Ministry of Health
& Family Welfare
Government of India

NATIONAL HEALTH MISSION

NATIONAL OPERATIONAL GUIDELINES



INTRODUCTION OF

PNEUMOCOCCAL CONJUGATE VACCINE (PCV)



Immunization Division
Ministry of Health & Family Welfare
Government of India
January 2021

It's Time!
Get your child fully immunized

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डॉ हर्ष वर्धन
Dr Harsh Vardhan

Union Minister for Health & Family Welfare, Science & Technology and Earth Sciences
Government of India

MESSAGE

I am proud to reiterate that India's Universal Immunization Programme is one of the largest Public Health Programmes in the world with an annual target of 2.67 crore new born and 2.9 crore pregnant women. We are committed to ensure good health for our children and protect them from all vaccine preventable diseases.

Pneumococcal Conjugate Vaccine (PCV) is one of the new vaccines that we have introduced in select States under the UIP in 2017. PCV provides protection against pneumococcal pneumonia, a common and severe form of pneumonia contributing significantly to under-five morbidity and mortality. It is heartening to state that through sustained efforts, country has achieved success in developing indigenous PCV vaccine. The availability of this Make in India PCV product along with already existing ones will enable us to reach effectively to every child of our country. I am glad to convey that Government of India has already planned the expansion of PCV to all States/UTs of country so that burden of pneumococcal disease can be brought down further.

To provide guidance to States/UTs for the PCV introduction, the operational guidelines have been updated by the Immunization Division, Ministry of Health and Family Welfare with support from experts and immunization partners. I am hopeful that these guidelines will be useful in facilitating the PCV introduction in States/UTs.

I take this opportunity to thank everyone who has joined us as team so that our immunization programme reaches to every last mile and beneficiary. I urge that such momentum should be sustained so that we can protect our children against all deadly diseases. I am sure that having come so far, we will not rest on the plateau and continue to climb in our fight against vaccine preventable diseases. This will definitely lay the strong foundation of safe and healthy India for our new generation and future.

(Dr. Harsh Vardhan)

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संदेश

जीवन की स्वस्थ आधारशिला रखने में प्रतिरक्षण एक सर्वाधिक किफायती जन-स्वास्थ्य कार्यकलाप है। इसे महसूस करते हुए भारत सरकार का यह सतत् प्रयास रहा है कि देश के प्रत्येक बच्चे को ऐसे टीका-निवारणीय रोगों से संरक्षित किया जाए जिनके टीके उपलब्ध हैं।

निमोनिया 5 साल से कम आयु के बच्चों में रोग और मृत्यु का एक प्रमुख कारण है। निमोनिया से जुड़ी अनेक बीमारियों और मौतों को समय पर किए गए पूर्ण टीकाकरण के माध्यम से रोका जा सकता है। सरकार द्वारा किए जा रहे अन्य प्रयासों के साथ-साथ सार्वभौमिक प्रतिरक्षण कार्यक्रम (यूआईपी) में न्यूमोकोकल कन्जुगेट वैक्सीन (पीसीवी) की शुरुआत से इस रोग भार में और कमी आएगी। पीसीवी अब चरणबद्ध रूप में पूरे देश में प्रदान की जा रही है। इस प्रक्रिया के एक बार पूरा हो जाने पर यह महंगा टीका भारत के कोने-कोने में नागरिकों के लिए निःशुल्क उपलब्ध हो जाएगा।

मुझे यह बताते हुए हर्ष हो रहा है कि अब हमारे पास पीसीवी के स्वदेशी विनिर्माता भी हैं और इससे भारत में प्रत्येक बच्चे के लिए इस जीवन रक्षक टीके की आत्मनिर्भर आपूर्ति सुनिश्चित करने के सरकार के प्रयासों में और तेजी आएगी।

मैं उन सभी विशेषज्ञों और प्रतिरक्षण भागीदारों को शुभकामनाएं देता हूं जिन्होंने इस प्रचालन दिशा-निर्देशों को तैयार करने में स्वास्थ्य और परिवार कल्याण मंत्रालय के प्रतिरक्षण प्रभाग को सहयोग प्रदान किया है। मुझे विश्वास है कि यूआईपी के तहत पीसीवी लागू करने के दौरान ये दिशा-निर्देश अत्यंत उपयोगी सिद्ध होंगे।

(अश्विनी कुमार चौबे)

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MESSAGE

India's Universal Immunization Programme (UIP), launched in 1985, is the largest immunization programme in the world. It caters to an annual cohort of nearly 2.6 crore, with around 1.2 crore vaccination sessions planned annually. The Government of India is making constant efforts to improve the coverage and quality of the programme to ensure that all available vaccines are administered to the children for ensuring protection from vaccine preventable diseases.

2. To expand the basket of vaccines under the UIP, Government of India has introduced 5 new vaccines during the past 6 years, including Pneumococcal Conjugate Vaccine (PCV) in 2017. PCV will provide protection against pneumococcal disease.

3. Pneumococcal diseases are one of the most common causes for morbidity and mortality in children under 5 years of age in India and across the world. Pneumococcal Conjugate Vaccine (PCV) is an effective tool to reduce the burden of childhood pneumonia caused by Pneumococcus. The PCV has already been introduced in a phased manner since 2017 in the states of Bihar, Himachal Pradesh, Gujarat, Madhya Pradesh and Uttar Pradesh. Now we have decided to expand PCV Pan India to all the remaining States/UTs.

4. I take this opportunity to thank all the experts and partners who have contributed in the revision of Operational Guidelines for Pneumococcal Conjugate Vaccine. I look forward for their continued support in universalizing the PCV vaccine. I am sure that these guidelines will go a long way in delivering PCV effectively to all children of the country.

(RAJESH BHUSHAN)

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Additional Secretary & Mission Director (NHM)

MESSAGE

It gives me immense pleasure to present the updated version of Operational guidelines for introduction of the Pneumococcal Conjugate Vaccine (PCV) in the Universal Immunization Programme (UIP). These guidelines have been updated with the recent developments related to the burden of pneumococcal disease and also the availability of an indigenously developed PCV licensed for use in the UIP.

India has a high burden of pneumonia as evident by the fact that it killed an estimated of 1,27,000 under-five children in 2018, more than 14 children every hour. It is estimated that pneumonia caused by Streptococcus Pneumoniae (known as pneumococcal pneumonia) is an important cause of pneumonia in children and responsible for 35% of severe pneumonia episodes and 30% of pneumonia deaths in 2030. Therefore, expansion of PCV vaccine nationwide will help us to save our children from this potentially fatal disease. It is important to note that PCV vaccine in private sector is an expensive vaccine and now through UIP, it will be provided free of cost across the Country thereby helping those who are in most in need of it.

I am also very hopeful that the expansion of PCV in all states in the country will act synergistically with the recent country wide expansion of the rotavirus vaccine to further bring down the under-five morbidity and mortality. Mere introduction of the vaccine under the programme will not serve the purpose if it does not have high coverage and does not reach the most vulnerable communities. Therefore, we have conducted immunization drives under the umbrella of Intensified Mission Indradhanush so that the vaccines under UIP reach every child and there is rapid increase in immunization coverage.

I appreciate the efforts of all experts and partners who have supported the Ministry of Health Family Welfare (MoHFW) in development of these guidelines and urge the States and UTs to use these guidelines effectively while rolling out the PCV.

(Vandana Gurnani)

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MESSAGE

As we are all aware that Pneumonia is one of the leading causes of deaths of under-five children. As per 2015 estimates, nearly 49.8 million pneumonia cases were reported in under-five children in India out of which 8.4 million cases were severe pneumonia cases. Pneumococcal Pneumonia (Streptococcus Pneumoniae) is the most common cause of severe pneumonia and a significant cause of morbidity and mortality in under-five children.

