Pneumococcal Vaccine Introduction Plan

Ministry of Health & Family Welfare

Government of India

Pneumococcal Vaccine Introduction Plan

1. Background

Reduction of under-five and infant mortality in India is a priority goal under the National Health Mission and the Twelfth Five year plan of the Government of India.[1,2] The Universal Immunization Programme (UIP) is one of the major interventions to achieve this. This is the largest programme in the world with an annual target of more than 26 million children and 30 million pregnant women. The comprehensive Multi Year Plan (2013-2017) has envisaged introduction of new and underutilized vaccines.[3] The UIP has been expanded to include Hib vaccine as a combined pentavalent vaccine (DPT + Hep. B + Hib vaccines), in a phased manner in the country. On July 3, 2014 the Government of India announced that the country will introduce four new vaccines into their immunization programme [IPV, MR, Rotavirus and JE (adult) vaccines]. IPV and Rotavirus vaccine have been launched recently. It is proposed that pneumococcal vaccine be introduced in UIP in a phased manner in the first quarter of 2017 initially with Gavi support. Gavi, in principle, has agreed to support PCV introduction by providing Pneumococcal Conjugate Vaccine (PCV) for 20% birth cohort per year for three years.

2. Rationale

Pneumonia and diarrhea are the major contributors to infant and under five mortality in India[4]. As per the latest Pneumonia & Diarrhea Progress Report, 2015,[5] an estimated 5.9 million children around the world would have died before reaching their fifth birthday in 2015, of which pneumonia was responsible for 16% and diarrhea for 9%. In 2010, it is estimated that there were 120 million episodes of pneumonia (of which 4 million were severe episodes in children less than 5 years. The estimated pneumonia deaths were 1.3 million; 81% of these occurred in children less than 2 years.

Streptococcus pneumoniae is the leading cause of bacterial pneumonia in children. The infection is transmitted through respiratory droplets. While commonly found in the nasopharynx (nose and throat) of healthy children and adults, pneumococcus can also cause serious disease and death due to pneumonia as well as meningitis. Globally *S. pneumoniae* causes about 11% of all deaths in children

[1] Framework for Implementation. National Health Mission 2012-2017. P.32-33. Ministry of Health and Family Welfare, Government of India

[2] Twelfth Five Year Plan (2012-2017), Social Sectors, Vol. III, p.31. Planning Commission, Government of India, 2013.

[3] The Multi Year Strategic Plan (2013-2017). Ministry of Health and Family Welfare, Government of India.

[4] Walker CLF, Rudan I, Liu L, Nair H, Theodoratou E, Bhutta ZA, O''Brien KL, Cmpbell H, Black RE. Global burden of childhood pneumonia and diarrhea. Lancet 2013;381(9875):1405-1416.

[5] Pneumonia and Diarrhoea Progress Report 2015: Sustainable Progress in the Post 205 Era. International Vaccine Access Centre, Johns Hopkins Bloomberg School of Public Health, Baltimore, USA.

1-59 months of age[6].

Invasive pneumococcal disease (IPD) is commonly defined as morbidity associated with the isolation of pneumococci from a normally sterile body site, such as the blood stream, or those secondary to blood stream spread, e.g. meningitis or septic arthritis; it does not include sites such as the middle ear which are infected by contiguous spread from the nasopharynx.[7] A systematic review of burden of IPD in children aged 1 month to 12 years in South East Asia showed that In India the incidence of IPD was 10.58% in children admitted to hospitals with suspected pneumococcal disease and 24% of all bacterial pneumonia cases were due to *S. pneumoniae*[8]. A recent modelling study on pneumonia in children under five years in India estimated that in 2010, 3.6 million (3.3-3.9 million) episodes of severe pneumonia and 0.35 million (0.3-0.40 million) episodes of all cause pneumonia deaths occurred. The estimated incidence of severe pneumonia was 30.7 (95% CI, 28.1-33.5) per 1000 children less than 5 years of age. The model also estimated 0.56 million (0.49-0.64 million) severe pneumococcal pneumonia episodes and 105 thousand (92-119 thousand) pneumococcal pneumonia deaths in children less than 5 years in India. The annual incidence of severe pneumococcal pneumonia in India was estimated to be 4.8 episodes (95% CI 4.2-5.5) per 1000 children less than 5 years.[9]

The most common serotypes in children less than 5 years of age causing invasive infections were 14, 19F, 5, 6A and 6B; 96.4% of the isolates were resistant to co-trimoxazole, 30% to erythromycin, 5.2% to penicillin. The study showed that PCV-10 can protect against 64% and PCV-13 upto 74.6% of serotypes causing invasive pneumococcal disease. For PCV-10, while serotype 19A polysaccharide conjugate is not contained in the vaccine, it provides cross protection against serotype 19A (as approved by EMA). Vaccination in children indirectly provides protection to the unvaccinated older population and would contribute to reduced nasopharyngeal carriage of antibiotic resistant serotypes.[10]

WHO recommends inclusion of pneumococcal vaccine in national immunization programme complementary to use of other pneumonia control measures.[7] In August 2015, NTAGI reviewed the available global and national evidence and recommended introduction of PCV in the national

[6] O'Brien K, Wolfson LJ, Watt JP, Henkle E, Deloria-Knoll M, McCall N, Lee E, Mulholand K, Levine OS, Cherian T. Burden of disease caused by Streptococcus pneumoniae in children younger than 5 years: global estimates. Lancet 2009; 374 (9693):893-902.

