

NEW EPI VACCINES GUIDELINES

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Table of contents

Page No.

A.	INTRODUCTION TO EPI-SA	3
B.	REVISED SCHEDULE WITHOUT PENTAVALENT VACCINES	4
C.	REVISED SCHEDULE WITH PENTAVALENT VACCINES.....	5
D.	ROUTINE SCHEDULE FOR PREGNANT WOMEN.....	6
E.	IMMUNISATION OF HIV-INFECTED CHILDREN	7
F.	IMMUNISATION SCHEDULE FOR OTHER CASES	7
G.	STRATEGIES FOR IMMUNISATION PRACTICES	8
H.	CATCH UP: PCV AND OTHER VACCINES	8
I.	CONTRA-INDICATIONS TO IMMUNISATION	10
J.	COLD CHAIN	12
K.	INJECTION SAFETY	13
L.	ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)	14
M.	ROUTINE IMMUNISATION DATA.....	14

A. INTRODUCTION TO EPI-SA

Immunisation is the most precious gift that a Health Care Worker can give a child.

The aim of the Expanded Programme on Immunisation in South Africa (EPI-SA) is to prevent death and reduce suffering from infections that can be prevented by immunisation of children and women. Immunisation against infections like; measles, polio, diphtheria, whooping cough (pertussis), tetanus, hepatitis B, haemophilus influenza type b, rotavirus diarrhoea, pneumococcal diseases and tuberculosis, remains the most cost effective health intervention currently available.

The main target audiences are Health Professional in:

- Public health facilities (provincial, district and municipalities)
- Private health facilities
- South African National Defence Force
- Correctional Services
- Academics

The purpose of this document:

- To provide an updated EPI schedule that includes three new vaccines; Pneumococcal Conjugate (Prevenar®), Rotavirus (Rotarix®) and the Pentavalent (Pentaxim®) Vaccines
- To standardise immunisation practices throughout the country
- Address common challenges that vaccinators may face
- To address the issue of catch up with Pneumococcal Conjugate Vaccine
- To address the issue of catch up with Rotavirus Vaccine

What is New?

- The introduction of new vaccines: Pneumococcal Conjugate Vaccine, Rotavirus Vaccine and Pentavalent Vaccine.
- The revised EPI schedule with and without the Pentavalent vaccine.

- The introduction of injectable polio vaccine (IPV) and the reduction in the number of oral polio vaccine (OPV) doses to only two: at birth and 6 weeks.
- Concurrent administration of live attenuated vaccines: Measles and BCG.

This document should be used in conjunction with the Vaccinators' Manual, which is currently being revised.

B. REVISED SCHEDULE WITHOUT PENTAVALENT VACCINES

<u>Age of child</u>	<u>Vaccine needed</u>	<u>How and Where is it given?</u>
At birth	OPV(0) Oral Polio Vaccine	Drops by mouth
	BCG Bacillus Calmette Guerin	Intradermally / Right arm
6 weeks	OPV(1) Oral Polio Vaccine	Drops by mouth
	RV (1) Rotavirus Vaccine	Liquid by mouth
	DTP/HIB(1) Diphtheria, Tetanus, Pertussis, & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(1) Hepatitis B Vaccine	Intramuscularly / Right thigh
	PCV(1) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
10 weeks	OPV(2) Oral Polio Vaccine	Drops by mouth
	Hep B(2) Hepatitis B Vaccine	Intramuscularly / Right thigh
	DTP/HIB(2) Diphtheria, Tetanus, Pertussis, & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
14 weeks	OPV(3) Oral Polio Vaccine	Drops by mouth
	RV (2) Rotavirus Vaccine	Liquid by mouth
	DTP/HIB(3) Diphtheria, Tetanus, Pertussis, & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(3) Hepatitis B Vaccine	Intramuscularly / Right thigh
	PCV(2) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
9 months	Measles Vaccine(1)	Intramuscularly / Left thigh
	PCV(3) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
18 months	OPV(4) Oral Polio Vaccine	Drops by mouth
	DTP (4) Diphtheria, Tetanus, Pertussis	Intramuscularly / Left arm
	Measles Vaccine (2)	Intramuscularly / Right arm
6 years	OPV(5) Oral Polio Vaccine	Drops by mouth
	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm
12 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm

C. REVISED SCHEDULE WITH PENTAVALENT VACCINES

This schedule will be effective from April 2009.

