain maintenance related expenditure in Figure 9. Government finances the most for cold chain maintenance and the requirement increases from INR 39 crore in 2012 to INR 218 crore if all assumptions related to cold chain requirement in India are fulfilled.

**Figure 9: Cold Chain Maintenance Costs, 2012-2017, INR Crore**

**5.0. Future Resource Requirements**

Table 11 and Figure 10 show the future resource requirements for the routine immunization programme by programme components. Total requirements for the five year period are INR 34,336 crore ($5,282 million). Resource requirements for vaccines and logistics increase rapidly from INR 510 crore in 2013 to INR 3,587 crore in 2017 as new vaccines are assumed to be introduced in the programme. The amount in USD is presented in Annex Table A.8.

**Table 11. Resource Requirements for India National Immunization Programme, INR crore, 2013-2017**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Cost Category** | **2013** | **2014** | **2015** | **2016** | **2017** | **Total** |
| Vaccines (routine vaccines only) | 510.6 | 632.8 | 1,455.1 | 1,769.9 | 3,587.1 | 7,955.5 |
| Injection supplies | 71.8 | 72.3 | 89.7 | 84.7 | 102.9 | 421.4 |
| Personnel | 78.7 | 84.7 | 89.9 | 95.5 | 101.4 | 450.2 |
| Transportation | 203.4 | 234.9 | 271.3 | 313.3 | 361.9 | 1,384.8 |
| Cold chain and other capital equipment maintenance | 116.3 | 149.4 | 175.9 | 207.0 | 220.9 | 869.4 |
| Training | 30.8 | 36.5 | 41.5 | 47.4 | 54.1 | 210.3 |
| Social mobilization / advocacy / communication activities | 284.1 | 373.8 | 421.3 | 467.9 | 483.1 | 2,030.3 |
| Disease surveillance | 132.9 | 161.4 | 186.4 | 215.3 | 248.7 | 944.7 |
| Programme management | 94.1 | 225.5 | 215.4 | 231.7 | 248.5 | 1,015.2 |
| Other routine recurrent costs | 219.3 | 248.4 | 266.3 | 282.0 | 300.2 | 1,316.3 |
| Cold chain equipment | 131.4 | 198.2 | 269.2 | 343.6 | 419.7 | 1,362.1 |
| Supplemental Immunization Activities | 789.6 | 740.6 | 1,520.7 | 1,522.6 | 813.5 | 5,386.9 |
| Shared personnel costs | 1,907.1 | 2,042.5 | 2,187.5 | 2,342.8 | 2,509.1 | 10,989.0 |
| Total | 4,570.0 | 5,201.0 | 7,190.2 | 7,923.9 | 9,451.0 | 34,336.1 |

**Figure 10. Total Resource Requirements for UIP, 2013-2017, INR Crore**

**6.0. Future Financing and funding gap analysis**

Figure 11 shows the future secure financing and gaps in financing for 2013-2017. This figure does not include other financing that is probable[[4]](#footnote-4). The largest source of financing for UIP is the government. The financing gap increases from INR 56 crore in 2013 to 815 crore in 2015 and further to INR 3,537 crore in 2017 and reflects the fact that funding has not yet been secured for the new vaccines to be introduced during those years.

**Figure 11. Future Secure Financing and Funding Gaps**

Figure 12 shows the programme financing with probable as well as secure funding. In this scenario, the government and GAVI will provide financing for the new vaccines. As can be seen, if probable funding is included, funding gap is insignificant.

**Figure 12. Future Secure and Probable Financing and Funding Gaps, 2013-2017**

**Conclusion**

Total UIP costs in 2012 were INR 3,446 crore ($718 million), including shared health systems costs, and INR 2,131 crore ($444 million) without shared costs. Expenditures on the routine program were INR 1,253 crore ($261 million) and, on the supplemental immunization activities, were INR 878 crore ($182 million). The cost per capita for the programme was INR 9.6 ($0.2) and cost per DTP3 child was INR 672 ($14).

