Tetanus, reduced-strength diphtheria and acellular pertussis (Tdap)

Knowledge Hub Webinar

October 2023

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NATIONAL DEVELOPMENT PLAN 2030

Phila

Outline

- Disease description, clinical presentation and burden
- Vaccines: Tdap
- Immunisation schedule & transition
- Immunisation practices including AEFI
- Data management

Tetanus

Tetanus

- ***Clostridium tetani (C. tetani),* are rod-shaped Gram positive bacilli**
  - Found extensively in the environment (ubiquitous)
  - On exposure to oxygen, *C. tetani* forms spores
  - produces an exotoxin (tetanospasm) when spores germinate after entering an anaerobic environment (e.g. when enters skin through deep penetrating wound)

- **Tetanospasm disseminates via blood and lymph to nervous tissue**
  - Binds to ganglioside-containing receptors at nerve terminals
  - Disrupts release of GABA and glycine from Renshaw cells
  - Leads to increased muscle tone and painful spasms
  - Cannot be neutralised once bound to nerve terminals

Presentation of Tetanus

There are 4 recognised forms of Tetanus

Generalised tetanus
- Trismus (lock-jaw)
- Typical facial expression (risus sardonicus)
- Powerful muscle contractions -> opisthotonis (impairs respiration, tears muscles, breaks bones)

Neonatal tetanus
- Occurs in newborn infants
- Exposure to *C. tetani* spores through umbilical stump:
- Unsterile instruments used to cut cord, poultices, herbs, dung, used on cord
- Present 3-14 days after exposure to spores
- Infant loses ability to suck or cry, develops severe muscle spasms

Cephalic tetanus
- Affects muscles supplied by 12 cranial nerves
- Caused by injuries to head, otitis media

Localised tetanus
- Localised around wound

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Tetanus in South Africa

- Tetanus is a category **2 Notifiable Medical Condition (NMC)**
- A review of all hospital admissions in the Mpumalanga province, between 1996-2000, on the case definition for NNT found that most cases occurred as a result of the cultural practice of applying cow dung or rat faeces to the umbilical stump in the neonatal period.

Immunisation

- Tetanus-toxoid (TT)-containing vaccines introduced into EPI in 1974

Administered at:

- *6, 10 & 14 weeks (primary infant series)
- *18 months (booster)
- School entry/ 6-years (Td) - replaced with Tdap in 2024
- 12 years (Td) – replaced with Tdap in 2024
- TT administered to pregnant women in antenatal clinics

- replaced with Tdap in 2024

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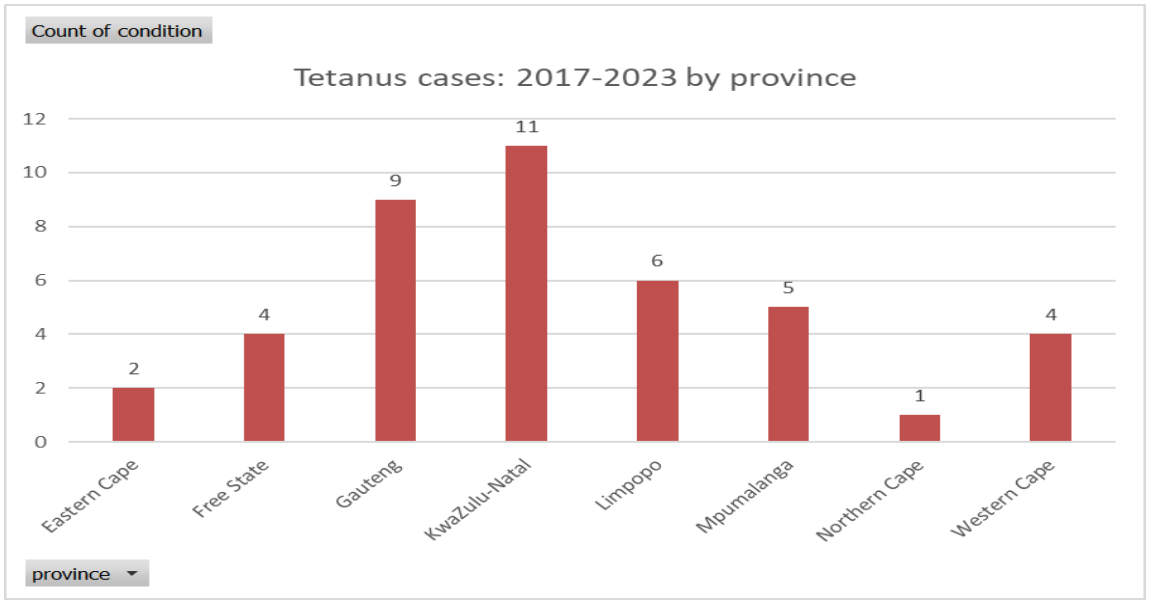
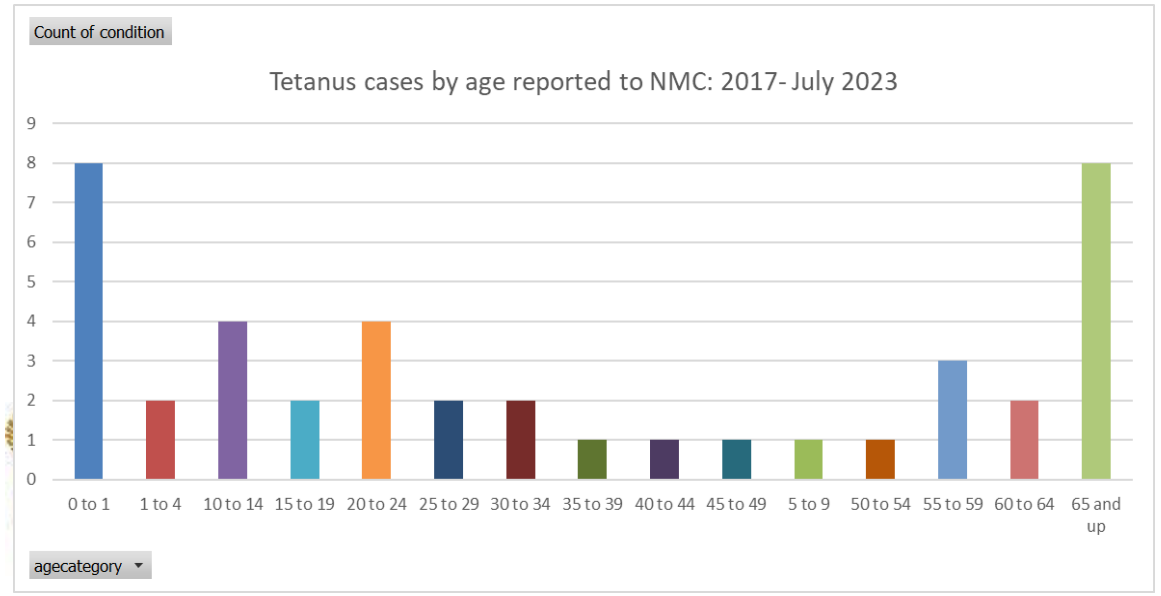
*TT Included in Hexavalent vaccine
https://www.nicd.ac.za/wp-content/uploads/2017/06/TetanusFAQ_20170601.pdf

