Annex A. IPV introduction plan

**1. Justification for introduction of IPV and national decision-making process**

**1.1 Introduction of IPV - Rationale**

Oral Polio Vaccine has been the sheet anchor in the battle against polio globally and in India. The vaccines safety record, ease of use and efficacy has been instrumental in eliminating the transmission of polio in India. Its role continues to be crucial, in sustaining India’s polio free status.

India’s polio-free status has been realized with a heavy investment of manpower, material and money. The protection of this investment is of paramount importance.

Presently trivalent OPV is used in routine immunization and during national immunization days across the country. The trivalent oral polio vaccine is a live attenuated vaccine containing all three strains (Types 1, 2 and 3) of the virus and is very effective against the wild virus. In very rare cases the vaccine can lead to paralysis. There are two ways this can occur:

1. *Vaccine Associated Paralytic Poliomyelitis (VAPP):* for every birth cohort of 1 million children, there are 2-4 cases of VAPP. This translates to an estimated 250–500 VAPP cases globally per year and 25–30 cases per year for India. Of these, about 40% are caused by OPV’s type 2 component.

2) *Circulating Vaccine Derived Poliovirus (cVDPV)*: these rare outbreaks occur when a vaccine-related virus is passed from person-to-person, mutating over time and acquiring an ability to transmit like a wild virus and have disease causing characteristics. Almost all cVDPV outbreaks in recent years have been caused by a type 2 vaccine-derived virus

Globally, of the 716 cases of cVDPVs reported between 2000 and 2013, 88% were due to the type 2 component. In India, since 2009, 97% of all VDPVs have been due to the type 2 component.

OPV type 2 now carries more risk than benefit and undermines global polio eradication efforts. Thus, tOPV will be replaced with bivalent oral polio vaccine which contains only two strains (Type 1 and 3) of the virus. This bOPV will continue to target the remaining polio types (WPV1 and WPV3). Once these two strains are also eradicated, bOPV will be withdrawn and replaced by Inactivated Polio Vaccine (IPV) in routine immunization.

The sixty–fifth World Health Assembly in May 2012, declared the completion of poliovirus eradication to be a programmatic emergency for global public health. In response, *The Eradication and Endgame Strategic Plan 2013–2018* was developed. This describes the comprehensive, long-term strategy that addresses what is needed to deliver a polio-free world by 2018.

Under this endgame plan, the use of oral polio vaccine (OPV) must eventually be stopped worldwide. All oral polio vaccines containing the type 2 polio virus must be removed and replaced by the bivalent OPV which contains type 1 and type 3 polio viruses. This requires a switch from tOPV to bOPV in routine immunization as well as in supplementary immunization campaigns for polio.

The switchover from trivalent OPV to bivalent OPV which does not contain type 2 vaccine virus has been timed for 2016. WHO no longer recommends an OPV-only vaccination schedule. For all countries currently using OPV only, WHO recommends the inclusion of at least 1 dose of IPV in a countries routine immunization schedule.

The primary purpose of the IPV dose is to maintain immunity against type 2 poliovirus during and after the planned global withdrawal of OPV2 and switch from tOPV to bOPV.

**1.2 Decision process**

In early 2013, the India Expert Advisory Group recommended that the Indian Council of Medical Research Expert Group should study the proposal for the inclusion of IPV in India. The expert group met in April, August and October of 2013. The immunization decision-making process has been institutionalized by the establishment of an independent advisory body, the National Technical Advisory Group on Immunization (NTAGI) in 2001, comprising of independent experts from diverse fields such has immunology, community medicine and health economics; representatives from partner organizations like WHO, UNICEF, ICMR and DCGI as well as liaison officers from the government. To address the issue of resurgence of polio following India’s successful elimination of the disease, the National Technical Advisory Group on Immunization (NTAGI) in its June 12th, 2014 meeting recommended the following:

* India should work towards a withdrawal of OPV2 from the immunization programme and comply with timelines of the globally synchronized tOPV to bOPV switch;
* India should introduce a single, full dose of IPV into the routine immunization schedule in all states, to be given at 14 weeks of age with DPT3; and
* Routine immunization needs to be strengthened to ensure high coverage with all vaccines, including IPV.