Total projected resource requirements for 2013-2017 are INR 34,336 crore ($5,282 million). The resource requirement will increase from INR 4,570 crore in 2013 to INR 9,451 crore in 2017 due to the new vaccine introduction and other programme improvements. Supplementary immunization activities are projected to cost INR 5,387 crore ($829 million) during the five year period. However, it should be noted that the vaccine requirement in 2017 is overestimated as we assumed PCV will be introduced throughout the country in 2017 while probably it will be introduced in a phased manner. Secondly, the total resource requirement is under estimated as we couldn’t project anything for JE campaign in coming years as the campaign will depend on the epidemiological situation.

The majority of the UIP resource requirements is financed by the Government of India. External partners do, however, provide critical funding support to technical partners such as WHO and UNICEF for training, disease surveillance, IEC/social mobilization. As the total resource requirement increases steadily, the funding gap also increases and in order to fill this gap, the government health budget needs to increase in the coming years.

One way that the UIP could improve its financial sustainability is through improving programme efficiency – i.e. lower the costs of programme components, reduce wastage, or introduce less resource-intensive means of service delivery. The programme should investigate some potential strategies to improve programme efficiency, particularly since India will be taking over more of the costs of the programme after the funding from GAVI and other donors ends.

**Annex**

**A.1 Wastage rates**

Proposed wastage rates for single and ten dose vials are in line with WHO/UNICEF recommendations and others are as per government wastage rate calculations.

**Table A.1. Assumptions on Wastage Rates by Antigen**

|  |  |  |
| --- | --- | --- |
| **Vaccine** | **2013** | **2017** |
| BCG | 50% |  |
| Hep B (birth dose) | 15% |  |
| OPV | 25% | 10% |
| DTP-Hep B- Hib (Penta) | 25% | 10% |
| DTP3 | 25% |  |
| Measles | 25% |  |
| MR | 25% | 25% |
| Hepatitis B | 25% | 10% |
| IPV | 30% | 30% |
| JE | 25% |  |
| TT | 25% | 10% |

**Table A.2. Vaccine Resource Requirements for Routine Immunization by Type and Year, US$ millions, 2013-2017**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Vaccines | 2013 | 2014 | 2015 | 2016 | 2017 |
| BCG | 2.3 | 2.4 | 2.4 | 2.5 | 2.5 |
| Hep B (Birth dose) | 1.0 | 0.9 | 1.1 | 1.3 | 1.4 |
| OPV3 | 5.8 | 5.2 | 5.5 | 5.8 | 6.3 |
| DTP-Hep B-Hib (Pentavalent) | 48.1 | 70.8 | 132.0 | 124.2 | 119.0 |
| DTP | 3.2 | 1.9 | 1.2 | 0.0 | 0.0 |
| Measles | 8.2 | 8.3 | 9.2 | 9.9 | 10.6 |
| TT | 1.2 | 1.0 | 1.0 | 1.1 | 1.1 |
| JE | 5.8 | 4.7 | 4.8 | 4.9 | 4.9 |
| Hep B (primary schedule) | 3.0 | 2.0 | 1.2 | NA | NA |
| IPV | NA | NA | 35.4 | 31.3 | 31.3 |
| MR | NA | NA | 30.0 | 28.3 | 34.3 |
| Rotavirus | NA | NA | N | 63.1 | 72.9 |
| PCV | NA | NA | N | NA | 267.5 |
| Total | 78.5 | 97.4 | 223.9 | 272.3 | 551.9 |

**Table A.3. Vaccine Resource Requirements for Supplementary Immunization Activities by Type and Year, US$ millions, 2013-2017**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Vaccine** | **2013** | **2014** | **2015** | **2016** | **2017** |
| OPV | 48.5 | 42.9 | 42.9 | 37.3 | 37.3 |
| Measles | 6.1 | NA | NA | NA | NA |
| MR | NA | NA | 108.3 | 108.3 | NA |
| **Total** | **54.6** | **42.9** | **151.2** | **145.6** | **37.3** |

