Ministry of Health
& Family Welfare
Government of India

सत्यमेव जयते

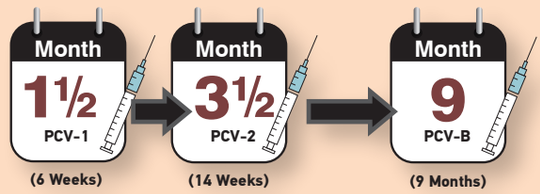
NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

NATIONAL OPERATIONAL GUIDELINES



INTRODUCTION OF

PNEUMOCOCCAL CONJUGATE VACCINE (PCV)





India 2017
Reprint

स्वच्छ भारत
एक कदम स्वच्छता की ओर

NATIONAL OPERATIONAL GUIDELINES

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Abbreviations

AD syringe	auto-disable syringe
AEFI	adverse event following immunization
ANM	auxiliary nurse midwife
ASHA	accredited social health activist
AWW	anganwadi worker
BCC	behavior change communication
CHC	community health center
CSF	cerebrospinal fluid
CSO	civil society organizations
CTC	controlled temperature chain
DF	deep freezer
DIO	district immunization officer
DPT	diphtheria-pertussis-tetanus
DTFI	district task force for immunization
EPI	Expanded Programme on Immunization
eVIN	electronic vaccine intelligence network
EVM	effective vaccine management
FAQs	frequently asked questions
GHS	Global Health Strategies
HIV	human immunodeficiency virus
HMIS	health management information system
Hib	Haemophilus influenzae
HRAs	high-risk areas
IAP	Indian Academy of Pediatrics
ICDS	Integrated Child Development Services
IEC	information, education and communication
ILR	ice-lined refrigerator
IMA	Indian Medical Association
IPHA	Indian Public Health Association
IPV	inactivated polio vaccine
MCTS	mother-child tracking system
MOHFW	Ministry of Health & Family Welfare
MO	medical officer
NCCMIS	National Cold Chain Management Information System
NHM	National Health Mission
NPSP	National Polio Surveillance Project
NTAGI	National Technical Advisory Group on Immunization
PCV	pneumococcal conjugate vaccine
PHC	primary health center
PIE	post introduction evaluation
RSOC	Rapid Survey on Children
SAGE	Strategic Advisory Group of Experts on Immunization
SHS	State Health Society
SMNet	Social Mobilization Network
STFI	state task force for immunization
STSC	Standing Technical Sub-Committee
TT	tetanus toxoid
ToT	training-of-trainers
UIP	Universal Immunization Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VHND	village health & nutrition day
VVM	vaccine vial monitor
WHO	World Health Organization

Contents

राष्ट्रीय स्वास्थ्य मिशन
सी.के.मिश्रा
सचिव
C.K.Mishra
Secretary

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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

Message

It gives me great pleasure to present the Operational Guidelines for Introduction of Pneumococcal Conjugate Vaccine (PCV) under Universal Immunization Programme (UIP). The vaccine is planned for introduction in a phased manner across the country. In the first three years of introduction, the vaccine is planned for introduction in five states.

The UIP was launched in India in 1985 and since then India has made significant progress in expanding the coverage and improving the quality of routine immunization across the country. With our untiring efforts, we have been successful in making our nation polio-free despite unique challenges. India has also been validated for maternal and neonatal tetanus elimination. These two successes are testimony to our commitment to save our children from preventable diseases.

While we take pride in these accomplishments, substantial efforts are still needed to end child deaths due to preventable causes. Immunization is considered to be one of the most cost-effective public health interventions to provide protection against preventable childhood diseases. Pneumonia is a known significant cause of childhood mortality globally as well as in India.

PCV vaccine has been in use in the private sector, however, these are expensive and, therefore, not affordable by a large proportion of India's population. This endeavor will enable us to reach out to the children who are in most need.

The operation guidelines for PCV introduction are meant to enhance the capacity of the immunization program managers at the state, district and sub-district level to operationalize the introduction of the PCV vaccine. I am very positive that the document will strengthen the states in roll out of the vaccine. I commend the sincere efforts of all the partners, especially WHO, UNICEF, UNDP and ITSU who have contributed to the development of this document.

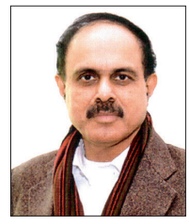
(C. K. Mishra)

Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@nic.in
Room No. 156, A-Wing, Nirman Bhavan, New Delhi-110 011

Arun Kumar Panda
Additional Secretary &
Mission Director, NHM
Tele : 23063155, Fax : 23063156
E-mail : asmd-mohfw@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य एवं परिवार कल्याण विभाग
निर्माण भवन, नई दिल्ली-110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
DEPARTMENT OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

Message



India's Universal Immunization Programme (UIP), launched in 1985 is the largest immunization programme in the world catering to 26 million newborns, with over 9 million immunization sessions planned per year. It has been the Government's constant effort to not only improve access, coverage and quality of immunization services but also to reach the un-reached and to ensure full immunization coverage to all children under the UIP.

To expand the coverage under the immunization programme, new vaccines (such as Pentavalent 2011-15, IPV 2015, Rotavirus vaccine 2016, Measles-Rubella 2017) have been recently introduced in the programme. To take further this momentum of protecting children from more and more diseases, Government of India has decided to introduce Pneumococcal Conjugate Vaccine (PCV) in the country. This will help us in reducing the burden of pneumonia and other illnesses caused by Streptococcus pneumoniae.

It is a well-known fact that pneumonia is one of the most common causes of morbidity and mortality in children younger than 5 years. In India, pneumonia caused by Streptococcus pneumoniae (pneumococcal pneumonia) is responsible for nearly 30% of pneumonia deaths. Therefore, it was felt necessary to introduce the PCV vaccine in UIP.

I thank all my colleagues who have contributed to pneumococcal conjugate vaccine introduction and also look forward to their support to make it a successful endeavor so as to move ahead in the direction of building our nation as a safe place for children.

(Dr. Arun K. Panda)

वन्दना गुरनानी,भा.प्र.से.
संयुक्त सचिव

VANDANA GURNANI, I.A.S.
JOINT SECRETARY
Tel. : 011-23061706
E-mail : vandana.g@ias.nic.in

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - **110011**
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

Foreword

Reduction of under-five mortality is an important indicator of child health and well-being. Vaccination against vaccine preventable diseases plays a pivotal role in reducing it. The Universal Immunization Program (UIP) of the country undertakes extraordinary efforts to identify at-risk populations and overcome inequities in vaccination. Besides undertaking steps to increase coverage and reaching out to the unreached, the programme is also expanding its horizon by introducing new vaccines, which were earlier not within the reach of a large section of the population.

The National Technical Advisory Group on Immunization (NTAGI) has recommended the introduction of pneumococcal conjugate vaccine (PCV) in UIP. Pneumococcal conjugate vaccine will prevent pneumonia due to Streptococcus pneumoniae, which is the leading cause of bacterial pneumonia in children. India has a high burden of pneumonia and it is estimated that pneumococcal pneumonia was responsible for 16% of severe pneumonia episodes and 30% of pneumonia deaths in 2010.

As children who do not have access to care are the most at risk for disease and death, vaccines serve as an especially important tool to reach the marginalized communities. Introduction of vaccine in national programme helps to further strengthen the programme.

The Operational Guidelines have been developed with valuable technical inputs from various partners like WHO, UNICEF, UNDP and ITSU among other significant ones. The guide is intended for managers of immunization program and other professionals working in this field, as a tool for introduction of pneumococcal conjugate vaccine in the immunization program.

(Vandana Gurnani)

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन

Dr. PRADEEP HALDAR
Deputy Commissioner (IMM)
Telefax : 23062728, 23062126
email : pradeephaldar@yahoo.co.in

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110108
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110108

Preface

The introduction of pneumococcal conjugate vaccine (PCV) has widened the ambit of the Universal Immunization Programme (UIP) in terms of providing protection to children from vaccine preventable diseases. Pneumonia is a major cause of under- five mortality, and it is a known fact that pneumococcal pneumonia, caused by *Streptococcus pneumoniae*, is a major contributor to that. Pneumococcal disease is the number one vaccine-preventable cause of death in children under 5 years of age globally and in India. In that direction, the National Technical Advisory Group on Immunization (NTAGI) recommended the introduction of pneumococcal conjugate vaccine (PCV) in UIP.

PCV is planned for introduction in a phased manner, and by the end of third year the vaccine will be introduced in five states. The schedule of PCV, as two primary doses (at 6 and 14 weeks) and one booster dose (at 9 months of age), is in alignment with the national immunization schedule. PCV introduction will provide another opportunity to states to strengthen their health system.

To guide the health personnel of states for introduction of PCV vaccine, operational guidelines have been developed by Ministry of Health and Family Welfare with inputs from immunization partners like WHO, UNICEF, ITSU, UNDP and others. These guidelines will help the states to conduct trainings, plan vaccine & other logistics and monitor the introduction of PCV in their respective states. I thank all those who have contributed to bring this publication in light and convey my best wishes for states for PCV introduction.

7/4/17

(Dr. Pradeep Haldar)

1 Background and Introduction

1.1 BACKGROUND

India has achieved impressive milestones through immunization and continues with its efforts to achieve comprehensive immunization coverage through the Universal Immunization Programme (UIP). The UIP provides all vaccinations free-of-cost to all eligible infants to ensure equity to children accessing the public health system. This is one of the largest programmes in the world with an annual target of nearly 2.5 crores (25 million) children and 3 crores (30 million) pregnant women.

Reduction of under-five and infant mortality in India is a priority goal under the National Health Mission (NHM) and the Twelfth Five-year plan of the Government of India. After the first month of life, vaccine-preventable diseases remain the biggest threat to children, accounting for more than 500,000 deaths annually in India, as of 2008[1]. Immunization is considered to be one of the most cost-effective public health interventions for protection of children, especially under-5 years of age, from life-threatening conditions which are preventable. The immunization programme has contributed significantly in bringing down infant mortality rate (IMR) from 60/1000 live births in 2005 to 34/1000 live births in 2016[2].

With an annual birth cohort of 2.5 crores (25 million), India has the largest commitment to keep in its national immunization program[3]. As per the latest evaluated coverage NFHS-4 (2015/16), the full immunization coverage is 62%. To ensure the full impact of both current and new vaccines, there has to be very high full immunization coverage in the country. Each great stride helps save more lives and prevent illness. It is important to continue to maintain the same level of momentum for the fight against vaccine-preventable diseases. As envisaged under the comprehensive Multi-year Plan (2013-2017), the Ministry of Health & Family Welfare (MoHFW), Government of India, has implemented various routine immunization intensification strategies to reduce under-five morbidity,

mortality and disability due to vaccine preventable diseases by providing quality immunization services to all eligible populations.

As part of Government of India's accelerated efforts, pledging to reach full immunization coverage in the next 5 years, the UIP is already implementing strategies to reduce left-outs, missed opportunities and drop-outs by using due list by front-line health workers for tracking beneficiaries, strengthening mother-child tracking system (MCTS) and conducting special immunization drives at regular intervals.

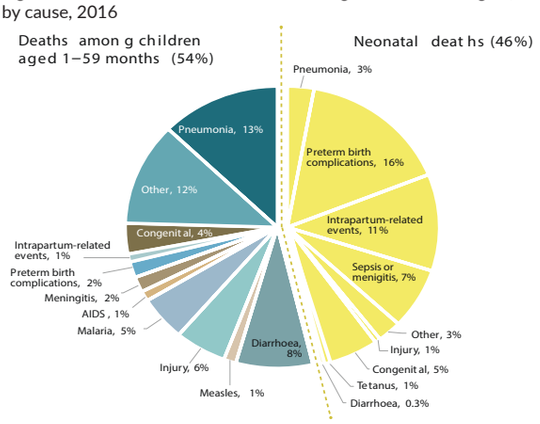
The efforts to strengthen political commitment and mobilize communities to scale up efforts that target the hardest-to-reach communities signal the renewed commitment of India's leadership to improve child survival. India has now been increasingly focusing its efforts on hard-to-reach populations and addressing the coverage and equity agenda through evidence-based strategies. 'Mission Indradhanush,' launched in 2014, is one of the recent

1 Data from the Registrar General of India, 2008.
2 Sample Registration System 2016
3 http://pib.nic.in/newsite/PrintRelease.aspx?relid=171251

initiatives to help achieve 90% immunization coverage by 2020 by addressing equity gaps and increasing demand for immunization. Approximately 2.94 crores (29.4 million) children have been covered in 528 districts under this ambit. To accelerate the achievement of 90% full immunization coverage target by December 2018, the Ministry of Health & Family Welfare launched Intensified Mission Indradhanush to improve immunization routine immunization performance in select 190 districts/urban areas with low coverage through targeted interventions focusing on routine immunization microplanning and greater inter-ministerial/departmental convergence. Under the UIP, significant achievements have been made in preventing and controlling vaccine-preventable diseases through introduction of various new and underutilized vaccines. These include nationwide introduction of *Hameophilus influenzae* type b (Hib)-containing pentavalent vaccine and inactivated polio vaccine (IPV), as well as phased introduction of rotavirus vaccine and measles-rubella (MR) vaccine.

Pneumococcal disease is the biggest vaccine-preventable cause of death in children under five,

Figure 1. Global distribution of deaths among children under age 5, by cause, 2016



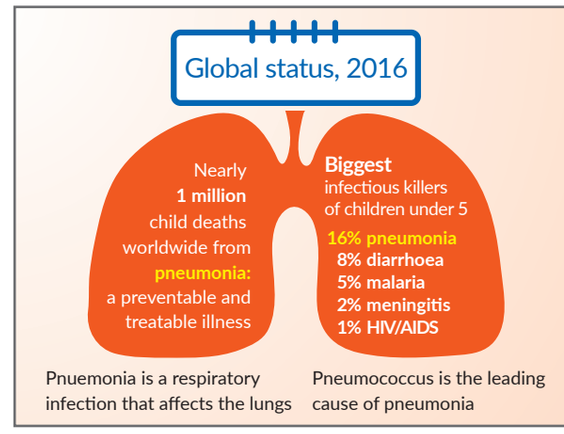
Source:http://www.childmortality.org/files_v21/download/IGME%20report%202017%20child%20mortality%20final.pdf

globally and in India. Pneumococcus is the leading-cause of pneumonia identified as one of the major causes of death in children globally. India accounted for one-fifth (20%) of the global pneumonia deaths in 2015. The figure 1 illustrates global causes of deaths among children under 5 years, 2016. India is now introducing the pneumococcal conjugate vaccine (PCV) into its national immunization program, which is recommended by World Health Organization (WHO) for all countries, especially those with under-five mortality rates over 50 per 1000 live births[5]. Thus, currently pneumococcal vaccines seem to be the only public health tool capable of rapidly reducing the burden of pneumococcal diseases in India and this justifies its inclusion in the national immunization program.

Based on literature review and available evidence on disease burden, safety and efficacy, cost-effectiveness, sustainability and global experience, the National Technical Advisory Group on Immunization (NTAGI) recommended the introduction of pneumococcal vaccine in the national immunization schedule. PCV has been introduced in the UIP in a phased manner starting from June 2017 onwards in select districts of Bihar, Himachal Pradesh and Uttar Pradesh. Further phase-wise expansion is planned.

1.2 CHILDHOOD PNEUMONIA

Pneumonia is the single largest infectious cause of death among children under five worldwide, accounted for nearly 10 lakhs (1 million) deaths in

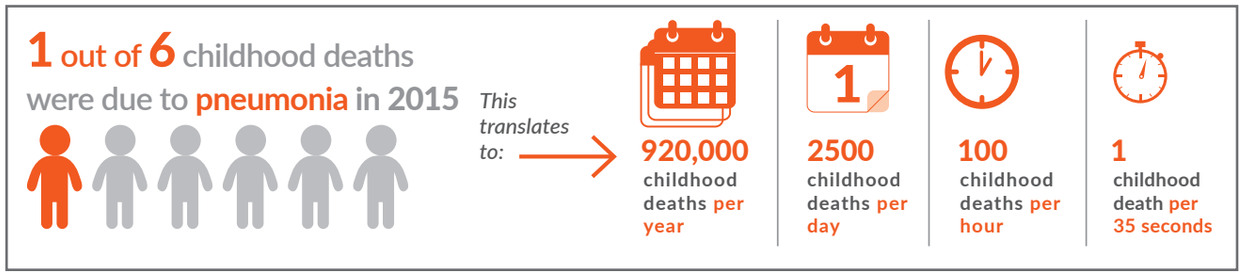


4 The Power of Vaccines: Protecting India's future. http://www.jhsph.edu/research/centers-and-institutes/ivac/resources/factsheets/The%20Power%20of%20Vaccines%20Brochure.pdf

5 Pneumococcal vaccines WHO position paper – 2012. Weekly epidemiological record. No 14, 2012, 87, 129-144. http://www.who.int/wer/2012/wer8714.pdf?ua=1

6 https://data.unicef.org/wp-content/uploads/2016/11/UNICEF-Pneumonia-Diarrhoea-report2016-web-version_final.pdf; Liu et al. Lancet 2015; 385:430-440.

7 https://data.unicef.org/wp-content/uploads/2016/11/UNICEF-Pneumonia-Diarrhoea-report2016-web-version_final.pdf; Fisher-Walker et al. Lancet 2013; 381:1406-16



under-five children in 2015. It is estimated that 1 in 6 under-five childhood deaths were due to pneumonia in 2015[6]. Young children are at particularly high risk of developing severe pneumonia disease and death. More than 80% of deaths associated with pneumonia occur in children during the first 2 years of life[7].

Pneumonia affects children and families everywhere, but is most prevalent in the developing world in South Asia and sub-Saharan Africa. Children infected with pneumonia require early diagnosis and treatment. Many cases of pneumonia are vaccine-preventable.

Pneumonia is caused by a number of infectious agents, including viruses, bacteria and fungi. The most common are:

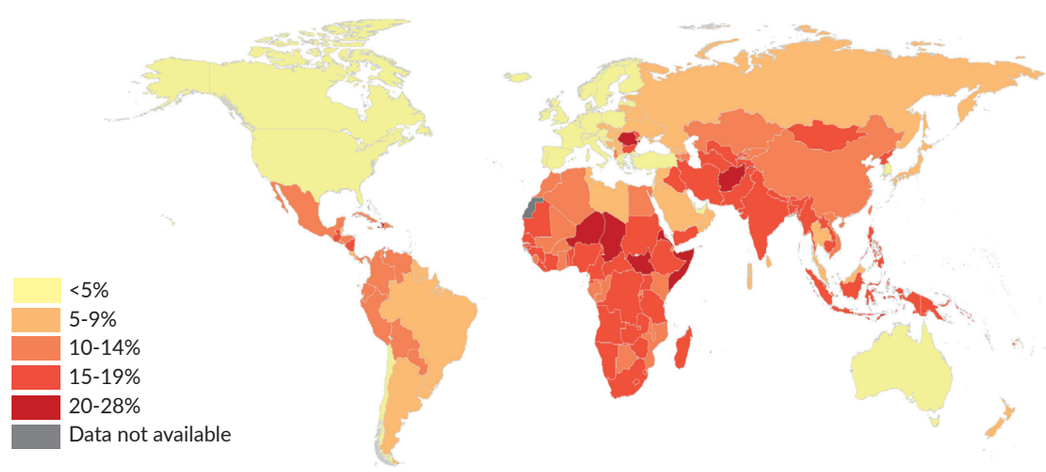
- *Streptococcus pneumoniae* – the most common cause of bacterial pneumonia in children;
- Hib – the second common cause of bacterial pneumonia;
- Respiratory syncytial virus – is the most common viral cause of pneumonia;
- *Pneumocystis jiroveci* – responsible for at least one quarter of all pneumonia deaths in human immunodeficiency virus (HIV)-infected infants.

1.3 GLOBAL SCENARIO OF PNEUMOCOCCAL DISEASE

Pneumococcal disease is the name given to a group of diseases caused by a bacterium called *Streptococcus pneumoniae* (also known as pneumococcus). Pneumococcal disease can occur in multiple organ systems, causing pneumonia, meningitis, bacteraemia/sepsis, sinusitis, bronchitis and middle ear infection (see Chapter 2).

Pneumococcal mortality is a significant contributor to

Figure 2. ***Percentage of deaths among children under age 5 attributable to pneumonia, 2015***



8 IVAC-2016-Pneumonia-Diarrohea-Progress Report

9 Estimated pneumococcal deaths for children under 5 years of age, 2008. http://www.who.int/immunization/monitoring_surveillance/burden/estimates/Pneumo_hib/en/

10 Source: WHO and Maternal and Child Epidemiology Estimation Group (MCEE) provisional estimates 2015; https://data.unicef.org/topic/child-health/pneumonia/

the under-five mortality rate worldwide. As per WHO 2008 estimates, among an estimated 88 lakhs (8.8 million) global annual deaths among children younger than 5 years of age, 5.4 lakhs (0.54 million) were due to pneumococcal infections[9]. About 90% of these child deaths occur in developing countries. Severe pneumococcal disease is most common among children under 2 years (including newborn infants) and elderly population.

The figure 2 depicts the percentage of deaths among children under age 5 attributable to pneumonia for each country in 2015. Despite steady progress, pneumonia remains one of the single largest killers of young children worldwide.

Pneumococcal pneumonia in particular is a major public health concern for children globally. This infection accounts for 18% of all severe pneumonia cases and 33% of all pneumonia deaths worldwide[7].

The high concentration of pneumonia deaths among poor and marginalized populations is a key marker of inequaity both across and within countries, and much more needs to be done to reach the most vulnerable children.

1.4 INDIA SCENARIO

Pneumococcal infection, a common cause of pneumonia, remains the leading cause of vaccine-preventable deaths and illnesses among children under 5 globally and in India. India has a pneumonia mortality rate of 7 per 1000 live births.[8] As in the global scenario, pneumonia due to *Streptococcus pneumoniae* (pneumococcal pneumonia) is responsible for a large portion of pneumonia episodes and deaths.

In India, in 2010, 36 lakhs (3.6 million) episodes of severe pneumonia occurred in children under 5 years, of which 5.6 lakhs (0.56 million) episodes (16%) were caused by pneumococcal pneumonia.In the same year approximately 3.5 lakhs (0.35 million) all-cause pneumonia deaths occurred in children under 5 years, of which 1.05 lakhs (0.10 million) deaths (30%) were caused by pneumococcal pneumonia[11]. The figure 3 depicts under-five pneumococcal pneumonia episodes and deaths in India.

Figure 3. ***Under-5 Pneumococcal pneumonia episodes & deaths in India, 2010***

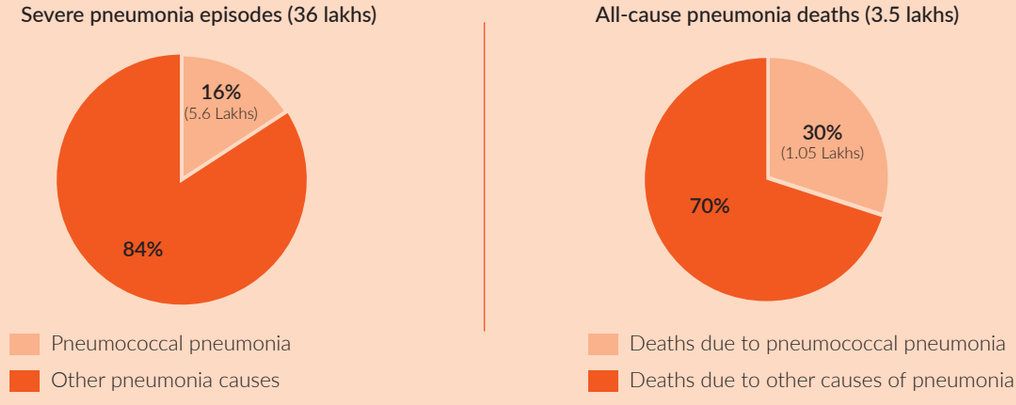
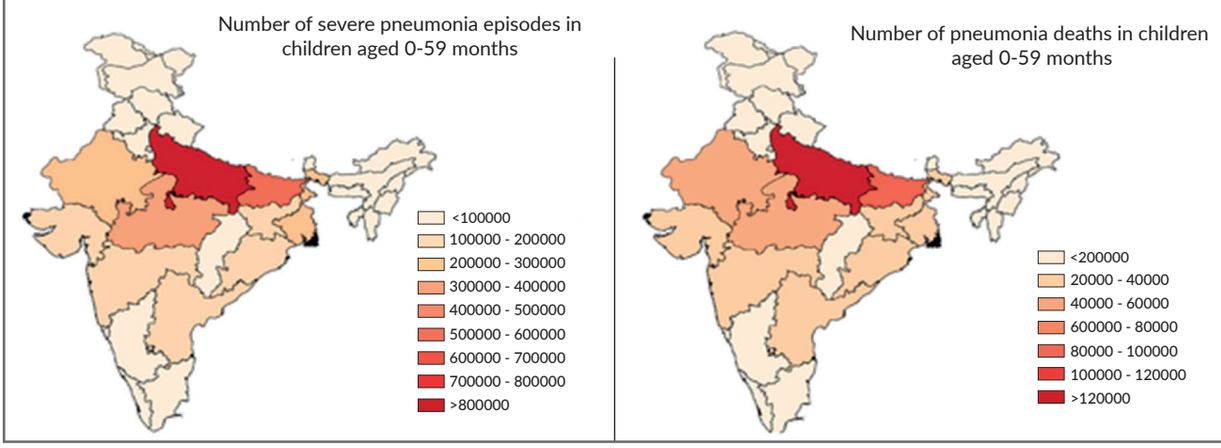


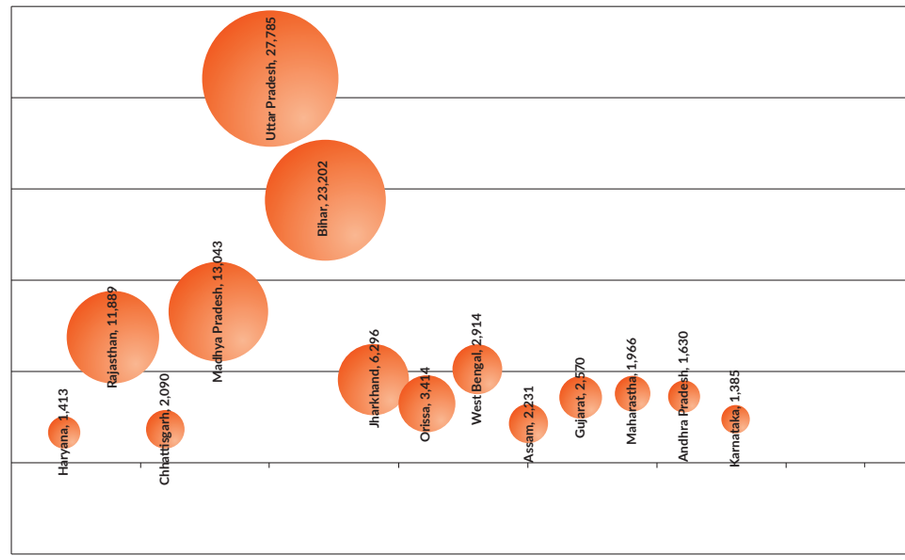
Figure 4 depicts the distribution of severe pneumonia episodes and pneumonia deaths in children younger than 5 years in India[11]. Severe pneumonia frequently requires hospitalization for treatment, leading to emotional and financial burden for caregivers and stress on the public

Figure 4. ***Distribution of severe pneumonia episodes and deaths in children younger than 5 years, 2010, India***



healthcare system.Risk of pneumonia is largely driven by factors associated with malnutrition, poverty, air pollution and other environmental factors (see section 2.5). As mentioned above, India contributes to a substantial portion of pneumococcal pneumonia burden across the globe. Within India, the states with the greatest estimated pneumococcal pneumonia burden are Bihar, Madhya Pradesh, Rajasthan and Uttar Pradesh. These four states account for an estimated 71% of all pneumonia deaths and 57% of severe pneumonia cases. The figure 5 depicts the selected Indian states with the highest number of pneumococcal pneumonia deaths in children younger than 5 years in India, 2010. Bubble size indicates the number of pneumococcal pneumonia deaths.[11]

Figure 5. ***States with highest burden of pneumococcal pneumonia deaths in children under five, 2010, India***



Bubble size denotes pneumococcal pneumonia deaths in children less than 5 years
Figures denote severe pneumonia episodes in children less than 5 years

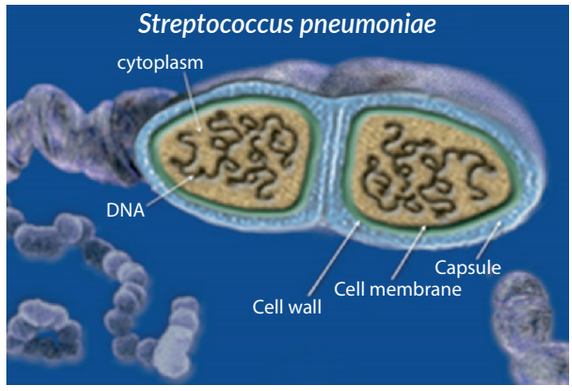
11 Farooqui H, Jit M, Heymann DL, Zodpey S (2015) Burden of Severe Pneumonia, Pneumococcal Pneumonia and Pneumonia Deaths in Indian States: Modelling Based Estimates. PLoS ONE 10(6): e0129191. doi:10.1371/journal.pone.0129191; http://journals.plos.org/plosone/article?id=info:doi/10.1371/journal.pone.0129191

2 Pneumococcal Disease

2.1 THE ORGANISM

Pneumococcal disease is the name given to a group of diseases caused by a bacterium called *Streptococcus pneumoniae* (also known as pneumococcus) as shown in the figure 6. S. pneumoniae is a Gram-positive encapsulated diplococcus. The polysaccharidecapsule is an essential virulence factor for invasive pneumococcal disease. Pneumococcus is classified into 93 known serotypes,

Figure 6. ***Magnified image of Streptococcus pneumoniae***



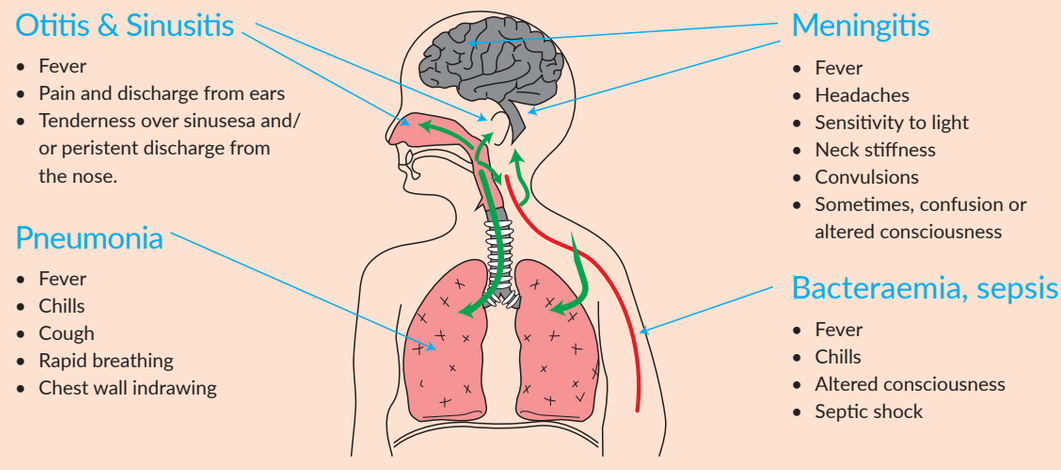
based on the identification of differences in the composition of its outer capsule[13]. The different serotypes have varying potential to cause disease with relatively few serotypes associated with severe disease in children. Globally, about 20 serotypes are associated with >80% of invasive pneumococcal disease occurring in all age groups; the 13 most common serotypes included in the PCV cause at least 70–75% of invasive disease in children[5]. Most illnesses are sporadic. Outbreaks of pneumococcal disease are uncommon, but may occur in closed populations, such as nursing homes, childcare centers or other institutions.