These recommendations are far reaching in their vision as they give a new direction to India’s polio eradication program and reemphasize the importance and need to strengthen the routine immunization service delivery mechanism.

**2. Overview of IPV**

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|  |

2.1 Vaccine preference

IPV is available in standalone and combination presentations. Presently, only the standalone presentations are WHO prequalified and/or licensed for use in India. IPV is available from multiple manufacturers in presentations of single dose pre-filled syringe, single dose and ten dose vials.

National Technical Advisory Group on Immunization (NTAGI) has recommended a multi-dose presentation with a vial size not exceeding five doses per vial. All vaccine manufacturers have initiated processes for the production of five dose vials and sufficient quantity is expected to be available for introduction in India. The lead time for delivery of vaccine is 9 to 12 months for all manufacturers.

The vaccine will be introduced in the third quarter of 2015 in all states across the country. With the roll out planned for the third quarter, India is within the timeline required for initiation of procurement procedures that will ensure vaccine availability. In the event of a delay in the availability of the five dose vials, the IPV introduction could begin as planned with a 10-dose vial and then switch to the five dose presentation. The country’s vaccine preference is as given in Table 1 below

**Table 1. IPV vaccine preferences and estimated date of introduction**

|  |  |  |  |
| --- | --- | --- | --- |
| **Preferred IPV vaccine** | **Month and year of first vaccination** | **Preferred second presentation** | **Preferred third presentation** |
| 5-dose vial | September 2015 | 10-dose vial |  |

2.2 Country licensure status

The Central Drugs and Standards Control Organization (CDSCO) is the National Regulatory Authority (NRA) in India. CDSCO is headed by the Drugs Controller General (India) [DCG (I)]. It approves vaccines that are introduced in the country. The Central License Approving Authority (CLAA) issues licenses for the manufacture of vaccines, while the Central Drugs Laboratory (CDL), Kasauli performs lot release for all imported vaccines as well as locally produced vaccines.

Licensure for the one-dose pre-filled syringe and the ten-dose vials has been completed for all manufacturers. Manufacturers will initiate the license applications for five-dose vial during the last quarter of 2014. The process for licensing usually takes four to six months. The licensing process will not affect the timely delivery of the vaccine.

The vaccine manufacturers in India who are committed to IPV production are: Panacea, Sanofi Pasture, Shantha Biotechnics Ltd, Serum Institute of India and Biological E Ltd.

2.3 Target population and vaccine supply

The birth cohort in India is estimated to be 27 million children per year. Vaccination with IPV ensures the development of immunity for the entire cohort and prepares for the switch from tOPV to bOPV. In addition, this dose will also play a vital role in boosting immunity against Type 1 and 3. The target population for IPV introduction is given in Table 2 below

#### Table 2: Year-wise estimated target population for IPV introduction

|  |  |  |
| --- | --- | --- |
| **Year** | **Number in target population for IPV\*** | **Number in birth cohort** |
| 2015\*\* | 6,526,620 | 6,848,500 |
| 2016 | 26,106,482 | 27,394,000 |
| 2017 | 26,106,482 | 27,394,000 |
| 2018 | 26,106,482 | 27,394,000 |
| **Total** | **78,319,446** | **82,182,000** |

\* Excludes infant deaths

\*\*Target population for the last quarter only

2.4 Vaccine Wastage & Buffer stocks

Vaccine wastage is an important feature in determining the quantity of vaccine required to be procured. Considering national data and as per a study conducted by Immunization Technical Support Unit (ITSU) 10 dose vial will result in considerable vaccine wastage of 70% and 30% wastage for 5-dose vials in India. A contributory factor to wastage is the non-applicability of the Open Vial Policy for IPV, i.e. once opened, the vial must be discarded after six hours, irrespective of utilization or VVM status.

