Rubella-Containing Vaccine introduction in the EPI Schedule, South Africa

Knowledge Hub Webinar

Date: October 2023

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL DEVELOPMENT PLAN 2030

Phila

Outline

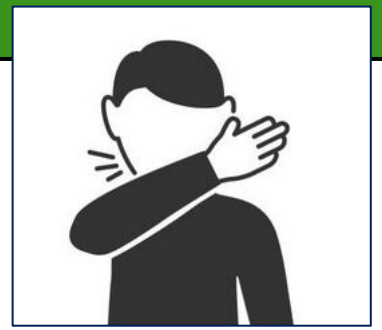
- Background
- Public Health rationale
- Vaccine presentation and logistics
- Updated immunisation schedule
- MR vaccine administration
- Vaccine safety surveillance
- Data management

Rubella virus

- Rubella is an RNA virus and humans are the only known host
- It is the only species of the genus Rubivirus under the Matonaviridae family of viruses

Transmission occurs :

Horizontally: through droplets expelled from the nose or mouth of patients when coughing or sneezing



Vertically:
During pregnancy from the mother to the foetus through the placenta

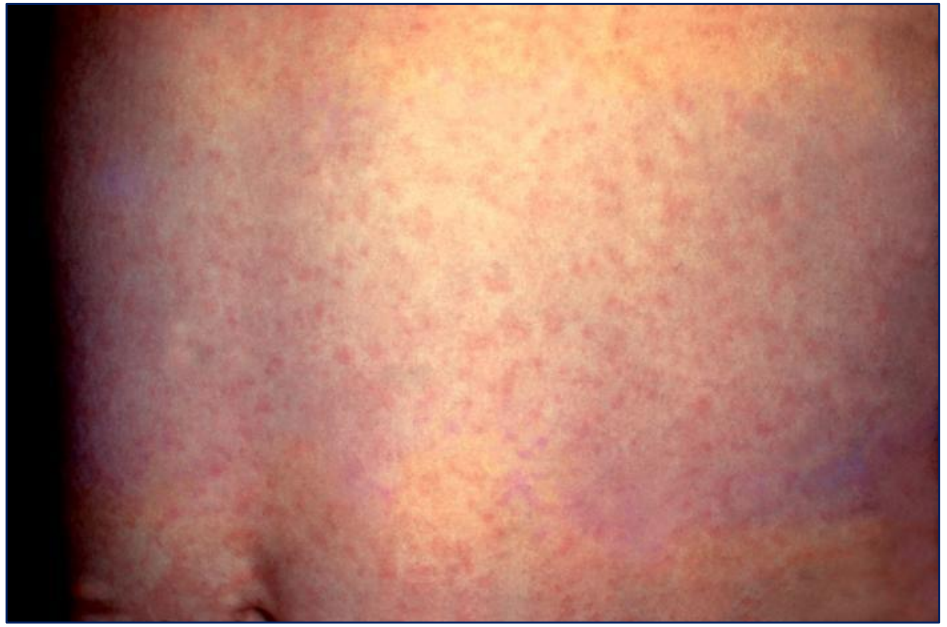
Rubella is endemic, in South Africa with epidemics every 5 to 9 years in the absence of mass vaccination

Clinical presentation of rubella

- The name “Rubella,” meaning “little red,” was previously called “German measles” and was first used to describe an outbreak at a boys’ school in India.
- Rubella is generally a mild disease in children and adults.
- Patients often initially present with a variety of signs/symptoms over a few days (2-5) including:
  - ❑Low grade fever
  - ❑Malaise
  - ❑Lymphadenopathy
  - ❑Upper respiratory symptoms such as cough, nasal congestion and sore throat
  - ❑Conjunctivitis (red eye)
  - ❑Anorexia (loss of appetite)
  - ❑Fatigue

Clinical presentation of rubella

- A generalized, itchy maculopapular rash appears on the face before spreading rapidly to the chest, arms and legs.
- Up to 50% of individuals infected with rubella do not present with rash
- Complications include:
  - ❑ Arthritis
  - ❑ Hemorrhagic manifestations
  - ❑ Orchitis
  - ❑ Neuritis
  - ❑ Progressive panencephalitis
  - ❑ Congenital rubella syndrome (CRS)



Congenital rubella syndrome (CRS)

- CRS is the most severe presentation of rubella infection
- Congenital cataracts were first linked to maternal rubella infection in 1941
- WHO estimates that >100,000 infants are born with CRS annually worldwide
- Rubella infection in pregnancy can lead to adverse foetal outcomes including miscarriages, stillbirths and severe birth defects
- The risk of birth defects is highest when rubella infection occurs during first 12 weeks of gestation
- Infants with CRS can excrete rubella virus for about 1 year

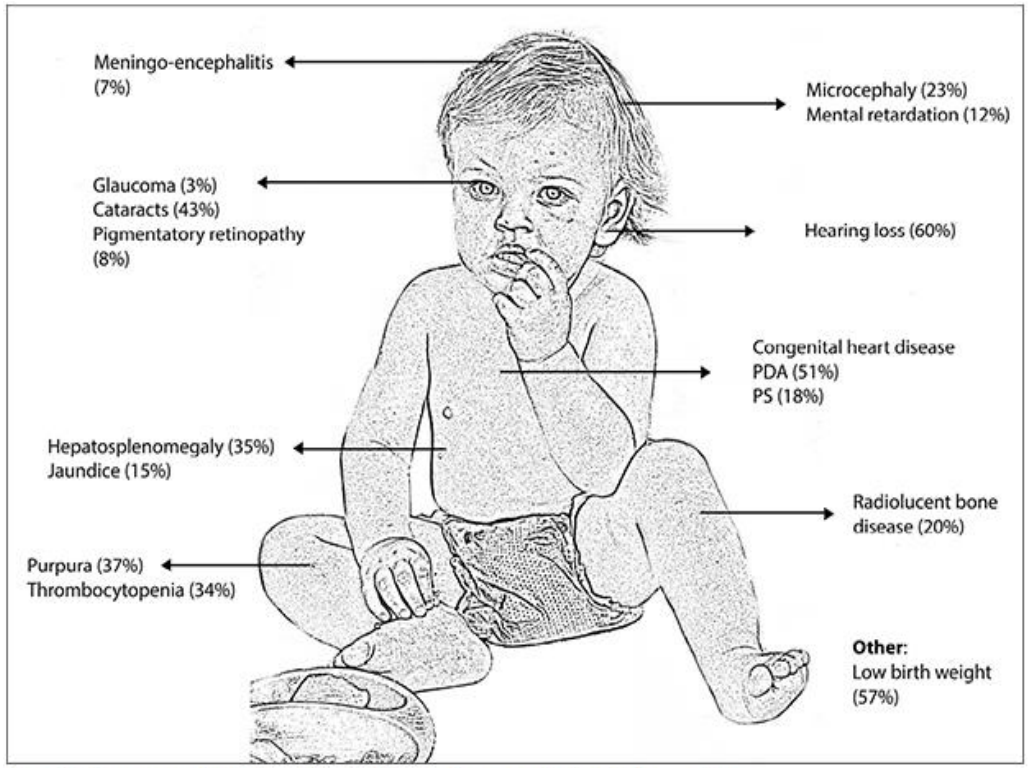


Fig. 1. Common clinical manifestations of congenital rubella syndrome.

