Picture Box

Refresher training on Pneumococcal Disease & new Multi-Dose Vial (MDV) presentation

Picture Box A

All content is developed and owned by Agence de Médecine Préventive (AMP),
under technical guidance and review of World Health Organization (WHO).
Training is funded by Pfizer Inc.

Pfizer

amp AGENCE DE MEDECINE PREVENTIVE

World Health Organization

Foreword

The aim of this refresher training is to strengthen capacity of local health workers to ensure pneumococcal conjugate vaccine 13 (PCV13) deployment and use, including use and handling of PCV13 multi-dose vials in accordance with WHO Multi-Dose Vial Policy.
This first Picture Box includes training content for module 1 ‘Pneumococcal Diseases’, Module 2 ‘Current PCV and New PCV13 MDV’, and Module 3 ‘Handling of Multi-Dose Vial in Accordance with WHO Policy’.



Learning Objectives

- Explain pneumococcal disease
- Explain treatment and prevention measures
- Describe the characteristics of pneumococcal vaccines and their administration
- Describe the specificities and benefits of the new multi-dose presentation
- Explain WHO Multi-Dose Vial Policy
- Describe how to properly store and handle PCV13 single- and multi-dose vials, in accordance with WHO Multi-Dose Vial Policy
- Explain the purpose and use of the Vaccine Vial Monitor (VVM)



Duration

- Introduction, pre-test, and modules 1 to 3 will last approximately 2h 30
- This duration does not include time for breaks and lunch

Table of contents (1)

Module 1: Pneumococcal Diseases

Sequence 1: Generalities on Pneumococcal Diseases *p6*

- What is Pneumococcal Disease?
- What Diseases does Pneumococcus Cause?
- Other Causes of Pneumonia and Meningitis?
- Who is most at Risk?

Sequence 2: Disease Transmission *p10*

- How is Pneumococcal Disease Spread?

Sequence 3: Pneumococcal Disease Treatment and Prevention *p11*

- What Treatment and Prevention Measures?

Memorization *p12*

- What do you Remember?

Table of contents (2)

Module 2: Current PCV and New PCV13 MDV

Starter Activity *p14*

- What do you already know?

Sequence 1: Characteristics of Pneumococcal Vaccines *p15*

- What are Pneumococcal Vaccines?
- What Protection is Offered by PCVs?
- What Presentations Exist for PCV?

Sequence 2: Vaccine Administration *p18*

- When is PCV Given to Children?

Sequence 3: PCV Contraindications and Side Effects *p19*

- Who Should not be Given PCV?
- What are the Side Effects of PCV?

Memorization *p21*

- What do you Remember?

Table of contents (3)

Module 3: Handling of Multi-Dose Vial in Accordance with WHO Policy

Sequence 1: WHO Multi-Dose Vial Policy *p23*

- What is WHO Multi-Dose Vial Policy?
- What about Risks of Contamination?

Sequence 2: Monitoring Heat Exposure *p25*

- What are Vaccine Vial Monitors (VVMs)?
- What is the Purpose of VVM?
- How to Read and Interpret the VVM?
- Where is VVM Located for PCVs?

Sequence 3: Vaccine Storage *p29*

- What are PCV Storage Temperatures?
- PCV Storage in Front-Opening Refrigerators?
- PCV Storage in Top-Opening Refrigerators (1)?
- PCV Storage in Top-Opening Refrigerators (2)?
- What are the Rules for PCV Storage?

Memorization *p34*

- What do you Remember?

Picture Box

Refresher training on Pneumococcal Disease & new Multi-Dose Vial (MDV) presentation

Module 1: Pneumococcal Diseases

What is Pneumococcal Disease?

Instructions: Explain the illustration to the participants, then ask them, in their opinion and based on the illustration, what other organs can be infected by S. Pneumoniae and what kind of diseases this bacterium may cause.

Explanation

- Pneumococcal disease: **disease** caused by bacterium *Streptococcuus pneumoniae*, also known as **pneumococcus**
- **It is a bacterial infection**
- Common cause of morbidity and mortality worldwide, rates of disease and death are higher in developing countries, with the majority of deaths in sub-Saharan Africa and Asia
- *S. pneumoniae*: **part of normal flora of upper respiratory tract**, resides in the nasopharynx of healthy carriers
- Infections of the upper respiratory tract e.g., sinuses and middle ear can occur **through contiguous spread** from nasopharynx leading to sinusitis and otitis media
- In some individuals the organism can spread to other locations and **cause other diseases**

Expected Answers

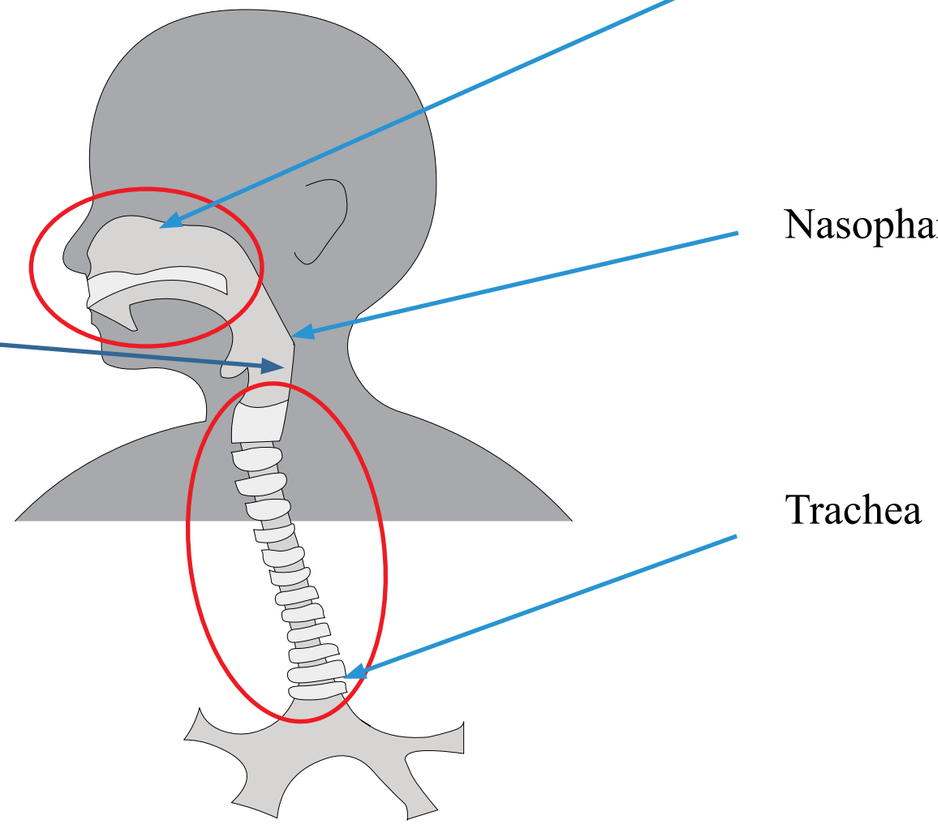
- ► Other locations: lung, bloodstream, meninges (brain)
- ► Diseases: otitis (middle ear infection), pneumonia (lung infection), meningitis, sepsis or bacteremia (bloodstream infections)
- ► Note: despite its name, “pneumonia” is just one type of disease caused by pneumococcus, it can cause many other types of diseases (see next slide)

What is Pneumococcal Disease?

Streptococcus pneumoniae
Pneumococcus



A bacterial infection



What Diseases does Pneumococcus Cause?

Instructions: Explain the illustration to the participants.

Explanation

- Different types of diseases caused by pneumococcus:
  - » **Pneumonia:** inflammation of the lungs
  - » **Bacteraemia, sepsis:** bloodstream infection, with or without infection of secondary sites, e.g., meningitis (see below)
  - » **Bacterial meningitis:** infection of the membranes that cover and protect the spinal cord and brain
  - » **Middle ear infection (otitis)**
  - » Sinusitis, bronchitis
- Symptoms and signs:
  - » All types of pneumococcal disease - fever with or without shaking or chills
  - » Pneumonia - fever with or without shaking or chills, cough, rapid breathing, chest wall indrawing
  - » Meningitis - fever, headaches, sensitivity to light, neck stiffness, convulsions, and sometimes confusion or altered consciousness
  - » Bacteraemia and sepsis - fever, chills, low alertness
  - » Otitis and sinusitis - fever, pain, and discharge from the ears (otitis), tenderness over sinuses and / or persistent discharge from the nose

Key Messages

- ► Besides pneumonia, pneumococcus can cause different kind of diseases: meningitis, bacteraemia, sepsis, otitis, and sinusitis, etc

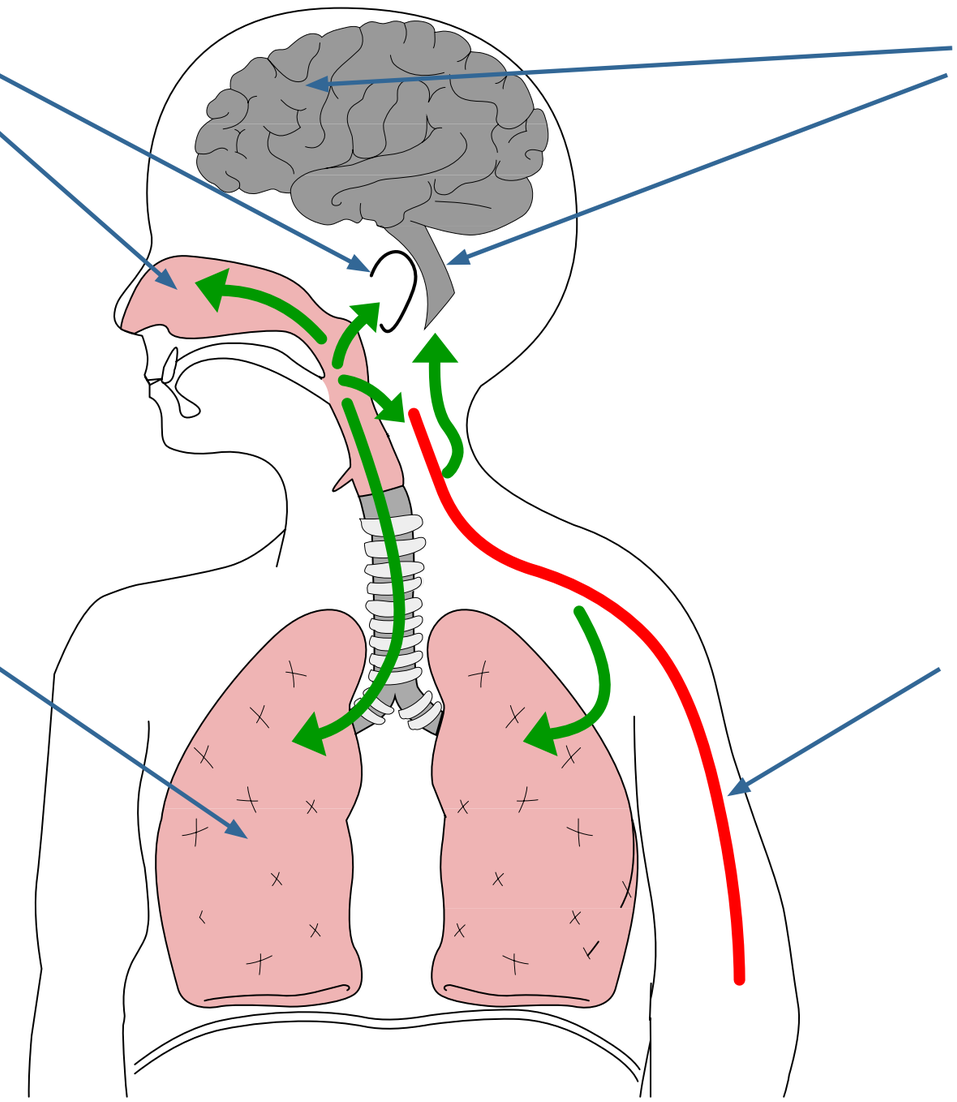
What Diseases does Pneumococcus Cause?