The buffer stock recommended is 25% for the first year of vaccine introduction and in subsequent years, the data on coverage and vaccine utilization can be analyzed and appropriate buffer stocks calculated for the following years. Reduction of vaccine wastage will be a focus; refresher trainings for all frontline health staff will be conducted to help them better understand the importance of careful utilization of the vaccine.

2.5 Vaccine requirement

India will require approximately 26 to 60 million doses of IPV each year depending on the vial size. Taking into consideration the national annual cohort of surviving infants and the vaccine wastage rates for the 5 and 10-dose vial size, the projected requirements of vaccine are given in the Table 3 and Table 4 below. Till the time there is an open vial policy for IPV, the 10-dose vial will continue to incur high wastage rates in India, given that the average number of children coming for DPT 3 in a session is less than 3. The vaccine coverage rates are taken as 100% for the first year of introduction and the coverage figures from second year onwards is in line with the national DPT-3 coverage of 70%. This will enable the vaccine requirement to be streamlined and fill in the gaps for the supply from year two onwards.

**Table 3** – IPV doses requirement based on targeted population.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **For 5 dose vials (30% wastage rate)** | | | | | |
| Year | Target Population | Doses required\* | Doses including Vaccine wastage @ 30% per year(Doses x 1.43) | TOTAL(Including 25% buffer for first year) |
| 2015 | 6,526,620 | 6,526,620 | |  | | --- | | 9,333,067 | | 11,666,333 |
| 2016 | 26,106,482 | 18,274, 537 | |  | | --- | | 26,132,588 | | 26,132,588 |
| 2017 | 26,106,482 | 18,274, 537 | 26,132,588 | 26,132,588 |
| 2018 | 26,106,482 | 18,274, 537 | 26,132,588 | 26,132,588 |

**\* Vaccine coverage is taken as 100% for 2015 (Year 1) and 70% from 2016 onwards**

**Table 4** – IPV doses requirement based on targeted population.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **For 10 dose vials (at 70% wastage rate)** | | | | |
| Year | Target Population | Doses required\* | Doses including Vaccine wastage @ 70% per year(Doses x 3.33) | TOTAL(Including 25% buffer for first year) |
| 2015 | 6,526,620 | 6,526,620 | 27,167,056 | 33,958,820 |
| 2016 | 26,106,482 | 18,274, 537 | 60,854,210 | 60,854,210 |
| 2017 | 26,106,482 | 18,274, 537 | 60,854,210 | 60,854,210 |
| 2018 | 26,106,482 | 18,274, 537 | 60,854,210 | 60,854,210 |

**\* Vaccine coverage is taken as 100% for 2015 (Year 1) and 70% from 2016 onwards**

The above-mentioned quantity of IPV Vaccine has to be procured through UNICEF by GAVI resources. However, onetime Introductory Grant shall be transferred to WHO & UNICEF as per the budget.

**3. Introduction and implementation considerations**

3.1 Policy development

The Indian Council of Medical Research (ICMR) constituted an expert group to assess the operational and programmatic aspects of introducing IPV along with the vaccine development plans and national capacity to produce the vaccine. The expert group recommended the introduction of IPV in the national immunization schedule along with DPT-3/Pentavalent-3 in 2015. The expert group also recommended that an open vial policy should not be used with IPV (which will impact on the wastage rates).

**Vaccination Schedule**

As per the present routine immunization schedule in India, a child receives oral polio vaccine at birth followed by three OPV doses at 6, 10 and 14 weeks. The NTAGI recommends the administration of a full dose (0.5ml) of IPV by intramuscular route at 14 weeks, along with DPT3/Penta3/OPV3. This dose is to be co-administered along with OPV. There will be no change in the current OPV schedule.

The vaccine shall also be administered to all children of more than 14 weeks of age who are still eligible for DPT3/Penta3/OPV3. This will ensure that children who are brought late for the DPT3/Penta3/OPV3 also receive the IPV dose. In situations of late start of schedule (age >3months) IPV will be administered at the first possible immunization contact.

