सत्यमेव जयते
Ministry of Health & Family Welfare
Government of India

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

# Frequently Asked Questions

## for Medical Officers



# PNEUMOCOCCAL CONJUGATE VACCINE (PCV)




Immunization Division
Ministry of Health & Family Welfare
Government of India
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स्वच्छ भारत
एक कदम स्वच्छता की ओर

# Frequently asked questions on Pneumococcal conjugate vaccine (PCV) introduction for Medical Officers

**Question 1. Which vaccine is being introduced in the universal immunization programme (UIP) to protect against pneumococcal disease?**

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

**Question 2. What is pneumococcal disease?**

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

**Question 3. What is pneumococcal pneumonia?**

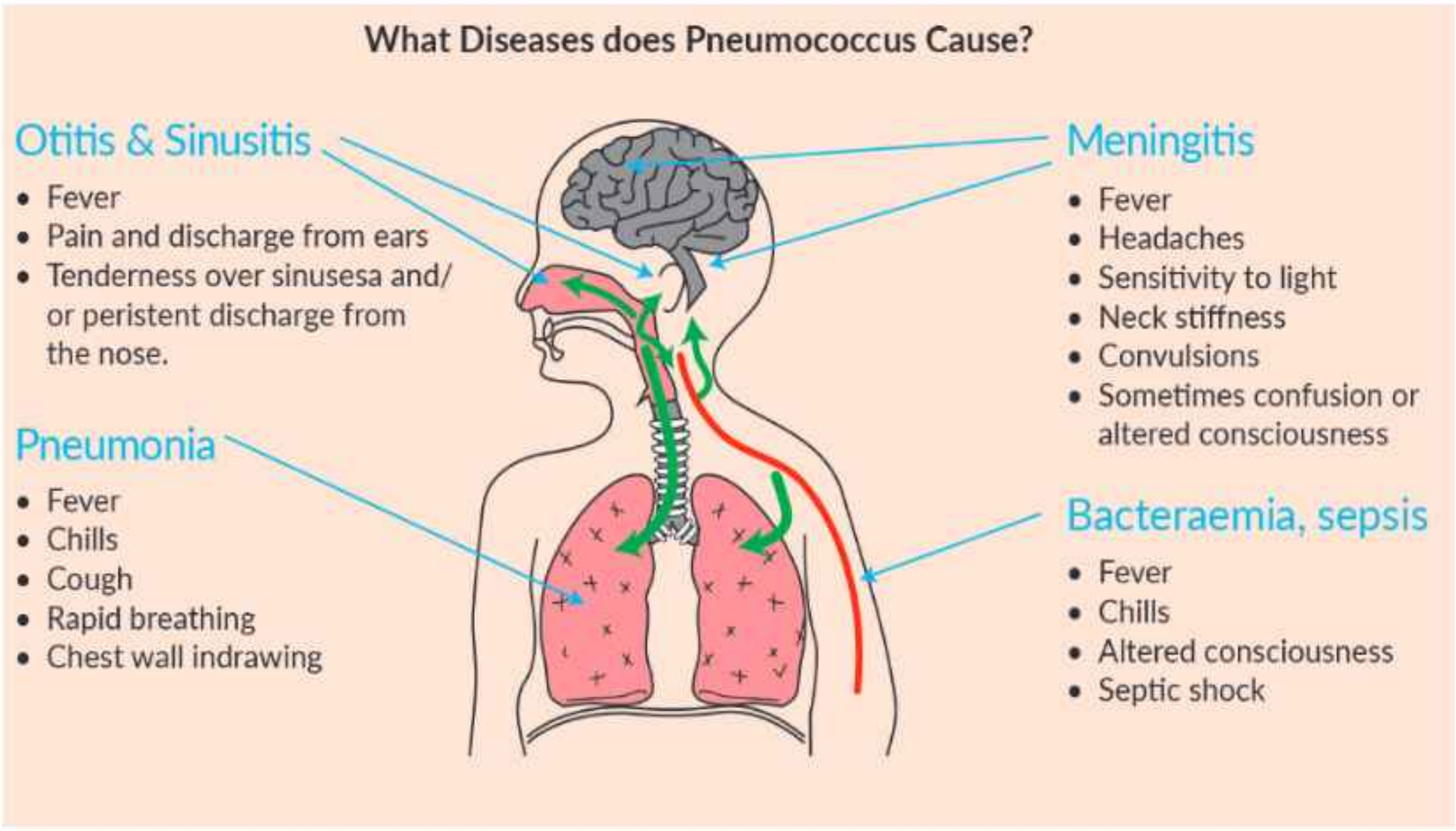
Pneumococcal pneumonia is a form of acute respiratory infection that causes inflammation and accumulation of fluids in the lungs. It makes breathing difficult and limits oxygen intake. Symptoms include cough, chest in-drawing, difficult and rapid breathing. Severely ill infants may be unable to feed or drink and may have convulsions, become unconscious and may even die.

