



# Hepatitis B Vaccine - targeted birth dose

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Knowledge Hub webinar

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31<sup>st</sup> October 2023

# Outline

- Background
- Vaccine characteristics
- Hep B administration
- Data management



**health**

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



# BACKGROUND



health

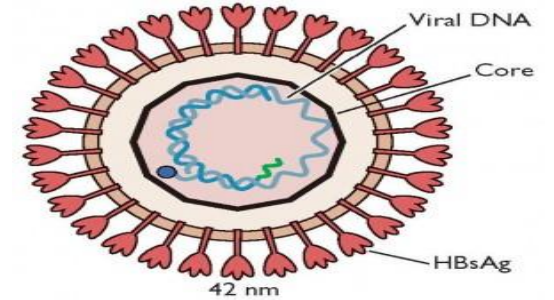
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Department:  
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# Hepatitis B



- HBV is a DNA virus
- 100 times more infectious than HIV
- Can survive 7 days outside the body
- Transmitted through contaminated **blood** and **bodily fluids**
  - **Vertical:** Mother-to-child-transmission (MTCT) at birth
  - **Horizontal:** Exposure to blood, saliva, vaginal secretions, menstrual blood or semen
  - **Parenteral:** Re-use of needles and syringes or tattoo / surgical instruments
  - **Sexual:** Higher risk if damage to vagina or anal lining or co-infection with STI



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# Course of disease

## Hepatitis can be acute and self-limiting or chronic

- **Acute infection:**

- ❖ Mostly asymptomatic
- ❖ Symptoms include: yellowing of the skin and eyes (jaundice), dark urine, extreme fatigue, nausea, vomiting and abdominal pain
- ❖ Small proportion develop acute liver failure → death

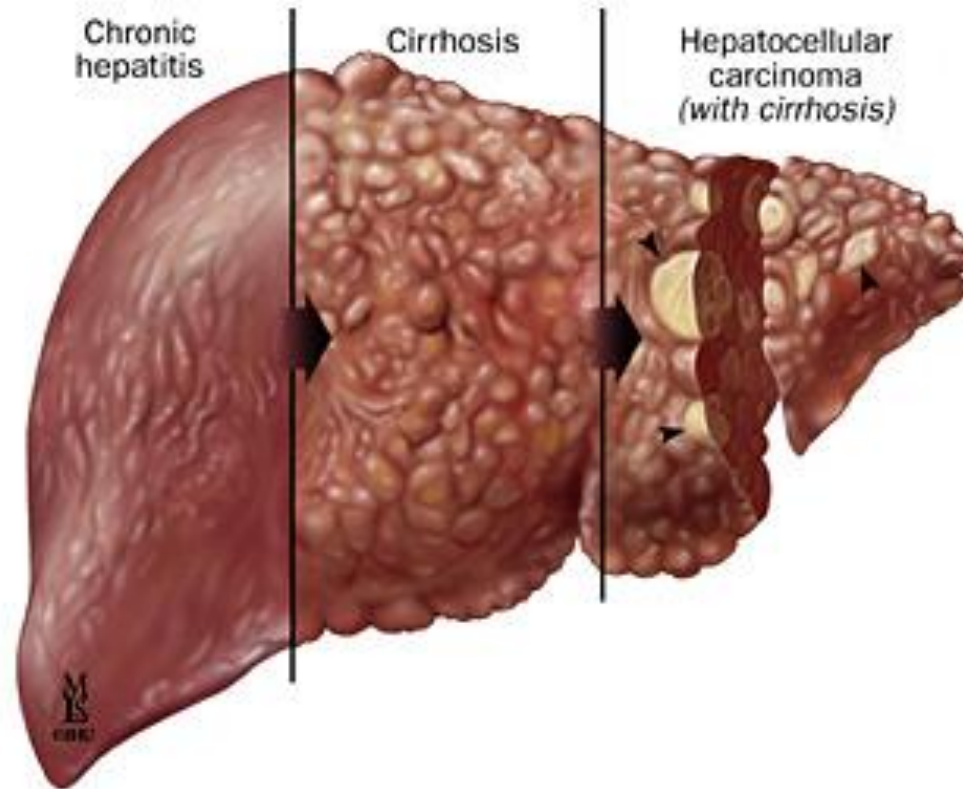
- **Chronic infection:**

- ❖ Asymptomatic typically
- ❖ Malaise, fatigue, anorexia, vague abdominal discomfort
- ❖ Signs of cirrhosis and chronic liver failure (ascites, varices, telangiectasia)