<u>Age of child</u>	<u>Vaccine needed</u>	<u>How and Where is it given?</u>
At birth	OPV(0) Oral Polio Vaccine	Drops by mouth
	BCG Bacillus Calmette Guerin	Intradermally / Right arm
6 weeks	OPV(1) Oral Polio Vaccine	Drops by mouth
	RV (1) Rotavirus Vaccine	Liquid by mouth
	DTaP-IPV//HIB(1) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(1) Hepatitis B Vaccine	Intramuscularly / Right thigh
	PCV(1) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
10 weeks	DTaP-IPV//HIB(2) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(2) Hepatitis B Vaccine	Intramuscularly / Right thigh
14 weeks	RV (2) Rotavirus Vaccine	Liquid by mouth
	DTaP-IPV//HIB(3) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(3) Hepatitis B Vaccine	Intramuscularly / Right thigh
	PCV(2) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
9 months	Measles Vaccine(1)	Intramuscularly / Left thigh
	PCV(3) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
18 months	DTaP-IPV//HIB(4) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left arm
	Measles Vaccine (2)	Intramuscularly / Right arm
6 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm
12 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm

- Do not administer any dose of Rotavirus to a child that is **more than 24 weeks**.
- Rotavirus Vaccine first dose can now be given to children older than 12 weeks but younger than 20 weeks.

KEY POINTS TO REMEMBER

- We will give DTaP-IPV//HIB (Pentaxim) at 18 months when we have used up all the DTP.
- Children who received Measles, DTP and OPV at 18 months (those children in the old schedule) will continue to receive Td and OPV at 6 years, for some years.
- When the children who received DTaP-IPV//HIB (Pentaxim) at 18 months are 6 years old, OPV will not be given only Td will be given.
- Always give OPV when giving DPT/Hib and DPT.
- Do not administer OPV from **10 weeks** of age if the child is receiving **DTaP-IPV//Hib** (OPV should be given at birth & six weeks only).

D. ROUTINE SCHEDULE FOR PREGNANT WOMEN

First pregnancy	3 doses of Tetanus Toxoid (TT) correctly spaced even if the last dose is given in the postnatal period TT1 at the first antenatal visit TT2 four weeks after TT1 TT3 6 months after TT2
Later pregnancies	2 TT booster doses: One dose given for each pregnancy on the first antenatal care visit and or given during other health facility visits. The 2 booster doses must be at least 1 year apart (i.e. minimum 1 year interval). This gives a total of 5 adequately spaced doses. If there is no record of immunisation for the previous antenatal care doses, vaccinate as for first pregnancy and give three doses.

E. IMMUNISATION OF HIV-INFECTED CHILDREN

Vaccine	Asymptomatic HIV infection	Symptomatic HIV infection
BCG	Vaccinate	Do not vaccinate
DTP/Hib or DTaP-IPV//Hib	Vaccinate	Vaccinate
OPV	Vaccinate	Vaccinate
PCV	Vaccinate	Vaccinate
Rotarix (RV)	Vaccinate	Do not vaccinate
Hepatitis B	Vaccinate	Vaccinate
Measles	Vaccinate	Do not vaccinate
DTP	Vaccinate	Vaccinate
Td	Vaccinate	Vaccinate
Tetanus toxoid	Vaccinate	Vaccinate

F. IMMUNISATION SCHEDULE FOR OTHER CASES

Trauma

- Give booster dose of Tetanus Toxoid (TT) after each trauma episode (unless there is proof that it was given in the preceding 5 years).