Pneumococcal Pneumonia contributes to more than 50,000 U-5 deaths, highlighting the importance of pneumococcal disease as significant public health problem in country. Some of these are vaccine preventable and can be addressed through vaccination.

Realizing the burden of Pneumococcal Pneumonia, Government of India in 2017 introduced Pneumococcal Conjugate Vaccine (PCV) in a phased manner under Universal Immunization Programme and was expanded to 5 States. As a part of phase introduction, PCV will be expanded nation-wide in 2021. PCV introduction will not only reduce the burden of Pneumonia due to Pneumococcal Pneumonia but will also address to equity issues. It will also address the anti-microbial resistance.

Government of India introduced several new vaccines in past couple of years under Universal Immunization Programme to provide the expanded coverage against vaccine preventable diseases. Therefore, due to our rich experience, I would like to reiterate that during new vaccine introduction, all required preparatory activities like advocacy, trainings, microplanning, communications, vaccine & logistics planning, monitoring & supervision etc. must be paid due attention to make the PCV introduction successful. States/UTs must undertake cold chain assessment and adequate measures for its strengthening. Training of health personnel and health workers should be planned in advance to orient them about the operational aspects of PCV introduction. A sound communication plan must be developed to inform the community, stakeholders and media about the PCV introduction and its benefits.

I am sure that these guidelines will help the States/UTs to conduct the trainings, plan vaccine and other logistics and monitor the introduction of PCV. I thank all those who have contributed to bring this publication in light and convey my best wishes for States/UTs for PCV introduction.

(Dr. Pradeep Haldar)

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
CPCB	central pollution control board
CSF	cerebrospinal fluid
CSO	civil society organizations
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
NCCVMS	National Cold Chain Management Information System
NHM	National Health Mission
NPSP	National Public Health 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
SHTMs	Social Mobilization Networks
STFI	state task force for immunization
STSC	Standing Technical Sub-Committee
TD	Tetanus and adult Diphtheria
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

Chapter 1 Background and Introduction

1.1 BACKGROUND

India has made impressive gains in immunization and continued efforts are being made to achieve comprehensive immunization coverage through the Universal Immunization Programme (UIP). The vaccines given under the UIP are provided free of cost to beneficiaries including infants. The UIP is one of the largest immunization programmes in the world with an annual target of nearly 2.67 crores (26.7 million) infants and 3.0 crores (30 million) pregnant women.[1]

Reduction of underfive and infant mortality in India is a priority goal under the National Health Mission (NHM) of the Government of India. After the first month of life, vaccine-preventable diseases remain the biggest threat to children, accounting for more than 300,000 deaths annually in India, as of 2008.[2] 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 80/1000 live births in 2009 to 32/1000 live births in 2018. Similarly the under 5 mortality rate has decreased from 43 in 2014 to 34.6 in 2018.[3]

To achieve the full impact of vaccines, both current and new, high full immunization coverage (FIC) every state must be ensured. As per the recently released NFHS 5 (2019-20) data, evaluated full immunization coverage has improved compared to the NFHS-4 (2015-16) in majority of the 22 states where the survey was conducted.[4] As envisaged under the Comprehensive Multi-Year Plan for Immunization (2018-22), the Ministry of Health & Family Welfare (MoHFW), Government of India, has implemented various routine immunization intensification strategies to reduce underfive morbidity, mortality and disability due to vaccine preventable diseases by providing quality immunization services to all eligible populations. Each such effort helps to save more lives and prevent illness and it is important to continue to maintain the same level of momentum for the fight against vaccine-preventable diseases.

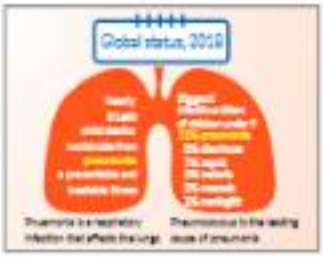
As part of Government of India's accelerated efforts, pledging to achieve full immunization coverage in coming years, the UIP is already implementing strategies to reduce left-outs, missed opportunities and drop-outs. Some of the notable interventions are by using due list by mobile health workers for 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 hard-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 key initiatives to rapidly improve immunization coverage by addressing equity gaps and increasing demand for immunization. As on March 2020 during the various phases of "Mission Indradhanush," a total of 6.5 crore children and 84.2 lakh pregnant women have been vaccinated across 470 districts in the country.

To rapidly improve the full immunization coverage, the Ministry of Health & Family Welfare launched Intensified Mission Indradhanush in selected 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 (Annexure 1). These include nationwide introduction of Haemophilus influenza type b (Hib)-containing pentavalent vaccine, inactivated polio vaccine (IPV), rotavirus vaccine (RVV) and measles-rubella (MR) vaccine.

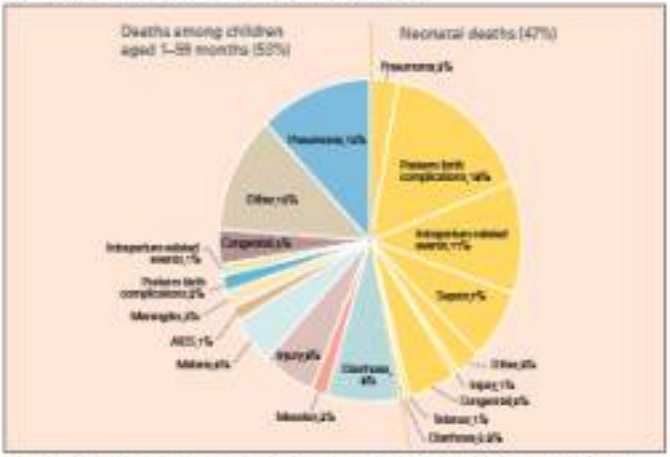
Pneumococcal disease is the biggest vaccine-preventable cause of death in children under five, globally and in India (Figure 1-5). Pneumococcus is the leading cause of pneumonia, identified as one of the major causes of death in children globally. India accounted for one-fifth (2016) of the global pneumonia deaths in 2015. The figure 2 illustrates global causes of deaths among children under 5 years, 2015.[3]

Figure 2: Global Burden of pneumonia 2015[3]



WHO recommends the inclusion of PCVs in childhood immunization programme worldwide. Use of pneumococcal vaccine should be complimentary to other disease prevention and control measures, such as appropriate case management, promotion of exclusive breastfeeding for the first 6 months of life and reducing known risk factors such as indoor air pollution and tobacco smoke.[4]

Figure 1: Global distribution of deaths among children under age 5, by cause, 2015[3]



Source: Levels and trends in child mortality: Estimates developed by the UN Inter-agency Group for Child Mortality Estimation. Child Mortality Report 2015[3]

Figure 2: Infographic showing global burden of pneumonia among under 5 children in 2019

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. Under the UIP the PCV is now being administered to eligible children in 9 states - Bihar, Himachal Pradesh, Madhya Pradesh, Rajasthan and Uttar Pradesh. Further phase-wise expansion is planned to cover the remaining states and union territories.

1.2 CHILDHOOD PNEUMONIA

Pneumonia continues to kill more children under five worldwide than any other single infectious disease, claiming an estimated 800,000 children's lives in 2019[1]. 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.

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 affect multiple organ systems, causing pneumonia, meningitis, bacteraemia/sepsis, sinusitis, bronchitis and middle ear infection (see Chapter 2).