Viral hepatitis is responsible for an enormous health burden, mostly due to chronic hepatitis B and C infection

# Complications of chronic viral hepatitis infection

- Cirrhosis (scarring)
- Chronic liver failure
- Hepatocellular carcinoma (HCC)



# Viral hepatitis elimination

## ■ Prevention

- Vaccines (hepatitis A and B)
  - All children have received four doses of Hep B vaccine since 1995 (one of the components of hexavalent vaccine)
- Prevention of mother to child transmission
- Avoidance of contact with infected blood and blood products
- Rational use of safe medical injections
- Consistent condom and lubricant use
- Avoid sharing needles, toothbrushes, razors or nail scissors
- Sterile injecting equipment and opioid substitution therapy for people who inject drugs
- For hepatitis A & E: hand washing, safe food and water and safe sanitary waste disposal

## ■ Treatment

- HBV can be effectively managed and HCV cured, preventing onwards transmission

# WHO goals on the elimination of viral hepatitis by 2030

## 2030 Goal:

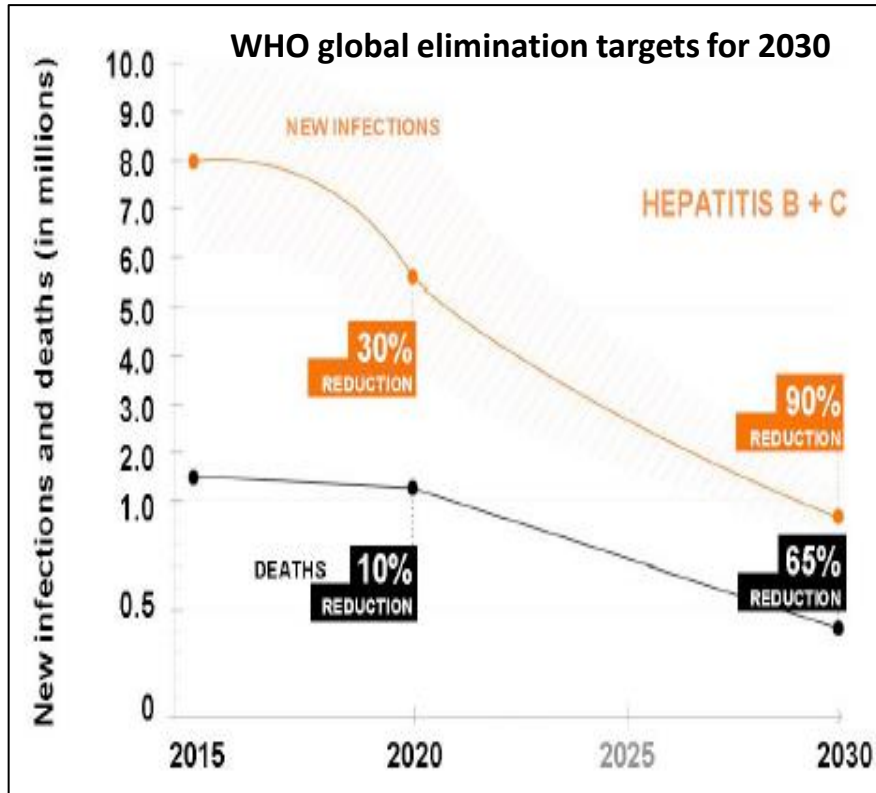
Eliminate viral hepatitis as a major public health threat

## 2030 Targets:

- Reduce incidence of HBV and HCV by 90%, **<0.1 incidence in <1 year olds**
- Reduce HBV and HCV deaths by 65%
- Reduce mother-to-child transmission of HBV by 90%
- Diagnose 90% of HBV and HCV cases
- Treat 80% of eligible HBV and HCV patients



# Viral hepatitis elimination



WHO, 2015

## South Africa has developed:

- National guidelines for the management of viral hepatitis
- A National Hepatitis Action Plan
  - Priorities:
    - HBV birth dose vaccination
    - Health worker screening and vaccination
    - Health worker training
    - Expanded HCV treatment, including services for people who inject drugs
    - Awareness raising

