Switching from PVC13 to PCV10

Knowledge Hub webinar

Date: 31st October 2023

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL DEVELOPMENT PLAN 2030

Phila

Outline

- Background and Public Health rationale (including surveillance)
- New vaccine characteristics
- Updated immunisation schedule
- PCV10 administration
- Data management

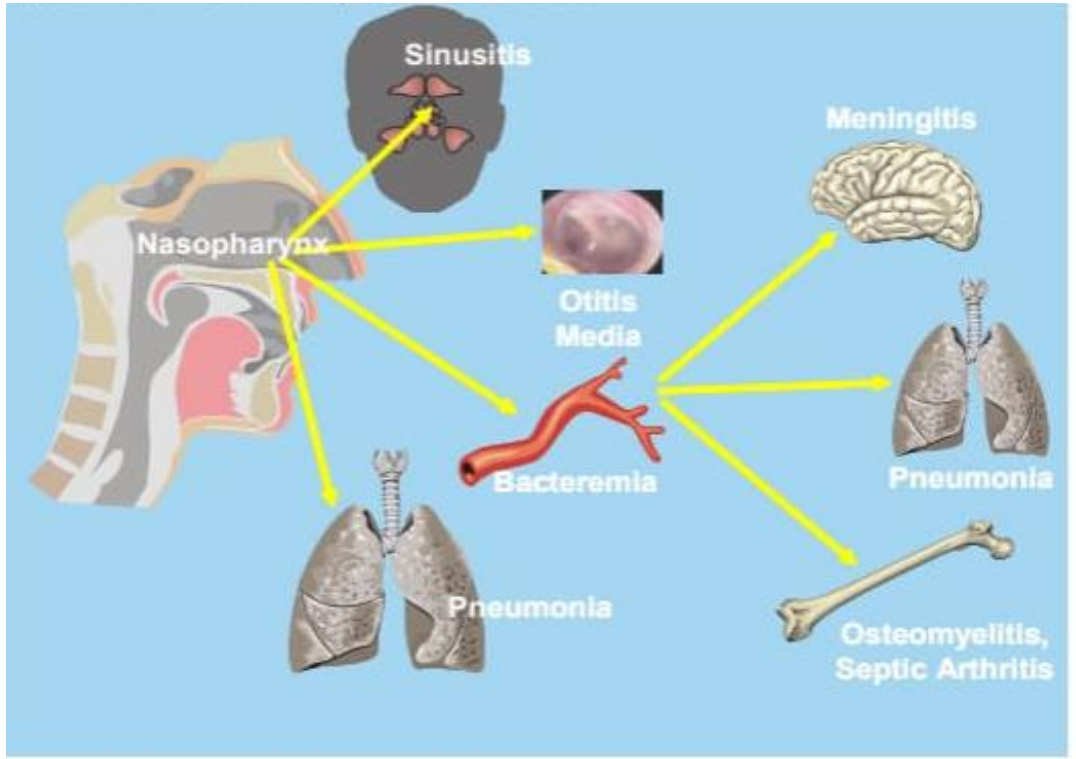
BACKGROUND AND PUBLIC HEALTH RATIONALE

The causative organism

- The **causative agent for pneumococcal disease** is the bacteria called ***Streptococcus pneumoniae.***
- *S. pneumoniae* is found in the **respiratory tract of health people** especially children and may be isolated from the **nasopharynx of 5% to 90%** of healthy persons
- There are **> 100 known serotypes** of *S. pneumoniae.*
- Transmission of *S. pneumoniae* occurs as the result of **direct person-to-person contact** via respiratory droplets
- The distribution of serotypes that cause **disease varies over time and by age**
- Before the introduction of pneumococcal conjugate vaccines (PCVs) 6–11 serotypes accounted for ≥ 70% of all invasive pneumococcal disease (IPD)

The disease

- **The clinical spectrum of pneumococcal infection:**
- **Non-invasive infection**
  - Contiguous spread from the nasopharynx can cause diseases such as **pneumonia without bacteremia, otitis media or sinusitis**.
- **Invasive disease** (Invasive Pneumococcal Disease- IPD)
  - Pneumococcal infection and disease can affect various organ systems. **Bloodstream invasion results in bacteraemia** that causes infection at secondary sites, such as the **meninges, joints and peritoneum.**
  - Results in: osteomyelitis, bacteremia without focus of infection, pneumonia with bacteremia, septic arthritis, and meningitis



The disease

Diagnosis

- Clinical diagnosis of pneumonia or meningitis is based **on symptoms, signs and radiological tests**
- Diagnosis of pneumococcal disease requires **laboratory confirmation**.
- A definitive diagnosis of pneumococcal infection is made by **isolating the bacterium from blood or other normally sterile body sites**, such as cerebrospinal fluid.
- The appearance of lancet-shaped diplococci on Gram stain is suggestive of pneumococcal infection