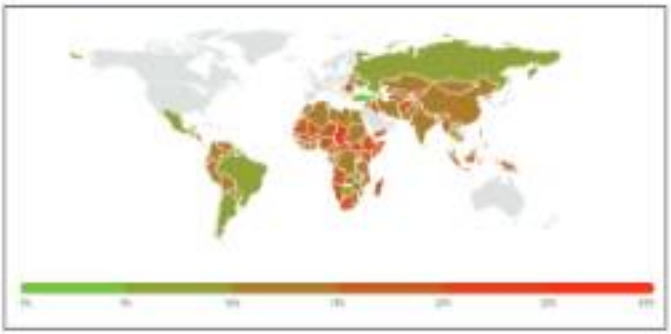
Pneumococcal mortality is a significant contributor to the underfive mortality rate worldwide. As per WHO position paper-2019, of the estimated 5.56 million deaths among children <5 years of age globally in 2015, 294 000 were estimated to be caused by pneumococcal infections.[2] An additional 30 000 deaths were estimated to have occurred in children co-infected with HIV. Disease and mortality rates are higher in developing than in industrialized settings, with most deaths occurring in Africa and Asia.[3]

The figure 4 depicts the percentage of deaths among children under 5 attributable to pneumonia for each country in 2017.[1] 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 13% of all severe pneumonia cases and 30% of all pneumonia deaths worldwide.[4]

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

Figure 4. Percentage of deaths among children under age 5 attributable to pneumonia, 2017[1]



1.4 INDIA SCENARIO

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.

It has been estimated, that in year 2010, 6.6 (5.6–8.0 million) million episodes of severe pneumonia and 0.83 (0.8–0.4 million) million pneumonia deaths (all-cause) occurred in children younger than 5 years in India. The estimated incidence of severe pneumonia was 60.7 (95% CI, 56.1–65.6) per 1000 children per year in those less than 5 years of age, and 57.6 (95% CI, 50.1–66.2) in children aged less than 1 year. Further, it has been estimated that in year 2010, 0.56 million (0.49–0.64 million) severe pneumococcal pneumonia episodes and 105 thousand (93–119 thousand) pneumococcal pneumonia deaths had occurred in children younger than 5 years of age in India. The annual incidence of severe pneumococcal pneumonia in India was estimated to be 4.8 episodes (95% CI, 4.3–5.3) per 1000 children younger than 5 years. The figure 5 depicts the estimated under-five pneumococcal pneumonia episodes and deaths in India.[2]

Figure 5. Estimated under-5 Pneumococcal pneumonia episodes & deaths in India, 2010[2]

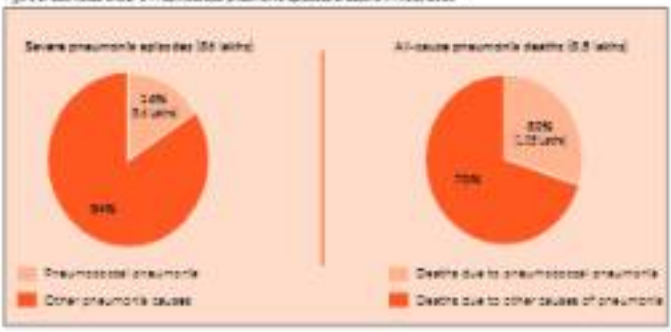


Figure 6 depicts the distribution of severe pneumonia episodes and pneumonia deaths in children younger than 5 years in India. Severe pneumonia frequently requires hospitalization for treatment, leading to emotional and financial burden for caregivers and stress on the public healthcare system. Risk of pneumonia is largely driven by factors associated with malnutrition, poverty, air pollution and other environmental factors (see section 2.5). As mentioned, 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 (Figure 6). These four states account for an estimated 71% of all pneumonia deaths and 67% of severe pneumonia cases. The figure 7 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.[17]

Figure 6. Distribution of severe pneumonia episodes and deaths in children younger than 5 years, 2010, India[17]

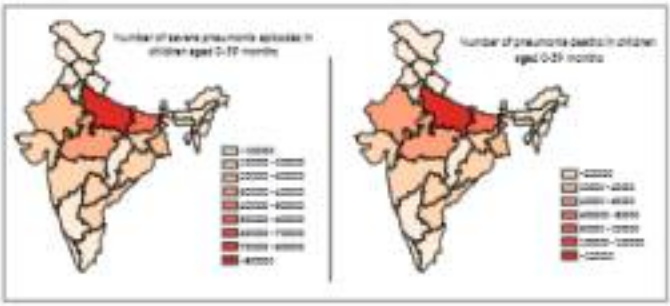
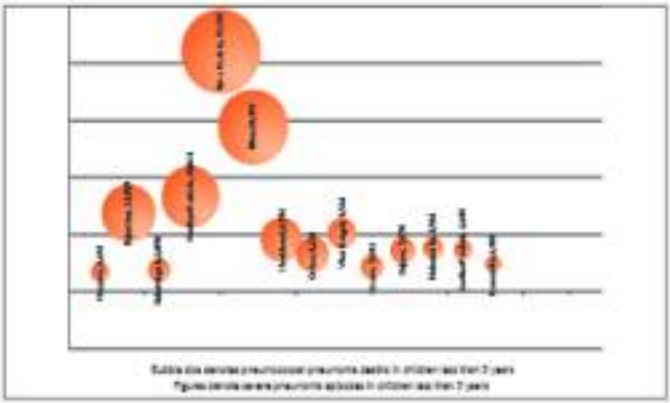


Figure 7. States with highest burden of pneumococcal pneumonia deaths in children under five, 2010, India[17]



As per the 2015 estimates available, severe pneumococcal disease in India manifests primarily as severe pneumonia. There were 1.6 million (UR 1.0–1.8) estimated cases of severe pneumococcal pneumonia in 2015, accounting for more than 87% of all severe pneumococcal disease. Despite substantial reductions in mortality, pneumococcal accounted for 14% (UR 9–17) of all deaths among children aged 1–59 months in India in 2015. In 2015, 65700 (UR 44600–86000) pneumococcal deaths were estimated to have occurred in children aged 1–59 months in India. Of these, an estimated 56000 (UR 37900–73500) deaths were due to pneumococcal pneumonia [1].

Chapter 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 2.1[1]

S. pneumoniae is a Gram-positive, encapsulated diplococcus. The polysaccharide capsule of this bacterium is an essential virulence factor, and pneumococcal serotypes are defined on the basis of differences in its composition.[2] Antibody to the capsular polysaccharide protects against disease. In general, immunity from natural infection or vaccination is serotype-specific, but cross-protection among related serotypes can occur. There are >90

Figure 2.1 Morphology of Streptococcus pneumoniae[1]

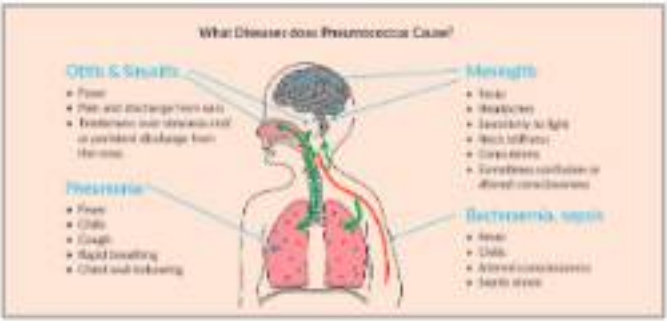
known serotypes of S. pneumoniae. The distribution of serotypes that cause disease varies over time and by age, disease syndrome, disease severity, geographical region and the presence of antimicrobial-resistant genes.