# Rationale for the introduction of targeted birth dose

- HBV can be transmitted through vertical transmission (mother-to-child)
- Although studies suggest that the risk of transmission is relatively low in the South African setting, vertical transmission in neonates is associated with a high risk of chronic (lifelong) infection.
- The Hepatitis Guidelines recommend that all pregnant women are screened for Hepatitis surface antigen (sAg).
- The EML Standard Treatment Guidelines recommend that:
  - All infants born to mothers who are HBV positive (surface antigen or e-antigen) receive:
    - A birth dose of Hep B vaccine
    - Hepatitis B immunoglobulin (not currently available).
- Discussions are underway regarding Hep B immunisation of other groups.
- **For now, targeted birth dose will be implemented.**

# VACCINE CHARACTERISTICS

# Tender information for Hep B Vaccine Paed

Tender Information	Details
<b>Description</b>	Vaccine, hepatitis B, containing purified hepatitis B surface antigen (HBsAG) in strength of 10mcg / 0.5ml per dose, 10 multi-dose vial (100mcg/5ml), for paediatric use. For intramuscular administration.
<b>Period</b>	01 Jan 2024-31 Dec 2026
<b>Product code (NSN)</b>	180323312
<b>Product description</b>	Hep B Vaccine Paed Cipla
<b>Price</b>	R98.04
<b>Minimum order quantity</b>	10 vials

# Change in Vaccine Vial Presentation - Hep B Vaccine Paed

- ✓ While Heberbiovac paediatric vaccine is being phased out it is considered **interchangeable** with Hep B Paed Cipla
- ✗ There is no need to keep both vaccines in stock
- ✓ Once your available Heberbiovac paediatric vaccine stock is depleted the new Hep B-paed Cipla vaccine should be order on the **SAME stock code**
- ✓ SVS and NCS will be used to **monitor availability** at all levels Hepatitis B paediatric vaccines

Description	Details
Ordering the new Hep B paediatric vaccines	<ul style="list-style-type: none"><li>• Monitor SVS</li><li>• Order on the same stock code</li></ul>

# Introducing Hep B vaccine Pead Cipla

Description	Details
<b>Manufacturer</b>	Cipla (SII)
<b>Composition</b>	<p>Each dose of 0.5 ml contains :-</p> <p>10 mcg of purified Hepatitis B surface antigen</p> <p>Adsorbed on Aluminium hydroxide (Al+++ ) 0.25 mg to 0.40 mg</p> <p>Preservative : Thiomersal 0.005%</p> <p>Produced in Hansenula polymorpha (yeast)</p> <p>Dose : 0.5 ml by intramuscular injection</p>
<b>Schedule</b>	2
<b>Approved for</b>	Active immunisation against Hepatitis B
<b>Identification</b>	Fully liquid. White turbid suspension, settles down slowly when stored



# Introducing Hep B vaccine Paed Cipla

Description	Details
Presentation	5ml glass vial contains 10-doses of 0.5ml
Pack Size	10 vials
Diluent required	No
VVM - present on vial	Yes
Type of VVM	30
Storage temperature	2-8° C
Light sensitive	Yes
Aluminium Adjuvant	Yes
Freeze sensitive	Yes



# Storage and temperature excursions Hep B Vaccine Paed Cipla

Description	Details
<b>Front loading fridge</b>	Vaccine: Middle shelf
<b>Top loading fridge</b>	Vaccine: Upper basket
<b>Shake test applies</b>	Yes
<b>Multi-dose vial policy applies</b>	Yes
<b>Temperature excursion</b>	<b>Do not freeze.</b> Perform the “shake test” if freezing suspected to determine if the vaccine is safe for use
<b>More info on temperature excursions</b>	Contact the supplier or your EPI or pharmacy manager

Front loader fridge



Top loader fridge



## HINT

**Do not expose vaccine to freezing conditions**

**Use conditioned ice packs  
Use correctly prepared coolant packs**

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



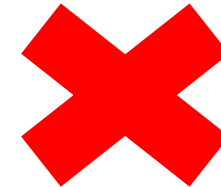
# Vaccine Wastage Hep B Vaccine Paed

Description	Details
SA acceptable wastage rate	<ul style="list-style-type: none"><li>• 50% for routine immunisation (estimated)</li></ul>
Buffer	<ul style="list-style-type: none"><li>• 15% for routine immunisation</li><li>• 5% for campaign</li></ul>