http://www.sajch.org.za/index.php/SAJCH/article/view/461/358

Epidemiology of rubella

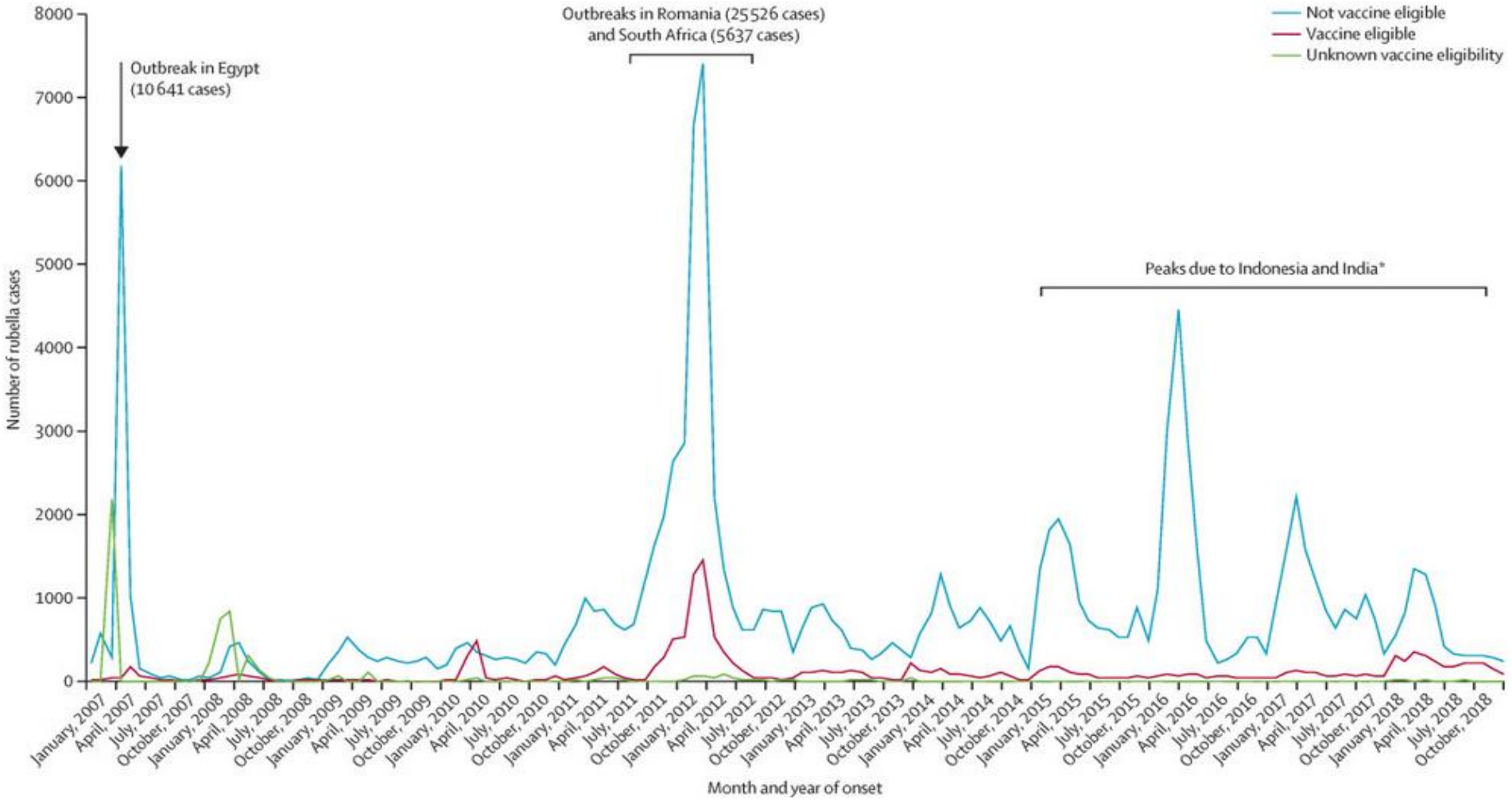


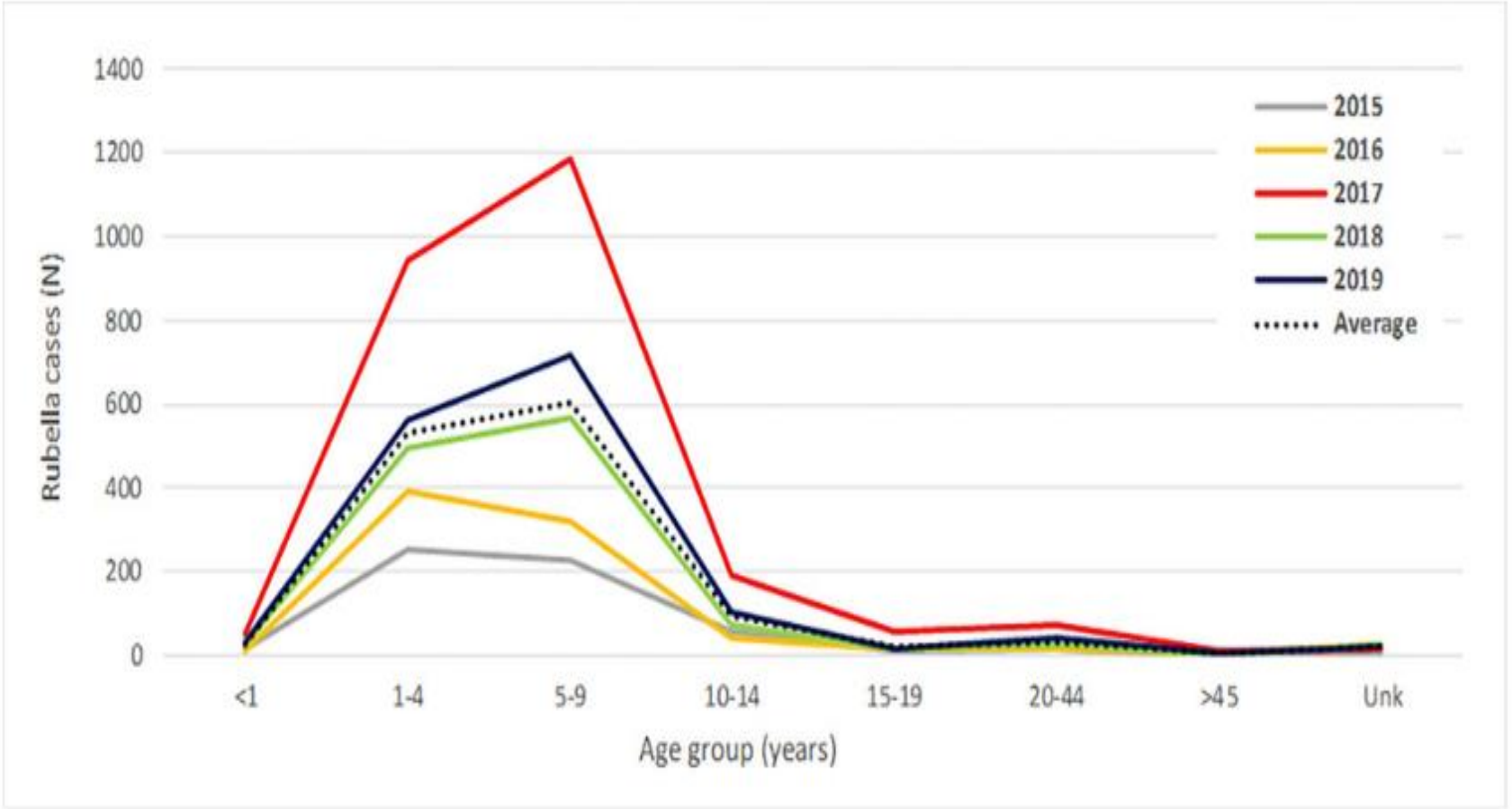
Figure 2 Reported rubella cases by date of onset and by vaccine eligibility, 2007–18

https://www.thelancet.com/journals/langlo/article/PIIS2214-109X%2820%2930320-X/fulltexta