2.2 DIFFERENT TYPES OF DISEASES CAUSED BY PNEUMOCOCCUS

Pneumococcal infections can lead to serious invasive diseases such as meningitis, septicaemia and pneumonia, as well as milder but more common illnesses such as sinusitis and otitis media (Figure 2). The causative agent, Streptococcus pneumoniae, frequently colonises the human nasopharynx and is transmitted mainly through respiratory droplets. Infants and young children are the main reservoir of this organism, in whom the cross-sectional point prevalence of nasopharyngeal (N.P) carriage ranges from 27% to 65%. Most illnesses occur sporadically. Outbreaks of pneumococcal disease, although uncommon, may occur in closed institutions, such as in nursing homes and military barracks.

About 75% of invasive pneumococcal disease and 85% of pneumococcal meningitis occur in children aged <2 years, among which many cases occur in neonates and children under 6 months of age.

Figure 2. Diseases caused by Streptococcus pneumoniae

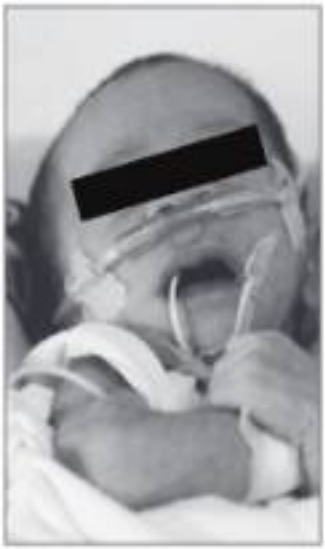


2.3 TRANSMISSION

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 2.2 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 and accumulation of fluid in the lungs. It makes breathing difficult and limits oxygen intake. Symptoms include cough, chest indrawing, difficult and rapid breathing, and wheezing. If infants are severely ill, they may also be unable to feed or drink and may have convulsions, become unconscious and may even die.

Figure 2.2: How pneumococcal disease spreads?

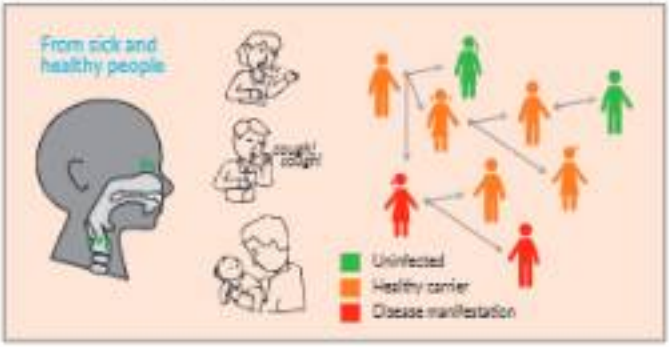
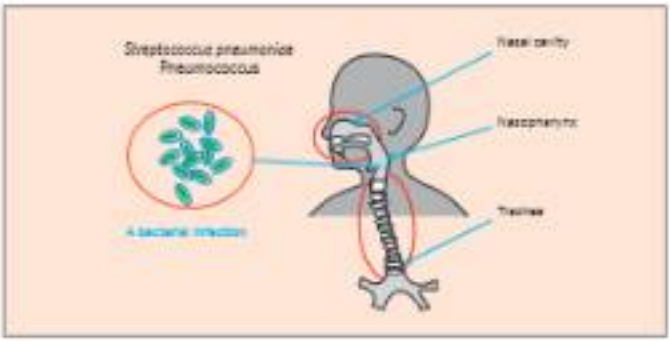


Figure 11. Spread of pneumococcal pneumonia



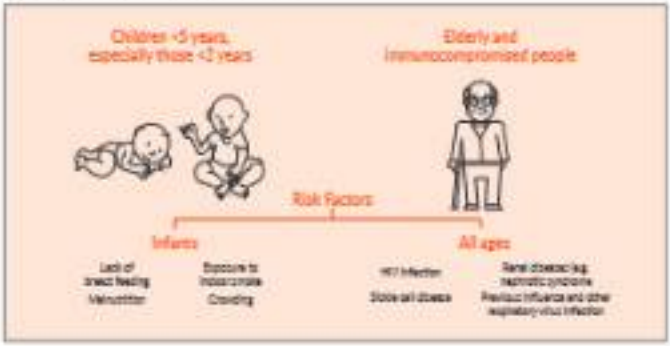
The figure 11 depicts spread of pneumococcal pneumonia.

2.5 RISK FACTORS

The figure 12 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 disease 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.
- Elderly and immunocompromised people.
- Poor and marginalized populations with poor access to health care.

Figure 12. Who is most at risk of pneumococcal disease



2.6 SIGNS AND SYMPTOMS

Pneumococcal disease can affect multiple organ systems, causing pneumonia, meningitis, bacteraemia/sepsis, sinusitis, otorrhoea 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 than the symptoms of bacterial pneumonia. In children under 5 years of age, who have cough and/or difficulty in 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 have convulsions, become unconscious and may even die.

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 bacteraemia/sepsis or meningitis, which require antibiotic treatment and have high mortality rates (Table 1).

2.8 DIAGNOSIS

Pneumonia is diagnosed based on clinical evaluation and X-ray imaging when available. The figure 1.2 depicts clinical signs of pneumonia and X-ray imaging.[4,5,6] It can be difficult to establish whether pneumococcal infection is the cause of the patient's symptoms because even in true pneumococcal cases, the specimens collected often do not yield the pathogen. 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 pneumonia) 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).

Figure 1.2: Diagnosis of pneumonia based on clinical evaluation and X-ray imaging[4,5]

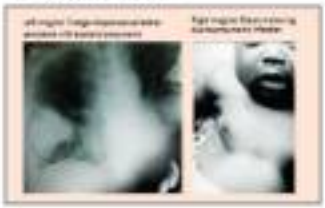


Table 1. Signs and Symptoms of diseases caused by pneumococcus

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, skin shakiness
Otitis and sinusitis	fever, pain and discharge from the ears (otitis), tenderness over sinuses and/or persistent discharge from the nose

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.

Figure 14. Interventions to Prevent, protect and treat children from 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 (Figure 14).

In 2009 and 2013, the World Health Organization (WHO) and UNICEF published the Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhea (GAPPD), a tool to act on with the goal of achieving a global 75% reduction in incidence of severe pneumonia and diarrhea in children under 5 by 2025. GAPPD outlines a set of core interventions to successfully prevent, protect, and treat children who are at risk of serious illness or death due to these two diseases.[24]

2.10 TREATMENT

Pneumonia is diagnosed clinically based on the signs and symptoms described above. Primary 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 centres 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 14 and 15 depicts 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.[25]

Figure 13: Interventions to Prevent, protect and treat children from pneumonia

Chapter 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 vaccine-preventable 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 invasive pneumococcal 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.

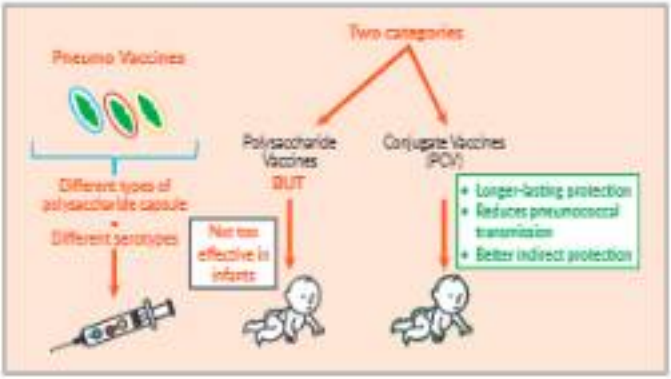
Hib-containing pentavalent vaccine

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

Pneumococcal vaccines are derived from sugars (polysaccharides) from the capsule of the bacterium *Streptococcus pneumoniae*. They may or may not be attached to the carrier protein. Based on the presence of carrier protein, two broad categories of pneumococcal vaccines are available in market. Polysaccharide vaccine (with no carrier) and

Figure 1.1: Types of pneumococcal vaccines



Conjugate vaccines (with protein carrier) (Figure 1.2):

- 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.