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

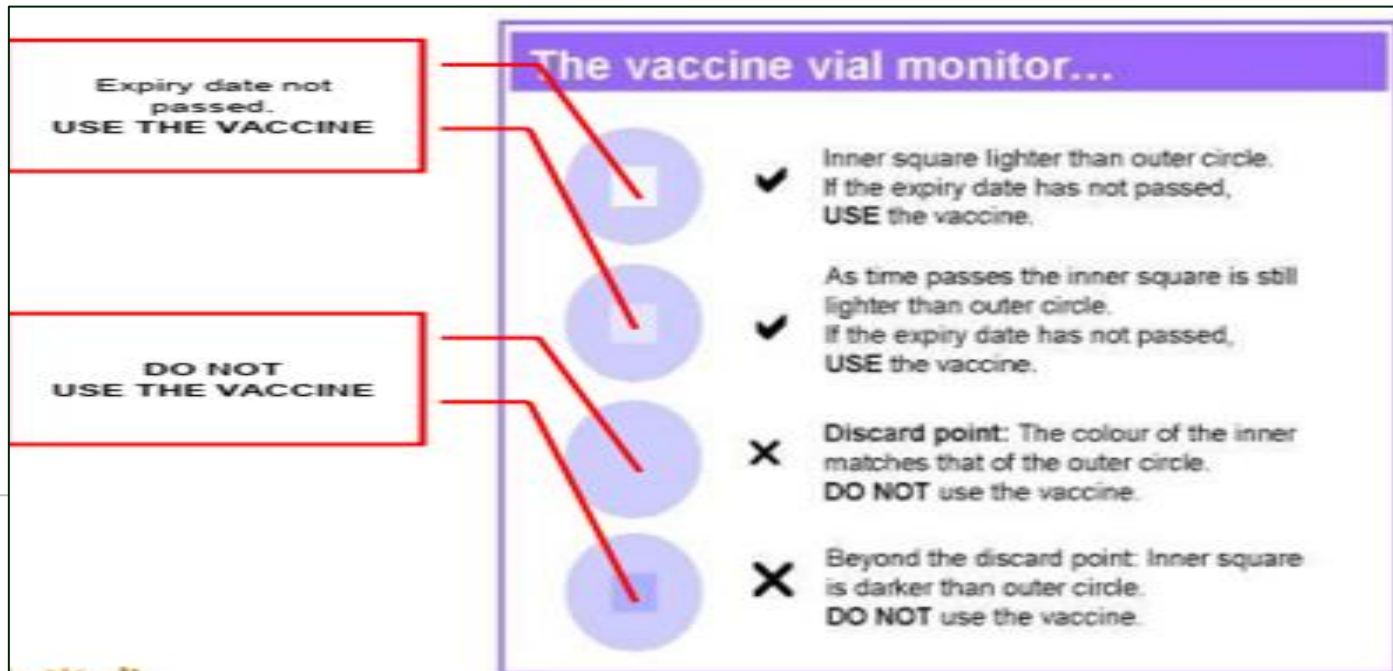


# Vaccine Vial Monitor

*Hep B Vaccine Paed is assigned a Type 30 VVM*  
*Hep B Vaccine Paed Cipla vial has a VVM on the label*

## How does a VVM work?

VVMs are small indicators attached to vaccine vials and change colour as the vaccine is exposed to cumulative heat, letting health workers know whether the vaccine has exceeded a pre-set limit beyond which the vaccine should not be used.



Category	No. of days to End point at +37°C	No. of days to End point at +25°C	No. of days to End point at +5°C
<b>VVM 2:</b> Least stable	2	N/A	225 days
<b>VVM 7:</b> Moderate stability	7	45	> 2 years
<b>VVM 14:</b> Medium stability	14	90	> 3 years
<b>VVM 30:</b> High Stability	30	193	> 4 years

# Handling of multi-dose vials after opening



Opened vials of bOPV, TT, Hepatitis B and Td may be used in subsequent immunisation sessions for a maximum of **28 days** after opening if all of the following rules are met:

- The expiry date has not passed; and the **vial was dated when opened**
- The vaccines are stored under appropriate cold chain conditions (2-8° C with temperature monitoring and recording);
- The vaccine vial septum was not been submerged in water
- Aseptic technique has been used to withdraw all doses
- The vial has not reached its discard point

NB: The VVM on these vaccines, regardless of the formulation of the product (liquid or lyophilized), if attached, is on the **label** of the vaccine.

