PHC Chapter 13: Immunisation

The contents of this chapter are based on the current recommendations from the National Advisory Group on Immunisation (NAGI).

13.1 IMMUNISATION SCHEDULE

Any medical incident that takes place after immunisation and may be potentially related to immunisation should be reported (See Section 13.6).

- » Every clinic day is an immunisation day.
- » Never miss a chance to immunise – never turn a person away if an immunisation is needed, even if it means opening a multi-dose vial for just one person.
- » Check the Road to Health Booklet every time the child visits the clinic and give missed immunisations. These should be given according to the catch-up schedule which is shown in the table on page 13.4.
- » Mild illnesses are not a contra-indication to immunisation – most children who are well enough to be sent home, are well enough to be immunised. Do not immunise a sick child if the mother seriously objects but encourage her to bring the child for immunisation on recovery.
- » Give an extra dose if in doubt whether a child has had a certain dose or not, as extra doses are not harmful.
- » The measles/rubella vaccine must not be given with other childhood vaccines when administered at 6 months of age. The measles/rubella vaccine can be co-administered with other vaccines from 9 months of age. All other vaccines listed in the table below can be given safely at the same time but should not be given in the same syringe or at the same site.
- » Serious adverse events following immunisation are uncommon. All adverse events should be reported.
- » For management of anaphylaxis associated with vaccinations, See Section 22.2.10: Anaphylaxis.

Adverse events following immunisation (AEFI) definition

Any untoward medical occurrence which follows immunisation, irrespective of whether there is a causal relationship with the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

All AEFI should be reported. Serious and severe AEFI or cluster of events are investigated, and causality assessed by the National Immunisation Safety Expert Committee (NISEC) which is an independent committee appointed by the Minister of Health. Further information is available in the *vaccine safety surveillance in South Africa - Manual for Surveillance and Response to Adverse Events Following Immunisation***.**

Conditions that are not contraindications to any of the standard EPI vaccines

There are very few contra-indications, but many missed opportunities.

» Family history of any adverse reactions following vaccination.
» Family history of convulsions.
» Previous convulsions.
» Egg allergy
» Previous measles, mumps, rubella, or pertussis-like illness.
» Preterm birth.
» History of jaundice after birth.
» Stable neurological conditions such as cerebral palsy or trisomy 21.
» Contact with an infectious disease.
» Minor illness (without systemic illness and with a temperature below 38.5°C).
» Treatment with antibiotics.
» Asthma, eczema, hay fever or 'snuffles'.
» Treatment with locally acting (inhaled or low-dose topical) steroids.
» Child's mother is pregnant.
» Child being breastfed.
» Underweight, but otherwise healthy child.
» Over the age recommended in vaccination schedule but not above the allowable upper age limit per manufacturer's recommendations.
» Recent or imminent surgery.

13.2 CHILDHOOD IMMUNISATION SCHEDULE

Immunisation schedule

Age of child	Vaccine
At birth	OPV0 BCG
6 weeks	OPV1 RV1 Hexavalent (DTaP-IPV-HB-Hib)1 PCV1
10 weeks	Hexavalent (DTaP-IPV-HB-Hib)2
14 weeks	RV2 Hexavalent (DTaP-IPV-HB-Hib)3 PCV2
6 months	Measles/Rubella1
9 months	PCV3
12 months	Measles/Rubella2
18 months	Hexavalent (DTaP-IPV-HB-Hib)4
6 years	Tdap
12 years	Tdap

Note:

» Exception: patients with primary immune deficiency or known HIV-infection should not be given BCG vaccine. *LoE:IVb*
» Children with HIV should receive the rest of the full schedule of vaccines.

Catch-up doses

Any child who is unimmunised should be given a full schedule of immunisations.

Vaccine	Age of child	First dose	Interval for subsequent doses		
			Second	Third	Fourth
BCG	< 10 year	Give one dose			
	≥ 10 year	Do not give			
OPV	< 6 months	Give first dose	4 weeks		
	≥ 6 months	Do not give			
Hexavalent (DTaP-IPV-HB-Hib)	Up to 5 years	Give first dose	4 weeks	4 weeks	12 months (do not give before child is 18 months old)
Rotavirus	< 20 weeks	Give first dose	4 weeks		
	20–24 weeks	Give one dose			
	> 24 weeks	Do not give			
PCV	< 6 months	Give first dose	4 weeks	Give at 9 months of age	
	6–24 months	Give first dose	4 weeks	8 weeks	
	2-6 years	Give one dose			
Measles/rubella	< 11 months	Give first dose	At 12 months of age		
	≥ 11 months	Give first dose	4 weeks		
Tdap	> 6 years	Give first dose	At 12 years of age		

13.3 VACCINES FOR ROUTINE ADMINISTRATION

Vaccine	Form	Dose	Route	Recommended site	Age
BCG	Powder	0.05 mL	Intra-dermal	Right upper arm, at the deltoid muscle	Birth
OPV	Liquid	2 drops	Oral	Oral	Birth, 6 weeks
RV	Liquid	Administer the full vial (1 or 2 mL depending on the product used)	Oral	Oral	6, 14 weeks
Hexavalent (DTaP-IPV-HB-Hib	Liquid and Powder	0.5 mL	IM	< 1 year: lateral aspect of the left thigh ≥ 1 year: left upper arm	6,10,14 weeks, 18 months
Measles/Rubella	Powder	0.5 mL	SC	< 1 year: lateral aspect of the left thigh ≥ 1 year: right upper arm	6, 12 months
PCV	Liquid	0.5 mL	IM	Lateral aspect of the right thigh	6, 14 weeks, 9 months
Tdap	Liquid	0.5 mL	IM	Upper arm	5-7 years, ≥12 years

BCG *(Bacillus calmette-guerin)*
Z23.2

Protects against TB meningitis and miliary TB in children < 2 years of age.

- BCG, 0.05 mL of reconstituted intradermal BCG vaccine.
  - Administered into the skin (intradermally) on the right upper arm, overlying insertion of the deltoid.
  - Storage:
    - Fridge: In a vaccine fridge at 2–8°C.
    - Discard opened vial after 6 hours or at end of immunisation session, whichever occurs first. (It is acceptable to open a BCG vial for just one infant)
  - Adverse events:
    - Initial reaction to intradermal vaccination is a papule formation that lasts a maximum of 4–6 weeks. This develops into a scar (visible in 40% of vaccinated infants).

- In 1–10% there is oozing, ulceration and lymphadenopathy after vaccination. This is a usual reaction and not a cause for alarm. Lymphadenopathy < 1.5 cm is not clinically significant.
- Occasionally the papule becomes a pustule.
- Complete AEFI notification and refer all cases with significant lymphadenopathy or a draining sinus.

○ Recommendations for providing BCG Vaccine:

» **Initial dose of BCG vaccine**

- All newborns regardless of HIV status or TB exposure status should receive BCG at discharge.
- For infants that are transferred to a neonatal unit, the timing of BCG vaccination will depend on the infant's clinical status. Neonatal units should have a policy to ensure vaccination occurs prior to hospital discharge.

» **Repeat dose of BCG vaccine**

- If the infant initiates TPT or TB treatment in the first six weeks of life, the effectiveness of the live, attenuated BCG vaccine may be negatively impacted. Therefore, the BCG vaccine should be repeated on completion of either TPT or TB treatment.
- Infants or children living with HIV should only receive a repeat dose if they are 1) on ART, 2) clinically well, and 3) have a CD4 > 25%.
- If the criteria to receive BCG are not met, i.e., the infant is 1) Not on ART, 2) or Unwell, or 3) CD4 < 25%
    - Delay repeat dose of BCG until on ART and immunologically stable (CD4 > 25%)
    - Start/continue TPT until the child is eligible to receive BCG.
- After TPT/TB treatment is completed, a CD4 count should be done to determine if the infant meets the above criteria for receiving BCG even if the annual CD4 count is not yet due. Do not wait for the routine annual CD4 count, as this delay may result in many infants not receiving BCG at all.
- If the infant received the standard first-line TB treatment regimen BCG vaccination may be administered from 24 hours after the last anti-TB treatment dose. If the infant received rifapentine give BCG from 5 days after the last dose, and if the infant received bedaquiline or clofazamine give BCG vaccination two months after the last dose.