Otitis and Sinusitis

- **Fever**
- Pain and discharge from ears
- Tenderness over sinuses and / or persistent discharge from the nose

Meningitis

- **Fever**
- Headaches
- Sensitivity to light
- Neck stiffness
- Convulsions
- Sometimes, confusion or altered consciousness



Pneumonia

- **Fever with or without shaking or chills**
- Cough
- Rapid breathing
- Chest wall indrawing

Bacteraemia, sepsis

- **Fever**
- Chills
- Altered consciousness
- Septic shock

Other Causes of Pneumonia and Meningitis?

Instructions: Explain the illustrations to the participants.

Explanation

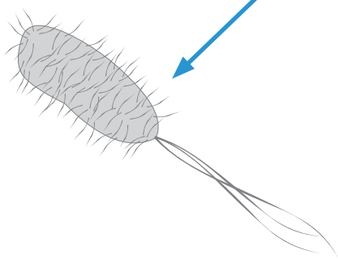
- Pneumonia and meningitis can be caused by micro-organisms other than *S. pneumoniae*
- Pneumonia is caused by:
  - » A variety of bacteria including *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Haemophilius influenzae* (Hib)
  - » Viruses: respiratory syncytial virus (RSV), influenza virus
  - » Often, a disease episode is caused by several pathogens
- Meningitis is also caused by:
  - » A variety of **bacteria** including *Streptococcus pneumoniae*, *Neisseria meningitidis,* and also *Haemophilus influenzae* type b (Hib). Can be **life threatening** and requires immediate **medical attention.** Can lead to **life-long disability** in a large fraction of survivors
  - » Several viruses, including enteroviruses, Japanese encephalitis, arboviruses, herpesviruses, and mumps. **Less severe** than bacterial meningitis, and people with normal immune system usually get better on their own

Key Messages

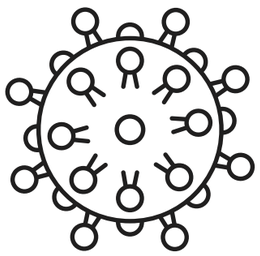
- ► Pneumococcus **is not the only cause** of pneumonia and meningitis among children
- ► Pneumonia is a very important health problem in children causing about **15-20% of deaths** among young children
- ► Meningitis among children can lead to **life-long disability in 15-20% of surviving children** - hearing loss, learning disability, and other physical disabilities. **Bacterial meningitis is deadly** unless **treated immediately with the relevant antibiotics**. Even with proper treatment, 3-25% of affected children may die

Other Causes of Pneumonia and Meningitis?

Pneumonia



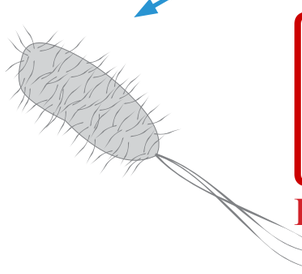
Several bacteria:
- *Streptococcus pneumoniae*
- *Staphylococcus aureus*
- *Klebsiella pneumoniae*
- *Haemophilius influenzae*



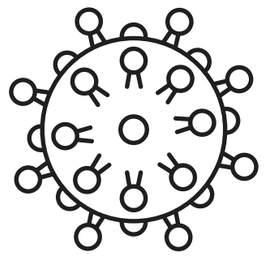
Viruses:
- RSV
- Influenza virus

15-20% deaths among young children

Meningitis



Several bacteria:
- *Streptococcus pneumoniae*
- *Neisseria meningitidis*
- *Haemophilus influenzae type b*



Viruses:
- Enteroviruses
- Japanese encephalitis
- Arboviruses
- Herpesviruses
- Mumps

Deadly unless treated immediately
Life-long disability for survivors

Who is most at Risk?

Instructions: Explain the illustrations to the participants.

Explanation

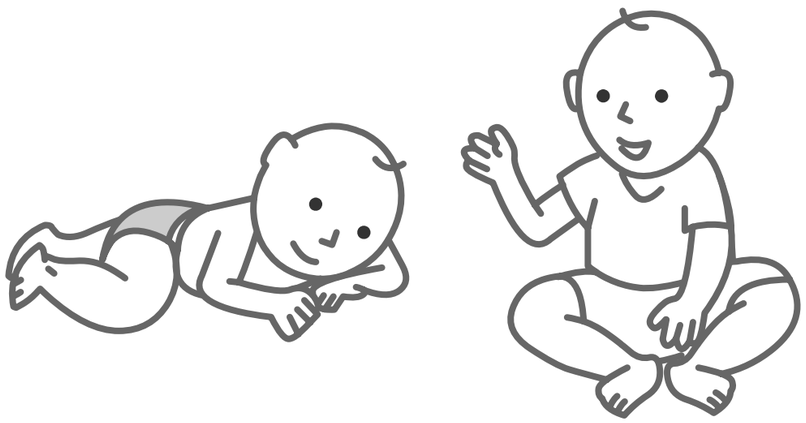
- Those most at risk of pneumococcal disease are:
  - » Children under five years of age and **especially those under two years of age**. They are the most at risk of developing and dying from the disease
  - » Elderly and immunocompromised individuals
- Other risk factors include:
  - » For infants: lack of breastfeeding, exposure to indoor smoke, malnutrition, crowding, etc
  - » Even among young children, the risk is not uniform and is highest in poor and marginalized populations with poor access to health care
  - » For all ages: HIV infection, sickle cell disease, renal diseases (e.g., nephrotic syndrome), previous influenza, and other respiratory virus infection

Key Messages

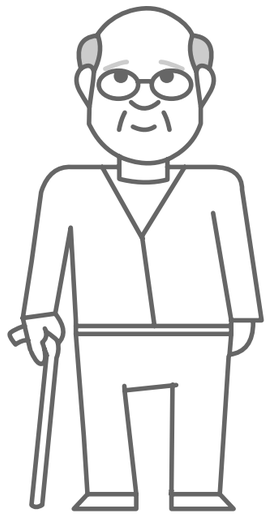
- ► Pneumococcus mainly causes disease among children under two years of age and older adults, or those with underlying risk factors (e.g., HIV, sickle cell disease)
- ► Risk is highest in poor and marginalized populations with poor access to health care. For this reason, promoting equitable coverage is very important. This is an important message in terms of promoting equitable coverage

Who is most at Risk?

Children < 5 years, especially those < 2 years



Elderly and immunocompromised people



Risk factors

Infants

Lack of breastfeeding

Malnutrition

Exposure to indoor smoke

Crowding

All ages

HIV infection

Sickle cell disease

Renal diseases (e.g., nephrotic syndrome)

Previous influenza and other respiratory virus infection

How is Pneumococcal Disease Spread?

Instructions: Explain the illustration to the participants.Then ask participants if pneumococcal disease can be treated and / or prevented, and how.

Explanation

- Children and adults may carry pneumococcus in their throats and noses (nasopharynx). The risk of carriage varies by age group, geographic setting, and other risk factors
- Respiratory droplets spread bacteria. Therefore similar to flu, pneumococcus is spread from one person to the other by coughing, sneezing, or through close contact
- Explanation of the transmission scheme:

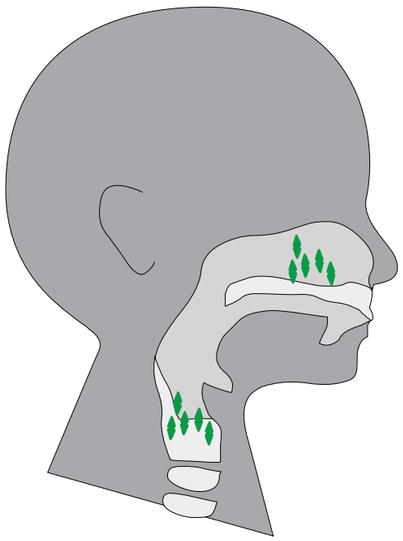
1. Some individuals exposed will not become a carrier or be infected
2. A subset of those exposed can develop the disease
3. Over a year, a lot of individuals are infected. That is, over the course of a year, a lot of people will have pneumococcus identified in their nasopharynx
4. Among these infected individuals, some develop invasive pneumococcal disease (IPD). IPD incidence is highest in young children under five years. Global estimate for the year 2000 was 2,330 per 100,000

Key Messages

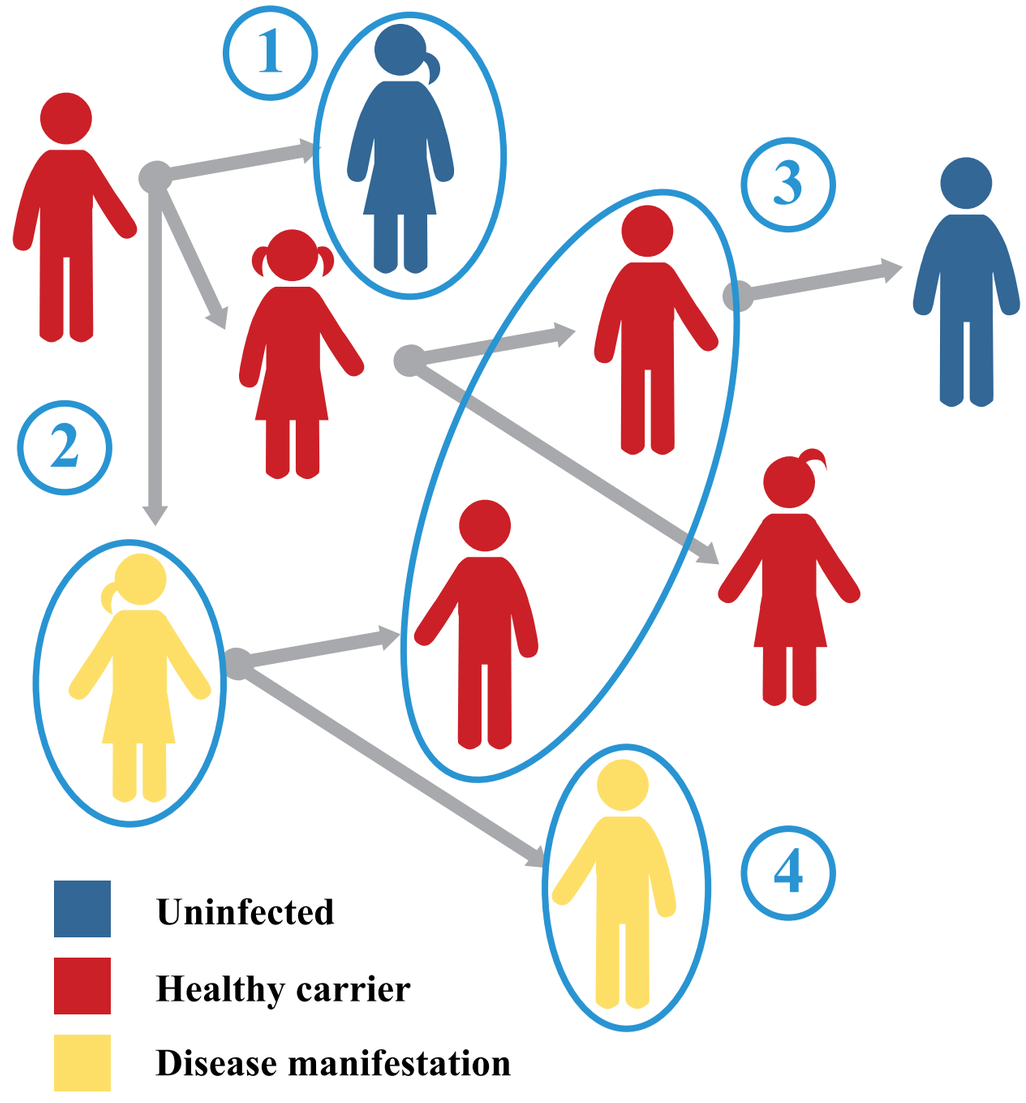
- Pneumococcus spreads mainly through coughing or sneezing via air droplets
- Not all individuals exposed will become a carrier or be infected
- A subset of those exposed will develop the disease

How is Pneumococcal Disease Spread?