# VACCINE ADMINISTRATION

# Schedule & administration Hep B Vaccine Paed

Description	Details
<b>Recommended Age (as PI)</b>	All ages at risk
<b>Recommended Schedule (as per EPI)</b>	At birth, babies born to mothers with acute hepatitis B infection at the time of delivery or to mothers who are HBsAg-positive or HBeAg-positive
<b>Timing of vaccination</b>	As soon as possible after birth Must be administered within 24 hours of birth. Doctor may recommend that dose is delayed in small or sick newborns
<b>Recommended max age (follow recommended catch-up schedule)</b>	2 weeks

# Vaccine Administration

## Step 1.

- First check the mother's HBV status
  - **Only infants of mothers who are HBsAg-positive or HBeAg-positive should be vaccinated.**
- Inform the caregiver what vaccine the child is receiving and allow questions to be asked

# Vaccine safety Hep B Vaccine Paed Cipla

Description	Details
<b>Contra indications</b>	Do not administer the vaccine to anyone with known hypersensitivity, previous allergic reactions or anyone who had a severe or life-threatening allergic reaction to the vaccine or any component of the vaccine.
<b>Precautions</b>	<ul style="list-style-type: none"><li>• Appropriate medical treatment and supervision must be available during immunisation.</li><li>• In babies with an impaired immune system, sufficient immunity may not be obtained with the primary immunisation course and such patients may therefore require additional doses of vaccine (see Dosage recommendation for Immunocompromised persons).</li></ul>
<b>Possible events</b>	<ul style="list-style-type: none"><li>• Side effects are mostly mild and transient and may include mild soreness, erythema, induration, fatigue, malaise, influenza like symptoms.</li><li>• <b>Less common</b> systemic reactions include nausea, vomiting, diarrhoea, abdominal pain, abnormal liver function tests, arthralgia, myalgia, rash, pruritus, urticaria.</li><li>• For more information consult the package insert.</li></ul>

# Vaccine Administration

## Step 2.

- Take the vaccine out of the vaccine carrier and remove it from its packaging.
- Check the expiry date, VVM 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;

# Recommended syringe & needle for reconstitution & administration Hep B Vaccine Paed

Description	Details
Reconstitution syringe	Not required
Reconstitution needle	Not required
Administration syringe	1ml syringe: 42142609-00003/4/8/22/25 2ml syringe: 42142608-00000/4/34
Administration needle	<b>Needle Gauge and Length:</b> 25g x 16mm: 42142523-00008 <b>Needle Length/Age:</b> Neonates <=28 days: 16 mm

- 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.

# Schedule & Administration Hep B Vaccine Paed

Description	Details
<b>Route &amp; Site of administration</b>	<b>Neonates:</b> IM. Vastus lateralis muscle of anterolateral thigh. Subcutaneously in patients with bleeding disorders
<b>Co-administration</b>	May be administered simultaneous with other vaccines, in accordance with the EPI schedule and as appropriate for the recipient's age and previous vaccination status. Separate injection sites and separate syringes must be used in case of concomitant administration.
<b>Preparation/ Reconstitution</b>	Fully liquid, no dilution required
<b>Dose</b>	0.5ml
<b>Storage after 1<sup>st</sup> puncture of vial</b>	28 days

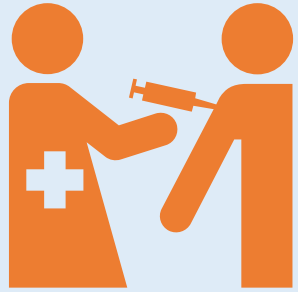
# Vaccine Administration

## Step 5.

- Record dose on Road to Health Booklet

## Step 6.

- Indicate to the caregiver what to do if there any adverse events following immunisation
- Indicate when the child should receive the next immunisation (6 weeks of age)