**Question 4. Why do we vaccinate children against pneumococcal disease?**

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

**Question 5. What diseases does pneumococcus cause?**

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.

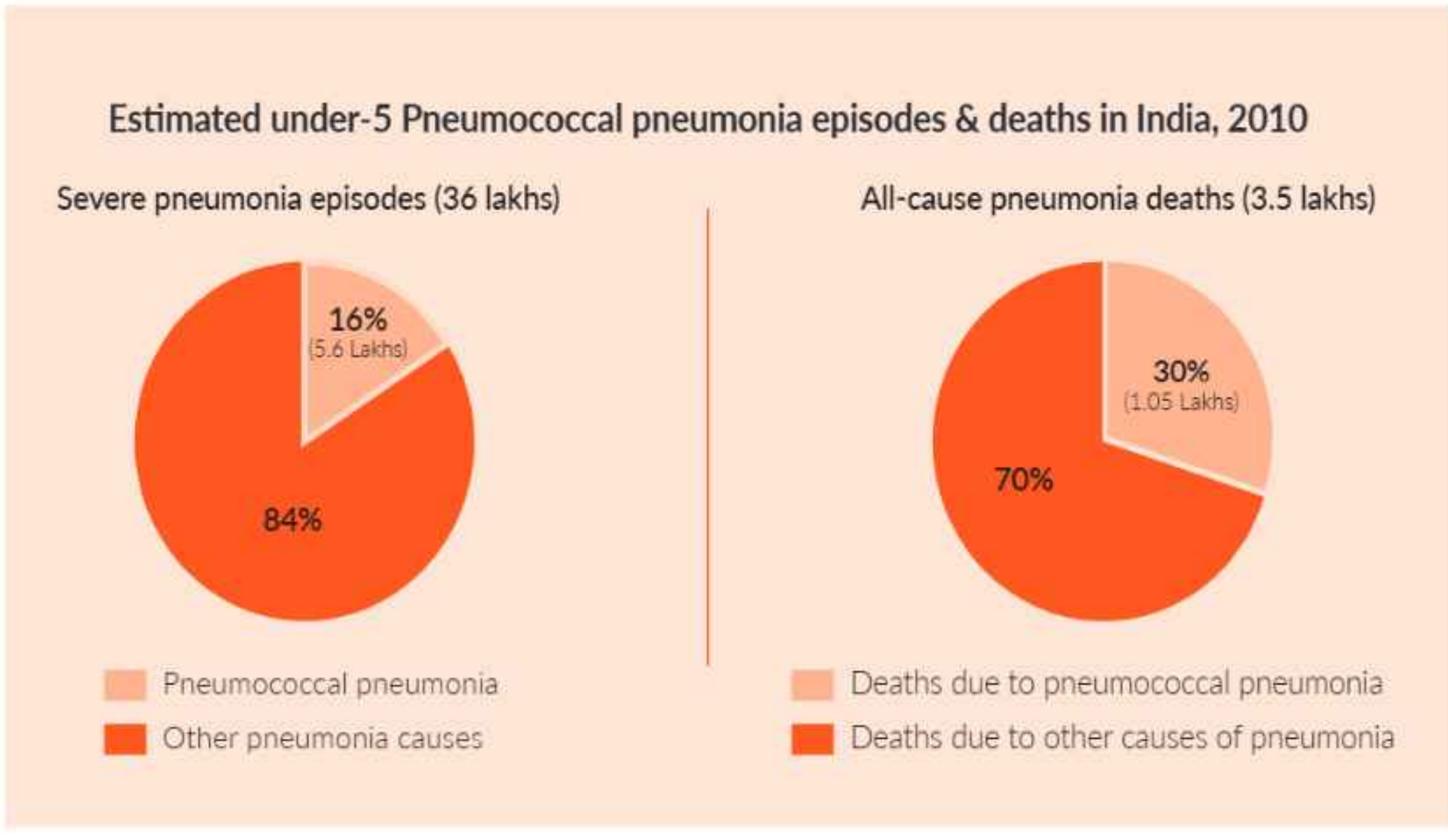



## Question 6. How pneumococcal disease spreads?

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