» **Catch-up dose of BCG vaccine**

- A 'catch-up' BCG should be administered to any child <10 years of age who did not get a BCG at birth.
- Infants or children living with HIV should only receive "catch up" BCG vaccination if they are 1) on ART, 2) clinically well, and 3) have a CD4 > 25% (if ≤5 years of age) or >200 cells (if >5 years of age).
- Children older than > 10 years of age should not get BCG vaccination.

CAUTION

Children with suspected or confirmed inborn errors of immunity or other acquired immunodeficiencies should be evaluated by an expert before BCG vaccination.

Hexavalent (DTaP-IPV-HB-Hib) vaccine
Z27.8

(Diphtheria, tetanus, acellular pertussis, inactivated polio, hepatitis B and *Haemophilus influenzae* type b vaccine).

Protects against diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B infection, and invasive infections caused by *Haemophilus influenzae* type b.

- Hexavalent (DTaP-IPV-HB-Hib), IM, 0.5 mL.
  - < 1 year of age: administer into outer side of left thigh.
  - > 1 year of age: administer into upper left arm.

Hexavalent (DTaP-IPV-HB-Hib) vaccine is a fully liquid combination of diphtheria toxoid, Tetanus toxoid, acellular pertussis vaccine, inactivated polio vaccine, hepatitis B vaccine and Haemophilus influenzae type b vaccine.

- Storage:
  - Fridge: In a vaccine fridge at 2–8°C.
  - Hexavalent (DTaP-IPV-HB-Hib) vaccine should never be frozen.
- Adverse events:
  - Irritability.
  - Fever ≥ 38°C and acute illness.
  - Redness and induration at the site of the injection.
- Contra Indications:
  - Known hypersensitivity to any component of the vaccine or pertussis vaccine (acellular or whole cell pertussis) or a life-threatening reaction after previous administration of the vaccine or a vaccine containing the same substance.

Tdap (Tetanus, reduced diphtheria and acellular pertussis vaccine)
Z27.8

Protects against diphtheria, tetanus and pertussis.

- Tdap, IM, 0.5 mL in upper arm.
  - Storage:
    - Fridge: In a vaccine fridge at 2–8°C.
    - Easily damaged by freezing.
  - Adverse events:
    - Mild fever.
    - Pain
    - Local swelling occasionally.
  - Contraindications:
    - Previous anaphylaxis to the vaccine.
    - Children < 4 years of age should not get Tdap.

Tdap in pregnancy

Tdap protects pregnant women and newborn infants against tetanus, diphtheria and pertussis.

- Pregnant women should routinely receive a single dose of Tdap during each pregnancy between 26–34 weeks' gestation to maximise protection of preterm infants.
- If not administered between 26–34 weeks, a catch-up dose should be given at any time, including in the immediate post-partum period.

bOPV (Oral polio vaccine)
Z24.0

Protects against polio.

- bOPV, oral, 2 drops given by mouth.
  - If spat out or vomited, repeat immediately.
  - Not affected by feeding (breast or other).
  - Storage:
    - Fridge: In a vaccine fridge at 2–8°C; or freezer (in pharmacy).
    - Not damaged by freezing.

Easily damaged by temperature > 8°C.

    - Keep open, uncontaminated vials at the correct temperature.
    - Record date of opening on the vial.
    - Discard after 30 days.
  - Adverse events:
    - May be associated with a flu-like illness and gastroenteritis.
    - Mild fever.
  - Contraindications:
    - Previous anaphylaxis to the vaccine.
    - bOPV is not contraindicated in HIV-infected children but should not be administered to children with primary immune deficiency.

RV (Rotavirus vaccine)
Z25.8

Protects against gastro-enteritis caused by rotavirus.

- RV, oral, administer the full vial (1 or 2 mL depending on the product used).
  - Squeeze the entire contents of the tube in the inner cheek.
  - Storage:
    - Fridge: In a vaccine fridge at 2–8°C.
    - Easily damaged by freezing.
    - Protect the vaccine from light.
  - Adverse events:
    - Mild fever.
    - Irritability.
  - Contra-indications:
    - Previous anaphylaxis to rotavirus or any ingredients in the formulation.

- Do not give rotavirus vaccine if a child has a history of chronic gastro-intestinal disease or severe diarrhoea including children with any history of uncorrected congenital malformation of the gastrointestinal tract. Refer the child for medical opinion.
- A history of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever).
- Rotavirus vaccine should not be given after 24 weeks of age (See table on page 13.4 for catch-up schedule).

PCV (Pneumococcal conjugated vaccine)

Z23.8

Protects against invasive pneumococcal disease (meningitis, septicaemia), pneumonia and otitis media.

- PCV, IM, 0.5 mL
  - < 1 year of age: administer into outer side of right thigh.
  - > 1 year of age: administer into upper arm in the deltoid muscle.
  - PCV and Hexavalent (DTaP-IPV-HB-Hib) can be administered at the same time, but at different sites.
  - Storage:
    - Fridge: middle shelf at 2–8°C.
    - Do not freeze as the vaccine is easily damaged by freezing.
    - Do not mix PCV in the same syringe with other vaccines.
    - Shake the vaccine well before use.
  - Contra- indications:
    - Previous anaphylaxis to the vaccine.

Measles/Rubella

Z24.4

- Measles/Rubella vaccine, SC, 0.5 mL.
  - < 1 year of age: administer subcutaneously on lateral aspect of the left thigh.
  - ≥ 1 year of age: administer subcutaneously on right upper arm.
  - Avoid administering the measles/rubella vaccine at the same time as other vaccines at 6 months of age. However, it is considered safe to co-administer the measles/rubella vaccine with other vaccines in children 9 months and older. If a child requires measles/rubella vaccine and other vaccines at 6 months, give measles/rubella vaccine immediately and schedule visit to receive remaining vaccines 1 month later.
  - Storage:
    - Fridge: In a vaccine fridge at 2–8°C.
    - Discard opened vial after 6 hours or at end of immunisation session (whichever occurs first).
  - Adverse events:
    - Burning or stinging at the injection site, fever.
    - Transient morbilliform rash and mild pyrexia up to 30 days after vaccination.
  - Contra-indications:
    - Previous anaphylaxis to the vaccine.

- Uncontrolled convulsions: consult a doctor.

13.4 THE COLD CHAIN

Maintaining the cold chain means keeping vaccines at the right temperature throughout distribution, storage, and use. The cold chain can be maintained by:

» Never exposing vaccines to heat or freezing conditions, especially during transportation from one point to another.
» Always using a cold box to keep the vaccines cold during transport and immunisation.
» All vaccines should be kept in a refrigerator at a temperature of 2–8°C.
» Open vials of OPV should not be kept in the freezer or be allowed to freeze again. However, closed vials of OPV may be thawed and frozen, multiple times and should ideally be stored at -20°C.
» Use continuous temperature monitoring device e.g. fridge-tag for all vaccines (Min-max thermometer/dial thermometer not recommended).
» Ensure that Hexavalent (DTaP-IPV-HB-Hib), HPV, PCV, RV, Tdap, and TT vaccines do not come into contact with the refrigerator's evaporator at the back/sides, as they are sensitive to freezing. Do not freeze these vaccines, and do not use any vaccines that have been frozen. If there is a suspicion of freezing, conduct the shake test to determine if the vaccines have frozen and need to be discarded.
» Monitor and record fridge temperature twice daily.
» Leave space between each tray to allow cold air to circulate.
» Do not keep food in the same fridge as the vaccines.
» If possible do not keep other medications e.g. insulin etc. in the vaccine fridge.
» Do not keep blood and other specimens in the vaccine fridge.

Correct packing of the cold box

» Conditioned ice packs (the ice should rattle inside the pack) are placed on the bottom, at the sides and on top.
» If there are not enough ice packs, place available ice packs at the sides and on top of the vaccines.
» Tdap, TT, HPV, PCV, RV and Hexavalent vaccines must not be allowed to freeze.
» Keep measles/rubella and polio vaccines very cold - place on bottom of the cold box, closest to the ice packs.
» BCG can be placed anywhere in the box.
» Keep the lid firmly closed and the box out of the sun.
» Keep a continuous temperature monitoring device in the cold box with the vaccines and the temperature at 2–8°C.
» Live attenuated vaccines (BCG, OPV, measles/rubella) are very sensitive to heat, sunlight, and skin antiseptics.

How to pack your fridge correctly

» Vaccines should be stored in a purpose-built vaccine fridge. However, if unavailable store the vaccines in a domestic fridge, as follows:
» Top shelf: measles and polio vaccines in the coldest part.