Tetanus in South Africa

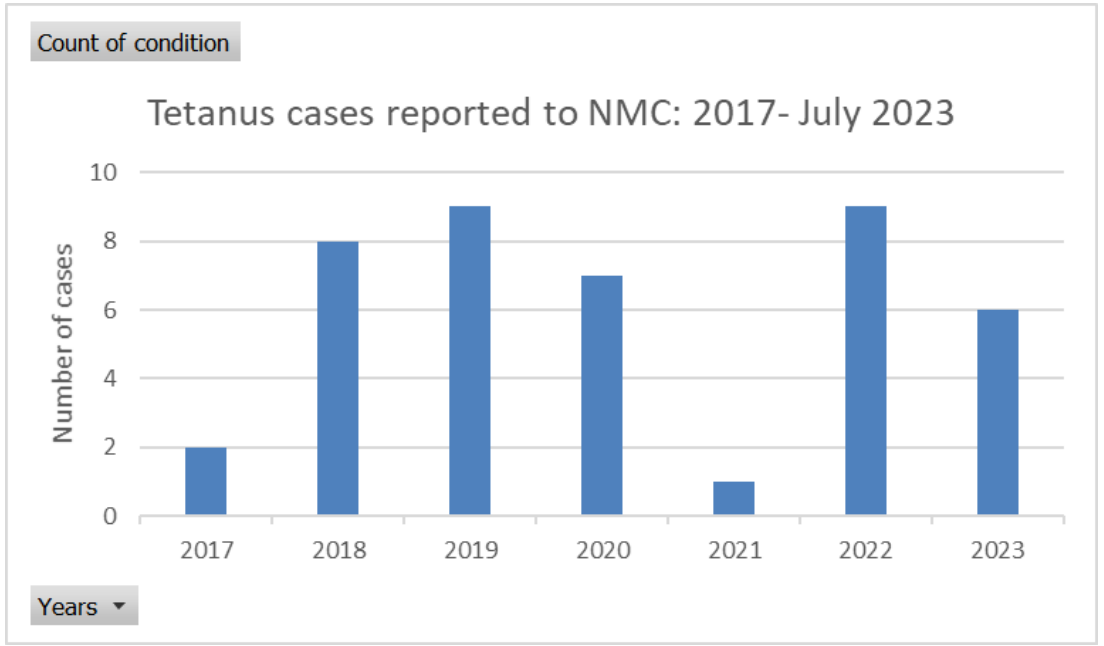




- **Total of 42 cases of tetanus reported** to NMC between 2017 & July 2023

Neonatal tetanus:

**3 cases reported in 2022 (KZN) and 1 in 2023 (Mpumalanga)



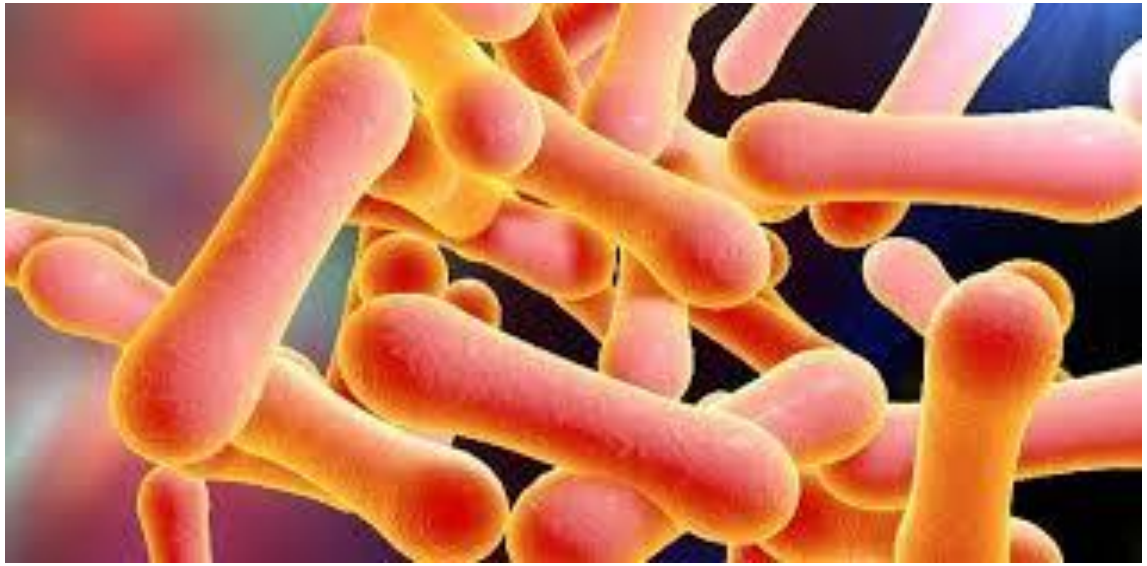
*NICD Communicable Diseases Communique, April 2020, Vol 19 (4)

** S. Nzenze, NICD

Diphtheria

Diphtheria

- *Corynebacterium diphtheriae* is a bacterium that affects mucous membranes of nose and throat
- Spread by airborne droplets and contaminated items (fomites)
- Toxin produced, which damages tissues
- **Risk factors:**
  - Unvaccinated
  - Crowded/ unsanitary living conditions



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Diphtheria clinical presentation

- Sore throat, hoarseness
- White or grey patches/ membrane in throat
- Bull neck- enlarged lymph nodes in neck
- Rhinitis (nasal discharge)
- Fever, chills, fatigue

- **Complications**
  - Sloughing of membrane can block airway, suffocation
  - Heart damage by toxin
  - Nerve damage by toxin
  - Fatality rate: 5-10%

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Diphtheria in South Africa

Immunisation

Diphtheria vaccines introduced into EPI in 1974

Administered at

- *6, 10 & 14 weeks (primary infant series)
- *18 months (booster)
  - School entry/ 6-years (Td)

  replaced with Tdap in 2024
  - 12 years (Td)

  replaced with Tdap in 2024

- Diphtheria is a **Notifiable Medical Condition** (NMC) in South Africa
- There have been **50 cases** of Diphtheria reported to NMC in South Africa since 2018

Disease burden prior to 2018

- March to June 2015, a cluster of 15 respiratory diphtheria cases with a case-fatality ratio of 27%.
- The 2015 outbreak prompted immediate health promotion activity in the country, including notifications to all healthcare practitioners and laboratories to consider and exclude *C. diphtheriae*.