**Adverse event of concern**



**Health facility**



**Med Safety App**

**MILD/MINOR EVENTS Expected**



**SEVERE EVENTS Not expected**

**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

**Investigated**

# Vaccine safety surveillance cycle in SA

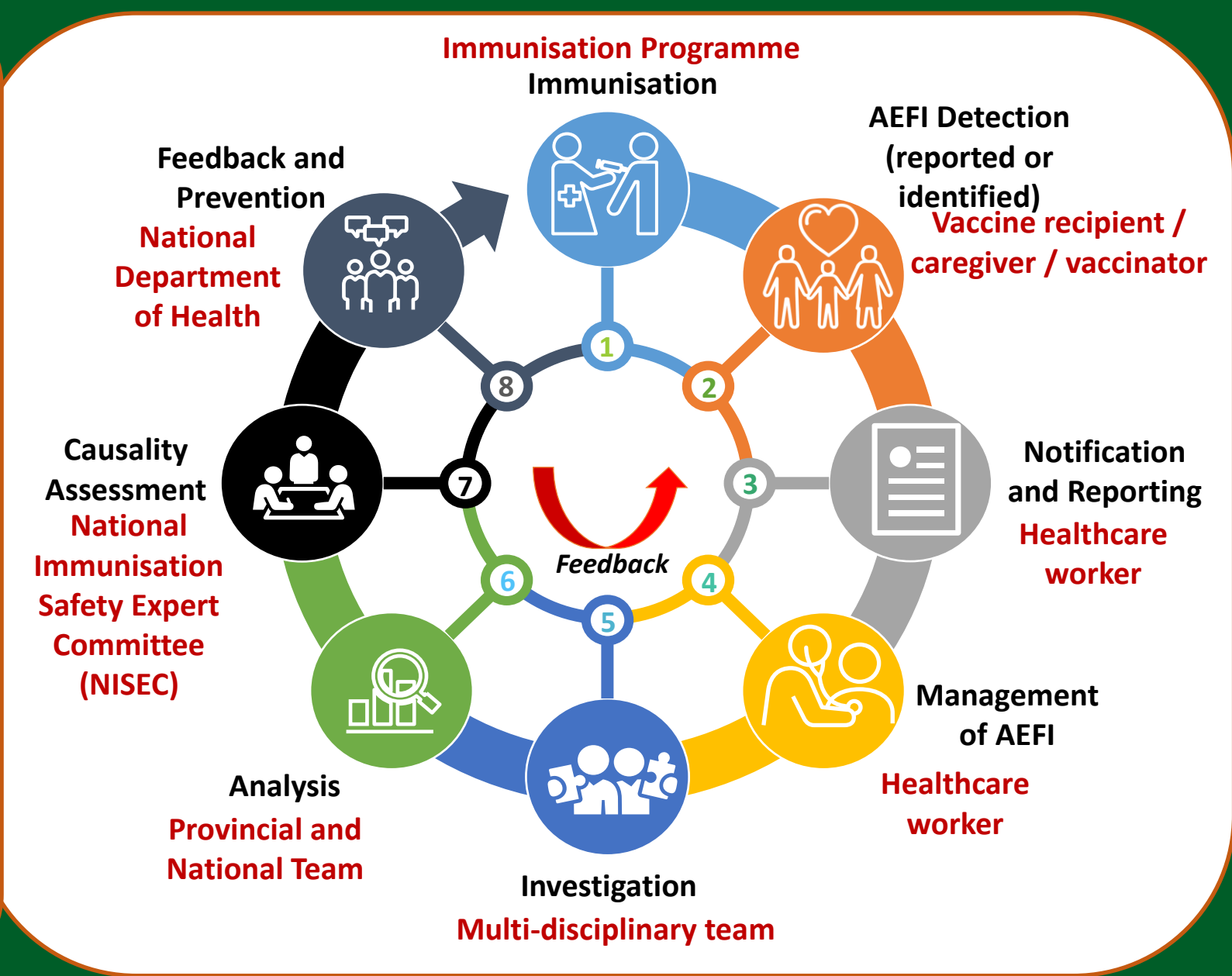
**Vaccine Manufacturing Industry**

**South African Health Products Regulatory Authority (SAHPRA)**

**National Department of Health (NDoH)**

**World Health Organization (WHO)**

**Ministerial Advisory Committees on Vaccines and Immunisation**



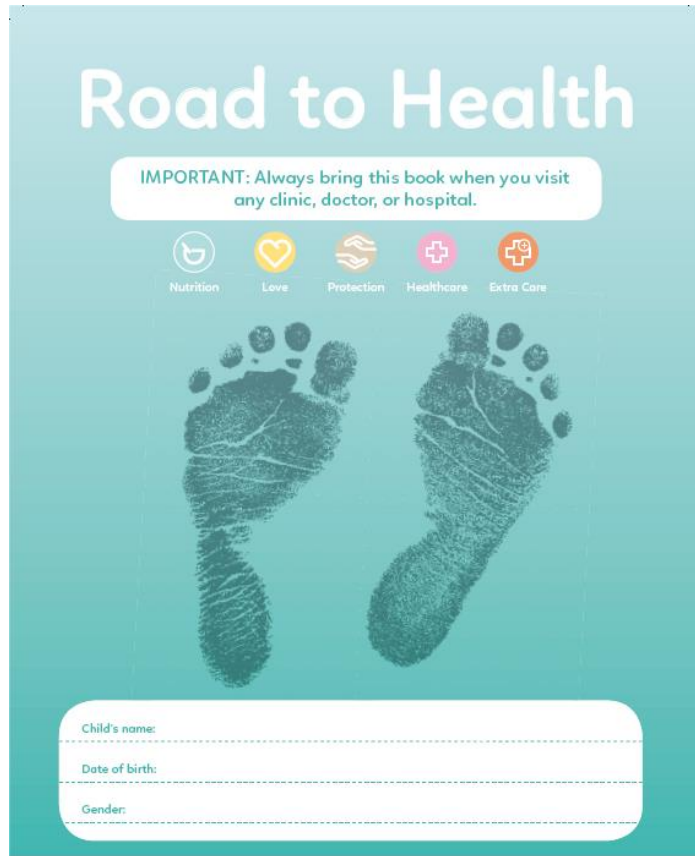
# Hep B Data Management



# Recording the Hep B doses

- Hep B. 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 or hospital tick register
  - Vaccine Stock cards
  - Maternity case record.

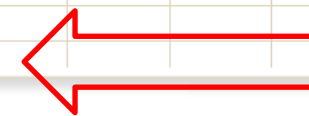
# Road to Health Booklet



## 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			
	Rotavirus 2	Oral			
14 weeks	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				



# Heb B for pregnant women: New data elements

- All ANC clients tested for HBsAg for the first time in this pregnancy
- ANC clients with HBsAg positive result
- ANC clients vaccinated with HepB vaccine

DE Group	Expanded Program on Immunisation (NEW Data Element)
Data Element Name	HBV (0) dose of HBsAg POSITIVE women
Bulleled Definition	Hepatitis B vaccine, birth dose is given within 24 hours after birth to infants born to HBsAg POSITIVE women . The cut-off age is 2 weeks after birth.