**Table A.4. Assumptions on health staff on salaries, annual increases in number and salary, and time spent on immunization**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Staff category** | **% time spent on Immunization** | **Salary range** | **Increase in number per year** | **Salary increase per year** |
| ANM, MPW, LHV | 33% | Rs. 10000 – Rs. 15000 per month | 2% | 5% |
| MOs | 10% | Rs. 35,000 – Rs. 45,000 per month | 2% | 5% |
| SIO / DIO | 100% | Rs. 40,000 – Rs. 50,000 per month |  NA | 5% |
| State cold chain officer | 100% | Rs. 30,000 – Rs. 40,000 per month | NA | 5% |
| ASHAs | Based on sessions |  | 2% increase in sessions per year |  |
| Data entry operators from PHC to block level | 5% | Rs. 8,000 – Rs. 15,000 per month |  | 5% |
| Cold chain technician | 100% | Rs. 12,500 per month |  | 5% |
| At Ministry | 15 staff (100%)(including contract staff) | 991,200 per annum (Total) |  | 5% |
| At Ministry (Partner support) | 8 staff (100%) | Rs. 637,700 per annum (Total) |  | 5% |
| **AEFI related staff (from 2013-14)** |
| Research Consultant | 100% | Rs. 50,130 per month |  | 5%  |
| Data analyst | 100% | Rs. 22,355 per month |  | 5% |
| Admin staff | 100% | Rs. 12,496 per month |  | 5% |
| NRHM consultants | 100% | Rs. 75,000 per month |  | 5% |

**Table A.5. Assumptions on New Immunization Staff**

|  |  |  |  |
| --- | --- | --- | --- |
| **Staff category** | **Salary range** | **Where posted** | **Year of recruitment** |
| District vaccine logistics manager | Rs. 15,000 – Rs. 22,000 per month | Should be one in each district | 2014-15 |
| Cold chain / vaccine handler | Rs. 15,000 – Rs. 22,000 per month | Two in each state vaccine store | 2014-15 |
| Divisional Vaccine logistics manager | Rs. 35,000 per month | One handles four districts | 2014-15 |
| State HEMR unit with engineers supported by state vaccine store technician | Rs. 30,000 per month | Two in large states – population 40 million and above; one in small states | 2014-15 |
| WIC/WIF handler in govt. medical store depot (in shift) | Rs. 8,000 per month | 4 in each depot (semi- skilled helper) | 2014-15 |
| Refrigerator technician at Govt. medical store depot | Rs. 12,500 per month | one in each depot | 2014-15 |
| State vaccine logistics manager  | Rs. 35,000 per month | One in each state | 2014-15 |
| Vaccine logistics manager at GMSD | Rs. 45,000 per month | One each at GMSD | 2014-15 |

**Table A.6. New proposed staff in Mavalankar report (these positions will be started filling up from 2014 onwards in phased manner)**

|  |  |
| --- | --- |
| **Staff category** | **Gross salary per month** |
| Deputy Commissioners at ministry (3 Nos.) | Rs. 200,000 |
| Assistant commissioners at ministry (12 nos.) | Rs. 150,000 |
| State programme officer (immunization) (2 Nos. in each state) | Rs. 35,000 – Rs. 45,000 |
| State logistics manager (immunization) (1 No. in each state) | Rs. 35,000 – Rs. 45,000 |
| State MIS manager (immunization) (1 No. in each state) | Rs. 35,000 – Rs. 45,000 |
| Administration and Finance officer (immunization) (1 No. in each state) | Rs. 35,000 – Rs. 45,000 |
| State immunization technology and research officer (1 No. in each state) | Rs. 35,000 – Rs. 45,000 |
| Quality control and AEFI officer (immunization) (1 No. in each state) | Rs. 35,000 – Rs. 45,000 |
| IEC officer (immunization) (1 No. in each state) | Rs. 35,000 – Rs. 45,000 |
| Assistant cold chain officer (1 No. in each state) | Rs. 30,000 – Rs. 35,000 |
| Store officer (immunization) (1 No. in each state) | Rs. 30,000 – Rs. 35,000 |
| Data analyst (1 No. in each state) | Rs. 15,000 – Rs. 18,000 |