- Middle shelf: BCG, Tdap, Hexavalent (DTaP-IPV-HB-Hib), HPV, RV, PCV and TT vaccines (do not freeze) with sufficient diluent for the BCG and measles/rubella for 2 days.
- Do not let Tdap, Hexavalent (DTaP-IPV-HB-Hib) HPV, RV, PCV and TT vaccines touch the evaporator plate at the back/side of the fridge as they are destroyed by freezing.
- Do not keep vaccines in the fridge door.
- Store the same kind of vaccines together in one tray.
- Leave about 2 cm space between each tray to allow the cold air to move around.
- Saltwater-filled bottles placed at the bottom of the fridge can prolong the holdover time, enabling the fridge to return promptly to its set temperature after being opened
- **Do not keep food in the same fridge as the vaccines to avoid unnecessary opening of the door.**

» There should be a contingency plan written and posted on every vaccine fridge of what to do in the event of a power failure.
» Monitor and record temperature twice daily.

CAUTION
Do not use vaccines that have expired, reached discard point as indicated by the VVM, or where the cold chain has been compromised.
Keep the fridge temperature between 2–8°C.

Note: All vaccines with a "T" in the name are sensitive to freezing: TT, Tdap, HexavalenT, RoTavirus, HepaTiTis B and even diluenTs. Diluents (for measles/rubella and BCG) should never be frozen.

13.5 OPEN MULTI-DOSE VIAL POLICY

Opened vials of TT HepB and OPV vaccines:

» May be used in subsequent immunisation sessions **for a maximum of one month**, if each of the following conditions have been met:
  - the expiry date has not passed
  - each vial must be dated when opened
  - the vaccines are stored under appropriate cold chain conditions (2–8°C with temperature monitoring and recording)
  - the vaccine vial septum has not been submerged in water
  - aseptic technique has been used to withdraw all doses

Opened vials of measles/rubella, BCG

Check the vaccine vial monitor (VVM) and expiration date prior to reconstitution.
Reconstituted vials of measles/rubella and BCG vaccines must be discarded at the end of each immunisation session or at the end of 6 hours, whichever occurs first.
Always label the vials with the date and time when opening or reconstituting.
All opened vials must be discarded immediately if:

» sterile procedures have not been fully observed,

» there is even a suspicion that the opened vial has been contaminated,
» there is visible evidence of contamination such as a change in appearance or floating particles, etc.

Discard the needle after using a multi-dose vial to avoid compromising the sterility of the vial.

INJECTION SAFETY

» Always wash hands before and after administering the vaccine.
» Always keep a fully equipped emergency tray at the immunisation point.
» Use a sterile syringe and sterile needle for each immunisation.
» Clean the skin adequately with cotton wool and water, do not use alcohol swabs.
» Check all vaccines for safety.
» Return all unsafe vaccines back to the pharmacy.
» Use the same needle for drawing up and administering the vaccine. “One Needle, One Syringe”.
» Diluents are not interchangeable. Different vaccines require different diluents.
» Always use the same diluent from the same manufacturer as the vaccine.
» Used needles and syringes must be disposed of safely.
» Discard all used empty vaccines in the sharps container.

13.6 ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

Report all AEFIs to the local EPI Coordinator.

AEFI form may be accessed at: at https://www.nicd.ac.za/diseases-a-z-index/adverse-event-following-immunization-aefi/ and https://www.sahpra.org.za/health-products-vigilance/ . AEFI forms should be emailed to AEFI@health.gov.za

Alternatively, AEFI can be reported on the MedSafety application on a mobile device. Search for **“Medsafety”** on apple store or google play store and install the app on your mobile device. Select **South Africa**. If you need any additional information on what to report and how to report, please contact SAHPRA on 012 501 0311

13.7 OTHER VACCINES

TT (Tetanus toxoid)
Z23.5

Protects against tetanus (post trauma)

- TT, IM, 0.5 mL into arm
  - Storage:
    - Fridge: middle shelf at 2–8°C.
    - Easily damaged by freezing.

  - Keep opened vials for next session if kept at correct temperature and not contaminated.
  - Discard after 30 days.
  - Record date of reconstitution.
- Contraindications:
  - Previous anaphylaxis.

Trauma

- Give booster dose of TT/Tdap after every traumatic injury (unless administered in previous 5 years).

Human Papilloma Virus (HPV) Vaccine

Z25.8

Protects against infection with HPV serotypes 16 and 18.

Persistent HPV infection is associated with the development of several reproductive tract cancers, especially cancer of the cervix.

A single dose is offered as part of the **Integrated School Health programme** to Grade 5 girls (≥ 9 years of age) in public schools.

- HPV, IM, 0.5 mL
  - Administered into the deltoid of the non-dominant arm.
  - Storage:
    - Fridge: middle shelf at 2–8°C.
    - Easily damaged by freezing – do not freeze and discard any vaccine which has been frozen.
    - Store in original package and protect from light.
    - Use immediately once withdrawn into a syringe.
  - Contraindications:
    - Previous anaphylaxis to the vaccine.
    - Febrile illness (≥ 38.5°C).
    - Should not be administered to girls/women who are known to be pregnant.
  - Adverse events:
    - Injection site pain and swelling in the arm are common.
    - Itching, rash, redness and urticaria may also occur.
    - Nausea, diarrhoea, abdominal pain, headache, myalgia, fever (38^{o}C) are not uncommon.
    - Syncope, dizziness, lymphadenopathy, and anaphylaxis have been reported.

Hepatitis B

Z24.6

All personnel working in a health care facility (including support staff) and student health care workers.

- Hepatitis B vaccine, IM, 3 adult doses of 1 mL.
  - **first dose** administered immediately;
  - **second dose** 1 month after the first dose;
  - **third dose** 6 months after the first dose.

Perinatal transmission
Babies born to mothers with acute hepatitis B infection at the time of delivery or to mothers who are HBsAg-positive or HBeAg-positive, See Section 6.6.5: Perinatal transmission of hepatitis B.

Influenza vaccine
Z25.1

- Influenza vaccine, IM, 0.5 mL.
  - Trivalent influenza vaccine or quadrivalent influenza vaccines may be used, depending on cost and availability considerations.
  - Contraindication: < 6 months of age.
  - Severe egg allergy is not a contraindication to the inactivated influenza vaccine. However, it is recommended that individuals reporting a history of severe egg allergy are vaccinated in a setting equipped to manage allergic reactions. *LoE:IVb*[1]
  - Based on available data and resources, the following groups are prioritised for influenza vaccination in the annual influenza campaign and during influenza or COVID-19 pandemic: *LOE:IVb*[2]
    - » Healthcare workers
    - » Age > 65 years
    - » People with the following risk factors for severe influenza:
      - Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke, and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease) and malignancy
      - HIV infection *LoE:IVb*[3]
    - » Pregnant women at all stages of pregnancy, including women up to 6 weeks postpartum
  - Commercially available products may differ in terms of the age-groups in which they can be used – check the specific package insert.
  - General recommended dosage of influenza vaccine for patients of different age groups:

Age group	Dose	Number of doses
• ***Trivalent influenza vaccine:***		
Adults and children ≥ 9 years	0.5 mL, IM	Single dose.
Children: > 3 to < 9 years	0.5 mL, IM	2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum.
Children: > 6 months to < 3 years	0.25 mL, IM	2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum. *LoE:IIIb*[4]
• ***Quadrivalent influenza vaccine:***		
Adults and children ≥ 9 years	0.5 mL, IM	Single dose

6 months to < 9 years	0.5 mL, IM	2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum. *LoE:IIIb*[5]

Note:

» The influenza vaccine should not be given at the same time as the live measles/rubella vaccine at 6 months of age. *LoE:IVb*[6]

» Influenza vaccines can be given concurrently with other injectable vaccines but must be administered at different injection sites.

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SOUTH AFRICAN PRIMARY HEALTHCARE LEVEL ESSENTIAL MEDICINES LIST
PHC CHAPTER 13: IMMUNISATION
NEMLC RECOMMENDATIONS FOR MEDICINE AMENDMENTS (2020-2024 REVIEW CYCLE)

Medicine amendment recommendations, with supporting evidence and rationale are listed below.
Kindly review the medicine amendments in the context of the respective standard treatment guideline (STG).

All reviews and costing reports may be accessed at: https://www.knowledgehub.org.za/content/standard-treatment-guidelines-and-essential-medicines-list or https://www.health.gov.za/nhi-edp-stgs-eml/.

