

**SOUTH AFRICAN PRIMARY HEALTHCARE LEVEL ESSENTIAL MEDICINES LIST
CHAPTER 13: IMMUNISATION
NEMLC RECOMMENDATIONS FOR MEDICINE AMENDMENTS (2016 – 2018)**

Medicine amendment recommendations, with supporting evidence and rationale are listed below. Kindly review the medicine amendments in the context of the immunisation chapter

SECTION	MEDICINE	ADDED/DELETED/AMENDED
13.2 Childhood immunisation schedule	Measles vaccine, IM	Deleted
	Measles vaccine, SC	Added
	BCG vaccine, intradermal	Recommendations for HIV-infected babies amended
13.3 Vaccines for routine administration	Hexavalent vaccine, IM	Directions for use not amended
13.7 Other vaccines	Influenza vaccine, IM	Amended

13.2 CHILDHOOD IMMUNISATION SCHEDULE

Measles vaccine, intramuscular: *deleted*

Measles vaccine, subcutaneous: *added*

The EPI schedule was updated in 2015 to provide amended recommendations for the administration of the measles vaccine. The supplier of the previous MCC registered measles vaccine (administered intramuscularly) has discontinued the product. This vaccine was administered at 9 months concurrently with pneumococcal vaccine (PCV) and at 18 months concurrently with the 6-in-1 hexavalent vaccine. The discontinued vaccine is being replaced with a recently MCC registered product, that is administered subcutaneously, not in combination with other childhood vaccines and at the age of 6 months and 12 months, requiring two additional visits in the EPI schedule.

Previously, South Africa used an additional 6-month dose of vaccine during outbreak situations or for those living with HIV. From a pragmatic perspective, it was recommended that vaccinating against measles occur at 6 months of age to prevent high morbidity and mortality associated with the disease. A second dose is then administered at 12 months to ensure adequate population immunity rates.

BCG vaccine, intradermal: *recommendations for HIV-infected babies amended*

Following comments received from NAGI and the EPI Directorate, the text of the STG was updated as follows:

» Exception: patients with primary immune deficiency or known HIV-infection e.g.: Symptomatic HIV infected children (WHO Stage 3 or Stage 4) should not be administered BCG vaccine.

Contra-indications:

- Children with known HIV infection should not get BCG vaccination. Do not delay BCG vaccination if HIV status is unknown. signs of symptomatic HIV infection (AIDS) should not get BCG vaccination.

Rationale: Asymptomatic HIV-exposed newborns may be discharged from the healthcare facility, prior to HIV DNA PCR tests becoming available and may be lost to follow up for BCG vaccination.

Level of Evidence: III Expert opinion

13.3 VACCINES FOR ROUTINE ADMINISTRATION

Hexavalent vaccine, IM: *directions for use not amended*

Hexavalent use in children > 2 years of age

The Paediatric Hospital Level Committee had reported that there is no published literature supporting the safe use of hexavalent vaccine in children older than 2 years of age, and that the currently revised Paediatric Hospital Level STG and EML recommends single dose *H.influenza b* vaccine rather than hexavalent vaccine post-splenectomy in the older child. However, NAGI recommended hexavalent vaccine in the EPI schedule for the older child as they believe that the benefits outweigh the risks.

Recommendation: Dosage recommendations be aligned with guidance provided by NAGI (as per the National Vaccinators Manual).

Rationale: Aligned with the National Vaccinators Manual.

Level of Evidence: III Guidelines

13.7 OTHER VACCINES

Influenza vaccine, intramuscular: amended

- *Influenza vaccination - priority groups:*

The following was updated, aligned with NAGI recommendations¹ and the NDoH/NICD Healthcare workers handbook on influenza, May 2016².

- » All women who are pregnant at the time of the annual immunisation campaign should be immunized.
- » Persons with the following risk factors may be offered immunisation during the annual campaign
 - HIV infection
 - Chronic cardiac or pulmonary conditions
 - Age > 65 years

Health care 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.,

Recommendations have taken into account the scarcity of resources.

- *Influenza vaccine dosing in children:*

Children aged 6 months through 8 years require 2 doses of influenza vaccine (administered ≥ 4 weeks apart) during their first season of vaccination to optimize response^{3 4 5}. A single dose may be insufficient for an adequate immune response in young children who have not been exposed to natural influenza, and 2 doses may be required.

The STG was updated as follows:

Influenza vaccine

- Influenza vaccine, IM, 0.5 mL

~~Should be given annually to:~~

- ~~» Elderly patients > 65 years of age.~~
- ~~» Medical and nursing personnel.~~
- ~~» HIV infected people.~~
- ~~» All patients with chronic cardiac or pulmonary conditions.~~

- » All women who are pregnant at the time of the annual immunisation campaign should be immunised.
- » Persons with the following risk factors may be offered immunisation during the annual campaign
 - HIV infection

¹ NAGI Minutes, 9 April 2015

² NDoH/NICD/NHLS: Healthcare workers handbook on influenza, May 2016

³ Neuzil KM, Jackson LA, Nelson J, et al. 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;194:1032–9.

⁴ Allison MA, Daley MF, Crane LA, et al. Influenza vaccine effectiveness in healthy 6- to 21-month-old children during the 2003-2004 season. *J Pediatr* 2006;149:755–62.

⁵ Ritzwoller DP, Bridges CB, Shetterly S, Yamasaki K, Kolczak M, France EK. Effectiveness of the 2003–2004 influenza vaccine among children 6 months to 8 years of age, with 1 vs 2 doses. *Pediatrics* 2005;116:153–9.

- Chronic cardiac or pulmonary conditions
 - Age > 65 years
- » Health care 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.

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

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

The PHC Committee recommends that NEMLC accepts the updated STG for influenza vaccination, aligned with NAGI recommendations and the NDoH/NICD/NHLS: Healthcare worker’s handbook on influenza, May 2016.

13.6 ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

The current AEFI form is under review by the EPI Directorate. However, a hyperlink was added to the chapter to access the current AEFI form that is available on the NDoH website.