From sick and healthy people







What Treatment and Prevention Measures?

Instructions: Explain the illustration to the participants. Then ask which is better, prevention or treatment.

Explanation

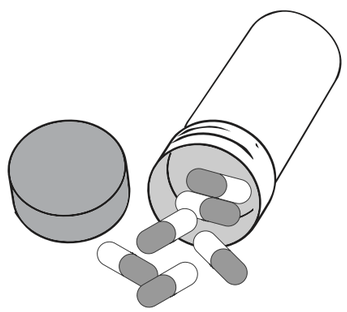
- Treatment:
  - » Pneumococcal disease can be treated with **antibiotics**, such as amoxicillin, penicillin and co-trimoxazole, that are commonly used to treat pneumococcal infections
  - » However, in many countries, strains of pneumococcus are **becoming resistant to these antibiotics**, so they are **no longer effective**
  - » Moreover, some children will die despite treatment or have long-term consequences in terms of disability, growth, or cognitive functions
- Prevention: Pneumococcal disease **can be prevented by vaccination = most efficient preventive measure**
- Protection: The risk of pneumococcal disease and death can be reduced through: hand washing, exclusive breastfeeding for first six months, and reducing indoor air pollution (tobacco smoke and pollutants)
- Prevention and protection are better together: they help infants to stay healthy by strengthening their immune system

Key Messages

- ► Treatment is not always efficient and vaccines do not work against all pneumococcal disease
- ► For these reasons, control of pneumococcal disease can only be achieved by a combination of strategies to prevent, protect, and treat (according to Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea - GAPPD)
- ► So we should not say that prevention is better than treatment

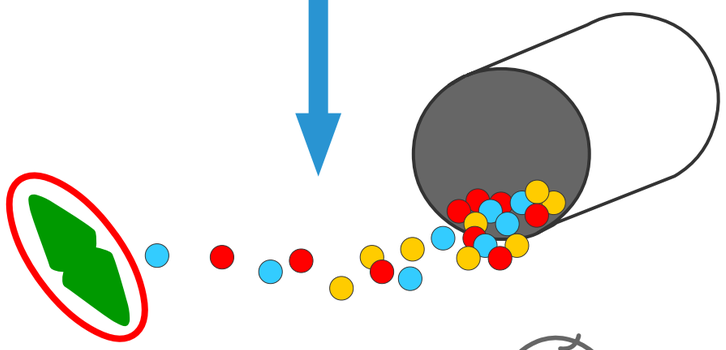
What Treatment and Prevention Measures?

Treatment



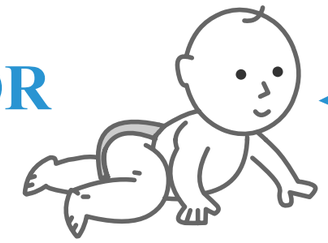
Antibiotics:
- **Amoxicillin**
- **Penicillin**
- **Co-trimoxazole**

BUT



Develop resistance to antibiotics

OR



Die despite treatment

Life-long disability

Prevention + Protection

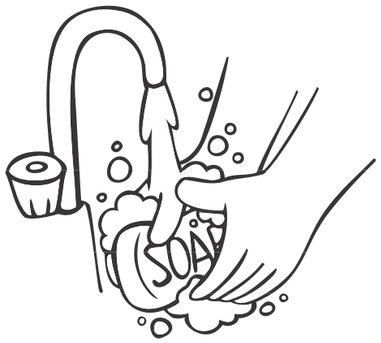


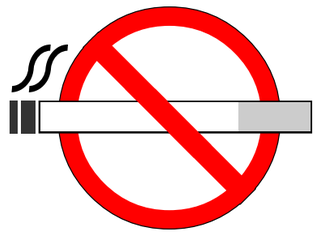
BUT

Not efficient against all types of pneumococcus disease



First six months





What do you Remember?

Instructions: Ask the participants the following questions, gather the responses and complete if necessary.

Questions

- Where can you find pneumococcus, and what kind of disease does it cause, and with what consequences?
- Who are most at risk of catching pneumococcal disease?
- How are pneumococcal diseases transmitted?
- How can you treat / prevent / protect against pneumococcal diseases?

Expected Answers

- Pneumococcus is part of the normal upper respiratory tract and resides in the nasopharynx of healthy carriers. Infections of the upper respiratory tract e.g., sinuses and middle ear can occur through contiguous spread from nasopharynx leading to sinusitis and otitis media. In susceptible individuals (children, elderly, immunocompromised individuals), the bacterium can spread to: the lungs and cause pneumonia; the bloodstream and cause bacteremia or sepsis; the spinal cord and brain and cause meningitis. Bacterial pneumonia causes about 15-20% of deaths among young children. Bacterial meningitis is deadly unless treated immediately with the relevant antibiotics, and even survivors may have severe disabilities
- The most at risk are children under two years of age. But the risk is not uniform and is highest in poor and marginalized populations with poor access to health care
- Pneumococcal diseases are transmitted by air droplets during coughing, sneezing, or close contact
- Can be treated by antibiotics, but not effective in some cases due to antibiotic resistance. Can be prevented by vaccination, and risk can be reduced by washing hands, exclusive breastfeeding for first six months, and reducing indoor air pollution

What do you Remember?



► Where can you find pneumococcus, and what kind of disease does it cause, and with what consequences?

► Who are most at risk of catching pneumococcal disease?

► How are pneumococcal diseases transmitted?

► How can you treat / prevent / protect against pneumococcal diseases?

Picture Box

Refresher training on Pneumococcal Disease & new Multi-Dose Vial (MDV) presentation

Module 2: Current PCV and New PCV13 MDV

What do you already know?

Instructions: Ask the participants to use Post-it notes to write what they already know about pneumococcal vaccines. Next, ask them to stick their notes on the Picture Box page. discuss with the group, and sort true / false information with them.

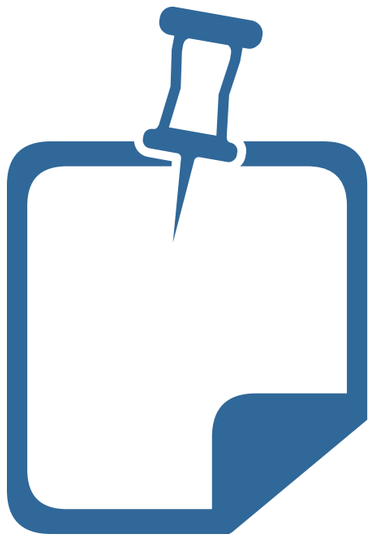
Questions

- What do you already know about pneumococcal vaccines?

Expected Answers

- No specific answers are expected. This activity will allow you to take into account the knowledge of the participants on the subject

What do you already know?



Stick your notes here

What are Pneumococcal Vaccines?

Instructions: Explain the illustration to the participants.

Explanations

- What are pneumococcal vaccines?
  - » Pneumococcus = a bacterium with an outer **polysaccharide (or sugar) capsule**
  - » **Many serotypes of pneumococcus** have been identified, based on the different types of capsule
  - » Pneumococcal vaccines have been developed based on the serotypes frequently found in severe pneumococcal disease (IPD) patients
- Two categories of pneumococcal vaccines:
  - » **Pneumococcal polysaccharide vaccines**: were used for many years; they contain the purified capsule of up to 23 serotypes of pneumococcus but only produce **short-term protection** and are **not too effective in infants and young children**
  - » **PCV:** overcome the limitations of polysaccharide vaccines by conjugating, or binding, the capsule with a protein; this results in **longer-lasting protection** and makes the vaccine **more effective in children**. In addition, PCV reduces nasopharyngeal carriage and, thereby, reduces pneumococcal transmission, leading to indirect protection of unimmunized individuals

Key Messages

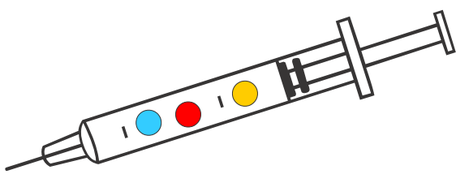
- ► Pneumococcal vaccines have been developed based on the serotypes frequently found in severe pneumococcal disease
- ► PCVs offer longer-lasting protection, and are the most effective in infants and young children

What are Pneumococcal Vaccines?

Pneumo vaccines



Different types of polysaccharide capsule
=
Different serotypes

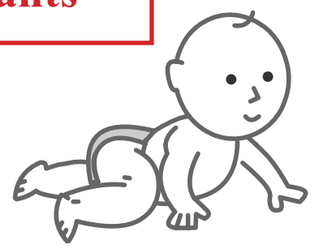


Two categories

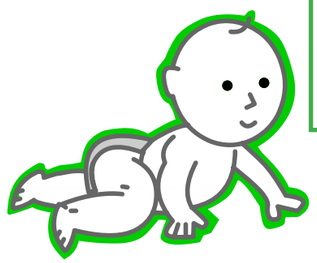
Polysaccharide vaccines

BUT

Not too effective in infants



Conjugate vaccines (PCV)



- **Longer-lasting protection**
- **Reduces pneumococcal transmission**
- **Better indirect protection**

What Protection is Offered by PCVs?

Instructions: Explain the illustrations to the participants.

Explanation

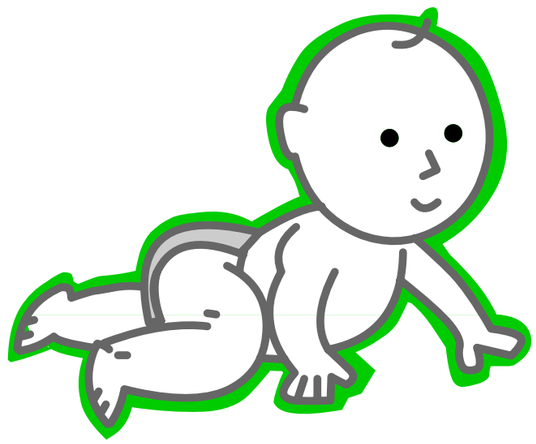
- PCVs are highly effective.
- **They protect against severe forms of pneumococcal disease, such as meningitis, pneumonia, and bacteremia,** and diseases caused by vaccine type pneumococcus (non-bacteraemic pneumonia, otitis media)
- But it will not protect against these conditions if they are caused by non-vaccine serotypes of pneumococcus, and other agents, including non-vaccine serotypes of pneumococcus

Key Messages

- PCVs are **highly effective against severe forms of pneumococcal disease,** such as meningitis, pneumonia, and bacteremia

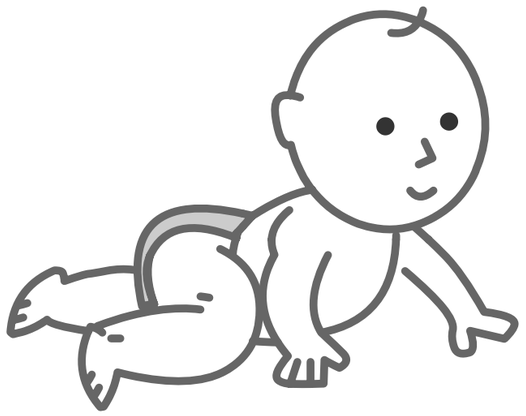
What Protection is Offered by PCVs?