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.

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 PCV13 provides 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 June 2020, 148 countries have introduced PCV.

The figure 1.3 depicts PCV introduction scenarios[8]. In India, in the private sector, PCV7 was introduced in 2006 and was phased out in 2010 when PCV10 and PCV13 were introduced.

The table 2 depicts characteristics of available PCV products under UIP.

Figure 17: PCV introduction worldwide[7]

WHO recommends the inclusion of PCVs in childhood immunization programmes worldwide. The most recent WHO position paper on PCV published in February 2019, states that the currently available PCVs are safe and effective, and the increase in the number of serotypes in these vaccines as compared with the first licensed PCV7 represents significant progress in the fight against pneumococcal disease-related mortality and morbidity, particularly for developing countries (Figure 18).

3.2 DECISION-MAKING PROCESS FOR PCV INTRODUCTION IN INDIA (FIGURE 19)

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

Table 2: Characteristics of available PCV products under UIP

Characteristics of available PCV products under UIP		
Discussion point	Prevnar13®	Pneumosil®
Manufacturer	Pfizer Inc.	Serum Institute of India Limited
Presentation	4 dose vial	5 dose vial
Preservative	Yes	Yes
Serotypes	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F	1, 3, 6A, 7F, 9V, 14, 19A, 19F, 23F, 6B
WHO Prequalification	Yes	Yes
National Regulatory approval	Yes	Yes
Administration	Intramuscular	Intramuscular
Schedule	3 doses at 6 weeks, 14 weeks and 9 months	3 doses at 6 weeks, 14 weeks and 9 months
Storage temperature	2-8 °Celcius	2-8 °Celcius
Cold chain volume per dose	5.6 cm^3	5.5 cm^3
Permissible wastage rate	10%	10%

Figure 18. WHO position paper–February 2019 provided recommendation for inclusion of PCV vaccine under national immunization programme[8]

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Weekly epidemiological record

Relevé épidémiologique hebdomadaire

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Introduction

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 STAG.

The recommendations of the Working Group and STAG 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 with a dosing schedule of 3 primary doses at 6 weeks and 14 weeks, followed by a booster dose at 9 months is recommended. The 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 three pneumococcal conjugate vaccines that are licensed and available in the private sector in India.

Figure 19. Decision-making process for Pneumococcal Conjugate

The National Technical Advisory Group for Immunization (NTAGI) in 2015, based on the available documents regarding product specifications, projected availability, and operational feasibility including multi-dose presentation and compliance with open vial policy, recommended PCV10 (4-dose vial) as the preferred vaccine type for introduction in the UIP. The PCV10 4-dose vial is WHO prequalified. In case of shortage of supply of PCV10, the NTAGI recommended that other vaccine types may also be considered.[7]

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 premature born infants (i.e. <37 weeks gestation) at the recommended chronological age consistent with other routine vaccinations, unless there are contraindications.

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 1A, 1SP, 5, 6A and 6B.[8] Both PCV10 and PCV13 would be expected to provide coverage for these serotypes.

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) (Figure 20).

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.

Figure 20. Holding the child for Vaccination

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.
- Ensure the child's feet firmly between their thighs.

- The first dose, PCV1, will be administered at 6 weeks of age with the first dose of pentavalent vaccine, oral polio vaccine (OPV), Rotavirus dose (RV) and Measles vaccine. Please refer to the scenarios depicted in figures 21.
- 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. Please refer to the scenarios depicted in figures 21.

Figure 21: PCV vaccination schedule

- The PCV booster dose will be administered at 9 months of age with the first dose of measles-rubella (MR) vaccine 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 8 weeks & 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.

3.6 COMPARISON OF IMMUNIZATION SCHEDULE BEFORE AND AFTER PCV INTRODUCTION

The table 8 describes the current immunization schedule (i.e., prior to PCV introduction) and immunization schedule after the introduction of PCV.

Table 3. National immunization schedule after 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 can be given up to 7 years of age. • Pentavalent vaccine should be given under 1 year of age. In delayed cases, doses above 1 year of age can be given to a child only if the child has received at least one dose of pentavalent vaccine before his/her first birthday. Doses should be given at a minimum interval of 4 weeks, at the earliest available opportunity. • In delayed cases, IPV can be given maximum up to 1 year of age. • PCV should be given under 1 year of age. In delayed cases, 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. • MR 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	MR-1, JE-1*, PCV-B	
16-24 months	DPT first booster dose, OPV booster dose, MR-2, JE-2* Vit A	
5-6 years (up to 7 years of age)	DPT second booster dose	
10 years	Td	
16 years	Td	

[illegible]
[illegible]
[illegible]
*JE in endemic districts

2.7 KEY OPERATIONAL ASPECTS OF PCV UNDER UIP (REFER TABLE 4 BELOW)

Table 4: Key operational aspects of PCV under UIP

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 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 (3 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 immunocompetent 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 shown to be safe and well-tolerated even among children infected with HIV. Children with HIV infection require a booster dose to sustain protection.
Immunogenicity, efficacy and effectiveness	• PCV vaccines are safe and being used in 144 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 chronological 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 who 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 vide effects: irritability, crying, swelling and tenderness at injection site, transient fever <39°C (102°F)
Vaccine cost	• PCV is an expensive vaccine in the private sector. • Under the UIP of Government of India, PCV will be given free of cost to all eligible infants in the fixed and outreach session sites.

2.8 OPEN VIAL POLICY

- The Open vial Policy guidelines, when followed correctly ensure effective utilization of vaccines and minimize wastage.
- Open vial policy is applicable to PCV 4/more dose vial.
- 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-stopper has not been contaminated in anyway); and
  - vaccine vial/s has not been submerged in water or contaminated in any way.

2.9 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 JEV 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 (3 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 ensured that high coverage rates of pentavalent1, OPV1, rotavirus, measles/rubella (MR), 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 RCH (mother-child protection [MCP] card, vaccine registers, due lists, tally sheets, reporting coverage comes such as health management information system [HMIS] and mother-child tracking system [MCTS] (Reproductive & Child Health [RCH] needs 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.

Chapter 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 micro-plans on state and national levels (Figure 22).

Figure 22: Bottom up approach for ID microplanning

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 (Figure 23). 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 PCV-containing pentavalent vaccine, PV and rotavirus vaccine in the UIP.

WHO, UNICEF, JSI and other immunization partners 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 10 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

Figure 23: State and district preparedness checklist for PCV introduction

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 (WebPCV). These checklists can also be filled in an online tool.

National assessors 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 2 lists the components incorporated in the checklist.

Table 2: Components of preparedness assessment checklists for PCV introduction

ESSENTIAL COMPONENTS	
1. Human resources data	2. Background information
3. Microplanning status	4. Mission indicators/sub-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

Chapter 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 2019). A good training gives confidence to health workers to introduce new vaccines (Figure 24).

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 8 lakh deaths in 2018.

Figure 24: Key take home messages for PCV trainings

Health-care personnel who require training on introduction of PCV include district immunization officers (DIOs), urban nodal officers (UNHM-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 (AAP, IAP) 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 state/districts. Trainers should be patient listeners to any feedback from trainees. It is important to conduct interactive 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.

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 units.

Timely trainings/orientation of health care service providers, monitors 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 6 below depicts the state training plan for PCV introduction.