Chapter Updates

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SECTION A

MEDICINE AMENDMENTS: March 2023

SECTION	MEDICINE/MANAGEMENT	ADDED/DELETED/AMENDED/ NOT ADDED/ RETAINED
13.7 Other vaccines	Influenza vaccine, IM	Amended

13.7 OTHER VACCINES

Influenza vaccine: *indications and contraindications amended*

- **Indications**

Prioritisation of risk groups are aligned with the most current National Influenza policy[1], but consideration of the current COVID-19 pandemic the following note was added to the STG text:

NOTE: Prioritisation strategies may vary in a pandemic.

- **Contraindications**

As allergy to eggs is not an absolute contraindication, STG text was amended as follows:

o Contraindication: severe egg allergy, age <6 months.

Level of Evidence: III Guidelines[2]

[1] National Department of Health: National Influenza Policy and Strategic Plan, 2017 to 2021
- Programme advised that updated policies are not routed through NAGI; NAGI to address this matter.

[2] SAMF, 2016

SECTION B

MEDICINE AMENDMENTS: July 2023

SECTION	MEDICINE/MANAGEMENT	ADDED/DELETED/AMENDED/ NOT ADDED/ RETAINED
13.1 Immunisation schedule	COVID-19 vaccination	Guidance added
	Anaphylaxis management	Cross reference added
13.3 Vaccines for routine administration	RV (Rotavirus vaccine)	Dose Amended, depending on product used
13.7 Other vaccines	Influenza vaccine	Options provided, priority groups and directions for use amended Severe egg allergy removed as a contra-indication

The preface was expanded to include the National Department of Health COVID-19 vaccine guide:

The contents of this chapter are based on the current National Vaccinators Manual, the current COVID-19 Vaccine Implementation Guide and Toolkit and recommendations from the National Advisory Group on Immunisation (NAGI).

13.1 IMMUNISATION SCHEDULE

COVID-19 vaccination: *guidance added*

The following text was included in the STG, aligned with the National Department of Health COVID-19 Vaccine Implementation Guide and Toolkit[3]:

- As COVID vaccination recommendations are being updated regularly as new evidence emerges, please consult the latest National Department of Health vaccine policy recommendations.
- **Note:** COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day. If multiple vaccines are administered at a single visit, administer each injection in a different injection site (different arm), with the COVID-19 vaccine administered on the LEFT arm.

Level of Evidence: Guidelines

Anaphylaxis associated with vaccines: *cross-reference added*

For management of anaphylaxis associated with vaccinations, a cross-reference to Section 22.2.10: Anaphylaxis in the emergencies and injuries chapter was added.

13.3 VACCINES FOR ROUTINE ADMINISTRATION

RV (Rotavirus vaccine): *Dose Amended, depending on product used*

A 1 or 2 mL RV product is available in South Africa, as single doses for reconstitution and administration. The dose of RV was amended from 1.5 mL to 1 or 2 mL, depending on the product used. The amendment was made in the vaccines for routine administration table and narrative.[4]

The STG text was amended as follows

Vaccine	Form	Dose	Route	Recommended site	Age
BCG	Powder	0.05 mL	Intra-dermal	Right upper arm, at the deltoid muscle	Birth
OPV	Liquid	2 drops	Oral	Oral	Birth, 6 weeks
RV	Liquid	~~1.5 mL~~ Administer	Oral	Oral	6, 14 weeks

[3] National Department of Health. COVID-19 Vaccine Implementation Guide and Toolkit, 2022. https://www.knowledgehub.org.za/elibrary/covid-19-field-guide-and-sops

[4]

		the full vial (1 or 2 mL depending on the product used)			
Hexavalent (DTaP-IPV-HB-Hib	Liquid and Powder	0.5 mL	IM	< 1 year: lateral aspect of the left thigh ≥ 1 year: left upper arm	6,10,14 weeks, 18 months
Measles	Powder	0.5 mL	SC	< 1 year: lateral aspect of the left thigh ≥ 1 year: right upper arm	6, 12 months
PCV	Liquid	0.5 mL	IM	Lateral aspect of the right thigh	6, 14 weeks, 9 months
Td	Liquid	0.5 mL	IM	Upper arm	5–7 years, ≥ 12 years.

And

RV (Rotavirus vaccine)
Z25.8
Protects against gastro-enteritis caused by rotavirus.
- RV, oral, ~~1.5mL~~ administer the full vial (1 or 2 mL depending on the product used). ~~given by mouth.~~

For measles, an editorial amendment was made removing the statement that "The new guideline is to administer the measles vaccine at 6 (range 7-11 months) and 12 months" as this guidance is no longer new but historical.

The STG text was amended as follows

Measles
Z24.4
- Measles vaccine, SC, 0.5 mL.
  - < 1 year of age: administer subcutaneously on lateral aspect of the left thigh.
  - ≥ 1 year of age: administer subcutaneously on right upper arm.
  - ~~The new guideline is to administer the measles vaccine at 6 (range 7-11 months) and 12 months.~~
  - Do not give the currently available measles vaccine at the same time as other vaccines. If a child requires measles vaccine and other vaccines at the same time, give measles vaccine immediately and schedule visit to receive remaining vaccines 1 month later.
  - Storage:
    - Fridge: In a vaccine fridge at 2–8°C.
    - Discard opened vial after 6 hours or at end of immunisation session (whichever comes first).
  - Adverse events:
    - Burning or stinging at the injection site, fever.
    - Transient morbilliform rash and mild pyrexia up to 30 days after vaccination.
  - Contra-indications:
    - Previous anaphylaxis.
    - Uncontrolled convulsions: consult a doctor.

13.7 OTHER VACCINES

Influenza vaccine: *options provided, priority groups and directions for use amended, double-dosing in children retained and referenced*

- ***Options provided:*** The option of trivalent (TIV) or quadrivalent (QIV) influenza vaccines was provided, aligned with the NAGI recommendations included in the National Department of Health 2021 Influenza Guide[5].

[5] National Department of Health. Influenza Vaccination Guide, 2021. https://www.knowledgehub.org.za/

Boer et al & Milne et al: Despite a cost-effectiveness analysis[6] (shared by NAGI as supporting evidence for QIV) showing that QIV would provide a greater reduction in influenza-related morbidity in low-middle income countries (ICER of $4183/QALY), budgetary impact depends on influenza B burden and whether the influenza B lineage in the TIV matches the circulating B lineages.[7]

Surveillance data: NICD surveillance data for influenza from sentinel sites (public sector hospitals) for the period 3 January 2022 to 17 July 2022 (week 28) showed that 228 cases had been detected - 142 (62%) were influenza A(H1N1) pdm09, 57 (25%) influenza A(H3N2), 7 (3%) influenza A (subtype inconclusive), 4 (2%) influenza A (pending results), 12 (5%) influenza B (Victoria), 3 (1%) influenza B (lineage inconclusive and 3 (1%) influenza B (pending results).[8]

Cost and availability: Although there is no compelling basis on which to recommend QIV over TIV, supply concerns need consideration, and thus a general statement indicating that either the TIV or QIV be considered depending on availability and cost.

- ***Priority groups for influenza vaccination:*** Noting the disclaimer at the beginning of the PHC immunization chapter that the contents of this chapter are based on the current National Vaccinators Manual, and recommendations from the National Advisory Group on Immunisation (NAGI), the STG was updated listing priority target groups for influenza vaccination during various settings.

- **Cancer patients as a targeted priority group for annual influenza vaccination campaigns**
  NEMLC noted that the NDOH Influenza guidelines for 2022 omitted "cancer" as a risk for influenza vaccination, despite being listed in the NICD Guidelines for influenza, 2022. NEMLC recommended that 'malignancy' be included in the list of chronic conditions for eligibility of influenza vaccines under both pandemic and non-pandemic conditions; and, the NDoH Programme to be informed of the omission, requesting that this be addressed in the 2023 iteration of the guidelines.