## Question 7. How common is pneumococcal disease?

Pneumococcal disease constitutes a major public health problem. It is the leading cause of pneumococcal pneumonia. In India, pneumococcal pneumonia was estimated to have caused 105,000 deaths in 2010 and nearly 53300 deaths in 2015.

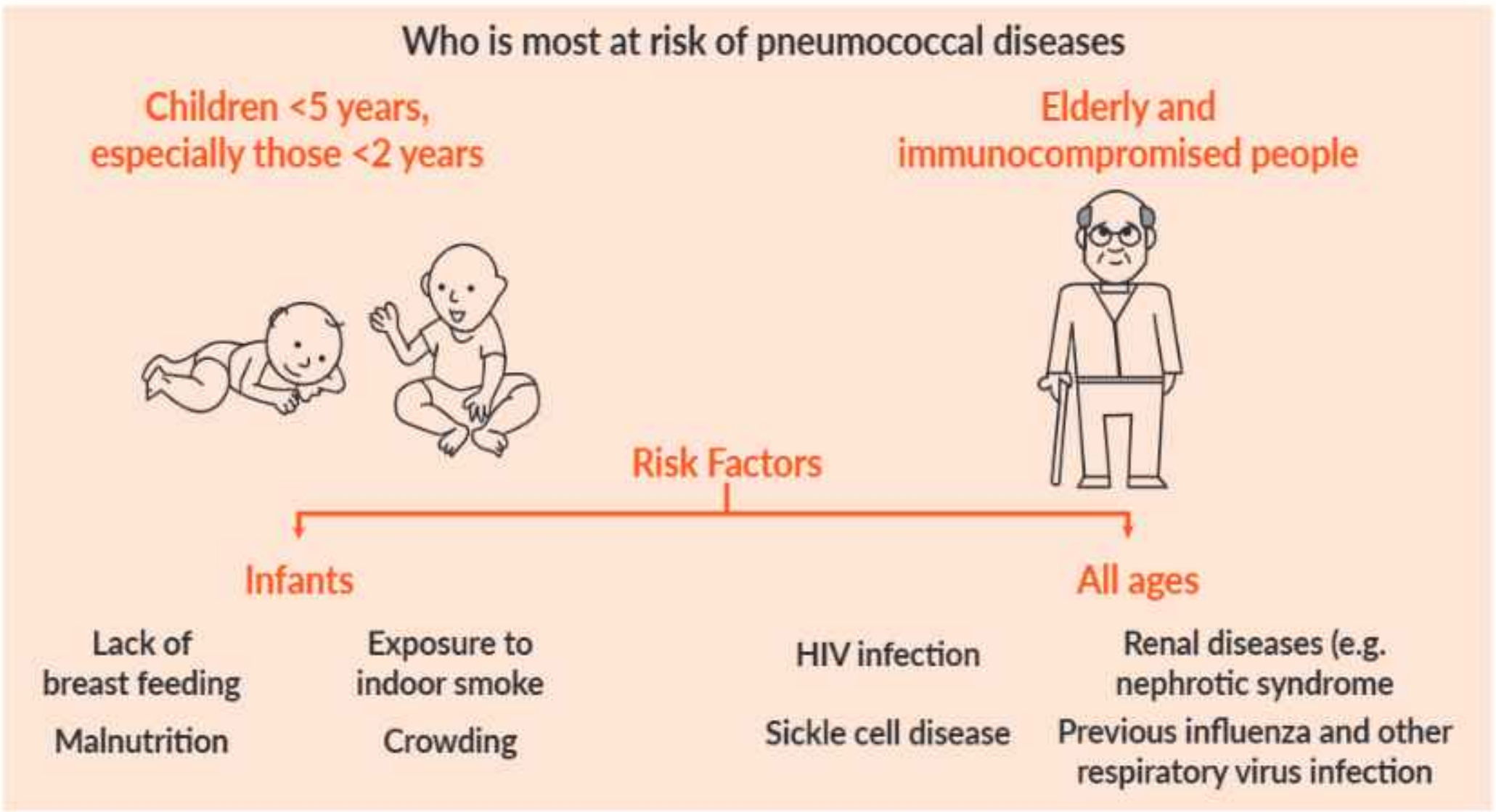


## Question 8. Who is at increased risk of pneumococcal disease?

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

The children most at risk of pneumococcal disease are:

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




## Question 9. What is pneumococcal conjugate vaccine (PCV)?

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

## Question 10. Can pneumococcal disease be treated?

Yes, frontline health workers should be well- trained to identify cases and refer to health facilities for evaluation and treatment. Patients with pneumonia will require antibiotics and supportive care, as per treatment protocols. The antibiotic of choice is amoxicillin. Early diagnosis and appropriate treatment leads to better outcomes. Failure to get treatment early in the course of disease may lead to serious disease, long-term complications or death.

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

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

## Question 11. How is pneumococcal disease diagnosed?

Pneumonia is diagnosed based on clinical evaluation and X-ray imaging. 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 bacterium. This is particularly true of pneumococcal pneumonia because specimens from the actual site of infection (i.e., the lung) cannot be collected and in only a small fraction of pneumococcal pneumonia cases is the blood also infected.

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

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

## Question 12. Will vaccination with PCV prevent all types of Pneumonia?

Vaccination with PCV will mainly protect the child from pneumococcal disease caused by the S. Pneumoniae serotypes present in the vaccine. It will not protect against pneumonia caused by agents other than pneumococcus.

# PCV Implementation

**Question 1. What types of PCV are available?**

PCV is available as PCV10 and PCV13. Both PCV 10 and PCV13 are currently available under the UIP.

**Question 2. What is the difference between PCV10 and PCV13?**

The key features of PCV 10 and PCV 13 available under the UIP are summarised in the table below

| Characteristics of available PCV products under UIP | | |
|---|---|---|
| Discussion point | Prevnar® | Pneumosil ® |
| Manufacturer | Pfizer Inc. | Serum Institute of India Pvt. Ltd. |
| 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, 5, 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, 14 weeks and 9 months | 3 doses at 6, 14 weeks and 9 months |
| Storage temperature | 2-8 °Celsius | 2-8 °Celsius |
| Cold chain volume per dose | 3.6 $cm^3$ | 3.5 $cm^3$ |
| Permissible wastage rate | 10% | 10% |

**Question 3. Is PCV a new vaccine?**

- No, PCV is not a new vaccine. 146 countries are using PCV in the national immunization program.
- In India, under the UIP, PCV has already been introduced in a phased manner, starting 2017. Currently it is available under the the UIP in 5 states namely Himachal Pradesh, Rajasthan, Uttar Pradesh, Madhya Pradesh and Bihar

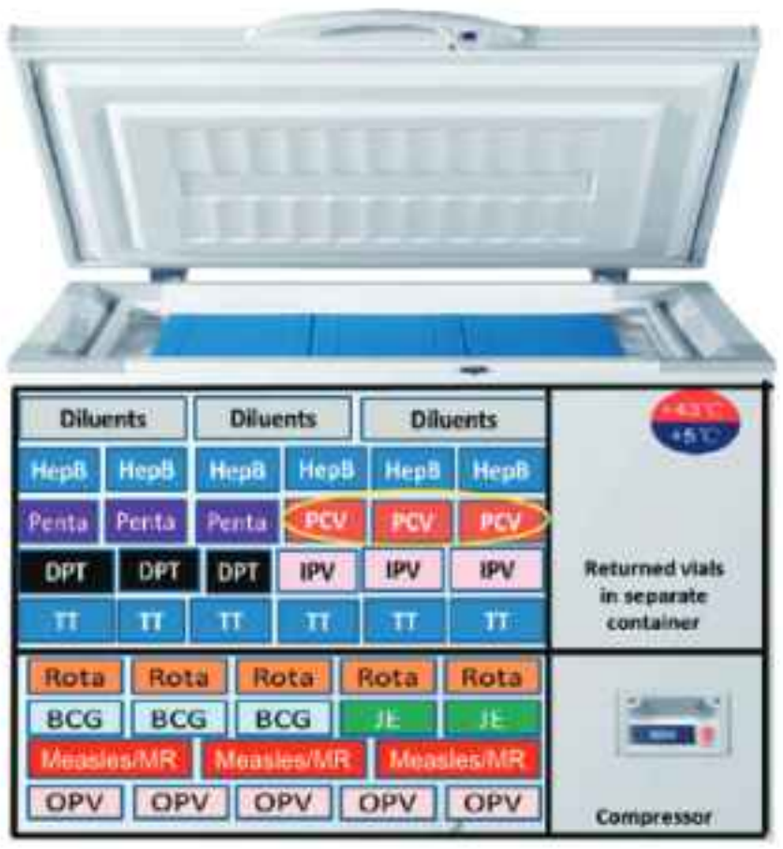
## Question 4. Why is PCV being introduced in India?