HIGHLY EFFECTIVE



PROTECT AGAINST SEVERE FORMS OF PNEUMOCOCCUS DISEASE (meningitis, bacteremia, and bacteraemic pneumonia)

BUT



Do not protect against: meningitis, pneumonia, and bacteremia caused by non-vaccine serotypes of pneumococcus and other agents

What Presentations Exist for PCV?

Instructions: Explain the illustrations to the participants.

Explanations

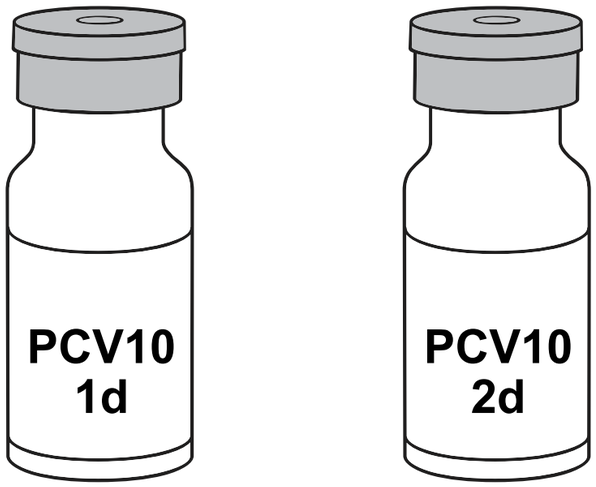
- All PCVs have a liquid formulation
- PCV10:
  - » Single-dose vial, preservative free
  - » 2-dose vial, preservative free
  - » Prefilled syringe
- PCV13:
  - » Single-dose vial without preservative
  - » New 4-dose vial, with preservative
  - » Prefilled syringe
  - » Note that **PCV13 4-dose vial occupies the same storage volume as a single-dose vial** (2ML)

Key Messages

- ► The main value of PCV13 MDV is:
  - » Possibility to **vaccinate up to four children with one vial**
  - » **Reduced cold chain requirements,** which has huge programmatic **implications in terms of cost** (transport, storage,…), coverage, risk of stock out, etc
  - » **Reduced cost per dose,** which is an important factor for long-term vaccine availability

What Presentations Exist for PCV?

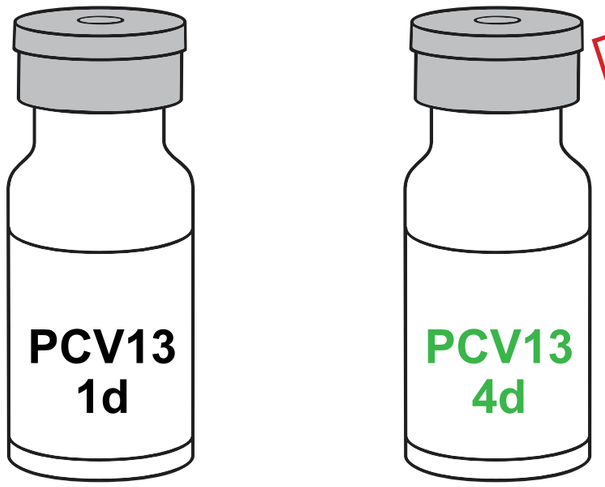
PCV10



Single dose preservative free

2 doses preservative free

PCV13



Single dose preservative free

4 doses with preservative



Prefilled syringe



Prefilled syringe

When is PCV Given to Children?

Instructions: Explain the illustration to the participants.

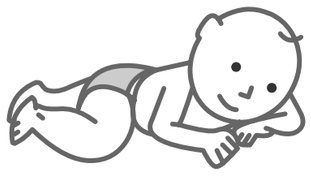
Explanations

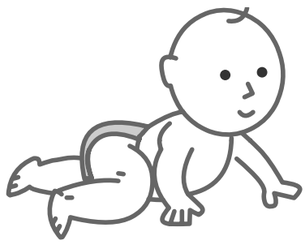
- PCV should be given **priority in childhood immunization programmes**, particularly in countries with high mortality in children under five years of age
- Two options for PCV schedule:
  - » First dose of PCV13 is given as early as **six weeks of age**, then two other doses are given at **four-week intervals** (at 10 and 14 weeks) in a three-dose primary series schedule
  - » First dose of PCV13 can be given at six weeks, followed by a second dose at least eight weeks later (14 weeks or more) and a third dose (booster dose) later in the first year, or early in second year of life (9-15 months of age)
- It is delivered at a young age because most of the children are infected in this period of time, and **the highest risk of bad outcomes are in the first year of life**
- PCV was inserted into the pentavalent schedule for programmatic ease
- If a child is late for the second or third dose: give the remaining doses with at least one month interval between the doses.
- Note that this schedule is mostly focused on PCV13. Other vaccines may be added to the vaccination schedule, according to the country

Key Messages

- ► PCV is given **in the first months of a child's life**
- ► First dose of PCV13 should be given at **six weeks of age**, followed by the two other doses with the same schedule as pentavalent vaccine (3+0 schedule), or in an alternative 2+1 schedule (two doses before six months of age + booster dose at 9-15 months of age)

When is PCV Given to Children?







Birth	BCG	Hepatitis B (monovalent)		**Option 1 (3+0)**	**Option 2 (2+1)**
6 weeks	OPV1	DTP-HepB-Hib (pentavalent 1)		PCV13 (1)	PCV13 (1)
10 weeks	OPV2	DTP-HepB-Hib (pentavalent 2)		PCV13 (2)	
14 weeks	OPV3	DTP-HepB-Hib (pentavalent 3)	IPV	PCV13 (3)	PCV13 (2)
9 months	Measles			PCV13 (3) = Booster dose	
15 months					

Who Should Not be Given PCV?

Instructions: Explain the illustrations to the participants.

Explanations

- Pneumococcal vaccine **should NOT be given to an infant** if he / she:
  - » Has **had a severe allergic reaction** to a prior dose of PCV or to any vaccine containing **diphtheria toxoid**, including pentavalent vaccine, such as anaphylaxis or hypersensitivity (that can manifests as an itchy rash, swelling of the eyelids, lips, or tongue, shortness of breath, vomiting, lightheadedness, low blood pressure, etc.)
  - » Has moderate or severe illness (temperature ≥39°C). In this case, he / she should not be vaccinated until health conditions improve
  - » Note that mild illness such as an upper respiratory tract infection is NOT a contraindication, so you should give PCV in this case

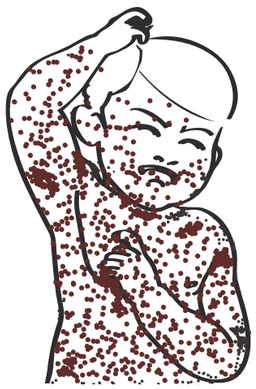
Key Messages

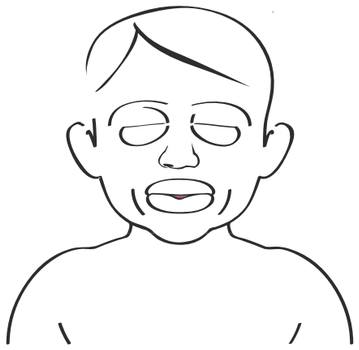
- ▸ Pneumococcal vaccine **should NOT be given to infants with an allergic reaction to a vaccine**, especially if this is a severe allergic reaction, or if the reaction occured after injection of pentavalent vaccine
- ▸ For a child with a **temperature ≥39°C**, wait until his / her **condition improves**

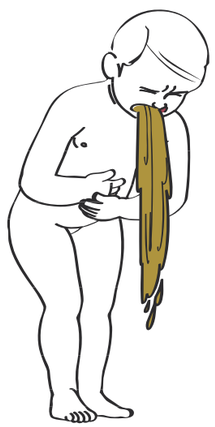
Who Should Not be Given PCV?

Contraindication to vaccination
Vaccine should <u>NOT</u> be given when:

The individual has a severe allergic reaction to a prior dose, or to vaccines containing diphtheria toxoid

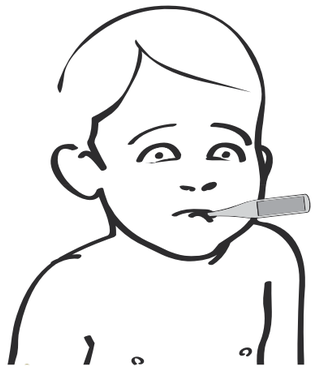






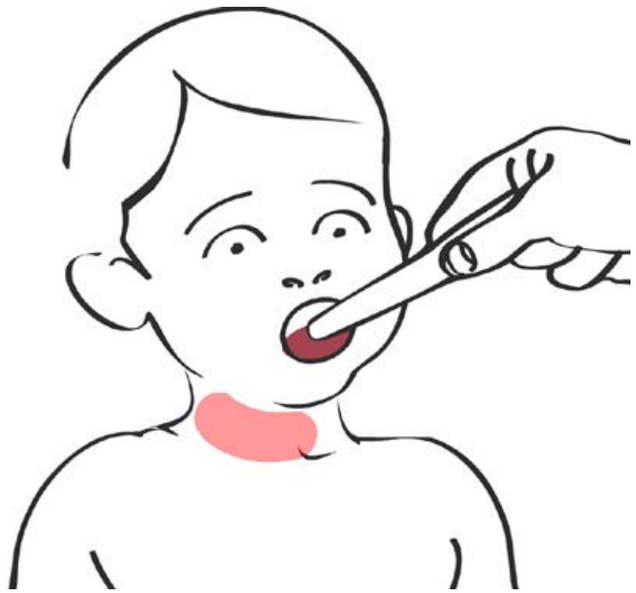


T° ≥ 39°C



BUT

Mild illness such as upper respiratory tract infection



is <u>NOT</u> a contraindication!

What are the Side Effects of PCV?

Instructions: Explain the illustration to the participants.

Explanations

- Most common side effects for PCVs are:
  - » Mild reactions, such as irritability and crying (very common)
  - » Swelling and tenderness at injection site (also common - about one in two)
  - » Transient fever >39˚C (about one in 20)

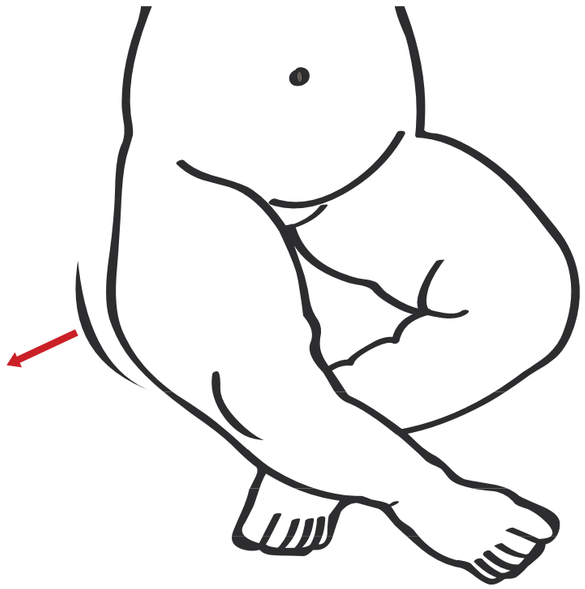
Key Messages

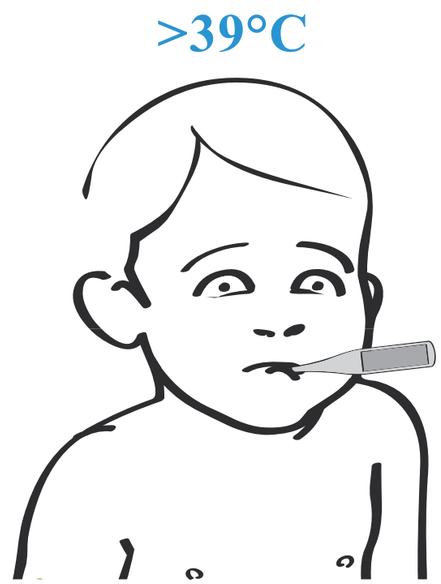
- ► PCV vaccines have some side effects that need to be considered, taken care of and / or treated
- ► Serious adverse events are very rare

What are the Side Effects of PCV?