Treatment

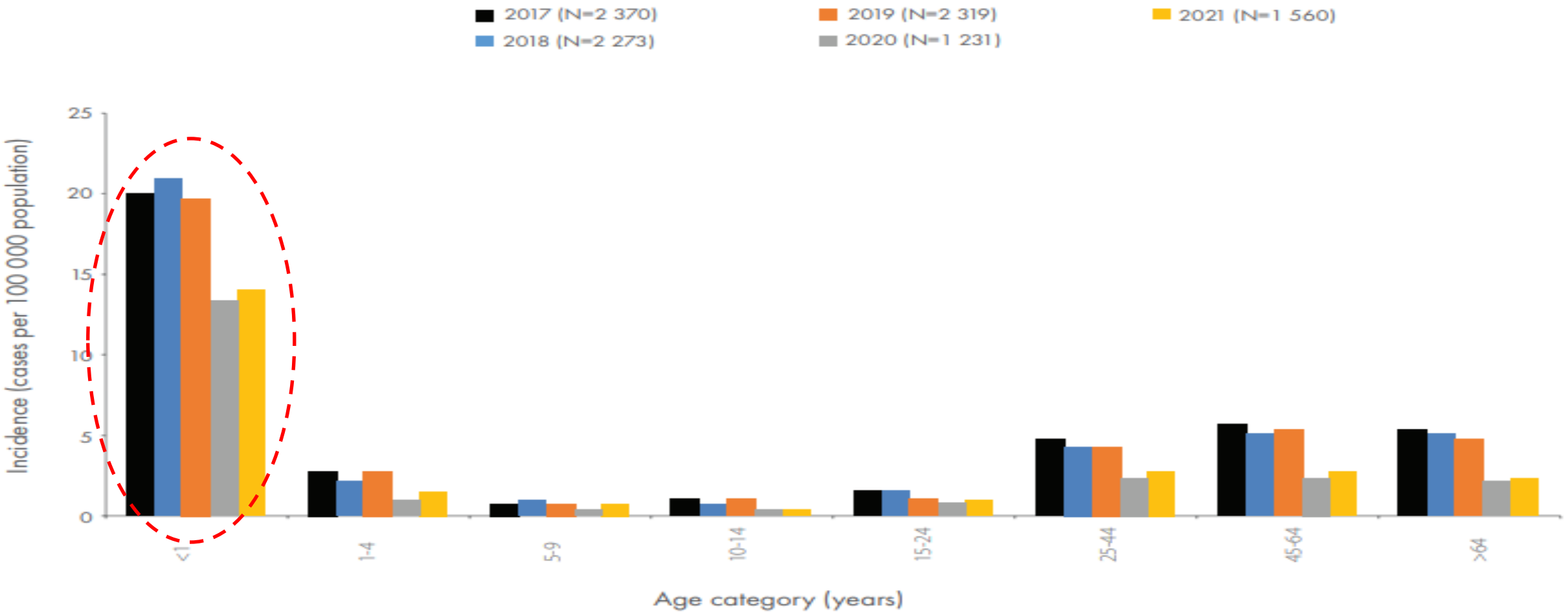
- Pneumococcal disease is **treated with antibiotics**.
- The **choice of antibiotics and the duration of treatment depend on the site of infection** and the pattern of susceptibility to antibiotics
- The **outcome depends on age, disease syndrome, severity, duration of illness** before initiation of treatment and susceptibility to the antimicrobials used.

Non-severe Pneumonia	**Amoxycillin, oral, 45mg/kg/ dose 12hourly x 5 days** **Penicillin allergy: Azithromycin, oral, 10mg/kg/dose daily x 3 days**
Severe Pneumonia	Oxygen, using nasal cannula at 1-2L/minute before and during transfer Ceftriaxone, IM, 80mg/kg/dose immediately as a single dose Refer EML, 2020, Pg 417 for use of Ceftriaxone in Neonates and Children
Referral –URGENT **Referral –NON-URGENT**	All children with severe pneumonia, i.e. chest indrawing (of the lower chest wall), flaring of nostrils or cyanosis All children < 2 months Inadequate response to treatment Children coughing for > 3 weeks to exclude other causes such as TB, foreign body, aspiration or pertussis

Prognosis

- **Case fatality rates** from IPD in children can be high, ranging up to **20% for septicaemia**
- Long-term neurological sequelae such as **hearing loss, mental retardation, motor abnormalities and seizures** have been observed in 24.7% of survivors of childhood pneumococcal meningitis
- **Lack of exclusive breastfeeding, nutritional deficiency and indoor air pollution are risk factors for pneumonia**, including pneumococcal pneumonia, in infants and young children.

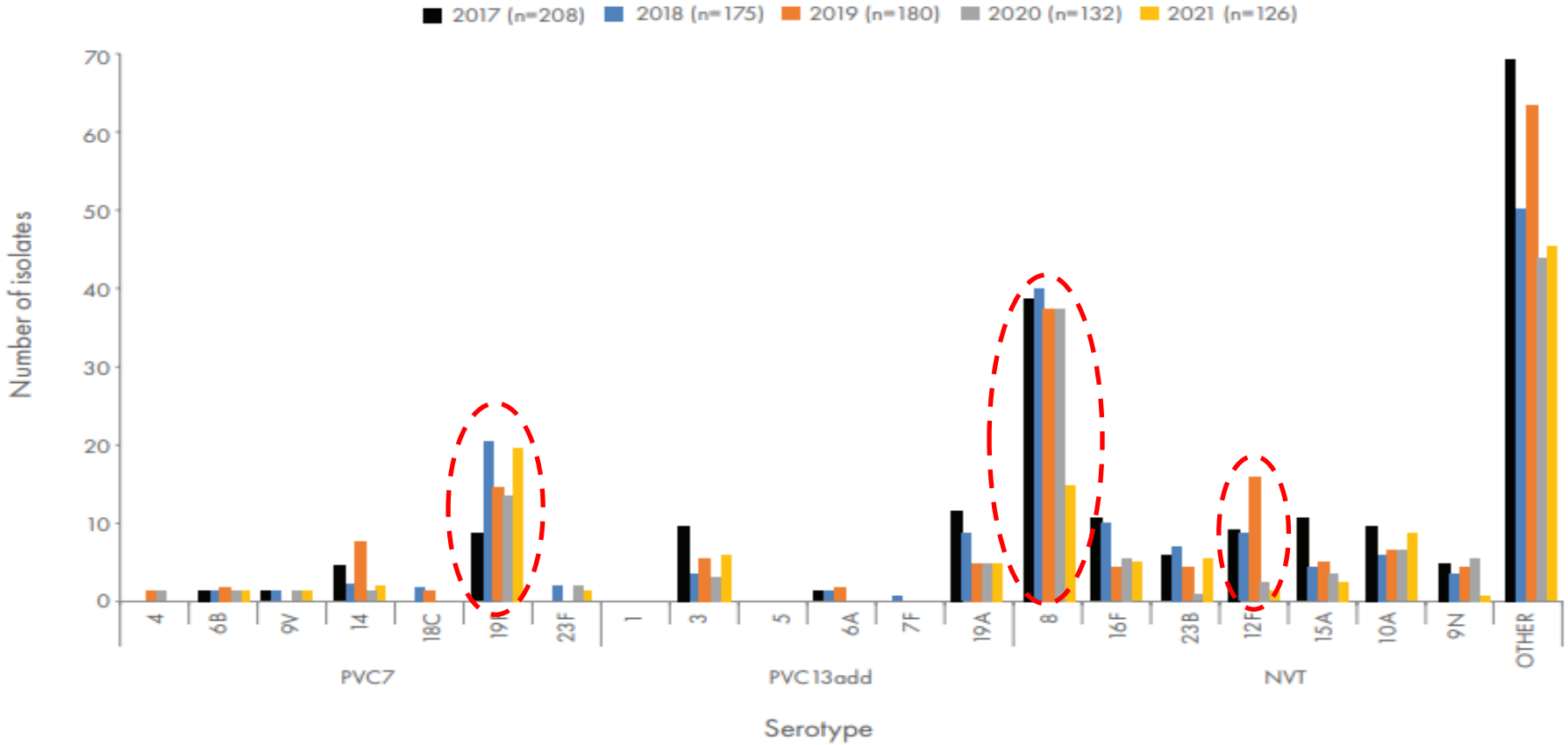
Invasive pneumococcal disease (SA 2017 - 2021)