PCV has been deemed essential to reduce disease burden and mortality in children under five due to pneumococcal disease.

Pneumococcal disease is the number one vaccine-preventable cause of death in children under five, globally and in India. The NTAGI has recommended introduction of PCV in UIP in India based on disease burden data, safety and efficacy, cost-effectiveness, sustainability and global evidence.

## Question 5. What is the presentation of PCV and how is it stored?

Both PCV10 and PCV13 are liquid vaccines. Under UIP, PCV13 is available in 4-dose vials and PCV 10 is available in 5 dose vials. PCV is a freeze-sensitive vaccine and should not be frozen. It should be stored at temperatures ranging between +2°C and +8°C in the basket of an ice-lined refrigerator. In the ILR, PCV should be placed adjacent to pentavalent vaccine.




## Question 6. How should PCV be transported between different cold chain points?

Like other UIP vaccines, PCV should be transported in cold boxes with conditioned ice-packs.

## Question 7. Will the PCV vials have vaccine vial monitor (VVM)?

Yes, PCV vials will have a vaccine vial monitor (VVM) on the body of vaccine vial. If the VVM reaches the discard point, do not use the vaccine. As long as the color of inner square is lighter than the colour of the outer ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, the vial should be discarded.

## Question 8. How many doses does each PCV vial have?

Each PCV13 and PCV 10 vial used in the UIP will contain four and five doses of PCV respectively. This means that one vial of PCV13 and PCV 10 will have enough vaccine to vaccinate four and five children respectively.

### Question 9. Will Open Vial Policy be applicable to PCV?

Yes, PCV13 (4-dose vial) and PCV 10 (5-dose vial) can be used for a maximum of 28 days on the condition that cold chain principles have been respected, VVM has not reached the discard point, expiry date has not surpassed and has met all other criteria of open vial policy. Open Vial Policy helps to reduce the wastage of the vaccine.

**OPEN VIAL POLICY**

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

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

### Question 10. What is permissible wastage for PCV?

The permissible wastage for PCV is less than 10%.

### Question 11. What is the eligibility criterion for administering PCV?

- A child coming for vaccination at 6 weeks of age or for the first dose of OPV1 & Penta-1 is eligible for PCV-1 along with other scheduled vaccines.
- A child who has received PCV-1 is eligible for PCV-2 at 14 weeks.
- A child who has received PCV-2 is eligible for PCV booster dose at 9 months.
- All children can receive PCV including those born prematurely, those with immunodeficiency and/or malnutrition.
- Only children with an allergy to the vaccine components or a previous allergic reaction to PCV should not receive vaccination.
- In delayed cases beyond 1 year of age, due doses can be given to a child only if a child has received at least one dose of PCV before his/her first birthday.

## Question 12. Is PCV expensive?

- PCV is an expensive vaccine in the private sector.
- Under the UIP of Governemnt of India, PCV will be given free of cost to all eligible infants in the fixed and outreach session sites.

## Question 13. Why is PCV not given before 6 weeks of age?

PCV is licensed for use starting at 6 weeks of age, not before. Newborns have immature immune systems and have received maternal antibodies at birth which may interfere and prevent them from mounting a long-term protective immune response. Adding PCV to the existing UIP six-week vaccination is beneficial because it allows the child to receive multiple vaccines in one healthcare visit. Many newborns have maternal antibodies which provides some protection from disease in the first weeks of life.