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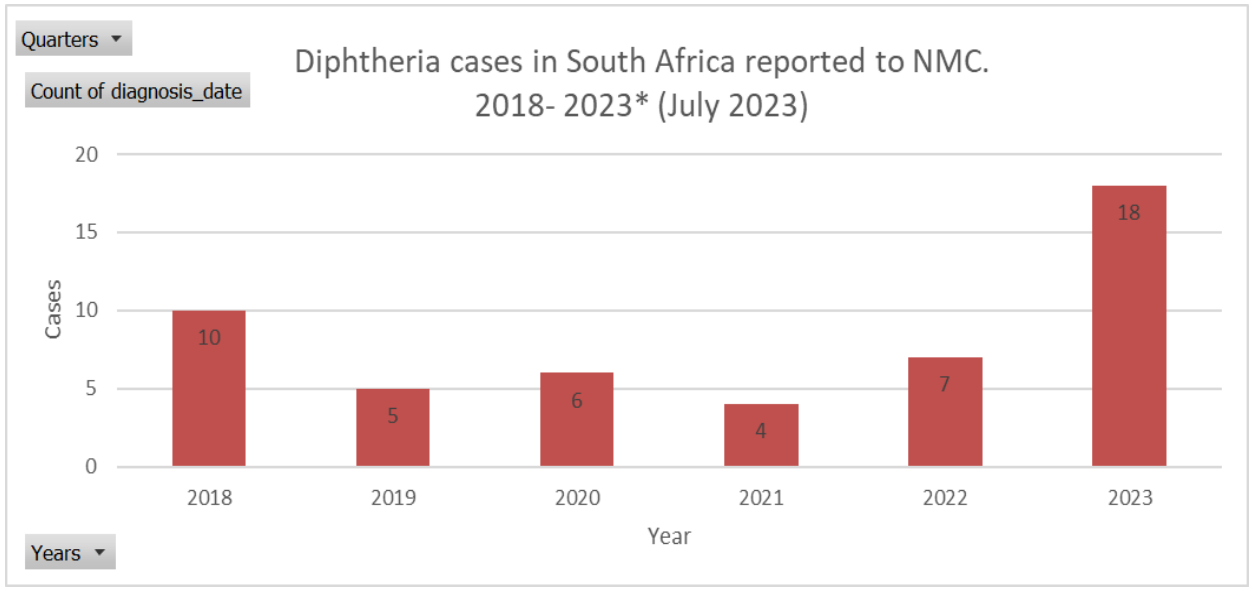
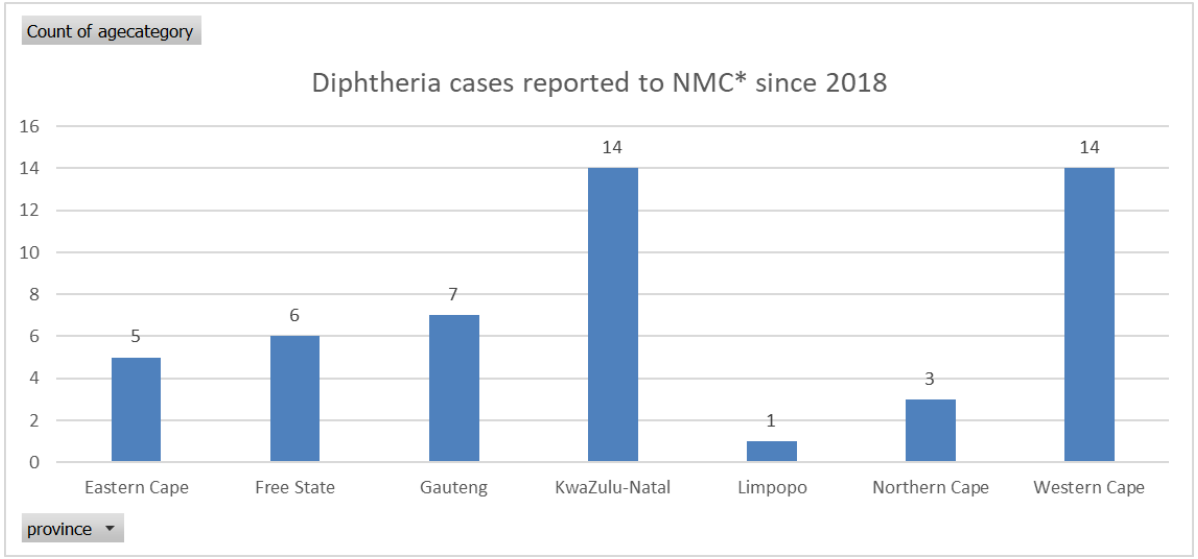
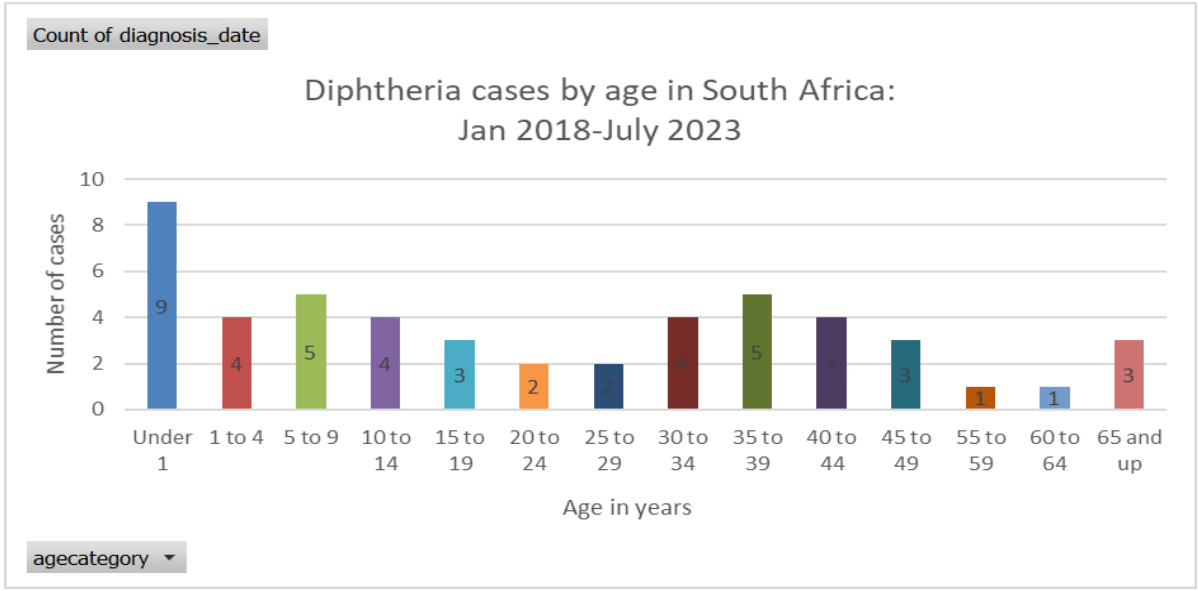
https://www.nicd.ac.za/wp-content/uploads/2023/05/Diphtheria_alert_16_5_23.pdf
https://www.nicd.ac.za/wp-content/uploads/2023/06/NICD-guidelines_diphtheria_v4_2023_updated-after-review_2-JUN-2023_Final.pdf

Diphtheria in South Africa







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Pertussis

Pertussis

- Pertussis is an **acute respiratory tract infection** caused by the *Bordetella pertussis* bacterium, characterised by paroxysmal coughing (**whooping cough**)
- *Bordetella pertussis,* is highly contagious, with a reproductive number of 12 -17(number of people infected per original index case)
- Affects people of all ages, but is of particular concern in young children
  - **Young infants (aged <2 months) are most at risk for pertussis-associated complications and death, having the highest rates of**:
    - hospitalisation (>90%), pneumonia (15–25%), seizures (2–4%), encephalopathy (0.5–1%)
    - death (0.5–1%)
- During 2004–2008 in the USA, 83% of all pertussis-related deaths were in infants aged ≤3 months
- In a study of pertussis disease in infants aged ≤3 months, the **younger the infant**, **the greater the likelihood of severe disease**

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1. Kretzschmar *et al*. *PLoS Med* 2010;7(6):e1000291; **2.** Spokes *et al. N S W Public Health Bull* 2010;21(7–8):167–173; **3.** Grant. In: Warrell, Cox, Firth, eds. *Oxford Textbook of Medicine* 2010: Section 7.6.14; **4.** WHO. Estimates of disease burden and cost-effectiveness. 2014. www.who.int/immunization/monitoring_surveillance /burden/estimates/en/index.html Accessed 24 Jan 2014; **5.** Hong. *Korean J Pediatr* 2010;53(5):629–633; 6. CDC. In: Atkinson, Wolfe, Hamborsky, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases* [Pink Book] 2012: 215–232; **7.** CDPH. Pertussis Report. 10 August 2011; **8.** Tan & Gerbie. *Obstet Gynecol* 2013;122. (2 Pt 1):370–373 9. Kilgore PE, et al. Clin Microbiol Rev. 2016;29(3):449–486. for both statements). CDC. Pertussis. In: Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E, et al, eds. 14th ed. Washington D.C. Public Health Foundation; 2021.

Pertussis in South Africa

Immunisation

- Pertussis vaccines introduced into EPI in 1974
- Administered at
- *6, 10 & 14 weeks (primary infant series)
  - *18 months (booster)

Disease burden

- Age distribution has shifted toward older children, adolescents, and adults in countries with high vaccination coverage
- Adolescents and adults also represent important conduits of infection to infants

Shift In Vaccines against Pertussis: wP verses aP

- Safety concerns with whole-cell pertussis vaccines led to the development of acellular pertussis (aP) vaccines
- aP vaccines are associated with fewer serious adverse events than wP-based vaccines (primary series), which may impact adherence to completion of primary series.
- Many countries have shifted from whole-cell to acellular pertussis vaccines

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DTwP=diphtheria, tetanus, and whole-cell pertussis; DTaP=diphtheria, tetanus, and acellular pertussis.
1. Esposito S. *J Prev Med Hyg.* 2018;59(3):E177-E186. **2.** Zhang L et al. Cochrane Database Syst Rev. 2014;(9):CD001478. **3.** Liang JL, et al. *MMWR Recomm Rep.* 2018;67(2):1-44. **4**. Lobzin YV, et al. Infect Dis Ther 2015;4:113–23 **5**. Amirthalingam G, et al. Clin Infect Dis 2016;63(Suppl) **6**. WHO Technical Report Series No 941, 2007**; 7**.WHO Technical Report Series No 979, 2013; 8. WHO Immunological Basis for Immunization Series Module 4: Pertussis Update 2017: LINK; 5Sato Y, et al. Lancet 1984;1(8369):122-126; 9. Cherry JD, et al. J. Infect. Dis. 1996;174(3):S259-63; 10.Dias WO, et al. Hum Vaccin Immunother. 2013;9(2):339–348. 8Higgs R, et al. Mucosal Immunol. 2012;5(5):485-500;9Muloiwa R, et al. Vaccine 2018;36:2385–2393

Pertussis in South Africa

Table 2. Incidence Risk of Pertussis-Associated Hospitalization by Age Group and HIV Status, South Africa[a], January 2013 Through December 2016