[7] Pneumococcal vaccines. WHO Position paper 2012. Weekly Epidemiological record 2012; 14 (87):129-144

[8] Jaiswal N, Singh M, Thumbru KK, Bharti B, Agarwal A, Kumar A, Kaur H, Chadha A. Burden of Invasive Pneumococcal Disease in children 1 mont to 12 years living in S.East Asia: A systematic review. PLoS One 204; 9(5): e96282.doi:10.1371/journal.pone.0096282

[9] Farouqui H, Jit M, Heyman DL, Zodey S. Burden of severe pneumonia, pneumococcal pneumonia and pneumonia deaths in Indian States: Modelling based estimates. PLoS ONE 2015; 10(6):e0129191.doi:10.1371/journal.pone.0129191

[10] Balaji V, Jayaraman R, Verghese VP, Baliga PR, Kurien T. Pneumococcal serotypes associated with invasive disease in under five children in India and implications for vaccine policy. Indian J Medical Research 2015; 142:286-292.

immunization programme. In addition, under the umbrella of National Health Mission (NHM), the Government of India is implementing maternal and child health interventions focused on early initiation of and exclusive breast feeding, use of oral rehydration salt (ORS) and Zinc tablets in children with diarrhoea, provision of Vitamin A, vaccination as per the national immunization schedule and in general, improving the access to health care.

3. Decision Process

The Standing Technical Sub-Committee (STSC) of the National Technical Advisory Group on Immunization (NTAGI), deliberated on pertinent issues regarding the potential inclusion of PCVs in India's UIP. In its December 22, 2014 meeting, the STSC reviewed available evidence on burden of pneumococcal disease in India and recommended the establishment of a Working Group for collating evidence on the burden of pneumococcal disease in India, including estimates of mortality and morbidity caused by the pathogen in the country. The Working Group met on April 6, 2015 to conduct critical review of evidence on burden of disease, serotype prevalence, prevalence of antibiotic resistance and surveillance of pneumococcal disease in India and submitted its recommendations to the STSC. On 25th August 2015, NTAGI discussed the recommendations of the Working Group and STSC and endorsed a phased introduction of Pneumococcal Conjugate Vaccine (PCV) in India's UIP in three doses, at 6 weeks, 14 weeks and 9 months, with initial introduction in at least some high priority areas (high under 5 mortality) with quality controlled surveillance systems.

The recommendation of the NTAGI were approved by the Empowered Programme Committee of the National Health Mission at its meeting held on 19th January, 2016 and subsequently by the Mission Steering Group at its meeting held on 29th March 2016.

4. Pneumococcal Vaccines and timeline for introduction

4.1) Vaccine presentation:

Currently, there are two pneumococcal conjugate vaccines that are licensed and available in the private sector in India as pre-filled syringes. These are 10-valent (PCV10) manufactured by GlaxoSmithKline Biologicals S.A and 13-valent (PCV13), manufactured by Pfizer Inc. New manufacturers, especially Indian manufacturers, are anticipated to enter the market by 2018-19. The 2 dose vial of PCV-10 vial and 1 dose vial of PCV-13 are WHO pre-qualified. Both these manufacturers are in the process of producing 4 dose vials of their respective vaccines. WHO –pre-qualification for 4 dose vial of PCV- 10 is expected in May 2018 and of PCV-13 in late 2016.

4.2) 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 of India (DCGI). The DCGI approves the manufacture and import of vaccines in the country. The Central License Approving Authority (CLAA) issues licenses for the import of vaccines, while the Central Drugs Laboratory (CDL), Kasauli performs lot release for all imported vaccines as well as locally produced vaccines.

Two dose vials of PCV-10 are currently licensed in India, but don't have a preservative essential for implementation of Open Vial Policy to minimize vaccine wastage. The company is also expected to obtain the license for 4 dose vial in India. For PCV- 13, the company is expected to license one dose vial by May 2016 and 4 dose vial by the end on 2016.[11] The 4-dose vials of both companies will have a preservative (2-phenoxyethanol).

4.3) Timelines for introduction and targeted population:

The Government of India has constituted a National Pneumococcal Vaccine Expert Committee to guide the introduction of pneumococcal vaccine in the country. The Committee, based on the available documents regarding product specifications, projected availability and operational feasibility including multi-dose presentation and compliance with open vial policy, recommended PCV13 (4 dose) as the preferred vaccine type for introduction in UIP with Gavi support. In case of shortage of supply of PCV13, the Committee recommended that other vaccine types may also be considered.