2.2 DIFFERENT TYPES OF DISEASES CAUSED BY PNEUMOCOCCUS

Diseases caused by pneumococcus (*Streptococcus pneumoniae*) are a major public health problem worldwide. Diseases that are often caused by pneumococcus (as depicted in figure 7) include:

- Pneumonia: inflammation of the lungs;
- Bacteraemia/sepsis: bloodstream infection, with or without infection of secondary sites, e.g., meningitis;
- Bacterial meningitis: infection of the membranes that cover and protect the spinal cord and brain;
- Otitis media: Middle ear infection; and

Figure 7. ***Diseases caused by Streptococcus pneumoniae***



12 Structure of Streptococcus pneumoniae (from The National Foundation for Infectious Diseases,http://www.chori.org/Principal_Investigators/Test_Samuel_T/test_research.html,)

13 Introduction of pneumococcal vaccine PCV13, A handbook for district and health facility staff. 2013. http://apps.who.int/iris/bitstream/10665/90380/1/WHO_IVB_13.10_eng.pdf

- Sinusitis, Bronchitis

About 75% of invasive pneumococcal disease and 83% of pneumococcal meningitis occur in children aged <2 years, among which many cases occur in neonates and children under 6 months of age.

2.3 TRANSMISSION

Pneumococcal infection is transmitted by direct contact with respiratory secretions from patients and healthy carriers. Transient nasopharyngeal colonization – not disease – is the normal outcome of exposure to pneumococcus. The figure 8 depicts how pneumococcal disease spreads.

Disease is caused either by contiguous spread to the sinuses or the middle ear, aspiration into the lower respiratory tract causing pneumonia, or by invasion of the bloodstream with or without spread to other sites. Most acute respiratory infections result in mild illnesses.

In vulnerable children, infections that begin with mild symptoms may sometimes lead to more severe illnesses, such as pneumonia – especially when they coincide with other illnesses like diarrhea or malaria.

HIV infection and other conditions associated with immune deficiency greatly increase the likelihood of contracting pneumococcal disease.

2.4 PNEUMOCOCCAL PNEUMONIA

Pneumonia is a form of acute respiratory infection that causes inflammation or fluid in the lungs. It makes breathing difficult and limits oxygen intake. Symptoms include cough, chest in-drawing, difficult and rapid breathing, and wheezing. If infants are severely ill, they may also be unable to feed or drink and may experience unconsciousness, convulsions and even death.

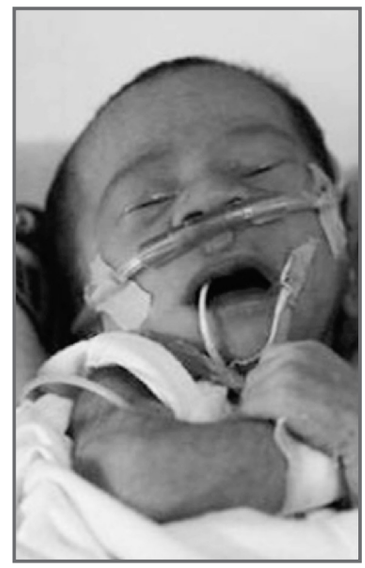
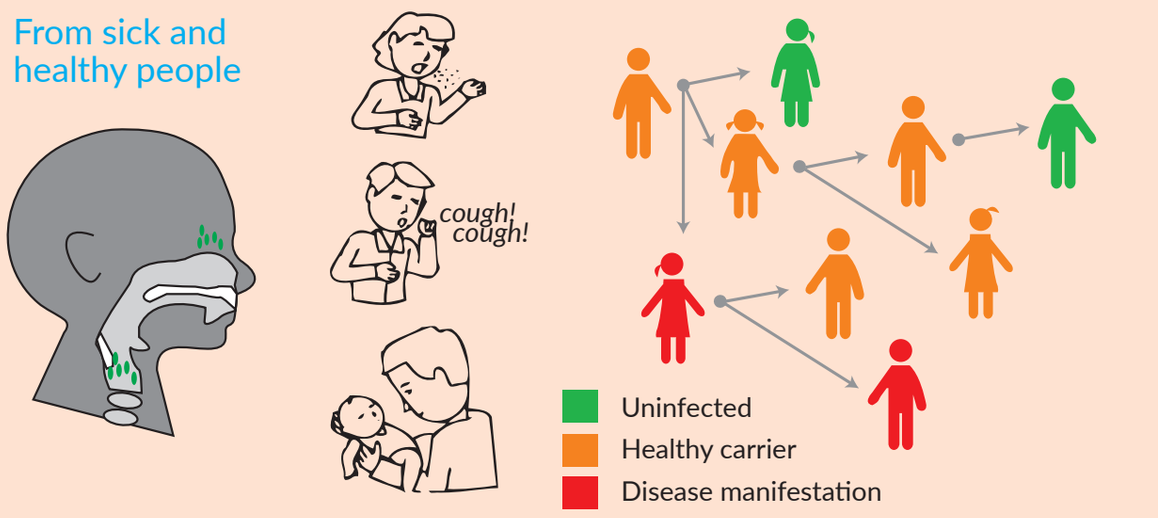
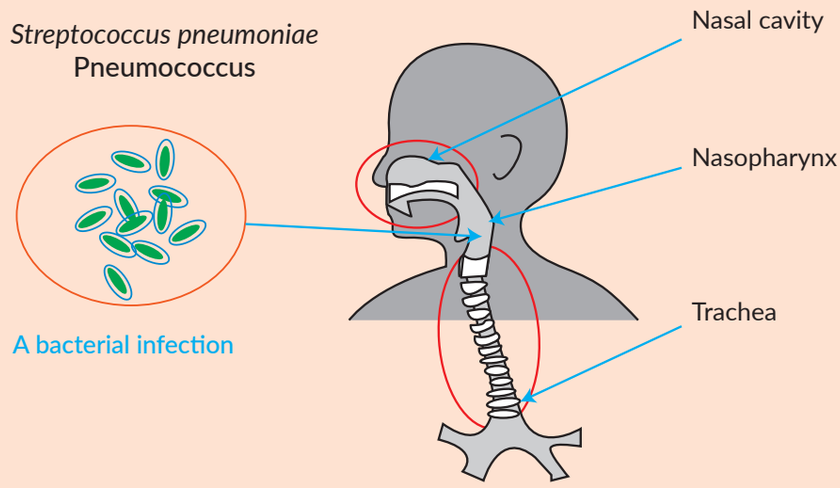


Figure 8. ***How pneumococcal disease spreads?***



The figure 9 depicts spread of pneumococcal pneumonia.

Figure 9. ***Spread of pneumococcal pneumonia***

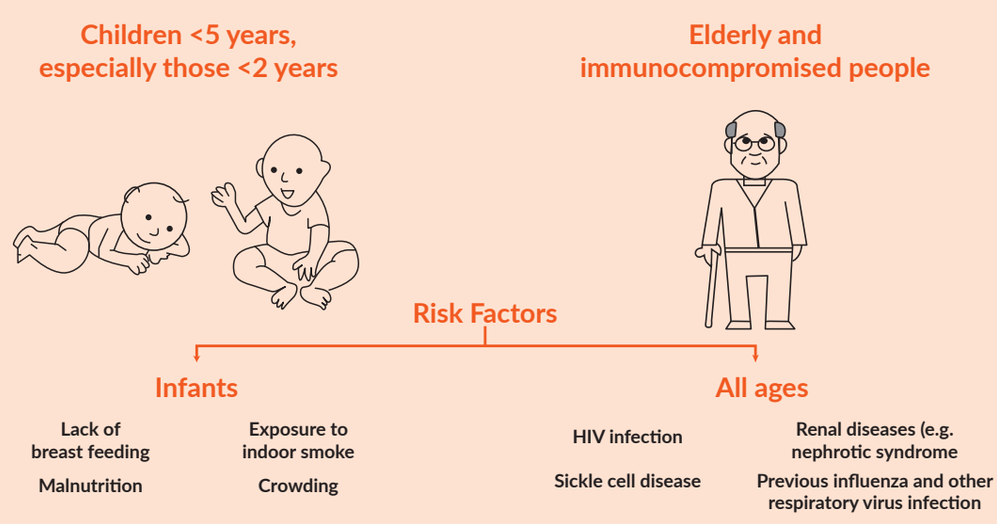


2.5 RISK FACTORS

The figure 10 depicts who is most at risk of pneumococcal disease. While most healthy individuals can fight the infection with their natural defenses, the children most at risk of pneumococcal disease are:

- Children under 5 years of age and especially those under 2 years of age are the most at risk of developing and dying from the disease.
- Children who are immunocompromised (HIV infection, sickle cell disease, renal diseases, e.g., nephrotic syndrome) or have history of

Figure 10. ***Who is most at risk of pneumococcal diseases***



previous influenza or other respiratory virus infection.

- Infants and children who are exposed to additional risk factors: Malnutrition, lack of breastfeeding, exposure to indoor smoke and crowded living conditions.
- Elderly and immunocompromised people
- Poor and marginalized populations with poor access to health care.

2.6 SIGNS AND SYMPTOMS

Pneumococcal disease can occur in multiple organ systems, causing pneumonia, meningitis, bacteraemia/sepsis, sinusitis, bronchitis and middle ear infection. Pneumococcal pneumonia in particular is a major public health concern for children globally.

The presenting features of viral and bacterial pneumonia are similar. However, the symptoms of viral pneumonia may be more numerous than the symptoms of bacterial pneumonia. In children under 5 years of age, who have cough and/or difficult breathing, with or without fever, pneumonia is diagnosed by the presence of either fast breathing or lower chest wall in-drawing where the chest moves in or retracts during inhalation (in a healthy person, the chest expands during inhalation). Wheezing is more common in viral infections. Very severely ill infants may be unable to feed or drink and may also experience unconsciousness, hypothermia and convulsions.

2.7 SEVERITY OF DISEASE

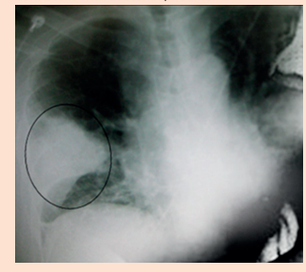
Pneumonia is a severe form of acute lower respiratory tract infection. The lungs are made up of small sacs called alveoli, which fill with air when a healthy person breathes. When an individual has pneumonia, the alveoli are filled with pus and fluid, which makes breathing difficult and limits oxygen intake. Severe pneumonia or sinusitis can progress to bacteremia/sepsis or meningitis, which require antibiotic treatment and have high mortality rates.

2.8 DIAGNOSIS

Pneumonia is diagnosed based on clinical evaluation and X-ray imaging when available. The figure 11 depicts clinical signs of pneumonia and X-ray imaging[14]. It can be difficult to establish whether pneumococcal infection is the cause of the patient's

Figure 11. ***Diagnosis of pneumonia based on clinical evaluation and X-ray imaging***

Left imagine: Wedge-shaped consolidation consistent with bacterial pneumonia



Right imagine: Chest in-drawing due to pneumonia infection

Type of pneumococcal disease	Signs/Symptoms
All types of pneumococcal disease	fever, chills
Pneumonia	fever, chills, cough, difficult and rapid breathing, chest wall in drawing
Meningitis	fever, headaches, sensitivity to light, neck stiffness, convulsions and sometimes confusion or altered consciousness
Bacteraemia and sepsis	fever, chills, low alertness
Otitis and sinusitis	fever, pain and discharge from the ears (otitis), tenderness over sinuses and/or persistent discharge from the nose

14 http://medicalobserverph.com/babyminder-factfile-focus-on-pneumonia/

symptoms because even in true pneumococcal cases, the specimens collected often do not yield the bacterium. This is particularly true of pneumococcal pneumonia because specimens from the actual site of infection (i.e., the lung) cannot be collected and in only a small fraction of pneumococcal pneumonia cases is the blood also infected.

When laboratory testing is possible, pneumococcal infections may be identified through testing of the blood (for bacteraemia and bacteraemic pneumonias) or in the case of suspected meningitis by performing a lumbar puncture, which involves inserting a needle into the epidural space to obtain a sample of cerebrospinal fluid (CSF).

Pneumococcus is a difficult bacterium to grow in the laboratory and frequently goes undiagnosed even when blood or CSF samples are truly infected with the pneumococcus. Testing to determine the pneumococcal serotype is used primarily for research purposes and is not available for patient diagnosis in most clinical settings.

2.9 PREVENTION

Preventing pneumococcal diseases, particularly pneumonia, in children is an essential component of a strategy to reduce child mortality. Immunization against Hib, pneumococcus, measles and whooping cough (pertussis) is the most effective way to prevent pneumonia.

Adequate nutrition is the key to improving children's natural defenses, starting with exclusive breastfeeding for the first 6 months of life. In addition to being effective in preventing pneumonia, it also helps to reduce the length of the illness, if a child does become ill. Addressing environmental factors such as indoor air pollution (by providing affordable clean indoor stoves, for example) and encouraging good hygiene in crowded homes also reduces the number of children who fall ill with pneumonia.

The Global Action Plan for Prevention and Control of Pneumonia (GAPP, 2009) aims to accelerate pneumonia control with a combination of interventions to protect, prevent and treat pneumonia in children with actions to:

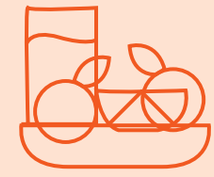
SIMPLE INTERVENTIONS

Prevent, protect and treat children from pneumonia

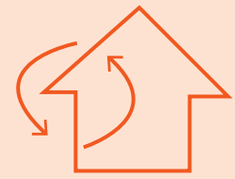
Routine immunizations, including pertussis, measles and Hib

Exclusive breastfeeding for first 6 months

Safe drinking water, good sanitation, and frequent hand washing with soap



Good nutrition, especially for children over 6 months of age



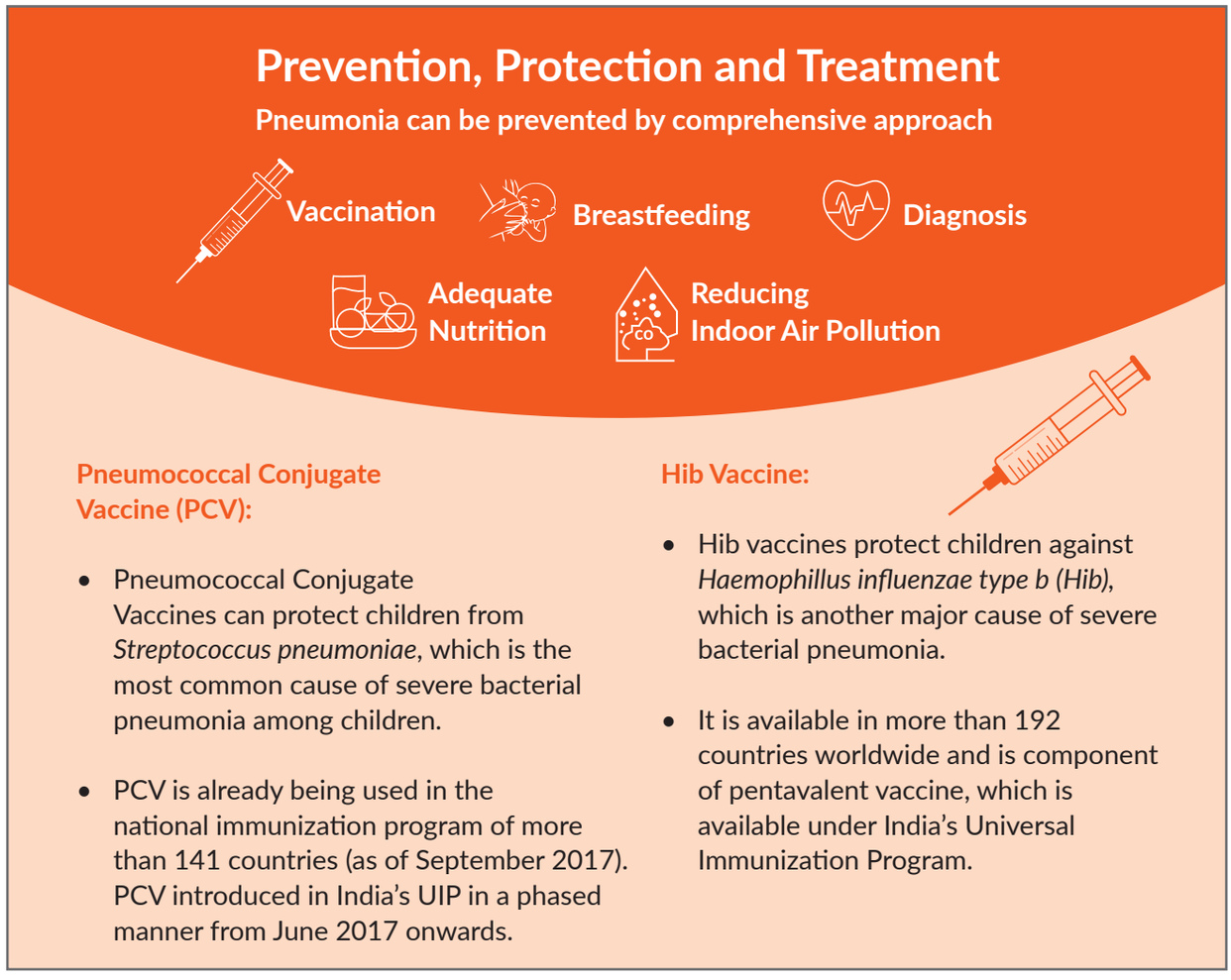
Improve indoor air quality

Recognizing danger signs of pneumonia and seek care quickly

2.10 TREATMENT

Pneumonia should be diagnosed clinically based on the signs and symptoms described above. Frontline health workers should be well-trained to identify cases and refer to health facilities for evaluation and treatment. As per treatment protocols, patients with pneumonia will require antibiotics and supportive care. Amoxicillin is the antibiotic of choice. Based on severity of the case, health facilities may refer to higher level care as needed. Facilities should ensure adequate documentation of clinical and laboratory diagnosis of pneumonia in order to support surveillance activities. Vaccination is not intended to be used for treatment of active infection.
The figure 12 depicts treatment and prevention measures for pneumonia.

Development of pneumococcal resistance to commonly used antibiotics such as penicillin, macrolides, cephalosporins and co-trimoxazole is a serious problem in some parts of the world. Large-scale pneumococcal immunization in many countries has resulted in a reduction in the circulation of drug-resistant strains in countries where it has been introduced[15].



15 Kyaw et al. NEJM 2006; 354:1455-1463

3 Vaccines Used to Prevent Pneumonia

Vaccination is a safe, effective and cost-effective tool for saving millions of children's lives by reducing deaths from pneumonia.

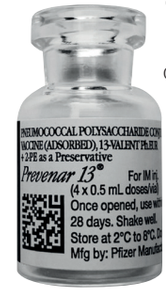
Currently, three vaccines have the potential to significantly reduce childhood mortality from and related to pneumonia: PCV, Hib-containing pentavalent vaccine and measles vaccine. PCV and pentavalent vaccines work directly to reduce the incidence of bacterial pneumonia by preventing *Streptococcus pneumoniae* and *Haemophilus influenzae* type b. Measles vaccine prevents the systemic viral infection caused by measles. Measles infection can affect multiple organ systems including the lungs and can suppress the immune response transiently, putting infected children at risk of secondary bacterial pneumonia, alongside other infections that can be fatal.

The WHO recommends that all routine childhood immunization programs should include these vaccines to protect against above-mentioned diseases. Vaccinations help reduce childhood pneumonia in two ways:

- First, vaccinations help prevent children from developing infections that directly cause pneumonia, such as Hib and *S. pneumoniae*.
- Second, vaccinations may prevent infections that can lead to pneumonia as a complication, such as influenza, measles and pertussis. This is also called indirect protection.

Pneumococcal conjugate vaccine

Pneumococcal pneumonia (*Streptococcus pneumoniae*) is the most common cause of severe pneumonia among children in the developing world. The fight against pneumonia-related deaths in children relies on prevention, protection and, when infections occur, on better treatment. PCV has demonstrated effectiveness in reducing incidence and severity of pneumonia and other lower respiratory infections in children. Children must receive all recommended doses in the vaccine schedule for maximum protection. Vaccination is not intended to be used for treatment of active infection. The figure is an illustrative image of PCV13.



Hib-containing pentavalent vaccine

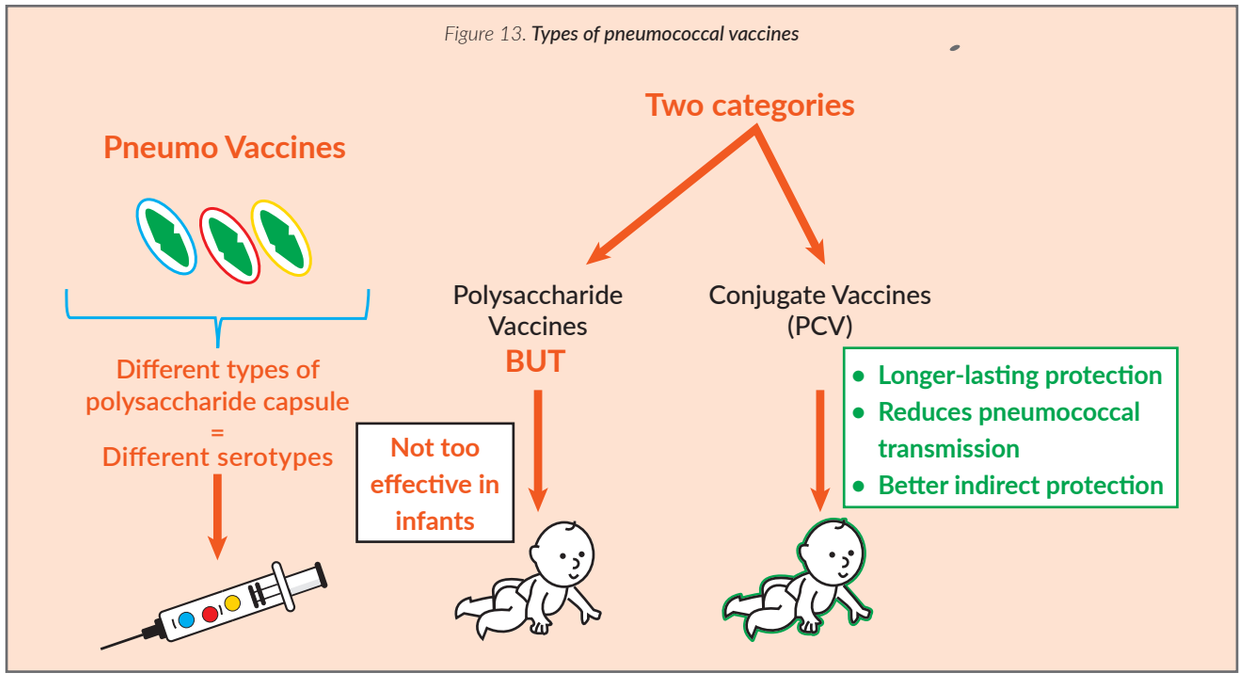
Hib is the second leading cause of bacterial pneumonia in children, but it is preventable with the highly effective Hib vaccine. In 2011, the Government of India introduced the Hib-containing pentavalent vaccine in a phased manner. The pentavalent vaccine provides protection against five diseases: diphtheria, tetanus, pertussis, hepatitis B and Hib. India has now successfully scaled up pentavalent vaccine across the country.

3.1 TYPES OF PNEUMOCOCCAL VACCINES

Currently, two different types of pneumococcal vaccines

Vaccines Used to Prevent Pneumonia

Figure 13. ***Types of pneumococcal vaccines***



(as depicted in figure 13) are available in the market:

- Pneumococcal polysaccharide vaccine (PPSV): 23-valent polysaccharide vaccine (PPSV23), available since the early 1980s.
- Pneumococcal conjugate vaccines (PCV): 10-valent (PCV10) and 13-valent (PCV13) are currently available. A 7-valent conjugate vaccine (PCV7), which was introduced in 2000, has been phased out

Both PPSV and PCV are made up of sugars (polysaccharides) from the capsule of the bacterium *Streptococcus pneumoniae*. In PCV, each polysaccharide is attached, or conjugated to, a carrier protein. The carrier protein is selected to improve the immune response in those vaccinated. In contrast to PCV, PPSV has poor or absent immunogenicity in children under 2 years of age. PCV has been shown to protect very young children starting at 6 weeks of age when infants are most at risk of infection. It protects against severe forms of pneumococcal disease, such as pneumonia, meningitis and bacteraemia. It will not protect against these conditions if they are caused by agents other than pneumococcus or by pneumococcal serotypes not present in the vaccine.

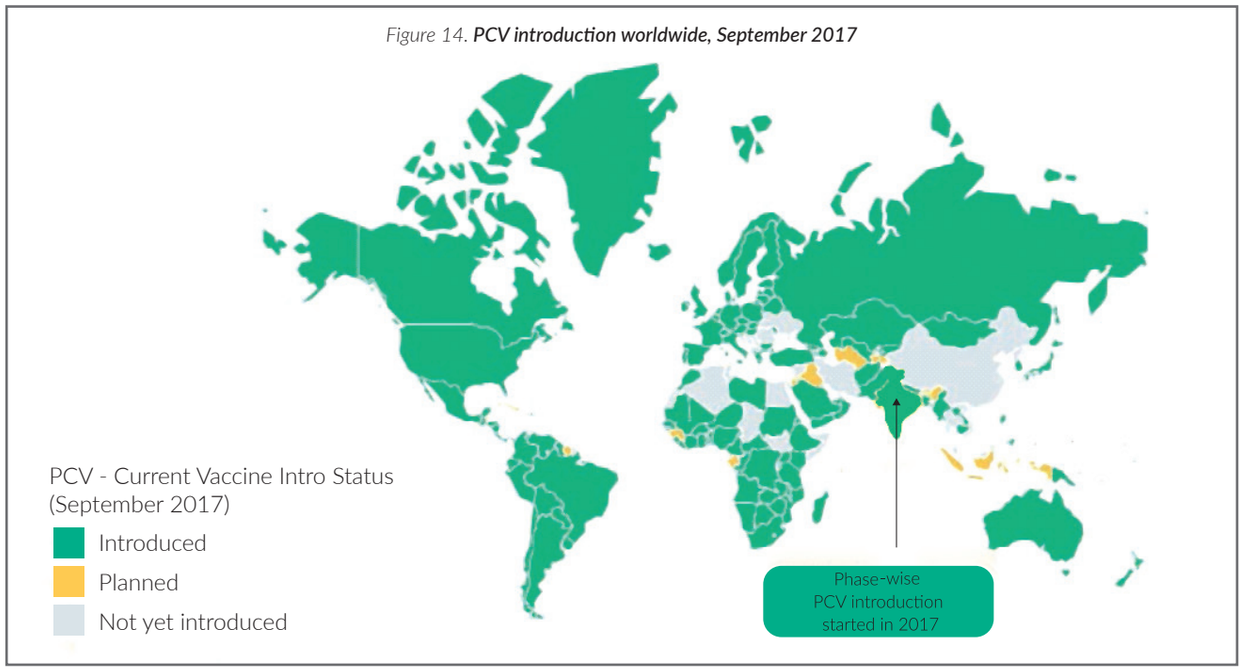
The PCV7 was first introduced in the United States in 2000, followed by many other countries in the subsequent years. As the first licensed conjugate vaccine, PCV7 demonstrated effectiveness against invasive (meningitis, bacteraemia, and bacteraemic pneumonia) and non-invasive (pneumonia and otitis media) pneumococcal disease. However, based on the available evidence, PCV7 was found not to contain all of the important serotypes that are prevalent in developing countries. PCV10 and

Vaccines Used to Prevent Pneumonia

PCV13 will provide increased coverage of the serotypes most commonly found in those areas. PCV13 was introduced in the United States in 2010, and subsequently into the national immunization programs of more than 100 countries . As of September 2017, 141 countries have introduced PCV[16].