Most common side effects







What do you Remember?

Instructions: Ask the participants the following questions, gather their answers, and complete if necessary.

Questions:

- How have pneumococcal vaccines been developed and what are the benefits of PCVs?
- What are the different presentations of PCV13?
- What is PCV13 vaccination schedule?
- What are the contraindications and side effects of PCV?

Expected Answers

- Pneumococcal vaccines have been developed based on the pneumococcus serotypes frequently found in severe pneumococcal disease or IPD patients. These serotypes are based on the different types of polysaccharide capsules enveloping the bacterium. Unlike pneumococcal saccharide vaccine, PCV offers a long-lasting protection for children, and are highly effective against severe forms of pneumococcal diseases, such as meningitis, pneumonia, and bacteremia
- PCV13 now has two presentations: (1) A single-dose vial with preservative or prefilled syringe, and now (2) a 4-dose vial allowing for the vaccination of four children with the same vial
- There are two options for PCV13 schedule: First dose is given as early as six weeks of age, then two other doses are given at four-week intervals (at 10 and 14 weeks); or first dose is given at six weeks, followed by a second dose at least eight weeks later (14 weeks or more) and a third dose later at 9-15 months of age
- PCV contraindications: Should not be given to infants with a severe allergic reaction to a prior dose, or to vaccines containing diphtheria toxoid, such as pentavalent. Most common PCV side effects: irritability, crying, swelling at injection site, transient fever >39°C

What do you Remember?



► How are pneumococcal vaccines developed and what are the benefits of PCVs?

► What are the different presentations of PCVs?

► What is the PCV vaccination schedule?

► What are the contraindications and side effects of PCVs?

Picture Box

Refresher training on Pneumococcal Disease & new Multi-Dose Vial (MDV) presentation

Module 3: Handling of Multi-Dose Vial in Accordance with WHO Policy

What is WHO Multi-Dose Vial Policy?

Instructions: Ask the participants to read the summary of the WHO Multi-Dose Vial Policy.

Key Messages

- **To be used several days after opening, four other conditions need to be met:**
  - The vaccine must be **prequalified by WHO**, a condition this vaccine meets
  - The vaccine must be approved for use **up to 28 days after opening** the vial, as determined by WHO; and PCV13 MDV can be used for up to 28 days. This applies generally for vaccines with preservative
  - The expiry date of the vaccine has not passed
  - The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures, the vaccine vial monitor has not past its discard point, and the vaccine has not been damaged by freezing

What is WHO Multi-Dose Vial Policy?

All opened WHO-prequalified multi-dose vials of vaccines **should be discarded at the end of the immunization session**, or within **six hours of opening**, whichever comes first, unless the vaccine meets **all four of the criteria listed below**.
If the vaccine meets the four criteria, the opened vial **can be kept and used for up to 28 days after opening**.

The criteria are as follows:

1. The vaccine is currently prequalified by WHO.
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
3. The expiry date of the vaccine has not passed.
4. The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures; furthermore, the **VVM**, if one is attached**, is visible on the vaccine label** and **has not past its discard point**, and the vaccine **has not been damaged by freezing**.

If **ALL of the criteria** cited above are present, the vaccine vial may be kept and used **for up to 28 days** after opening, or until all the doses are administered.

What about Risks of Contamination?

Instructions: Explain the illustrations to the participants.

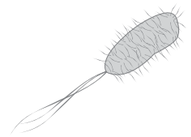
Explanation

- The **risk of contamination** with a pathogenic organism is **higher in a multi-dose vial** than in a single-dose vial, because the vaccine is repeatedly exposed - every time a dose is withdrawn
- **Preservatives prevent growth of bacterial contamination**, and for this reason MDV with preservative (4-dose PCV13) **can be kept longer after opening** than a MDV without preservative (2-dose PCV10). This is according to the WHO Multi-Dose Vial Policy
- PCV13 MDV can be used up to 28 days, if all the other conditions described previously are met, whereas **PCV10 MDV must be discarded after a maximum of six hours**

Key Messages

- Opened PCV13 MDV (with preservative) can be used up to 28 days after opening. Given that the expiry date has not passed, the VVM is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing
- PCV10 MDV (without preservative) must be discarded six hours max after opening, or at the end of the session, whichever comes first

What about Risks of Contamination?



MORE EXPOSED



Single-dose vial

Used one time, directly after opening



Partially used PCV multi-dose vial with preservative (4-dose PCV13)

Can be used up to 28 days



Partially used PCV multi-dose vial without preservative (2-dose PCV10)

Discard after 6 hours max

What are Vaccine Vial Monitors (VVMs)?

Instructions: Explain the illustrations to the participants.

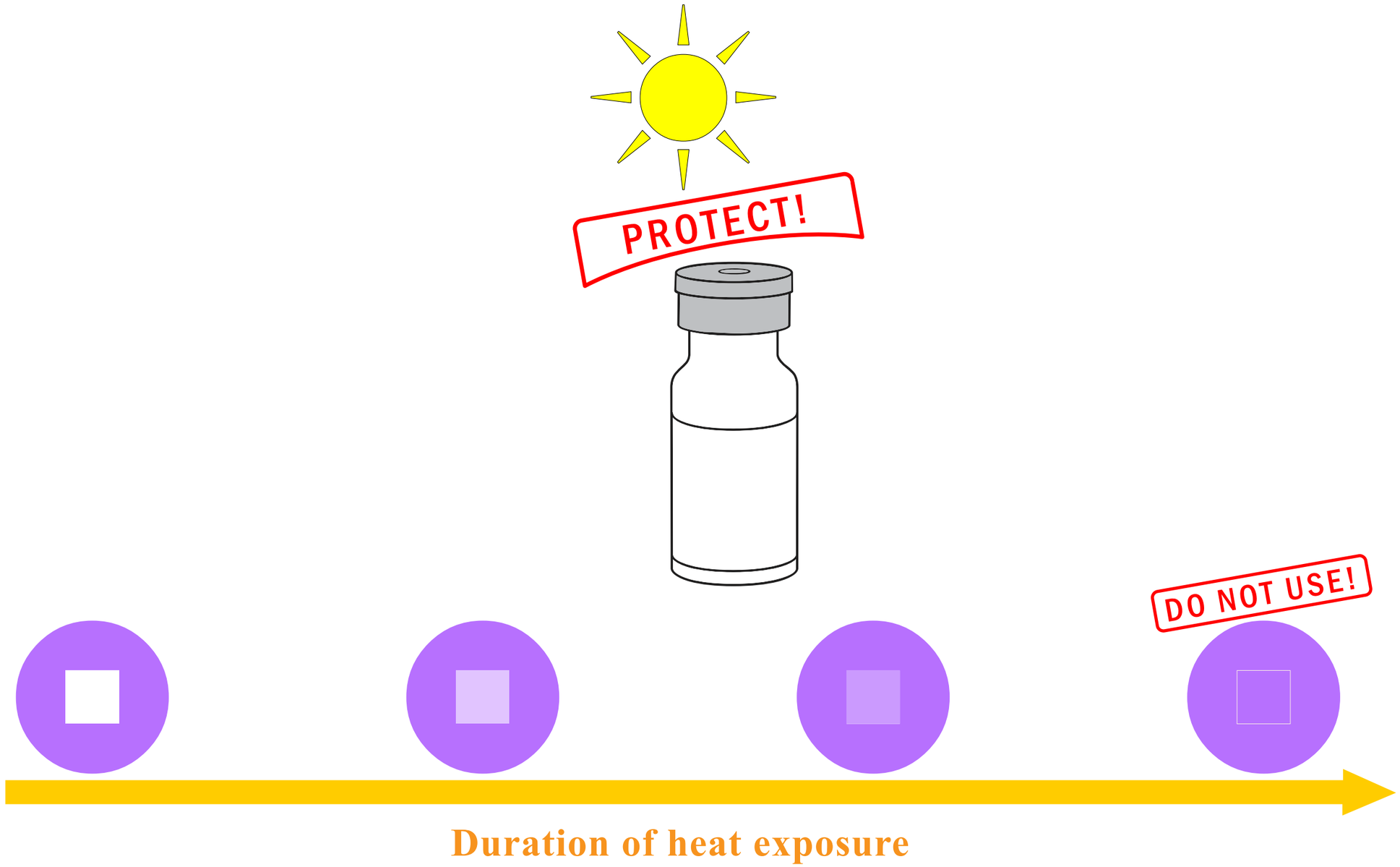
Explanation

- Besides freezing, exposure to excess heat can also reduce a vaccine's potency. It is necessary to **protect the vaccine** from excess exposure to **heat and light**
- Vaccine vial monitors (VVMs) are **the only temperature monitoring devices** that routinely accompany vaccines throughout the **entire supply chain** (from the manufacturer to user)
- A VVM is a chemical indicator label attached to the vaccine container (vial, ampoule, or dropper) by the vaccine manufacturer. As the container moves through the supply chain, the **VVM records its cumulative heat exposure** through a gradual change in color. If **the color of the inner square is the same color as the outer circle or darker**, **the vaccine has been exposed to excess heat** and should not be used

Key Messages

- ► It is necessary to **protect the vaccine** from excess exposure to **heat and light**
- ► VVMs are **the only temperature monitoring devices** that routinely accompany vaccines throughout the **entire supply chain.** VVMs record vaccine **cumulative heat exposure**
- ► If the color of the inner square of the VVM is **the same color as the outer circle or darker**, the vaccine **should not be used**

What are Vaccine Vial Monitors (VVMs)?



What is the Purpose of VVM?

Instructions: Explain the illustrations to the participants.

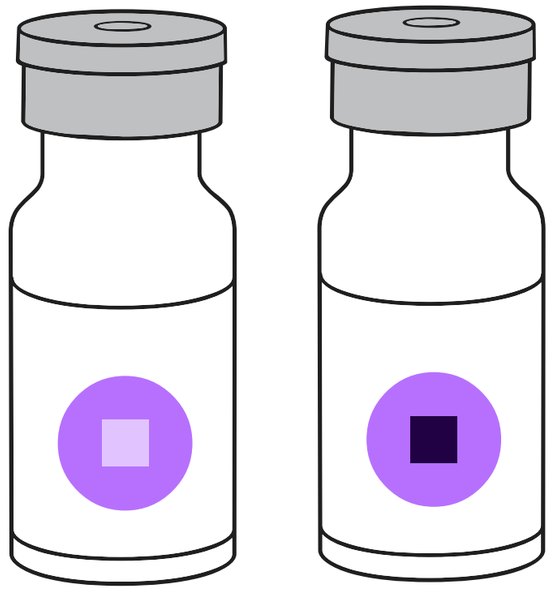
Explanation

- The main purpose of VVMs is to ensure that **heat-damaged vaccines are not administered**
- The VVM status is also used to decide **which vaccines can safely be used after a cold chain failure.** This allows programme managers to minimize wastage
- VVM status also helps to decide **which vaccines should be used first**: a batch of vaccine showing significant heat exposure should be distributed and used before a batch that shows lower heat exposure, **even if its expiry date is later**

Key Messages

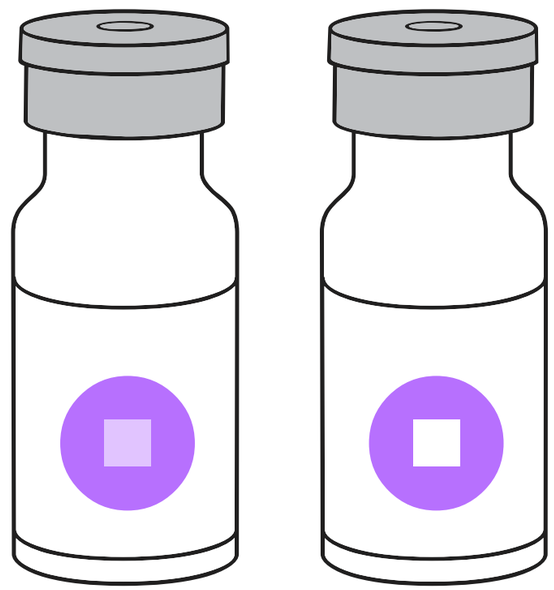
- The main purpose of VVMs is to ensure that **heat-damaged vaccines are not used**, thus preserving **vaccine quality and effectiveness, as well as minimizing vaccine wastage**

What is the Purpose of VVM?