2017: N=2 440, age unknown for n=70; 2018: N=2 315, age unknown for n=42; 2019: N=2 359, age unknown for n=40; 2020: N=1 262, age unknown for n=31; 2021: N=1 560, age unknown for n=97.

Figure 6. Age-specific incidence rates* for laboratory-confirmed, invasive pneumococcal disease, reported to GERMS-SA, South Africa, 2017 through 2021, n=9 936

Invasive pneumococcal disease (SA)



2017: N=374, n=167 without viable isolates; 2018: N=386, n=211 without viable isolates; 2019: N=361, n=181 without viable isolates; 2020: N=224, n=92 without viable isolates; 2021: N=253, n=127 without viable isolates.

PCV7: seven-valent pneumococcal conjugate vaccine; PCV13add: additional serotypes in the thirteen-valent pneumococcal conjugate vaccine; NVT: non-vaccine serotypes

Figure 8A: Most common pneumoccocal serotypes causing laboratory-confirmed, invasive pneumococcal disease, reported to GERMS-SA, in children <5 years, South Africa, 2017-2021

Prevalent serotypes: 14,19F,19A,16F,8,23B,12F,15A,10A,9N

NEW VACCINE CHARACTERISTICS

Why are we switching to PCV10?

- **PCV13 and PCV10 are considered interchangeable** where the PCV10 from SII (supplied by Cipla) contains the prevalent pneumococcal serotypes in South Africa
- Based on the minimum vaccine specification provided by NAGI, the pneumococcal conjugate vaccine (PCV13) supplied by Pfizer will change to **PCV10 (supplied by Cipla), following tender award of HP16-2024.**

Comparison between PCV10 and PCV13

	PCV10	PCV13
Vaccine Presentation	Single dose, ready to use vial, 0.5ml	Pre-filled syringes, 0.5ml
Pneumococcal serotypes covered	1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F	1, 4, 5, 6B, 7F, 9V,14, 18C, 19F, 23F and **3, 6A, 19A**
Immunogenicity	Comparable immunogenicity	Comparable immunogenicity
Safety Profile	Comparable safety	Comparable safety
Co-administration	Can be administered with other vaccines; at different injection sites	Can be administered with other vaccines; at different injection sites

Tender information for PCV10

Tender Information	Details
Description	Vaccine, conjugated, pneumococcal, multivalent, containing a of minimum 8 pneumococcal serotypes that includes 1, 5, 6B, 7F, 9V, 14, 19F and 23F in a single dose vial or pre-filled syringe. For intramuscular administration.
Period	01 Jan 2024 to 31 Dec 2026
Product code (NSN)	222001550 **(different to PCV13)**
Product description	PCV10 Cipla
Price	R97.06
Minimum order quantity	**50 vials (was previously 10 vials)**

Forecasting PCV10

- ✓ Prevenar 13 and PCV10 Cipla are considered **interchangeable**
- ✖ There is no need to keep both vaccines in stock
- ✓ Once your available Prevenar 13 vaccines stock is depleted the new PCV10 Cipla stock should be order on the **new stock code**
- ✓ SVS and NCS will be used to **monitor availability** at all levels and coordinate the phase out of Prevenar 13 and phase in of PCV10 Cipla