The figure 14 depicts PCV introduction worldwide. In India, in the private sector, PCV7 was introduced in 2006 and was phased out in 2010 when PCV10 and PCV13 were introduced.

Figure 14. ***PCV introduction worldwide, September 2017***



The table depicts characteristics of available PCV products.

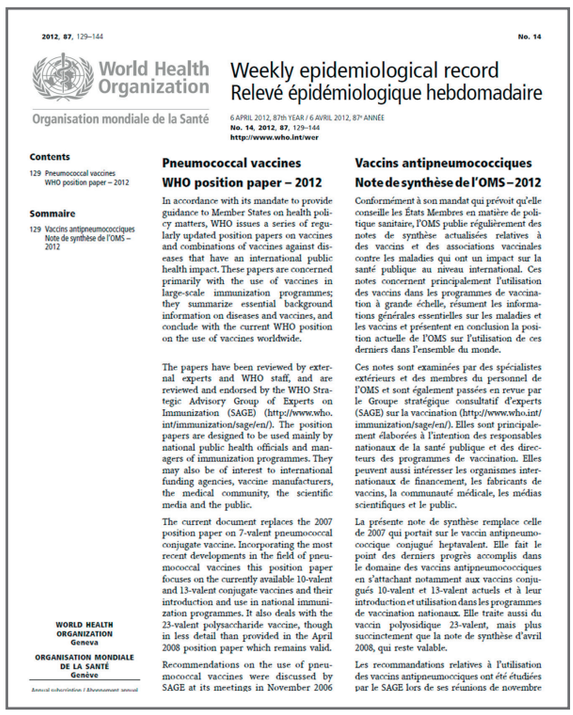
Characteristics of available PCV products

Vaccine (Manufacturer)	PCV-10 (GSK)			PCV-13 (Pfizer)	
Presentation	1-dose vial	2-dose vial	4-dose vial	1-dose vial	4-dose vial
Preservative	None	None	Yes*	None	Yes*
Serotypes present in Vaccine	1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F			1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F	
WHO Prequalified	Yes	Yes	In process	Yes	Yes
Regulatory approval	Yes	Yes	In process	In process	Yes
Cold chain volume per dose	9.6 cm^3	4.8 cm^3	2.4 cm^3	12 cm^3	3.5 cm^3
*2-PE: 2- phenoxyethanol					

16: https://www.jhsph.edu/research/centers-and-institutes/ivac/view-hub/IVAC%20ViewHub%20Sept%202017%20Report.pdf

Vaccines Used to Prevent Pneumonia

WHO recommends inclusion of PCV in routine childhood immunization programs in all countries and particularly in countries where all-cause under-five mortality among children is greater than 50 per 1000 live births, or where there are more than 50,000 children dying annually in countries with a high prevalence of HIV infection. The most recent WHO position paper from 2012 recommends 10-valent or 13-valent PCV introduction.



2012, 87, 129–144 No. 14

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

6 APRIL 2012, 87th YEAR / 6 AVRIL 2012, 87e ANNÉE
No. 14, 2012, 87, 129–144
http://www.who.int/wer

Contents

129 Pneumococcal vaccines
WHO position paper – 2012

Sommaire

129 Vaccins antipneumococciques
Note de synthèse de l'OMS – 2012

Pneumococcal vaccines
WHO position paper – 2012

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combinations of vaccines against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale immunization programmes; they summarize essential background information on diseases and vaccines, and conclude with the current WHO position on the use of vaccines worldwide.

The papers have been reviewed by external experts and WHO staff, and are reviewed and endorsed by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) (http://www.who.int/immunization/sage/en/). The position papers are designed to be used mainly by national public health officials and managers of immunization programmes. They may also be of interest to international funding agencies, vaccine manufacturers, the medical community, the scientific media and the public.

The current document replaces the 2007 position paper on 7-valent pneumococcal conjugate vaccine. Incorporating the most recent developments in the field of pneumococcal vaccines this position paper focuses on the currently available 10-valent and 13-valent conjugate vaccines and their introduction and use in national immunization programmes. It also deals with the 23-valent polysaccharide vaccine, though in less detail than provided in the April 2008 position paper which remains valid.

Recommendations on the use of pneumococcal vaccines were discussed by SAGE at its meetings in November 2006

Vaccins antipneumococciques
Note de synthèse de l'OMS – 2012

Conformément à son mandat qui prévoit qu'elle conseille les États Membres en matière de politique sanitaire, l'OMS publie régulièrement des notes de synthèse actualisées relatives à des vaccins et des associations vaccinales contre les maladies qui ont un impact sur la santé publique au niveau international. Ces notes concernent principalement l'utilisation des vaccins dans les programmes de vaccination à grande échelle, résument les informations générales essentielles sur les maladies et les vaccins et présentent en conclusion la position actuelle de l'OMS sur l'utilisation de ces derniers dans l'ensemble du monde.

Ces notes sont examinées par des spécialistes extérieurs et des membres du personnel de l'OMS et sont également passées en revue par le Groupe stratégique consultatif d'experts (SAGE) sur la vaccination (http://www.who.int/immunization/sage/en/). Elles sont principalement élaborées à l'intention des responsables nationaux de la santé publique et des directeurs des programmes de vaccination. Elles peuvent aussi intéresser les organismes internationaux de financement, les fabricants de vaccins, la communauté médicale, les médias scientifiques et le public.

La présente note de synthèse remplace celle de 2007 qui portait sur le vaccin antipneumococcique conjugué heptavalent. Elle fait le point des derniers progrès accomplis dans le domaine des vaccins antipneumococciques en s'attachant notamment aux vaccins conjugués 10-valent et 13-valent actuels et à leur introduction et utilisation dans les programmes de vaccination nationaux. Elle traite aussi du vaccin polysidique 23-valent, mais plus succinctement que la note de synthèse d'avril 2008, qui reste valable.

Les recommandations relatives à l'utilisation des vaccins antipneumocciques ont été étudiées par le SAGE lors de ses réunions de novembre

WORLD HEALTH ORGANIZATION
Geneva

ORGANISATION MONDIALE DE LA SANTÉ
Genève

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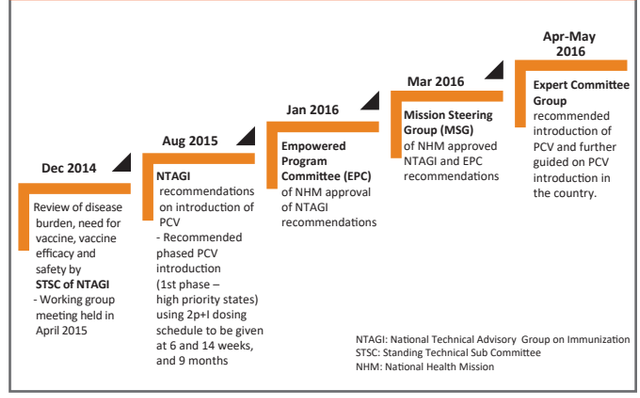
3.2 DECISION-MAKING PROCESS FOR PCV INTRODUCTION IN INDIA

India has planned for introduction of PCV into its universal immunization program based on global and Indian evidence and recommendations. The Standing Technical Sub-Committee (STSC) of the National Technical Advisory Group on Immunization (NTAGI) deliberated on pertinent issues regarding the inclusion of PCVs in India's UIP. The STSC reviewed available evidence and recommended the establishment of a Working Group for collating additional India-specific evidence. The Working Group conducted critical appraisal 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.

The recommendations of the Working Group and STSC were discussed in the NTAGI meeting. Based on disease burden, safety and efficacy, cost-effectiveness, sustainability and global evidence, NTAGI recommended a phased introduction of PCV in India's UIP. A dosing schedule of 2 primary doses at 6 weeks and 14 weeks, followed by a booster dose at 9 months is recommended. This dosing schedule also aligns with the UIP schedule. In the first phase, the vaccine should be introduced in at least some high priority areas (high under-five mortality areas) with quality controlled surveillance systems to conduct impact assessment of the vaccines. The recommendations of the NTAGI were approved by the Empowered Programme Committee of the NHM, and subsequently by the Mission Steering Group.

The Government of India has constituted a National Pneumococcal Vaccine Expert Committee to guide the introduction of pneumococcal vaccine in the country. Currently, there are two pneumococcal conjugate vaccines that are licensed and available in the private sector in India (PCV10 and PCV13).

Decision-making process for Pneumococcal Conjugate Vaccine (PCV) introduction, India



NTAGI: National Technical Advisory Group on Immunization
STSC: Standing Technical Sub Committee
NHM: National Health Mission

17 WHO Prequalification of Medicines Programme (PQP) helps ensure that medicines supplied by procurement agencies meet acceptable standards of quality, safety and efficacy. WHO's list of prequalified medicinal products is used by international procurement agencies and increasingly by countries to guide bulk purchasing of medicines.

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 vial) as the preferred vaccine type for introduction in the UIP. The PCV13 4-dose vial is WHO prequalified[17]. In case of shortage of supply of PCV13, the Committee recommended that other vaccine types may also be considered.

3.3 VACCINE EFFICACY & SAFETY

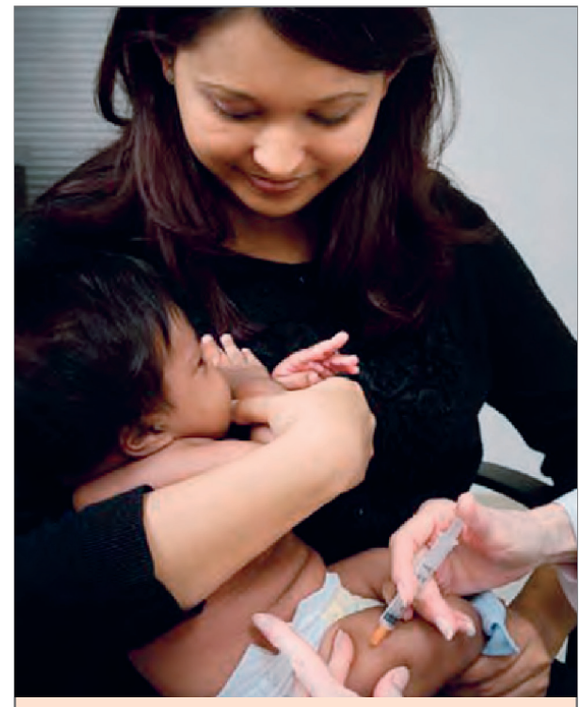
Based on efficacy data, PCV10 and PCV13 would provide good protection for pneumococcal disease in India. Based on the immunogenicity data, PCV10 and PCV13 show comparable vaccine efficacies for serotypes contained in the vaccines. PCVs are considered safe in all target groups for vaccination, including immunocompromised individuals. Protection by PCV vaccination (seroconversion) does not change when the vaccine is given along with other childhood vaccines. PCV can be administered to prematurely born infants (i.e., <37 weeks gestation) at the recommended chronologic age concurrent with other routine vaccinations, unless there are contraindications.[5]

Several studies have assessed pneumococcal disease serotype distribution in India. In a Vellore study among children under five, the most common serotypes causing invasive infections were 14, 19F, 5, 6A and 6B[18]. Both PCV10 and PCV13 would be expected to provide coverage for these serotypes.

PCV10 provides protection against approximately 70% of the prevalent serotypes, PCV13 provides protection against nearly 74% of the prevalent serotypes in the South-East Asia Region. PCV13 provides protection against three additional serotypes (3, 6A, and 19A) not included in PCV10, potentially covering an additional 4% of the prevalent serotypes[19].

3.4 ROUTE AND SITE OF ADMINISTRATION

The dose of the vaccine is 0.5 ml and to be administered by intramuscular injection in the anterolateral aspect of the right mid thigh of infants. If multiple injections must be given in the same thigh, the distance between the two injections should be at least 2.5 cm (1 inch).



The steps below detail how to hold a child (infant) for intramuscular injection in anterolateral aspect of right mid thigh.

- Hold the child on their lap.
- Place the child's arms under one of their own arms and around their back and apply gentle pressure for a secure, hug-like hold.
- Use their free arm and hand to hold the child's other arm gently but securely.
- Anchor the child's feet firmly between their thighs.

18 Balaji et al. Indian J Med Res. 2015 Sept; 142(3):286-292.

19 NTAGI meeting minutes, 2015.

3.5 VACCINATION SCHEDULE FOR PCV VACCINE

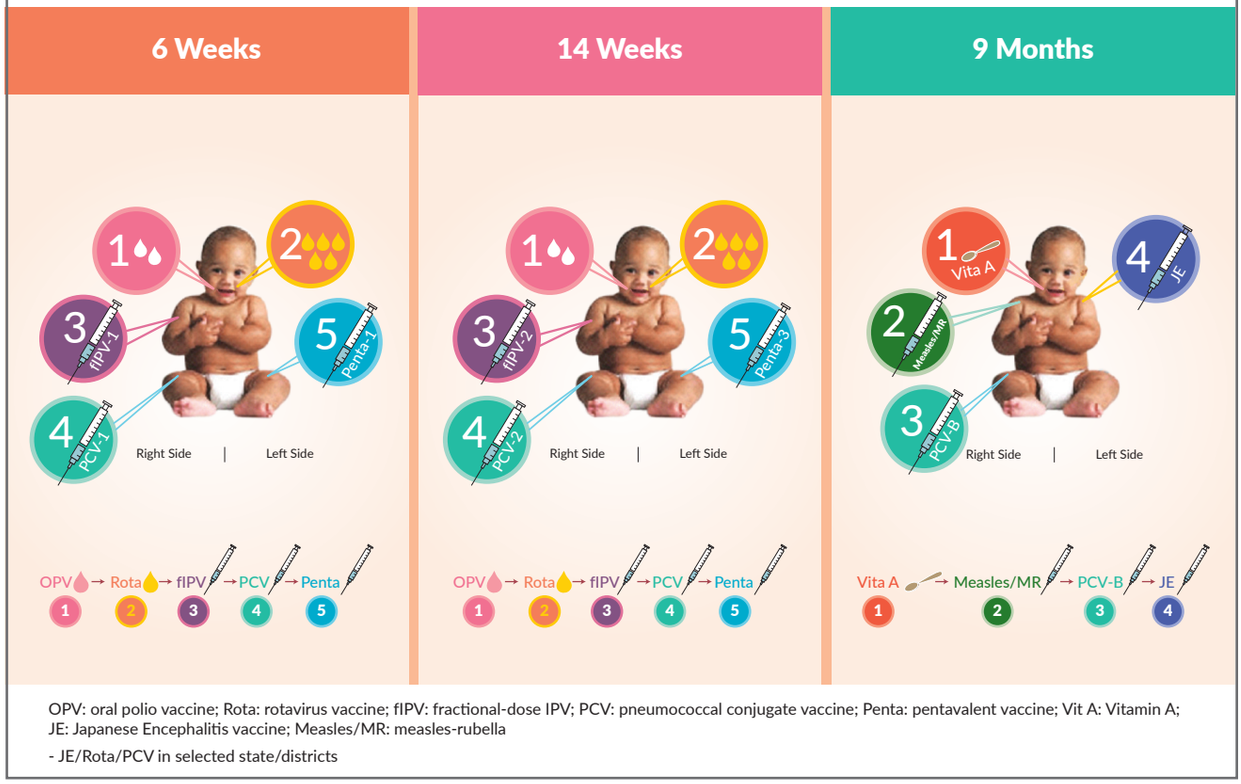
PCV will be administered in three doses (2 primary and 1 booster) at 6 weeks, 14 weeks and 9 months of age as part of routine immunization.

- The first dose, PCV1, will be administered at 6 weeks of age with the first dose of pentavalent vaccine, oral polio vaccine (OPV), fractional-dose IPV1 and rotavirus vaccine (in states that have introduced rotavirus vaccine). Please refer to the scenarios depicted in figures below.
- The second dose, PCV2, will be given at 14 weeks of age, with the third dose of pentavalent vaccine, oral polio vaccine, fractional-dose IPV2 and rotavirus vaccine (in states that have introduced rotavirus vaccine). Please refer to the scenarios depicted in figures below.
- The PCV booster dose will be administered at 9 months of age with the first dose of measles vaccine (or measles-rubella vaccine as applicable) and first dose of Japanese Encephalitis (JE) vaccine (in endemic districts).

The two primary doses and one booster dose of PCV should be given during the first year of life. If the doses are delayed within the first year of life, delayed doses must be separated by a minimum interval of at least 2 months, to be given at the next scheduled immunization visit.

PCV should be given under 1 year of age. In delayed cases beyond 1 year of age, due doses can be given to a child only if a child has received at least one dose of PCV before his/her first birthday.

Figure 15. ***PCV vaccination schedule in states with fractional-dose IPV schedule***



OPV: oral polio vaccine; Rota: rotavirus vaccine; fIPV: fractional-dose IPV; PCV: pneumococcal conjugate vaccine; Penta: pentavalent vaccine; Vit A: Vitamin A; JE: Japanese Encephalitis vaccine; Measles/MR: measles-rubella

- JE/Rota/PCV in selected state/districts

3.6 COMPARISON OF IMMUNIZATION SCHEDULE BEFORE AND AFTER PCV INTRODUCTION

The table below describes the current immunization schedule (i.e., prior to PCV introduction) and immunization schedule after the introduction of PCV.

Age	Vaccination schedule after PCV introduction	Remarks
At birth	BCG, OPV-zero dose, Hep B-birth dose	• BCG vaccine can be given up to 1 year of age. • DPT vaccine can be given up to 5-6 years (not beyond 7 years) of age • Pentavalent vaccine should be given under 1 year of age. In delayed cases, due doses above 1 year of age can be given to a child only if a child has received at least one dose of pentavalent vaccine before his/her first birthday. Due doses should be given at a minimum interval of 4 weeks, at the earliest available opportunity. • In delayed cases, fIPV/IPV can be given maximum up to 1 year of age. • PCV should be given under 1 year of age. In delayed cases, due doses above 1 year of age can be given to a child only if a child has received at least one dose of PCV before his/her first birthday. • Measles vaccine can be given up to 5 years of age. • JE vaccine can be given up to 15 years of age. • Vitamin A to be given every 6 months until 5 years of age.
6 weeks	OPV-1, Pentavalent-1, Rota-1*, fIPV-1, **PCV-1***	
10 weeks	OPV-2, Pentavalent-2, Rota-2*	
14 weeks	OPV-3, Pentavalent-3, Rota-3*, fIPV-2, **PCV-2***	
9 months	Measles-1/MR-1, Vit A, JE-1*, **PCV-B***	
16-24 months	DPT first booster dose, OPV-booster dose, Measles-2/MR-2, JE-2* Age	
5-6 years (up to 7 years of age)	DPT second booster dose	
10 years	TT	
16 years	TT	

BCG: Bacillus Calmette-Guerin; DPT: diphtheria-pertussis-tetanus; HepB: Hepatitis B; Hib: Haemophilus influenzae type b; JE: Japanese Encephalitis; MCV: Measles containing vaccine- measles alone or MR/MMR; OPV: oral polio vaccine; TT: tetanus toxoid; IPV: single-dose inactivated poliovirus vaccine; fIPV: fractional-dose IPV; Rota: Rotavirus vaccine; PCV: Pneumococcal conjugate vaccine; Vit A: Vitamin A; MR: Measles-Rubella vaccine

**JE/Rota/PCV in selected states/districts*
All states to switchover to fIPV soon

3.7 KEY FACTS ABOUT PCV

Type	Polysaccharide conjugate vaccine (adsorbed). The PCV10 vaccine contains 10 serotypes and PCV13 vaccine contains 13 serotypes.	
Formulation	Liquid formulation	
Composition	PCV10: • Serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F • Each polysaccharide conjugated to one of three proteins: non-typeable Haemophilus influenzae protein D, diphtheria or tetanus toxoid	PCV13: • All serotypes contained in PCV10 plus serotype 3, 6A, and 19A. • Polysaccharides are conjugated to a diphtheria carrier protein
Presentation & dosage form	PCV10: • Single-dose vial, preservative free • 2-dose vial, preservative-free • 4-dose vial with preservative, approval awaited	PCV 13: • Single-dose vial, preservative-free • 4-dose vial with preservative • 4-dose vial occupies the same storage volume as a single-dose vial
Storage temperature	• PCV is a freeze-sensitive vaccine. It should be stored at temperatures ranging between +2°C and +8°C in the basket of an ice-lined refrigerator (ILR). • Do not freeze PCV. • It is important to use conditioned ice packs to prevent freezing during transportation. • The Shake Test is applicable to PCV vaccine. Discard the vial/s if there is any doubt of vaccine having been frozen.	
Age group for vaccination	PCV in the UIP is recommended for infants (up to 1 year of age) in three doses (2 primary doses and 1 booster dose) at 6 weeks, 14 weeks and 9 months.	
Dosage and route	• 0.5 ml using auto-disable (AD) syringe available in program. • Intramuscular injection in the anterolateral aspect of the right mid thigh.	
Recommendations for immunodeficient children	• Regardless of the presence of underlying medical conditions (e.g., children with HIV infection, sickle cell disease or who are otherwise immunocompromised), the national schedule for giving PCV should be followed. • In fact these children are in particular need of PCV because their risk of pneumococcal disease is high. PCV has been proven to be safe and well-tolerated even among children infected with HIV. Children with HIV infection require a booster dose to sustain protection.	

Vaccines Used to Prevent Pneumonia

Immunogenicity, efficacy and effectiveness	• PCV vaccines are safe and being used in 141 countries. • PCV efficacy is more than 80% for serotypes present in the vaccine. • PCV10 and PCV13 show comparable vaccine efficacies for serotypes contained in the vaccines. • PCV10 and PCV13 have adequate efficacy to protect against the majority strains of pneumococcal disease in India. • PCVs are considered safe in all target groups for vaccination, including immunocompromised individuals. • PCV can be administered to prematurely born infants (i.e., <37 weeks gestation) at the recommended chronologic age concurrent with other routine vaccinations, unless there are contraindications. • PCV is not intended to be used for treatment of active infection.
Co-administration with other vaccines	• PCV can be co-administered with other UIP vaccines. • The vaccine cannot be mixed with other vaccines in the same syringe. • If two injections are being given in same limb, then they should be administered at least 1 inch apart.
Contraindications	• PCV is a safe vaccine. Severe reactions are extremely rare. • PCV should not be administered to children with severe allergic reaction to a prior dose, or to vaccines containing diphtheria toxoid, such as pentavalent vaccine. • PCV should not be given to a child with severe illness. However, PCV may be given in children with mild respiratory illness with or without low-grade fever. • Most common PCV side effects: Irritability, crying, swelling and tenderness at injection site, transient fever >39°C (102°F).
Vaccine cost	• PCV is an expensive vaccine. At present, cost is INR 800 per vial of 4 doses. • Open vial policy prevents any such wastage. • Cost of PCV in private sector: approx. INR 3,000-4,000 per dose (and child requires at least 3 doses). • Under UIP, PCV will be provided free-of-cost.

3.8 OPEN VIAL POLICY

- Open vial policy is applicable to PCV13 (4-dose vial).
- The guideline, when followed correctly, ensures effective utilization of vaccines and minimizes wastage.
- The permissible wastage for PCV is less than 10%.
- The states need to have a robust alternate vaccine delivery mechanism to ensure effective implementation of the open vial policy.
- Vaccine vials opened in a fixed or outreach session can be used at more than one

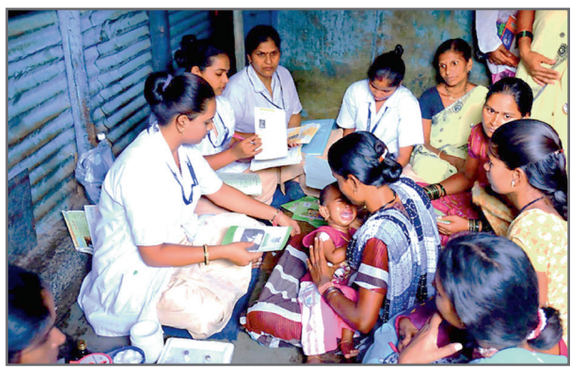
immunization session for up to 4 weeks, as per the open vial policy of Govt. of India, provided

- the expiry date has not been reached.
- the vaccine vial monitor (VVM) has not reached the discard point;
- vaccines are stored in appropriate cold chain conditions, both during transportation and in the cold chain storage point;
- aseptic technique has been used to withdraw vaccine doses. (That is needle/septum has not been contaminated in anyway); and
- vaccine septum has not been submerged in water or contaminated in any way.

3.9 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. Recent introduction of Hib-containing pentavalent, rotavirus and IPV vaccines have provided valuable experience and lessons to steer introduction of other vaccines.

As part of introduction, the main challenge will be at the level of the health worker to administer the three required PCV doses (2 primary doses and 1 booster dose) at 6 weeks, 14 weeks and 9 months of age along with other routine vaccines at the same age. Efforts to ensure high coverage of PCV or any routine immunization should translate to



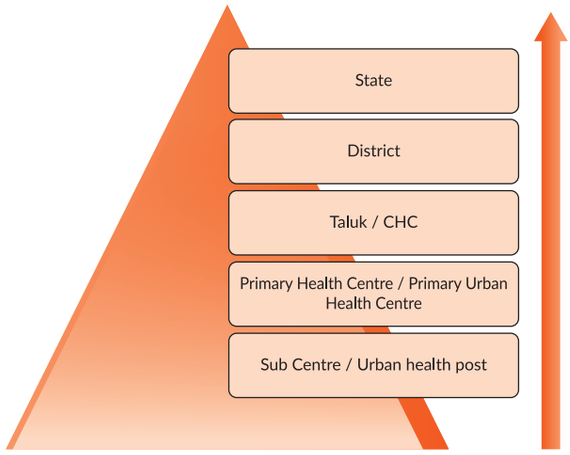
improve coverage of the vaccines given concomitantly at the same visits. Program officers must supervise closely to ensure that all scheduled vaccines are given concomitantly such that coverage of all vaccines scheduled together remains high. For example, at 6 weeks of age it should be assured that high coverage rates of pentavalent1, OPV1, rotavirus1 (where applicable), fractional-dose IPV1 (where applicable), and PCV1 coverage rates are achieved and consistent across vaccines. Similarly, coverage rates should be tracked for all scheduled vaccines at PCV2 and PCV booster dose time points, respectively.

Reporting and recording practices for PCV (mother-child protection [MCP] card, vaccine registers, due lists, tally sheets, reporting coverage portals such as health management information system [HMIS] and mother-child tracking system [MCTS] /Reproductive & Child Health [RCH] need to be updated) will require attention at all levels. Strong monitoring and supervision are required to identify gaps and to ensure accountability and take necessary corrective actions where needed.

Trainings for frontline health workers will be crucial for smooth introduction of PCV, particularly in terms of community mobilization and vaccine acceptance. These interventions will contribute to strengthening the routine immunization system overall and for increased PCV coverage.

4 Preparedness for PCV Introduction

The introduction of PCV vaccine should be viewed as an opportunity to strengthen the overall routine immunization service delivery in the states and districts. Introduction of any new vaccine in the program requires meticulous planning at all levels. This initially involves top-down microplanning at the national and state levels, followed by bottom-up microplanning and detailing precise logistic and financial needs for each district and sub-district, starting from the more peripheral levels and moving towards the higher levels, adjusting macro-plans on state and national levels.



Timely trainings/orientation/media briefing and information sharing with community helps in smooth launch at the level of health care service providers, mobilizers and community settings.

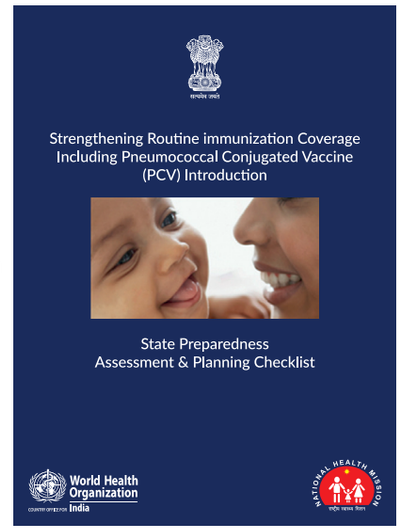
The PCV introduction plan encompasses all components, including a program assessment at all levels to determine what is required for the introduction. The introduction plan takes into account the timelines for successful completion including vaccine supply and estimated procurement requirements. The PCV introduction operational guidelines have been standardized for uniform understanding at all levels.