**Table A.7 Cold chain related assumptions**

|  |  |  |
| --- | --- | --- |
|  | **Assumptions** | **Sources** |
| Number of cold chain points (existing) | 27,000 | State report NCCMIS |
| Cold chain points required | One cold chain point per 30,000 population (2011 census) | CCO meeting minutes |
| Total cold chain points required | 40,340 | CCO meeting minutes |
| New cold chain points required | 28,238 | CCO meeting minutes |
| Present number of ILR in cold chain points | 27,000 (assuming one in each cold chain point) | CCO meeting minutes + standard assumptions |
| Present number of DF in cold chain points | 27,000 (assuming one in each cold chain point) | CCO meeting minutes + standard assumptions |
| Existing ILR/DF needs replacement | 50% (27,000 nos.) needs immediate replacement – should be replaced within 2-3 years | Based on NCCMIS of ageing and useful life of 10 years |
| New ILR / DF required at cold chain points | The required number (56,476 nos.) will be procured within 3 years | Based on NCCMIS of ageing and useful life of 10 years |
| Cold chain points need solar / hybrid | 30% of all PHCs will have less than 8 hours electricity; hence need solar or hybrid50% of these will be hybrid where there is supply for 4-6 hours | NCCMIS |
| Existing solar / hybrid | Solar – 270 nos.; Hybrid – 300 nos. | State CCO Report  |
| Solar / hybrid | The required number (Solar – 5,781 nos.; hybrid – 5,751 nos.) will be procured in 2-3 years | NCCMIS |
| At GMSD level | At each GMSD, 8 WIC of 40 cub. Mt; 4 WIF to accommodate rotavirus / IPV vaccine | National EVM, 2013 |
| Present number of WIC at GMSD | 8 | National EVM, 2013 |
| Present number of WIF at GMSD | 6 | National EVM, 2013 |
| Required WICs/WIFs | Required number at GMSD level (22 nos. WICs / 10 nos. WIFs) will be available in 2 years | National EVM, 2013 |
| At state vaccine store level | At each vaccine store, at least 4 WIC and 2 WIF of 40 cu. Mt | National EVM, 2013 |
| WIC/WIF needs replacement at state vaccine store level | 50% of the total needs replacement (117 nos.) – should be replaced within 2-3 years | NCCMIS |
| At divisional vaccine store level | At each store, at least 4 WIC of 40 cu. mt and 2 WIF of 20 cu. mt | Personal discussion with UNICEF and ministry |
| WIC/WIF required replacement at divisional store level | 50% of the total needs replacement (62 nos. each) – to be replaced within 2-3 years | Personal discussion with UNICEF and ministry |
| At district vaccines stores | District with population more than 20 lakh, one WIC and 6 DFs are requiredDistricts with population less than 20 lakh, 8 large ILR and 4 large DF | Personal discussion with UNICEF and ministry |
| WIC/WIF/ILR/DF required replacement at district store level | 231 WICs; 1,386 DFs; 3,272 ILRs and 1,636 large DFs need replacement within 2-3 years | NCCMIS |
| Cold boxes (large and small) at cold chain points | Every cold chain points (30,000 population) should have two 20 lit cold boxes; and four 5 lit cold boxes | CCO Meeting minutes |
| Cold boxes need replacement | 30% (40,340 nos. large; 80,680 nos. small) needs immediate replacement – should be replaced within 2-3 years | NCCMIS |
| Cold boxes at state / divisional vaccine stores | for 30000 population, 2 large cold boxes | Personal discussion with UNICEF and ministry |
| Cold boxes need replacement | 30% (1,034 nos.) needs immediate replacement – should be replaced within 2-3 years | NCCMIS |
| Cold boxes at district vaccine stores | Per store, 20 large cold boxes are required | Personal discussion with UNICEF and ministry |
| Cold boxes need replacement | 30% (6,400 nos.) need immediate replacement – should be replaced within 2-3 years | Personal discussion with UNICEF and ministry |
| Cold boxes at GMSD level | 50 large cold boxes are required at the GMSD level | Personal discussion with UNICEF and ministry |
| Cold boxes need replacement | 30% (100 nos.) need immediate replacement – should be replaced within 2-3 years | Personal discussion with UNICEF and ministry |
| Vaccine carrier | Each ANM should have 2 vaccine carriers | Personal discussion with UNICEF and ministry |
| Carriers replacement | 20% every 3 years (presently 103,789 nos. need replacement). Should be replaced within 2-3 years | Personal discussion with UNICEF and ministry |
| Ice packs | Each vaccine carrier should have 4 ice packs | Personal discussion with UNICEF and ministry |
| Ice packs replacement | Every 2 years, 50% ice packs should be replaced. (830,312 nos. needs immediate replacement – should be replaced within 2 years) | Personal discussion with UNICEF and ministry |
| Voltage stabilizer | Every ILR/DF will have its own stabilizer  | NCCMIS |
| Stabilizer needs replacement | 50% (31,385 nos.) needs immediate replacement – will be replaced within 2-3 years | NCCMIS |
| Tool kit | Each technician will have one toolkit – should be replaced within 3-5 years | NCCMIS |
| Total number of technicians / toolkit | 427 nos. | NCCMIS |
| Toolkit supplied by UNICEF | 200 nos. | NCCMIS |
| Toolkit to be procured | 227 nos. – To be procured within 2 years  | NCCMIS |
| Temperature monitoring device | Every ILR/DF should have one temperature monitoring device – should be replaced in 5 years | Personal discussion with UNICEF and ministry |
| Total number required | 75,615 nos.; should be procured within 2-3 years | Personal discussion with UNICEF and ministry |
| Spare parts | Every year 2 million dollar – presently supplied by UNICEF | Personal discussion with UNICEF and ministry |
| Wireless data logger required | One each in each WIC / WIF – total required – 743 nos. | NCCMIS / NEVM |
| UNICEF supply | 54 Nos. | UNICEF |
| Wireless data logger | The required number 689 will be procured in 3 years | Personal discussion with UNICEF and ministry |