	Incidence Risk per 100 000 Population (95% CI)			Risk Ratio (95% CI)
Age Group (y)	All Patients	HIV-infected Patients	HIV-uninfected Patients	HIV infected vs uninfected
<1	228.0 (183.8–278.9)	2116.7 (822.9–4217.2)	212.1 (169.8–262.2)	10.0 (4.7–21.2)
1–4	19.0 (12.9–26.9)	411.0 (213.1–720.3)	11.9 (7.1–18.5)	34.6 (16.8–71.2)
5–24	8.0 (6.0–10.3)	103.5 (76.3–136.3)	1.2 (.5–2.4)	83.9 (40.1–175.2)
25–44	14.4 (11.5–18.0)	48.0 (38.1–59.7)	0	…
45–64	10.9 (7.3–15.6)	41.6 (26.2–63.2)	3.4 (1.3–6.7)	12.2 (5.3–28.3)
≥65	28.3 (17.7–44.7)	412.7 (206.4–791.7)	15.0 (7.2–27.6)	27.6 (11.4–66.8)
<5	60.7 (50.4–72.3)	590.3 (351.8–912.4)	52.2 (42.7–63.2)	17.1 (10.5–27.8)[b]
≥5	11.6 (10.0–13.4)	59.6 (50.9–69.7)	1.9 (1.3–2.8)	50.0 (32.2–77.7)[b]
All	17.2 (15.3–19.2)	65.9 (56.7–76.3)	8.5 (7.1–10.1)	30.4 (23.0–40.2)[b]

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Wolter N et al. Epidemiology of Pertussis in Individuals of All Ages Hospitalized With Respiratory Illness in South Africa, January 2013—December 2018 DOI:10.1093/cid/ciab089

Pertussis in South Africa

- Significant increase in pertussis cases detected in the pneumonia surveillance program in 2022 & 2023 compared to the COVID-19 pandemic years (2020/2021).
- Overall 0.1% (2/3778) of patients enrolled into pneumonia surveillance tested positive for pertussis from 1 January to 30 June 2022.
- The increase in detection of pertussis cases started from 1 July 2022, with the detection rate at (3.0%, 239/8053) for the period through 17 June 2023.
- The majority of cases were in children aged < 5 years. Of these, 72.2% (120/165) were children aged < 3 months

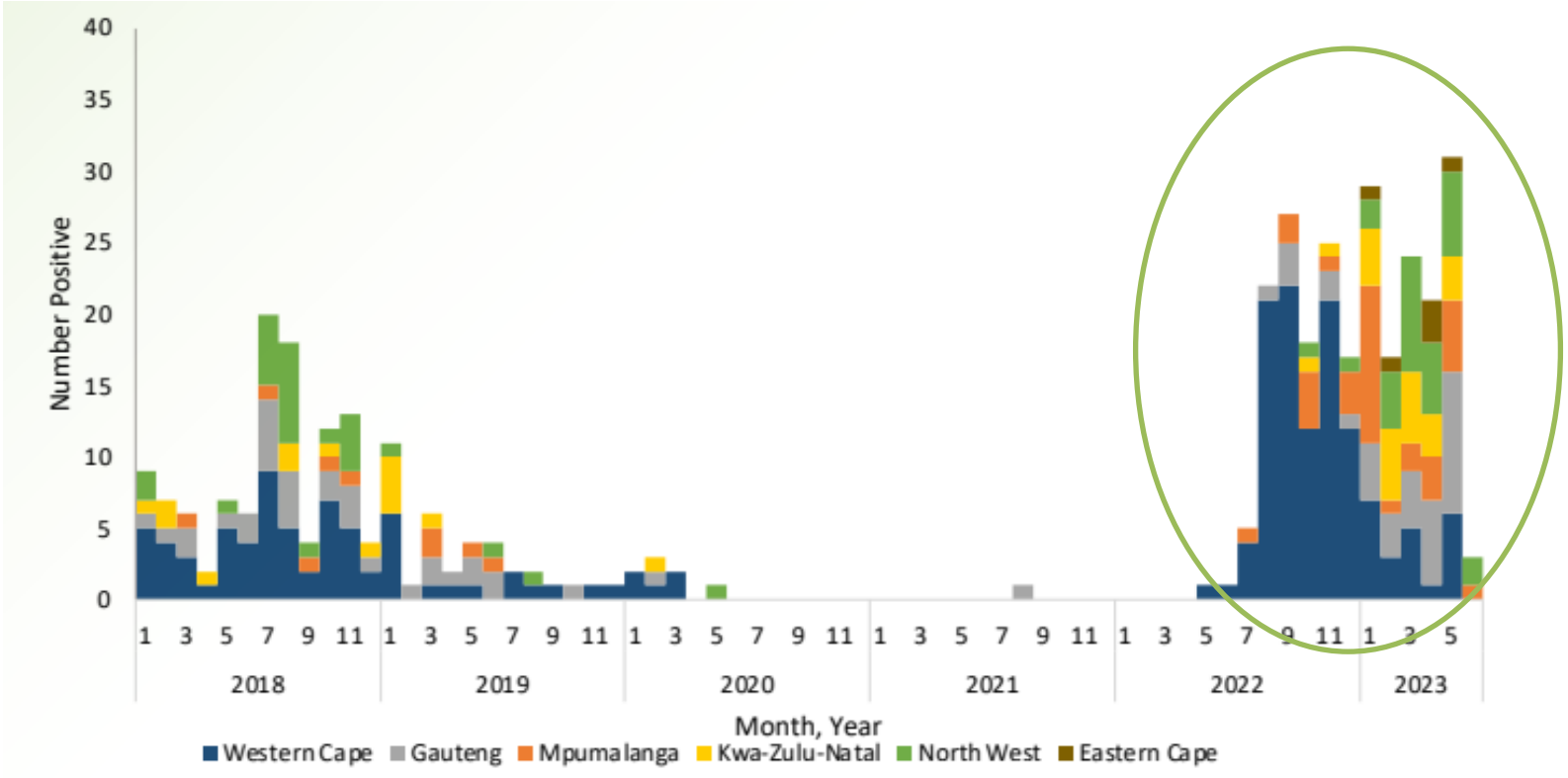

Figure 7. Number of laboratory-confirmed pertussis cases from pneumonia surveillance programme by year, month and province, South Africa 2018-2023

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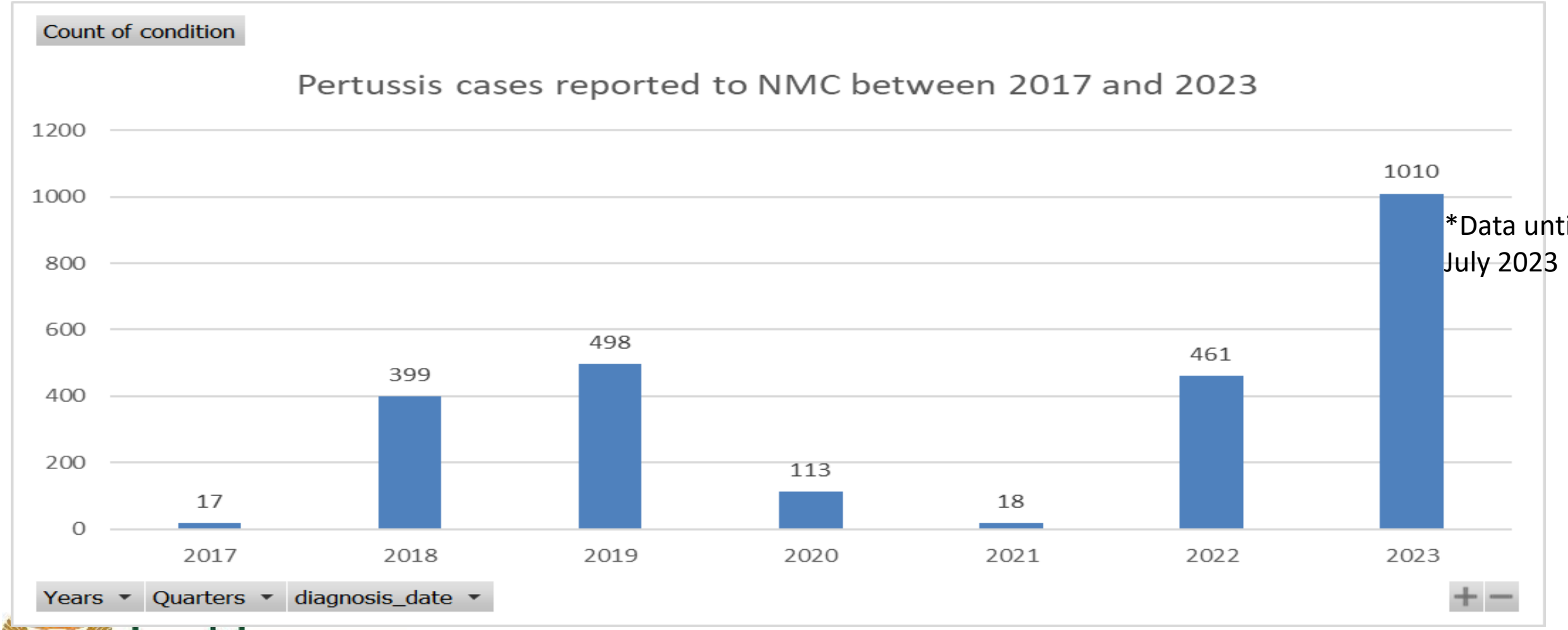
https://www.nicd.ac.za/wp-content/uploads/2023/06/NICD-JUNE-Communique-2023.pdf