## Question 14. What is the vaccination schedule for PCV?

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

| Age | Vaccines given |
|---|---|
| Birth | BCG, OPV-0, Hepatitis B Birth dose |
| 6 Weeks | OPV-1, Pentavalent-1, fIPV-1, Rota-1 & PCV-1* |
| 10 weeks | OPV-2, Pentavalent-2 & Rota-2 |
| 14 weeks | OPV-3, Pentavalent-3, fIPV-2, Rota-3 & PCV-2* |
| 9-12 months | MR1, JE1*, PCV-B* |
| 16-24 months | MR2, JE2*, DPT-B, OPV –B |
| 5-6 years | DPT-B2 |
| 10 years | Td |
| 16 years | Td |
| Pregnant Woman | Td1, 2 or Td Booster** |

*in select states and districts
** one dose if previously vaccinated within 3 years

## Question 15. What will be the sequence of administration of PCV?

OPV: Oral Polio Vaccine, → RVV: Rotavirus Vaccine, → fIPV: fractional-dose IPV, → PCV: Pneumococcal Conjugate Vaccine, → Penta: Pentavalent Vaccine.


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

- JE in endemic districts

## Question 16. What is the maximum age limit for giving the first dose of PCV?

The upper age limit for giving the first dose of PCV is one year of age.

## Question 17. What should be done if a PCV dose is delayed?

- The two primary doses and one booster dose of PCV should be given during the first year of life.
- If the doses are delayed within the first year of life,
  - Doses (both primary and booster) must be separated by a minimum interval of at least 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.
  - For those with at least one previous PCV dose, the series should be completed at the earliest available opportunity.

## Question 18. What are the route, dose and site of injection for PCV?

0.5 ml PCV is to be given as an intramuscular injection into the anterolateral aspect of the right mid-thigh in infants. If more than two injections are to be

given in the same thigh then the distance between the two injections should be at least 2.5 cm (1 inch).

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

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

### Question 19. How effective is PCV?

PCV is highly effective in preventing vaccine serotype pneumococcal disease. PCV covers most of the common serotypes in circulation. After receiving all three doses of pneumococcal vaccine, a child is protected against infections due to strains of pneumococcus in the vaccine but may still get meningitis, pneumonia, or bacteraemia since these can also be caused by other organisms. Timely vaccination during the first year of life is important to provide protection to children when they are most at risk of disease.

### Question 20. Is PCV safe?

The Indian National Regulatory Authority has reviewed available safety data and has approved its use in Indian children. PCV has been introduced into the routine immunization programme of 146 countries, as of June 2020. Multiple studies have shown that PCV can be given safely and effectively along with other routine vaccines.

### Question 21. Does PCV have any side effects?

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

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 the nearest health facility (AEFI management centre) and subsequent doses should not be given.

**Question 22. Can PCV be given to a premature infant (born before 37 weeks gestation)?**

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

**Question 23. Can PCV be given to a sick child?**

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

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

**Question 24. Can PCV be given to an immunodeficient child?**

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

**Question 25. Are there any contraindications for use of PCV?**

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

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

**Question 26. What should you do if you find a frozen PCV vial?**

PCV is a freeze-sensitive vaccine. If you find a frozen PCV vial, do not use the vaccine.

Suspected frozen vials of DPT, Pentavalent, Td, HepB, PCV vaccines can be tested for freezing through Shake Test procedure.

## REMEMBER

- PCV is a freeze sensitive vaccine.
- All vaccines come with VVM - Check VVM before use.
- As part of open vial policy, all partially used vials should be sent back to the vaccine storage point the same day.
- PCV is an expensive vaccine.
- It will be provided free-of-cost to children under the UIP.

**If PCV found frozen**

- Do not use
- Mark the vial as shown below
- Discard vaccine as per guidelines
- Inform MO incharge & cold chain handler