**Other cold chain related assumptions**

Price of ILR/DF (large) – Rs. 50,000

Price of ILR/DF (small) – Rs. 40,000

Price of solar – Rs. 200,000

Price of hybrid – Rs. 13, 00,000 (this is an alternative source of power – supports entire PHC with a load of 2.5 KVA including cold chain equipment)

Price of WIC / WIF of 40 cu. Mt – Rs. 18, 00,000 (including procurement / installation / 5 years CMC)

Price of WIF of 20 cu. Mt – Rs. 15, 00,000 (including procurement / installation / 5 years CMC)

Price of large cold box (20 lit.) – Rs. 7,350

Price of small cold box (5 lit) – Rs. 5,000

Price of vaccine carrier – Rs. 1,000

Price of ice packs – Rs. 35

Price of voltage stabilizer – Rs. 5,000

Price of toolkit – Rs. 115,500

Price of temperature monitoring device – Rs. 10,100 (including installation) (30% reduction of price for bulk purchase)

WIC/WIF wireless data logger - 1 lakh including equipment / installation / internet / AMC / CMC for 5 years

**Price increase over the years 10 %**

**Useful life**

ILR / DF/ WIC / WIF – 10 years; Cold boxes / Tool kit – 5 years

Voltage stabilizer / vaccine carrier – 3 years; Ice packs – 2 years

**Building**

The following numbers of buildings need to be built over the cMYP period

At the district level – 64% of the buildings need to be constructed (410 nos. of buildings need to be constructed) (Source: National EVM Assessment Report 2013)

At the state level – 75% of the buildings need to be constructed (29 nos. of buildings need to constructed)

At the divisional level - 75% of the buildings need to be constructed (92 nos. of buildings need to constructed)