The STG text was updated from:

- ~~All women who are pregnant at the time of the annual immunisation campaign should be immunised.~~
- ~~People with the following risk factors may be offered immunisation during the annual campaign:~~
  - ~~HIV infection.~~
  - ~~Chronic cardiac or pulmonary conditions.~~
  - ~~Age > 65 years.~~
- ~~Healthcare workers are not routinely offered immunisation during the annual campaign. Although it is recommended that healthcare workers are vaccinated against influenza, they will not be provided with publically funded vaccines unless they fall within any of the designated high risk groups.~~

~~NOTE: Prioritisation strategies may vary in a pandemic.~~

To:

Annual influenza campaign	**Influenza pandemic**	**COVID-19 pandemic**
Healthcare workers* without risk factors are not routinely immunised	All healthcare workers including those without risk factors	All healthcare workers including those without risk factors
Age > 65 years	Age > 65 years	Age > 65 years

[6] De Boer PT, Kelso JK, Halder N, Nguyen TPL, Moyes J, Cohen C, Barr IG, Postma MJ, Milne GJ. The cost-effectiveness of trivalent and quadrivalent influenza vaccination in communities in South Africa, Vietnam and Australia. Vaccine 2018; 36:997 - 1007

[7] Milne GJ, Halder N, Kelso JK, Barr IG, Moyes J, Kahn K, Twine R, Cohen C. Trivalent and quadrivalent influenza vaccination effectiveness in Australia and South Africa: results from a modelling study. Influenza Other Respir Viruses. 2016 Jul;10(4):324-32.

[8] NICD. Communicable Diseases Communiqué: Respiratory diseases, July 2022, Vol number 21 (7). https://www.nicd.ac.za/wp-content/uploads/2022/07/Influenza-season-update.pdf

People (including healthcare personnel) with the following risk factors for severe influenza: – Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease), malignancy – HIV infection	People (including healthcare personnel) with the following risk factors for severe influenza: – Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease), malignancy – HIV infection	People (including healthcare personnel) with the following risk factors for severe influenza: – Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease), malignancy – HIV infection
All women who are pregnant at the time of the campaign.	All women who are pregnant at the time of the campaign.	All women who are pregnant at the time of the campaign.

*(*Healthcare workers are not routinely offered immunisation during the annual influenza campaign. Although it is recommended that healthcare workers are vaccinated against influenza, they will not be provided with publicly funded vaccines unless they fall within any of the high risk groups).*

Level of Evidence: Guidelines[9]

- ***Directions for use:*** Amended for clarity purposes, and dosing interval with live measles vaccine aligned to current guidance on measles vaccination in section 13.3: Vaccines for routine administration.

The STG text was amended from:

~~o Recommended dosage of influenza vaccine for patients of different age groups:~~

~~Age group~~	~~Dose~~	~~Number of doses~~
~~Adults and children ≥ 9 years~~	~~0.5 mL, IM~~	~~Single dose.~~
~~Children: > 3 to < 9 years~~	~~0.5 mL, IM~~	~~2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum.~~
~~Children: > 6 months to < 3 years~~	~~0.25 mL, IM~~	~~2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum.~~

To:

- Commercially available products may differ in terms of the age-groups in which they can be used – check the specific package insert.
- General recommended dosage of influenza vaccine for patients of different age groups:

Age group	Dose	Number of doses
• ***Trivalent influenza vaccine:***		
Adults and children ≥ 9 years	0.5 mL, IM	Single dose.
Children: > 3 to < 9 years	0.5 mL, IM	2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum.
Children: > 6 months to < 3 years	0.25 mL, IM	2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum.
• ***Quadrivalent influenza vaccine:***		
Adults and children ≥ 9 years	0.5 mL, IM	Single dose
6 months to < 9 years	0.5 mL, IM	2 doses ≥ 4 weeks apart during first year of immunisation, thereafter one dose per annum.

Note:

» Influenza vaccines can be given concurrently with other injectable but must be administered at different injection sites.

» The influenza vaccine should not be given at the same time as the live measles vaccine. Give measles vaccine immediately and schedule visit to receive other vaccine(s) 1 month later.

Level of Evidence: Guidelines[10] [11]

- ***Double-dosing in children in 1st year of immunization:*** Several published studies confirm benefits of a two-dose strategy in children. Abraham et al found one dose provides less than half the protection of two doses, even in older children aged 6 to 8 years (Chua et al). Whilst an immunogenicity study supports two doses for children (Neuzil et al).

[9] National Department of Health. Influenza Vaccination Guide, 2021.
[10] SAMF, 2022
[11] National Department of Health. COVID-19 Vaccine Implementation Guide and Toolkit, 2022. https://www.knowledgehub.org.za/elibrary/covid-19-field-guide-and-sops

Level of Evidence: III Observational and Immunogenicity studies[12] [13] [14]

Further change after publication of chapter:

Following publication of the immunisation chapter of the primary health care standard treatment guideline in March 2023 (2022-23 review cycle) on the NDOH Knowledge Hub, a motivation was received by NEMLC to remove severe egg allergy as an absolute contraindication for influenza vaccine. NEMLC requested a review of evidence regarding safety of inactivated influenza vaccines when administered to egg-allergic individuals.

Refer to the scoping review: Inactivated influenza vaccines and egg allergy – scoping review – 30 May 2023:

Inactivated influenza vaccines and egg aller

One RCT, five prospective cohort studies, four retrospective reviews and ten international guidelines were identified for review. The definition of "egg-allergic" patients differed between the studies, as did primary outcomes. No anaphylactic reactions occurred in any of the 2612 patients included in the studies. Some studies reported milder reactions such as skin redness and urticaria, vomiting, and eczema, but reported rates were extremely low. Ten international guidelines that include recommendations for influenza vaccination in egg allergic patients were also identified. All but two (UK guidelines15,16) recommended that egg allergic patients should receive age-appropriate influenza vaccination. Most referenced some or all of the studies included in the scoping review as their evidence base. The UK guidance recommends that patients may receive inactivated influenza vaccines, unless they have experienced an anaphylactic reaction to egg, which required admission to intensive care. Generally, guidelines have evolved to amend recommendations from contra-indication of influenza vaccination to a permissive approach, based on the evidence documented. Recommendations are predominantly based on the understanding that available influenza vaccines (egg-derived or otherwise) now contain very low quantities of ovalbumin (<1mcg/ml).

Level of Evidence: Guidelines

In updating the STG the Committee considered:

- The relative versus no contraindication for egg allergy in influenza vaccination
- PHC as the setting for administration of influenza vaccination
- Low rate of fatal anaphylaxis
- If history of severe egg allergy reaction, recommend to administer in an environment capable to manage anaphylaxis under supervision of a clinician
- Patient/parental/guardian concerns.

The STG text was amended as follows:

- Influenza vaccine, IM, 0.5 mL.
  - Trivalent influenza vaccine or quadrivalent influenza vaccines may be used, depending on cost and availability considerations.
  - Contraindication: ~~severe egg allergy~~ < 6 months of age.
  - Severe egg allergy is no longer an absolute contraindication to the inactivated influenza vaccine. However, it is recommended that individuals reporting a history of severe egg allergy are vaccinated in a setting equipped to manage allergic reactions

Level of Evidence: Guidelines

[12] Abraham C, Stockwell MS. The Clinical Importance of a Second Dose of Influenza Vaccination in Young Children. JAMA Pediatr 2020;174:643–644. https://pubmed.ncbi.nlm.nih.gov/32364577/

[13] Chua H, Chiu SS, Chan ELY, Feng S, Kwan MYW, Wong JSC, Peiris JSM, Cowling BJ. Effectiveness of Partial and Full Influenza Vaccination among Children Aged <9 Years in Hong Kong, 2011-2019. J Infect Dis 2019;220:1568–1576. https://pubmed.ncbi.nlm.nih.gov/31290537/

[14] Neuzil KM, Jackson LA, Nelson J, Klimov A, Cox N, Bridges CB, Dunn J, DeStefano F, Shay D. Immunogenicity and reactogenicity of 1 versus 2 doses of trivalent inactivated influenza vaccine in vaccine-naive 5-8-year-old children. J Infect Dis 2006;194:1032–1039. https://pubmed.ncbi.nlm.nih.gov/16991077/

[15] Leech, SC, Ewan, PW, Skypala, IJ, et al. BSACI 2021 guideline for the management of egg allergy. Clin Exp Allergy. 2021; 51: 1262– 1278. https://doi.org/10.1111/cea.14009

16 Influenza: the green book, chapter 19. Influenza immunisation information including updates for public health professionals.