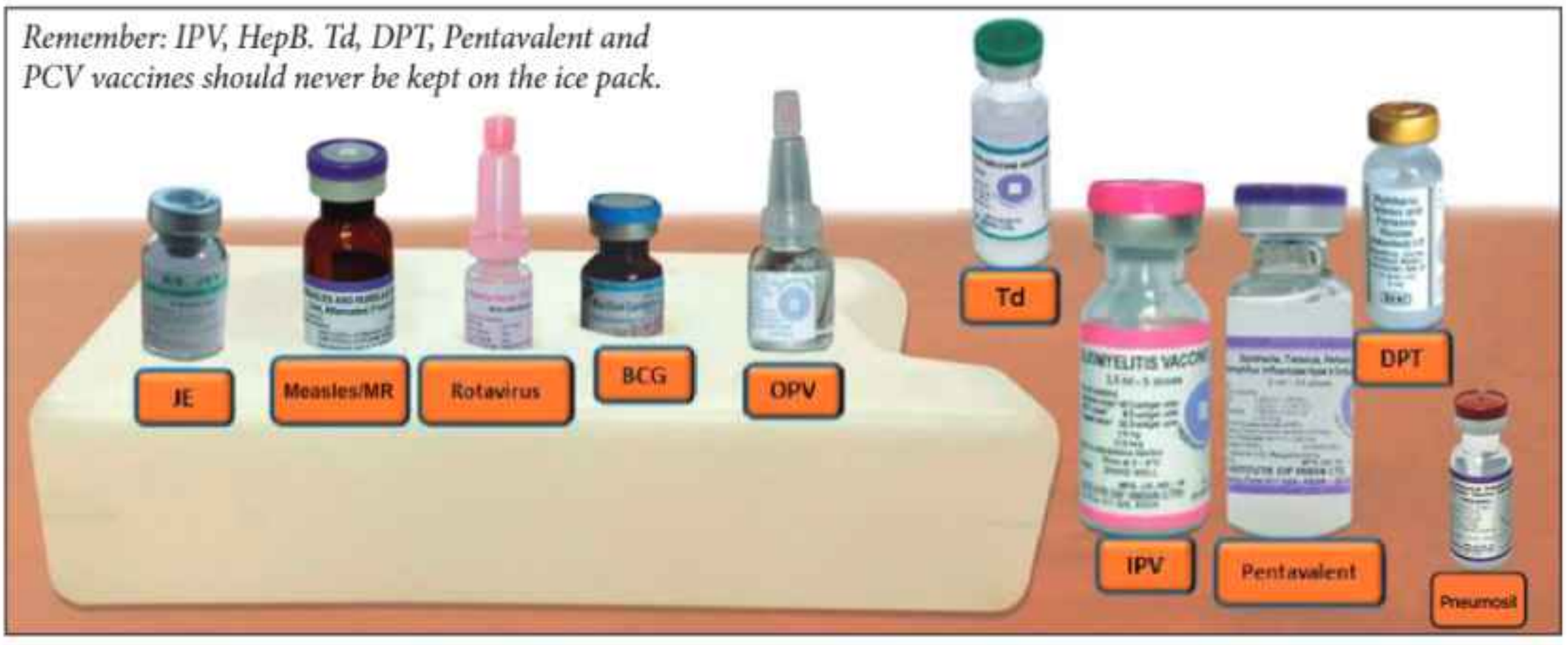
**Question 27. Which vaccines should be kept on an ice pack and which are the vaccines not to be kept on ice pack at the immunization site?**

As per routine immunization guidelines, health workers are expected to take out one ice pack at the session site and use the same after opening the heat-sensitive vaccine.

On the hole of Ice Pack: BCG and Measles Rubella (place them in the wells on ice pack).

On the surface of Ice Pack: OPV, RVV and JE vaccines

Not to be kept on Ice Pack: Penta, DPT, IPV, Td & PCV.




**Question 28. What key messages should be given to the parents or care-givers on the immunization session site after doing immunization?**

The four key messages should be given to parents/care-givers on the immunization session site.

## Four key messages for caregivers

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

**Question 29. Which government health facilities in our country will provide PCV?**

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

**Question 30. Should PCV be given to a child coming from a state which has not yet introduced PCV in its schedule?**

Yes, PCV should be given to a child irrespective of the state where she/he comes from, as per the current guidelines.