Extended Definition	Infants who received HBV 0 (Birth) dose, as a proportion of ANC clients tested POSITIVE for HBsAg. Hepatitis B is included in the DTaP-IPV-Hib-HBV (Hexavalent) vaccine and given to children at 6, 10, 14 weeks and 18 months. HBV 4th dose in DTaP-IPV-Hib-HBV vaccine is usually the last vaccine to be given for a child. HBV (0) is given together with BCG and OPV (0). To accommodate the 4 weeks intervals between HBV (0) and HBV (1) in DTaP-IPV-Hib-HBV vaccine, the last dose of HBV (0) should be given at 2 weeks after birth.
Use and Context	Monitors HBV vaccination given to infants at birth following the mother's HBsAb positive result. Monitors protection of infants against perinatal Hepatitis B virus transmission.
Inclusions	INCLUDE BBAs if they are given HBV birth dose INCLUDE doses given to children up to 2 weeks of age
Exclusions	EXCLUDE infants born to HBsAg NEGATIVE women
Collected by	Clinicians
Collection points	All facilities
Frequency	Monthly
Tools	PHC Comprehensive Tick Register, Maternity Registers & Hospital paediatric registers

# INTERIM EPI REGISTER FOR NEW VACCINES

## EPI NEW VACCINE REGISTER

Facility Name											
Consulting Room:											
Month			January	Year						2024	
Date	No.	File NO.	NAME	AGE	HBV (0) dose	MR 1st dose	MR 2nd dose	Tdap dose at 6 years	Tdap dose at 12 years	Tdap dose at 26 to 34 weeks of gestational age	
	1										
	2										
	3										
	4										
	5										
	6										
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 Verified by Operational Manager: \_\_\_\_\_

Signature \_\_\_\_\_  
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Date \_\_\_\_\_  
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- The **interim register** will be used from **January to March 2024**
- **From April 2024**, the new data elements will be included into all data tools (PHC tick register, Hospital registers, etc.,)

# THANK YOU