Rubella cases decreased globally as the number of countries that introduced vaccines increased substantially; from more than 4000 cases in the year 2016 to 173 in the year 2019.

Epidemiology of rubella

- Most rubella infections occur in children 5-9 years old
- Rubella case persists in adolescents and adults
- At least half of the cases are in females, thereby raising concerns about the risk of CRS



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Rubella vaccines

- Live attenuated vaccines were first introduced in 1969
- Vaccines resulted in a sharp decrease in rubella incidence
- **Rubella vaccine requires high coverage to avoid increase in CRS cases**
- Greece
  - From 1970s boys and girls were vaccinated at age 1 year
  - Coverage was consistently low (below 50%)
  - Outbreak of congenital rubella syndrome in Greece 1993

- Costa Rica
  - Introduced MMR vaccine in 1986 at 1 year
  - Increase in congenital rubella syndrome cases
  - Mass campaign targeting adults in 2001

Rubella vaccines

- Rubella vaccines can target rubella cases, CRS cases or both

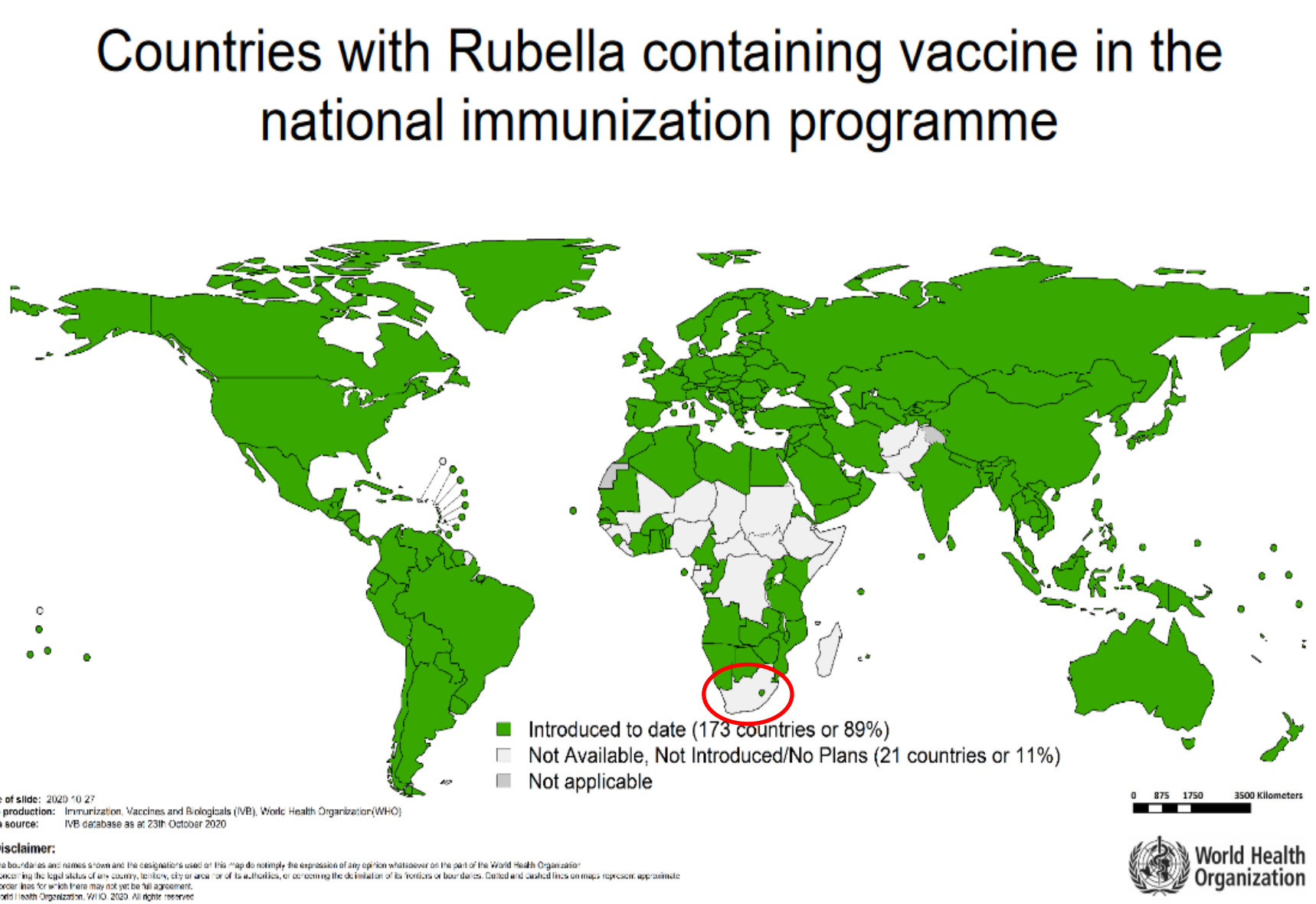
- **Prevention of CRS can be achieved through direct or indirect strategies:**

  - **Direct strategy:** Vaccinate the population directly at risk
    - For rubella, vaccinate children who have the highest disease incidence
    - For CRS, vaccinate pregnant women

  - **Indirect strategy:** Vaccinate the population not at risk
    - For rubella, vaccinate children reduces disease incidence in older individuals
    - For CRS, vaccinate children reduces rubella incidence among women of child-bearing age and therefore, reduce CRS incidence.

Rationale for rubella vaccine introduction

- Rubella vaccination is **aimed at interrupting rubella transmission which leads to rubella and CRS** elimination
- **South Africa is the only country** in the sub-region that is yet to introduce rubella vaccination in its EPI schedule
- Rubella vaccine is **available in the private health care** sector of South Africa in combination with measles and mumps.
- The absence of rubella vaccination in the public sector **increases the risk of rubella infections, and eventually, CRS cases**.