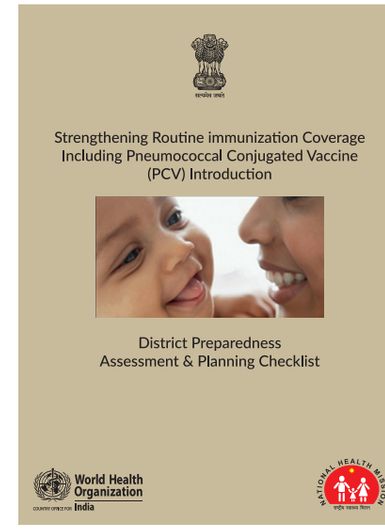
4.1 STATE AND DISTRICT PREPAREDNESS ASSESSMENT

The MoHFW, Government of India, has developed and disseminated state- and district-level preparedness assessment checklists to support the state and district program managers in assessing critical information prior to introduction of any new vaccine. These checklists helped in assessing and identifying strengths and weaknesses at state, district and block levels to take corrective actions for effective and successful introduction of new vaccines such as Hib-containing pentavalent vaccine, IPV and rotavirus vaccine (in nine select states) in the UIP.

WHO and UNICEF have been assisting MoHFW and will continue to support MoHFW in reviewing the preparedness based on information provided by states in the checklist. The district checklists duly completed and signed by district authorities should be forwarded to the state. All districts are to submit their filled checklists to states within 15 days of receipt of the checklist.

The states then review checklists received from districts and complete the state checklist within 2 weeks of receipt. These checklists are first analyzed by state immunization officers (SIOs) with support from partners to identify gaps and level of





preparedness through state- and district-level scoring systems before sharing it with the ministry. The state checklists duly completed and signed by state authorities should be forwarded to the national level (MoHFW).

National observers will review the preparedness, vaccine requirements and cold chain capacities at state and district levels during their field visits.

The key issues identified in checklists are discussed and sorted through task force mechanisms. PCV introduction should happen only when district preparedness is found satisfactory along with completion of trainings and other important activities. PCV vaccine will only be introduced in districts/blocks that have completed trainings.

These checklists will also help the districts to assess availability of resources, especially cold chain space.

The table below lists the 15 components incorporated in the checklists.

ESSENTIAL COMPONENTS	
1. Human resources vitals	2. Background information
3. Microplanning status	4. Mission Indradhanush-specific information
5. Training status	6. Reporting and recording practices
7. Vaccine coverage and wastage	8. Vaccine management, transport and logistics
9. Waste management & injection safety	10. Monitoring & supervision
11. Adverse Events Following Immunization (AEFI)	12. Mobilization
13. Advocacy & Communications	14. Surveillance
15. Cold chain maintenance	
ADDITIONAL COMPONENTS	
16. General impressions	17. Additional remarks/comments

5 Trainings

The successful introduction of PCV vaccine will largely depend upon trainings conducted for all levels of health functionaries. Health-care providers are not only responsible for handling and administering the vaccine, but are also an important source of information for parents as well as community. Strengthening capacity of health workers on interpersonal communication skills (IPC) is important to ensure effective delivery of PCV in routine immunization, particularly in terms of community mobilization and vaccine acceptance.

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. A systematic review found that parental acceptance of multiple injections during single visit was associated with a positive provider recommendation to the caregiver (Source: SAGE April 2015). A good training gives confidence to health workers to introduce new vaccines.

REMEMBER

- PCV introduction training should be conducted as per guidelines.
- Standardized training package to be used during the trainings.
- All trainings will have some common and cadre-specific messages.
- Key tips/messages for participants have been incorporated into respective agendas.
- Pneumonia is the single largest infectious cause of death in children worldwide, accounted for about 10 lakhs (1 million) deaths in 2015.

Health-care personnel who require training on introduction of PCV include district immunization officers (DIOs), urban nodal officers (NHM-Urban), medical officers (MOs), cold chain handlers, data managers, supervisors, ANMs and frontline health workers. The officials and staff of the Department of Women and Child Development such as child development project officers (CDPOs), integrated child development services (ICDS) supervisors and *anganwadi* workers also need to be trained at the same time. In addition, plans should be drawn up to orient the faculty of pediatrics and preventive and social medicine departments in medical colleges as well as professional bodies (IAP, IMA) involved in immunization service delivery.

All sessions must be interactive. Methodology should include PowerPoint presentations, role plays, exercises and interactive discussions. Each batch should not have more than 40 participants. More than one batch may have to be planned in large states/districts. Trainers should be patient listeners to any feedback from trainees. It is important to conduct intensive discussions on scenarios customized as per field experience from previously introduced new vaccines during trainings to sensitize health workers on issues anticipated in the field situations.

Trainings

5.1 TRAINING APPROACH FOR PCV INTRODUCTION

Training is a critical activity and needs timely planning and implementation. Cascaded trainings are envisaged for building capacity of all cadres of staff involved in routine immunization. Training activities will be conducted beginning at least 1-2 months before PCV introduction and will commence at the national/state/district level and to be cascaded up to sub-district level trainings of health workers and frontline health workers. Each district will prepare block/ planning unit wise training calendar and share it with state. SIO will track district-wise progress on trainings. DIO will ensure quality, participation and timely completion of district and all sub-district block/planning unit level trainings in the district. PCV will only be introduced once all trainings are completed in the district/block/planning unit.

Timely trainings/orientation of health care service providers, mobilizers and media as well as information sharing with community will help in smooth introduction of PCV. In order to train health workers, a pool of master trainers will be created through training-of-trainers (ToT) at national/state/district levels. Trainings will adhere to relevant guidelines and training material developed for each level. A comprehensive training plan developed for PCV introduction is attached as annexure 2.

State workshop (ToT) for PCV introduction

Training activities will commence at the state level with a one-and-a half day orientation of SIO, state cold chain officer, data manager, and other state trainers and partners on PCV introduction. Subsequently, these trained officers will conduct trainings in their respective districts, beginning with state-level training for district followed by block-level trainings. Ensure that at all levels key officials/program managers involved in urban health participate in trainings. The table below depicts the state training plan for PCV introduction.

Training	Trainers	Participants	Training Support
State Workshop (ToT) for PCV Introduction	MoHFW officials, WHO NPSP and other national-level partners	**State-level:** State Immunization Officer, State Cold Chain Officer, State IEC Officer (Mass Media Officer/State BCC Coordinator NHM), State Data Manager, State M&E (NHM), State Finance Officer (NHM), State ICDS Coordinator, State ASHA Coordinator, WHO NPSP and partners **District-level (maximum 4-5 participants):** DIO, District Program Manager (NHM), District Cold Chain Handler, WHO NPSP and partners	State Health Department and WHO with support of partners

State media workshop for PCV introduction

These trainings will be undertaken by the Immunization Technical Support Unit (ITSU) of MoHFW. The purpose of this training is to sensitize IEC officials and media. The table below depicts the state plan for media workshop on PCV introduction.

Trainings

Training	Trainers	Participants	Training Support
State Media Workshop for PCV Introduction	Chair: Principal Secretary (Health & FW) Co-chair: MD NHM Key facilitators: State Immunization Officer, Director Supporting partners: WHO NPSP, UNICEF with support of other partners (ITSU, GHS)	**State-level:** State Immunization Officer, State IEC Officer (Mass Media Officer/State BCC Coordinator NHM), WHO NPSP and partners **District-level (maximum 2 participants):** District Mass Media Officer, District Immunization Officer (if required), any other official identified as district spokesperson.	SEPIO and nodal officer at state for mass media Funding support (NHM): State Health Department

District workshop (ToT) for PCV introduction

Each district where PCV is to be introduced is expected to conduct training workshops of one-and-a-half day duration. District-level officers who received training at state will conduct training workshop in each district. Five trainers from each block/planning unit including block medical officers, block vaccine and data managers and block program managers from NHM, Assistant Research Officer (ARO), block eVIN focal person, block mobilization coordinator (SMNet [Social Mobilization Network])/ other partner agencies, ASHA coordinator, will participate in the district-level training workshop. Each batch should not have more than 40–50 participants. District level representatives from technical partner agencies such as WHO-National Polio Surveillance Project (NPSP) surveillance medical officers will also be engaged in state-level trainings. The table below depicts the district training plan for PCV introduction.

The details of the agenda for PCV training workshop for medical officers at state/district level attached as annexure 3.

Sub-district/block/planning unit training of frontline health workers

Training of health workers is the key to vaccine acceptance and community mobilization

Training	Trainers	Participants	Training Support
District Workshop (ToT) for PCV Introduction	District Immunization Officer, WHO NPSP, District Program Manager (NHM), District Cold Chain Handler and Partners	**District-level:** District Program Manager, District Cold Chain Handler, District Mobilization Coordinator (SMNet), Vaccine cold chain manager (UNDP) and partners **Block-level (maximum 4-5 participants from blocks and urban planning units):** Block MOICs, Block Program Manager (NHM), CDPO-ICDS, Block-IO/ICC/ARO, Block Cold Chain Handler, Block Mobilization Coordinator (SMNet)	District Health Department with funding support from WHO Technical support: WHO, UNDP, UNICEF, CSOs and other partners

Trainings

These block level trainers will, in-turn, be responsible for training health workers, including ANMs, supervisors and cold chain handlers. ANMs/ASHAs/AWWs/link workers will be trained at block PHC/additional PHC. Block-level trainings should be planned in such a way that there are not more than 40 participants per batch. If required, more than one batch can be planned accordingly.

The training should be planned in such a way that each ANM attends the training along with ASHA and *anganwadi* workers posted in her sub-centre area. This also means that for every ANM (sub-centre) there will be approximately 4-5 ASHAs/*anganwadi* workers each who will be attending these block/sub-block level trainings (preferably at block level). This will ensure good participation and uniform understanding on operational aspects of PCV introduction within different cadres and also help in harmonizing the process flow. The table below depicts the block training plan for PCV introduction.

Training	Trainers	Participants	Training Support
Block Workshop for PCV Introduction (for health workers and mobilizers)	Block MOICs, Block Program Manager (NHM), CDPO-ICDS, Block IO/ICC and Block Cold Chain Handler, Block Mobilization Coordinator (SMNet)	ANMs, front-level mobilizers (ASHA/AWW) and Health & ICDS supervisors Additional PHCs medical officers (if any)	District Health Department (NHM budget)

The frontline health worker is the keystone of community engagement. It is important to ensure that ANMs, AWWs, ASHAs and community volunteers are well trained before the PCV launch. Health workers, if properly trained and informed, can motivate and generate community interest in the UIP and the new vaccine. They are the main source of information for the general public. It is, therefore, critical to ensure that all ASHAs, AWWs and link workers are trained on key aspects of PCV, including the four key messages.

The details of the agenda for PCV training workshop for ASHA, AWW and link workers are attached as annexure 4.

If there are any pertinent issues in undertaking all these batches at the block level, the district may plan to do these trainings at sub-block level such as the PHC/planning unit. In all scenarios, ensure at least all ANMs are trained at block level. It has been observed that when ANMs are given the responsibility of training mobilizers, the quality of trainings may be compromised.

In case the trainings of mobilizers are planned at sub-block level, the training calendar/plan should clearly reflect the nodal officer responsible for planning, implementation and monitoring of trainings. All efforts should be made to undertake and monitor mobilizers' trainings. Partner agencies supporting mobilization activities will actively support other block-level trainers such as medical officers, AROs, block program managers (NHM) in imparting training to frontline health workers.

Trainings

REMEMBER

States are encouraged to conduct regular PCV preparedness and implementation review at district and block level. We are aware that the time interval as per the recommended immunization schedule between first and second doses of PCV is 2 months and between the second and booster doses of PCV is almost 5.5 months. A reorientation of health workers between PCV first and second doses, and then between PCV second and booster doses will be helpful in timely updating due list and mobilizing beneficiaries.

The DIO/block medical officer may include the following points as part of PCV review agenda at all levels:

- Reporting & recording issues in PCV administrative coverage, with a focus on left-out/drop-out between first and second doses of PCV/second dose and booster doses of PCV
- Vaccine & cold chain logistics, including high vaccine wastage (if any)
- Key lessons learned
- Communication & mobilization issues
- AEFI reporting
- Monitoring data

Every opportunity should be utilized for sensitization of PCV introduction. For example, state/district task force meetings and medical officers' trainings are ideal to discuss PCV introduction topics.

Training materials have been developed based on the past experiences of new vaccine introduction, post introduction evaluations as well as preparedness assessments conducted before the introduction of PCV. These include standardized

power-point presentations from operational guidelines for ToTs and handouts/information kits that include FAQs on PCV for health workers and mobilizers. These materials (FAQs) will be translated by state in the local language for appropriate use at health worker level. The FAQs on PCV vaccination should be widely used for dissemination of information, especially to medical officers, frontline health workers and mobilizers.

6 Vaccine and Cold Chain Management

An effective vaccine, logistics and cold chain system is an essential prerequisite for successful implementation of the immunization program. It is critical for immunization services to ensure the availability of appropriate equipment and an adequate supply of high-quality vaccines and immunization-related materials to all levels of the program. The key areas of logistics support include vaccine management and monitoring, cold chain management and immunization safety.

If vaccine, logistics and cold chain programs are well managed, it not only ensures that none of the eligible children are missed due to vaccine shortage, but also helps in saving on program costs in ensuring program implementation efficiently without sacrificing the quality of service delivery. Poorly managed logistics systems can lead to high and/or unnecessary vaccine wastage rates, stock-outs, or improper management of waste, resulting in significant operational program costs, as well as a negative impact on public health.

6.1 VACCINE MANAGEMENT

In general, PCV vaccine introduction should follow the standard procedures for calculating vaccine supply of other vaccines and be integrated into existing mechanisms for procurement. PCV vaccine should also be integrated into the stock-management system and vaccine orders must be timed such that the supply is not disrupted.

The number of doses required is based on the size of the target population and vaccine wastage. The simple formula below can assist:

Target population X Number of doses X Wastage factor = Total doses required

Vaccine stores at all levels (state, regional, district, primary health centers (PHCs), community health centers, other cold chain storage points) need to forecast their vaccine needs for the stipulated time period to ensure that the right amount of vaccines, logistics and cold chain equipment are available to vaccinate all eligible infants at a given time in a given area. Each of these levels should monitor the stock of vaccine and syringes in order to assess the lead-time and re-ordering levels.

$$\text{Wastage rate} = \frac{\text{doses supplied} - \text{doses administered}}{\text{doses supplied}} \times 100$$

Vaccine	Maximum acceptable wastage
BCG	50% and the wastage multiplication factor for calculation is 2.0.
Measles, Rota and JE	25% and the wastage multiplication factor for calculation is 1.33.
PCV, IPV, OPV, Pentavalent, Hepatitis B, DPT, TT	10% for all vaccines eligible for reuse under the open vial policy. The wastage multiplication factor for calculation is 1.11.

6.2 WASTAGE RATE AND BUFFER STOCK

PCV introduction recommends indicative wastage values of less than 10% for the 4-dose vial. The buffer stock recommended is 25% for the first year of vaccine introduction. All efforts should be made to minimize vaccine wastage at all levels.

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

6.3 ESTIMATING VACCINE AND SYRINGES NEEDED

The AD syringes (0.5 ml) available under the UIP are to be used to administer PCV. Number of AD syringes supplied is equal to the number of vaccine doses supplied. This means wastage rate calculated for vaccines by default gets calculated for the AD syringes. A child requires 3 doses and vial contains 4 doses per vial; hence wastage rate is negligible. PCV is a liquid vaccine, hence, no requirement of reconstitution syringe.

6.4 COLD CHAIN SPACE AND INVENTORY

The cold chain infrastructure in India is a wide network of cold chain stores consisting of government medical store depots, state, regional/divisional vaccine stores, and district and PHC/CHC. The cold chain system spans all 36 states/union territories, 666 districts, 28,882 CHCs and PHCs, along with cold chain points at other health facilities. The cold chain network in the country has been the backbone to ensure that correct quantity and quality of vaccine reaches the target population. The figure 16 depicts the cold chain system in India.

With the nation-wide roll out of pentavalent vaccine, there has been a significant increase in the cold chain space availability due to the reduced requirement of DPT and hepatitis B vaccines. However, districts and states must review the cold chain space available at different levels to ensure that adequate space is available to accommodate the PCV vaccine. Cold chain monitoring through National Cold Chain Management Information System (NCCMIS) is operational across all states/union territories. The cold chain inventory should be regularly reviewed and status of the same should be updated in the NCCMIS. India recently conducted a national EVM assessment and also developed electronic vaccine intelligence network (eVIN), an online system for assessing cold chain equipment functionality and vaccine storage status.

REMEMBER

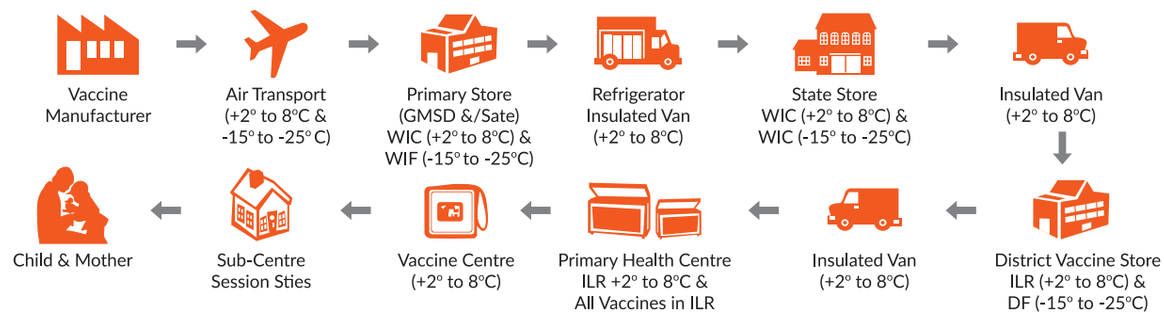
To avoid freezing of vaccine ensure cold chain point are visited and evaluated once before the start of the vaccination drive.

Vaccine and cold chain officials posted at all levels are expected to undertake field visits regarding cold chain preparedness.

6.5 COLD CHAIN MONITORING

PCV is a heat and freeze sensitive vaccine and loses its potency when exposed to temperatures outside

Figure 16: ***Cold chain network in India***



the range recommended by the manufacturer. Its capacity to produce neutralizing antibodies is destroyed by both heat and freezing. The heat impact on vaccines is cumulative. Proper storage of vaccines and maintenance of the cold chain during storage and distribution are essential to prevent the loss of potency. Once a vaccine loses its potency, this cannot be regained. Damaged vaccines should be discarded according to the guidelines.

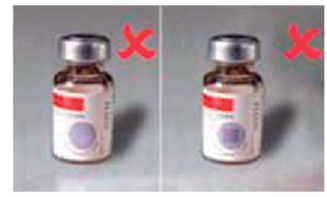
All PCV vaccine vials have a vaccine vial monitor (VVM-30). The VVM registers cumulative heat exposure, and changes from light to dark. Before use, check the VVM on each vaccine vial. If inside square is the same color, or darker than the outer circle, do not use the vaccine.

6.6 STORAGE AND HANDLING OF PCV VACCINE

- PCV vaccine management should follow the same procedures as for other vaccines in the cold chain.
- Upon receipt and confirmation of quantity and quality delivered, the vaccines should be placed in the designated ILR. All PCV vaccines should be stored between +2°C and +8°C.
- PCV vaccines SHOULD NOT BE FROZEN as they are exceptionally sensitive to temperatures lower than +2°C and lose efficacy if frozen. Any frozen vaccine should not be used and to be discarded as per policy guidelines.
- If there is suspicion that a vaccine has been frozen, a shake test should be done. (Refer to annexure for details on conducting shake test).
- PCV vaccines cannot be placed directly on or near the freezer portion of refrigerators, and should not be stored near the liners or walls of cold boxes and or ice-packs in vaccine carriers.
- Refer to section 6.7 for proper procedures on

REMEMBER

- PCV is stored at +2°C to +8°C in ILR along with other UIP vaccines at all levels.
- PCV should be transported with conditioned ice packs with other vaccines.
- Open vial policy is applicable to PCV.

Usable Stages	Unusable Stages
	
Reading the stages of the VVM • The inner square is lighter than the outer circle. • If the expiry date has not been passed: **Use the vaccine**	**Discard point** • The color of the inner square matches that of the outer circle: **DO NOT use the vaccine** • If the color of the inner square is darker than the outer circle: **DO NOT use the vaccine**

HOW TO READ A VVM

- ✓ Vaccine
- ✓ Vaccine OK use first
- ✗ Do not use the vaccine
- ✗ Do not use the vaccine

6.7 CONDITIONING OF ICE PACKS

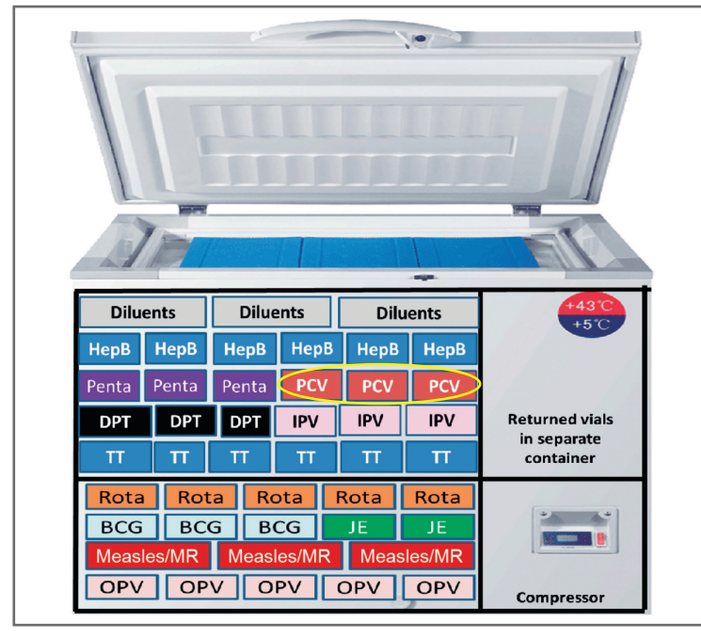
In order to ensure correct storage of vaccines, the following procedures should be followed:

- Ensure that the insulated vaccine carriers are clean before use and at end of the day.
- Use a packing table, and remove ice packs from freezer and place on table to defrost. Packs are ready to use when there are physical signs of thawing; no ice and drops of water on surface, and

conditioning ice-packs and use of ice packs in vaccine carrier.

To ensure efficacy of the vaccines, proper storage and packing are essential. The following are recommended for vaccine storage:

- In ILR, store PCV and other freeze-sensitive vaccines near the top of the basket. PCV should be placed adjacent to pentavalent vaccine. Refer to figure below.
- PCV could be damaged if placed in direct contact with frozen ice packs that were inadequately conditioned; therefore, water ice packs should be conditioned before use.

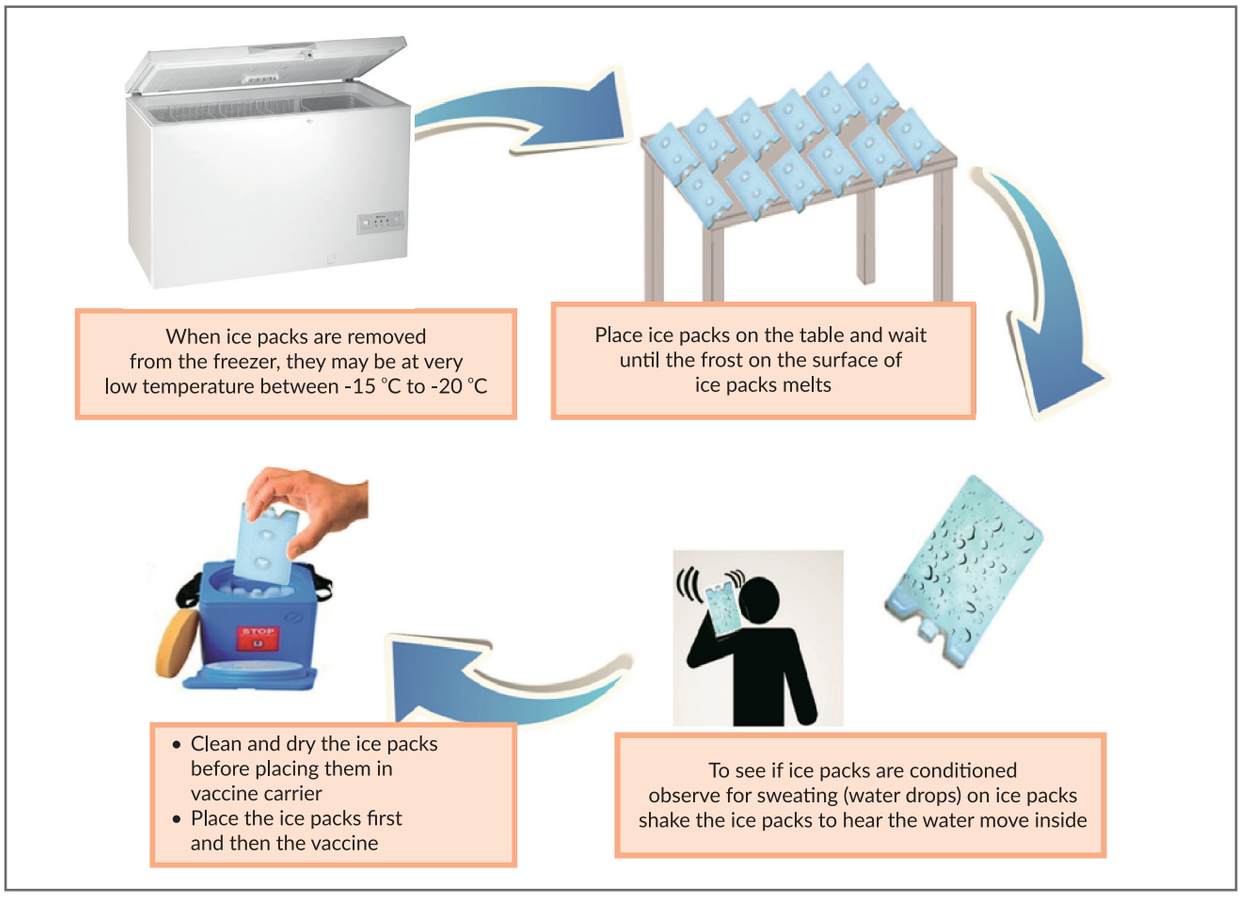


liquid is observed inside.

- Dry the packs and line the walls of the insulated vaccine carrier with them.
- Place the vaccines inside and ensure that the container is properly closed.
- Allowing ice packs to thaw means that the initial freezing temperature is lost, so the temperature in the insulated carrier does not drop below 0°C.
- Properly conditioned ice packs constitute the best method to maintain the temperature of the insulated carriers and cold boxes.
- There should be sufficient ice packs to ensure that the vaccines are totally surrounded during transportation.

6.8 PCV VACCINE HANDLING

For use of PCV, it is to be ensured that health workers are trained on appropriate handling of PCV vaccine, as per the revised open vial policy guidelines by MoHFW. Each vial contains a VVM to indicate cumulative exposure to heat. Any vaccine



vial beyond the discard point of VVM should not be used and to be discarded. The vaccine should be stored between +2°C and +8°C. Remember PCV is a freeze sensitive vaccine and shake test is applicable.

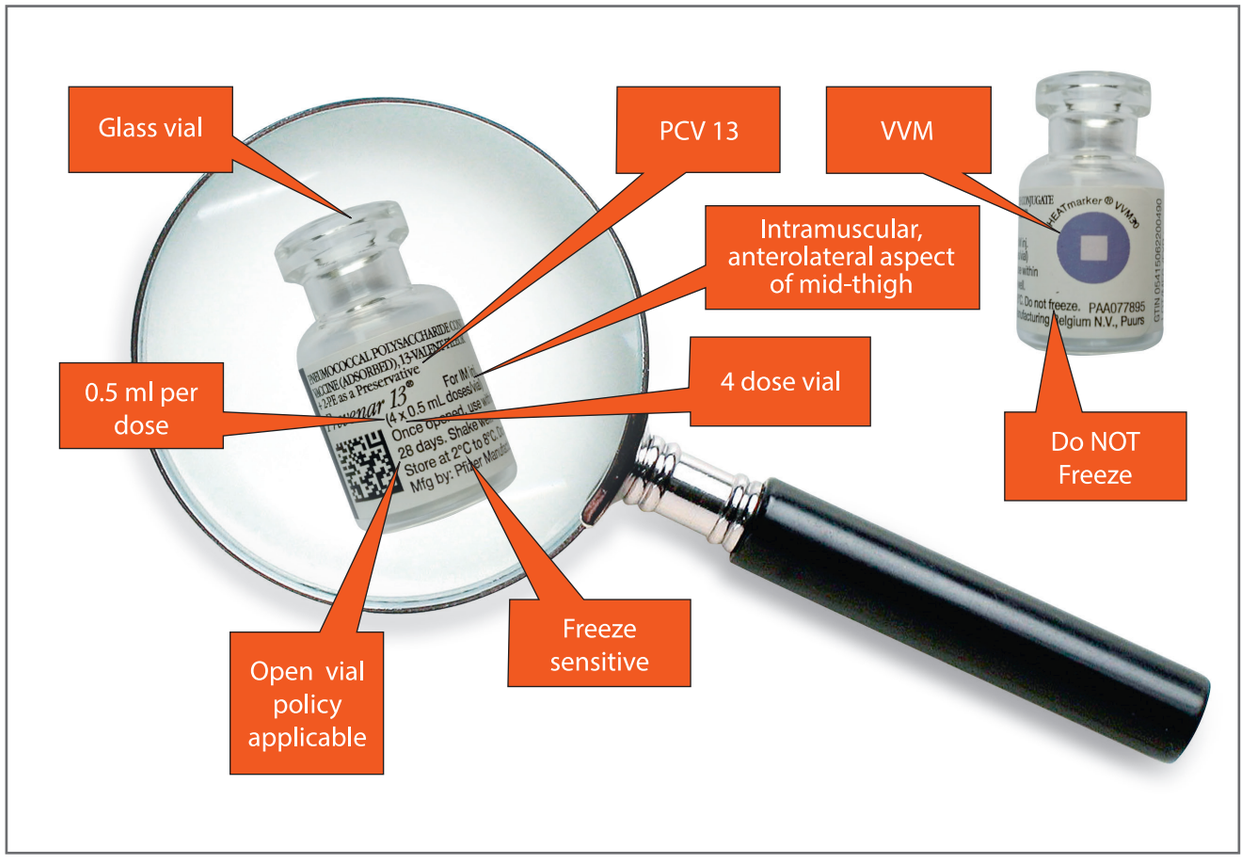
6.9 PCV STOCK MANAGEMENT (INVENTORY CONTROL)

The inventory system should ensure that units with the nearest expiry date are used first in a system known as EEFO (Early Expiry, First-Out). Expiry date should always be checked whenever a vial is opened. Never use vaccines after the expiry date.