State media workshop for PCV introduction

The purpose of this workshop is to sensitize IEC officials and media. The table 7 depicts the state plan for media workshop on PCV introduction.

Table 6: Details for State Workshop for PCV introduction

Training	Trainees	Participants	Training Support
State Workshop (ToT) for PCV Introduction	nt/nrhm and national level partners	State-level: Immunization partners District-level (maximum 4-5 participants): immunization partners	State Health Department with support from all immunization partners

Table 7: Details for State Media Workshop for PCV introduction

Training	Trainees	Participants	Training Support
State Media Workshop for PCV Introduction	Chair: Principal Secretary (Health & FW) Co-chair: MD/nrhm Key facilitators: State Immunization Officer, Director Supporting partners: WHO, NRSA, UNICEF, JSI with support of other partners (FRLI, SHS)	State-level: State Immunization Officer, State IEC Officer (Also: Media Officer) State IEC Coordinator, NPHO, WHO, NRSA and partners District-level (maximum 2 participants): District Info/ Media Officer, District Immunization Officer (if required), any other official identified as district spokesperson.	SSHO and media 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 day duration. District-level officers who received training at state will conduct training workshops in each district. The 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 ANM/ Nurse person, block mobilization coordinator (BHM) Social Mobilization Network/Cluster partner agencies, ASHA coordinators 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 5 depicts the district training plan for PCV introduction.

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

These block level trainers will, in turn, be responsible for training health workers, including ANMs, supervisors and cold chain handlers. ANMs/ASHAs/ AWWs/other workers will be trained at block PHC/ additional PHC (Table 6). 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).

Table 5. Details for District Workshop for PCV introduction

Training	Trainers	Participants	Training Support
District Workshop (ToT) for PCV introduction	District Immunization Officer, DPHO/DSO, District Program Manager (NHM), District Cold Chain Handler and Partners	District-level: District Program Manager, District Cold Chain Handler, District Mobilization Coordinator (DMC), Vaccine and cold chain manager (UNICEF) and partners Block-level (maximum 4-5 participants from blocks and urban planning units): Block MOIC, Block Program Manager (NHM), CDPO-ICDS, Block MO/CDPO-ICDS, Block Cold Chain Handler, Block Mobilization Coordinator (BMC)	District Health Department with funding support from WHO Technical support: WHO, UNICEF, JSI, CSO and other partners

Table 6. Details for Block Workshop for PCV introduction

Training	Trainers	Participants	Training Support
Block Workshop for PCV introduction (for health workers and vaccinators)	Block MO/CDPO, Block Program Manager (NHM), CDPO-ICDS, Block CHC and Block Cold Chain Handler, Block Mobilization Coordinator (BMC)	ANMs, front-line vaccinators (ASHA/AWW) and Health & ICDS supervisors Additional PHC medical officers (Tier)	District Health Department (NHM budget)

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 4 depicts the cross training plan for PCV introduction.

The frontline health worker is the backbone of community engagement. It is important to ensure that AVVAs, AVWAs, 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, AVWAs and the workers are trained on key aspects of PCV, including the four key messages.

If there are any pertinent issues in undertaking all these trainings 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 AVWAs are trained at block level. It has been observed that when AVWAs 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 roles/ 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, ANCs, block program managers (BPM) in imparting training to frontline health workers.

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

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 6 weeks 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

[illegible] to discuss PCV introduction topics. The state, district and sub-district program managers should remember that trainings should exclusively be held as per the recommended timelines.

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 powerpoint 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.

Chapter 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 in Table 10 can assist.

Table 10: Permissible wastage for vaccines under UIP

Wastage rate = (doses supplied – doses administered) x 100 / doses supplied

Vaccine	Maximum acceptable wastage
BCG	50% and the wastage multiplication factor for calculation is 2.0.
Hib, Rota and JE	25% and the wastage multiplication factor for calculation is 1.66.
PCV, IPV, OPV, Pentavalent, Hepatitis B, DPT, Td	10% for all vaccines eligible for reuse under the open vial policy. The wastage multiplication factor for calculation is 1.11.

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 equipments 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 need time and re-ordering levels.

6.2 WASTAGE RATE AND BUFFER STOCK

PCV Introduction recommends indicative wastage values of less than 10%. 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 vial requires 5 doses and vial contains 10 more 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 vital network of cold chain stores consisting of government medical store depots, state, regional/ divisional vaccine stores, and district and PHC/CHC. 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 20 depicts the cold chain system in India.

With the nationwide 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

Figure 20. Cold chain network in India

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.

Intelligence network (eVIN), an online system for assessing cold chain equipment functionality and vaccine storage status (Annexure II).

6.5 COLD CHAIN MONITORING

POV is a heat and freeze sensitive vaccine and loses its potency when exposed to temperatures outside 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 POV 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 the inner square is the same color, or darker than the outer circle, do not use the vaccine (Figure 2d).

HOW TO READ A VVM

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

6.6 STORAGE AND HANDLING OF POV VACCINE

- POV 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 POV vaccines should be stored between +2°C and +8°C.
- POV vaccines SHOULD NOT BE FROZEN as they are exceptionally sensitive to temperatures lower

Figure 2d: Stages of VVM

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

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.
- PCV vaccines cannot be placed directly on or near the freezer portion of refrigerators, and should not be stored near the inner walls of cold boxes and ice-packs in vaccine carriers.
- Refer to section 6.7 for proper procedures on 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 cooler. PCV should be placed adjacent to pentavalent vaccine. Refer to figure 27.
- PCV could be damaged if placed in direct contact with frozen ice packs that were inadequately conditioned; therefore, vaccine ice packs should be conditioned before use.

Figure 27: Storage of UIP vaccines in ILR

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.

6.7 CONDITIONING OF ICE PACKS

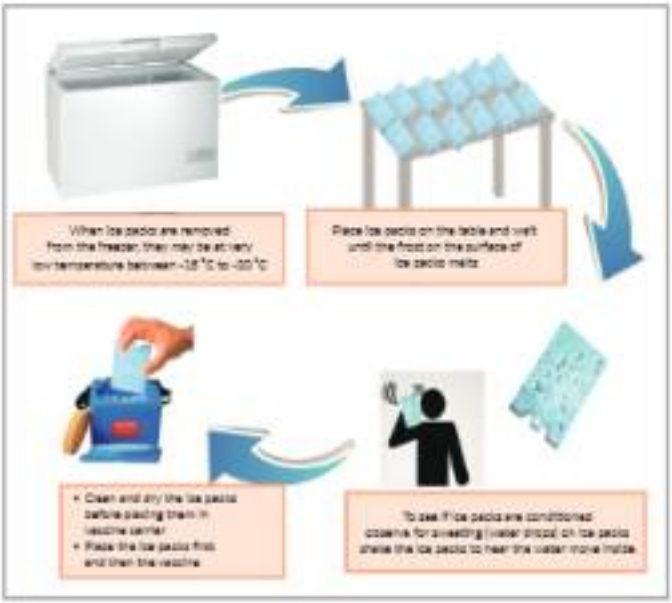
In order to ensure correct storage of vaccines, the following procedures should be followed (Figure 28):

- 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 sweating, no ice and drops of water on surface, and 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 cool 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.