Vaccine presentation and logistics – Tender information

Tender Information	Details
Description	Vaccine, containing AT LEAST THE FOLLOWING 1000 CCID50 of live attenuated measles and 1000 CCID50 of live attenuated rubella virus per 0.5ml. 10 dose vial with diluent if reconstitution is required. For subcutaneous administration. WITH Vaccine Vial monitor (Alternative to 1 dose presentation).
Period	01 Jan 2024 - 31 Dec 2027
Product code (NSN)	222001478
Product description	Measles Rubella Cipla
Price	R177.81 (10 dose vial)
Minimum order quantity	50 vials

Handling the MR introduction

- ✓ While Measbio is being phased out it is considered **interchangeable** with and MR-Cipla (SII)
- ✖ There is no need to keep both vaccines in stock
- ✓ Once your available Measbio (MCV) vaccines stock is depleted the new MR-Cipla (SII) 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 Measbio (MCV) and phase in of MR-Cipla (SII) 21

How to switch from Measles to MR	1. Monitor SVS 2. Order on the new stock code

MR vaccine presentation

Description	Details
Manufacturer	Cipla (SII)
Composition	Vaccine, containing AT LEAST THE FOLLOWING 1000 CCID50 of live attenuated measles and 1000 CCID50 of live attenuated rubella virus per 0.5ml.
Schedule	2
Approved for	Measles/Rubella Cipla is indicated for: active immunisation against measles and rubella in infants and children from the age of 9 months and older, adolescents and young adults at risk, immunisation of susceptible non-pregnant adolescent and adult females of childbearing age is indicated if certain precautions are observed. (use from 6 months recommended by NAGI following review of safety data)
Identification	Freeze dried powder. Lyophilised product with appearance of a yellowish-white dry cake

MR vaccine presentation

Description	Details
Presentation	10-dose vial supplied with diluent ampoule
Pack Size	50 vials
Diluent required	Yes - supplied by manufacturer
VVM - present on vial	Yes
Type of VVM	14
Storage temperature	Store between 2 to 8°C
Light sensitive	Yes
Aluminium Adjuvant	No
Freeze sensitive	No

MR vaccine presentation – General Export Pack

- To ensure an uninterrupted supply of Measles containing vaccine, the department has agreed to accept the Measles Rubella vaccine from Cipla in **General Export Pack from 1 January 2024**
- **The differences in the presentation include:**
- **The generic name:** MEASLES AND RUBELLA VACCINE manufactured for UNICEF by Serum Institute of India Pvt/Ltd
- **Package insert (PI)/ patient information leaflet (PIL)** all in English, French, and Spanish
- **Tradename** UNICEF MR vaccine appear on the label and
- **Batch and expiry dates** are reflected on the side in English

  Batches include: 0123W044; 0123W045; 0123W046
- **The South African packaging is expected to arrive in April – May 2024**

Storage and temperature excursions MR vaccine

Description	Details
Front loading fridge	Vaccine: Top shelf Diluent: Middle shelf
Top loading fridge	Vaccine: Bottom basket Diluent: Upper basket
Shake test applies	No
Multi-dose vial policy applies	Discard 6 hours after reconstitution or at the end of the immunization session, whichever occurs first
Temperature excursion	Reconstituted MR vaccine loses about 50% of its potency after 1 hour at 20 °C and almost all potency after 1 hour at 37 °C. Lyophilised vaccine: Follow the VVM. Diluent and reconstituted vaccine: **DO NOT FREEZE**. Discard if exposing to freezing conditions.
More info on temperature excursions	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 MR

Description	Details
SA acceptable wastage rate	• 55% 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

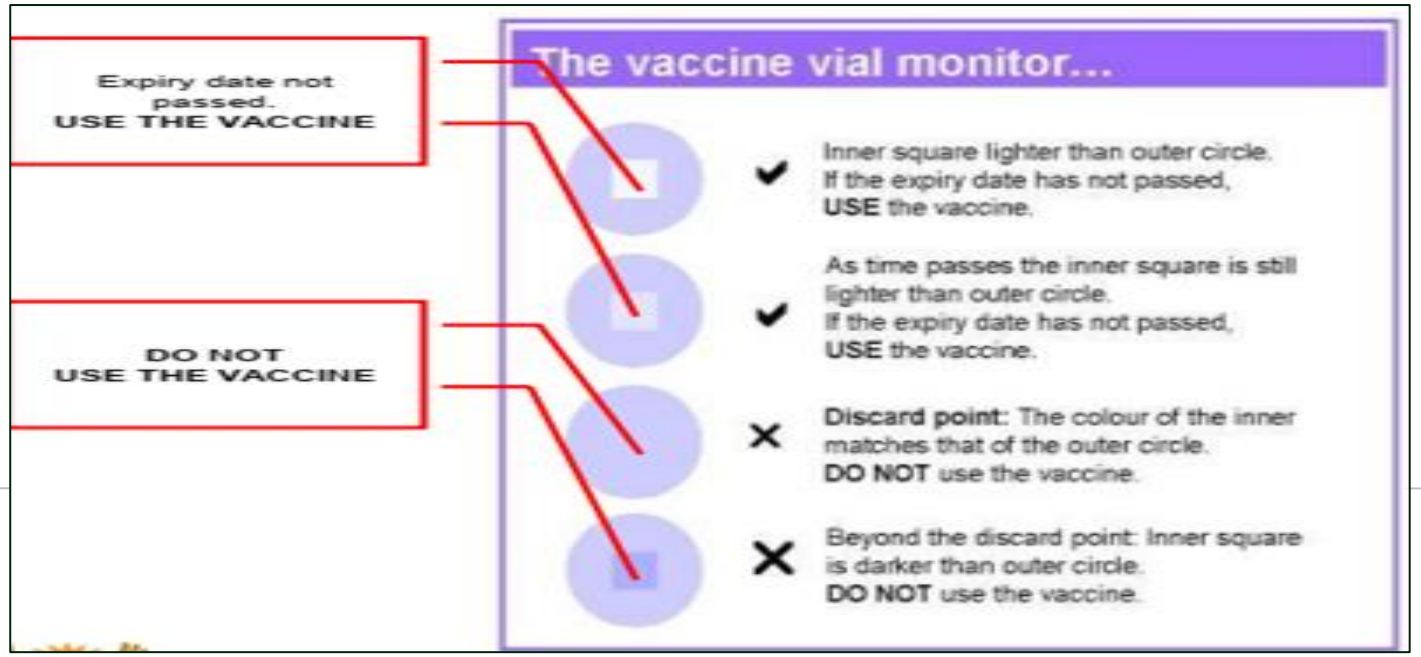
Reducing wastage must never come at the cost of immunizing an individual client

Vaccine vial monitor

MR –Cipla is assigned a Type 14 VVM
MR-Cipla 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
VVM 2: Least stable	2	N/A	225 days
VVM 7: Moderate stability	7	45	> 2 years
VVM 14: Medium stability	14	90	> 3 years
VVM 30: High Stability	30	193	> 4 years

Diluent handling & use

- The solution used for reconstitution of lyophilised vaccines are referred to as **DILUENTS**
- Diluents differ in composition therefore only the diluent assigned by the manufacturer for the specific vaccine must be used
- Diluents from different manufacturers are **not interchangeable**.
- **Never substitute** a vaccine diluent with water for injections or Sodium Chloride solution
- Unless otherwise specified by the manufacturer, diluents should be stored between +2°C to +8°C.
- Diluents must be recorded in stock cards as part of inventory