SECTION C

MEDICINE AMENDMENTS: October 2024

SECTION	MEDICINE/MANAGEMENT	ADDED/DELETED/AMENDED/ NOT ADDED/ RETAINED
13.1 Immunisation schedule	Measles/rubella (MR)vaccine	Guidance added
	Adverse events following immunisation	Guidance amended
	COVID-19 vaccination	Guidance removed
	Conditions that are not contraindications to any of the standard EPI vaccines	Amended
13.2 Childhood Immunisation Schedule	Measles Rubella (MR) vaccine	Added
	Tetanus, Diphtheria, Pertussis (Tdap) vaccine	Added
	PCV (Pneumococcal conjugated vaccine)	Retained
	(Tdap) vaccine	Guidance on the use of product added
	Oral polio vaccine (bOPV)	Guidance on storage added
	Measles Rubella (MR) vaccine	Guidance on the use of product added
13.3 Vaccines for routine administration	Tetanus, Diphtheria, Pertussis (Tdap) vaccine	Guidance amended
	bOPV (Oral polio vaccine):	Guidance on storage of bOPV added
	Measles/Rubella (MR) Vaccine:	Guidance on use of product added
13.4 The cold chain	Maintaining the cold chain	Guidance amended
13.5 Open multi-dose vial policy	Open multi-dose vial policy	Guidance amended
13.7 Other vaccines	Tetanus Toxoid vaccine (TT)	Guidance amended
	Human Papilloma Virus (HPV) Vaccine	Dosing schedule amended
	Hepatitis B vaccine	Guidance amended
	Influenza vaccine	Priority groups for vaccination amended

13.1 IMMUNISATION SCHEDULE

Measles/rubella vaccine: Guidance added

In the meeting held on the 12 October 2023 the NEMLC adopted the updates to the national expanded programme on immunisation (EPI). The 2024 EPI schedule has incorporated a Rubella-Containing Vaccine (RCV) to the current schedule.

The STG has been amended as follows:

> The ~~currently used~~ measles/rubella vaccine must not be given with other childhood vaccines when administered at 6 months of age. The measles/rubella vaccine can be co-administered with other vaccines from 9 months of age. All other vaccines listed in the table below can be given safely at the same time but should not be given in the same syringe or at the same site.

Adverse events following immunisation (AEFI): Guidance amended

In line with the Manual for Surveillance and Response to Adverse Events Following Immunisation[17], the definition of an AEFI has been added and clarity provided indicating that all adverse events regardless of intensity (minor or severe)

[17] SAHPRA.Vaccine safety Surveillance (VSS) in South Africa.2023. https://www.sahpra.org.za/document/vaccine-safety-surveillance-vss-in-south-africa/

and outcome (non-serious and serious) should be reported. In addition, contact details for reporting AEFIs have been included in section 13.6 of the STG.

The STG has been amended as follows:

Adverse events following immunisation (AEFI) definition ~~requiring reporting~~

Any untoward medical occurrence which follows immunisation, irrespective of whether there is a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

All AEFI should be reported and managed according to the standard treatment guidelines. Serious and severe AEFI or cluster of events are investigated and causality assessed by the National Immunisation Safety Expert Committee (NISEC) which is an independentcommittee appointed by the Minister of Health, Further information is available in the *VACCINE SAFETY SURVEILLANCE IN SOUTH AFRICA - Manual for Surveillance and Response to Adverse Events Following Immunisation*.

~~**Adverse events requiring reporting**~~

~~**Local reactions**~~
~~Pain, redness and / or swelling of more than 3 days' duration.~~
~~Swelling more than 5 cm from injection site.~~
~~BCG lymphadenitis following immunisation.~~
~~Injection site abscesses following immunisation.~~

~~**Systemic reactions**~~
~~All cases of hospitalisation (thought to be related to immunisation).~~
~~Encephalopathy within 7 days.~~
~~Collapse or shock-like state within 48 hours.~~
~~Fever of more than 38°C within 48 hours.~~
~~Seizures within 3 days.~~
~~All deaths (thought to be related to immunisation).~~

COVID-19 vaccine implementation: guidance removed

The following text, aligned with the National Department of Health COVID-19 Vaccine Implementation Guide and Toolkit[18] has been removed from the STG as the implementation of COVID-19 vaccination was concluded during the pandemic stage and no longer relevant to the chapter.

The STG has amended as follows:

- ~~As COVID vaccination recommendations are being updated regularly as new evidence emerges, please consult the latest National Department of Health vaccine policy recommendations.~~
- ~~**Note:** COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day. If multiple vaccines are administered at a single visit, administer each injection in a different injection site (different arm), with the COVID-19 vaccine administered on the LEFT arm.~~

Conditions that are not contraindications to any of the standard EPI vaccines: Amended

In line with the NEMLC scoping review[19] Egg allergy has been added as not being a contra-indication to any of the standard EPI vaccines. In addition, a text box to emphasise that there are a few contra-indications for standard EPI vaccines has been added.

The STG has been amended as follows:

[18] National Department of Health. COVID-19 Vaccine Implementation Guide and Toolkit, 2022. https://www.knowledgehub.org.za/elibrary/covid-19-field-guide-and-sops

[19] NDoH. Inactivated Influenza vaccines and egg allergy: A scoping review.2023.Available from: https://www.health.gov.za/wp-content/uploads/2024/03/Inactivated-influenza-vaccines-and-egg-allergy-scoping-review_Final.pdf

Conditions that are not contraindications to any of the standard EPI vaccines

There are very few contra-indications, but many missed opportunities.

Family history of any adverse reactions following vaccination.
Family history of convulsions.
Previous convulsions.
Egg allergy

13.2 CHILDHOOD IMMUNISATION SCHEDULE

Measles Rubella (MR) vaccine: Added
Tetanus, Diphtheria, Pertussis (Tdap) vaccine: Added
PCV (Pneumococcal conjugated vaccine): Retained
In line with the current implemented childhood EPI schedule, the following vaccines have been added to the STG:

- Straight switch from Measles vaccine to Measles Rubella (MR) vaccine at 6 and 12 months. Reference to measles vaccine has now been amended to measles/rubella vaccine in all sections of the STG in line with the updated EPI schedule.
- Straight switch from Tetanus, Diphtheria (Td) vaccine to TdaP as per the routine schedule at 6 and 12 years. (For pregnant women, Switch from Tetanus Toxoid (TT) to one dose of TdaP during pregnancy)
- Straight switch from PCV 13 to PCV10 at 6 weeks, 14 weeks and 9 months

The STG has been amended as follows:

Age of child	Vaccine
At birth	OPV0 BCG
6 weeks	OPV1 RV1 Hexavalent (DTaP-IPV-HB-Hib)1 PCV1
10 weeks	Hexavalent (DTaP-IPV-HB-Hib)2
14 weeks	RV2 Hexavalent (DTaP-IPV-HB-Hib)3 PCV2
6 months	Measles/Rubella1
9 months	PCV3
12 months	Measles/Rubella2
18 months	Hexavalent (DTaP-IPV-HB-Hib)4
6 years	Tdap
12 years	Tdap

13.3 VACCINES FOR ROUTINE ADMINISTRATION

Tetanus, Diphtheria, Pertussis (Tdap) vaccine: Guidance for use of Tdap vaccine amended to align with the switch from Td to Tdap vaccine.

The STG has been amended in line with the package insert to provide guidance on the use of Tdap in children and pregnant women. Pregnant women to receive one dose of Tdap during pregnancy between 26 and 34 weeks (to maximise protection of preterm infants)

The STG has been amended as follows:

Tdap (Tetanus, reduced ~~and~~ diphtheria and acellular pertussis vaccine)
Z27.8

Protects against diphtheria, ~~and~~ tetanus and pertussis.

Tdap, IM, 0.5 mL in upper arm.

Storage:

- Fridge: In a vaccine fridge at 2–8°C.
- Easily damaged by freezing.
- ~~Keep opened vials, record date of opening, for next session if kept at correct temperature and not contaminated.~~
- ~~Record date of reconstitution.~~
- ~~Discard after 30 days.~~

Adverse events:

- Mild fever.
- Pain
- Local swelling occasionally.

Contraindications:

- Previous anaphylaxis to the vaccine.
- Children <~~6~~ 4 years of age should not get Tdap.

Tdap in pregnancy

Tdap protects pregnant women and newborn infants against tetanus diphtheria and pertussis.

- Pregnant women should routinely receive a single dose of Tdap during each pregnancy between 26 weeks and 34 weeks of gestation to maximise protection of preterm infants.
- If not administered between 26 weeks to 34 weeks, a catch-up dose should be given at any time, including in the immediate post-partum period.

bOPV (Oral polio vaccine): Guidance on storage of bOPV added

The STG has been amended, adding guidance for the storage of bOPV as below:

- Keep open vials, record date of opening, for the next session; if kept at the correct temperature and not contaminated
- Record date of opening on the vial.