Pertussis in South Africa



*Data until July 2023

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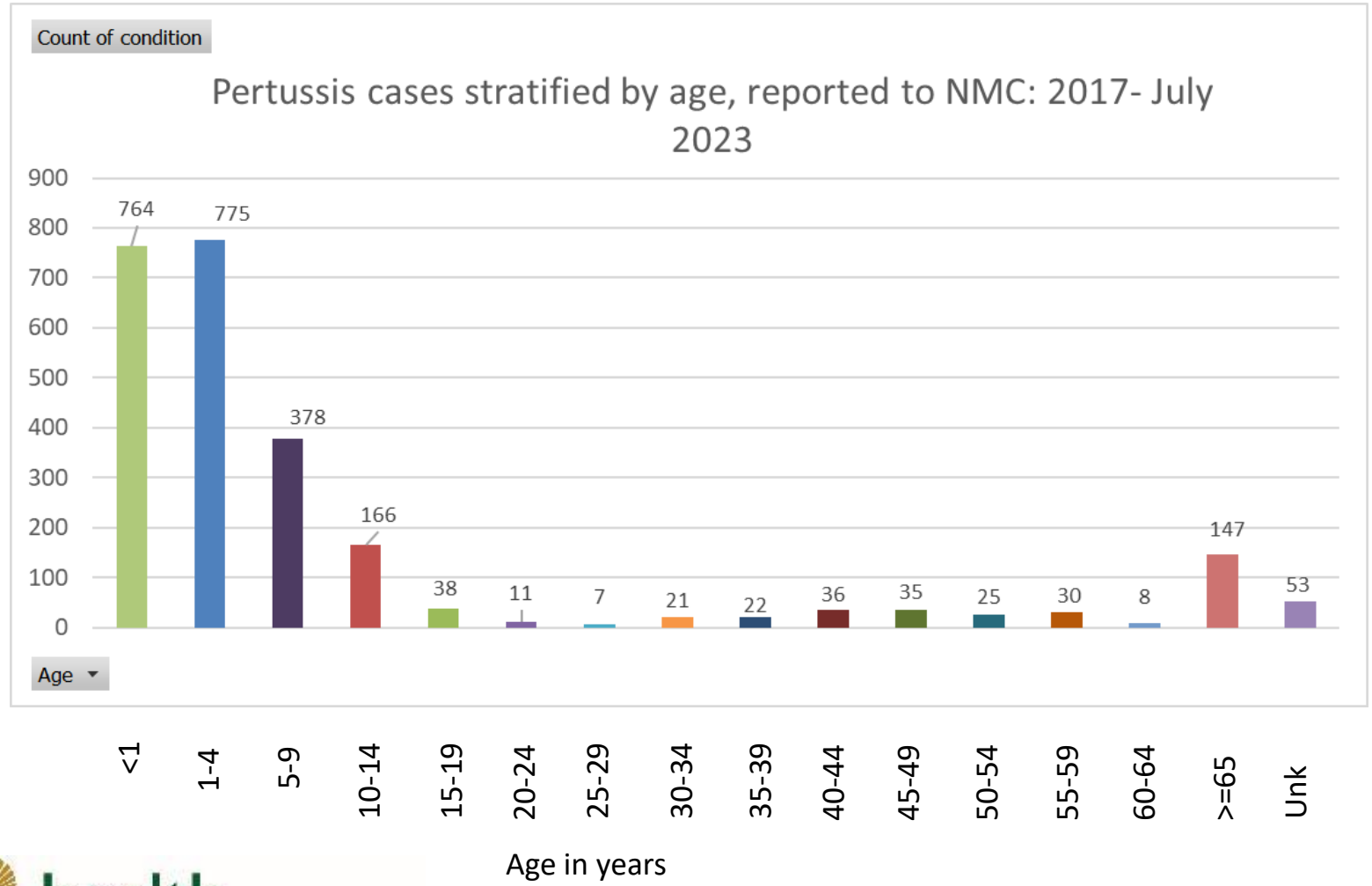

- 2516 pertussis cases reported to NMC between 2017- July 2023
- 764 (30%) in <1 year olds
- 1539 (61%) in <5 year olds

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Pertussis-containing vaccines in pregnancy

- Pertussis-containing vaccines included in WHO recommendations for pregnant women since 2015
- CDC first recommended the use of Tdap vaccines during the third trimester of every pregnancy in 2012
- Pertussis-containing vaccines approved for administration to pregnant women since 2019
- SASOG recommendation for Tdap vaccination in pregnancy since 2020.

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1. WHO. Weekly Epidemiol Rec 2015;90:433–60; 2. Committee on Obstetric Practice, Immunization and Emerging Infections Expert Work Group. Committee Opinion No. 718: Update on Immunization and Pregnancy: Tetanus, Diphtheria, and Pertussis Vaccination. Obstet Gynecol 2017;130:e153–7; 3. Liang JL, et al. MMWR Recomm Rep 2018;67:1–44. 4. Benedetto C, et al. Eur J Obstet Gynecol Reprod Biol 2019;240:375–6. 5. Healy CM, et al. Importance of timing of maternal combined tetanus, diphtheria, and acellular pertussis (Tdap) immunization and protection of young infants. Clinical infectious diseases. 2013 Feb 15;56(4):539-44.

Annual Incidence of laboratory-confirmed Cases of Pertussis by Age-group (England and Wales)