Hepatitis B Vaccine

- For all personnel working in health care facilities (including cleaning staff and porters) 3 doses of 1 ml should be administered: 1st dose immediately (or when they start employment), 2nd dose 1 month later and a 3rd dose 6 months after the first dose.

Concurrent administration of all vaccines with Anti-Retroviral drugs

- There are no drug interactions between anti-retroviral drugs and EPI vaccines.

Concurrent administration of BCG and Measles vaccines in missed opportunities

- In missed opportunities, BCG and Measles can be given on the same day BUT use separate sites.

G. STRATEGIES FOR IMMUNISATION PRACTICES

- Every Clinic Day is an Immunisation Day.
- Never miss a chance to immunise; never turn a child away if immunisation is due (even if it means opening a multi-dose vial for just one child).
- The Road to Health Chart should be checked for missed immunisation (doses) each time a child visits a health facility, including visits for minor ailments.
- Vitamin A and deworming should be given at the appropriate ages.
- Do not immunise a sick child if the mother seriously objects, but encourage her to bring the child for immunisation as soon as the child has recovered.
- If in doubt whether a child has had a certain dose or not, give that dose. Extra doses are not harmful.
- All premature or underweight babies should be immunised at the same age as other babies; immunisation of these children should not be postponed.
- If an infant is eligible for more than one type of vaccine, the vaccines may all be safely given during the same session, but at different injection sites.
- All vaccines can be administered concurrently with all antibiotics and anti-retroviral drugs.

H. CATCH UP: PCV AND OTHER VACCINES

Pneumococcal Conjugate Vaccine (PCV)(Prevenar®)

- All children who would have been 6 weeks old or younger on the 1st of April 2009 should receive Pneumococcal Conjugate Vaccine (PCV), Prevenar. That is to say, they were born into the new vaccine schedule.
- If a child presents to a health facility before he/she turns 6 months and has not been vaccinated with PCV, give 2 doses of PCV, 4 weeks apart and a third dose at 9 months.

- If a child presents between 6 months and 9 months of age and has not been vaccinated with PCV when he/she presents to a health facility, give the first (1st) dose of PCV, give the 2nd of PCV dose 4 weeks later. After the 2nd dose of PCV he/she should be asked to come back 8 weeks later for the third dose of PCV. The 9 months measles vaccine can be given with any of the 2 PCV doses (PCV 2 & 3). Ensure a minimum interval of 4 weeks between the first and second doses and 8 weeks minimum interval between the second and third doses.
- If a child presents for measles vaccine at 9 months and has not been vaccinated with PCV, give the first (1st) dose of PCV with measles vaccine, asked to come back 4 weeks later for the second (2nd) dose. The 3rd dose should be given after they have turned 1 year, it can be given together with Vitamin A. Ensure a minimum interval of 8 weeks between the 2nd and 3rd dose.
- Children who are older than 1 year but below 2 years, who have not been vaccinated with PCV when they present to a health facility (like children who present at 18 months who have never had a PCV dose) should be given 1 dose of PCV.
- ***Remember to keep a minimum interval of 4 weeks between the 1st and 2nd dose of PCV.***
- ***Remember to keep a minimum interval of 8 weeks between the 2nd and 3rd dose of PCV.***

Rotavirus Vaccine (RV) (ROTARIX ®) Catch Up

- If a child missed the 1st dose of RV (Rotarix®) at 6 weeks of age and is younger than 20 weeks, give the 1st dose of Rotavirus and the 2nd dose 4 weeks later.
- If a child missed the 1st dose at 6 weeks and is older than 20 weeks and younger than 24 weeks of age, give one dose of Rotavirus vaccine.
- NO Rotavirus vaccine can be given to any child older than 24 weeks of age.
- Keep a minimum interval of 4 weeks between the 2 doses of RV.

DTaP-IPV//Hib (Pentaxim®)

- Give all missed doses with the minimum interval of four **weeks**.
- Children who missed DPT/Hib doses at 6, 10 or 14 weeks should receive DTaP-IPV//Hib.