Measles/Rubella (MR) Vaccine: Guidance on use added

Guidance on the use of the combined Measles/Rubella vaccine has been added in line with the switch from measles to the combined Measles/Rubella (MR) Vaccine currently in use.

The STG text has been amended as follows:

Measles/Rubella

Z24.4

Measles/Rubella vaccine, SC, 0.5 mL.

- < 1 year of age: administer subcutaneously on lateral aspect of the left thigh.
- ≥ 1 year of age: administer subcutaneously on right upper arm.
- Avoid administering the measles/rubella vaccine at the same time as other vaccines at 6 months of age. However, it is considered safe to co-administer the measles/rubella vaccine with other vaccines in children 9 months and older. If a child requires measles/rubella vaccine and other vaccines at the same time at 6 months, give measles/rubella vaccine immediately and schedule visit to receive remaining vaccines 1 month later.

Storage:

- Fridge: In a vaccine fridge at 2–8°C.
- Discard opened vial after 6 hours or at end of immunisation session (whichever occurs first).

Adverse events:

- Burning or stinging at the injection site, fever.
- Transient morbilliform rash and mild pyrexia up to 30 days after vaccination.

Contra-indications:

- Previous anaphylaxis to the vaccine.
- Uncontrolled convulsions: consult a doctor.

13.4 THE COLD CHAIN

Maintaining the cold chain: Guidance amended

Guidance has been amended regarding maintaining vaccines at the right temperature throughout the value chain.

The STG has been amended as follows:

Maintaining the cold chain means keeping vaccines at the right temperature throughout distribution, storage, and use. The cold chain can be maintained by:

» Never exposing vaccines to heat or freezing conditions, especially during transportation from one point to another.
» Always using a cold box to keep the vaccines cold during transport and immunisation.
» All vaccines should be kept in a refrigerator at a temperature of 2–8°C.
» ~~Defrosted~~ Open vials of OPV should not be kept in the freezer or be allowed to freeze again. However, defrosted closed vials of OPV may be thawed and frozen, multiple times and should ideally be stored at -20°C.
» Use a ~~metal dial thermometer or a~~ continuous temperature monitoring device e.g. fridge-tag for all vaccines (Min-max thermometer/dial thermometer not recommended).
» Ensure that Hexavalent (DTaP-IPV-HB-Hib), HPV, PCV, RV, Tdap, and TT vaccines do not come into contact with the refrigerator's evaporator at the back/sides, as they are sensitive to freezing. Do not freeze these vaccines, and refrain from using any vaccines that have been frozen. If there is a suspicion of freezing, conduct the shake test to determine if the vaccines have frozen and need to be discarded. ~~Do not let Hexavalent (DTaP-IPV-HB-Hib), HPV, PCV, RV, Td and TT vaccines touch the evaporator at the back of the fridge as they may freeze. Do not freeze these vaccines. Do not use frozen vaccines. If unsure, do shake test to check whether vaccines have frozen.~~

~~»~~

Correct packing of the cold box: Guidance amended

Guidance on the correct packing of the cold box has been amended.

The STG has been amended as follows:

» ~~Fully~~ Conditioned ice packs (the ice should rattle inside the pack) are placed on the bottom, at the sides and on top.
» If there are not enough ice packs, place available ice packs at the sides and on top of the vaccines.
» Tdap, TT, HPV, PCV, RV and Hexavalent vaccines must not be allowed to freeze.
» Keep measles/rubella and polio vaccines very cold - place on bottom of the cold box, closest to the ice packs.
» BCG can be placed anywhere in the box.
» Keep the lid firmly closed and the box out of the sun.
» Keep a continuous temperature monitoring device ~~thermometer and freeze tag~~ in the cold box with the vaccines and the temperature at 2–8°C.
» Live attenuated vaccines (BCG, OPV, measles/rubella) are very sensitive to heat, sunlight, and skin antiseptics.

How to pack your fridge correctly: Guidance amended

Guidance on how to correctly pack the fridge has been amended.

The STG has been amended as follows:

» Vaccines should be stored in a ~~specific~~ purpose-built vaccine fridge. However, if unavailable store the vaccines in a domestic fridge, as follows:
» Top shelf: measles and polio vaccines in the coldest part.
  - Middle shelf: BCG, Tdap, Hexavalent (DTaP-IPV-HB-Hib), HPV, RV, PCV and TT vaccines (do not freeze) with sufficient diluent for the BCG and measles/rubella for 2 days.
  - Do not let Tdap, Hexavalent (DTaP-IPV-HB-Hib) HPV, RV, PCV and TT vaccines touch the evaporator plate at the back/side of the fridge as they are destroyed by freezing.
  - Do not keep vaccines in the fridge door.
  - Store the same kind of vaccines together in one tray.
  - Leave about 2 cm space between each tray to allow the cold air to move around.
  - Saltwater-filled bottles placed at the bottom of the fridge can prolong the holdover time, enabling the fridge to promptly return to its set temperature after being opened. ~~Bottles filled with salt water stored in the bottom of the fridge will keep the fridge contents cold when the door is opened.~~
  - **Do not keep food in the same fridge as the vaccines to avoid unnecessary opening of the door.**

CAUTION
Do not use vaccines that have expired, ~~missed~~ compromised the cold chain, or reached discard point as indicated by the VVM.
Keep the fridge temperature between 2–8°C.

Note: All vaccines with a "T" in the name are sensitive to freezing TT, Tdap, HexavalenT, RoTavirus, HepaTiTis B and even diluenTs. Diluents (for measles/rubella and BCG) should never be frozen.

13.5 OPEN MULTI-DOSE VIAL POLICY

Open multi-dose vial policy: Guidance amended

Guidance on the correct use of opened vials(multi-dose) for specific vaccines has been amended. In addition, a caution box has been added to ensure that the used needle is discarded after using a multi-dose vial.

The STG has been amended as follows:

Opened vials of TT,~~Td~~ HepB and OPV vaccines:
» May be used in subsequent immunisation sessions **for a maximum of one month**, ~~provided that~~ if each of the following conditions have been met:
  - the expiry date has not passed
  - each vial must be dated when opened
  - the vaccines are stored under appropriate cold chain conditions (2–8°C with temperature monitoring and recording)
  - the vaccine vial septum has not been submerged in water
  - aseptic technique has been used to withdraw all doses

Opened vials of measles/rubella, BCG
Check the vaccine vial monitor (VVM) and expiration date prior to reconstitution.
Reconstituted vials of measles/rubella and BCG vaccines must be discarded at the end of each immunisation session or at the end of 6 hours, whichever ~~comes~~ occurs first.
Always label the vials with the date and time when opening or reconstituting.
All opened vials must be discarded immediately if:
» sterile procedures have not been fully observed,
» there is even a suspicion that the opened vial has been contaminated,
» there is visible evidence of contamination such as a change in appearance or floating particles, etc.

Discard the needle after using a multi-dose vial to avoid compromising the sterility of the vial.

Injection safety: Editorial amendments

The STG has been editorially amended as follows

INJECTION SAFETY
» Always wash hands before and after ~~giving~~ administering the vaccine.
» Always keep a fully equipped emergency tray at the immunisation point.
» Use a sterile syringe and sterile needle for each immunisation.
» Clean the skin adequately with cotton wool and water, do not use alcohol swabs.
» Check all vaccines for safety.
» Return all unsafe vaccines back to the pharmacy.
» Use the same needle for drawing up and administering the vaccine. "One Needle, One Syringe".
» Diluents are not interchangeable. Different vaccines ~~have~~ require different diluents.
» Always use the same diluent from the same manufacturer as the vaccine.
» Used needles and syringes must be disposed of safely.
» Discard all used empty vaccines in the sharps container.

13.7 OTHER VACCINES

Tetanus Toxoid (TT) vaccine: Guidance amended

In line with the switch from TT to Tdap in pregnant women – see discussion under section 13.3 Vaccines for routine administration. Recommendation for vaccination of pregnant women with TT has been removed.

The STG has been amended as follows:

TT (Tetanus toxoid)
Z23.5

Protects against tetanus (~~neonatal and after wounds~~ post trauma)

TT, IM, 0.5 mL into arm

Storage:

- Fridge: middle shelf at 2–8°C.
- Easily damaged by freezing.
- Keep opened vials for next session if kept at correct temperature and not contaminated.
- Discard after 30 days.
- Record date of reconstitution.