REMEMBER

- PCV is a freeze-sensitive vaccine.
- Shake test is applicable.

If you find frozen vaccine vial, do not use it and record it in the vaccine stock and distribution register.



7 Safe Injection Practices and Management Of Adverse Events Following Immunization (AEFI)

7.1 QUALITY OF VACCINATION - SAFE INJECTION PRACTICES

Safe injection is defined as the one which causes no harm

- to the recipient
- to the provider
- to the community

Some steps to ensure injection safety are as follows:

- As in routine service, all vaccinators will use only AD syringes for PCV vaccination.

These syringes prevent person-to-person transmission of blood-borne pathogens.

- Use a new sterile packed AD syringe for each injection for each child.
- Use the same syringe to draw and administer the vaccine.
- Do not touch the needle at any stage.
- Do not touch or contaminate the septum of the vial.
- Do not pre-fill syringes.
- Do not attempt to recap the needle. This practice can lead to needle stick injuries.
- Immediately after injecting the child, the AD syringe must be cut from the hub (plastic part at base of needle) using the hub cutter, and put the cut part of the syringe in the red bag. DO NOT PUT the syringes on the table or in a tray after the injection.
- Do not use AD syringes that have damaged packaging, or have passed the manufacturer expiry date.
- Wash your hands with soap before and after the vaccination session.

7.2 SAFE DISPOSAL OF WASTE

- Cut the hub of the AD syringe immediately after administering the injection using the hub cutter.
- The cut needles will get collected in the puncture proof translucent container of the hub cutter.
- Segregate and store the plastic portion of the cut syringes and unbroken (but discarded) vials in the red bag.
- All other non-infectious wastes will go into black bag.
- The immunization waste generated during vaccination must be disposed of as per guidelines of biomedical waste disposal.
- Refer to annexure 5 for further details.

7.3 MANAGEMENT OF AEFIs DURING PCV VACCINATION

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

The experience of earlier vaccine introductions such as pentavalent vaccine have shown an increase in reporting of serious AEFI cases (deaths and hospitalizations) immediately after vaccine introduction due to increased sensitivity to safety as a result of training of health workers and awareness in the community and media as well as improved surveillance. Reporting of AEFIs should not be interpreted as an issue with the vaccine/vaccination. Ensure that before introduction of a new vaccine such as PCV, the AEFI surveillance system in the district/state has been strengthened and AEFIs are being reported for all vaccines.

Occurrence of an adverse event after immunization does not necessarily imply that the vaccine is the cause of the adverse event. It is important that all AEFIs thought by parents/community to be due to a vaccine/vaccination are reported and investigated completely. Parents/community must be kept informed about the results of the investigations. This will help maintain confidence in vaccines and the immunization program.

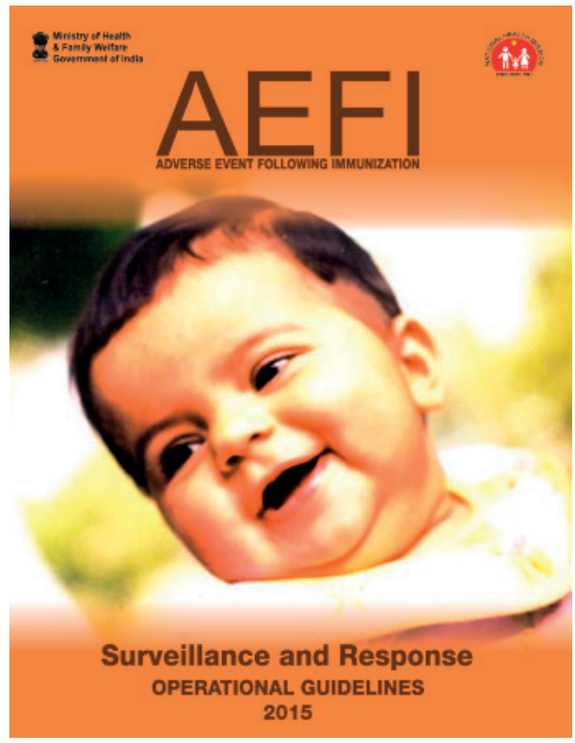
7.3.1 AEFI DURING PCV VACCINATION

PCV vaccines have an excellent track record for safety and efficacy, whether used alone or when co-administered with other vaccines. But a small percentage of children may experience some adverse effects from PCV. The vaccine may be associated with injection site reactions (redness, swelling, tenderness) in 10% of vaccine recipients. Generalized reactions such as fever occur in <1% of vaccine recipients.

Rarely, as with other drugs and vaccines, allergic reactions and anaphylaxis may occur with PCV. In such cases, the vaccine recipient should be rushed to nearest health facility (AEFI management centre) and subsequent doses should not be given.

During PCV vaccination, AEFIs must be quickly detected and promptly responded to. Lack of response can undermine confidence in the vaccine and immunization program. This will ultimately have a negative impact on immunization program and the program objectives will not be achieved.

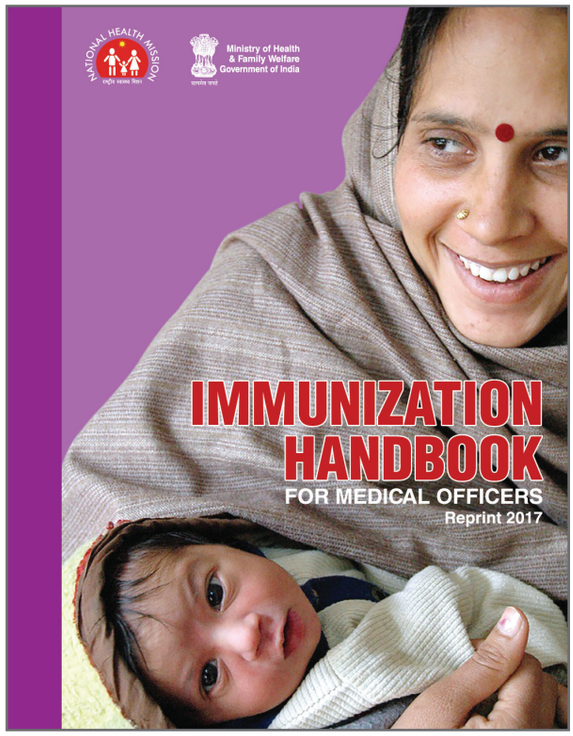
After an AEFI takes place, arrange to provide immediate and appropriate treatment to the child experiencing the event, and report and investigate the case. All efforts should be made to manage the adverse event (if any) followed by investigation of AEFIs as per guidelines. Reporting of AEFIs related to PCV should be conducted as per the Government of India's revised AEFI Surveillance and Response Operational Guidelines, 2015.



Safe Injection Practices And Management Of Adverse Events Following Immunization (AEFI)

Medical officers in charge of immunization at PHCs/CHCs/SDHs/District hospitals will be responsible for managing and reporting AEFIs. Ensure that all other MOs in the PHCs/CHCs/SDHs /District Hospitals are trained and sensitized on immediate reporting of serious/severe AEFIs. The AEFI management centers at select PHCs/CHCs /SDHs should be monitored, steps taken to ensure the staff are trained, and infrastructure and medical supplies must be in adequate supply (refer to Immunization Handbook for Medical Officers, MoHFW, GOI, third edition, 2016). Frontline health workers/link workers (AWW/ASHA/community volunteer)/ANM should immediately inform the MO of the AEFI and arrange for transportation to the nearest AEFI Management Center or health facility. If the case cannot be managed locally, arrange to refer the case to a higher treatment center.

It should be ensured that the AEFI management kit has all the required drugs, etc. (refer to AEFI kit contents).



7.3.2 AEFI SURVEILLANCE DURING PCV VACCINATION

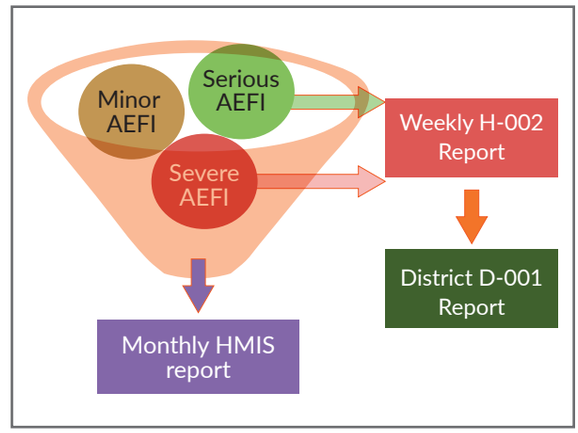
Standard operating procedures have been laid out by the Government of India for responding to AEFI (AEFI Surveillance and Response Operational Guidelines 2015).

As for other vaccines, these guidelines also apply to PCV vaccine. AEFI detection and management should be done according to the following plan:

- All ANMs/ASHAs/AWWs and MOs (in addition to MO in-charges) in PHCs/CHCs/SDHs/District hospitals, medical colleges and private practitioners must be sensitized to recognize, manage and report AEFIs promptly.
  They must know what to do in the event of an AEFI and the location of the nearest AEFI management center.

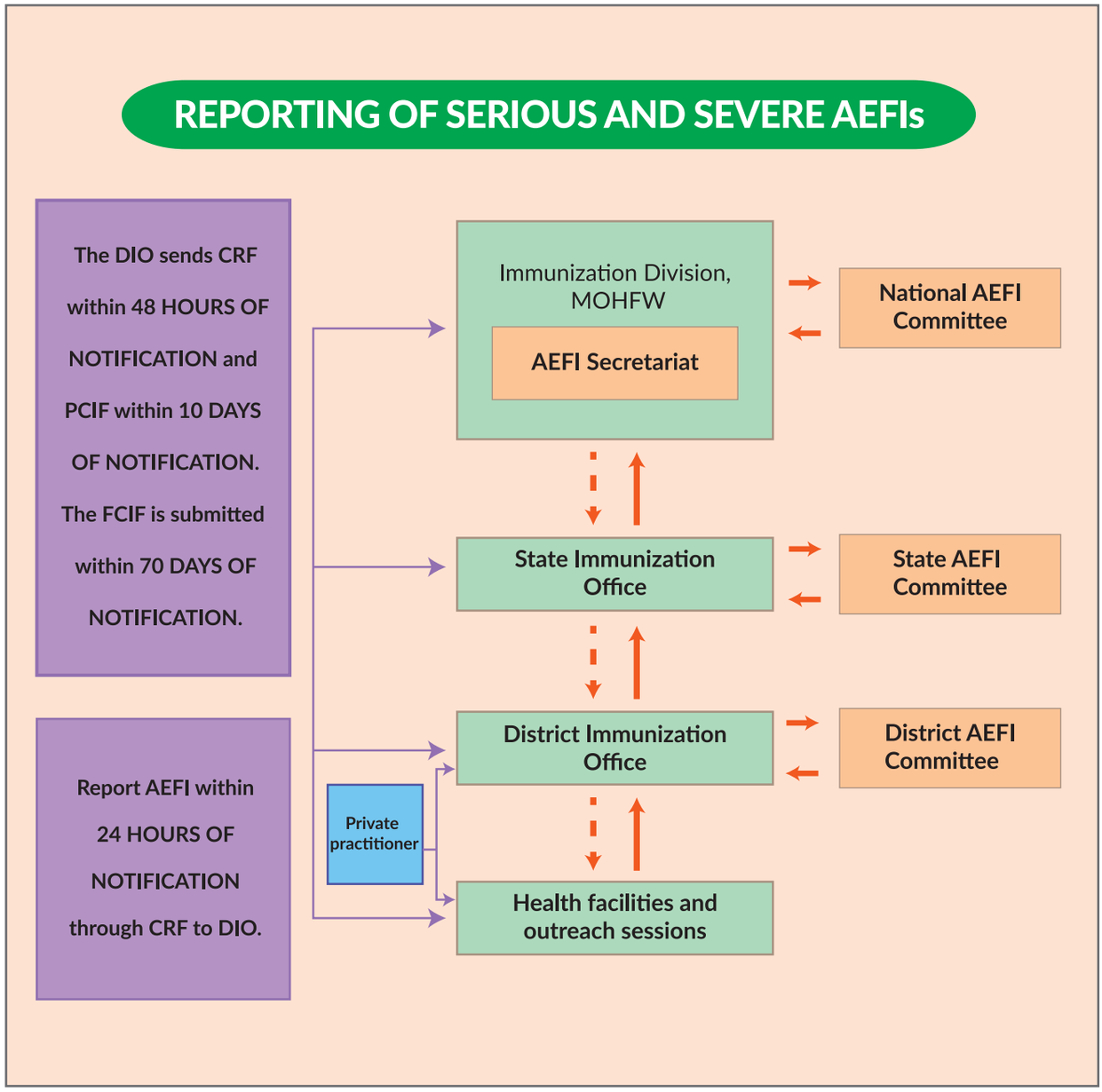
- All serious and severe AEFIs are to be reported using the Case Reporting Form (CRF) immediately (within 24 hours) to the District Immunization Officer. The form will be provided in the kits for AEFI management.

- Minor, serious and severe AEFIs will also be notified by the ANM/Health worker in the AEFI register maintained at the PHC/CHC every week. Serious and severe AEFIs will be reported in the weekly nil reporting VPD H-002 and district D-001



forms. Minor, serious and severe AEFIs should be appropriately reported in HMIS (abscesses, deaths and all others).

- The DIO will investigate all reported serious/severe AEFIs in Preliminary and Final Case Investigation Forms (PCIFs and FCIFs). The timelines for case investigations should be strictly adhered to.
- During the quarterly meeting of the district AEFI committee before the introduction of the PCV, the members must be informed and prepared to be involved in investigating AEFIs, if necessary. They can also contribute to managing the media as needed. The following figure depicts timelines for reporting and investigation of serious and severe AEFI.



7.3.3 CONTENTS OF AN AEFI TREATMENT KIT

- Injection adrenalin (1:1000) solution – 2 ampoules.
- Injection Hydrocortisone (100 mg) – 1 vial
- Disposable Syringe (insulin type) having 0.01 ml graduations and 26G IM needle – 2 sets
- Disposable Syringe (5 ml) and 24/26G IM needle – 2 sets
- Scalp vein set – 2 sets
- Tab Paracetamol (500 mg) - 10 tabs
- I/V Fluids (Ringer lactate/Normal Saline): 1 unit in plastic bottle
- I/V Fluids (5% Dextrose): 1 unit in plastic bottle.
- IV drip set: 1 set
- Cotton wool + adhesive tape : 1 each
- AEFI reporting form (FIR)
- Label showing: Date of inspection, Expiry date of Inj. Adrenaline and shortest expiry date of any of the components
- Drug dosage tables for Injection Adrenaline and Hydrocortisone
- At hospital setting, oxygen support and airway intubation facility should be available.

7.3.4 RUMORS AND CRISIS MANAGEMENT

While PCV vaccines have an excellent safety profile, misconceptions about its risks can have serious consequences. There should be clear communication about the safety and common side effects of the vaccine, together with endorsement from trusted leaders. Communication helps build trust with the public. This includes providing information on possible side effects in the information, education and communications (IEC) materials and when communicating with parents and the community.

Awareness among health workers and the public of possible adverse events will also reduce fear and misunderstanding and facilitate early recognition and management of AEFIs.

It is very important to engage the media (through journalist briefings, information packages, etc. prior to PCV vaccination, because if they are not well informed about the facts media can often amplify any rumors, leading to a larger crisis (for details, refer to Chapter 9: Communication Strategy & Social Mobilization for PCV Introduction).

Safe Injection Practices And Management Of Adverse Events Following Immunization (AEFI)

IMPORTANT AEFI MESSAGES

- Serious and severe AEFIs should be immediately reported to the appropriate authority.
- The MO and health worker at the vaccination site will provide primary management of AEFIs.
- If needed, they will refer serious and severe AEFI to the nearest higher AEFI management center.
- Transportation for referring patients, if needed, shall be provided by MO I/C.
- Benefit of immunization in preventing disease is well proven.
- It is very risky not to immunize vis-a-vis risk of disease and complications.
- Before the introduction of vaccines, vaccine-preventable diseases caused millions of deaths and/or disability. That situation would return without continued use of vaccines.
- Vaccines do cause some reactions, but these are rarely serious and hardly ever cause long-term problems.
- Well-established immunization safety surveillance is in place. Immunization safety is very important, and even the slightest suspicion of a problem is investigated.

Each state will prepare a crisis communications plan to allow for a rapid effective response to AEFIs, and any allegation that may have a negative effect on public acceptance of PCV or trust in the immunization program.

8 Reporting and Recording of PCV in Routine Immunization

All recording and reporting formats should be revised well in time to include PCV before the introduction of vaccine. All the revised formats should be distributed before introduction and ensure that during health workers' training, an exercise for filling the MCP card should be conducted.

Inclusion of PCV will be required in vaccine stock and distribution registers, immunization cards, due lists, tally sheets, monthly progress reports at all levels, maternal and child health (MCH)/immunization register, coverage monitoring charts, supervisory checklists, computer databases, immunization coverage surveys and evaluation formats, as well as AEFI reporting formats.

HMIS and MCTS/RCH portals are being modified to record the coverage of PCV. Till then, reporting of PCV coverage from state is to be done through manual reporting (format attached in annexure 6).

As part of introduction, the main challenge will be at the level of the health worker to understand and implement the overlapping vaccine schedule and administer multiple injections in one visit. Program officers should ensure quality trainings up to the level of health workers to make them understand that three required PCV doses (2 primary doses and 1 booster dose) at 6 weeks, 14 weeks, and 9

months of age need to be administered along with other routine vaccines at the same age, and no eligible child should be devoid of any of the scheduled vaccines. They should also closely supervise to ensure that all scheduled vaccines are given concomitantly such that coverage of all vaccines scheduled together remains high.

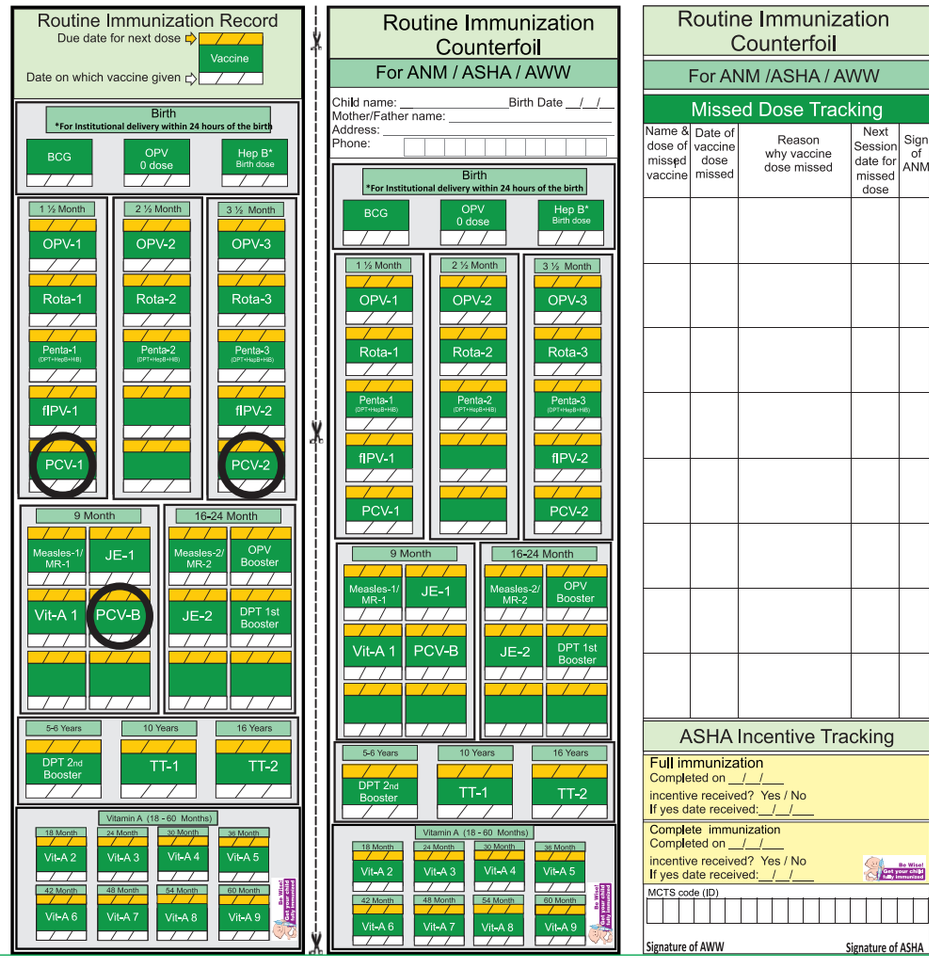
For example, at 6 weeks of age it should be ensured that high coverage rates of pentavalent1, OPV1, rotavirus1 (where applicable), fractional-dose IPV1 (where applicable), and PCV1 coverage rates are achieved and consistent across vaccines. Similarly, coverage rates should be tracked for all scheduled vaccines at PCV2 and PCV booster dose time points, respectively.

In case the printing of revised MCP card and other reporting formats is delayed in the initial few days of PCV introduction, program managers should ensure that they provide clear instructions to health workers/vaccinators in such situations how they should record vaccination data in the MCP card or which reporting formats are to be used alternatively to record vaccine coverage.

Reporting and recording practices for PCV (MCP card, vaccine registers, due lists, tally sheets, reporting coverage until HMIS and MCTS/RCH portals are updated) will also need attention at all levels. Strong monitoring and supervision are required to identify gaps and to ensure accountability and take necessary corrective actions where needed.

Reporting and Recording of PCV in Routine Immunization

Monthly reporting of PCV coverage should be collated at the state level and sent to the national level, so as to reach the national level by 7th of the next month. This manual reporting will continue until such time that the HMIS is updated to capture the same electronically. The manual reporting will be captured in the enclosed format (annexure 6). All blocks/planning units should send reports to the district and all districts should send reports to the state. The state report needs to be submitted to immcontrolroom@gmail.com with a copy to riindia2008@gmail.com by 7th of every month for the preceding month.



9 Communications Strategy & Social Mobilization for PCV Introduction

The success of a new vaccine is achieved when the supply and demand sides are in equilibrium. Communication approaches have proved effective in building the demand for the new vaccine and subsequently increasing the uptake of the vaccine among the communities with high burden of pneumonia.

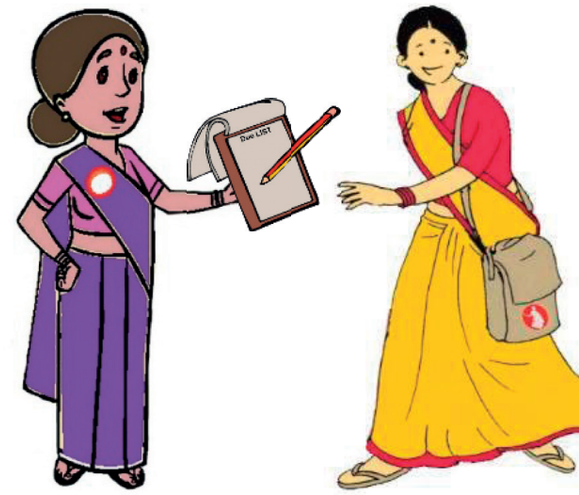
Considering the above factors, the communication strategy for PCV focuses on an integrated approach which includes:

9.1 SOCIAL MOBILIZATION

Social mobilization plays a vital role in building the trust and confidence of the community, dispelling myths and misconceptions, engaging multiple stakeholders for collaborative partnerships, and creating an enabling environment and a positive response towards the new vaccine.

Pre-introduction of vaccine

- District level officials should brief the block level health and IEC officers about the introduction of PCV.
- Health officials should orient officials of ICDS, PRI, RD and education departments on PCV during inter-departmental meetings and reviews.
- MOs should brief the ANMs and their supervisors, ASHA and their supervisors, IEC staff, about the introduction of PCV in the routine immunization program.
- MOs need to support frontline health workers in developing a social mobilization plan focused on PCV.
- ANMs with the support of ASHAs prepare the due list for PCV as part of the routine immunization activities.
- Inform local influencers, mobilizers and their networks about PCV, orient them about their roles and responsibilities, and develop a plan of action for mobilization.
- A template for developing a plan for social mobilization with indicative activities should be developed.



Post-introduction of vaccine

- Organize community meetings with community members and leaders.
- Conduct meetings for mothers with infants under 1 year of age during village health & nutrition day

(VHND) to explain about PCV and its benefits.

- Conduct sensitization meetings of local non-governmental organizations, community-based organizations and other networks.
- Facilitate announcements from mosques and temples about routine immunization sessions.
- Ensure that sessions are held in sites which are easier to access for the caregivers.

- Ensure that ANMs and ASHAs communicate the four key messages to child's caregivers and family members during sessions.

Advocacy is the process of building support and gaining consensus, building a positive environment by using various tools for fostering a commitment for the new vaccine/ immunization and thereby increasing its uptake.

The following are some of the advocacy activities that need to be carried out:

- Community meetings
- School meetings with teachers, parent-teacher groups and school management committees
- Meetings with religious leaders
- Meetings with VHSNC members

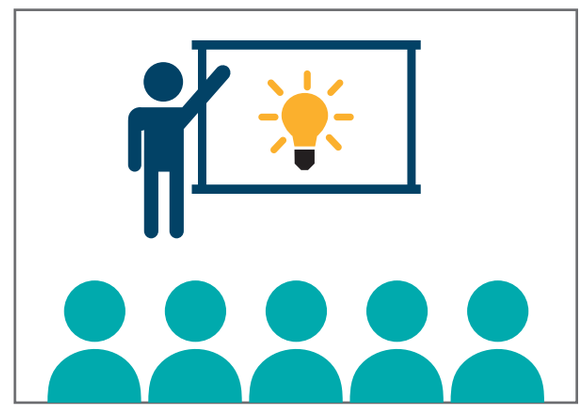
The advocacy and social mobilization activities for PCV should be conducted simultaneously to build a conducive environment for vaccine introduction and ensure its sustainability. Use of interpersonal channels is very effective in influencing the advocates . ANMs/frontline health workers/link workers need to mobilize influencers and mobilizers, and orient them about PCV through one-on-one meetings, and discussions with family members, peers, friends and co-workers.

9.2 CAPACITY BUILDING

It is essential to refresh and build the interpersonal skills of health workers for mobilizing caregivers and community members. Timely trainings/orientation of health care service providers and mobilizers on PCV introduction will build their confidence in the new vaccine, enable them to share essential and relevant information with the community which will eventually help in the smooth introduction of the vaccine.

The following trainings should be carried out at each level prior to the introduction of the new vaccine:

- Training of frontline health workers by trained block-level officials.
- Training of influencers, mobilizers on IPC skills, facilitating group meetings, delivering key messages and using lively interactive methods.
- Communication training sessions will be part of state and district ToTs. Use of IEC materials needs



to be emphasized during ToTs.

9.3 MEDIA MANAGEMENT

Media management is an important aspect of newvaccine introduction. The advocacy needs for any new vaccine are different from those that are already introduced. While traditional media like mass and mid-media will be utilized for visibility, new media (social and digital media) platforms will have to be utilized for further advocacy and awareness generation.

9.3.1 PLAN AND ACTIVITIES

Advocacy for new vaccine introduction needs to begin before the roll-out of the vaccine. The plan should include the following:

Pre-launch activities

- Media sensitization workshops: Need to be organized at the state level for providing journalists an overview of the routine immunization program, pneumococcal disease burden and need for the new vaccine.
- Informal media interactions by state government officials to engage the media and sensitize them regarding disease burden and need for the vaccine. These should begin at least a month before the launch and at least one should be planned every week with different media outlets each time.
- Opinion articles: On the need for the vaccine and the disease burden by either a state government official or a well-known public health expert should be given out at the state level.
- Media monitoring: To begin at least 2 weeks prior to launch.

Launch Activities

- Press conference : To be clubbed with the launch. This should be organized along with state/district Press Information Bureau.
- Opinion articles : On the launch of life-saving vaccine and how many children will benefit from the vaccine at the state level. This should be put out either on the day of the launch or a day after or within the week.

Post-launch activities

- Media monitoring: To continue at least 4 weeks post launch
- Formal media interactions with govt. officials: It is important that the media gets adequate opportunities with the state officials and independent public health experts to do stories apart from the launch of the vaccine. These ensure bigger and more in-depth stories.
- Opinion articles : On the roll-out of the vaccine, how many children have received it, and the benefit of the vaccine. This should be placed in the media a month after the launch with fresh details from the ground/field.