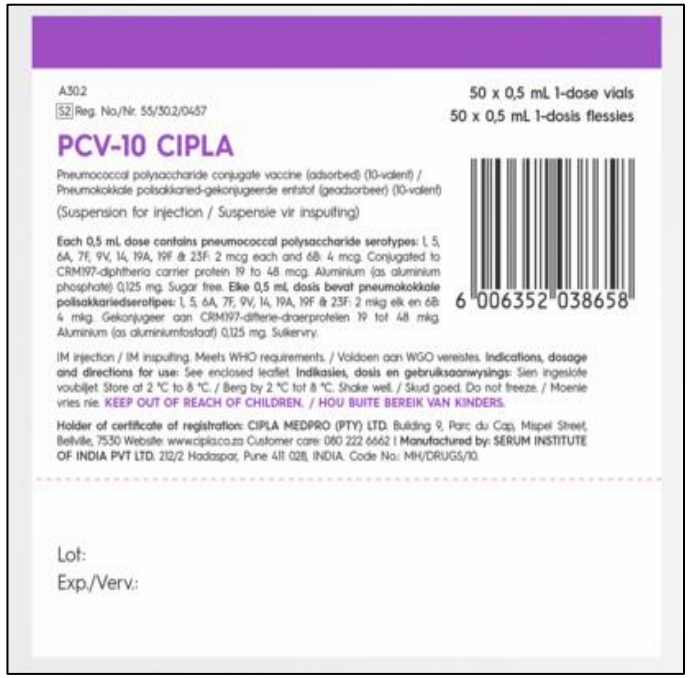
Description	Details
Handling the switch	• Monitor SVS • Order on the new stock code

Introducing PCV10 Cipla

Description	Details
Manufacturer	Cipla
Composition	Pneumococcal conjugate serotypes 1, 5, 6A, 6B, 7F, 9V, 14, 19, 19F and 23F (2mcg each). Serotypes are conjugated to CRM197 diphtheria carrier protein 19-48mcg, adsorbed on aluminium adjuvant, as aluminium phosphate (0.125mg).
Schedule	2
Approved for	Active immunisation against invasive disease, pneumonia and otitis media caused by Streptococcus pneumoniae serotypes 1,5,6A,6B,7F,9V,14,19,19F and 23F
Identification	Fully liquid. White turbid suspension, settles down slowly when stored

Introducing PCV10 Cipla

Description	Details
Presentation	**0.5ml vial, Single dose**
Pack Size	50 vials
Diluent required	No
VVM - present on vial	No
Type of VVM	30
Storage temperature	Between 2°C and 8°C
Light sensitive	Yes
Aluminium Adjuvant	Yes
Freeze sensitive	Yes



Storage and temperature excursions PCV10 Cipla

Description	Details
Front loading fridge	Store on the middle shelf
Top loading fridge	On the top only. In the upper basket - to keep away from the bottom where it may be exposed to freezing conditions
Shake test applies	Yes
Multi-dose vial policy applies	No
Temperature excursion	**Do not freeze.** Perform the "shake test" if freezing suspected to determine if the vaccine is safe for use
More info on temperature excursions	Contact the supplier or your EPI / Pharmacy manager

Front loader fridge

Top loader fridge

HINT

Do not expose vaccine to freezing conditions

Use conditioned ice packs or Correctly prepared coolant packs based on selected passive container

Monitor temperature at all times with a continuous temperature monitoring device.

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Vaccine wastage PCV10

Description	Details
SA acceptable wastage rate	• 5% for routine immunisation
Buffer	• 15% for routine immunisation • 5% for campaign

Vaccine wastage should be monitored to improve the efficiency and reduce the cost of the vaccination programme.

Reducing wastage must never come at the cost of immunizing an individual client

Shake test

Shake Test is a 'golden test' that indicate whether freeze-sensitive vaccines have been damaged by freezing
Why, When and How ?
Reported?

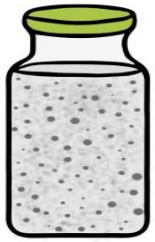
Suspect Vial: Freeze sensitive vaccine exposed to ≤0˚C

1. Create Control Vial: Freeze and thaw vaccine from same batch

3. Suspect Vial **immediately** appears cloudy and uniform

2. Shake Control and Suspect Vials vigorously

3. Control Vial **immediately** appears granular and not uniform



4. **Suspect Vial:** Clears **gradually** and sediment forms slowly -

SAFE TO USE

5-30 minutes later

4. **Control Vial:** Clears fast and thick sediment forms quickly -

DO NOT USE

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A useful 'tip' to remember which vaccines are sensitive to freezing, is to look for the 'T' in the name of these vaccines, which also applies to the vaccine 'diluent'.

UPDATED EPI SCHEDULE

EPI Schedule – no change

AGE	VACCINE
Birth	Bacille Calmette-Guérin (BCG)
	Oral Polio Vaccine (bOPV) -0
6 weeks	Oral Polio Vaccine (bOPV) -1
	Rotavirus (RV) -1
	Pneumococcal conjugate (PCV)-1
	Hexavalent (DTaP-IPV-HepB-Hib) -1
10 weeks	Hexavalent (DTaP-IPV-HepB-Hib) -2
14 weeks	Rotavirus (RV) -2
	Pneumococcal conjugate (PCV) -2
	Hexavalent (DTaP-IPV-HepB-Hib) -3

AGE	VACCINE
6m	Measles/Rubella (MR) -1
9 months	Pneumococcal conjugate (PCV) -3
12 months	Measles/Rubella (MR) -2
18 months	Hexavalent (DTaP-IPV-HepB-Hib) -4
6 years	Tetanus diphtheria, acellular Pertussis (TdaP) -1
9 years	Tetanus diphtheria, acellular Pertussis (TdaP) - Campaign
≥ 9 years	Human Papilloma Virus (HPV) 1+2
12 years	Tetanus diphtheria, acellular Pertussis (TdaP)-2