Many countries have already introduced inactivated polio vaccine into their immunization schedules. The experiences with the vaccine in these countries have shown that serious adverse reactions were found to occur very rarely. The administration of IPV along with DPT3 / Penta3 calls for multiple injections in one session. Evidence shows that IPV is well-tolerated and not associated with adverse events (this included not being associated with fever, convulsions or hypotonic-hypo-responsive episodes) when administered along with other vaccines.

3.2 National coordination mechanism to ensure the successful introduction

The Ministry of Health and Family Welfare (MoHFW) will coordinate the introduction of IPV across the country. The Immunization Division of MoHFW will oversee the process and regularly apprise the ministry of the state-wise progress. The Immunization Division will have the responsibility of deciding the activities and timelines required to ensure a pan India introduction of IPV. It will issue relevant guidelines, conduct sensitization and training meetings/workshops at the national level towards this objective. Support for state level training of health workers will be sourced from local partner agencies and from the national level.

The trainings will be completed before the launch of the vaccine. The state and district level trainings will build the capacity of frontline health workers and medical officers to effectively introduce the vaccine. Cold chain capacity will be reviewed to ensure space availability for both vaccine and related logistics at state, district and block levels.

A team of national observers will be constituted to supervise and monitor all activities in the pre-launch period across the country. Special focus will be made on states where routine immunization coverage requires to be strengthened and on the pre-identified High Priority Districts (HPDs) and polio high risk districts. These teams shall guide and evaluate the progress and share those findings with the states and immunization division for further action. Implementation of the communication plan well before the introduction will be essential to create awareness and generate demand.

3.3 Affordability and financial sustainability

The details for costing are mentioned in Annexe D, as part of this application. The Government of India has in its comprehensive Multi Year Plan 2013–2017 (cMYP) included the introduction of IPV into routine immunization with government financing as part of its strategic objectives on new vaccine introduction. The cMYP also has a detailed costing section with the underlying assumptions that have been considered for costing IPV introduction up until 2017. The cMYP document has been attached as part of this application. Government of India will seek financing for IPV for the duration that it is eligible for GAVI funding in the coming years.

3.4 Overview of cold chain capacity at district, regional and central levels

According to the National EVM conducted by UNICEF in 2013 and the data from national cold-chain MIS, India has sufficient cold chain space at district level (and levels below) and IPV introduction will not be a challenge. The EVM also suggested that introduction of pentavalent vaccine and its scale up will release additional cold chain space for IPV.

The cold chain infrastructure is a wide network of cold chain stores consisting of Government Medical Supply Depots (GMSD), State, Regional/Divisional Vaccine stores, District and PHC/CHC vaccine storage points. Cold chain network in the country has been the backbone to ensure that right quantity and right quality of vaccine reaches the target population.



**Fig. 1**: Vaccine storage network and storage timelines in India.

Source: National Cold Chain Assessment 2008

The introduction of pentavalent vaccine into the routine immunization schedule is being scaled up from two states in 2011 to the entire nation by 2015. Presently this vaccine is being administered through RI sessions in eight states, with 12 states scheduled to introduce the vaccine in October 2014. One of the benefits of this introduction has been on the availability of cold chain space at all levels of the vaccine storage network. This benefit will extend to all the states by mid-2015.

In states that have introduced the pentavalent vaccine, cold chain availability has increased due to the reduced requirement of DPT and Hepatitis B vaccines. With this freed capacity, there is no constraint envisaged on the cold chain capacity for storage of IPV. This capacity will be reviewed during the administration of special vaccine introduction checklists and also during field visits. Further strengthening of the existing network has been envisaged in the cMYP 2013-2017 which will further enhance cold chain capacity.

3.5 Waste management and injection safety

Injection safety protocols are incorporated into existing routine immunization guidelines. All health staff dealing with injections including routine immunization injectable vaccines are regularly trained on these protocols. Information from monitoring of sites is shared with districts and states for appropriate response. During training for IPV introduction, injection safety and its benefits for the health worker, beneficiary and community will be reemphasized.