9.4 CRISIS COMMUNICATION

Any new vaccine introduction generates a special interest among the community regarding the vaccine and its benefits. Since a lot of visibility is generated through effective advocacy, any adverse events following immunization that may be reported also get highlighted instantly in the media due to strengthening of the AEFI surveillance across the country,

9.4.1 WHAT NEEDS TO BE DONE?

A. PROACTIVE STEPS

IN A NUTSHELL

- Set up an internal information system.
- Identify and train media spokespersons.
- Media mapping.
- Pre-draft advocacy material (Press releases, info kits, opinion articles).
- Develop FAQs for program managers for use in crisis situations.
- Pre-draft AEFI responses with possible scenarios.
- Schedule regular news media interactions for pitching in positive stories.
- Media scanning.

ACTIVITIES

- Set up an internal information system (before the crisis occurs/before the roll out of the vaccine)
  - Flow of information: District → State → National
  - Timelines for sharing information and response at each level

  As soon as an AEFI occurs, all levels have to be immediately given the information (as FYI). This is important because the media may make queries at any level. If the first response of the govt. is that they know about it and are investigating, the media would tend to trust the system instead of raising negative questions.

- Identify spokespersons
- Primary spokespersons: to comment on the basic details of the case (no comment on causality until it is confirmed). Secondary spokespersons: to share positive messages on the vaccine, demystify AEFIs, support the government (no comment on causality until it is confirmed).
- Media mapping of the states where the vaccine is being introduced.
- Pre-draft
  - Press releases (national and state level)

- Develop info-kits for advocacy
- Opinion articles (Child health & immunization, pneumococcal disease burden, need for the vaccine)

- Develop FAQs and fact sheets
- Use AEFI responses/templates for response to possible crisis situations
- Schedule news media interactions
  - Formal briefings
  - Informal briefings (regular opportunities; to start at least a month before the launch/roll out)
- Media scanning: Scan through the pages of 2–3 newspapers for coverage regarding vaccine or AEFI reports every day and look out for news reports on local TV channels in the evening and/or through the day.

B. REACTIVE STEPS – what to do when the crisis has occurred?

IN A NUTSHELL

- Implement the AEFI Media Response Protocol.
- Swift/timely response. Do not neglect media queries.
- Use/Refer to the case specific response templates for possible crisis situations.
- How to respond? Media briefings/press statement/written responses.
- Media scanning and follow up.

Avoid press conferences

When a crisis occurs and the media picks up the news over 3–4 days or more, the states tend to call a press conference to address the issue. THIS MUST BE AVOIDED. The reason is when the reporters are given an opportunity to ask questions in a group, they tend to harp on the negative and not give the spokespersons time to respond properly.

Media scanning and follow up

It is imperative that the media reports are scanned especially when there is a crisis and see if the govt.'s response has been carried or not and judge whether the news is balanced or negative. If the news is negative, the reporter must be contacted to share the appropriate facts.

Messages to be given out by primary and secondary spokespersons

Spokespersons	Messages
Primary (government)	• The case is noted and is being investigated. • The state/district AEFI experts are analyzing the reports. • The vaccine is safe. (All other children who got the vaccine are well). • Side effects are very rare and can be managed. They also occur in children who have not received the vaccine. The vaccine has been in use in the private sector in India for many years and is being given in many other countries as part of national immunization systems.
Secondary (private practitioners/ medical experts)	• The vaccine has been in use in the private sector in India for many years and is being given in many other countries. • The vaccine is safe and beneficial. • Reporting an AEFI does not automatically mean the vaccine has caused it. Many cases are co-incidental. AEFI surveillance system acts as a disease surveillance system. It is beneficial and is being strengthened.

Monitoring the communication activities

State health officials should guide district-and block-level officials to develop district- and block-wise plans for undertaking communication activities. A plan for the dissemination of IEC materials for PCV needs to be developed at the state, district and block levels. Implementation of both the plans need to be monitored by the health and IEC staff (BEEs/MEIOs).

10 Monitoring & Supervision

The introduction of PCV in the UIP provides an opportunity to strengthen the overall monitoring of the routine immunization program. An intensified monitoring strategy should be used during PCV vaccinations. Appropriate information will be collected on the status of implementation through all components of routine immunization monitoring.

A team of national and state observers shall supervise and monitor all activities during the preparatory and implementation phases across the country. These teams shall guide and evaluate the progress and share their findings with the state and district task forces, and subsequently at the national level for further action. It is recommended that introduction activities start 2–3 months prior to the scheduled introduction of the vaccine.

10.1 SUPERVISION AND MONITORING OF IMPLEMENTATION

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

10.1.1 National Level

Review of the state preparedness checklists and assessment of progress achieved in addressing the identified issues at regular intervals will contribute to effective implementation and will also strengthen the routine immunization system in each state.

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

10.1.2 State Level

Review of the preparedness checklists of the districts will be done by the state immunization officer (SIO). It is recommended that a state team be formed to oversee the implementation process. Officers from various departments can also be involved in the state-level trainings to enable participation in monitoring.

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

State task force for immunization (STFI)

- STFI should be convened periodically to steer key messages for all activities for introduction of PCV in the state, including commitment and support from various departments and stakeholders.
- Issues identified in preparedness assessment should be addressed during meetings of the STFI, State AEFI committee and the State Health Society (SHS) for ensuring smooth introduction of the vaccine. Any funding issues related to new vaccine introduction should immediately be addressed by the STFI and SHS; and necessary instructions for the same should be communicated to the districts concerned.
- States should make best use of lessons learnt from the polio program to strengthen routine immunization. Opportunity like new vaccine introduction should be used to highlight issues that need attention for corrective action.

- Before introduction of the new vaccine, ensure that AEFI surveillance system is strengthened with reporting of AEFI cases following other

vaccines also. The increased AEFI reporting following new vaccine introduction may be blamed on the new vaccine. This may affect the acceptance of and demand for new vaccines in other states and districts. However, the medical fraternity across all cadres should be reassured as increased sensitivity in reporting of AEFIs actually is in the interest of the immunization program.

- WHO-NPSP, UNICEF and other key routine immunization partners involved in immunization at state and district levels are expected to proactively support the authorities in providing quality information/monitoring data at STFI and DTFI levels for appropriate actions.

10.1.3 District Level

In addition to officers of the health department, officials from Integrated Child Development Services (ICDS) department should also be involved in block-level monitoring of training. Child development project officers and local administrative officers should be invited by block MOs to observe training of ASHAs and AWWs at the PHC level. Issues identified must be shared with district task forces for corrective actions. Independent monitoring of preparatory activities, training and immunization will be undertaken by WHO.

District-level monitoring provides information on vaccine availability, engagement of ICDS and education department, microplanning, trainings, vaccine coverage, vaccine stocks, wastage rates, social mobilization and communications, etc.

District task force for immunization (DTFI)

- DTFI should be convened periodically to steer all activities for introduction of PCV vaccine in the district, including obtaining commitment and support for introduction of this vaccine from various departments and stakeholders. Issues identified in activities essential for smooth introduction of PCV in the district should be addressed during meetings of DTFI, district AEFI committee and District Health Society.
- Districts should make best use of lessons learnt from the polio program and introduction of other new vaccines to strengthen routine immunization. Make best use of this new vaccine introduction opportunity to highlight issues that need attention for corrective action.
- The DTFI should monitor preparations for reporting and managing AEFIs. It should monitor the status of AEFI trainings, reporting and investigation of serious/severe AEFIs following all vaccines (not just PCV). It should also ensure that the district AEFI committee is active and meets at least once a quarter.

- WHO, UNICEF and other key routine immunization partners at district level are expected to proactively extend support in providing quality information/monitoring data

to DTFI for guiding and taking appropriate actions.

10.2 MONITORING THE PROCESS OF PCV VACCINE IMPLEMENTATION

Standardized data collection formats and operating

procedures have been developed by MoHFW to monitor the provision of routine immunization services at immunization session sites and community level coverage of all antigens offered through UIP to detect coverage gaps. The introduction of PCV vaccine in the UIP provides an opportunity to strengthen the overall monitoring of the routine immunization program. The MoHFW mandated intensified routine immunization monitoring strategy should be used for PCV-related monitoring as well. Appropriate information may be collected on the status of implementation through all components of routine immunization monitoring.

10.2.1 District-Level Monitors' Briefing

To build capacity of district- and block-level officials, government and partners are responsible for monitoring the preparedness and implementation of PCV introduction in the districts. Monitors are expected to use standardized monitoring formats. These monitors will share monitoring feedback at respective levels as per timelines.

10.2.2 Monitoring vaccine, logistics and cold chain at PHC

PCV is a freeze sensitive vaccine. This vaccine should be stored between +2°C and +8°C. Available records must be examined for supply, utilization and balance of vaccines with AD syringes. Records should be cross-verified physically to see whether there is a logical association between vaccines and AD syringes supplied and used. eVIN is an important tool to monitor vaccine stock and cold chain status at all levels. Program officers are

encouraged to physically validate the data recorded in eVIN and also in the NCCMIS.

10.2.3 Session site monitoring

This captures information on vaccine supply and the availability of logistics, functioning of alternate vaccine delivery (AVD) system, injection practices of ANMs, injection safety and waste disposal, record keeping and inter-personal communication of service providers.

10.2.4 District and block level monitoring

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

10.2.5 House-to-house monitoring

This involves interacting with the caregivers of eligible children in the community both during the session as well as after immunization sessions through a standard format. This is done to assess the reach of utilization of services by the community and completeness of vaccination coverage. The monitoring will reveal the reasons as to why any child has missed the due PCV and/or any of the UIP vaccines appropriate for the age. The evidence generated through the community level monitoring in the form of percentage eligible children found not

to have received the due vaccine and full immunization status are the two key indicators that would be used to apprise the task forces and guide the mid-course corrective measures.

10.2.6 Rapid monitoring

Following PCV introduction, simultaneous rapid monitoring will also be initiated for at least 3 months to assess implementation status of PCV, identify gaps/bottlenecks and provide feedback for immediate corrections. The findings will be very useful in introduction/expansion of PCV in the country. WHO India NPSP will assist the MoHFW in undertaking rapid monitoring through standardized rapid monitoring formats along with standard operating procedures. Rapid monitoring will be done at block and session level, for which separate formats will be developed. This monitoring will be undertaken in addition to routine immunization monitoring.

10.3 LESSONS LEARNT FROM THE INTRODUCTION OF PCV VACCINE – POST INTRODUCTION EVALUATION (PIE)

The introduction of any new vaccine is an opportunity to strengthen health systems and improve the reach of immunization services to disadvantaged populations. WHO recommends that a post introduction evaluation (PIE) of new vaccines be conducted within 6–12 months of introduction of a new vaccine. The aim of such evaluation is to assess community acceptance, impact on the existing immunization system and derive lessons for necessary corrective measures. Although a PIE is done in the context of new vaccine introduction, the exercise provides a broad overview of the performance of the immunization program, and thus boosts the confidence to further scale up and introduce new and underutilized vaccines in the program.

Findings from PIE of nationwide pentavalent vaccine and measles-containing vaccine second dose, as well as lessons learnt from introduction of IPV (pan country), rotavirus vaccine (in four states) are being used to inform the introduction of PCV in the country.

11 Introduction Activities at State, District and Sub-district Levels

The inclusion of PCV into the UIP schedule requires careful preparation and implementation at all levels. This initially involves top-down macro-planning at the state level, followed by bottom-up micro-planning, detailing precise cold chain space at different levels, logistics and financial needs for each district and sub-district, starting from the more peripheral levels and moving towards the higher levels.

The broad steps involved for the introduction of PCV vaccine are similar to the recently introduced pentavalent, IPV and rotavirus vaccines. The specific learning and observations related to this process in the states where early implementation of the vaccine is being planned shall inform appropriate refinement in the operational guidelines.

11.1 STATE-LEVEL ACTIVITIES

The following activities need to be undertaken at state level for successful introduction of PCV vaccine:

State task force for immunization (STFI)

- STFI should be convened periodically to steer key messages for all activities for PCV introduction in state, including commitment and support from various departments and stakeholders.
- Issues identified for smooth introduction of the vaccine should be addressed during STFI.

Assess state preparedness

- The state needs to assess preparedness of districts using standardized checklists. The data should be reviewed, compiled and reflected in the state preparedness checklist.
- Assign state observers to track planning, preparation, launch and implementation of PCV in the districts.

Track preparation in high-priority districts

- Assign state observers to track planning, preparation, launch and implementation of PCV vaccine in priority districts.
- They should visit these districts and provide oversight to activities for introduction of PCV vaccine, including participation in DTFI and assessment of district preparedness using checklists.

Strengthening routine immunization micro-plans

- Ensure that all vulnerable sections are provided an equal opportunity to avail services.
- Monitor completeness of all components of microplanning.

Indenting and delivery of vaccine and logistics

- Ensure availability of required doses of PCV vaccine and other logistics.
- Assess cold chain space.

Introduction Activities at State, District and Sub-district Levels

- PCV is a freeze sensitive vaccine. To avoid freezing of vaccine ensure cold chain points are visited and evaluated once before the start of vaccination drive.

Training workshop at state level

- This is a critical activity and needs timely planning and implementation. Conducting this ToT will create a pool of master trainers who, in turn, will ensure that officials concerned at all levels are sensitized well in time prior to introduction.
- Key developmental partners such as WHO, UNICEF and others should proactively support the states and districts in planning, implementation and monitoring.
- The training at different levels including target trainees, trainers and duration is summarized in the Chapter 5 above.

Tracking beneficiaries (left-outs and drop-outs)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure it is a time-bound activity and gets completed in 1–2 weeks.
- State health authorities and partners should intensively monitor this activity and share findings at all relevant platforms.
- Implementation of immunization tracking bag (one per session site). ANM will keep one immunization tracking bag for each session site. She will make the ASHA/AWW of that area responsible for safe keeping of tracking bags containing counterfoils. The ANM will provide oversight and cross check counterfoils to ascertain reasons for dropouts.

Dissemination of operational guidelines/IEC materials

- Disseminate relevant guidelines and training materials to each category of staff during trainings for PCV introduction.
- Ensure printing of IEC material in local language in adequate numbers.

Intensified monitoring and supervision

- Intensify supervision and monitoring of program at district, block, session and house-to-house levels through government functionaries and partners.
- Use standardized routine immunization monitoring formats recently revised and shared with states by MoHFW. (Refer to the revised routine immunization session and house-to-house monitoring formats).
- Rapid monitoring will be initiated at block and session level for at least 3 months of new vaccine

introduction to assess the implementation status, identify gaps/bottlenecks and provide feedback for immediate corrections. This activity will be undertaken by WHO NPSP and other partners. Separate formats for rapid monitoring have to be filled in addition to the routine immunization monitoring formats.

11.2 DISTRICT LEVEL ACTIVITIES

The following activities should be undertaken at the district/block level for successful PCV vaccination:

District task force for immunization (DTF-I)

- DTFI should be convened to steer all activities for introduction of PCV vaccine in the district, including obtaining commitment and support from various departments and stakeholders.
- Representatives of urban local bodies should be part of DTFI.

Assess district preparedness

- The district needs to assess the preparedness of the blocks using standardized checklist. Quantitative and qualitative data should be compiled and reflected in the district preparedness checklists.

Track high-priority blocks

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

Strengthen routine immunization micro-plans

- Ensure all vulnerable sections and high risk groups are provided an equal opportunity to avail services.
- For improved microplanning, ANMs/ASHAs/AWWs should undertake a headcount survey for estimation of beneficiaries by using standardized tools. This has to be a time-bound activity (1–2 weeks) and has to be intensively monitored by government functionaries and partners. DTFI to monitor the completeness of microplans.

Indenting and delivery of vaccine and logistics

- Ensure availability of required doses of PCV and other logistics.
- Assess cold chain space.
- PCV is a freeze sensitive vaccine. To avoid freezing of vaccine ensure cold chain point are visited and evaluated once before the start of vaccination. Vaccine and cold chain officials posted at all levels are expected to undertake field visits regarding cold chain preparedness.
- Partners (UNDP, UNICEF, WHO NPSP, CORE and others) are expected to use standardized formats to assess cold chain preparedness at all levels.

Training workshop at district/block level

- Prepare a training calendar to train the health workforce.
- Conduct district-level ToTs to create a pool of trainers at district and block levels. The DIO

will be responsible for ensuring timely completion of training as per guidelines. Key development partners such as WHO, UNICEF and others are expected to proactively support the district in planning and sensitization for the workshop activities including monitoring the quality of training.

- The district- and block-level pool of trainers is expected to follow the cascading approach for sensitizing the health work force at district and block levels. (Refer to Chapter 5 on trainings for further information).
- Do not forget to train the staff posted in big government hospitals and medical colleges.
- Ensure that key officials identified under NHM (Urban) are included as participants.
- Each planning unit in urban area should be considered like a block. Develop training plan accordingly.
- Conduct training workshops with a maximum batch of 40 participants.
- For more details, refer to annexure 2.

Tracking beneficiaries (left outs and dropouts)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro-planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure that it is a time-bound activity and gets completed in 1–2 weeks.
- Ensure that vaccinators update due lists before every session. Following PCV introduction, ensure that PCV1 should be included as part of due lists for beneficiaries coming at 6 weeks for pentavalent1, OPV1, Rota1 (where applicable), fractional-dose IPV1 (where applicable); and subsequently for PCV2 at 14 weeks and PCV booster dose at 9 months.
- State health authorities and partners should intensively monitor this activity and share findings at all relevant platforms.
- Implementation of immunization tracking bag (one per session site). ANM will keep one immunization tracking bag for each session site. She will make the ASHA/AWW of that area responsible for safe keeping of tracking bags containing counterfoils. The ANM will provide oversight and cross check counterfoils to ascertain reasons for dropouts.

Assessment of cold chain capacity and functionality status

- Ensure that cold chain assessment is undertaken prior to PCV introduction.
- Key issues and gaps identified should be followed up and addressed at the earliest, preferably before PCV introduction.

Dissemination of operational guidelines/reporting formats/IEC materials

- Disseminate relevant guidelines and training materials to each category of staff during trainings for PCV introduction.
- Ensure dissemination of IEC materials well in time.

Intensified monitoring and supervision

- Use standardized routine immunization monitoring formats recently revised and shared

with states by MoHFW. (Refer to the revised routine immunization session and house-to-house monitoring formats).

- Rapid monitoring will be initiated at block and session level for at least 3 months of new vaccine introduction to assess the implementation status, identify gaps/bottlenecks and provide feedback for immediate corrections. This activity will be undertaken by WHO NPSP and other partners. Separate formats for rapid monitoring have to be filled in addition to the routine immunization monitoring formats.

11.3 BLOCK LEVEL ACTIVITIES

The following activities should be undertaken at the block level for successful introduction of PCV vaccine into UIP:

11.3.1 Strengthen routine immunization micro plans

- For improved microplanning, ANMs/ASHAs/AWWs should undertake a headcount survey for estimation of beneficiaries by using standardized tools. This has to be a time-bound activity (1–2 weeks) and has to be intensively monitored by government functionaries and partners. DTFI to monitor the completeness of micro-plans.
- DTFI to monitor progress.

11.3.2 Indenting and delivery of vaccine and logistics

- Ensure availability of required doses of PCV and other logistics. Official communications from the block medical officer in-charge should include the following key messages and the same should be reiterated in ANM monthly review meetings.
- Assess cold chain space
- PCV is a freeze sensitive vaccine. To avoid freezing of vaccine ensure cold chain point are visited and evaluated once before the start of vaccination. Vaccine and cold chain officials posted at all levels are expected to undertake field visits regarding cold chain preparedness.
- Partners (UNDP, UNICEF, WHO NPSP, CORE and others) are expected to use standardized formats to assess cold chain preparedness at all levels.

11.3.3 Block training workshop for training ANMs/ASHAs/AWWs

- ANMs/LHVs/health supervisors: The district should plan to train all the ANMs at district or block level
- Cadre-wise attendance should be closely monitored. Provide block attendance feedback to CMO/DIO, so that the same can be shared in the DTFI.
- Mobilizers (ASHAs and AWWs) are to be

Introduction Activities at State, District and Sub-district Levels

trained at block level by trained block-level officials.

- WHO, UNICEF and other partner agencies are expected to support PCV introduction activities at district/block level, including monitoring the quality of training.
- Details of training at block level are given in Chapter 5.

11.3.4 Dissemination of guidelines/revised formats/IEC materials

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

11.3.5 Tracking beneficiaries (left-outs and drop-outs)

- Undertake headcount for estimation of beneficiaries by ANMs/ASHAs/AWWs for improved micro-planning, due listing and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure that it is a time-bound activity and gets completed in 1–2 weeks.
- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro-planning and tracking.
- State and district observers and partners should intensively monitor head count activity and share findings at all relevant platforms.
- Implementation of immunization tracking bag (one per session site). ANM will keep one immunization tracking bag for each session site. She will make the ASHA/AWW of that area responsible for safe keeping of tracking bags containing counterfoils. The ANM will provide oversight and cross check counterfoils to ascertain reasons for dropouts.
- Ensure that vaccinators update due lists before every session. Following PCV introduction, ensure that PCV1 should be included as part of due lists for beneficiaries coming at 6 weeks for pentavalent1, OPV1, Rota1 (where applicable), fractional-dose IPV1 (where applicable); and subsequently for PCV2 at 14 weeks and PCV booster dose at 9 months.
- Share the due list formats and revised immunization component in the MCP card. Demonstrate the use of counterfoil using immunization tracking bag with a focus on "missed dose tracking."

11.3.6 Intensify monitoring and supervision

- Strengthen monitoring and supervision through LHVs and health supervisors. Explain preparation of supervision plan based on priority and use of standardized formats.
- MO in-charge and other nodal officers identified should supervise PCV implementation in the routine

immunization sessions.

- Blocks/planning units should be receptive to feedback from independent agencies for corrective action.
- Use reporting formats developed for monitoring of PCV vaccination drive.
- Use standardized routine immunization monitoring formats recently revised and shared with states by MoHFW. (Refer to the revised routine immunization session and house-to-house monitoring formats)
- Rapid monitoring will be initiated at block & session level for at least 3 months of PCV introduction to assess the implementation status, identify gaps/bottlenecks and provide feedback for immediate corrections. This activity will be undertaken by WHO NPSP and other partners. Separate formats for rapid monitoring have to be filled in addition to the routine immunization monitoring formats.

11.3.7 Communications planning

- Block MOICs should plan IEC and mobilization activities for greater community participation.
- Facilitate and coordinate all available human resources such as mobilizers and NGO volunteers to create awareness and enabling environment.

- List high-risk pockets and plan mobilization activities with mobilizers/volunteers.

- The communication plan must include strategic use of communications channels such as announcements from mosque/temples and meetings with local influencers, for example community leaders, panchayat members, local practitioners, teachers to mobilize families to bring their children for immunization.
- Ensure including the names of mobilizers/volunteers/influencers in the micro-plans.
- Distribute IEC materials well in advance as per guidelines.

12 Role of Partners

The technical and monitoring support of partner agencies such as WHO, UNICEF continues to be of significance in strengthening of the health systems and programs in the country. The technical support provided by WHO, UNICEF, UNDP and other partner agencies to the introduction of PCV vaccine is highly valuable in the introduction process.

WHO

- Shall provide technical expertise in the development of plans for PCV introduction at state and district levels.
- Provide recommendations on customization of the preparedness checklists and support the district and state governments in completion of these checklists.
- Assist in the review of information derived at the state and district level.
- Capacity building through state and district level ToTs.
- Monitor implementation at the block/district levels with feedback to DTFI and STFI.
- Conduct rapid monitoring of PCV preparedness and introduction.
- Track the progress in implementation of actions in strengthening routine immunization and sharing of the findings at district, state and national levels.
- Share feedback and recommendations to guide future strategies in PCV introduction.
- Conduct a PIE for PCV after 6 months of implementation.

UNICEF

- Support ITSU in developing communication strategy and its timeline for PCV introduction, and organizing media sensitization workshop.
- Provide assistance in information dissemination through its network.
- Capacity building through state and district level ToTs.
- Assist in cold chain assessment in states.
- Assist blocks in training of frontline health workers (through SMNet where present).
- Monitor communication and IEC activities related to PCV introduction.
- Provide regular feedback and recommendations.
- Assist in the development of behavior change communication (BCC) for PCV introduction.

UNDP

In states and districts with eVIN introduced:

- Develop a Vaccine Management plan including estimation, forecasting and establishing minimum/maximum stock for PCV through eVIN.
- Track stock movement of PCV from state to cold chain points through eVIN.
- Support districts in physical validation of cold chain points as part of cold chain assessment.
- Provide regular feedback and recommendations for stock availability and adequacy during DTFI and STFI.

GHS

- Support ITSU in development of communication strategy and its timeline for PCV introduction.
- Support ITSU by providing data/facts and evidence-based messages for development of communication material.
- Participate in and facilitate speakers/experts in state level technical workshops.

Role of partners

- Organize state-level CSO workshops involving technical experts and other key officials.
- Support advocacy efforts
- In coordination with ITSU/UNICEF, participate in and support/facilitate state level media sensitization workshops.

ITSU (MoHFW)

- Develop communication strategy for PCV introduction as well as communication material prototype, including relevant training materials for frontline health workers and mobilizers.
- Organize media sensitization workshops.
- Assist MoHFW in collating and analyzing PCV coverage data.
- AEFI reporting and surveillance for PCV.

State and Local Organizations

- Other organizations such as IMA, IAP and civil society bodies to extend support at national, state and district levels. These organizations can play an important role in information dissemination and advocacy at various levels.
- Their involvement at district and state task force meetings can be encouraged based on decisions by state and district health department needs.

13 Frequently Asked Questions

PCV INTRODUCTION BASICS

1. **Which vaccine is being introduced into the routine immunization system to protect against pneumococcal disease?**

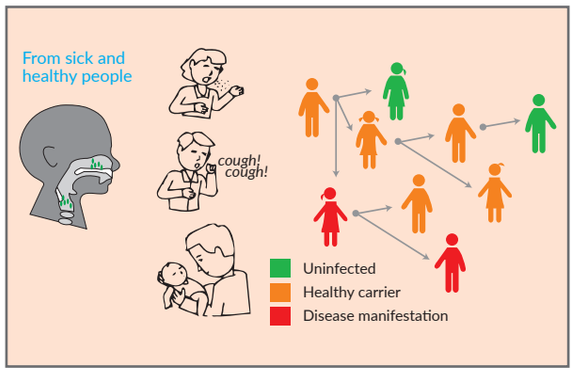
   The pneumococcal conjugate vaccine (PCV) is being introduced in the UIP to protect children against pneumococcal disease.

2. **What is pneumococcal disease?**

   Pneumococcal disease is the name of a group of diseases caused by a bacterium called *Streptococcus pneumoniae* (also known as pneumococcus). Pneumococcus bacteria can spread to different parts of the body to cause a variety of diseases. *Streptococcus pneumoniae* is the leading cause of bacterial pneumonia in children under 5 years of age.

3. **Why do we vaccinate children against pneumococcal disease?**

   Vaccination will prevent disease and deaths due to pneumococcal disease in children. The risk of serious pneumococcal disease is the highest in the first year of life, but remains high throughout the first 24 months of life. Vaccinating infants will protect not only the infant, but also reduce the risk of pneumococcal disease among others in the community by reducing the circulation of the pathogen. Vaccination against pneumococcal disease is also a very cost-effective way of preventing the disease.



4. **What diseases does pneumococcus cause?**

   Diseases that are often caused by pneumococci include:

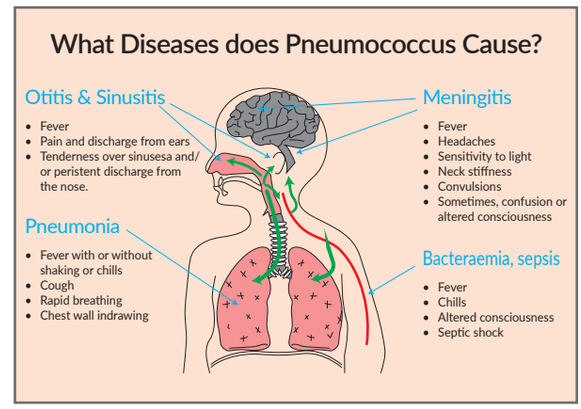
   - Pneumonia
   - Bacteraemia, sepsis: bloodstream infection
   - Bacterial meningitis: infection of the membranes that cover and protect the spinal cord and brain
   - Middle ear infection (otitis media)
   - Sinusitis, Bronchitis

5. **How is pneumococcal disease spread?**

   Pneumococcal disease spreads from person to person through respiratory droplets (e.g., due to coughing or sneezing).