Building construction cost in districts with 20 lakh population – 22-25 lakh

Building construction cost at state and divisional level – 50 lakh

**Table A.8. Resource Requirements for India National Immunization Program, US$ millions, 2013-2017**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Cost Category | 2013 | 2014 | 2015 | 2016 | 2017 | Total |
| Vaccines (routine vaccines only) | 78.5 | 97.4 | 223.9 | 272.3 | 551.9 | 1,223.9 |
| Injection supplies | 11.0 | 11.1 | 13.8 | 13.0 | 15.8 | 64.8 |
| Personnel | 12.1 | 13.0 | 13.8 | 14.7 | 15.6 | 69.3 |
| Transportation | 31.3 | 36.1 | 41.7 | 48.2 | 55.7 | 213.0 |
| Cold chain and other capital equipment maintenance | 17.9 | 23.0 | 27.1 | 31.8 | 34.0 | 133.8 |
| Training | 4.7 | 5.6 | 6.4 | 7.3 | 8.3 | 32.3 |
| Social mobilization / advocacy / communication activities | 43.7 | 57.5 | 64.8 | 72.0 | 74.3 | 312.3 |
| Disease surveillance | 20.4 | 24.8 | 28.7 | 33.1 | 38.3 | 145.3 |
| Programme management | 14.5 | 34.7 | 33.1 | 35.7 | 38.2 | 156.2 |
| Other routine recurrent costs | 33.7 | 38.2 | 41.0 | 43.4 | 46.2 | 202.5 |
| Cold chain equipment | 20.2 | 30.5 | 41.4 | 52.9 | 64.6 | 209.6 |
| Supplemental Immunization Activities | 121.5 | 113.9 | 234.0 | 234.2 | 125.1 | 828.8 |
| Shared personnel costs | 293.4 | 314.2 | 336.5 | 360.4 | 386.0 | 1,690.6 |
| Total | 703.1 | 800.2 | 1,106.2 | 1,219.1 | 1,454.0 | 5,282.5 |