Figure 28: Conditioning of ice packs



by WorkFW. 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)

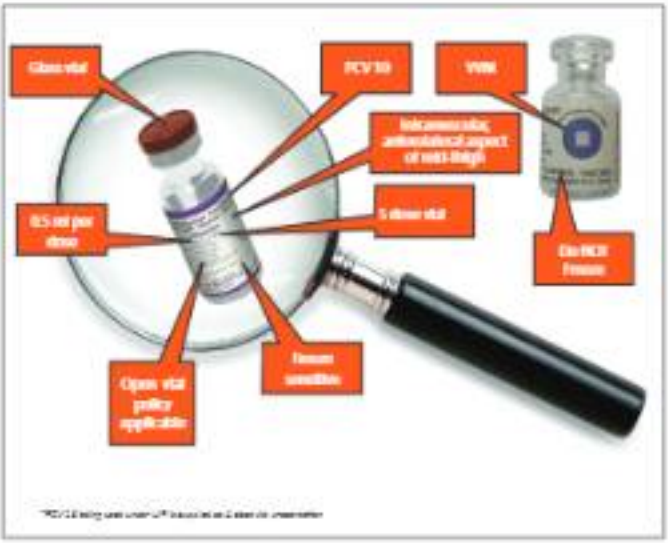
The inventory system should ensure that units with the nearest expiry date are used first in a system known as FEFO (Early Expiry, First-Out). Expiry date should always be checked whenever a vial is opened. Never use vaccines after the expiry date (Figure 29).

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

REMEMBER

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

Figure 2.9: Key operational aspects of PCV



Chapter 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 RCV vaccination. These syringes prevent person-to-person transmission of blood-borne pathogens (Figure 33).
- 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 rectum 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.

Figure 33: Using AD syringe for vaccination

7.2 SAFE DISPOSAL OF WASTE

- The immunization waste generated during vaccination must be disposed of as per current CPCB guidelines of biomedical waste disposal.
- Cut the nub of the AD syringe immediately after administering the injection using the nub cutter.
- The cut needles will get collected in the puncture proof translucent container of the nub cutter.
- Segregate and store the plastic portion of the cut syringes, plastic ampoules, used gloves in the red bag.
- Broken or discarded vaccines, broken vials, empty uncrushed vials, glass ampoules will go into Blue bag.
- All other non-infectious wastes will go into black bag.

7.3 MANAGEMENT OF AEFIs DURING PCV VACCINATION

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily has 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. Occurrence of an adverse event after immunization and its reporting does not necessarily imply that the vaccine is the cause of the adverse event. 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.

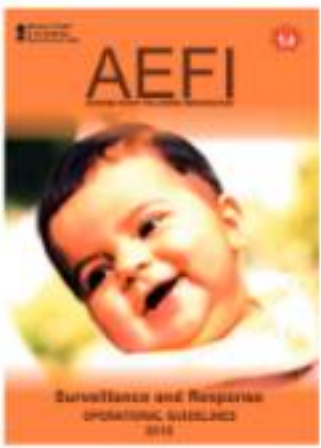
It is important that all AEFIs thought by parents/ community to be due to a vaccine/vaccination are reported and investigated as mandated. Parents/ community must be kept informed about the results of the investigations. This will help maintain confidence in vaccines and the immunization program.

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 <10% 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.



Frontline health workers/Link workers (ANMs/ ASHA/community volunteer)/AWW should immediately inform the MO of the AEFI and arrange for transportation to the nearest AEFI Management Center or health facility. 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.

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, NHM/IN-SOP, Reprint edition 2017). 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).

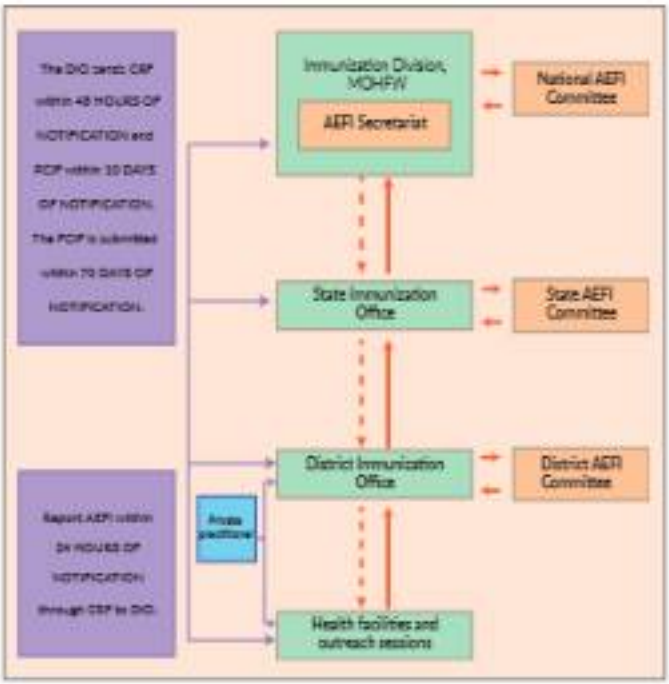
As for other vaccines, these guidelines also apply to PCV vaccine. AEFI detection and management should be done according to the following plan:

- All ANMs/ASHAs/AWWs and MOs (in addition to MO in-charge) 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 site 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 HI reporting (HIS HMIS) and district D-001 (Figure 01). Minor, serious and severe AEFIs should be appropriately reported in HMIS (processes, depots and all others).

Figure 01. Reporting of AEFI

- 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 (Figure 22).
- 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 (Figure 22).

Figure 22: Reporting of Serious and Severe AEFIs



7.3.3 CONTENTS OF AN AEFI KIT

What are the contents?

- adrenaline (5 in no.)
- tuberculin/insulin syringes (5 in no.)
- 24/26 gauge/inch needles (5 in no.)
- swabs (5 in no.)
- Injection hydrocortisone,
- Ringer lactate/normal saline (1)
- 5% dextrose (1)
- IV cannula/scalp vein set (2),
- IV drip set (1),
- Disposable syringe - 5 ml with 24 / 25G
- IM needle 5 sets,
- Adhesive tape

Guidelines/job aid with dose calculation, certification format for expiry date of adrenaline

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 needs 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).

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.

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.

Chapter 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, recording of PCV coverage from state is to be done through manual reporting.

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, hepatitis-B dose 1(Hep B1), 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 (Figure 66).

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.

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. All access/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 Immunization Division, MoHFW by 7th of every month for the preceding month.

Figure 10. Updated HCP card after introduction of PCV

Chapter 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 (Figure 04):

Figure 04: Key aspects of communication strategy

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 officials about the introduction of PCV.
- Health officials should orient officials of ICDS, PR, RD and education departments on PCV during inter-departmental meetings and reviews.

- VHSs should brief the ANMs and their supervisors, ASHA and their supervisors, IEC staff, about the introduction of PCV in the routine immunization program.
- VHSs need to support the 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 AVHs 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/frc 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 state/ district 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 new vaccine 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 workshop: To need to be organised 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 officials or a relevant 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 the existing vaccine and how many children will benefit from the vaccine at the state level. This should be out 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 3–5 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 5–7 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

Spokesperson	Messages
Primary (government)	• The case is noted and is being investigated. • The state/district AEFI experts are analysing 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 (SSBs/VHSCs).

Chapter 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 (Plan).

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 media frenzy across all states should be reassured as

increased sensitivity in reporting of AEFIs actually is in the interest of the immunization program.

- WHO, UNICEF, UNDP, JS 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 STF and DTF levels for appropriate actions.

10.1.3 District Level

In addition to officials 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 block administrative officers should be invited to cross VCMs to observe training of ASHAs and AWWs at the PHC level. Issues identified must be shared with district task forces for corrective actions. Monitoring of preparatory activities, training and field implementation will be done by all immunization partners.

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 (DTF)

- DTF 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 DTF, 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 DTF 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, UNDP, JS and other key routine immunization partners at district level are expected to proactively extend support in providing quality information/monitoring data to DTF 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 IntraPlus 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 VCCM tab.