6. **How common is pneumococcal disease?**

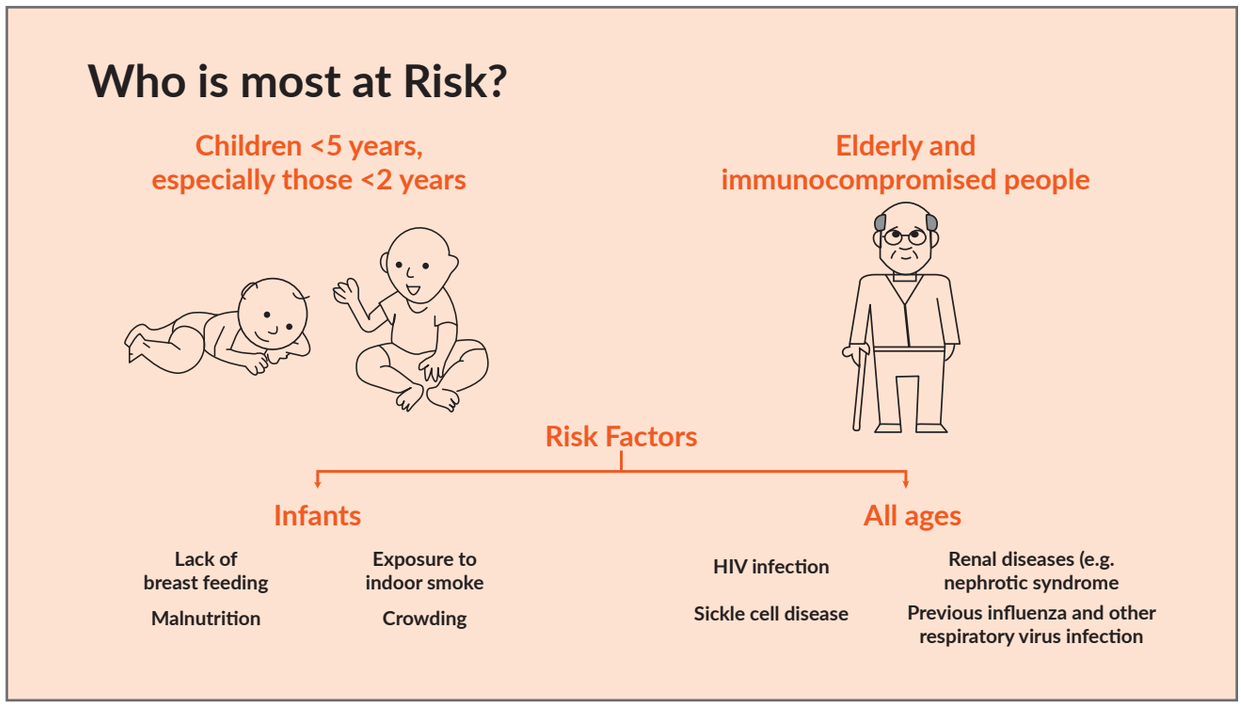
   Pneumococcal disease constitutes a major public health problem. It is the leading cause of



   pneumococcal pneumonia. In India, pneumococcal pneumonia was estimated to have caused 105,000 deaths in 2010.

7. **Who is at increased risk of pneumococcal disease?**

   Most healthy individuals can fight the infection with their natural defenses. Young children and elderly individuals are most at risk.



The children most at risk of pneumococcal disease are:

- Children under 5 years of age and especially those under two years of age are the most at risk of developing and dying from the disease.
- Children who are immunocompromised (symptomatic HIV infection, Sickle cell disease, renal diseases [e.g. nephrotic syndrome)], or have history of previous influenza or other respiratory virus infection.
- Infants and children who are exposed to additional risk factors: Malnutrition, lack of breastfeeding, exposure to indoor smoke and crowded living conditions.
- Poor and marginalized populations with poor access to health care.

8. What is pneumococcal conjugate vaccine (PCV)?

PCV is made up of sugars (polysaccharides) from the capsule of the bacterium *Streptococcus pneumoniae* that are attached (or conjugated) to a carrier protein. PCV protects young children starting at 6 weeks of age when infants are most at risk of disease. The vaccine protects against severe forms of pneumococcal disease, such as pneumonia, meningitis and bacteraemia. It will not protect against these conditions if they are caused by agents other than pneumococcus or by pneumococcal serotypes not present in the vaccine.

9. Can pneumococcal disease be treated?

Yes, frontline health workers should be well-trained to identify cases and refer to health facilities for evaluation and treatment. Patients with pneumonia will require antibiotics and supportive care, as per treatment protocols. The antibiotic of choice is amoxicillin. Early diagnosis and appropriate treatment leads to better outcomes. Accurate diagnosis and access to care is not always optimal. Failure to get treatment early in the course of disease may lead to serious disease, long-term complications or death.

Characteristic	PCV10	PCV13
Composition	Serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F Each polysaccharide conjugated to one of three proteins: non-typeable Haemophilus influenzae protein D, diphtheria or tetanus toxoid	All serotypes contained in PCV10 plus serotype 3, 6A, and 19A. Polysaccharides are conjugated to a diphtheria carrier protein.
Presentation & dosage form	• Single-dose vial, preservative free • 2-dose vial, preservative-free • 4-dose vial with preservative, approval awaited	• Single-dose vial, preservative-free • 4-dose vial with preservative • PCV13 4-dose vial occupies the same storage volume as a single dose vial.

Indiscriminate use of antibiotics to treat pneumonia has led to development of pneumococcal bacteria resistant to commonly used antibiotics such as penicillins, macrolides, cephalosporins and co-trimoxazole.
This has become a serious problem in some parts of the world. However, large-scale pneumococcal immunization in many countries has resulted in a reduction in the circulation of drug-resistant strains in countries where it has been introduced.

Vaccination with PCV is not intended to be used for treatment of active infection.

PCV IMPLEMENTATION

10. What types of PCV are available?

PCV is available as PCV10 and PCV13. PCV13 is the vaccine that will be introduced in the UIP.

11. What is the difference between PCV10 and PCV13?

PCV10 contains 10 pneumococcal serotypes and PCV13 contains 13 pneumococcal serotypes. These are the serotypes that cause the majority of severe pneumococcal diseases in India.

PCV13 provides protection against three additional serotypes (3, 6A, and 19A) that are not included in PCV10. In case of shortage of supply of PCV13, the National Pneumococcal Vaccine Expert Committee has recommended that other vaccine types may also be considered.

12. Is PCV a new vaccine?

- No, PCV is not a new vaccine. 141 countries are using PCV vaccine in the national immunization program.
- The first PCV was a 7-valent vaccine (PCV7) first introduced in the United States in 2000, followed by many other countries.
- PCV7 was phased out with the licensure of PCV13. PCV10 became licensed around the same time.
- In India, in the private sector, PCV7 was introduced in 2006, and continues to use PCV vaccine in various combinations.

13. Why is PCV being introduced in India?

PCV has been deemed essential to reduce disease burden and mortality in children under five due to pneumococcal disease.
Pneumococcal disease is the number one vaccine-preventable cause of death in children under five, globally and in India. The NTAGI has recommended introduction of PCV in UIP in

India based on disease burden data, safety and efficacy, cost-effectiveness, sustainability and global evidence.

14. What is the presentation of PCV and how is it stored?

Both PCV10 and PCV13 are liquid vaccines. PCV13 is available in 1-dose and 4-dose vials. In India, the 4-dose vial has been selected for use in the UIP. It is a freeze-sensitive vaccine and should not be frozen. It should be stored at temperatures ranging between +2°C and +8°C in the basket of an ice-lined refrigerator.

15. How many doses does each PCV vial have?

Each PCV13 vial used in the UIP will contain four doses of PCV. This means that one vial will have enough vaccine to vaccinate four children.

16. Will Open Vial Policy be applicable to PCV?

Yes, PCV13 (4-dose vial) can be used for a maximum of 28 days on the condition that cold chain principles have been respected, VVM has not reached the discard point, expiry date has not surpassed and has met all other criteria of open vial policy.

17. What is the eligibility criterion for administering PCV vaccine?

- A child coming for vaccination at 6 weeks of age or for the first dose of OPV1 & Penta-1 is eligible for PCV-1 along with other scheduled vaccines.
- A child who has received PCV-1 is eligible for PCV-2 at 14 weeks.
- A child who has received PCV-2 is eligible for PCV booster dose at 9 months.
- All children can receive PCV including those born prematurely, those with immunodeficiency and/or malnutrition.

OPEN VIAL POLICY

Vaccines opened in a fixed or outreach session can be used at more than one immunization session for up to 4 weeks, provided:

- Expiry date has not passed.
- VVM has not reached discard point.
- Vaccines stored at appropriate cold chain conditions: both during transport & storage in cold chain storage point.
- Vaccine septum has not been submerged in water or contaminated in any way.
- Aseptic technique used to withdraw all doses.
- If any adverse event happens – Do not use the opened vial, retain the vial for investigation.

- Only children with an allergy to the vaccine components or a previous allergic reaction to PCV should not receive vaccination.
- In delayed cases beyond 1 year of age, due doses can be given to a child only if a child has received at least one dose of PCV before his/her first birthday.

18. Is PCV expensive? What is the cost of each dose?

- PCV is an expensive vaccine. At present, cost is INR 800 per vial of 4 doses.
- Open vial policy prevents any such wastage.
- Cost of PCV in private sector: approx. INR 3,000-4,000 per dose (and child requires at least 3 doses)
- Under UIP, PCV will be provided free-of-cost.

19. Why is PCV not given before 6 weeks of age?

PCV13 is licensed for use starting at 6 weeks of age, not before. Newborn infants have

immature immune systems and have received maternal antibodies at birth which may interfere and prevent them from mounting a long-term protective vaccine response. Adding PCV to the existing UIP six-week vaccination is beneficial because it allows the child to receive multiple preventive vaccines in one healthcare visit. Many newborns have maternal antibodies which provides some protection from disease in the first weeks of life.

20. What is the vaccination schedule for PCV?

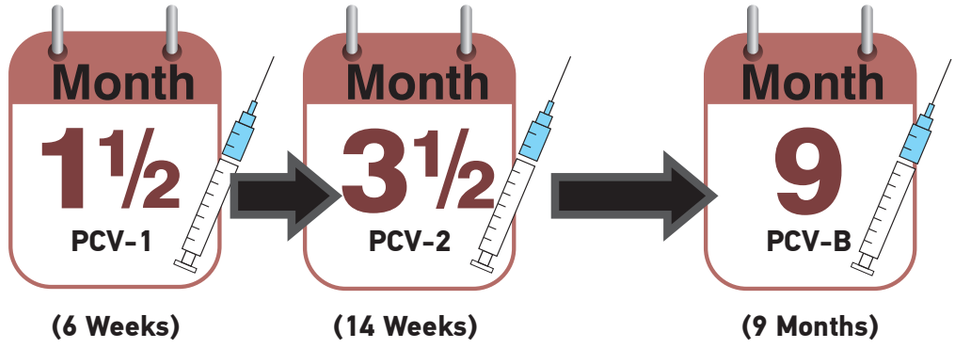
PCV will be given in three doses (2 primary doses and 1 booster) at 6 weeks, 14 weeks and 9 months of age.

21. What should be done if a PCV dose is delayed?

- The two primary doses and one booster dose of PCV should be given during the first year of life.
- If the doses are delayed within the first year of life,
  - Doses (both primary and booster) must be separated by a minimum interval of at least 2 months, to be given at the next scheduled immunization visit.
- In delayed cases beyond 1 year of age,
  - due doses can be given to a child only if a child has received at least one dose of PCV before his/her first birthday.
  - For those with at least one previous PCV dose, the series should be completed at the earliest available opportunity.

Age	PCV schedule	Other scheduled vaccines to be given along with PCV
6 weeks	PCV-1*	OPV-1, Pentavalent-1, Rota-1*, fIPV-1
14 weeks	PCV-2*	OPV-3, Pentavalent-3, Rota-3*, fIPV-2
9 months	PCV booster dose*	Measles-1/MR-1, JE-1*

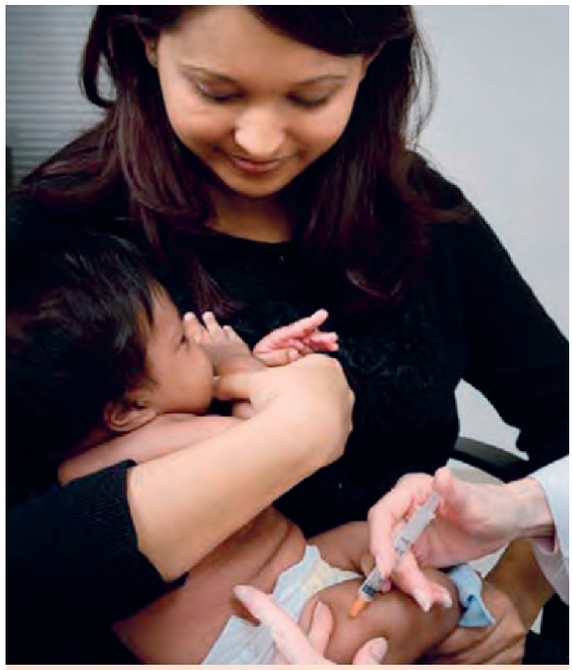
**JE/Rota/PCV in selected states/districts*
All states to switchover to fIPV soon.



Frequently Asked Questions

22. What are the route, dose and site of injection for PCV?

0.5 ml PCV is to be given as an intramuscular injection into the anterolateral aspect of the right thigh in infants. If more than two injections are to be given in the same thigh then the distance between the two injections should be at least 2.5 cm (1 inch).



The steps below detail how to hold a child (infant) for intramuscular injection in anterolateral aspect of right mid thigh.

- **Hold the child on their lap.**
- **Place the child's arms under one of their own arms and around their back and apply gentle pressure for a secure, hug-like hold.**
- **Use their free arm and hand to hold the child's other arm gently but securely.**
- **Anchor the child's feet firmly between their thighs.**

23. How effective is PCV?

PCV is highly effective in preventing vaccine serotype pneumococcal disease. Evidence from clinical trials show summary efficacy ranging from 27% for all-cause chest X-ray-confirmed pneumonia, to 80% against vaccine serotype invasive pneumococcal disease. PCV covers most of the common serotypes in circulation. After receiving all three doses of pneumococcal vaccine, a child is protected against infections due to strains of pneumococcus in the vaccine but may still get meningitis, pneumonia, or bacteraemia since these can also be caused by other organisms. Timely vaccination during the first year of life is important to provide protection to children when they are most at risk of disease.

24. Is PCV safe?

Yes, PCVs are considered safe in all target groups for vaccination, including immunocompromised individuals.

The Indian National Regulatory Authority has reviewed available safety data and has approved its use in Indian children. PCV10 and 13 have also been introduced into the routine systems of more than 100 other countries since 2010 without any safety concerns. Multiple studies have shown that PCV can be given safely and effectively along with other routine vaccines.

25. Does PCV have any side effects?

PCV is safe and well-accepted; severe adverse reactions attributable to the vaccine are extremely rare. Mild side effects such as pain at the injection site, and fever has been reported in less than 5% of vaccinees. A single dose of paracetamol may be given if the child develops fever.

Frequently Asked Questions

26. Can PCV be given to a premature infant (born before 37 weeks gestation)?

Yes, a premature child can and should be vaccinated at or after 6 weeks of age.

REMEMBER

- PCV is a freeze sensitive vaccine.
- All vaccines come with VVM – Check VVM before use.
- As part of open vial policy, all partially used vials should be sent back to the vaccine storage point the same day.
- PCV is an expensive vaccine. In the private sector, the current cost of PCV is about INR 10,000-12,000 per child for three doses (approx. INR 3,000-4,000 per dose).
- It will be provided free-of-cost to children under the UIP.

27. Can PCV vaccine be given to a sick child?

Yes, the vaccine can be safely administered to a child with minor respiratory illness with or without low-grade fever.

If the child is severely ill then a doctor should be consulted, and the caregiver should bring the child back when he/she is well.

28. Can PCV be given to an immunodeficient child?

Yes, PCV can be safely administered to a child with immunodeficiency (e.g., HIV/AIDS, congenital or acquired immunodeficiency, sickle cell disease) using the same schedule as for any other child. These children are in particular need of PCV because their risk of pneumococcal disease is high.

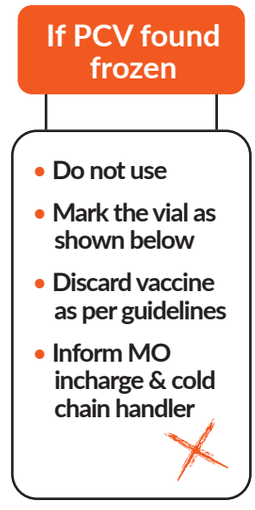
29. Are there any contraindications for use of PCV?

The pneumococcal vaccine should not be given to the following persons:

- those who have had severe allergic reactions to a prior dose.
- those who are known to have had a severe reaction to another vaccine containing diphtheria toxoid.
- those who have a severe illness; vaccination should be delayed until the condition improves.

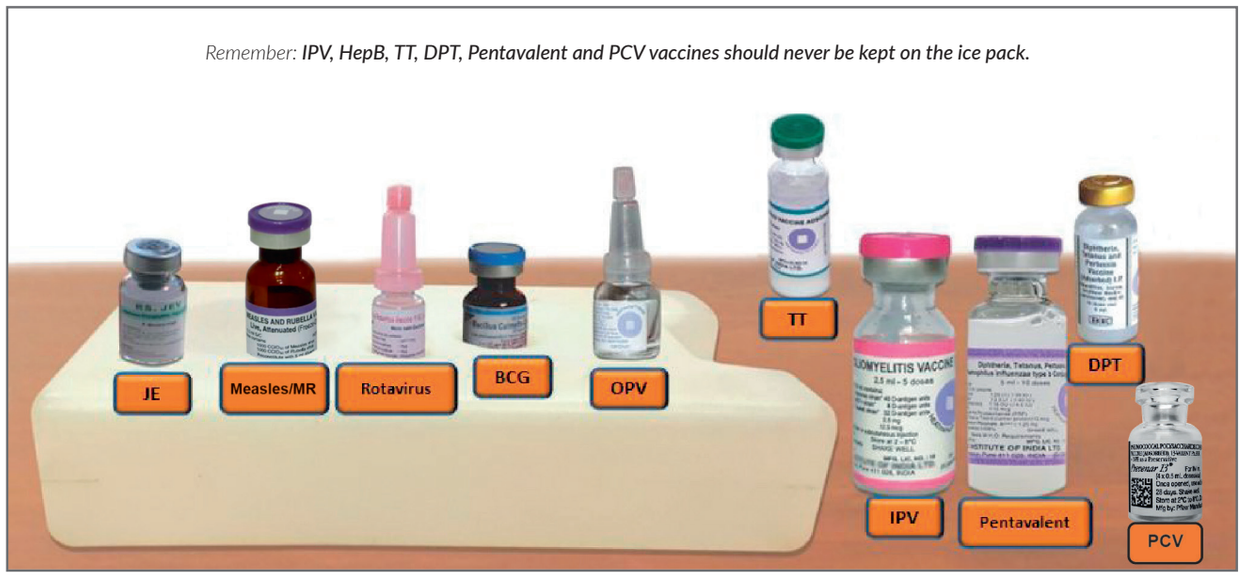
30. What should you do if you find a frozen PCV vial?

- PCV is a freeze-sensitive vaccine. If you find a frozen PCV vial, do not use the vaccine.
- Suspected frozen vials of DPT, Pentavalent, TT, HepB, PCV vaccines can be tested for freezing through Shake Test procedure.



31. Which vaccines should be kept on an ice pack at the immunization site?

As per routine immunization guidelines, health workers are expected to take out one ice pack



at the session site and use the same after opening the heat-sensitive vaccine.

On Ice Pack: BCG and Measles (place them in the wells on ice pack). OPV and JE vaccines should be placed on the surface of ice pack.

32. **What messages should be given to the parents or care-givers?**

The four key messages should be given to parents/care-givers:

Four key messages for caregivers

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

33. **Which government health facilities in our country will provide PCV?**

- PCV will be provided free-of-cost through routine immunization sessions in all government hospitals, dispensaries, PHCs, CHCs, sub-centers and outreach session sites.
- PCV will not be given in a house-to-house campaign mode.

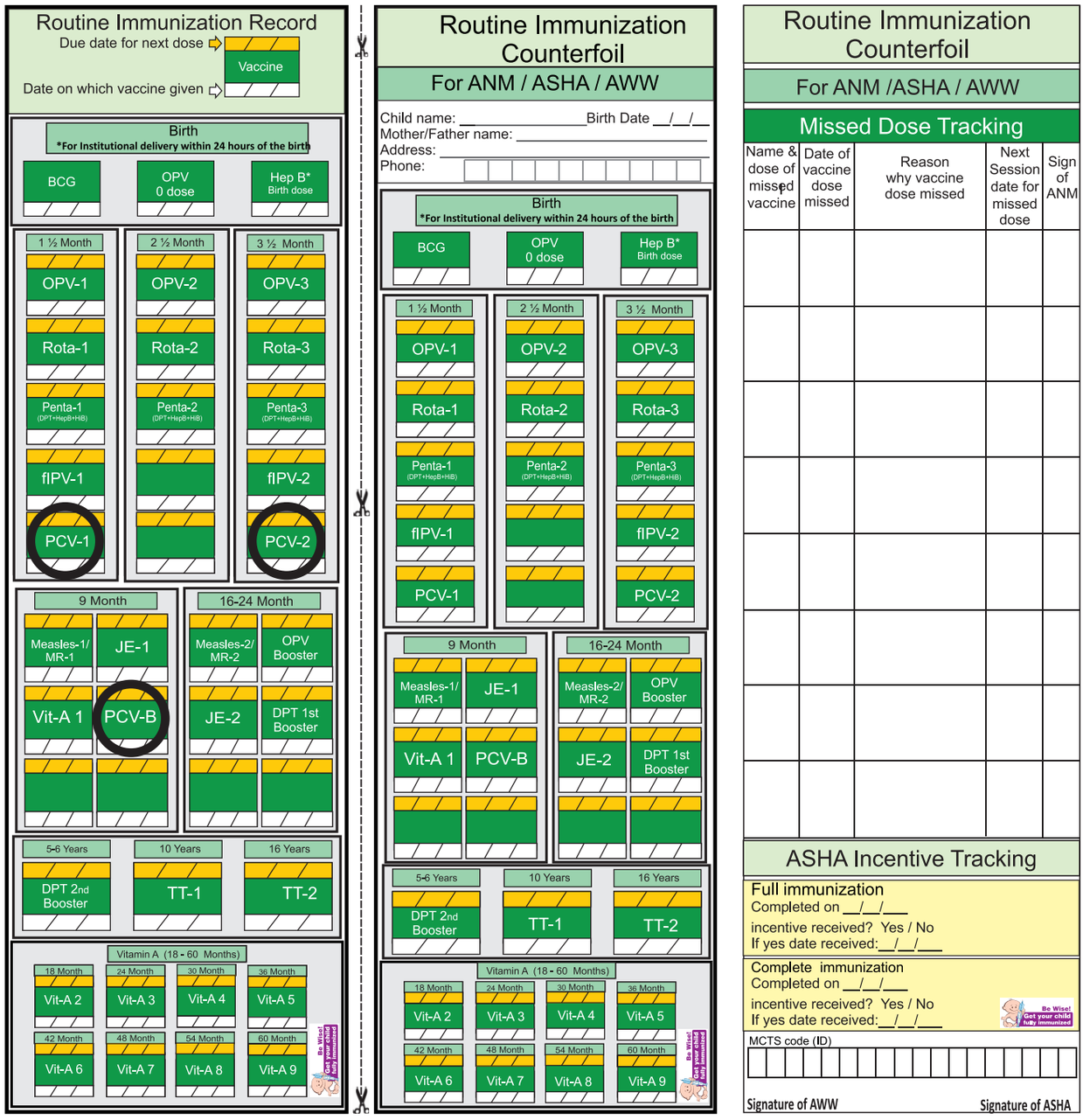
34. **Where will the PCV dose be recorded in the MCP card?**

The immunization component of MCP card has been revised to include PCV schedule (2 primary doses and 1 booster dose) at 6 weeks, 14 weeks and 9 months. The revised immunization component of MCP card is given on the next page.

35. **Will PCV be a part of ASHA's full immunization incentive?**

Yes, PCV will be a part of the national immunization schedule. The ASHA will be eligible for the full immunization incentive only if the child has received all vaccinations (within 1 year) as per the schedule.

Frequently Asked Questions



Frequently Asked Questions

SOME FAQs ON MULTIPLE INJECTIONS:

36. **Why do children need multiple injections on one visit?**

    Giving a child several vaccinations during the same visit allows the child to be immunized as soon as possible. This provides protection during the vulnerable early months of your child's life. In addition, giving multiple vaccinations at one time means fewer vaccination visits.

> **REMEMBER**
>
> ASHA is eligible for the full immunization incentive only if child has received all vaccines due in the first year as per the national immunization schedule and this now includes PCV.

37. **Is it safe to give multiple injections at one visit?**

    Numerous studies have shown that giving multiple vaccinations during the same visit does not result in higher incidence of adverse events.

38. **Why can PCV not be given at a separate visit from the other scheduled vaccines to avoid giving multiple injections at one visit?**

    It is safer for the child to receive all vaccinations at one visit. Spreading out vaccinations leaves babies unprotected for a longer time. Patient and health worker compliance is also better when vaccines are scheduled together.

Annexures

Annexure 1: Key lessons learned from new vaccine introduction in India (Measles vaccine, Hib-containing pentavalent vaccine, Inactivated Poliovirus Vaccine (IPV), Rotavirus vaccine, etc.)[20]

Planning & Introduction

- State and district workshops should be organized to sensitize stakeholders on the technical and operational aspects of vaccine introduction at least 2–3 months prior to the vaccine launch.
- Each state should use standard assessment checklists to review district-level preparedness before allowing introduction of new vaccines.

Program stewardship

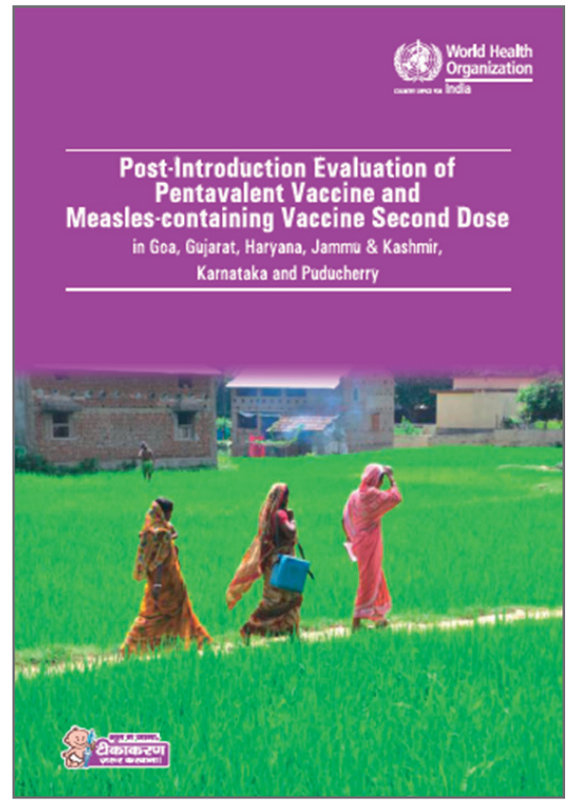
- Each state should have a functioning STFI and DTFI to regularly review and guide the new vaccine introduction and immunization program.

Sensitization of all key stakeholders and partners

- Sensitizing leading pediatricians, including IAP, IMA and IRC local chapters is an absolute requirement before launching PCV vaccination drive at both the state and district level.

Human resources

- The immunization management structure should particularly be strengthened at state and district levels.
- Additional special sites need to be planned for targeting the high risk groups scattered within urban areas identified in advance through field validation.
- Vaccinators, identified from medical colleges, nursing colleges, ANM training schools, pharmacy colleges and private nurses, need to be trained in advance on new vaccine before the introduction. The plan should be made to include them in the respective urban area micro plans.



Microplanning

- Micro-planning should be initiated 1-2 months prior to new vaccine introduction using bottom-up approach to ensure inclusion of all components. Availability of micro-plans for outreach sessions (who will get vaccinated, where, who vaccinates, when vaccination will be done, team information, number of beneficiaries, nearest health facility etc.,) is the most crucial component of the program.
- Existing routine immunization micro plans in all districts should be revised to include high-risk areas, including urban slums and missed areas, so that vulnerable populations are not missed.

20 For details, refer to report titled "Post Introduction Evaluation of Pentavalent vaccine & Measles-containing vaccine second dose" - 2014

Annexures

Due-listing by health-link workers in advance for true enumeration is an absolute requirement

- Due-listing through house visits by link workers will help in enumerating the true target population for high vaccination coverage.
- Preparation of due lists based on head count survey should capture information on beneficiaries under 2 years of age. This head count survey will provide the authorities with almost close to actual number of target beneficiaries.
- Refer to annexures for standardized formats to conduct head count survey.

REMEMBER

It will be important to ensure that these recommendations are acted upon during PCV introduction process in states.

Training and knowledge of healthcare 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 trainings at all levels should be tracked. These trainings should begin at least 2-3 months before new vaccine introduction.
- Districts should be allowed to introduce new vaccine only after block-level trainings have been completed.

Health financing

- Funds for the introduction of vaccine should be ensured beforehand.
- The incentives of ASHAs and health workers should be released timely. This is important to ensure their motivation and commitment.

Vaccine, cold chain and logistics management

- Cold chain & vaccine management should be reviewed and strengthened before any new vaccine introduction to ensure space availability for both vaccine and related logistics at state, district and block levels.
- Cold chain inventory should be regularly reviewed and status of the same should be updated in the NCCMIS.
- A quarterly review of district cold chain handlers should be organized at the state level and on a monthly basis at the district level.
- Recording of temperatures in ILRs and deep freezers (DFs) should be done regularly even on weekends.