Opening glass ampoules with necessary care and inspection

- Care should be taken to ensure that pieces of glass are prevented from getting into the vaccine when opening ampoules
- Following reconstitution, the vaccine should be inspected visually for any foreign matter prior to administration

Handling of multi-dose vials after opening

Opened vaccine vials of Measles-Rubella containing vaccine may be used up to **a maximum of 6 hours or the end of the immunisation session** (whichever occurs first), after opening, if each of the following rules are met:

- The expiry date has not passed; and the **date and time was recorded on the vial when opened;**
- The vaccines are stored **under appropriate cold chain conditions** (2-8° Celsius 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 for these vaccines, regardless of the formulation of the product (liquid or lyophilized), if attached, is on the **cap** of the vial or **neck** of the

Continuous temperature monitoring devices

Only comprehensive temperature monitoring system can record the temperature history of vaccines passing through the supply chain

Updated EPI Schedule

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 **Do not co-administer with other vaccines.**
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

Vaccine2	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	
	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	*If 1st dose is MCV, 2nd dose is MR – no catch up with MR required*	
	≥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

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 MR-CIPLA

Description	Details
Contraindications	**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 (e.g. neomycin or gelatine).
Precautions	• Appropriate medical treatment and supervision must be available during immunisation. • 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	• The type and rate of severe adverse reactions do not differ significantly from the measles and rubella vaccine reactions described separately. • Side effects that may occur include mild pain and tenderness at the vaccination site, mild fever, rash, encephalitis, joint symptoms, lymphadenopathy, myalgia, paraesthesia, thrombocytopaenia and anaphylactic reactions. • For more information consult the package insert.

Risk groups

- ***HIV-infected children**:* The limited evidence available indicates that measles vaccines are safe in HIV-infected individuals unless severely immunocompromised.
- There is no increased risk of serious adverse events among HIV-infected children when compared with uninfected children.
- ***Children with neurological disorders**:* Benefits of administering measles-containing vaccine in children with severe neurologic disease outweighs the risks and parents should be supported and advised to immunize their children.
- However, when addressing parents of children with known epilepsy or with a personal or family history of febrile seizures, it is advisable to inform them of the **known increased risk of febrile seizures post administration of the MR vaccines**

Hum Vaccin Immunother. 2021; 17(12): 5384–5387.

Ref: WEEKLY EPIDEMIOLOGICAL RECORD, NO 17, 28 APRIL 2017

Risk groups

- ***Children with known allergies:***
  - it is safe to administer measles-containing vaccines to children with known egg allergy since the amount of residual ovalbumin from hen's egg is minimal.
  - MR vaccines that contain traces of gelatin and neomycin should be used with caution in children with a history of anaphylaxis due to allergy to these components.
- ***Pregnant women:*** Because MR is a live attenuated vaccine and may pose a theoretical risk to the developing fetus, in particular due to fever that may result from vaccination, as a precautionary measure it is not recommended for pregnant women
- ***Health-care workers:*** The importance of vaccinating health workers is underlined by the numerous measles outbreaks occurring in health institutions, affecting both health workers and patients.

Hum Vaccin Immunother. 2021; 17(12): 5384–5387.

Ref: WEEKLY EPIDEMIOLOGICAL RECORD, NO 17, 28 APRIL 2017

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.

SCHEDULE & ADMINISTRATION MR

Description	Details
Route & Site of administration	<=12 months: SC in the thigh (May be administered into the upper outer triceps area if necessary); >12 month: SC in the upper outer triceps area
Co-administration	From 9 months of age 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.
Preparation/ Reconstitution	• ONLY USE DILUENT SUPPLIED BY MANUFACTURER. • The vaccine and diluent must be stored at the same temperature at the point of use. The vaccine must be reconstituted by adding the entire contents of the supplied diluent to the vaccine vial. • The vaccine pellet should be completely dissolved in the diluent. • Following reconstitution, the vaccine should be inspected, visually for any foreign particles prior to administration.
Dose	0.5ml
Storage after 1st puncture of vial	Store in the dark at 2–8 °C and used within 6 hours

Vaccine administration

Step 3

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

Step 4

- **Administer a subcutaneous (SC)** injection in the right thigh of the infant < 1 year and on the right arm in >1 year.
- All used injection equipment should be placed in a safety box (without recapping), immediately after use.

Step 5

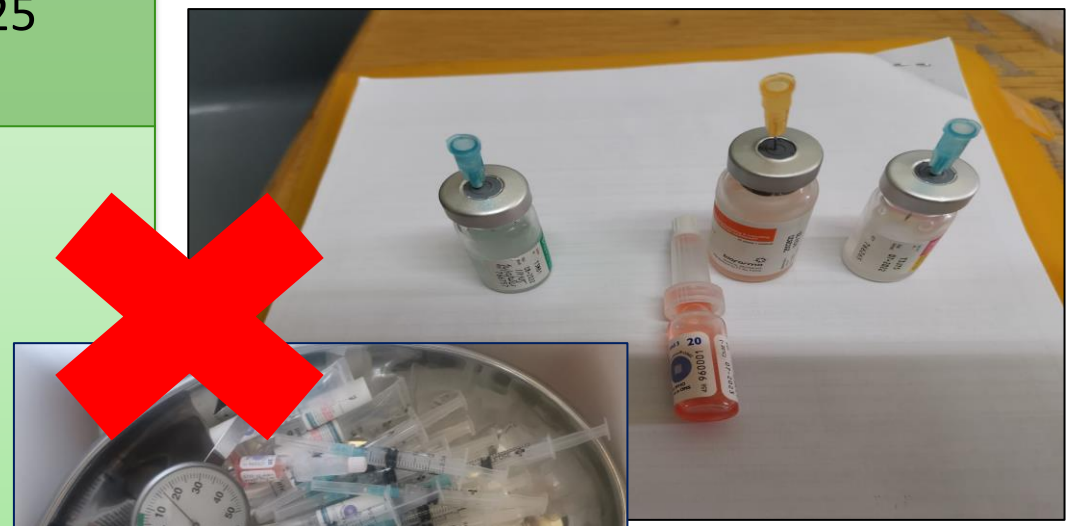
- **Record dose** on Road to Health Booklet and the PHC tick register

RECOMMENDED SYRINGE & NEEDLE FOR RECONSTITUTION & ADMINISTRATION MR

Description	Details
Reconstitution syringe	5ml syringe: 42142608-00022/35/36/37
Reconstitution needle	18 gauge needle: 42142523-00014 19 gauge needle: 42142523-00013
Administration syringe	1ml syringe: 42142609-00003/4/8/22/25 2ml syringe: 42142608-00000/4/34
Administration needle	All ages and both genders 42142523-0008 Needle Guage: 25g needles Needle Length: 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 6

- Indicate to the caregiver what to do if there any adverse vents following immunization
- 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.

Co-administration

MR vaccine **CANNOT be co-administered with other EPI vaccines at 6 months of age**

MR vaccine **CAN be co-administered with other EPI vaccines from 9 months of age**

- The vaccine **cannot be mixed** with other vaccines in the same syringe.
- If two injections are being given at the same immunisation session, they should be administered at different injection sites - for example, where Hexavalent vaccine is given in the left thigh, then PCV injection is given in the right thigh.