The pneumococcal vaccine will be administered in a phased manner throughout the country. Given the available information on vaccine supply and based on eligible children, infant mortality, disease burden, potential deaths averted, state willingness, the National Pneumococcal Expert Committee identified the following states for introduction of PCV vaccine with Gavi support:

- Year 1 – Bihar (50% state birth cohort [SBC]), Uttar Pradesh (10% SBC)
- Year 2 - Bihar (100% SBC), Uttar Pradesh (20% SBC), Madhya Pradesh (100% SBC), Rajasthan (25% SBC)
- Year 3 – Bihar (100% SBC), Uttar Pradesh (30% SBC), Madhya Pradesh (100% SBC), Rajasthan (50% SBC)

Selection of states for introduction of PCV is tentative and may undergo change. The scale-up to other states by the Govt. of India would be according to the availability of vaccine and funds.

4.4) Vaccine wastage and buffer stock

The vaccine presentation that is preferred for the programme is 4 dose vial of PCV-13 with preservative, so that open vial policy can be implemented. Vaccines have to be delivered to the consignee points. The wastage rate for PCV is presumed to be 15% and buffer stock is kept at 25% in

[11] As per Gavi update in March 2016

the first year. The training programme at all levels, especially of frontline workers will emphasise on implementation of open vial policy for reduction in wastage of vaccine.

4.5) Vaccine requirement

Before introduction of new vaccines, the Government of India procurement of vaccines ensures that all nodes of vaccine storage from national stores up to last cold chain points are adequately stocked to prevent any stock out situation and handle unforeseen circumstances. This enables the Government to ensure that the supply of vaccine is smooth and there is no interruption due to vaccine shortage. It also ensures that there are adequate vaccines for its intensified efforts to increase coverage through special drives such as Mission Indradhanush. Therefore, the doses of PCV calculated are not on the basis of Penta1 and Penta3 coverage but on the basis of 100% coverage in the first year of introduction with 25% buffer and 15% wastage. For subsequent years, it will be based on replacement of consumption of vaccine, assuming that the coverage is 90% and wastage is 15%. All calculations have been done using no. of births, as 1st dose of PCV is given at 6 weeks. The above considerations can help avoid vaccine shortages which were observed in the case of IPV supply, possibly due to an underestimation of vaccine requirements. Same principles had governed proposals submitted previously to Gavi for new vaccine introductions. The wastage rate has been observed to be 15% while using multi-dose vials with open vial policy. Any calculations based on wastage rate less than 15% can lead to vaccine stock-outs. In addition, for smooth vaccine supply, any changes in price of vaccine or freight costs must be factored in by Gavi only in the last tranche of PCV supply and not in the initial stages.

Gavi also has an objective of improving coverage and equity and calculation of dose on the basis of current coverage will not be in alignment with this objective and leaves no scope for improving the programme by increasing coverage.

The vaccine requirement for introduction of PCV in UIP in a phased manner with Gavi support (calculated as given above) is given the **Table 1**. The estimated vaccine requirement from Gavi is ~ 60 million doses covering on an average of nearly 20% of target population each year for a period of three years. In all likelihood this dose requirement will not change much; though the states indicated in the table above are tentative and subject to change. The Govt. of India will continue PCV immunization in these states once Gavi support is over, as has been done in the past with pentavalent and hepatitis B vaccines. The Government of India will scale up vaccine introduction in the rest of the country in a phased manner. The specific states and the timing of scale up will be decided when the next plan is finalized as per financial allocations, as the current plan will be over in 2017.

Table 1: Vaccine requirement for PCV introduction (tentative plan, subject to change)

Year	No. of states & UTs	Estimated target infant population	% of total infant population	PCV doses required
Year 1 (2017)	2	2,014,900	7.7%	8,915,933
Year 2 (2018)	4	6,407,550	24.5%	25,865,001
Year 3 (2019)	4	7,390,500	28.4%	24,797,213

Assumptions

For 1st year of PCV introduction in a state, it is assumed that there will be 100% coverage, 15% wastage and 25% buffer to ensure sufficient availability of the vaccine in the pipeline.

For subsequent years, it is assumed that vaccine requirement will be based on replacement level of 90% coverage and 15% wastage.

5. Introduction and implementation Plans

5.1) Vaccination Schedule

PCV will be administered in 3 doses as part of routine immunization.

The first dose of the vaccine will be administered at the time of first dose of Pentavalent, OPV and Rotavirus vaccine (in states introducing Rotavirus vaccine). The second dose will be given at the time of 3rd dose of Pentavalent, OPV, IPV and Rotavirus vaccine (in states introducing Rotavirus vaccine). The third dose of the vaccine will be administered at 9 months of age at the time of 1st dose of measles vaccine (or MR vaccine when it is introduced in routine immunization programme) and first dose of JE vaccine (in endemic areas)

The dose of the vaccine 0.5 ml and is to be administered by intramuscular injection in the anterolateral aspect of the thigh of infants.