Annex 4: Hib Implementation Activities and MonitoringTimeline

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Hib Implementation Strategies**  | **Activities** | **2014** | **2015** | **2016** | **2017** | **Indicators** |  **Targets** |
| **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** |  |  |
| **1. Advocacy and Information, education and Communication (IEC)** | 1.State level workshops with political decision makers and program managers |   |   |   |   |   |   |   |   |   |   |   |   | 1. Proportion of districts where social mobilization plan has been developed and implemented | 100% of districts |
| 2. Develop key advocacy messages for the implementation of the pentavalent vaccine |   |   |   |   |   |   |   |   |   |   |   |   | 2. Number and type of media workshops | Oneworkshop in each state |
| 3. Create a media toolkit |   |   |   |   |   |   |   |   |   |   |   |   | 3. Number workshops conducted | One workshop in each state |
| 4. Plan for state launch of the new vaccine |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 5. Develop educational and promotional materials ( brochures, posters, etc.) for key stakeholders ( i.e. parents, health providers, community mobilizers, traditional healers, teachers, etc.) |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **2. Training and retraining of immunization staff** | 1.Prepare standard operational procedures for introduction of the pentavalent vaccine in the UIP |   |   |   |   |   |   |   |   |   |   |   |   | \* Proportion of districts in a state which have developed a training plan | 100% of implementing districts |
| \* Revise tracking sheets, immunization schedules, immunization cards, daily tally sheets, vaccine registers, monthly RIMS reporting forms |   |   |   |   |   |   |   |   |   |   |   |   | \* Finalized SOPs and tracking sheets |   |
| \* Training of EPI managers at the state, district, and block level using the existing training mechanisms |   |   |   |   |   |   |   |   |   |   |   |   | \* % of planned training sessions conducted | 90% of training sessions conducted |
| \* Training of immunization staff (PHC staff, private physicians, public physicians) |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **3.Improved vaccine and Immunization Supplies:** | \* Timely vaccine supply through existing procurement and supply chains |   |   |   |   |   |   |   |   |   |   |   |   | \* Cold chain equipment assessed and installed as required; | Assessment to be completed in 80% of states 3 months prior to the introduction |
| \* Evaluate the cold chain capacity at districts, blocks and PHCs to ensure sufficient space for the new vaccine |   |   |   |   |   |   |   |   |   |   |   |   | \* % of centres tracking supplies received and distributed at the district, block and PHC levels | >80% of centres |
| \* Incorporate supply logistics and cold chain monitoring in the training sessions |   |   |   |   |   |   |   |   |   |   |   |   | \* % of centres having shortages of vaccine in last 3 months | <10% of centres |
| \* Monitor VVMs and cold chain at the PHC, block, and district level |   |   |   |   |   |   |   |   |   |   |   |   | \* % of vaccine wastage in the district | <25% vaccine wastage |
| \* Conduct EVSM |   |   |   |   |   |   |   |   |   |   |   |   | \* Number and type of cold chain breaks by district, block and PHC | <15% breakdowns |
| \* Conduct a post implementation evaluation |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **4. Injection Safety** | \* Develop an implementation plan for ordering and procuring injection safety and safe disposal equipment |   |   |   |   |   |   |   |   |   |   |   |   | \* Percentage of districts, blocks and PHCs that have uninterrupted supply of needle destroyer and hub cutters for last 3 months | 80% of districts with uninterupted supply |
| \* Incorporate the use of injection safety equipment and safe disposal principles in all the training sessions |   |   |   |   |   |   |   |   |   |   |   |   | \* Percentage of blocks and PHCs safely disposing immunization equipment | 100% |
| \* “Bundle” order the injection safety supplies and safe disposal equipment |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **5. Strengthen Supervision, Follow-Up and Evaluation** | \* Develop a post-implementation evaluation plan, to be implemented at the state, district, block and PHC levels |   |   |   |   |   |   |   |   |   |   |   |   | \* Report from post-implementation plan | Report finalized by Q1 2015 |
| \* Develop a supervisor’s monitoring tool that can be used at the block and PHC levels |   |   |   |   |   |   |   |   |   |   |   |   | \* Number of supervisory visits conducted per medical officer in PHC | 1 visit per quarter |
|   |   |   |   |   |   |   |   |   |   |   |   |   | \* Percentage of supervisors using the monitoring tool | 100% |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **6. Improved utilization of services and the coverage assessment** | \* Revise the tracking sheets, immunization schedule, immunization cards, daily tally sheets, vaccine registers, vaccination registers, and RIMS forms |   |   |   |   |   |   |   |   |   |   |   |   | \* Percentage of coverage of the pentavalent vaccine | 70% 2015; 80% 2016; >85% 2017 |
|  | \* Revise forms and formats for assessing coverage and drop out rates  |   |   |   |   |   |   |   |   |   |   |   |   |  |  |
|  | \* Disseminate revised forms to states and districts |   |   |   |   |   |   |   |   |   |   |   |   | \* DPT1- DPT3 Dropout rate | < 20% |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **7. Strengthen epidemiological and AEFI Monitoring** | \* Incorporate pentavalent vaccine in the AEFI reporting form |   |   |   |   |   |   |   |   |   |   |   |   | \* AEFI system updated to incorporate pentavalent vaccine | By Q4;2014 and Q2 of 2015 |
| \* Train the district, state and national AEFI committees to recognize AEFI related to pentavalent vaccine |   |   |   |   |   |   |   |   |   |   |   |   | \* Number of AEFI training sessions planned and completed | At least one in each state |
| \* Incorporate AEFI training in the staff training (how to recognize AEFI, what to do and how to report AEFI) |   |   |   |   |   |   |   |   |   |   |   |   | \* Number of AEFI events reported and % followed-up through the appropriate mechanisms for the 10 states | 80% reported and 100% followed up |
|   |  |  |  |  |  |  |  |  |  |  |  |  | \* Percentage of districts (in the 5 states) reporting AEFI | 100% of districts reporting  |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **8. Renew Operational Research**  | \* Identify and prioritize operational research needs (related to the implementation of pentavalent vaccine) |   |   |   |   |   |   |   |   |   |   |   |   | \* Timely data and report available in order to use recommendations to improve the program | Final report available Q1 2015 |
| \* Support the implementation of the research studies |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **9. Financial Sustainability beyond GAVI support:** | \* Ensure that appropriate internal funding mechanisms are in place |   |   |   |   |   |   |   |   |   |   |   |   | \* States where separate budget is allocated for the pentavalent vaccine procurement | 100% self-sufficiency in Hib vaccine procurement by Q1 of 2016 |
| \* Vaccine procurement tender prepared with UNICEF |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| \* Injection safety self-procurement |   |   |   |   |   |   |   |   |   |   |   |   |   | 100% procurement of injection safety materials |
| \* Training in resource management, forecasting, and timely procurement for State, district and block EPI managers |   |   |   |   |   |   |   |   |   |   |   |   | 2 training workshops per annum | < 20% wastage by 2015 |
| \* Improve the efficiency of the programme |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Note: This time line has been prepared for the initial 3 years of pentavalent vaccine introduction in these states of the country. Subsequently, these activities will be carried forward as needed.