Vaccine safety surveillance cycle in SA

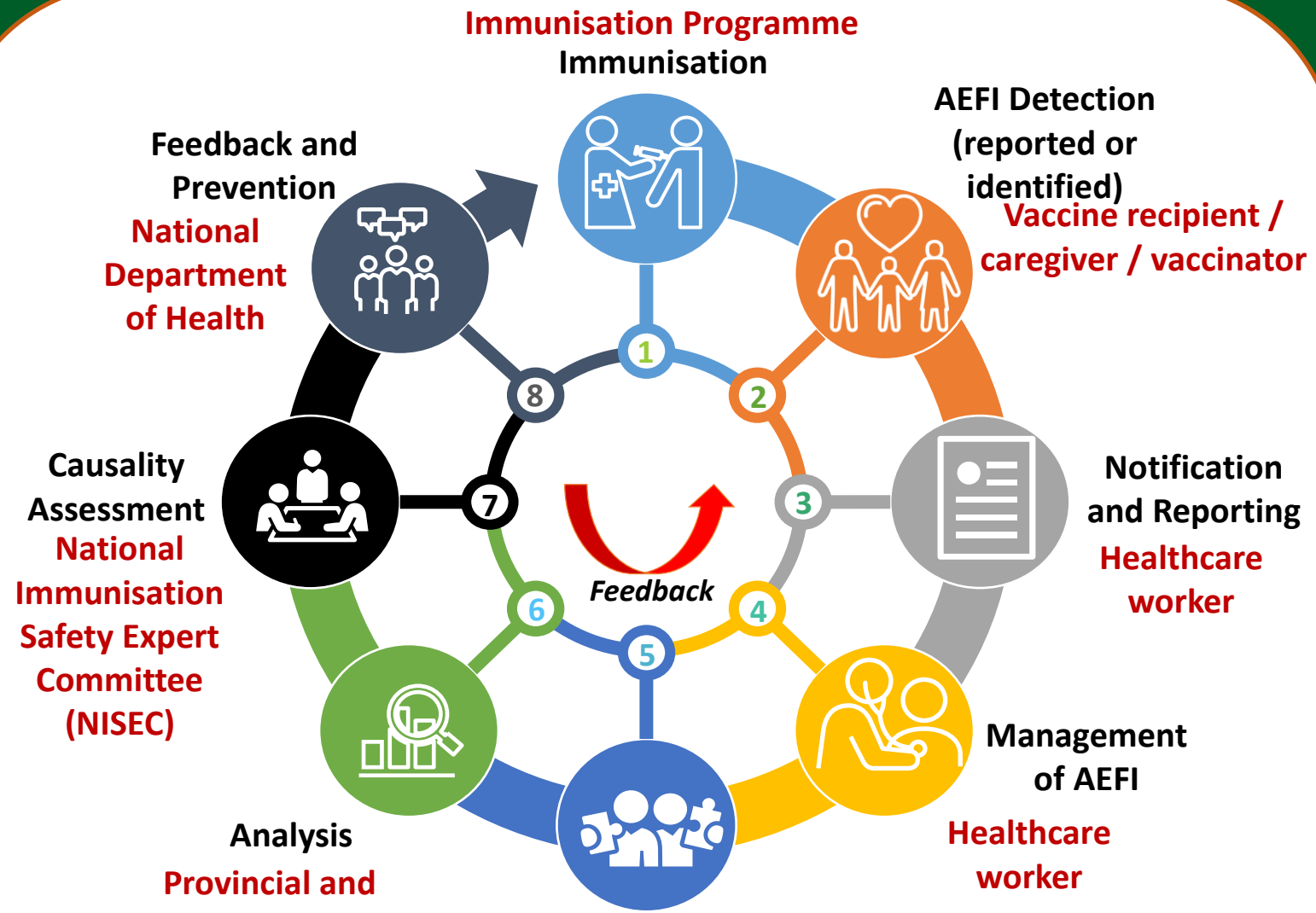
Vaccine Manufacturing Industry

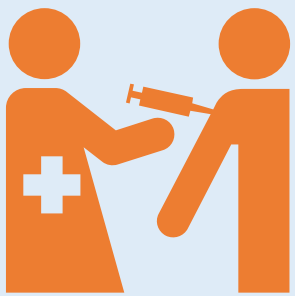
South African Health Products Regulatory Authority (SAHPRA)

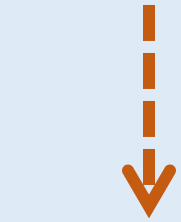
National Department of Health (NDoH)

World Health Organization (WHO)

Ministerial Advisory Committees on Vaccines and Immunisation







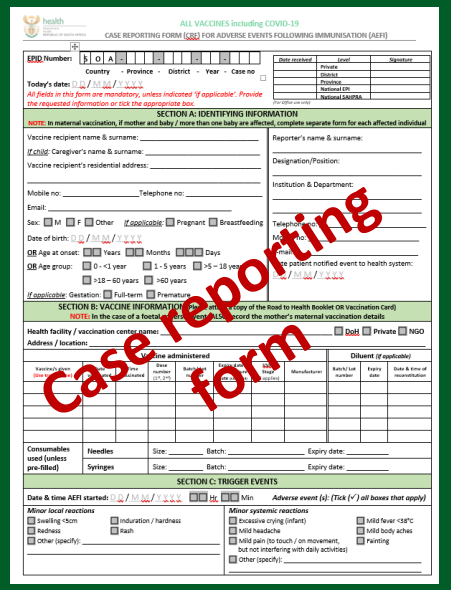
Adverse event of concern

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

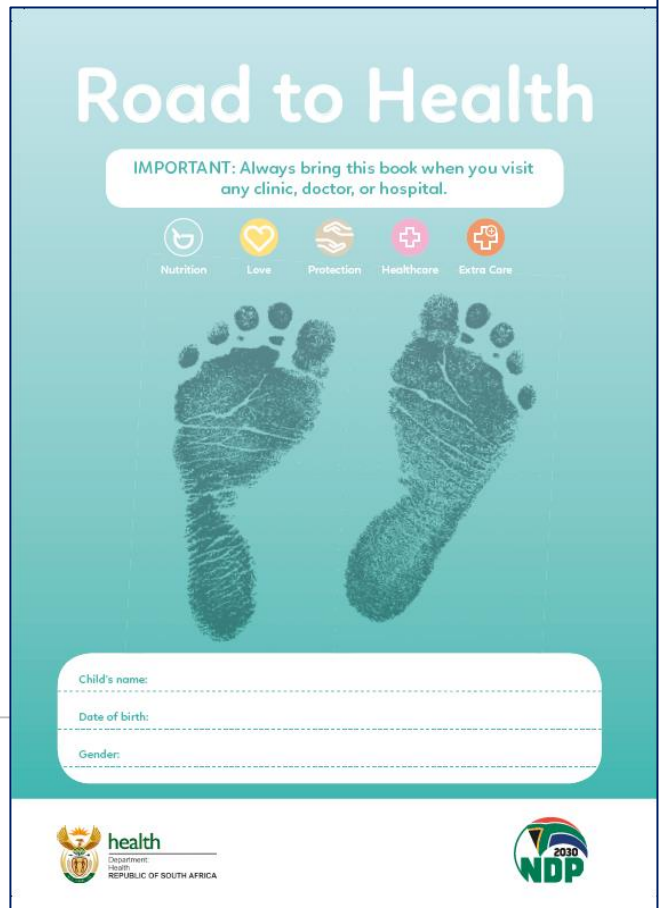
- Result in death
- Require inpatient hospitalisation
- Life threatening
- Result in persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Medically important event or reaction