Updated EPI Catch-up Schedule

Vaccine	Age of child	First dose	Interval for subsequent doses		
			Second dose	Third dose	Fourth dose
Bacille Calmette-Guérin (BCG)	<1 year	Give one dose			
	≥1 year	**Do NOT give**			
Oral Polio Vaccine (bOPV)	<6 months	Give first dose	4 weeks		
	≥6 months	**Do NOT give**			
Hexavalent (DTaP-IPV-HepB-Hib)	Up to 5 years	Give first dose	4 weeks	4 weeks	12 months (Do not give before child is 18 months old)
Pneumococcal conjugate (PCV)	<6 months	Give first dose	4 weeks	Give at 9 months of age	*PCV13 and PCV10 will be considered interchangeable – no catch up of PCV10 required if child previously received PCV13 as per EPI schedule*
	6 - < 9 months	Give first dose	4 weeks	8 weeks	
	9 - < 24 months	Give first dose	4 weeks	8 weeks	
	2 up to 6 years	Give one dose			
Rotavirus	<20 weeks	Give first dose	4 weeks		
	20-24 weeks	Give one dose			
	>24 weeks	**Do NOT give**			
Measles/Rubella (MR)	<11 months	Give first dose	At 12 months		
	≥11 months	Give first dose	4 weeks		
Tetanus diphtheria acellular Pertussis (TdaP)	≥6 years	Give first dose	At 12 years	*4 week interval should be observed*	

VACCINE ADMINISTRATION

Vaccine Administration

Step 1.

- First check the **child's immunisation status and any contraindications**
- **Inform the caregiver** what vaccine the child is receiving and allow questions to be asked

Vaccine safety PCV10 Cipla

Description	Details
Contraindications	Known hypersensitivity. Anyone with a previous allergic reaction to this vaccine.
Precautions	• Appropriate medical treatment and supervision must be available during immunisation. • Parent/caregiver must be questioned about **ANY PREVIOUS** adverse events following immunisation. • Vaccines should be given with caution in children with blood clotting disorders or on treatment that result in children being prone to bleeding disorders. • The decision to delay vaccination due to a current or recent febrile illness depends on the severity of the symptoms and the cause of the disease (systemic illness with temperature > 38.5°C).
Possible events	• Side effects are **mostly mild and transient** including flu-like illness, decreased appetite, irritability, rash, fever, tenderness, induration and reddening at the injection site, drowsiness, and pain. • **Less frequent side effects:** Diarrhoea. • **Rare side effect:** Anaphylaxis. • For more information, consult the package insert

Vaccine Administration

Step 2.

- Take the **vaccine out of the vaccine carrier** and remove it from its packaging.
- Check the **expiry date and vial appearance**
- Besides freezing, heat exposure can also reduce the vaccine's potency, so the vaccine needs to be protected from **heat and sun exposure**.

Vaccine Administration

Step 3.

- Draw up **0.5 ml with a new 1ml or 2ml syringe**

SCHEDULE & ADMINISTRATION PCV10

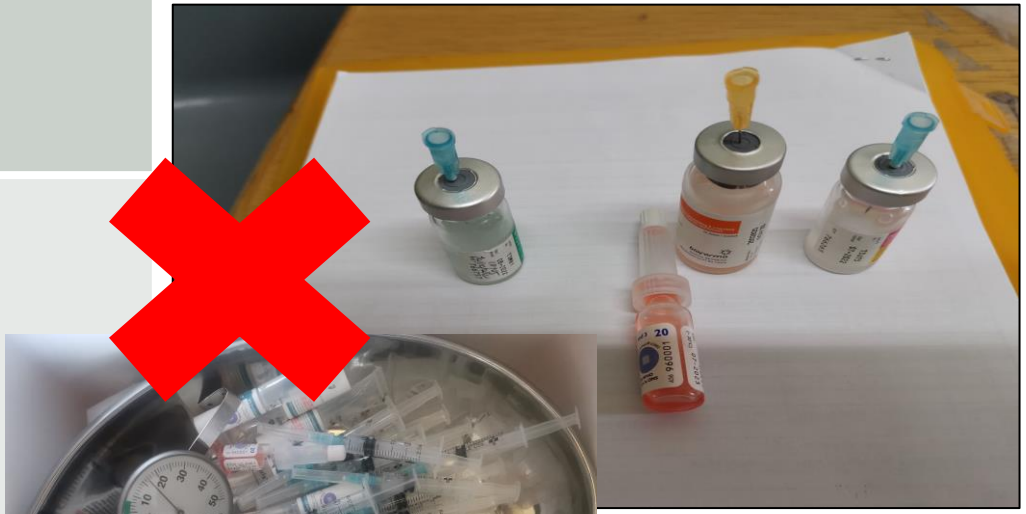
Description	Details
Route & Site of administration	**<=12 months**: IM. Vastus lateralis muscle of anterolateral thigh **1-2 years**: IM. Vastus lateralis muscle of anterolateral thigh (preferred site). Deltoid muscle of arm (if the muscle mass is adequate) **2-6 years**: IM. Deltoid muscle (preferred site). Vastus lateralis muscle of anterior lateral thigh (alternative site if the deltoid site cannot be used)
Co-administration	May be administered simultaneously with other vaccines in accordance with EPI schedule and as appropriate for the recipients age and previous vaccination status. Separate injection sites and separate syringes must be used in case of concomitant administration
Preparation/ Reconstitution	Fully liquid. No reconstitution required.
Dose	0.5ml
Storage after 1st puncture of vial	Not applicable as single use vial

Recommended syringe & needle for reconstitution & administration PCV10

Description	Details
Reconstitution syringe	Not required
Reconstitution needle	Not required
Administration syringe	1ml syringe 2ml syringe: 42142608-00000/4/34
Administration needle	**Needle Guage and Length**: 22g x 32mm: 42142523-00010 23g x 25mm: 42142523-00009 25g x 16mm: 42142523-00008 **Needle Length/ Age**: Age 1-12 months: 25 mm Age 1-10 years: 25-32 mm (Thigh) Age 1-10 years: 16-25 mm (Deltoid)

HINT

- **Never leave a needle in the vial septum (NO PORCUPINES)**
- **Use the same needle to draw up and administer the vaccine**
- **Never prefill syringes to store before use (ADMINISTER THE VACCINE IMMEDIATELY)**



Vaccine Administration

Step 4.