Table 1: Comparison of current and post PCV introduction Routine Immunization schedule in India

Age	Current scheduled vaccines	After introduction of PCV and MR
At Birth	BCG, bOPV-0, Hep B-0	BCG, bOPV-0, Hep B-Birth Dose
6 weeks	bOPV-1, Pentavalent-1, Rota*	bOPV-1, Pentavalent-1,Rota*, **PCV1***

10 weeks	bOPV-2, Pentavalent-2, Rota*	bOPV-2, Pentavalent-2, Rota*,
14 weeks	bOPV-3, Pentavalent-3, Rota*,fIPV	bOPV-3, Pentavalent-3, , Rota*, fIPV, **PCV 2***
9 months	Measles-1, JE-1*	MR-1* , JE-1* , **PCV 3***
16-24 months	Measles-2, DPT-B1, bOPV-B, JE-2*	DPT-B1, bOPV-B, JE-2*, MR-2*
5-6 years	DPT-B2	DPT-B2

*where applicable

5.2) Injection safety and waste management

Disposal of wastes and sharps will be carried out as per the Bio-medical and waste (Management and Handling) Rules for generating, collecting, receiving, storing, transporting, treating, disposing, and/or handling bio-medical waste in any manner. These are included in the guidelines for routine immunization. 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 session-sites is shared with districts and states for appropriate response. During training for pneumococcal vaccine introduction, injection safety and its benefits for the health worker, beneficiary and community will be re-emphasized.

5.3) National co-ordination mechanism for introduction of pneumococcal vaccine

The overall co-ordination of introduction of pneumococcal vaccine will be by the Ministry of Health and Family Welfare with Immunization Division of the Ministry providing oversight and monitoring of progress. A National Pneumococcal Vaccine Expert Committee to guide the introduction of the vaccine in the country. The committee consists of independent experts and liaison members from concerned Government departments and partners. The committee is responsible for advising the MoHFW on preferred specifications, identification of states for initial introduction and advising the Vaccine Introduction Working Group on developing tools and guidelines for training, program operations and communication, developing introduction plans, monitoring progress in implementation and measuring impact of PCV introduction. Meetings of the Expert Committee was held on 1st April 2016 and 5th July 2016 for identifying the preferred product and the States for initial introduction of the vaccine with support from Gavi.

Partners will support the Ministry in training and support to States for introduction.

5.4) Cold Chain capacity and vaccine logistics management

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. The Cold Chain system spans all 36 States and UTs, 666 districts, 28882 CHCs and PHCs, along with Cold Chain points at Defence/Railway/ESI hospitals and such associated health facilities, and even up to sub-centres and immunization sites level in certain places.

The logistics is managed through storing and transporting vaccine in a pre-defined network. The vaccines typically arrives at the primary stores and then are transported to regional vaccine stores and through district vaccine store, it reaches the service delivery point. Cold chain network in the country has been the backbone to ensure that right quantity and right quality of vaccine reaches the target population (Figure 3).

The monitoring of the Cold Chain system in India takes place through the National Cold Chain Management Information System (NCCMIS) operational across all States and UTs. The NCCMIS has the provisions for providing the mandated proforma based reports as required to be submitted by the district and State to the MoHFW. It can provide more than 60 detailed reports on cold chain inventory, cold chain point information, equipment related information and performance indicators at all levels of the immunization supply chain.

India recently conducted a national EVM assessment; the progress report on status of implementation of EVM assessment is Annexed as Document 7. An electronic vaccine intelligence network (eVIN), an online system for assessing cold chain equipment functionality and space availability has also been developed. Under Gavi Health System Strengthening Grant phase I, eVIN is being scaled up to 12 states. It has already been scaled up to Madhya Pradesh, Uttar Pradesh and Rajasthan; and it will be extended to the remaining states by the end of current grant period.

Introduction of Pentavalent vaccine across the country has further freed cold chain space within the existing equipment. Additionally, there is an ongoing procurement which will substantially extend the cold chain space availability sufficiently to accommodate all new vaccine introductions. With these procurements, soon the cold chain space in terms of number of ILRs and Deep Freezers is expected to increase by over 30%; walk-in coolers and walk-in freezers would increase by 8% and 26% respectively.[12] Also, if required, additional human resource such as cold chain technicians and