Use

Do not use



Expire in one month

Expire in two weeks

Use first

How to Read and Interpret the VVM?

Instructions: Explain the illustrations to the participants.

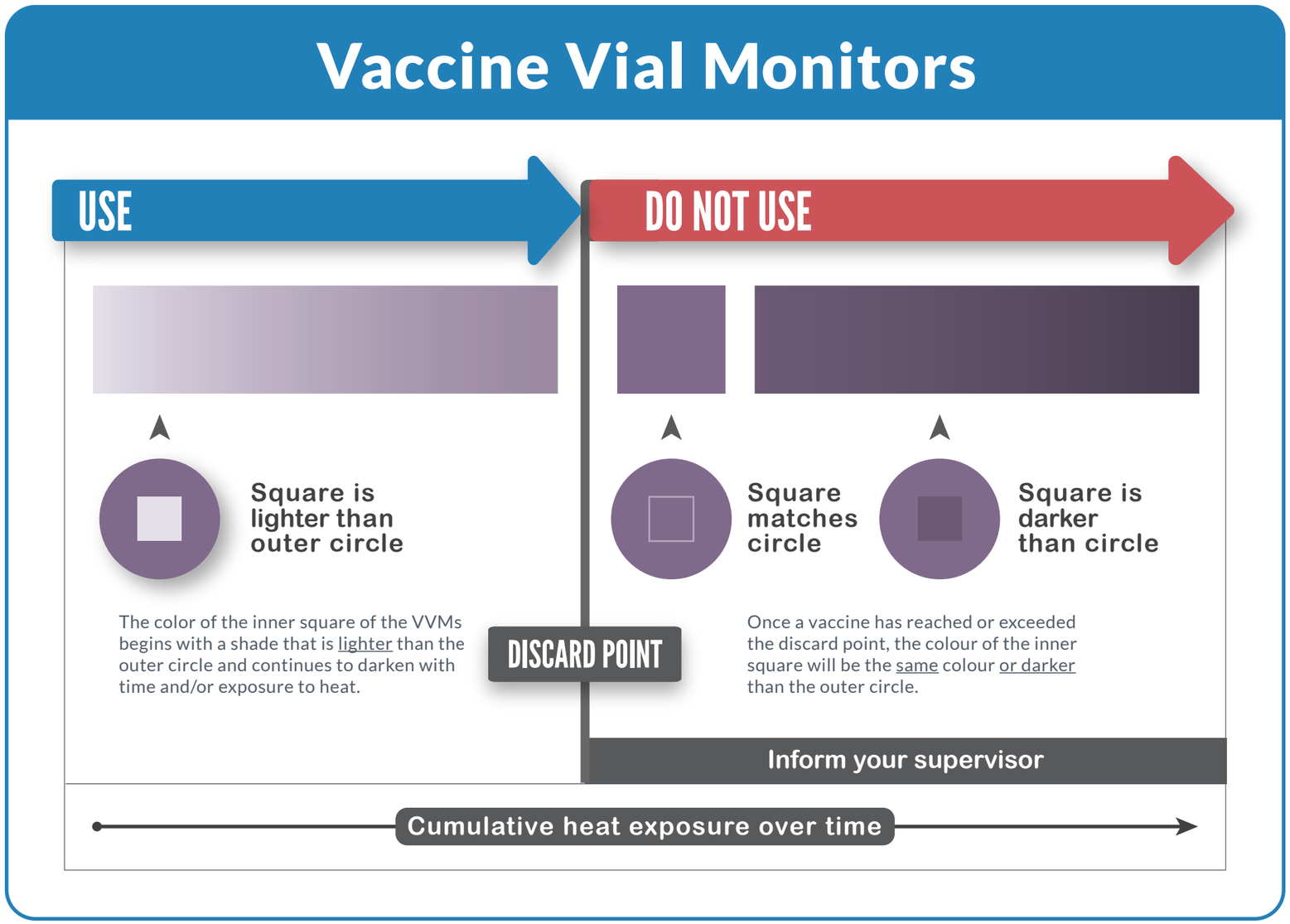
Explanation

- The initial VVM color of the inner square is much lighter in shade than the outer circle - never pure white, but always slightly purple
- From this point onward, the inner square starts to darken in color as a consequence of the vial exposure to heat. As long as the inner square is **lighter than the outer circle**, you can **use the vaccine**, but you need to **check the expiry date**
- When the temperature and / or duration of heat exposure reaches a level which **degrades the vaccine**, the square becomes **as dark as the outer circle**: this is the VVM discard point. At this point, **do not use the vaccine**, and **report quickly to your supervisor**
- Of course, you need to apply the same procedure if the inner square is **darker than the outer circle**

Key Messages

- ► As long as the inner square is **lighter than the outer circle**, you can **use the vaccine**, but you need to **check the expiry date**
- ► **Do not use the vaccine**, and **report quickly to your supervisor** if the inner square is **as dark as,** or **darker than** the outer circle

How to Read and Interpret the VVM?



Where is VVM Located for PCVs?

Instructions: Explain the illustrations to the participants. Then ask why, in their opinion, VVM is placed on the label (and not on the top) for multi-dose vials.

Explanation

- For PCV13 single-dose vial, VVM is placed on the cap of the vial
- For PCV13 multi-dose vial, **VVM is placed on the label**, according to WHO Multi-Dose Vial Policy
- Expected answers to the question "Why, in your opinion, is VVM placed on the label (and not on the top) for PCV13 multidose vial?":
  - » PCV13 multi-dose vial (four doses) can be used to vaccinate up to four children. If at the end of the session, doses remain in the vial, you can keep it for successive immunization sessions
  - » If the VVM was placed on the cap, it would have been disposed off while opening the vial, and so not able to provide information on vaccine heat exposure

Key Messages

► For PCV13 multi-dose vial, VVM is placed on the label to allow use of remaining doses of open vials, in successive immunization sessions

Where is VVM Located for PCVs?

PCV13
single-dose vial



PCV13
multi-dose vial



WHY?

What are PCV Storage Temperatures?

Instructions: Ask the participants in what temperature range oral polio vaccine (OPV), lyophilized, and PCV should be stored, at district and service level. Then, discuss with the group and sort the true / false information with them.
At the end of the presentation, ask the participants how to monitor vaccine heat exposure.

Expected Answers

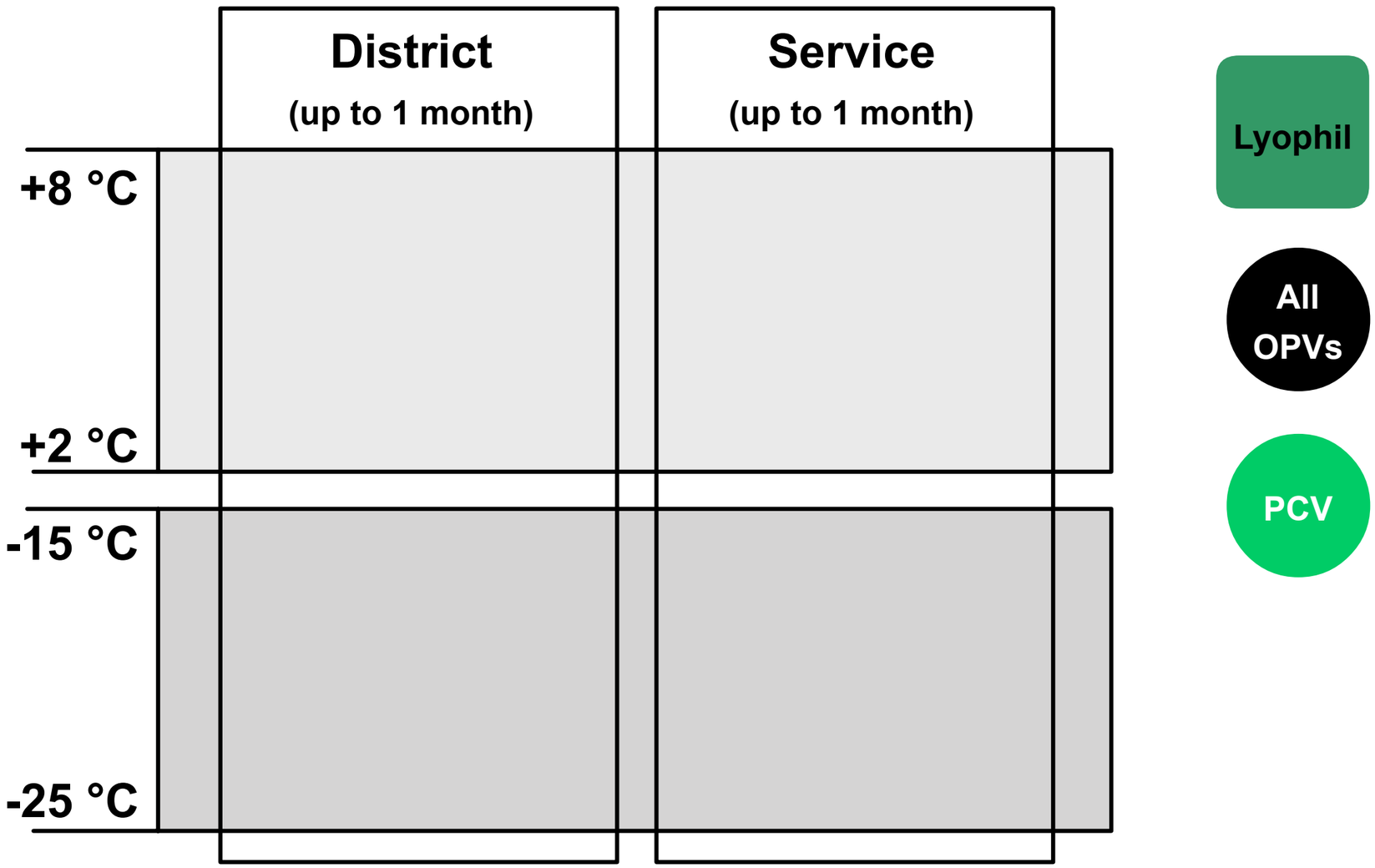
- Pneumococcal vaccine should be stored between 2 and 8°C, and **must not be frozen**
- At district and service level, OPV and lyophilized vaccines are usually stored between 2 and 8°C. However, OPV and lyophilized vaccines can be frozen. At national and sub-national level, OPVs are stored frozen

Key Messages

- Pneumococcal vaccine must be stored **between 2 and 8°C**
- **Liquid vaccines** including pneumococcal vaccine, pentavalent vaccine, TT vaccine, and hepatitis B vaccine **must not be frozen**
  - If frozen, they lose their potency and provide no protection against the disease
  - Previously frozen liquid vaccines may also cause “aseptic abscesses”

What are PCV Storage Temperatures?

In what temperature range should the following vaccines be stored?



PCV Storage in Front-Opening Refrigerators?

Instructions: Ask the participants where each of the PCV vials presented must be placed in a front-opening refrigerator. Refer to the training guide for more explanations.