- Administer an **intramuscular (IM) injection** in the right thigh of the infant.
- All used injection equipment should be placed in a safety box (without recapping), immediately after use.

Step 5.

- **Record dose** on Road to Health Booklet and the PHC tick register

Vaccine Administration

Step 6.

- Indicate to the caregiver what to do if there any **adverse events following immunisation**
- Indicate when the child should **come back** for the next injection
- **Reinforce messages about care-seeking** for pneumonia since the child may still get pneumonia from other pathogens in spite of vaccination.

Vaccine safety surveillance cycle in SA

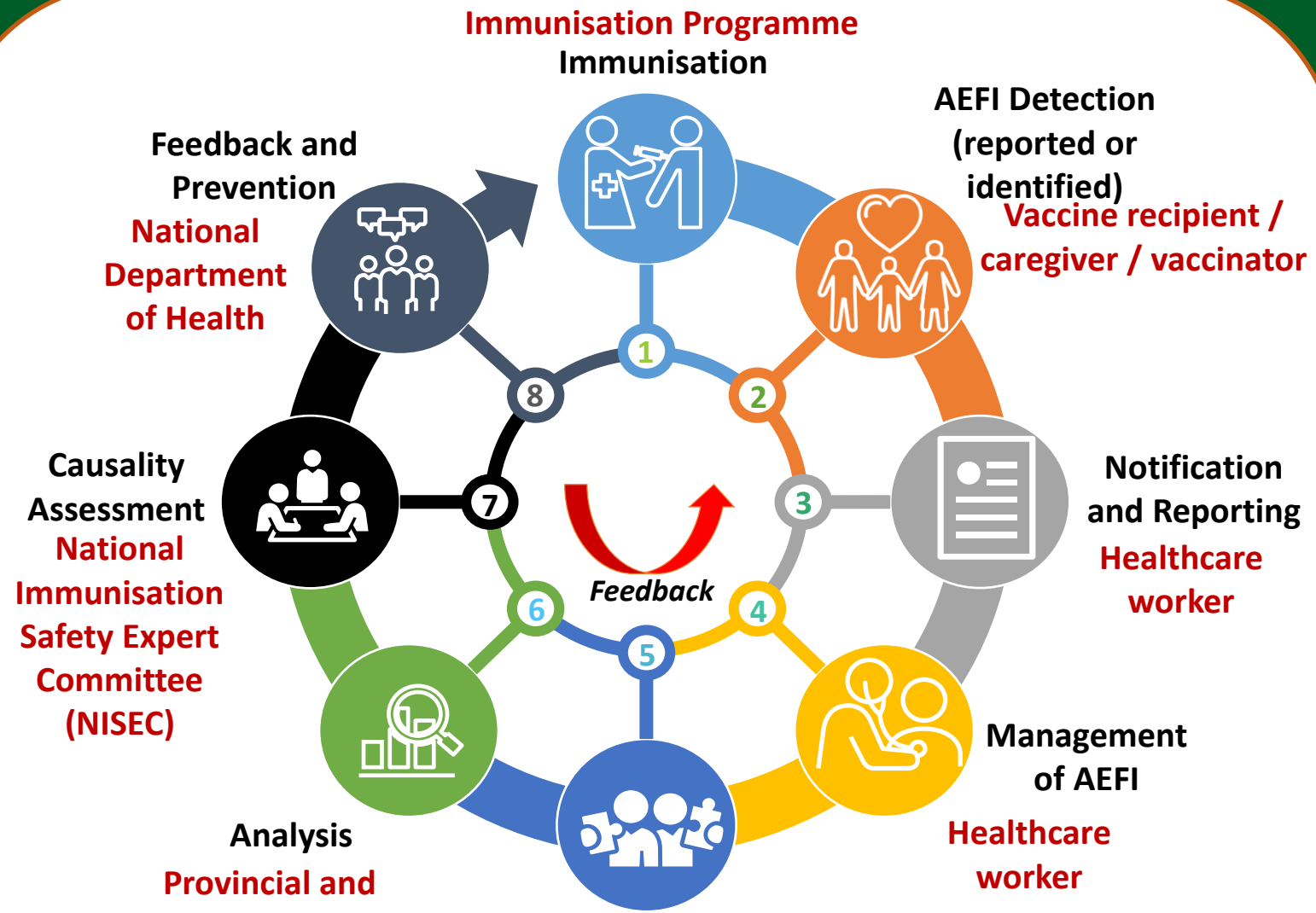
Vaccine Manufacturing Industry

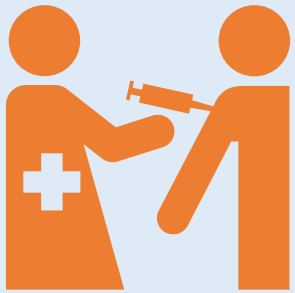
South African Health Products Regulatory Authority (SAHPRA)

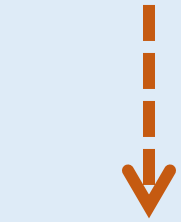
National Department of Health (NDoH)

World Health Organization (WHO)