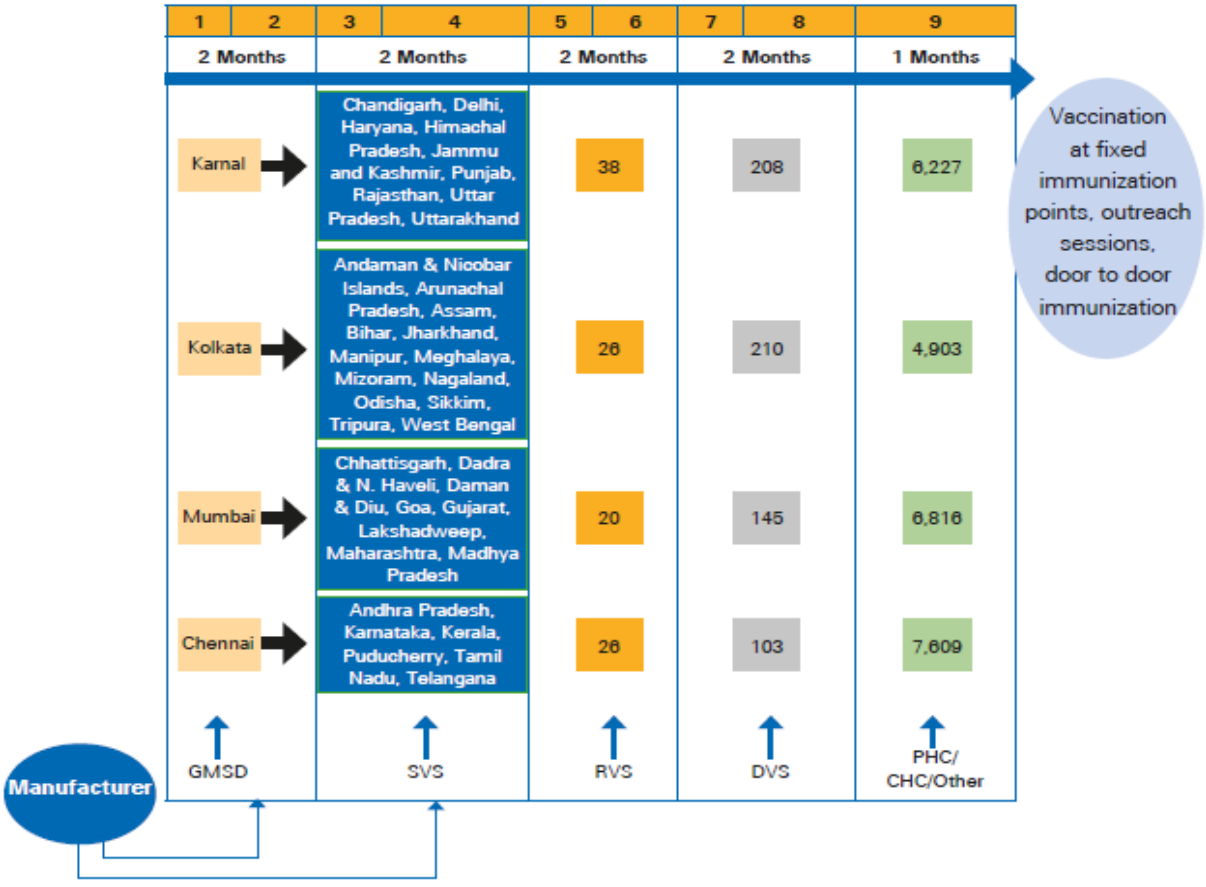
[12] Source: MoHFW, Govt. of India

cold chain handlers will be hired and trained to support vaccine logistics and cold chain management.

The Government of India is implementing an alternate vaccine delivery (AVD) system, to ensure that the immunization session starts on time, vaccines are collected on the same day and unused/opened vials and immunization waste are brought to PHC on the same days. There are various ways of implementation of AVD system such as hiring of vehicle/auto-rickshaw, motor cycle/bicycle, potter, boats etc. Under the National Health Mission, flexible funds are available for the AVD system, which can be utilized based on the local conditions.

There is sufficient availability of power supply as the majority of cold chain equipment require only up to 8 hours of electricity per day. In selected areas, where power supply may be limited, solar cold chain equipment are being installed.

Fig. 3: Vaccine storage network and storage timelines in India. (Source: National Cold Chain Assessment 2014)



5.5) AEFI surveillance system

Adverse events following vaccination with PCV will be reported and investigated through the current AEFI surveillance system. The current AEFI surveillance system in place in India involves the immediate reporting of any adverse events after vaccination. This is followed by detailed investigation by the members of district AEFI committee. Causality assessment of each case is done by state and national AEFI committee.

In the recent past, lot of efforts have gone in strengthening the AEFI surveillance system. AEFI Surveillance and Response Operational guidelines were revised in 2015, in sync with Global AEFI Guidelines (2014), to ensure use of standardized definitions and terminologies and improve quality of case investigations. Based on these guidelines, all medical officers and health workers are being trained on AEFI Surveillance, across the country. During the trainings of medical officers and health staff for PCV introduction, refresher training on AEFI will be given. This will have the added benefit of strengthening the existing AEFI surveillance system. It was observed during Pentavalent vaccine introduction that there was simultaneous strengthening of AEFI surveillance and increase in number of districts reporting serious AEFI cases.