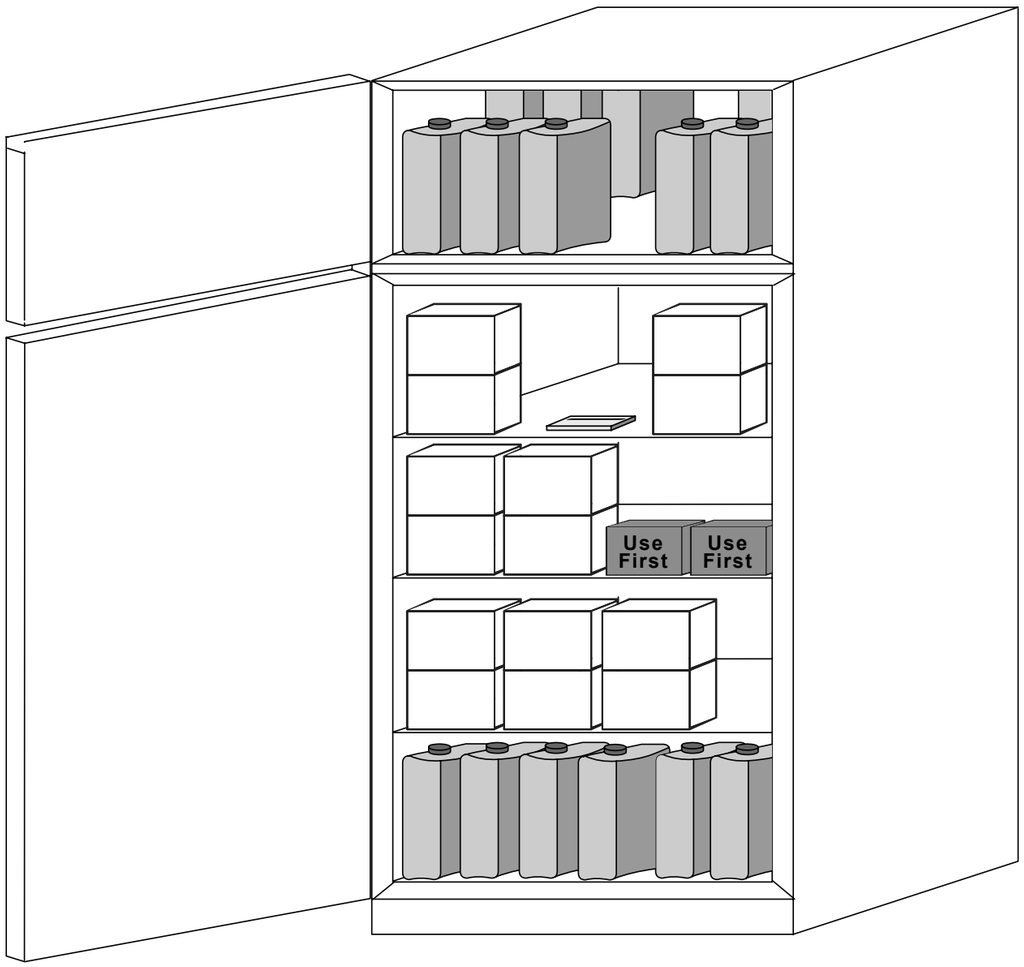
Expected Answers

- Vials 1, 2, and 3 must be placed on the middle-shelf, and should not touch the walls / lining of the inner compartment, to avoid exposure to freezing, because PCV are freeze-sensitive. On the top-shelf they would be too close to the freezer compartment, or to the evaporator plate, and on the bottom shelf they would be too close to the icepacks
- Vials 1 and 3 must be placed in the front, because they have a shorter expiry date
- Vial 4 is already open, so it must be placed in one of the "use first" boxes, with other opened vials
- Vial 5 has been exposed to heat, so it must be placed in the other "use first" box, with other heat exposed vials

Key Messages

- ► In front-opening refrigerators, freeze-sensitive vaccines, including liquid vaccines like PCV, must be placed on the middle shelf, as far as possible from cold sources
- ► Vials with shorter expiry dates must be stored at the front

PCV Storage in Front-Opening Refrigerators?



1



Expiry date: in one week

2



Expiry date: in three weeks

3



Expiry date: in one week

4



Expiry date: in two weeks

5



Expiry date: in two weeks

PCV Storage in Top-Opening Refrigerators (1)

Instructions: Ask the participants where each of the PCV vials presented must be placed in a top-opening refrigerator without baskets. Refer to the training guide for more explanations.

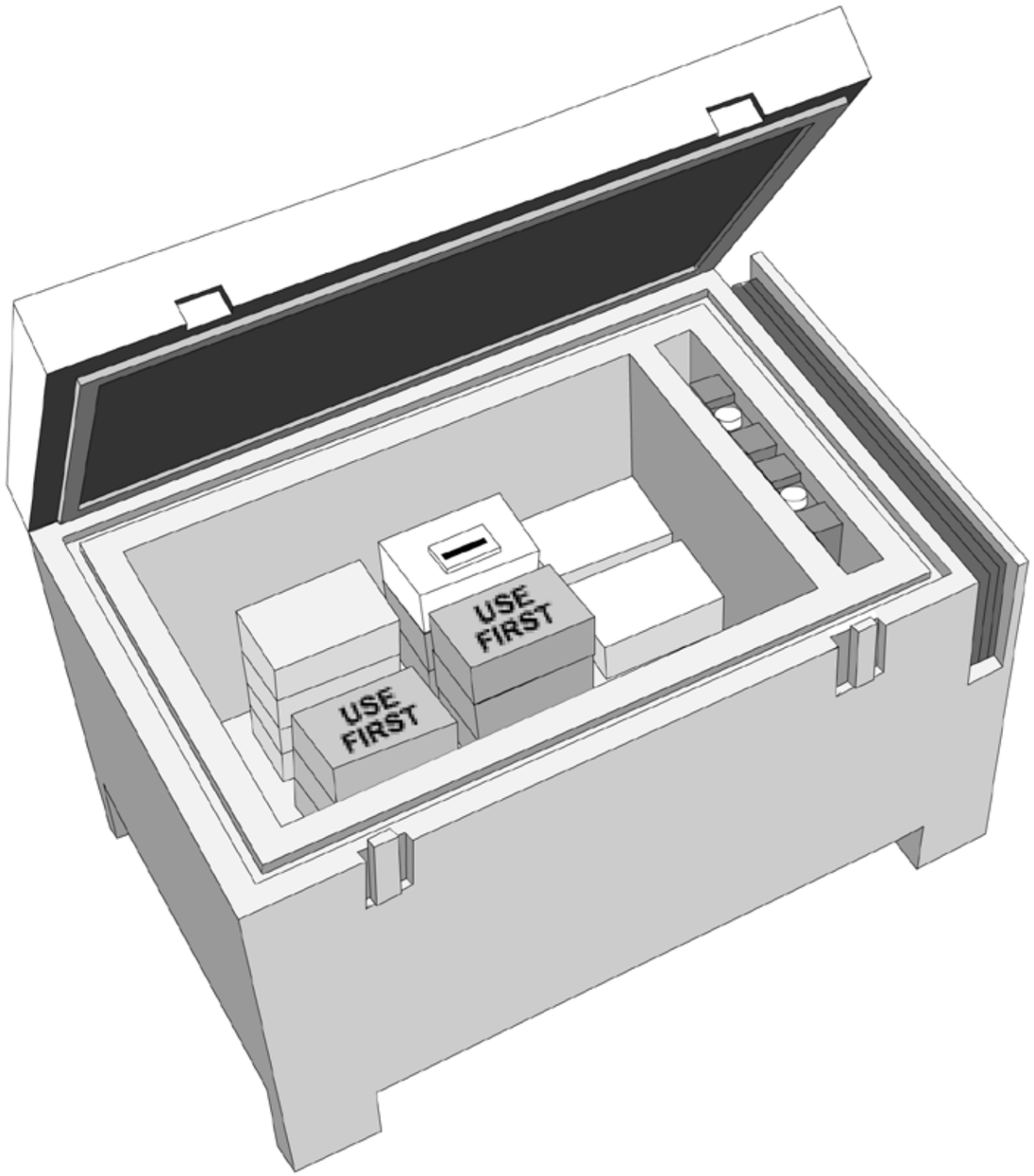
Expected Answers

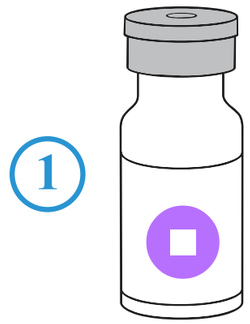
- Colder zones are situated:
  - » On the left of the refrigerator (right of the illustration): evaporator
  - » Near the walls
  - » In the bottom of the unit
- So vial 1 must be placed on the right of the refrigerator, in the upper part of the unit
- Vial 2 is already open, so it must be placed in one of the "use first" boxes, with other opened vials
- Vial 3 has been exposed to heat, so it must be placed in the other "use first" box, with other heat exposed vials
- Note that this kind of refrigerator (gaz or kerosene), is being replaced with solar-powered refrigerators. Therefore there is no longer an evaporator. For the latter, vaccines should not be in contact with the inner walls, and should be placed with insolation barriers or covers

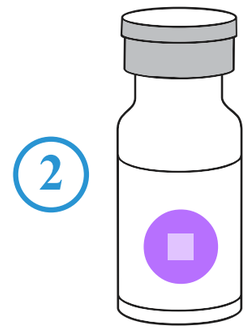
Key Messages

► In top-opening refrigerators without baskets, freeze-sensitive vaccines, including liquid vaccines like PCV, must be placed as far as possible from colder zones (evaporator, the bottom, and the walls of the unit)

PCV Storage in Top-Opening Refrigerators (1)









PCV Storage in Top-Opening Refrigerators (2)

Instructions: Ask the participants where each of the PCV vials presented must be placed in a top-opening refrigerator with baskets. Refer to the training guide for more explanations.