Ministerial Advisory Committees on Vaccines and Immunisation







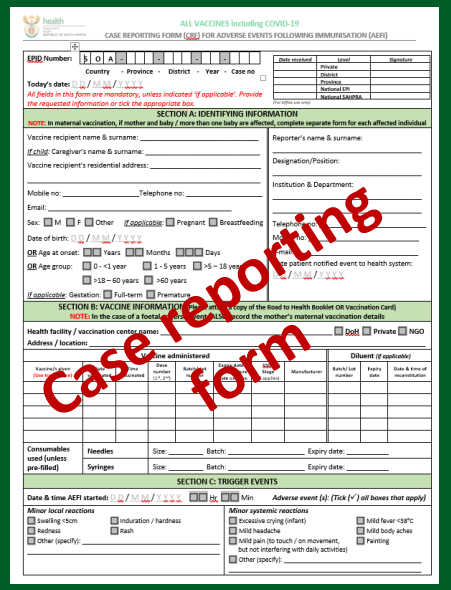
Adverse event of concern

Health facility

Med Safety App

MILD/MINOR EVENTS

Expected



SEVERE EVENTS

Not expected

Arm is sore or red at the injection site

Fever/ chills

Headache

Fatigue

Muscle aches

Nausea

Investigated

Serious events

- Result in death
- Require inpatient hospitalisation
- Life threatening
- Result in persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Medically important event or reaction

Non-serious events

- Need clinical management
- Usually do not result in long-term problems

Co-administration

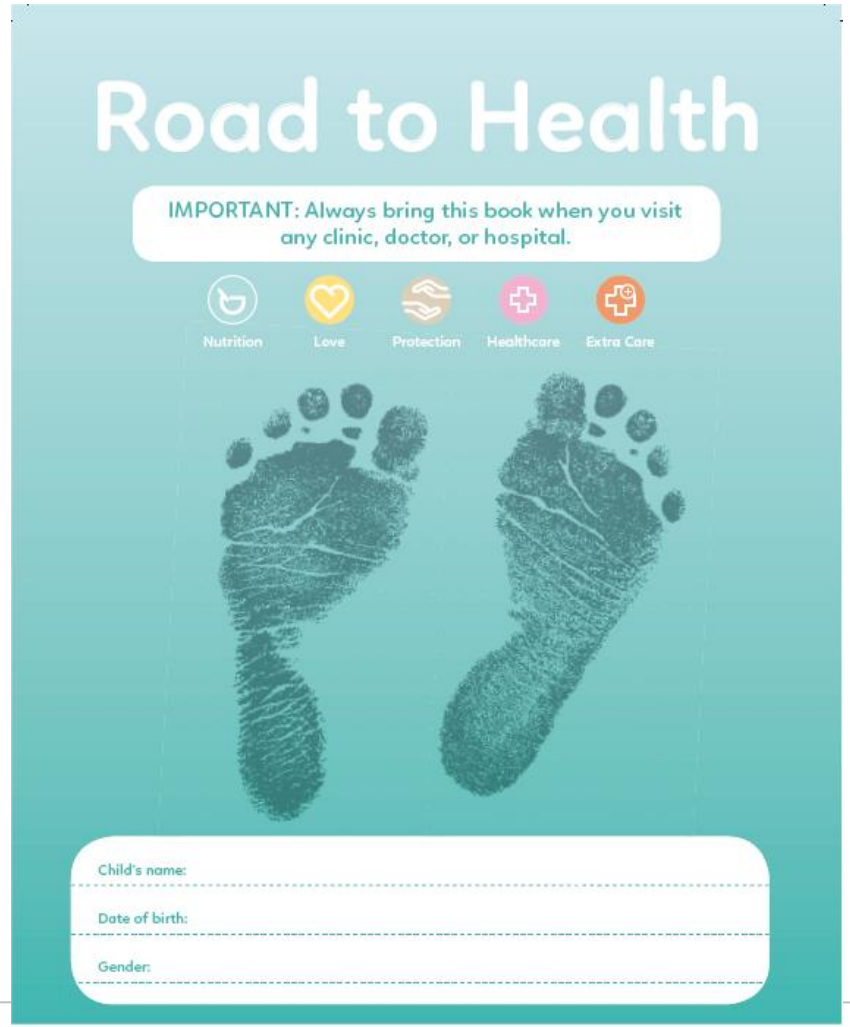
- PCV10 can be **co-administered** with other EPI vaccines.
- The vaccine **should not be mixed** with other vaccines in the same syringe.
- PCV10 is given into the **right thigh** (only EPI vaccine routinely given at this site).

PCV10 Data Management

Recording the PCV10 doses

- Pneumococcal vaccinations given to infants should be recorded in the same way as other vaccines in the programme.
- **At the service delivery level these are**:
  - Road to Health booklet
  - PHC tick register
  - Vaccine Stock cards

Road to Health Booklet



Immunisations

EPI (Expanded Programme of Immunisation) Schedule

Child's Name				Child's Date of Birth	
Age	**Vaccine**	**Route & Site**	**Batch no.**	**Date given**	**Signature**
Birth	BCG	Intradermal Right arm			
	OPV0	Oral			
6 weeks	OPV1	Oral			
	Rotavirus 1	Oral			
	PCV1	IM Right thigh			
	Hexavalent (DTaP-IPV-Hib-HBV)1	IM Left thigh			
10 weeks	Hexavalent (DTaP-IPV-Hib-HBV)2	IM Left thigh			
14 weeks	Rotavirus 2	Oral			
	PCV2	IM Right thigh			
	Hexavalent (DTaP-IPV-Hib-HBV)3	IM Left thigh			
6 months	Measles 1	S/C Right thigh			
9 months	PCV 3	IM Right Thigh			
12 months	Measles 2	S/C Right arm			
18 months	Hexavalent (DTaP-IPV-Hib-HBV)4	IM Left arm			
6 years	Td	IM Left arm			
12 years	Td	Left arm			
Additional Vaccinations					
Girls 9 years and older	HPV1	IM Non-dominant arm			
	HPV2				

PHC Comprehensive Tick Register (zoom-in EPI & Child and nutrition)