Non-serious events

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

Data management - recording the MR doses

- MR 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



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				

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	CURRENT VACCINE	NEW VACCINE
Data element name	Measles 1st dose	**Measles & Rubella (MR) 1st dose**
Bulleted definition	Measles vaccine 1st dose given to a child under one year of age at 6 months after birth. The cut-off age is under 12 months.	**MR vaccine 1st dose given to a child under one year of age at 6 months after birth. The cut-off age is under 12 months**
Extended Definition	Measles is an acute viral infection transmitted by close respiratory contact and may also spread via inhaled droplets. All children older than 12 months who have missed the 1st measles dose at 6 months, should receive this dose immediately and receive the second dose with a 4 week interval. Do not give measles vaccine to children who are sick with AIDS and other immune suppressing conditions.	**Both measles and rubella are acute viral infections transmitted by close respiratory contact and may also spread via inhaled droplets. All children older than 12 months who have missed the 1st dose of MR vaccine at 6 months, should receive this dose immediately and receive the second dose with a 4 week interval. Do not give MR vaccine to children who are sick with AIDS and other immune suppressing conditions.**
Use and Context	Monitors the Expanded Program on Immunisation policy	**Monitors the Expanded Program on Immunisation policy**
Inclusions	INCLUDE 1st doses given to children between 6 and 12 months	**INCLUDE 1st doses given to children between 6 and 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 (Clinics, CHCs & hospitals)	**All health facilities (Clinics, CHCs, Mobiles & hospitals)**
Tools	PHC Comprehensive Tick Register	**PHC Comprehensive Tick Register & Hospital paediatric registers**

	CURRENT VACCINE	NEW VACCINE
Data element name	Measles 2nd dose	**Measles & Rubella (MR) 2nd dose**
Bulleted definition	Measles vaccine 2nd dose given to a child at 12 months after birth. The cut-off age is under 23 months	**MR vaccine 2nd dose given to a child at 12 months after birth. The cut-off age is under 23 months**
Extended Definition	Measles is an acute viral infection transmitted by close respiratory contact and may also spread via inhaled droplets. All children older than 12 months who have missed the 1st measles dose at 6 months, should receive this dose immediately and receive the second dose with a 4 week interval. If any child older than 2 years has not received any 1st and 2nd dose of Measles vaccine, it should be given but not recorded here	**Both measles and rubella are acute viral infections transmitted by close respiratory contact and may also spread via inhaled droplets. All children older than 12 months who have missed the 1st MR dose at 6 months, should receive this dose immediately and receive the second dose with a 4 week interval. If any child older than 2 years has not received an 1st and 2nd dose of Measles vaccine, it should be given but not recorded under routine file**
Use and Context	Monitors the Expanded Program on Immunisation policy	**Monitors the Expanded Program on Immunisation policy**
Inclusions	None	**INCLUDE 2nd doses given to children between 12 and 23 months**
Exclusions	EXCLUDE vaccines given as part of a national mass vaccination campaign; EXCLUDE 2nd dose given after the age of 2 years	**EXCLUDE vaccines given as part of a national mass vaccination campaign;** **EXCLUDE 2nd dose given after the age of 2 years**
Collected by	Clinicians	**Clinicians**
Collection points	All health facilities	**All health facilities (Clinics, CHCs, Mobiles & hospitals)**
Tools	**PHC Comprehensive Tick Register**	**PHC Comprehensive Tick Register & Hospital paediatric registers**

INTERIM EPI REGISTER FOR NEW VACCINES

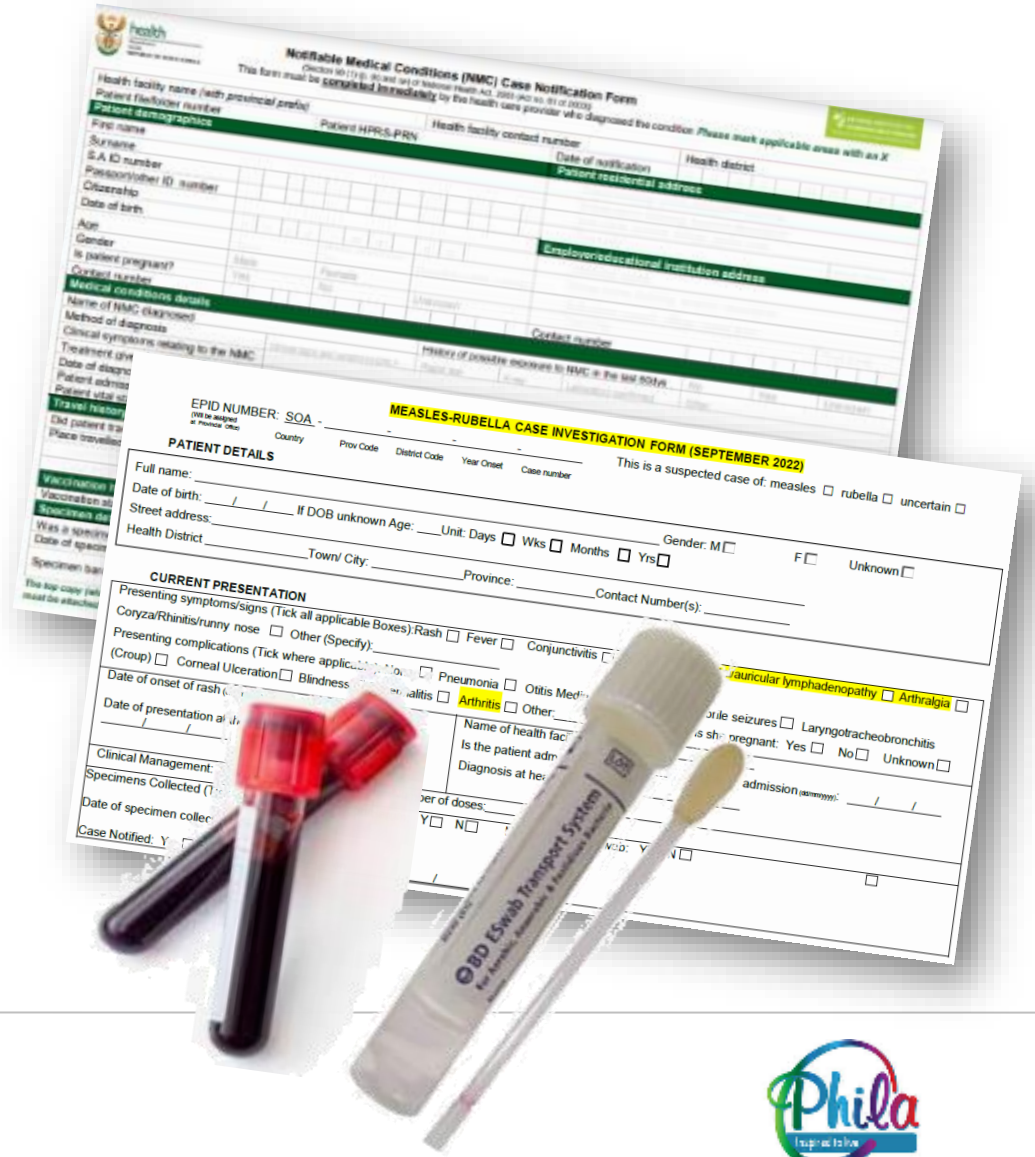
EPI NEW VACCINE REGISTER										
Facility Name										
Consulting Room:										
Month			January	Year						2024
Date	No.	File NO.	NAME	AGE	HBV (0) dose	MR 1st dose	MR 2nd dose	Tdap dose at 6 years	Tdap dose at 12 years	Tdap dose at 26 to 34 weeks of gestational age
	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									
	11									
	12									
	13									
	14									
	15									
	16									
	17									
	18									
	19									
	20									