5.6) Training

The successful introduction of PCV vaccines will largely depend upon the quality of training conducted for all levels of health functionaries. Health-care providers are not only responsible for handling and administering the vaccine but are also a major source of information for parents and the community. A good training gives confidence to the health workers to introduce new vaccines. Trainings shall particularly focus on building capacity of vaccinators to alleviate any anxiety of vaccinators and community occurring due to multiple injections at the same visit (14 weeks). A systematic review of evidence on safety of administering multiple injectable vaccines during a single visit and evidence on healthcare provider and infant caregiver attitude found that parental acceptance of all injections was associated with a positive provider recommendation to the caregiver.[13]

Health-care personnel who require training include national and state level program managers, district immunization officers (DIOs), medical officers (MOs), cold chain handlers, supervisors, data managers and frontline health workers and their supervisors. The ASHAs are also to be oriented for effective community mobilization. The officials and staff of the Department of Women and Child Development such as child development project officers (CDPOs), integrated child development services (ICDS) supervisors and Anganwadi workers also need to be trained at the same time. In addition, the faculty of Paediatrics and Preventive and Social medicine departments in medical

[13] Meeting of the Strategic Advisory Group of Experts on Immunization, April 2015: conclusions and recommendations. Weekly Epidemiological Record 2015; 90 (22): 261-280.

colleges as well as professional bodies (IAP, IMA) involved in immunization service delivery and monitoring.

Cascaded trainings for all levels will be conducted. It will begin with a national level training of state level officers. Subsequently the state level officers will conduct trainings in their respective states, beginning with a state level training for district level officials, followed by training of block medical officers by district level officers who will in turn train the including ANMs, supervisors and cold chain handlers, data mangers, frontline workers and their supervisors.

5.7) Monitoring & Evaluation

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:

- *Preparatory Phase*

During the preparedness phase, districts and states will be expected to assess their preparations through PCV introduction check-lists that will be devised for this purpose at all levels. 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.

- *Implementation Phase*

Standardized data collection formats and operating procedures, developed by the GoI will be used to monitor the provision of RI services at immunization session sites and community level coverage of all antigens (including PCV) offered through UIP to detect coverage gaps and take corrective action.

Partner agencies will actively support to monitor the implementation. Feedback will discussed during district and state task force meetings for immunization for corrective actions.

- *Post Introduction Evaluation*

Post Introduction Evaluation (PIE) survey will be conducted 6 to 12 months after the introduction of PCV.

6. Surveillance for *S. pneumoniae* and Impact assessment for PCV

The NTAGI recommended that a quality controlled surveillance systems and carefully designed and conducted impact assessment with appropriate oversight must be carried out. Surveillance for pneumococcal meningitis, pneumonia and nasopharyngeal carriage will be established. As recommended by the National Pneumococcal Vaccine Expert Committee, sites for establishment of pneumococcal disease surveillance will have to be carefully decided and an expert group will be established to arrive at an appropriate methodology for PCV impact assessment.

7. Affordability and sustainability

Gavi has agreed, in principle to support PCV introduction by providing Pneumococcal Conjugate Vaccine (PCV) for 20% birth cohort per year for three years. During the Gavi support, Government of India will provide all other logistics such as Auto Disable (AD) syringe and training required for the PCV introduction. Assuming a cost of US $ 3.1 per dose Gavi price for PCV 13, the total cost for introduction amounts to US$185 million with Gavi support (excluding freight costs). However, past experience has shown that vaccine price comes down after new vaccine introduction in the national immunization programme. Also, indigenous pneumococcal vaccines are expected to be available by 2018-19 The Govt. of India will continue PCV immunization in these states once Gavi support is over, as has been done in the past with pentavalent and hepatitis B vaccines. The remaining financial support will be provided by the Government of India for scaling up vaccine introduction in the rest of the country in a phased manner. The specific states and the timing of scale up will be decided when the next plan is finalized as per financial allocations, as the current plan will be over in 2017.

8. Ensuring Equitable access to PCV

Immunization is provided free of cost to all eligible infants who access the public health system and efforts will be made to ensure PCV reaches all targeted beneficiaries. In fact, PCV and other new vaccines are being introduced in UIP to ensure equitable access to them across all sections of the population, as these vaccines are not otherwise affordable to majority of the population due to their high retail prices.. UIP is also implementing specific strategies to reduce left outs, missed opportunities and drop outs by using due list by front line health workers for tracking beneficiaries and strengthen name based mother and child tracking system (MCTS). Gender disaggregated data is reported for full immunization coverage through the health management information system (HMIS). In addition, Pulse Polio campaigns identified and reached more than 4,00,000 high risk areas inhabited by the most disadvantaged segment of population. Subsequently, Mission Indradhanush (MI), which was launched in 2014, aims to cover all such under-served areas and help achieve 90% immunization coverage by addressing equity gaps and increasing demand for immunization. Three phases of MI have

been completed. Each phase is spread over 4 months (rounds) and during each month, a special week of intensified immunization activities is organized in the most under-served areas of districts with low/medium immunization coverage. The first, second and third phases of MI were conducted in 201, 273 and 352 districts across the country respectively. The cumulative reported coverage of three phases is as follows: 2.7 million sessions were conducted; over 19.5 million children and nearly 5.2 million pregnant women were immunized; and over 5.1 million children were fully immunized (received BCG, three doses of DPT/Pentavalent and one dose of measles vaccine) and 2.7 million pregnant women were completely immunized (received two doses of TT). Based on learnings of MI, these areas are being incorporated into the routine immunization, so that the increase in immunization coverage and equity could be sustained. MI has led to health systems strengthening through meticulous planning and preparation of robust micro-plans for the frontline health workers, along with accountability framework through task forces and rigorous monitoring structures.