- Children who missed DPT doses at eighteen months will receive DTaP-IPV//Hib if they are still below 24 months.
- Do not administer DTaP-IPV//Hib when the child is **above 24 months**.
- Children above 24 months who did not receive DTaP-IPV//Hib and other vaccines should receive: TOPV, Measles, HepB, and TT; all at the same time.
- **Once a suitable DTP-Hib combination is available for children older than 24 months you will be informed.**

Hepatitis B Vaccine (HBV)

- Give all missed doses in children below five years with the minimum interval of four weeks (Vaccinators' Manual says up to 10 years).

Measles Vaccine

- All children **below seventeen months**, who have missed the nine months measles dose, should receive their first measles vaccine dose and receive the second dose at eighteen months.
- All children **from seventeen months** and above who have missed first dose measles vaccine, should receive the first measles vaccine dose and receive the second dose after **four weeks**.

Tetanus reduced amount of diphtheria Vaccine/ Td (Diftavax®)

- Give Td from six years of age.

I. CONTRA-INDICATIONS TO IMMUNISATION

General Contra-indication

- Children who have a known severe hypersensitivity to any component of the vaccine, or who have had a serious allergic reaction to a previous dose of a specific vaccine, should not receive such a vaccine.
- Postpone vaccination if the temperature is **38,5°C** or above.

Specific Contra-indication

Oral Polio Vaccine (OPV)

- Do not give Oral Polio vaccine to children who are sick with AIDS. Refer for medical opinion.

Bacille Calmette Guerin (BCG)

- Do not give BCG to a child that is **more than 12 months old**.
- Do not give BCG vaccine to children who are sick with AIDS.
- If a child is HIV exposed and you seriously fear that the child may be infected with HIV and or the child is sick, do not give BCG at birth. Do PCR at six weeks and give BCG if results are negative.
- Do not give BCG to a newborn if the mother is on anti -TB drugs, this child should be on TB prophylaxis and be followed up for BCG later.

BCG should still be given to HIV exposed children

DTP/Hib, DTaP-IPV//Hib and DTP

- Do not give DTP/Hib, DTaP-IPV//Hib and DTP to a child with epilepsy that is not controlled or when the child is 24 months and above.
- Do not administer DTaP-IPV//Hib when the child is above 24 months.

Pneumococcal Conjugate Vaccine (PCV) (Prevenar®)

- Do not give PCV on the same site with DTaP-IPV//Hib, DPT/Hib and DPT but PCV can be given concurrently with any of these vaccines at different sites.

Measles Vaccine

- Do not give Measles vaccine to children who are sick with AIDS. Refer for medical opinion.

Rotavirus Vaccine (RV) (Rotarix®)g

- Do not give Rotavirus vaccine if a child has history of chronic gastro-intestinal disease or severe diarrhoea. Refer the child for medical opinion.
- Do NOT give the first dose of Rotavirus vaccine if the child is ≥ 24 weeks.
- Do not give the second dose of Rotavirus vaccine if the child is above 24 weeks.

Tetanus and reduced amount of diphtheria Vaccine (Td) (Diftavax®)

- Do not administer Td for children who are below **6 years** of age.

Note!

Any child who is well enough to be sent home, is well enough to be immunised

J. COLD CHAIN

- All vaccines should be kept in the refrigerator between **2 and 8°C**.
- Defrosted OPV should not be kept in the freezer or be allowed to freeze again.
- Use a Dial thermometer for all vaccines (Min-Max thermometer not recommended).
- Do not let DTP/Hib, DTaP-IPV//Hib, PCV, RV, DTP, Td, HBV, Hib and TT vaccines touch the evaporator plate at the back of the fridge as they may freeze. **DO NOT FREEZE THESE VACCINES! DO NOT USE IF FROZEN! DO shake test to check whether vaccines have frozen, if unsure.**
- Monitor and record temperature twice daily.
- Leave space between each tray to allow the cold air to circulate.
- Do not keep food in the same fridge as the vaccines.