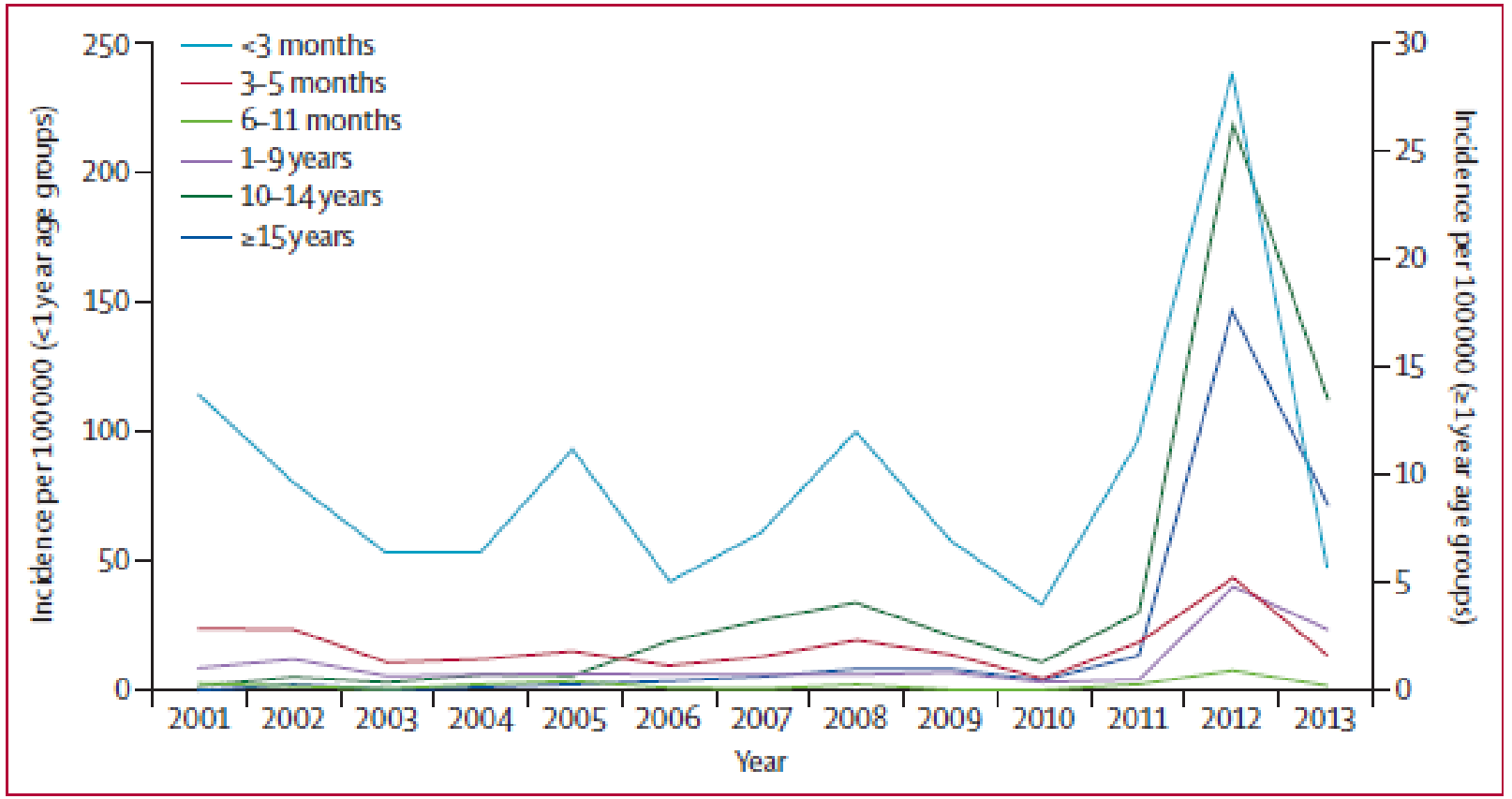

Figure 2: **Annual incidence of laboratory-confirmed cases of pertussis by age group**
Figure shows incidence from 2001 to 2013 in England only.

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Amirthalingam G et al. Lancet; 16 July 2014 (on line)

Tdap Vaccine

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Tender information for Tdap

Tender Information	Details
Description	Vaccine, combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) per 0.5ml dose, single or multidose vial or pre-filled syringe presentation. For intramuscular administration.
Period	01 Jan 2024-31 Dec 2026
Product code (NSN)	181756185
Product description	Adacel
Price	R139.52
Minimum order quantity	30 vials (3 boxes)

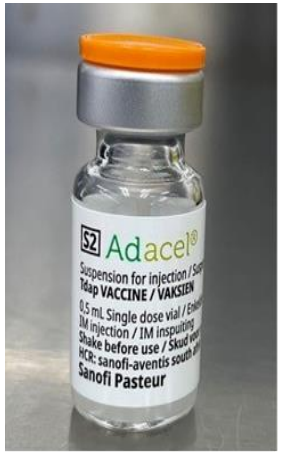
Forecasting Tdap

- ✓ While Td (Tetanus-reduced diphtheria) is being phased out it is considered **interchangeable** with and Tdap
- ✖ There is no need to keep both vaccines in stock
- ✓ Once your available Td vaccines stock is depleted the new Tdap stock should be order on the **new stock code.** There is no need to keep both vaccines in stock
- ✓ SVS and NCS will be used to **monitor availability** at all levels and coordinate the phase out of Td and phase in of Tdap

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

Introducing Adacel

Description	Details
Manufacturer	Sanofi
Composition	Each 0,5 ml dose contains: Tetanus toxoid (T) 5 Lf (not less than 20 IU*) Diphtheria toxoid (d) 2 Lf (not less than 2 IU*) Pertussis toxoid (PT) 2,5 micrograms Filamentous haemagglutinin (FHA) 5 micrograms Pertactin (PRN) 3 micrograms Fimbriae types 2 and 3 (FIM) 5 micrograms Sugar free. (*as per PI - "As lower confidence limit (p = 0,95) of activity measured according to the assay described in the European Pharmacopoeia)
Schedule	2
Approved for	1. Active booster immunisation for the prevention of tetanus, diphtheria and pertussis (whooping cough) in persons 4 years of age and older, according to local immunisation recommendations. 2. Passive protection against pertussis in early infancy following maternal immunisation during pregnancy.
Identification	Fully liquid sterile, uniform, cloudy white suspension for injection.



Introducing Adacel

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

Storage and temperature excursions Adacel

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. Refer to Sanofi Quality department if outside normal temp. ranges (ZAQuality@sanofi.com)
More info on temperature excursions	Contact the EPI/Cold Chain/ Pharmacy Manager & the Supplier

Front loader fridge

Top loader fridge

HINT

Do not expose vaccine to freezing conditions

Use conditioned ice packs

Use correctly prepared coolant pack

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

Vaccine wastage Tdap

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?

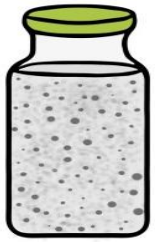
Suspect Vial: Freeze sensitive vaccine exposed to ≤0˚C

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'.

Immunisation schedule update: Tdap introduction

6 and 12 year boosters

- Straight switch from Td to Tdap as per the routine schedule at 6 and 12 years
- Td provided to all learners in Grade 5 in public schools during the HPV campaign (additional booster) will also be switched to Tdap

Maternal vaccination

- Switch from TT to one dose Tdap.
- Pregnant women will get a dose of Tdap during each pregnancy between 26 weeks and 34 weeks to maximise protection of infants including preterm infants.

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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 (PCV10) -1
	Hexavalent (DTaP-IPV-HepB-Hib) -1
10 weeks	Hexavalent (DTaP-IPV-HepB-Hib) -2
14 weeks	Rotavirus (RV) -2
	Pneumococcal conjugate (PCV10) -2
	Hexavalent (DTaP-IPV-HepB-Hib) -3

AGE	VACCINE
6m	Measles/Rubella (MR) -1
9 months	Pneumococcal conjugate (PCV10) -3
12 months	Measles/Rubella (MR) -2
18 months	Hexavalent (DTaP-IPV-HepB-Hib) -4
6 years	Tetanus diphtheria, acellular Pertussis (TdaP) -1
Grade 5 ≥ 9 years	Human Papilloma Virus (HPV) 1+2
12 years	Tetanus diphtheria, acellular Pertussis (TdaP)-2

Pregnancy vaccination:

Tdap vaccine offered during pregnancy

(26 to 34 weeks)

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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	
	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	*One year interval should be observed*	

Td and TdaP will be considered interchangeable – no catch up of TdaP required if child previously received Td as per EPI schedule

Immunisation schedule in pregnancy vs BANC plus visit schedule

Immunisation schedule for pregnant women

- BANC-plus 8-visit schedule
- Tdap to be administered at 26-34 weeks: aligns with BANC-plus visits 3/4/5
- **If not administered between 26 weeks to 34 weeks**
- **Tdap can be administered to the woman from 26 weeks up post delivery**

First visit for all women at first contact with clinics, regardless of gestational age. If first visit later than recommended, carry out activities up to that time	VISITS 1	2	3	4	5	6	7	8
DATE :								
Approximate gestational age (weeks)	<14	20	26	30	34	36	38	40
Classifying form indicating eligibility for BANC		■	■	■	■	■	■	■
History taken		■	■	■	■	■	■	■
Full clinical examination		■	■	■	■	■	■	■
Estimated date of delivery calculated		■	■	■	■	■	■	
Blood pressure taken								
Maternal height/weight/MUAC		■	■	■	■	■	■	■
Haemoglobin test		■	■		■	■		■
RPR performed		■	■	■	■	■	■	■
Urine tested for protein, sugar and nitrites		■	■	■	■	■	■	■
Rapid Rh performed		■	■	■	■	■	■	■
HIV counselling and testing		Retest every 12 weeks if negative						
ART for HIV-infected women		Viral load monitoring as per guidelines						
Tetanus toxoid given		■	■	■	■	■	■	■
Iron and folate supplementation provided						■		■
Calcium supplementation provided						■		■
Information for emergencies given								
Antenatal record completed and given to woman								
Asked if fetal movements felt and normal	■							
TB symptom screen								
Clinical examination for anaemia						■		■
Urine tested for protein	■							
Uterus measured for growth - twins, IUGR	■					■		■
Instructions for delivery/transport to institution	■	■	■					
Recommendations for lactation and contraception	■	■	■			■		■
Detection of breech presentation and referral	■	■	■	■		■		■
Remind woman to bring antenatal record in labour	■	■	■	■	■			
Doctor or senior midwife to review gestational age	■	■	■	■	■	■	■	
Give hospital visit date at 41 weeks for induction	■	■	■	■	■	■	■	
Initials staff member responsible								

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Vaccine administration

Step 1

- First check for any contraindications or precautions
- Inform the caregiver/ pregnant woman what vaccine they are receiving and allow questions to be asked

Vaccine safety Tdap

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. • **Febrile or Acute Disease:** Vaccination must be postponed in cases of moderate or severe febrile and/or acute disease. Low-grade fever does not constitute a contraindication. • **Neurological disorders:** Encephalopathy within 7 days of a previous dose of pertussis-containing vaccine not attributable to another identifiable cause
Precautions	• Appropriate medical treatment and supervision must always be readily available during immunisation. • The decision to administer or delay vaccination due to a current or recent febrile illness depends on the severity of the symptoms and the cause of the disease. • Special precautions should be taken in patients with previous Guillain-Barre syndrome, unstable neurological disorders and immuno-compromised patients. • For further details consult the package insert.