**References:**

* 1. Government of India. National Cold Chain Assessment 2008. Ministry of Health and Family Welfare and UNICEF, July 2008.
	2. Government of India. Operational Guidelines: Introduction of Haemophilus influenzae type b as pentavalent vaccine in Universal Immunization program of India. Ministry of Health and Family Welfare, Govt. of India, New Delhi, 2011.
	3. Government of India. Multi-year strategic Plan (2005-10) for Universal Immunization Program in India. Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi, 2005.
	4. Govt of India. Draft Comprehensive Multi Year strategic Plan for Universal Immunization Program in India (2013-17). Ministry of Health and Family Welfare, Govt. of India, New Delhi, 2013.
	5. International Institute for Population Sciences and MoHFW. District Level Household Survey-3 (2007-8) 3. IIPS, Mumbai and Ministry of Health and Family Welfare, Govt. of India. 2009.
	6. National Family Health Survey 2005-06, International institute of Population Sciences, Mumbai and ORC Macro, Mumbai October 2007.
	7. National Technical Advisory Group on Immunization Subcommittee on Hib vaccine. NTAGI subcommittee recommendations on Haeomphilus influenzae type b (Hib) vaccine introduction in India. Indian Pediatr 2009; 46: 945-954.
	8. Sample Registration system. Directorate General of Census Operations, Government of India. 2012
	9. UNICEF and Govt. of India. Coverage Evaluation Survey-2009. United Nations Children’s Fund, New Delhi. 2010.
	10. Watt JP, Wolfson L, O’ Brien KL, Henkel E, Deloria-knoll M, McCall M et al. Burden of disease caused by Haemophilus influenzae type b in children younger than 5 years: global estimates. Lancet 2009; 374:903-11.
	11. WHO Position Paper on Haemophilus influenzae type b conjugate vaccines. Weekly epidemiological record, WHO 2006 (81): 445-452.
	12. WHO and UNICEF. WHO/UNICEF estimates of immunization coverage for India, 2011. Available from [*http://www.who.int/immunization\_monitoring/data/ind.pdf*](http://www.who.int/immunization_monitoring/data/ind.pdf)
	13. World Health Organization. New vaccine Post Introduction Evaluation (PIE) tool. Geneva: World Health Organization, 2010.
	14. World Health organization. Post Introduction evaluation of Pentavalent (DPT+HepB+Hib) vaccine in Tamil Nadu and Kerala states, report 2012. WHO India, New Delhi; pg 1-60. 2013
1. Countries’ GAVI eligibility for the year 2014 is GNI per capita lower or equal to $1,570. [↑](#footnote-ref-1)
2. Shared costs include the value of inputs that are not specific to immunization and which are used by different programmes or activities in the health sector — i.e. their utilization for immunization is less than 100%. [↑](#footnote-ref-2)
3. It should be noted that WHO and UNICEF are implementing partners and their activities are funded by BMGF, GAVI and other external partners. [↑](#footnote-ref-3)
4. cMYP costing & financing tool has two categories of funding: 1) Secure funding refers to projected future financing available in the short term, that is considered assured; 2) Probable funding refers to all other funding that is not assured but is likely to be made available in the short and medium term. [↑](#footnote-ref-4)