The Revised Open-Multi-dose Vial Policy

- Previously opened DTP, TT, Td, HBV may be used for a maximum of one month (30 days), provided the vial is clearly dated when first opened. Opened vials of OPV may be used as long as Vaccine Vial Monitor (VVM) has not reached the discard point. The above mentioned vaccines may be used in subsequent immunisation sessions, provided that each of the following conditions has been met:
 - The vial is clearly dated when first opened.
 - The expiry date has not passed.
 - The vaccines are stored under appropriate cold chain conditions.
 - The vaccine vial septum has not been submerged in water.
 - Aseptic technique has been used to withdraw all doses.
 - The inner square of the Vaccine VVM is lighter than the outer ring.
- Reconstituted Measles and BCG vaccines (check VVM prior to reconstituting) **must** be discarded at the end of each immunisation session or at the end of **six hours**, whichever comes first.
- Reconstituted DTP/Hib must be discarded after seven days.
- Always label vaccine vials with the date and time when opening or reconstituting.

Note: All vaccines with a “T” in the name are sensitive to freezing – DTP/Hib, DTaP-IPV//Hib, DTP, TT, Td, HepaTiTis B, liquid Hib-Type B and even diluent. PCV and Rotavirus vaccine are also sensitive to freezing.

K. INJECTION SAFETY

- Always wash hands before and after giving the vaccine.
- Always keep a fully equipped emergency tray at the immunisation point.
- Use a sterile syringe and a sterile needle for each immunisation or do NOT immunise and only touch the safe parts of both syringe and needle.
- The skin should be adequately cleaned with cotton wool and water – no alcohol swabs must be used.
- Check all vaccines for safety.
- Return all unsafe vaccines back to the pharmacist.

- Use the same needle for drawing up and administering vaccines, “One Needle, One Syringe”.
- Diluents are not interchangeable. Different vaccines have different diluents.
- Always use the diluent from the same manufacturer as the vaccine.
- Used needles and syringes must be disposed of safely.
- Discard all used/empty vaccine vials in the sharps container/box.

L. ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

- All AEFIs should be reported and have the case investigation form completely filled in.
- All deaths should be reported within 24 hours to the National department.
- All deaths, hospitalisations and other severe unusual medical incidents which occur within a month of immunisation and are thought by health workers and/or the public to be related to immunisation should be reported.
- Other similar incidents with delayed onset thought by health workers or the public to be related to immunisation should also be reported.

M. ROUTINE IMMUNISATION DATA

- Every health facility needs a system of recording immunisation data.
- New vaccine doses must be entered into the standardised data collection tools in use.
- Where clinic data collection tools have not been updated, simply add columns for the three PCV and two RV doses.
- Record the new vaccine doses on the RTHC. If unsure, ask your supervisor.
- Each child or pregnant woman should have a card with immunisation doses recorded correctly. Issue an immunisation card if the client does not have one.
- Remember to record the next appointment date on the immunisation card.
- At the end of each immunisation session, total the number of doses administered during that session.
- Always **double check your data for discrepancies and errors** weekly and monthly before submitting to the next level.

The total doses of PCV 2 & Rotavirus 2 given monthly should be the same as Hep.B3, or DTaP-IPV//Hib3 since they are given at the same time with these other vaccines, provided there has been No stock out & No catch up.

Similarly, the total doses of PCV 1 and Rotavirus 1 given each month should be the same as Hep.B1, or DTaP-IPV//Hib1.

If you are unsure of where to enter new vaccine doses, ask your supervisor.

The main recording tools that each health facility must use are:

1. Immunisation Register / Tick Register/ Reminder files or another system for tracking defaulters.
2. Vaccination card /RTHC.
3. Tally sheets.
4. Routine Monthly Input Form.
5. District Health Information System (DHIS) where applicable.

Keeping records systematically and regularly after each session will help you to follow up on defaulters and solve other problems.

If you are unsure or uncertain, ASK!