**Question 31. Will PCV be given in Intensified /Mission Indradhanush?**

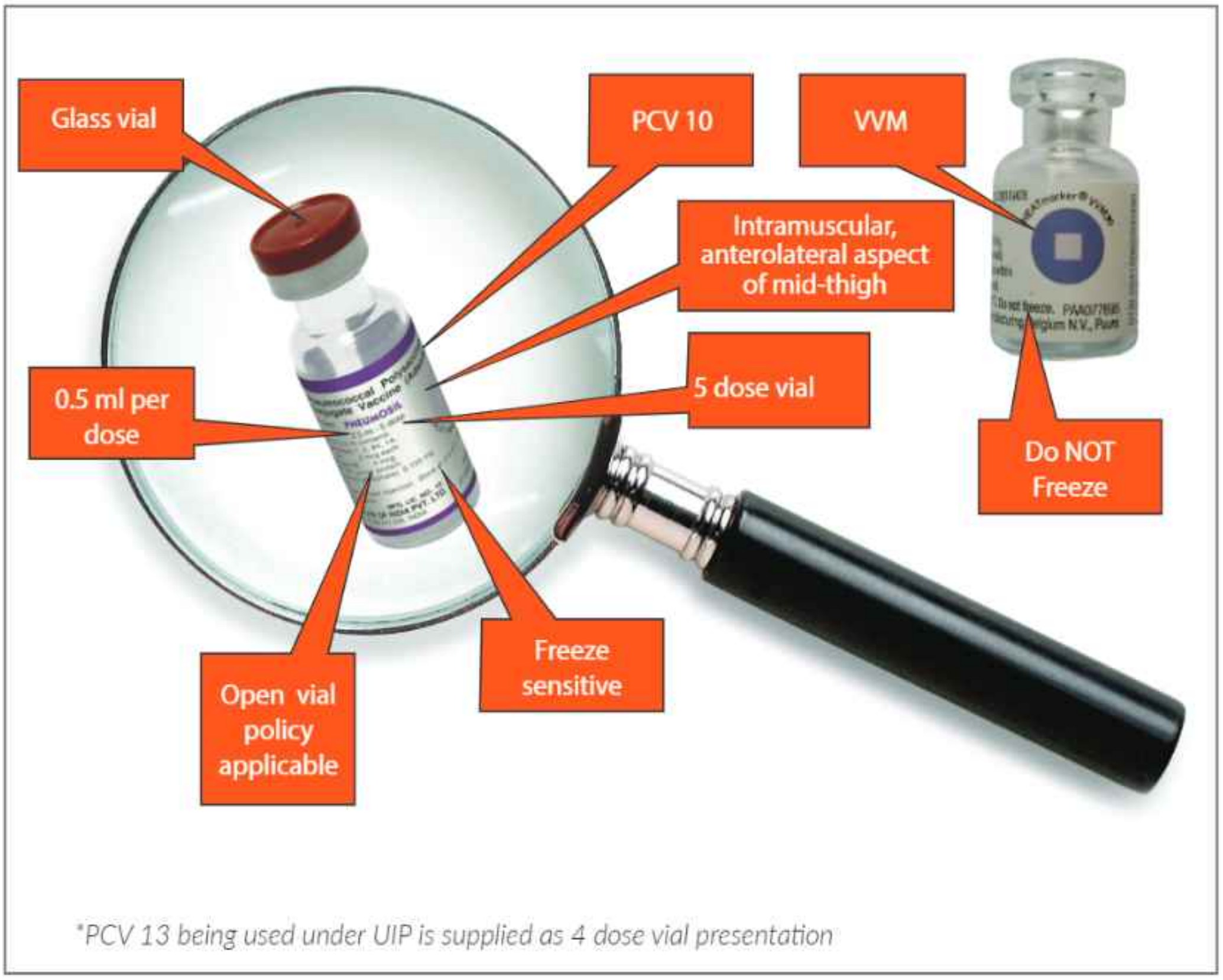
Yes, PCV will be given in Intensified /Mission Indradhanush following the same guidelines as for Routine Immunization.

**Question 32. Where will the PCV dose be recorded in the MCP card?**

- PCV doses have to be recorded in the MCP card.
- If the card has been revised to include PCV doses, it should be recorded at appropriate columns 1 ½ month (6 weeks) of age and 3 ½ month (14 weeks) of age and 1 booster dose at 9 months
- If the card has not been revised to include PCV doses, separate manual entries should be made to record PCV doses in the card.

**Question 33. Will PCV be a part of ASHA's full immunization incentive?**

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




*PCV 13 being used under UIP is supplied as 4 dose vial presentation

# Some FAQs on Multiple Injections

**Question 1. Why do children need multiple injections on one visit?**

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

**Question 2. Is it safe to give multiple injections at one visit?**

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

**Question 3. Why can PCV not be given at a separate visit from the other scheduled vaccines to avoid giving multiple injections at one visit?**

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

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