Waste sharps generated from immunization with IPV will be handled as per guidelines prescribed by the Biomedical Waste Management and Handling Rules.

3.6 Health worker training and supervision

The training component of the IPV introduction will be implemented by a cascading approach. Training material will be geared to strengthen knowledge and skills of personnel at all levels. IPV specific as well as RI strengthening teaching materials such as flip charts, handouts, information kits and other visual aids will be developed. States will be encouraged to translate training materials into local languages. These materials will be combined into a training kit which will be the tool for training at the district and block levels. Cascaded trainings for all levels will be conducted beginning at least four months before IPV introduction.

Developing the trainer resource will commence with a one day national workshop to orient all national and state level managers including partners on the introduction of IPV. This workshop will be supported by WHO Country Office for India and will build the required resource of state level master trainers, to impart quality training in their respective states.

Four training packages will be rolled out in coordination with partners at the state level targeting Medical Officers, Data Handlers, Cold Chain Handlers and IEC/ Media focal persons.

Personnel trained in the state workshops will conduct a one day workshop at respective districts targeting block medical officers, data handlers, cold chain handlers and officials of other related sectors.

The next level of training will be conducted at the block level for all medical officers, ANMs, ASHAs and anganwadi workers.

The ASHAs and AWWs will play a crucial role for the successful and smooth implementation of the introduction. The Child Development Project Officers, ICDS supervisors will also be sensitized on the need and process for the introduction of IPV. The state / district Health departments and the departments of women and child development will coordinate their efforts to ensure smooth implementation of these trainings (for ASHA and AWW), sensitization and further implementation.

Sensitization of paediatricians / medical practitioners through involvement of Indian Medical Association (IMA); Indian Academy of Paediatrics (IAP) , Indian Public Health Association (IPHA) and Rotary will also help in information dissemination as well as encouraging active participation of all sectors in the IPV introduction.

State, district and sub-district training activities will be monitored by the WCO India network who will also provide regular feedback through district and state task force meetings for immunization.

3.7 Risks and challenges

The introduction of a new vaccine into any routine immunization schedule poses challenges at various levels. In India, the health system provides a strong infrastructure for delivering these services to all parts of the country. The major risks and challenges for the UIP have been identified in the cMYP (2013-17) and the program strategies have been developed to address these risks and challenges. The government has demonstrated its commitment to the immunization program and to strengthening services in the cMYP 2013-2017 (See attached with the application).

**4. Situational analysis of the immunisation programme**

4.1 Immunization coverage and trends

Immunization is a critical component of the Government of India's child survival strategy. In 1997 the MoHFW launched a Reproductive and Child Health (RCH) program to reduce infant and maternal mortality, total fertility rate and to increase immunization coverage, especially in rural areas. With a view to strengthen public health system in rural areas, the Government of India launched the National Rural Health Mission (NRHM) in 2005. The NRHM (now called NHM – National Health Mission) was established as a single platform to bring together all of the national health efforts, including Reproductive and Child Health (RCH) which included immunization.

At the national level, the NHM has a Mission Steering Group (MSG) headed by the Union Minister for Health & Family Welfare and an Empowered Program Committee (EPC) headed by the Union Secretary for Health & Family Welfare. EPC implements the Mission under the overall guidance of the MSG.

In the 12th Five Year Plan, the Government of India has proposed a National Health Mission for improving healthcare in rural as well as urban areas. Routine immunization is an integral component that has been identified for strengthening. With IPV being introduced along with DPT3/Penta3/OPV3, it is essential to review its coverage as given in the Figure 2 below.



**Fig. 2:** Percentage of immunization coverage of various antigens among 12 to 23 months children

*Source: Coverage Evaluation Survey 2009*

The coverage in India for DPT3 as determined by various surveys and evaluations is around 70%. While the goal for any immunization program is to vaccinate every child, the current estimated coverage of DPT3 allows for the introduction of IPV. Variations in coverage exist between states and districts. The data gathered identifies those districts and states that require additional attention. Routine immunization strengthening is a major activity being undertaken under the cMYP 2013-17 as well as through special frontline worker trainings, which are focused on improving mobilization of children to sessions. These interventions will contribute to improving the coverage further and hence increase the number of children administered IPV.