Vaccine safety Tdap - continue

Description	Details
Precautions	• If Guillain-Barré syndrome or brachial neuritis has occurred following receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks. • ADACEL should not be administered to individuals with progressive or unstable neurological disorders, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established, the condition has stabilised and the benefit clearly outweighs the risk.
Possible events	• Side effects are mostly mild and transient and may include pain and redness at injection site, tiredness, headache, myalgia, fever, nausea, diarrhoea, vomiting, anorexia, rash, body aches or muscle weakness, sore or swollen joints, tiredness or malaise, chills and axillary lymph node swelling and anaphylaxis. • For more information including other less common and more serious side effects, 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, 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

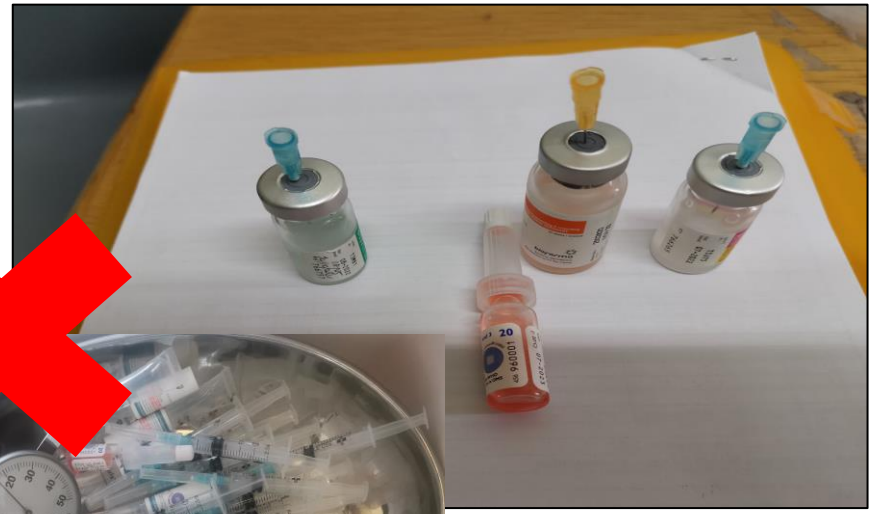
- Draw up 0.5 ml with a new 1ml or 2ml syringe;

Recommended syringe & needle for Reconstitution & administration Tdap

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	Needle Gauge and Length: 22g x 32mm: 42142523-00010 23g x 25mm: 42142523-00009 25g x 16mm: 42142523-00008 Needle length/Age or Age and Weight: Age 4–10 years: 25–32 mm (Thigh) Age 4–18 years: 16 - 25 mm (Deltoid) Woman Aged 19 and older <70kg: 25mm ; 70 -90kg: 25-38mm ; > 90kg: 38mm

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 non-dominant arm of the vaccine recipient
- All used injection equipment should be placed in a safety box (without recapping), immediately after use.

Schedule & administration Tdap

Description	Details
Route & Site of administration	Intramuscularly (IM). Preferably in the deltoid muscle >=4 years: IM. Deltoid muscle (preferred site). Vastus lateralis muscle of anterolateral thigh (alternative site if the deltoid sites cannot be used.)
Co-administration	In accordance with national recommendations, other live or inactivated parenteral vaccines may be administered simultaneously. Separate injection sites and separate syringes must be used in case of concomitant administration.
Preparation/ Reconstitution	Fully liquid, no dilution required
Dose	0.5ml
Storage after 1st puncture of vial	N/A as single use vial

Vaccine administration

Step 5

- Record dose on Road to Health Booklet, Maternity record and the PHC tick register

Vaccine Administration

Step 6

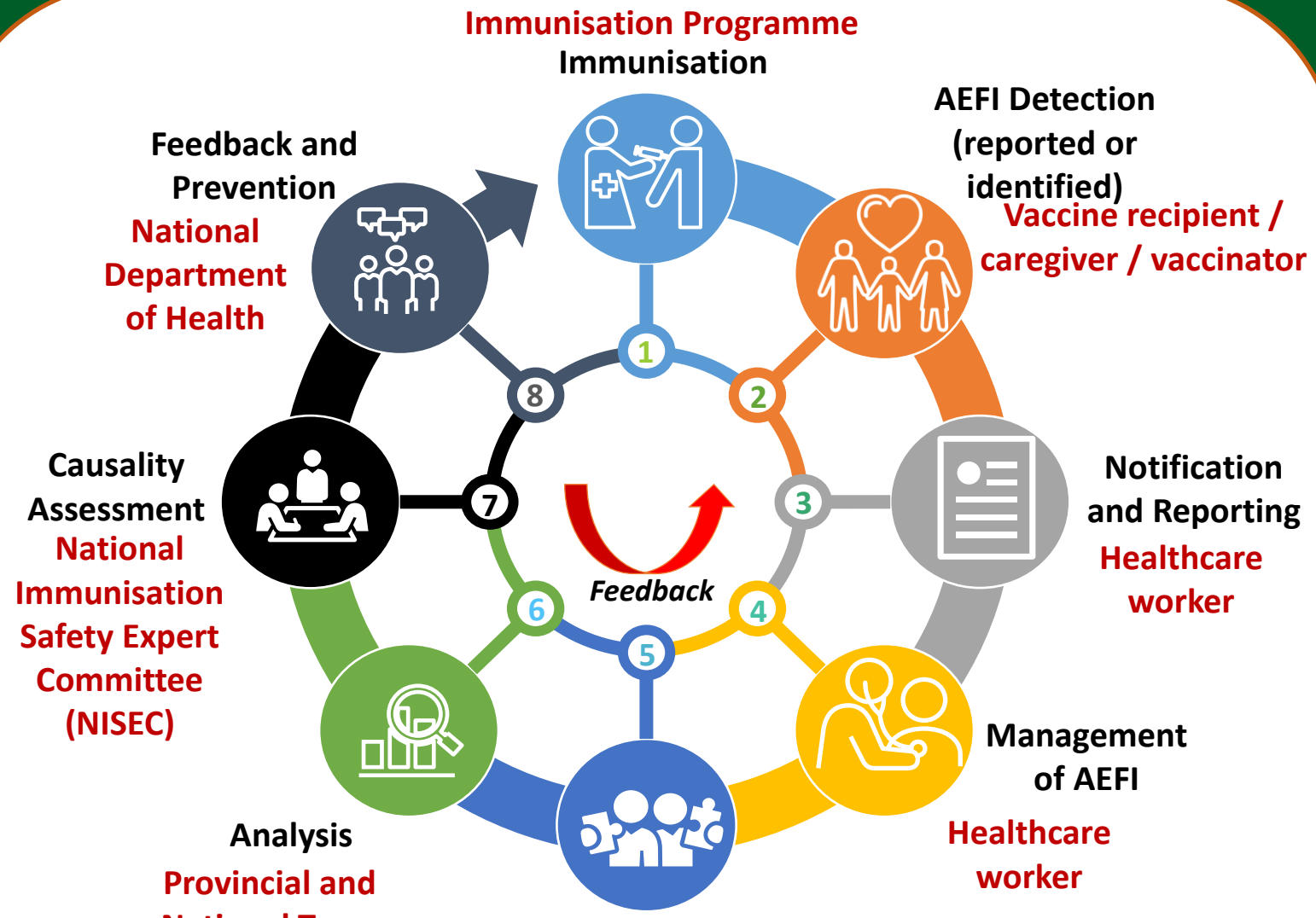
- Indicate to the vaccine recipient what to do if there are any adverse events following immunization
- Indicate when the child should come back for the next injection (i.e. the 6 year old) in the Road to Health Booklet
- For pregnant women record the Tdap dose in the Maternity Case Record