Contraindications:

- Previous anaphylaxis.

~~**Pregnant women**~~
~~All pregnant women should routinely receive Tetanus toxoid.~~

	~~**TT or Td**~~	~~**TT or Td**~~	~~**TT or Td**~~	~~**TT or Td**~~	~~**TT or Td**~~
~~Pregnant women with no previous immunisation (or unreliable immunisation information)~~	~~As early as possible in 1st pregnancy~~	~~At least 4 weeks later~~	~~At least 6 months later, or in next pregnancy~~	~~At least 1 year later, or in next pregnancy~~	~~At least 1 year later, or in next pregnancy~~
~~Pregnant women with 3 childhood DTP, DTP-Hib or DTaP-IPV//Hib doses~~	~~As early as possible in 1st pregnancy~~	~~At least 4 weeks later~~	~~At least 1 year later~~		
~~Pregnant women with 4 childhood DTP, DTP-Hib or DTaP-IPV//Hib doses~~	~~As early as possible in 1st pregnancy~~	~~At least 1 year later~~			

Trauma

- Give booster dose of TT/Tdap after ~~each~~ every ~~trauma~~ traumatic injury ~~episode~~ (unless ~~given~~ administered in the previous 5 years).

Human Papilloma Virus (HPV) Vaccine: Dosing schedule amended

The STG has been amended from a two dose to a single dose (HPV) Vaccine schedule for girls ≥9 years

STG has been amended as follows:

A ~~two~~ single dose ~~schedule (6 months apart)~~ (is offered as part of the **Integrated School Health programme** to Grade 4-5 girls (≥ 9 years of age) in public schools.

Hepatitis B vaccine: Guidance amended

The STG has been amended in line with the NDoH viral Hepatitis B guidelines[20] , to include student healthcare workers as individuals recommended to receive preexposure HBV immunisation.

The STG has been amended as follows:

Hepatitis B
Z24.6
All personnel working in a health care facility (including support staff) and student health care workers.

- Hepatitis B vaccine, IM, 3 adult doses of 1 ml.
  - **first dose** administered immediately;
  - **second dose** 1 month after the first dose;
  - **third dose** 6 months after the first dose.

Influenza vaccine: Priority groups for influenza vaccination amended

In line with the updated NICD influenza guidelines for 2023[21],the table listing the indications and prioritization for influenza vaccine in different settings has been removed in favour of listing the high risk groups in a text. Healthcare workers regardless of risk factors for severe influenza now qualify for annual influenza campaign vaccination.

The STG has been amended from:

Indications, and prioritisation for influenza vaccination in various settings:

Annual influenza campaign	Influenza pandemic	COVID-19 pandemic
Healthcare workers* without risk factors are not routinely immunised	All healthcare workers including those without risk factors	All healthcare workers including those without risk factors
Age > 65 years	Age > 65 years	Age > 65 years
People (including healthcare personnel) with the following risk factors for severe influenza: – Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease), malignancy *LoE:IVb*[22] – HIV infection	People (including healthcare personnel) with the following risk factors for severe influenza: – Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease), malignancy – HIV infection	People (including healthcare personnel) with the following risk factors for severe influenza: – Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease), malignancy – HIV infection
All women who are pregnant at the time of the campaign.	All women who are pregnant at the time of the campaign.	All women who are pregnant at the time of the campaign. *LoE:IIIa*[i]

*(*Healthcare workers are not routinely offered immunisation during the annual influenza campaign. Although it is recommended that healthcare workers are vaccinated against influenza, they will not be provided with publicly funded vaccines unless they fall within any of the high risk groups).*

Amended to:

- Based on available data and resources, the following groups are prioritised for influenza vaccination in the annual influenza campaign and during influenza or COVID-19 pandemic:

[20] NdoH.National guidelines for the management of viral Hepatitis.2019

[21] NICD.Influenza: NICD recommendations for the diagnosis, management, prevention and public health response. April 2023. Available from : https://www.nicd.ac.za/

» Healthcare workers
» Age > 65 years
» Pregnant women at all stages of pregnancy, including women up to 6 weeks postpartum
» People (including healthcare personnel) with the following risk factors for severe influenza:
  - Chronic cardiac or pulmonary conditions (including chronic heart disease, hypertension, stroke, and diabetes), chronic lung disease (including asthma and chronic obstructive pulmonary disease) and malignancy
  - HIV infection

LoE:IVb[ii]

SECTION D

MEDICINE AMENDMENTS: November 2024

SECTION	MEDICINE/MANAGEMENT	ADDED/DELETED/AMENDED/ NOT ADDED/ RETAINED
13.2 Childhood Immunisation Schedule	BCG Vaccine	Birth dose retained, repeat dose and catch-up dose added

In the October 2024 chapter update, COVID-19 vaccine recommendations were removed from the STG as the implementation of COVID-19 vaccination was not considered to be relevant to the current chapter.

The preface of the chapter has been editorially amended as follows:

The contents of this chapter are based on the current National Vaccinators Manual~~, the current COVID-19 Vaccine Implementation Guide and Toolkit~~ and recommendations from the National Advisory Group on Immunisation (NAGI).

13.2 CHILDHOOD IMMUNISATION SCHEDULE

BCG Vaccine: Birth dose retained, repeat dose and catch-up dose added

The STG has been aligned with the updated National Advisory Group on Immunisation (NAGI) guidance for BCG vaccine as contained in the National Guidelines for the management of TB in children and adolescents[23]. The updates have been incorporated into the STG to optimise BCG vaccination uptake and to enhance protection of children from the development of severe forms of TB such as TB meningitis or Miliary TB. The key changes to the chapter are:

- To vaccinate all newborns with BCG vaccine regardless of HIV status or TB exposure at discharge.
- Infants who are started on TB treatment or TB therapy (TPT) within the first 6 weeks of life are to receive a second dose of BCG upon completion of anti-TB therapy.
- Any infant or child <10 years who did not receive BCG at birth is to receive a "catch-up" dose of BCG vaccine.

The STG guidance has been amended as follows:

Recommendations for providing BCG Vaccine:

» **Initial dose of BCG vaccine**

- All newborns regardless of HIV status or TB exposure status should receive BCG at discharge.
- For infants that are transferred to a neonatal unit, the timing of BCG vaccination will depend on the infant's clinical status. Neonatal units should have a policy to ensure vaccination occurs prior to hospital discharge.

» **Repeat dose of BCG vaccine**

- If the infant initiates TPT or TB treatment in the first six weeks of life, the effectiveness of the live, attenuated BCG vaccine may be negatively impacted. Therefore, the BCG vaccine should be repeated on completion of either TPT or TB treatment.
- Infants or children living with HIV should only receive a repeat dose if they are 1) on ART, 2) clinically well, and 3) have a CD4 > 25%.
- If the criteria to receive BCG are not met, i.e., the infant is 1) Not on ART, 2) or Unwell, or 3) CD4 < 25%
    - Delay repeat dose of BCG until on ART and immunologically stable (CD4 > 25%)
    - Start/continue TPT until the child is eligible to receive BCG.
- After TPT/TB treatment is completed, a CD4 count should be done to determine if the infant meets the above criteria for receiving BCG even if the annual CD4 count is not yet due. Do not wait for the routine annual CD4 count, as this delay may result in many infants not receiving BCG at all.

[23] NDoH. Management of Tuberculosis in children and adolescents. 2024. Available from: https://knowledgehub.health.gov.za/elibrary/management-tuberculosis-children-and-adolescents

- If the infant received the standard first-line TB treatment regimen BCG vaccination may be administered from 24 hours after the last anti-TB treatment dose. If the infant received rifapentine give BCG from 5 days after the last dose, and if the infant received bedaquiline or clofazamine give BCG vaccination two months after the last dose.

» **Catch-up dose of BCG vaccine**

- A 'catch-up' BCG should be administered to any child <10 years of age who did not get a BCG at birth.
- Infants or children living with HIV should only receive "catch up" BCG vaccination if they are 1) on ART, 2) clinically well, and 3) have a CD4 > 25% (if ≤5 years of age) or >200 cells (if >5 years of age).
- Children older than > 10 years of age should not get BCG vaccination.

CAUTION

Children with suspected or confirmed inborn errors of immunity or other acquired immunodeficiencies should be evaluated by an expert before BCG vaccination.