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 AVMs, injection safety and waste disposal, record keeping and interpersonal 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 assess 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 6 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. All immunization partners 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 division 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 define 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 rotavirus containment vaccine and measles-containing vaccine second dose, as well as lessons learnt from introduction of IPV, rotavirus vaccine are being used to inform the introduction of PCV in the country.

Chapter 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 standardised 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 STFI 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 micro-planning.

Indenting and delivery of vaccine and logistics

- Ensure availability of required doses of PCV vaccine and other logistics.
- Assess cold chain space.
- PCV is a freeze sensitive vaccine. To avoid freezing of vaccine ensure cold chain points are rolled 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 sensitised well in time prior to introduction.
- Key developmental partners such as WHO, UNICEF, UNDP, JSI 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 3 above.

Tracking beneficiaries (left-outs and drop-outs)

- Undertake headcount for estimation of beneficiaries by AWWs/ASHAs/AWWs to improve micro planning and tracking.
- Use standardised tools for micro-planning and estimation of beneficiaries. Ensure 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 PCV3 should be included as part of due lists for beneficiaries coming at 6 weeks for pentavalent, OPV-1, fIPV-1, Rotavirus dose (RV1 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): AWW 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 AWW will provide oversight and cross check counterfoils to ascertain reasons for processes.

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 standardised 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 all immunization 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)

- DTF 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 DTF 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, ANM/ASHA/ AWW 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. DTF 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 points are noted 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.
- All immunization partners 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 trainings 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 various 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 workforce at district and block levels. (Refer to Chapter 8 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 ANM/ASHA/AWW for improved micro-planning and tracking.
- Use standardised tools for microplanning and estimation of beneficiaries. Ensure that it is time bound activity and gets completed in 1-2 weeks.
- Ensure that vaccinators update due lists before every session. Following PCV introduction, ensure that PCV2 should be included as part of due lists for beneficiaries coming at 6 weeks for pentavalent1, OPV1, Rota1, Hepatitis-B1 (if), and subsequently for PCV2 at 14 weeks and PCV booster dose at 9 months.
- State health authorities and partners should iteratively 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 standardised 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 2 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 an immunization 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, ANM/ASHA/AWW should undertake a headcount survey for estimation of beneficiaries by using standardised tools. This has to be a time-bound activity (1-2 weeks) and has to be iteratively monitored by government functionaries and partners. DPR to monitor the completeness of micro-plans.
- DPR 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 activities 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.

- All immunization partners 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

- ANM/LHV/Health supervisors: The district should plan to train all the ANMs at district or block level.
- Date-wise attendance should be closely monitored. Provide block attendance feedback to DVO/DIO, so that the same can be shared in the DPR.
- Mobilizers (ASHAs and AWWs) are to be trained at block level by trained block-level officials.
- WHO, UNICEF, UNDP, JS and other partner agencies are expected to support PDV introduction activities at district/block level, including monitoring the quality of training.
- Details of training at block level are given in Chapter 7.

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 digital the updated recording and reporting tools including immunization components in MCP cards, registers, due lists, etc. are shared during the training workshop.

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 themselves 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. For using PDV introduction, ensure that PDV1 should be included as part of due lists for beneficiaries coming at 6 weeks for pentavalent1, OPV1, Rota1, fractional-dose IPV1 and subsequently for PDV2 at 14 weeks and PDV booster dose at 9 months.

- Share the due list formats and revised immunization component in the VCP card. Demonstrate the use of counterfoil using immunization reading tag 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.
- VHC incharge and other model officers identified should supervise PCV implementation in the routine immunization sessions.
- Discuss planning units should be reactive 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 6 months of PCV introduction to assess the implementation status, identify gaps/bottlenecks and provide feedback for immediate corrections. This activity will be undertaken by all immunization 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 ensure plan IEC and mobilization activities for greater community participation.
- Facilitate and coordinate all available human resources such as mobilizers and VHSC volunteers to create awareness and enabling environment.
- Use high-risk zones 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.

Chapter

12 Role of Partners

The technical and monitoring support of partner agencies such as WHO, UNICEF, UNDP, PSI, JSI, and others is critical for the introduction of PCV in the UIP.

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 state/district levels with feedback to DFW 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.

UNICEF

- Support 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/ assess in training of frontline health workers (through SHIVAN 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

- Develop a Vaccine Management plan including estimation, forecasting and establishing minimum/maximum stocks 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 DFW and STFI.

JSI

- Provide overall technical/managerial support for the rollout of PCV.
- Development of preparedness assessment tool and plan for PCV introduction in States/UTs in coordination with partners.
- Support government and partners for capacity building of health personnel at various levels for PCV introduction.
- Assist in cold chain assessment in states as needed.
- Location of existing guidelines and select IEC materials to support PCV introduction in States/UTs.
- Track the progress on implementation of PCV introduction, prepare progress reports, dashboards, bulletins and share with MoHFW and other stakeholders for necessary corrective measures.

GHS

- Support PSU 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.
- 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 in/Participate 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 heads.

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.)[2]

Planning & introduction

- State and district orientations should be organized to sensitize stakeholders on the technical and operational aspects of vaccine introduction at least 3–6 months prior to the vaccine launch.
- Each state should use standard assessment checklists to review district-level preparedness before ensuring introduction of new vaccines.

Program stakeholders

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

Sensitization of allied stakeholders and partners

- Sensitizing leading pediatricians, including IAP, IMA and FOG over 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.

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.

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 cascade trainings have been completed.

Health financing

- Funds for the introduction of vaccine should be ensured beforehand.
- The incentives of ASHA 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 adequate 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 eVIN.
- 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 visits 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.
- Coverage, reporting and data collection
- Channel for ensuring HMIS should be strengthened. The data collected from cluster reports and drop-out and vaccine stock should be readily retrievable at all levels and should be checked for accuracy. Data should be analysed to improve program performance and fill in gaps.
- Reporting and recording tools such as HCP 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 charge) at 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 WHO PQS 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 3–4 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.

- ICC is the best tool to connect with community mobilization and vaccine acceptance.

Annexure 2: Training Plan for PCV Introduction

Training	Trainers	Participants	Technical support
State Workshop (ToT) for PCV Introduction Duration: 1.5 days	MoHFW and national level partners	State-level immunization partners District-level (maximum 4-5 participants) immunization partners	State Health Department with support from all immunization partners
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, JSI with support of other partners (ITSU, GHS)	State-level: State Immunization Officer, State IEC Officer (Mass Media Officer) State SBCC 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 Duration: One day	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 (UNICEF) and partners Block-level (maximum 4-5 participants from block and urban planning units): Block MO-ICs, Block Program Manager (NHM), CDPO-ICDS, Block IO/BEE/APO, Block Cold Chain Handler, Block Mobilization Coordinator (SMNet)	District Health Department with with technical support from immunization partners
Block Workshop for PCV introduction (for health workers and mobilizers) Duration: One day	Block MO-ICs, Block Program Manager (NHM), CDPO-ICDS, Block IO/BEE 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)

Annexure 3: Electronic Vaccine Intelligence Network (eVIN)

The Ministry of Health and Family Welfare has rolled out an innovative electronic vaccine intelligence network called eVIN in all states. 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 stockouts of vaccines in storage centers.

The integrated solution comprises:

- 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 automating record keeping through standardizing stock and distribution registers, identifying gaps and improving parity on vaccine cold chain network, paying 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 districts.

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 30 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 alerts 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 alongwise as well as antigenwise and generate relevant reports.

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 officers.

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.

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.

MK142 (Vestfrost) at KNK Hospital CH has reached a high of 8.70 degrees for Top sensor on 1/11/16 10:31 AM. [evin]

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

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Notes

Notes

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