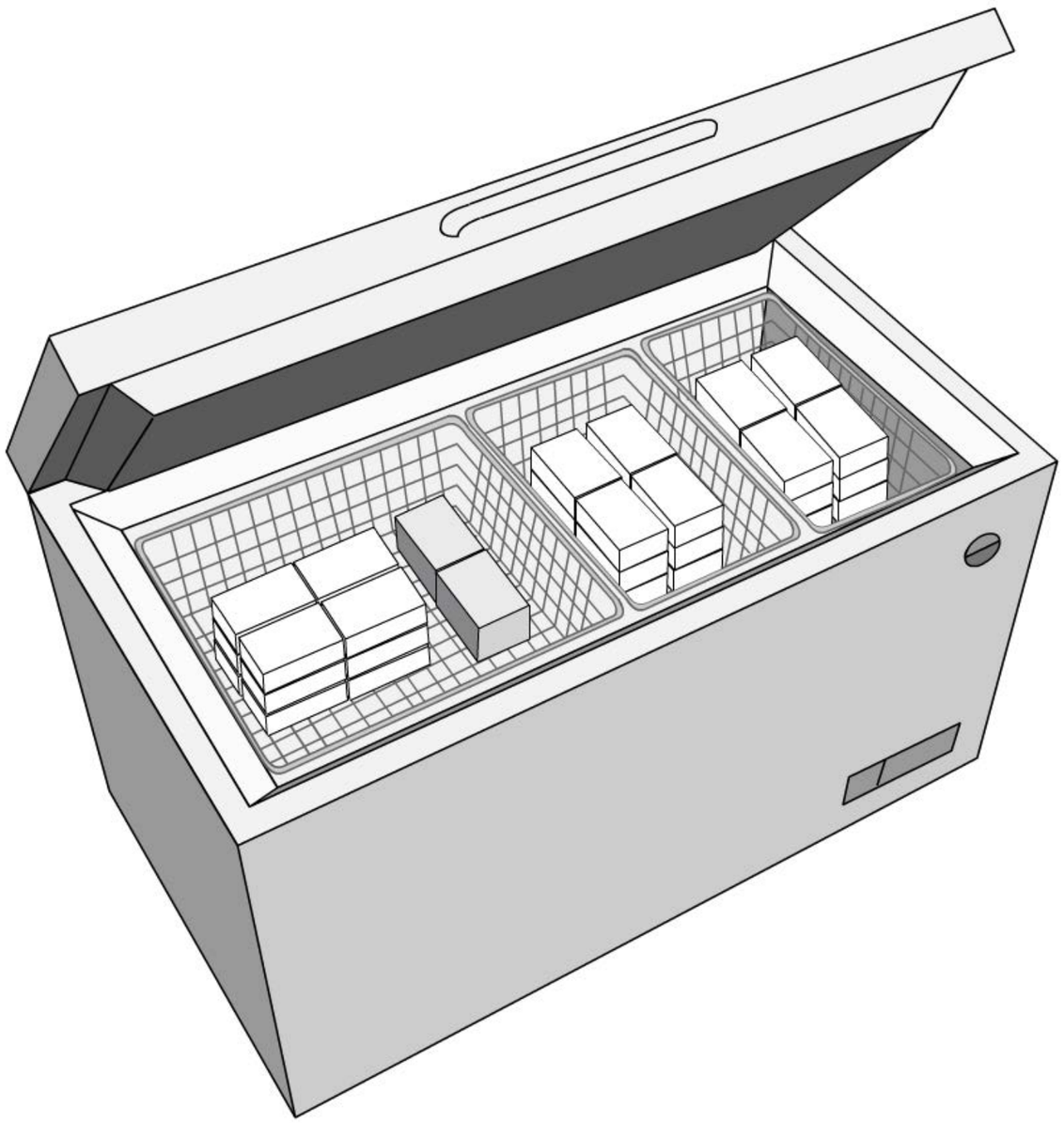
Expected Answers

- Colder zones are situated in the bottom of the unit and on the walls / liner
- All vaccines must be stored in the baskets provided. Never store them outside the baskets
- Vial 1 must be placed in one of the top baskets, like all other freeze-sensitive vaccines
- Vials 2 and 3 must be placed in the “use first” boxes, in the top baskets

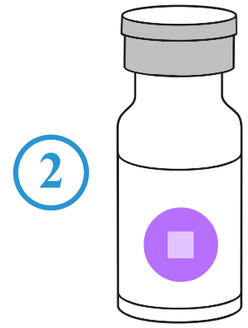
Key Messages

- In top-opening refrigerators with baskets, freeze-sensitive vaccines, including liquid vaccines and PCV, must be placed as far as possible from colder zones (bottom of the unit), and not be in contact with the walls / liner

PCV Storage in Top-Opening Refrigerators (2)









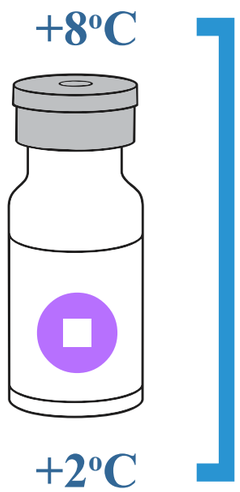
What are the Rules for PCV Storage?

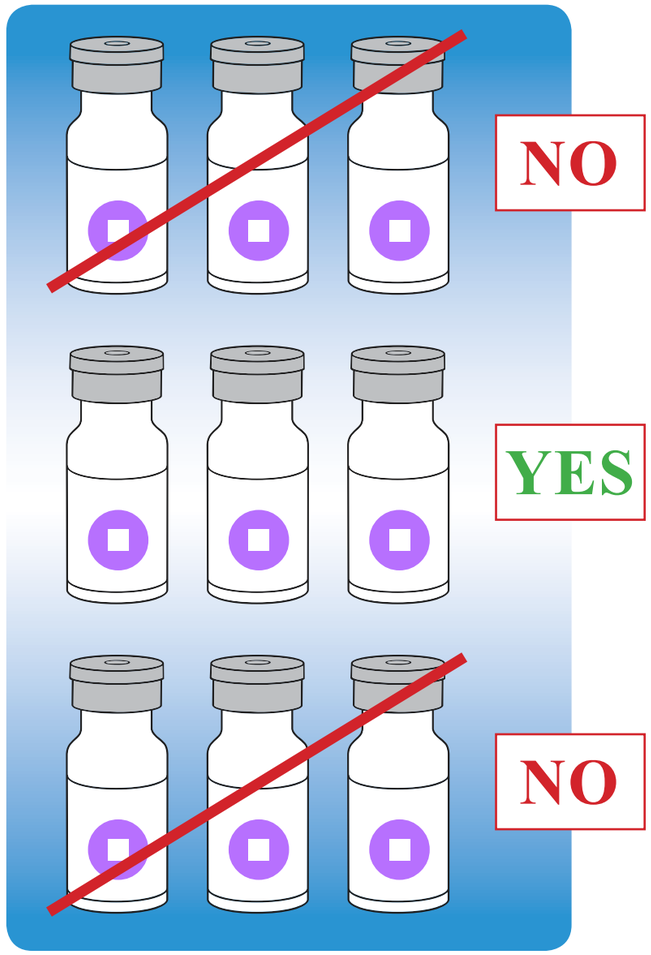
Instructions: Explain the illustrations to the participants.

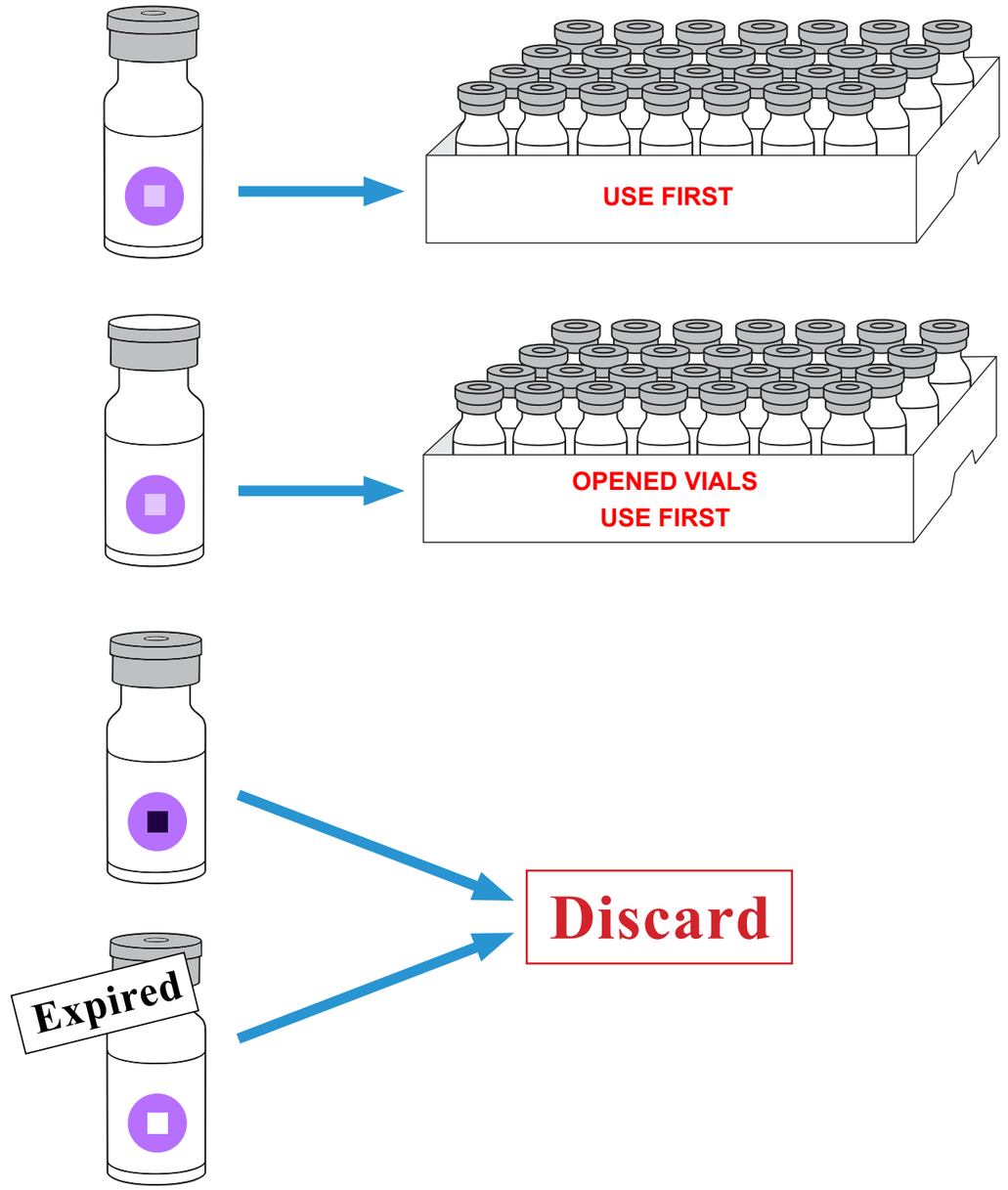
Explanation

- PCV, like other liquid vaccines, must be stored **between 2 and 8°C**
- Inside refrigerators, freeze-sensitive vaccines, including liquid vaccines like PCV, must be placed **as far as possible from colder zones**
- Specific storage rules apply for the following vials:
  - » Vials with VVMs that show the most heat exposure must be stored **in a separate container in the refrigerator**, clearly marked "**Use first**"
  - » All opened multi-dose vial that will be used for the next session, must be placed **in a separate container in the refrigerator**, which is clearly marked "Opened vials – use first"
- Do not keep in the refrigerator:
  - » Expired vaccines
  - » Vials with VVMs that have reached, or are beyond, their discard point
  - » These vials should be discarded according to your national guidelines

What are the Rules for PCV Storage?







What do you Remember?

Instructions: Ask the following questions to the participants, gather their answers, and complete if necessary.

Questions

- What can you say about VVM, in general and for PCVs?
- What are the main guidelines of WHO Multi-Dose Vial Policy, for MDV with or without preservative?
- What are the main instructions for PCV storage?

Expected Answers

- VVMs are the only temperature monitoring devices that accompany vaccines throughout the entire supply chain. Their main purpose is to ensure that heat-damaged vaccines are not administered. VVM records vaccine cumulative heat exposure through a gradual change in color. If the color of the inner square is the same color or darker than the outer circle, the vaccine has been exposed to excess heat and should not be used. For PCV13 MDV, VVM is placed on the label; for PCV13 SDV, VVM is placed on the cap of the vial
- PCV13 MDV can be used in successive immunization sessions after opening for up to 28 days, provided that: the expiry date has not passed; the VVM is visible on the vaccine label and is not past its discard point; and the vaccine has not been damaged by freezing. MDV vaccines without preservative must be discarded six hours max after opening
- PCV vaccine vials should be stored at 2-8°C. In refrigerators, freeze-sensitive vaccines must be placed as far as possible from cold sources (evaporator, freezer compartment, walls and liner, etc.). Vials with the shortest expiry dates must be easy to distinguish from other vials. Place vaccines with VVMs that show the most heat exposure and opened multi-dose vial in separate “use first” containers in the refrigerator. Do not keep in the refrigerator vaccines or vaccines with VVM having reached or passed the discard point

What do you Remember?



► What can you say about VVM, in general and for PCV13?

► What are the guiding principles of Multi-Dose Vial Policy for multi-dose vials, with or without preservative?

► What are the main instructions for PCV storage?

AGENCE DE MEDECINE PREVENTIVE

World Health Organization

All content is developed and owned by Agence de Médecine Préventive (AMP),
under technical guidance and review of World Health Organization (WHO).

Training is funded by Pfizer Inc.

Pfizer

© copyright 2016