**Table 5. Trends in national vaccine coverage**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trends of national vaccine coverage (percentage)** | | | | |
| **Vaccine** | **Vaccine Used** | **Target population**  **(number by age and sex,**  **if available)** | **Coverage reported (JRF)** | |
| **Most recent year** | **Previous year** |
| BCG | Lyophilized vaccine | 25,760,000 | 91.73% | 93 % |
| OPV 3 | Liquid vaccine | 25,760,000 | 88% | 85% |
| DTP 1 / Penta 1 | Liquid vaccine | 20,938,000 | 98.7 % | 88 % |
| DTP 3 / Penta 3 | Liquid vaccine | 20,938,000 | 76 % | 85 % |
| Measles 1 | Lyophilized vaccine | 25,760,000 | 88.3 % | 88 % |
| Measles 2 | Lyophilized vaccine | 25,760,000 | 38.84 % | 23 % |

4.3 Findings from recent programme reviews

A post-introduction evaluation (PIE) of pentavalent vaccine and measles-containing vaccine second dose (MCV-2) was conducted in six states—Goa, Gujarat, Haryana, Jammu & Kashmir, Karnataka and Puducherry from 6 to 11 March 2014. Pentavalent vaccine was introduced in these six states in early 2013. This was the second group of states to introduce Pentavalent vaccine, the first group being Tamil Nadu and Kerala where a PIE was conducted earlier.

The findings of these evaluations suggested the following:

* Preparations for roll out of new vaccine should begin early, at least three to four months in advance of the actual vaccine launch.
* A state-level official launch ceremony should be organized under strong political leadership, with the engagement of media, to increase programme visibility and boost confidence among public about the new vaccine. Districts should also organize launches for greater public awareness.
* Staff vacancies at all levels particularly in high risk areas should be filled up.
* Existing RI microplans should be revised to include high-risk areas (HRAs) and migratory/non migratory settlements identified under the polio programme and new microplans should be prepared using bottom-up approach to ensure inclusion of all components.
* Good quality training should be provided to health staff at all levels prior to the introduction of new vaccine on all aspects of vaccine delivery, from operations to appropriate use of communications channels.
* Reporting and recording tools such as MCP cards, registers, tally sheets etc. must be revised timely before introduction.
* Cold chain & vaccine management should be strengthened to avoid vaccine stock-outs and wastage. Cold chain handlers should also be trained.
* Supportive supervision and appropriate oversight should be maintained and a feedback mechanism should be put in place.
* Information, education and communications (IEC) materials should be made available in adequate quantities to raise awareness among community.
* Data generated from programme implementation, including monitoring, should be utilized for action. State and district task forces for immunization should regularly review this data to assess performance of the immunization programme and monitor routine immunization (RI) activities. The task forces should also review preparedness for vaccine introduction.

These findings have been taken into consideration and will be focused on during coordination meetings at the national and state levels. All measures will be taken to ensure that these recommendations are acted upon during the IPV introduction process.

**5. Monitoring and evaluation**

5.1 Supervision and Monitoring

With the introduction of any new vaccine, regular monitoring of the process combined with timely feedback will ensure effective implementation. Progress in implementation will be monitored over all the phases of preparation, introduction and post-introduction.

During the preparedness phase, districts and states will be expected to assess their preparations through check-lists that will be devised for this purpose. These check-lists will be reviewed at state and national levels to identify gaps and suggest solutions.

National observers will review the preparedness, vaccine requirements and cold chain capacities at state and district levels during their field visits. This will provide the state and national level with information on progress as well as reflect on the capacity of a state / district to effectively introduce the vaccine. Special attention will be paid to high priority districts and the districts at high risk of poliovirus importation under the Emergency Preparedness and Response Plan.