Supervision and monitoring

- Supportive supervision and appropriate oversight should be maintained and a regular feedback mechanism should be in place.
- Identify supportive supervisors and independent external monitors at all levels and make a plan for supervision – monitoring with emphasis on the high risk areas/populations as part of the micro plan.
- Rapid monitoring should be initiated at block & session level for at least 3 months of new vaccine introduction to assess implementation status, identify gaps/bottlenecks and provide feedback for immediate corrections. Separate formats for rapid monitoring have to be filled in addition to the routine immunization monitoring.
- Monitoring data from the field is fed back to the block, district and state task forces to guide programmatic decision-making and actions.
- Conducting a PIE within 6–12 months of new vaccine introduction helps in identifying gaps

Annexures

Coverage, reporting and data collection

- Channel for e-reporting (HMIS) should be strengthened. The data collected from paper reports and drop-out and vaccine stock should be readily retrievable at all levels and should be checked for accuracy. Data should be analyzed to improve program performance and fill in gaps.
- Reporting and recording tools such as MCP cards, registers, tally sheets, etc. should be timely updated to include columns for recording of new vaccines.

Surveillance for adverse events following immunization (AEFI)

- Training and sensitization for reporting and investigation of all serious/severe AEFIs for all frontline health workers, MOs (and not just MO in charges) all PHCs/CHCs/SDHs/District Hospitals and private practitioners.
- All AEFI cases should be investigated promptly, as this helps to establish causality and builds trust among the community.
- Standardized AEFI management kits should be procured by the district health team in advance for distribution to all AEFI treatment centers before any new vaccine introduction drive as per micro-plan. For more details, refer to AEFI chapter.

Open vial policy

- The Open Vial Policy is applicable to PCV vaccine. Refer to the most recent MoHFW letter regarding open vial policy.
- Vaccine wastage records should be analyzed to identify poor-performing areas and corrective action taken.

Injection safety and waste management

- States should consider adopting the outsourced models of waste management for more efficient waste management and ensure regular review at all facilities.
- Hub cutters and black and red bags should be made available at immunization sites as part of waste disposal mechanism (refer guidelines).

Advocacy, social mobilization and communications

- A media sensitization workshop should be conducted before the vaccine launch to increase public awareness and deal with vaccine-related queries.
- IEC materials prepared in local language should be made available to the community at least 2–4 weeks prior to vaccine launch.
- Health workers should also deliver the key messages to all caregivers and explain the need for the newly introduced vaccine.
- IPC is the best tool to connect with community mobilization and vaccine acceptance.

Annexure 2: Training Plan for PCV Introduction

Training	Trainers	Participants	Training support
State Workshop (ToT) for PCV Introduction Duration: Two days	MoHFW officials, WHO NPSP and other national-level partners	**State-level:** State Immunization Officer, State Cold Chain Officer, State IEC Officer (Mass Media Officer/State BCC Coordinator NHM), State Data Manager, State M&E (NHM), State Finance Officer (NHM), State ICDS Coordinator, State ASHA Coordinator, WHO NPSP and partners **District-level (maximum 4-5 participants):** (maximum 4-5 participants): DIO, District Program Manager (NHM), District Cold Chain Handler, WHO NPSP and partners	State Health Department and WHO with support of partners. Funding Support WHO NPSP.
State Media Workshop for PCV Introduction	Chair: Principal Secretary (H & FW) Co-chair: MD NHM/ Director Health Services Key facilitators: State Immunization Officer Supporting partners: UNICEF, WHO-NPSP, ITSU, GHS	Print and electronic media persons/ journalists, radio jockeys, etc. Other participants as desired by SEPIO.	SEPIO and Nodal officer at state level for mass media. Funding support : UNICEF Supporting agencies UNICEF and ITSU, and other partner agencies GHS, WHO NPSP, UNDP. JSI
District Workshop (ToT) for PCV Introduction Duration: One day	District Immunization Officer, Surveillance Medical Officer (WHO NPSP), District Program Manager (NHM), District Cold Chain Handler and partners trained at state ToT	**District-level:** D: District Program Manager (NHM), District Cold Chain Handler, District Mobilization Coordinator (SMNet), Vaccine cold chain manager (UNDP) and partners **Block-level** (Maximum 4-5 participants from blocks and urban planning units): Block MOICs, Block Program Manager (NHM), CDPO-ICDS, Block IO/ICC/ARO, Block Cold chain Handler, Block Mobilization Coordinator (SMNet)	District Health Department with funding support from WHO NPSP Technical support: WHO, UNDP, UNICEF, CSOs and other partners
District level sensitization of professional bodies/leading private practi-tioners Duration: Two hours	Chief Medical Officer, District Immunization Officer, Surveillance Medical Officer (WHO NPSP), UNICEF, UNDP representatives	District-level: IAP members, IMA, leading private practitioners in district, Medical college (Pediatrics & PSM wing), Chief Medical Superintendent of large hospitals	District Health Department with funding support from WHO NPSP Technical support: WHO NPSP
Block Workshop for PCV Introduc-tion (for health workers and mobilizers) Duration: One day	Health workers trainings: Block MOICs, Block Program Manager (NHM), CDPO-ICDS, Block IO/ICC and Block Cold chain Handler, Block Mobilization Coordinator (SMNet) trained at district training workshop	ANMs, Heath & ICDS supervisors, ASHA coordinator, LHVs, Health supervisors Additional PHCs medical officers (if any)	District Health Department (NHM budget)
	Mobilizers' training	ANMs, ASHA + AWW	
Monitors' briefing at district level	District Immunization Officer, Surveillance Medical Officer (WHO NPSP) and other state/district-level partners	Field monitors (FMs), external monitors (EMs), Immunization field volunteers (IFVs), District Mobilization Coordinator (SMNet), Vaccine cold chain manager (UNDP) Monitors identified from lead partner agency supporting high priority districts (if any)	District health department and WHO NPSP along with other partners UNICEF, UNDP and others. Funding support WHO NPSP

Annexures

Annexure 3: Agenda PCV training workshop for medical officers at state/district level

Day-1 **Duration: 1.5 days**

Time	Session	Facilitator
GENERAL INSTRUCTIONS FOR TRAINERS	• Each batch should not have more than 40 participants. • Keep two coffee breaks and one lunch break on Day 1 & keep one coffee break and lunch break on Day 2. • Adjust the timings of sessions keeping in mind 1-hour lunch break and 20 minutes coffee/tea breaks • Make the participants feel special and important since they are master trainers for introduction of a new vaccine in the state. They must understand that they are playing a key role in strengthening the health system, particularly the immunization program in the state. • Only the officials that have been trained on PCV introduction will impart trainings. • All sessions must be interactive. Methodology should include presentations, role-plays, exercises and interactive discussions.	
15 minutes	OBJECTIVES OF THE WORKSHOP AND OPENING REMARKS Tips for trainers • Explain why PCV being introduced in our state/ district under UIP due to high disease burden. • PCV is the costliest vaccine in use under UIP. • Objective of this training is to train master trainers for district/ block level trainings and that master trainers will be imparting these trainings in their district/ block as per guidelines. • Quality training is the key to success for new vaccine introduction. PCV will be introduced once trainings are completed. • WHO-NPSP will be supporting state and district level trainings. Sub-district (block) trainings will be supported through NHM funds. DIO and Block MOICs are responsible for preparing the detailed training plan. Master trainers will impart the trainings. • WHO-NPSP with support of other partners will monitor the trainings and share the feedback.	MD (NHM), Director (FW), SIO/CMO/DIO
30 minutes	GLOBAL AND NATIONAL UPDATE ON PNEUMOCOCCAL DISEASE Tips for trainers • Overview of pneumococcal diseases • Epidemiology: *Streptococcus pneumoniae* (pneumococcus) - The organism • Pneumococcal pneumonia • Childhood pneumonia burden • Global childhood pneumonia burden • Disease burden in India	MD (NHM), Director (FW), SIO/CMO/DIO

Annexures

Time	Session	Facilitator
45 minutes	INTRODUCTION TO PCV VACCINE Tips for trainers • PCV is safe and effective; introduction plan • Use of PCV vaccine in other countries since 2000 and in our country through private sector since more than 10 years. • PCV is a freeze sensitive vaccine. PCV is available as a liquid formulation in 4-dose vial. • Open vial policy applicable to PCV. • Let participants know that PCV vaccine is expensive. The cost of vaccination of a child with three doses is approximately INR 10,000-12,000 in the private market.	SEPIO/DIO/ Partners
30 minutes	VACCINE AND COLD CHAIN MANAGEMENT OF FREEZE AND HEAT SENSITIVE PCV Tips for trainers • PCV storage and vaccine handling - PCV is heat and freeze sensitive vaccine and comes with VVM. Storage of PCV vaccine in ILRs should be between +2°C and 8°C. Explain the level in ILRs where PCV will be stored. • Explain that the shake test is applicable to PCV (show shake test film). • Vaccine buffer stock and wastage rate - Emphasize on minimizing vaccine wastage. Each cold chain point should review vaccine wastage on amonthly basis and districts should review wastage during review meeting. • Role of NCCMIS and eVIN. These will help them know the inventory status of cold chain equipment. • Revised open vial policy guidelines – Open vial policy is applicable to PCV • Introduce them to revised recording and reporting formats.	Partners/SEPIO /DIO
20 minutes	REVISED NATIONAL IMMUNIZATION SCHEDULE Tips for trainers • Discuss the existing vaccination schedule. Emphasize on administering PCV vaccine at 6 weeks, 14 weeks and 9 months. 0.5 ml intramuscular at right anterolateral thigh. • It is safe to give multiple injections on the same day. Remember – PCV introduction should not lead to drop of coverage of any other vaccine (IPV, Penta, measles). • Focus on the first dose cohort that will receive this vaccine, i.e., children coming for OPV1 and Penta 1.	SEPIO/DIO/ Partners

Annexures

Time	Session	Facilitator
20 minutes	INTRODUCTION TO THE REVISED MCP CARD AND COUNTERFOIL Tips for trainers • Talk about the revised immunization component in the MCP card. Focus on what gets recorded where. • Update participants on PCV specific modifications in reporting and recording tools – MCP cards, tally sheets, MCH and vaccine logistics registers. • Introduce them to the revised MCP cards with emphasis on counterfoil use. Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/duelist registers, tools, etc.).	Partners/SEPIO /DIO
20 minutes	UNDERSTANDING FULL IMMUNIZATION AND COMPLETE IMMUNIZATION Tips for trainers • Provide clarity on the terms "full immunization" and "complete immunization". • Disseminate the information regarding ASHA incentives (enlisting of beneficiaries, updating due list, mobilization of beneficiaries, full immunization, complete immunization). • Sensitize participants about entitlements of ASHA specific to immunization (INR 100 for estimation of beneficiaries once in 6 months, INR 100 for updating due list per month, INR 150 per session for mobilization to session site, INR 100 for each fully immunized child, and INR 50 for each completely immunized child). • Remember to mention that now PCV is included as part of full immunization incentive.	SEPIO/DIO/ Partners
30 minutes	PCV COVERAGE AND TRACKING Tips for trainers • Understanding importance of session-wise coverage reports. This will help program managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc. • Manual reporting of PCV coverage along with other new vaccines such as IPV and rotavirus vaccine until the HMIS portal gets updated. • Importance of due list preparation for tracking beneficiaries (drop outs and left outs). • Understanding the coverage trends of PCV-1 & 2 along with first and third doses of OPV and PCV with Measles vaccine. • Focus on the fact that PCV coverage should from now on be the same as other vaccines being given at 6 weeks, 14 weeks and 9 months. • Multiple injections are safe. Remember the sites identified for each vaccination as per guidelines.	Partners/SEPIO/ DIO

Annexures

Time	Session	Facilitator
15 minutes	ROLE OF PARTNERS IN PCV INTRODUCTION	SIO/DIO/ Partners
20 minutes	DEALING WITH HEALTH WORKERS: PCV RELATED FAQs Tips for trainers • FAQs are the most important component of trainings. Trainers should ensure that ANMs are fully aware of PCV and are comfortable administering PCV as per the immunization schedule at 6 weeks, 14 weeks and 9 months. • Make the ANMs thorough on the vaccines that will be given concomitantly with PCV at 6 weeks, 14 weeks and 9 months. • Adopt role play methodology to ensure interactive discussions for this session. • Reiterate as to when to give and when not to give PCV vaccination. Discuss how ANM has to deal with children coming for vaccination later or earlier than recommended age.	Partners/SIO/DIO
30 minutes	WAY FORWARD: SENSITIZING HEALTH WORKERS, TIMELINES FOR PCV TRAININGS Tips for trainers • Explain to them what they have to do when they go back to their districts/planning units. • These officials must know that as master trainers they will have to further conduct training at block/planning unit level. • The master trainers will have to take the help of other officials that have been trained at the state/district level such as NHM finance officials, data handlers (HMIS and MCTS coordinators, district computer assistants, DIOs, district M&E focal person/coordinators (NHM), focal person responsible for immunization reports in CMO office), cold chain handlers (district vaccine store keeper, district cold chain handlers) and district IEC focal persons. • Master trainers must ensure that a timeline for training is prepared and followed for training the health workforce involved in the immunization programme. • Ensure there is a plan to monitor planning, trainings, introduction and implementation of PCV vaccine. • Share monitoring feedback with government, WHO and other partners.	Partners/SIO/DIO

Annexures

Day-2

Time	Session	Facilitator
20 minutes	RECAP WITH A FOCUS ON FAQs AND SCENARIOs	
60 minutes	COMMUNICATION AND MEDIA MANAGEMENT Tips for trainers • Emphasize as to how ANM will convince the parents for administering PCV with other vaccines as per the national immunization schedule at 6 weeks, 14 weeks and 9 months. • Share revised communication/IEC material with state/district program managers. • State and district spokesperson will be responsible for media interactions.	Partners/SIO/DIO
30 minutes	VACCINE SAFETY (AEFI) AND IMMUNIZATION WASTE MANAGEMENT Tips for trainers • Explain in brief about managing AEFIs • Referral and reporting mechanisms for AEFIs.	Partners/SIO/DIO
15 minutes	ROLE PLAY ON DEALING WITH MEDIA ON PCV INTRODUCTION Tips for trainers • Anticipated questions from media to the spokesperson.	
15 minutes	INTERACTION ABOUT WAY FORWARD Tips for trainers • Reiterate the “remember” messages. • Master trainers must ensure that a timeline for training is prepared and followed for training the health workforce involved in the immunization program • Clarify role of partners • Ensure no district/block should introduce PCV until all their health workers have been trained.	SIO/DIO
15 minutes	REMARKS BY PARTNERS Tips for trainers • Let participants know that partner agencies have been requested to monitor planning and implementation of PCV introduction activities. • Brief comments form partners	SIO/DIO

Annexures

Annexure 4: Agenda for PCV training workshop for ASHA, AWW and link workers

Duration:1 day

Time	Session	Facilitator
GENERAL INSTRUCTIONS FOR TRAINERS	• Make the participants feel special and important since they are master trainers for introduction of a new vaccine in the state. They must understand that they are playing a key role in strengthening of the health system, particularly the immunization program in the state. • Only the officials that have been trained on PCV introduction will impart trainings. • All sessions must be interactive. Methodology should include presentations, role-plays, exercises and interactive discussions. Each batch should not have more than 40 participants.	
15 minutes	OBJECTIVES OF THE WORKSHOP AND OPENING REMARKS Tips for trainers • Make the mobilizers feel special and important. • They should understand that it is because of them that the country has made progress in polio eradication, maternal and neonatal tetanus elimination, new vaccine introductions and reduction of morbidity and mortality due to other vaccine preventable diseases. • Explain to them that immense progress has been made in routine immunization, but to reach the beneficiaries who have not yet been reached will require special efforts and initiatives. • Make them feel accountable for their area of work. • Inform them about the PCV vaccine introduction in their district and the expectation from them to improve coverage related to all vaccines, with emphasis on PCV vaccine. • Equip them to address frequently asked questions (FAQs) from community. • They should understand the value of timely tracking of beneficiaries using tracking tools such as tracking bags, counterfoils and due lists. • Focus on introduction of PCV and the expectation in regard to due listing and tracking of immunization coverage related to all vaccines, with emphasis on PCV.	Partners/MoIC
15 minutes	INTRODUCTION TO PCV VACCINE Tips for trainers • PCV is safe and effective; it is being introduced across five states in India in a phased manner. • Touch base on the use of PCV vaccine under immunization program in more than 100 countries and since more than 10 years in our country through private sector. • PCV vaccine is expensive. Vaccination of a child with three doses cost approximately INR 10,000-12,000 in the private market. Emphasize on minimizing vaccine wastage.	Partners/MoIC

Annexures

Time	Session	Facilitator
15 minutes	• PCV is both freeze as well as heat sensitive vaccine and comes with VVM. PCV is available as a liquid formulation in 4-dose vial. Open vial policy applicable to PCV. • During the immunization session, PCV vaccine should not be kept on icepack.	Partners/MoIC
20 minutes	REVISED NATIONAL IMMUNIZATION SCHEDULE Tips for trainers • Discuss the existing vaccination schedule. Emphasize on administering PCV vaccine at 6 weeks, 14 weeks and 9 months. • It is safe to give multiple injections on the same day – vaccinators and mobilisers should confidently assure parents about safety of taking multiple vaccination. • Remember – PCV introduction should not lead in drop of coverage of any other vaccine (IPV, Penta, measles).	Partners/MoIC
30 minutes	INTRODUCTION TO THE REVISED MCP CARD AND COUNTERFOIL Tips for trainers • Update participants on PCV specific modifications in MCP cards. • Introduce them to the revised MCP cards with emphasis on counterfoil use. Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, tools, etc.). Discuss where and how to record PCV vaccine in case updation of reporting and recording tools is delayed.	Partners/MoIC
20 minutes	UNDERSTANDING "FULL IMMUNIZATION" AND "COMPLETE IMMUNIZATION" Tips for trainers • Provide clarity on the terms "full immunization" and "complete immunization". • Disseminate the information regarding ASHA incentives (enlisting of beneficiaries, updating due list, mobilization of beneficiaries, full immunization, complete immunization). • Resensitize participants about entitlements of ASHA specific to immunization (INR 100 for estimation of beneficiaries once in 6 months, INR 100 for updating due list per month, INR 150 per session for mobilization to session site, INR 100 for each fully immunized child, and INR 50 for each completely immunized child). • Remember to mention that now PCV is included as part of full immunization incentive.	Partners/MoIC

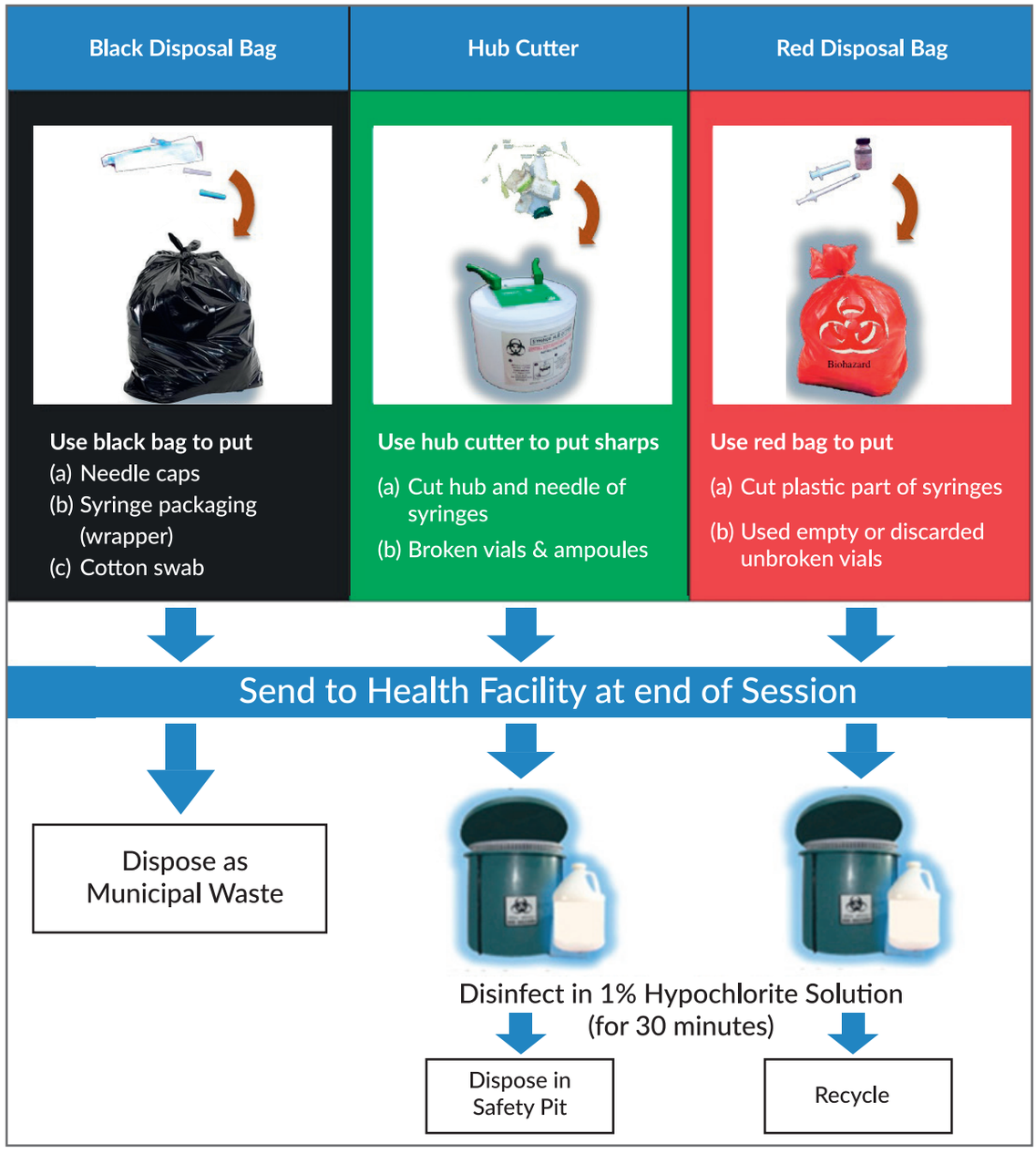
Annexures

Time	Session	Facilitator
60 minutes	DEALING WITH FREQUENTLY ASKED QUESTIONS AND DIFFERENT SCENARIOS Tips for trainers • FAQ • Scenarios -role play • Mobilizers must understand clearly about what to do with children coming for vaccination later or earlier than recommended age. • Ensure that mobilizers are fully aware of PCV and are comfortable mobilizing beneficiaries for PCV vaccination as per the immunization schedule at 6 weeks, 14 weeks and 9 months. • Administration of multiple vaccines is completely safe and convenient.	Partners/MoIC
30 minutes	COMMUNICATION AND SOCIAL MOBILIZATION Tips for trainers • Show the available PCV vaccine-related materials. Discuss how effectively these can be used. • Mobilizers should know important messages need to be percolated in the community regarding PCV. • Critical messages related to PCV should be provided in addition to the four key messages.	Partners/MoIC
15 minutes	WHAT DO HEALTH WORKERS/MOBILIZERS NEED TO DO WHEN THEY GET BACK TO THEIR SUB-CENTERS/AREAS? Tips for trainers • Explain them their roles. • Community participation, mothers' meeting, advocacy during VHND and immunization days, etc.	Partners/MoIC

Annexure 5: Waste management

The existing Central Pollution Control Board (CPCB) guidelines for disposal of biomedical waste generated during Universal Immunization Programme will be applicable to PCV, including segregation of immunization waste at source and its treatment and disposal.

The principles followed are segregation of waste at source (at the session site), transportation to the PHC/CHC, treatment of sharps and potentially bio-hazardous plastic waste, disposal of sharps and treated plastic waste through proper recycling.



Annexure 6: New Vaccines (IPV/Rota/PCV) Reporting Format

Please fill only whichever is applicable in your state

State/District/Block/Planning Unit: **Month / Year:**

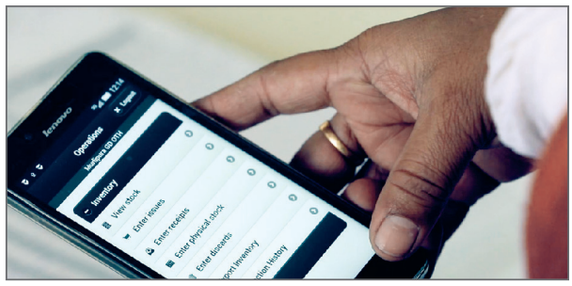
S.No	Name of District/Block/Planning Unit/Subcentre	Inactivated poliovirus vaccine			Rotavirus vaccine			Pneumococcal vaccine			No. of Vials Received				No. of Vials Utilized			
		fIPV-1	fIPV-2	IPV-full dose	RVV-1	RVV-2	RVV-3	PCV-1	PCV-2	PCV-B	IPV-5 dose*	IPV-10 dose*	RVV	PCV	IPV-5 dose*	IPV-10 dose*	RVV	PCV
	Total																	

*as per label on the vial

Note: All blocks/planning units should send reports to the district & all districts should send reports to the state. The state report needs to be submitted to immcontrolroom@gmail.com with a copy to riindia2008@gmail.com by 7th of every month for the preceding month.

Signature of SEPIO/DIO/MOIC: **Date**

Annexure 7: Electronic Vaccine Intelligence Network (eVIN)



The Ministry of Health and Family Welfare is currently rolling out an innovative electronic vaccine intelligence network called eVIN in 12 states of the country. eVIN aims to support the Government of India's Universal Immunization Programme by providing real-time information on vaccine stocks and flows, and storage temperatures across all cold chain points in these states.

eVIN provides an integrated solution to address widespread inequities in vaccine coverage by supporting state governments in overcoming constraints of infrastructure, monitoring and management information systems and human resources, often resulting in overstocking and stock-outs of vaccines in storage centers.

eVIN is currently operational across 11 states, i.e., Assam, Bihar, Chhattisgarh, Gujarat, Jharkhand, Madhya Pradesh, Manipur, Nagaland, Odisha, Rajasthan and Uttar Pradesh.

The integrated solution combines:

- **Technology:** to facilitate evidence-based decision-making by making available online real-time information on vaccine stocks and storage temperature through the eVIN application software and temperature loggers;
- **Governance:** to ensure efficient vaccine logistics management by systemizing record keeping through standardizing stock and distribution registers; identifying gaps and improving clarity on vaccine cold chain network; drawing attention to infrastructure upgrades; developing standard operating procedures; and encouraging good practices;
- **Human Resources:** to empower the state cold chain network by building the capacities of government cold chain handlers and deploying vaccine and cold chain managers in every district for constant support to estimate vaccine requirements, supervise cold chain handlers and coordinate with cold chain technicians across the district.

Cold chain handlers are provided smart phones with the eVIN application which allows for the digitization of vaccine inventories. As a routine task, every cold chain handler enters the net utilization for each vaccine in the standardized registers at the end of every immunization day. This is simultaneously updated in the eVIN application and uploaded on a cloud server which can then be viewed by programme managers at district, state and national level through online dashboards. In addition to providing real-time information on vaccine stocks, the system also helps to track storage temperature of vaccines. SIM-enabled temperature loggers attached to the cold chain equipment capture temperature information through a digital sensor placed in the refrigerator. Temperature data is recorded every 10 minutes and updated at an interval of 60 minutes on the server via General Packet Radio Service (GPRS). In case of temperature breach, the logger alarms and sends email and SMS alerts to responsible cold chain technicians and managers.

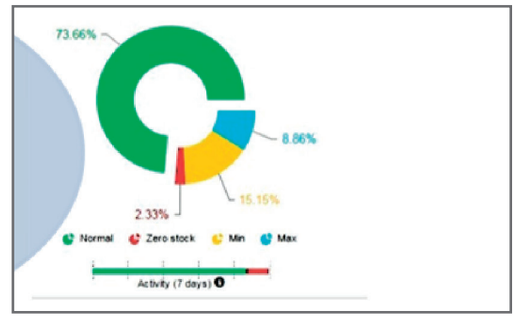
eVIN Process Flow

After the RI session day, cold chain handler enters the net utilization of each vaccine, including open vials, in Immunization Session Register.

After completing RI session site and updating Immunization Session Register, cold chain handler updates the stock of each vaccine in Stock Register.

Cold chain handler then punches data in eVIN mobile application to update the stock for each vaccine.

After data punching with eVIN mobile application, data is updated in the cloud server. District- and state-level officers can view the real-time stock status store-wise as well as antigen-wise and generate relevant reports.

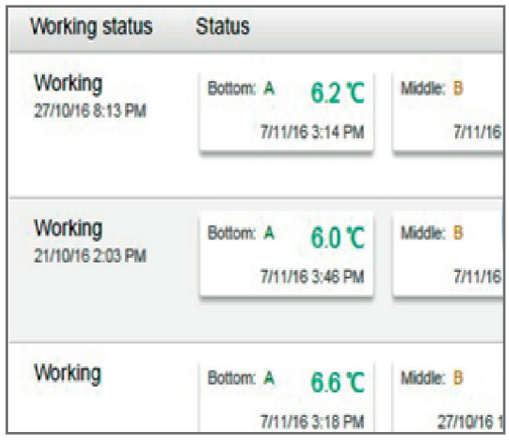


Annexures

Remote Temperature Monitoring

Temperature logger installed with all cold chain equipment meant for vaccine storage.

Cold chain handler and store keeper receive instant SMS and email alert in case of temperature breach.



Temperature can be remotely monitored by district- and state-level officials.

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NATIONAL GUIDELINES FOR IMMUNIZATION

INDIA 2017

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India

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