9. **Communication Plan**

Communication strategy and materials will be developed to support the introduction of PCV vaccine. Partner agencies 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 along with prototypes of communication materials which will assist immunization partners and stakeholders in understanding and implementing the introduction of PCV. The states will be responsible for dissemination of the information prior to introduction.

The communication plan will include objectives and rationale for PCV introduction; key communication messages and messaging challenges National and State officials, health workers and other healthcare delivery staff, community and traditional leaders, National and local medical bodies – IAP/IMA as well as parents and caregivers.

The communication materials and prototypes to be developed include briefs and FAQs – both general and technical; media and issues management; social mobilization; health worker training materials, guidance on event planning.

Multiple media channels will be utilized to ensure wide and effective dissemination.

10. **Role of Partner Agencies**

As done in the past vaccine introductions, Govt. of India will collaborate with all partner organizations actively working in immunization at various levels and leverage all opportunities for synergy, in activities for PCV introduction.

Technical support for new vaccine introduction is provided by Immunization Technical Support Unit (ITSU). The ITSU is the nodal agency for new vaccine introduction expert groups including National Expert Pneumococcal Committee and also coordinates Gavi supported activities for the MoHFW.

Different partner organization have their core competence in various thematic areas of the program and would support GoI in all activities related to these areas, such as technical support for developing guidelines, trainings at various levels, monitoring and impact assessment. A description of broad roles of various immunization partners is given below. These are illustrative and not exhaustive, as there are several cross cutting areas for which support is provided to the MoHFW depending on need and availability:

- Organizations which support immunization program operations and monitoring at various levels include World Health Organization (WHO), United Nations' Children's Fund (UNICEF), ITSU and John Snow Inc. (JSI).
- Communications is focus area for organizations such as UNICEF, ITSU, and Global Health Strategies (GHS).
- Organizations actively supporting cold chain and vaccine logistics management include UNICEF through the National Vaccine Cold Chain Management Resource Centre (NCCVMRC), United Nations Development Programme (UNDP), ITSU and Clinton Health Access Initiative (CHAI).
- AEFI Surveillance has been the key focus area of WHO and ITSU, which have supported the program through initiatives for improved and timely reporting, investigation and classification of AEFI cases.
- Other organizations which actively technical support to UIP in key program areas (innovation, research, technology assessment etc.) include the Bill and Melinda Gates Foundation (BMGF), International Clinical Epidemiology Network (INCLEN), Indian Council of Medical Research (ICMR) and Program for Appropriate Technologies in Health (PATH).
- Professional bodies which have also wholeheartedly supported GoI in new vaccine introductions include the Indian Academy of Paediatrics (IAP), Indian Medical Association (IMA), Indian Public Health Association (IPHA), Indian Association of Preventive and Social Medicine (IAPSM).

In addition, all partners provide support for training, monitoring during introduction and post introduction evaluation.

11. Challenges and how to overcome them based on lessons learnt from past new vaccine introductions in India

11.1) Availability of vaccine

- The 4 –dose vial PCV-13 is currently not licensed for use in India and any delay in registration will delay vaccine introduction.

11.2) Planning introduction of new vaccines

- Each state should prepare an introduction for new vaccines with detailed activities and timelines, at least 3–4 months before the new vaccine launch.
- Every state should have a functioning state and district task forces for immunization for regular review of the immunization programme. Standard assessment checklists should be used by each state and district to review their preparedness by deploying review teams.
- Vaccine launches should be organized with the involvement of celebrities, leaders, media and professional bodies, with minimum gap between the launch and actual start of immunization.
- Existing staff vacancies should be filled at the earliest, and staff deployment rationalized to ensure presence in high-risk districts/blocks.

11.3) Microplanning

- Existing routine immunization microplans in all districts should be revised to include high-risk areas and migratory/non migratory settlements mapped under the polio programme. Microplans should include all programme components.

11.4) Training and motivation of health workers

- Cascaded trainings are envisaged for building capacity of all cadres of health staff involved in new vaccine introduction and other routine immunization strengthening activities. The completion of all trainings should be tracked.
- The incentives of ASHAs should be released timely to ensure their motivation and commitment. The incentives for ASHA and mobilizers will have to be updated to include PCV for full immunization coverage. This would need to be conveyed timely and uniformly to all ASHAs and mobilizers across the states introducing PCV.

11.5) Cold chain and vaccine logistics management

- Cold chain inventory should be regularly reviewed and status of the same should be updated in National Cold Chain Management Information System (NCCMIS). Recording of temperatures in ice-lined refrigerators (ILRs) and deep freezers should be done regularly even on weekends.
- Vaccine management should be strengthened so that forecasting and indenting are accurate to avoid stock-outs or excess vaccines. The Open Vial Policy (OVP) guidelines should be available at all facility levels. Health workers should be trained to comply with OVP to reduce vaccine wastage.