Compiled by:	Signature	Date
Verified by Operational Manager:		

- 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.,)

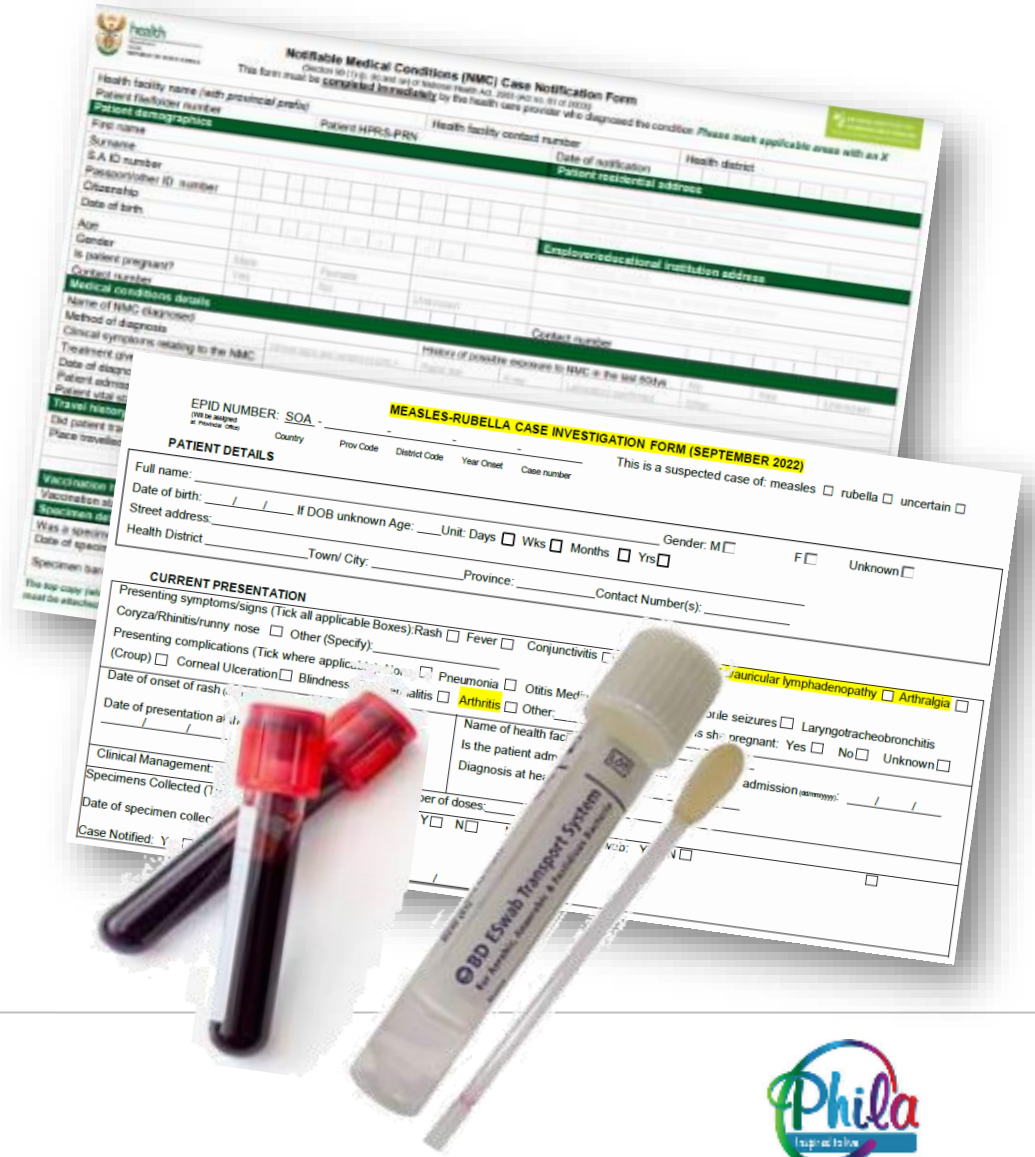
Surveillance for acute Rubella

- Acute rubella is a **category 1 notifiable medical** condition, which requires notification on suspicion, before laboratory diagnosis
- Surveillance for acute rubella is conducted through the **NICD's 'fever rash surveillance programme'** for measles and rubella
  - ❑ Clinicians submit a blood (serum) sample with/without a throat swab to the NICD for serology (IgM) and PCR (direct detection of virus)
  - ❑ Clinicians should also notify the patient using the NMC notification system.
  - ❑ Clinicians should also complete the measles-rubella case investigation form



Surveillance for acute Rubella

- **Challenges**
  - Sometimes clinicians do one part of surveillance and not the other – e.g. they notify but don't send a sample; or – they send samples but don't send forms
- **Anticipated changes**
  - The Measles CIF on the NICD website needs to be replaced with the recently approved 'Measles-Rubella' CIF which has additional fields for clinical features compatible with rubella, a field for pregnancy status of a person, and a field for rubella vaccine history.
  - The provincial health departments need to be trained in using the new form



Surveillance for Congenital Rubella Syndrome

- **Congenital rubella is a category 2 notifiable medical condition**, which requires notification after laboratory confirmation
- **Surveillance for CRS currently has two components**
  - Clinicians may notify a case of CRS based on **clinical features** (see previous slide) and laboratory test results
  - The NHLS data warehouse flags **IgM positive test results in infants/children under the age of 2 years**. These results are uploaded into the NMC database; however, they cannot be automatically classified as CRS because of the absence of clinical details
    - The CVI at NICD currently sends out line lists of IgM positive infants to provincial CDCs and asks them to obtain the case notes from the admitting hospital.
    - Clinical notes are reviewed by CVI pathologist and case is classified according to WHO criteria

Surveillance for Congenital Rubella Syndrome

- **Challenges**
  - It is very hard to obtain clinical case notes for review. In 2022 only 16 cases notes from over 90 IgM positive infants were obtained. Therefore CRS cases cannot be classified.
  - Clinicians do not notify CRS cases
- **Anticipated changes**
  - Training of clinicians to support improved diagnosis and notification of CRS cases
  - Stronger relationships with provincial and district CDCs in order to obtain clinical notes
  - Stronger working relationships with ophthalmologists at tertiary hospitals to support sending of cataract tissue for rubella PCR

THANK YOU