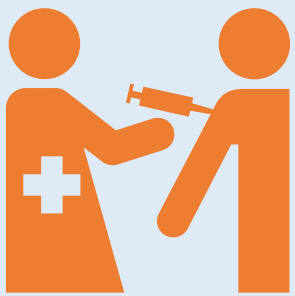
Recording the Tdap doses

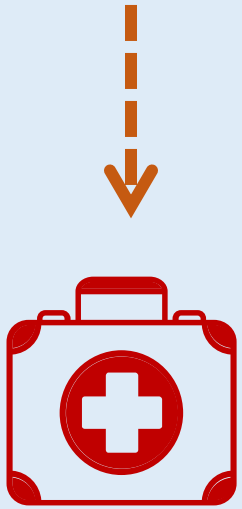
- Tdap should be recorded in the same way as other vaccines in the programme.
- At the service delivery level these are:
  - Road to health booklet
  - PHC tick register
  - Vaccine Stock cards
  - Maternity Case records

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







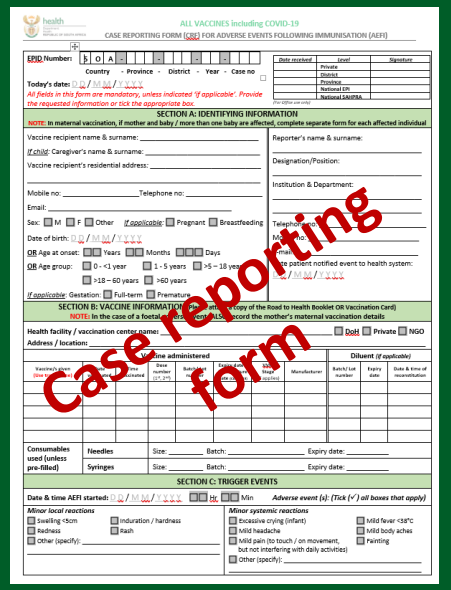
Adverse event of concern

Health facility

Med Safety App

MILD/MINOR EVENTS

Expected



Case reporting form

SEVERE EVENTS

Not expected

Arm is sore or red at the injection site

Fever/ chills

Headache

Fatigue

Muscle aches

Nausea

Investigated

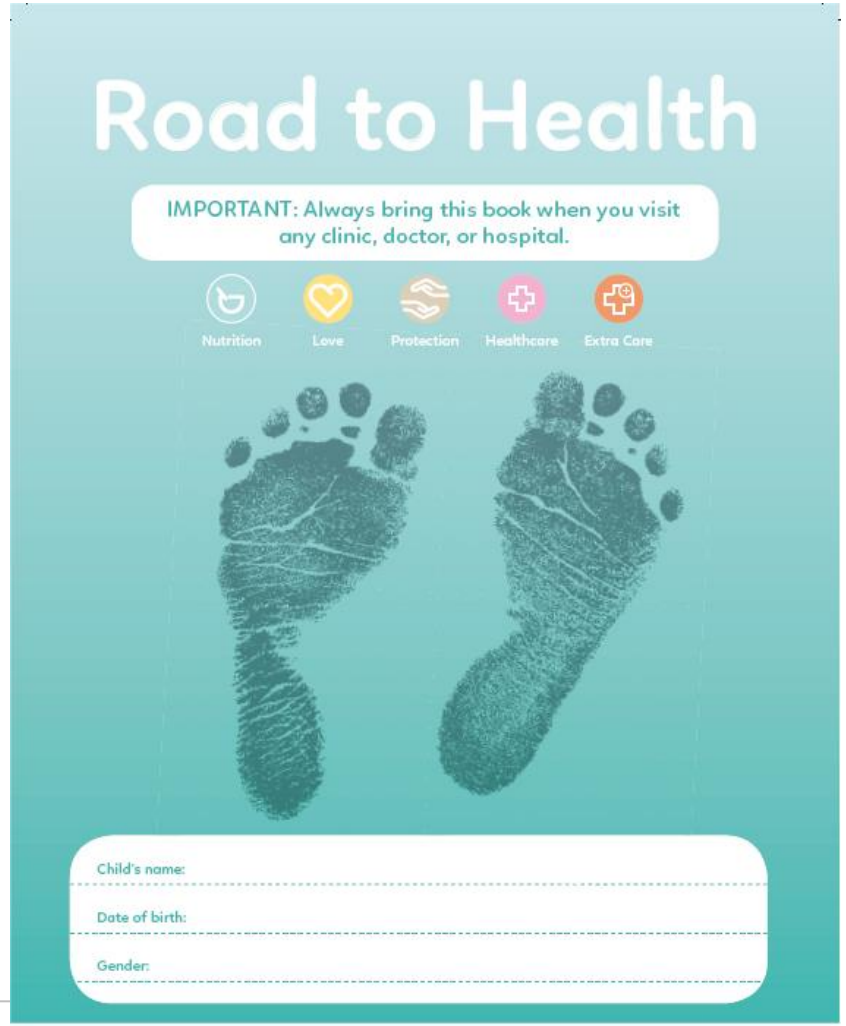
Serious events

- 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

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				

DE group	Current vaccine	New vaccine
Data element name	**Tetanus & diphtheria (Td) at 6 years**	**Tetanus, diphtheria & acellular pertussis** (Tdap) at 6 years
Bulleted definition	Td booster dose given to a child at 6 years of age. The cut-off age is under 9 years	Tdap booster dose given to a child at 6 years of age. The cut-off age is under 9 years
Extended Definition	Td is tetanus plus diluted diphtheria. Do not administer Td for children who are younger than 6 years of age	Tdap is tetanus plus diluted diphtheria plus acellular pertussis. Do not administer Tdap for children who are younger than 6 years of age
Use and Context	Monitors the Expanded Program on Immunisation policy	Monitors the Expanded Program on Immunisation policy
Inclusions	INCLUDE doses given in 'mopping-up' awareness programs; INCLUDE Td doses given routinely; INCLUDE Td dose at 6 years given at schools as part of school health services	INCLUDE doses given in catch-up campaigns to children between 6 and 9 years; INCLUDE Tdap doses given routinely; INCLUDE Tdap dose at 6 years given at schools as part of school health services
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) & School Health
Tools	PHC Comprehensive Tick Register	PHC Comprehensive Tick Register, Hospital paediatric registers & School Health registers
DE GROUP	CURRENT VACCINE	NEW VACCINE

DE group	Current vaccine	New vaccine
Data element name	**Tetanus & diphtheria (Td) at 12 years**	**Tetanus, diphtheria & acellular pertussis** (Tdap) at 12 years
Bulleted definition	Td booster dose given to a child at 12 years of age. The cut-off age is under 14 years	Tdap booster dose given to a child at 12 years of age. The cut-off age is under 14 years
Extended Definition	Td is tetanus plus diluted diphtheria. Do not administer Td for children who are younger than 6 years of age	Tdap is tetanus plus diluted diphtheria plus acellular pertussis. Do not administer Tdap for children who are younger than 6 years of age
Use and Context	Monitors the Expanded Program on Immunisation policy	Monitors the Expanded Program on Immunisation policy
Inclusions	None	INCLUDE doses given in catch-up campaigns to children between 12 and 14 years; INCLUDE Tdap doses given routinely at 12 years; INCLUDE Tdap dose at 12 years given at schools as part of school health services
Exclusions	None	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) & School Health
Tools	PHC Comprehensive Tick Register	PHC Comprehensive Tick Register, Hospital paediatric registers & School Health registers
Tools	PHC Comprehensive Tick Register & Maternity registers	

DE Group	Expanded Program on Immunisation (NEW Data Element)
Data Element Name	Tdap dose at 26 to 34 weeks of gestational age.
Bulleted Definition	Tdap booster dose given to a pregnant woman at 26 to 34 weeks of gestational age. Include doses given after 34 weeks during pregnancy
Extended Definition	Tdap is tetanus plus diluted diphtheria plus acellular pertussis. The woman will receive one dose in each pregnancy at 26-34 weeks gestational age.
Use and Context	Monitors protection of pregnant and newborns against tetanus, diphtheria and pertussis infections. Vaccines given as part of mass vaccination campaigns should not be counted here
Inclusions	INCLUDE catch-up doses given after 34 weeks DURING pregnancy
Exclusions	EXCLUDE doses given during post natal period EXCLUDE doses given as part of a national mass vaccination campaign
Collected by	Clinicians
Collection points	All facilities conducting ante natal services
Frequency	Monthly
Tools	PHC Comprehensive Tick Register & Maternity 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.,)

THANK YOU