Facility Name

Consulting room/Area

Month : **Year**

Date	No.	File No.	NAME	PHC Management			EPI																Child and Nutrition									
				PHC client seen by professional nurse	PHC client seen by public doctor	PHC client seen by sessional doctor	BCG dose	OPV 0 dose under 1 year	DTaP-IPV-Hib-HBV (Hexavalent) 1st dose	OPV 1st dose under 1 year	RV 1st dose under 1 year	PCV 1st dose under 1 year	DTaP-IPV-Hib-HBV (Hexavalent) 2nd dose	RV 2nd dose under 1 year	PCV 2nd dose under 1 year	DTaP-IPV-Hib-HBV (Hexavalent) 3rd dose	Measles 1st dose	PCV 3rd dose under 1 year	Immunised fully under 1 year new	Measles 2nd dose	DTaP-IPV-Hib-HBV (Hexavalent) 4th dose	Td dose at 6 years	Td dose at 12 years	Infant exclusively breastfed at DTaP-IPV-Hib-HBV (Hexavalent) 3rd dose	Vitamin A dose 12-59 months	Deworming dose 12-59 months	Diarrhoea with dehydration new in child under 5 years	Pneumonia new in child under 5 years	Moderate acute malnutrition in child under 5 years new	Severe acute malnutrition in child under 5 years new	Child under 5 years on food supplementation new	Child under 5 years overweight or obese new
	1																															
	2																															
	3																															
	4																															
	5																															

DE GROUP	CURRENT VACCINE (PCV13)	NEW VACCINE PCV10 – NO CHANGES IN TOOLS
Data element name	**PCV 1st dose under 1 year**	**PCV 1st dose under 1 year**
Bulleted definition	Pneumococcal conjugate vaccine 1st dose given to a child under 1 year at 6 weeks. The cut-off age is under 12 months	Pneumococcal conjugate vaccine 1st dose given to a child under 1 year at 6 weeks. The cut-off age is under 12 months
Extended Definition	PCV is given to children at 6, 14 weeks and 9 months. PCV 1st dose is given together with OPV1, DTaP-IPV-Hib, HBV 1 and RV1 at 6 weeks	PCV is given to children at 6, 14 weeks and 9 months. PCV 1st dose is given together with OPV1, DTaP-IPV-Hib, HBV 1 and RV1 at 6 weeks
Use and Context	Monitors the Expanded Program on Immunisation policy	Monitors the Expanded Program on Immunisation policy
Inclusions	None	INCLUDE doses given to children between 6 weeks and under 12 months
Exclusions	EXCLUDE vaccines given as part of a national mass vaccination campaign	EXCLUDE vaccines given as part of a national mass vaccination campaign
Collected by	Clinicians	Clinicians
Collection points	All health facilities & School Health	All health facilities (Clinics, CHCs, Mobiles & hospitals)
Tools	PHC Comprehensive Tick Register	PHC Comprehensive Tick Register & Hospital paediatric registers

DE GROUP	CURRENT VACCINE (PCV13)	NEW VACCINE PCV10 – NO CHANGES IN TOOLS
Data element name	**PCV 2nd dose under 1 year**	**PCV 2nd dose under 1 year**
Bulleted definition	Pneumococcal conjugate vaccine 2nd dose given to a child under 1 year at 14 weeks. The cut-off age is under 12 months	Pneumococcal conjugate vaccine 2nd dose given to a child under 1 year at 14 weeks. The cut-off age is under 12 months
Extended Definition	PCV is given to children at 6, 14 weeks and 9 months. PCV 2nd dose is given together with DTaP-IPV-Hib, HBV 2 and RV2 at 14 weeks	PCV is given to children at 6, 14 weeks and 9 months. PCV 2nd dose is given together with DTaP-IPV-Hib, HBV 2 and RV2 at 14 weeks
Use and Context	Monitors the Expanded Program on Immunisation policy	Monitors the Expanded Program on Immunisation policy
Inclusions	None	INCLUDE doses given to children between 14 weeks and under 12 months
Exclusions	EXCLUDE vaccines given as part of a national mass vaccination campaign	EXCLUDE vaccines given as part of a national mass vaccination campaign
Collected by	Clinicians	Clinicians
Collection points	All health facilities & School Health	All health facilities (Clinics, CHCs, Mobiles & hospitals)
Tools	PHC Comprehensive Tick Register	PHC Comprehensive Tick Register & Hospital paediatric registers

DE GROUP	CURRENT VACCINE (PCV13)	NEW VACCINE PCV10 – NO CHANGES IN TOOLS
Data element name	**PCV 3rd dose under 1 year**	**PCV 3rd dose under 1 year**
Bulleted definition	Pneumococcal conjugate vaccine 3rd dose given to a child under 1 year at 9 months. The cut-off age is under 12 months	Pneumococcal conjugate vaccine 3rd dose given to a child under 1 year at 6 weeks. The cut-off age is under 12 months
Extended Definition	PCV is given to children at 6, 14 weeks and 9 months. PCV 3rd dose is usually the last vaccine to be given for a child to be fully immunised	PCV is given to children at 6, 14 weeks and 9 months. PCV 3rd dose is usually the last vaccine to be given for a child. The child will be regarded as being fully immunised if ALL other under 1 year vaccines are given
Use and Context	Monitors the Expanded Program on Immunisation policy	Monitors the Expanded Program on Immunisation policy
Inclusions	None	INCLUDE doses given to children between 9 months and under 12 months
Exclusions	EXCLUDE vaccines given as part of a national mass vaccination campaign	EXCLUDE vaccines given as part of a national mass vaccination campaign
Collected by	Clinicians	Clinicians
Collection points	All health facilities & School Health	All health facilities (Clinics, CHCs, Mobiles & hospitals)
Tools	PHC Comprehensive Tick Register	PHC Comprehensive Tick Register & Hospital

THANK YOU