State observers and WHO-NPSP will monitor district and block level trainings. Data on the conduction of trainings will be collected bi-monthly from districts and states. Feedback on trainings will be shared during district and state task force meetings for immunization for corrective actions.

During the phase of introduction, regular monitoring of routine immunization sessions will be done to provide feedback to district and state health departments to enable timely response. Partner agencies such as WHO and UNICEF will actively support the introduction phase.

Strengthening of RI and the introduction of IPV are synergistic and require the involvement of all stakeholders for success. At the national, state and district levels, the departments of Child development, education and panchayat raj will be sensitized and encouraged to be actively involved in monitoring of the IPV introduction and RI strengthening activities in all phases.

As Surveillance Medical Officers of WCO India will closely monitor all activities at state, district and sub-district levels and provide regular feedback for corrective actions, WHO Country Office for India will conduct training programs on IPV introduction and RI strengthening for these field officials.

Post Introduction Evaluation (PIE) survey will be conducted by WCO India 6 to 12 months after the introduction of IPV.

5.2 Adverse Event Following Immunisation (AEFI) monitoring and reporting

National AEFI Guidelines had been first prepared in 2005, further revised in 2010 and a summary Standard Operating Procedures (SOP) on AEFI surveillance were prepared and disseminated in 2011. But these are being currently updated based on new WHO Causality assessment methodology and will be published by October 2014. These are equipped to report, investigate and respond to AEFI reports in the field. Extensive collaboration exists between the national pharmacovigilance program, the regulator (CDSCO) and AEFI surveillance program in the country.

In addition, Communication Guidelines for building vaccine confidence and respond to AEFI have been developed and disseminated in Dec 2013. The National AEFI Committee has been in place since 2008 and was reconstituted in 2013 to make it broader in terms of medical speciality representation, geographic representation and includes independent experts as well as ex officio members from different agencies (governmental and non-governmental )involved in AEFI surveillance

The Operational Guidelines for AEFI Surveillance delineate and specify the processes and procedures for monitoring of adverse events with any vaccine including IPV. However when new vaccine introduction is undertaken, guidelines regarding managing different aspects of immunization including AEFI are included for orientation and capacity building of health workers in the field.

**6. Advocacy, communication, and social mobilisation**

Communication strategy and materials will be developed to support the introduction of IPV. Partner agencies including WHO and UNICEF will support the development of this plan. The plan will guide national, state and district level communication efforts. It will provide a set of standardized messages which will assist immunization partners and stakeholders in understanding and implementing the introduction of IPV. The communication material must be made available to states in the local languages. It shall be the responsibility of each state to disseminate the information as per the timeline recommended. The communication plan will also entail advocacy meetings and developing capacity of government officials at all levels for handling the media on IPV introduction so that they become effective spokespersons for addressing media queries.

The communication plan shall include the following content:

1. Objectives and rationale for IPV introduction
2. Key communication messages and messaging challenges
3. Advocacy meetings with:
   * National and State officials
   * Health workers and other healthcare delivery staff
   * Community and traditional leaders
   * National and local medical bodies – IAP/IMA
   * Parents and caregivers
4. Mass media campaigns to disseminate messages
5. List of communication materials and templates to be developed (in local languages), with corresponding timelines and responsible individuals/organizations. This will include:
   * Briefs and FAQs – both general and technical
   * Media and issues management
   * Social mobilization
   * Health worker training materials
   * Guidance on event planning

Communication will commence at least six months before the planned introduction. Multiple media options will be utilized to ensure wide and effective dissemination. Advocacy for the inclusion of IPV will have to also focus on particular target audiences such as parliamentarians, paediatricians and the media. Each of these groups is a key influencer and requires special information and attention.

**Timelines for communication activities**

Following is a draft timeline of subsequent steps for communication activities:

* Q3 2014: Development of detailed communication plan
* Q3 2014 to Q4 2015: Development and finalization of all materials and messaging
* March 2015: initiation of national and state communication plans and trainings
* From October 2015: follow up and any communications technical support for states to assist in adaptation of messaging, as well as to capture and document any relevant learning