11.6) Surveillance for adverse events following immunization (AEFI)

- Training of health workers for identifying and reporting AEFI. Private practitioners should also be sensitized for reporting and managing AEFI cases. District officials should be trained on media handling. AEFI kits should be in place during all immunization sessions.

11.7) Injection safety and waste management

- Outsourced models of waste management usually work better than the model of making the PHC responsible for disposal of waste through waste pits. States should consider adopting these models for more efficient waste management.
- Health workers should be trained on injection safety and waste management. Hub cutters, and black and red bags should be made available at session sites.

11.8) Advocacy, social mobilization and communication

- Efforts to raise community acceptance should be undertaken both before the launch of a new vaccine and periodically thereafter.
- State-level media sensitization workshops should be conducted before the vaccine launch to increase public awareness and deal with vaccine-related queries. All states should strengthen their print/electronic media engagement and handling plans.
- Information, education and communications (IEC) materials should be clear, attractive, easy to read and containing focused and sufficient information. If needed, they should be translated into local languages for wider dissemination.

11.9) Supervision and monitoring

- Supportive supervision and appropriate oversight should be maintained through State nodal officers and Field monitors (FMs) and a regular feedback mechanism should be in place.
- Rapid monitoring should be initiated at block & session level within 3 months of new vaccine introduction to assess identify gaps/bottlenecks and provide feedback for immediate corrections.

11.10) Coverage, reporting and data collection

- Data entry portals should be upgraded in the HMIS software before the vaccine launch. The data collected from paper reports and HMIS/MCTS on coverage should be readily retrievable at all levels and should be checked for accuracy, and analysed to provide feedback.
- Reporting and recording tools such as mother-child protection (MCP) cards, tally sheets, etc. should be timely updated to include columns for recording of new vaccines. Due lists should be prepared based on head count of under five year old children. Health workers should be trained to correctly fill these revised tools.

11.11) Private sector involvement in new vaccine introduction

- The private sector should be actively involved in immunization activities from pre-launch stage, including reporting of vaccine preventable diseases and AEFI. Private practitioners should be included in training and monitoring of activities for implementation of new vaccine introduction.

11.12) Leveraging synergies with other new vaccines introductions

- The Government of India is also going to conduct MR vaccine campaigns and will also be expanding rotavirus vaccine beyond the initial 4 states. Activities for these simultaneous vaccine introductions will have to be managed to ensure maximum synergy and efficiency in implementation.
- Training, monitoring and communication plans for MR and PCV vaccines will be developed keeping this synergy in mind so that duplication of efforts is minimised in a state.
- Trainings for IPV and pentavalent vaccines were also carried out together in states with simultaneous vaccine introduction. Communication activities such as media sensitization workshops were synchronized in the past for multiple new vaccine introductions in many states. Post introduction evaluation can be also clubbed as was done in the past with both 2nd dose MCV and pentavalent vaccine introductions in states.
- The country National Pneumococcal Vaccine Expert Committee has recommended introduction of PCV in some states where Rotavirus is also introduced to enable impact assessment of these two vaccines on diarrhoea and pneumonia morbidity and mortality.

Annexure: PCV Introduction Activity Checklist & Timeline (tentative)

Country: **India** New Vaccine: **Pneumococcal Conjugate Vaccine (PCV)**

Planned introduction date: **Q1 2017** Lead Agency: **MoHFW and RI Partners**

		2016										2017						
Theme	Activity/Action to be taken	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July
											Introduction of PCV							
Preparatory activities	Establish the national expert committee for introduction of PCV																	
	Prepare the PCV Introduction plan																	
	Draft the NVS application proposal																	
	Submission of the application and introduction plan to GAVI																	
	Preparedness Assessment Checklist at state and district levels																	
Development & revision of immunization guidelines	Prepare the operational guidelines for introduction of PCV																	
	Revision of existing UIP guidelines																	
Strengthening and building capacity of the immunization staff	Develop training materials and standard package of education materials																	
	Review and update UIP training manuals and reference materials																	
	Develop a training plan																	
	Training of trainers																	
	Conduct training at state/ district level																	
	Conduct training for block level																	
Logistics, injection safety, wastage & procurement management	Monitor and replace/ provide/ repair cold chain equipment at all levels																	
Strengthening monitoring and supervision	Revision of supervisory checklists																	
	Revise immunization recording and reporting forms																	
	Establishment of supervisory teams																	
	Conduct supervision visits at all levels																	
	Coverage Monitoring																	
	Post Introduction Evaluation																	
Communication & Advocacy	Develop IEC materials and messages																	
	Develop media kit for journalists																	
	Publish information about new vaccine in mass media including TV, radio, online information agencies, medical journals																	
	Conduct meetings with community leaders																	
	Monitor communication activities at all levels																	
Disease burden surveillance	Establish surveillance sites																	
	Conduct baseline surveillance and impact assessment																	
AEFI Surveillance	Strengthen AEFI surveillance system																	
	Develop AEFI crisis communication plan																	