Ministry of Health

NATIONAL VACCINES AND IMMUNIZATION PROGRAM
ROTAVIRUS VACCINE SWITCH TRAINING 2022

Vaccinate to Protect.
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MODULE: 1
Introduction to Rotavirus Diseasease and Vaccine

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Learning objectives

- At the end of the module, the participant will be able to:
  - Describe the main characteristics of rotavirus disease
  - Present prevention methods against rotavirus disease

- Duration

Key issues

1. What is rotavirus disease?
2. What are the signs and symptoms of rotavirus?
3. How is rotavirus spread?
4. Who is most at risk?
5. What are rotavirus prevention strategies?

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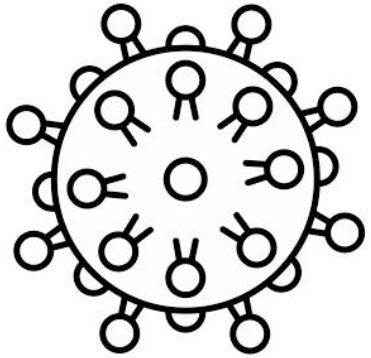
What is rotavirus disease?

- Rotavirus disease is a diarrhoeal disease caused by a virus called rotavirus
- The name rotavirus comes from the wheel-like appearance of the virus under the microscope
- It is a virus that affects the intestines
- Rotavirus is the most common cause of severe diarrhoeal disease in infants and young children worldwide
- Rotavirus is not the only cause of diarrhoea, several other agents may also cause diarrhoea



What are the signs and symptoms of rotavirus infection?

- Three main symptoms of rotavirus infection are;
  - Fever
  - Vomiting
  - Watery diarrhoea
- Abdominal pain may also occur
- Diarrhoea usually stops after 3 to 7 days
- Infants and young children can become dehydrated, requiring urgent treatment

How is rotavirus disease diagnosed?

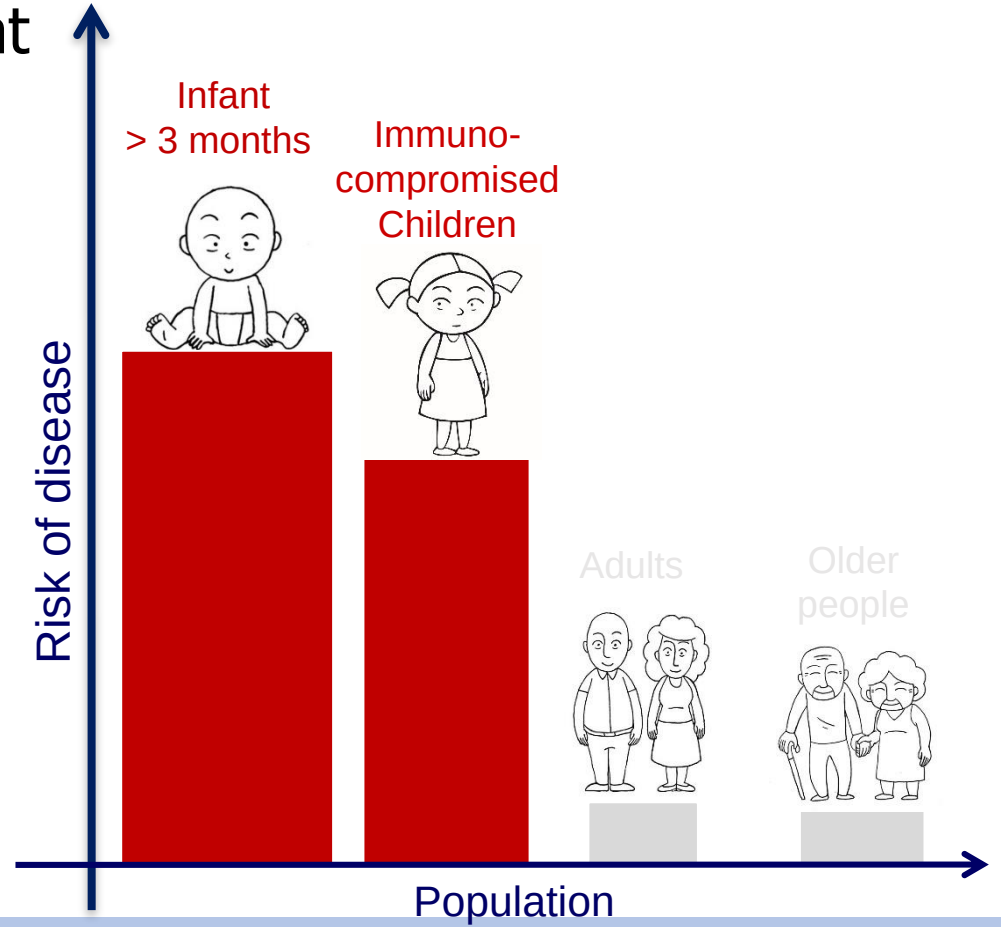
- Confirmation of a diarrhoeal illness such as rotavirus requires laboratory testing
- Strains of rotavirus may be further characterized by special testing with enzyme immunoassay or polymerase chain reaction
  - Such testing is not commonly available or necessary

How does rotavirus spread?

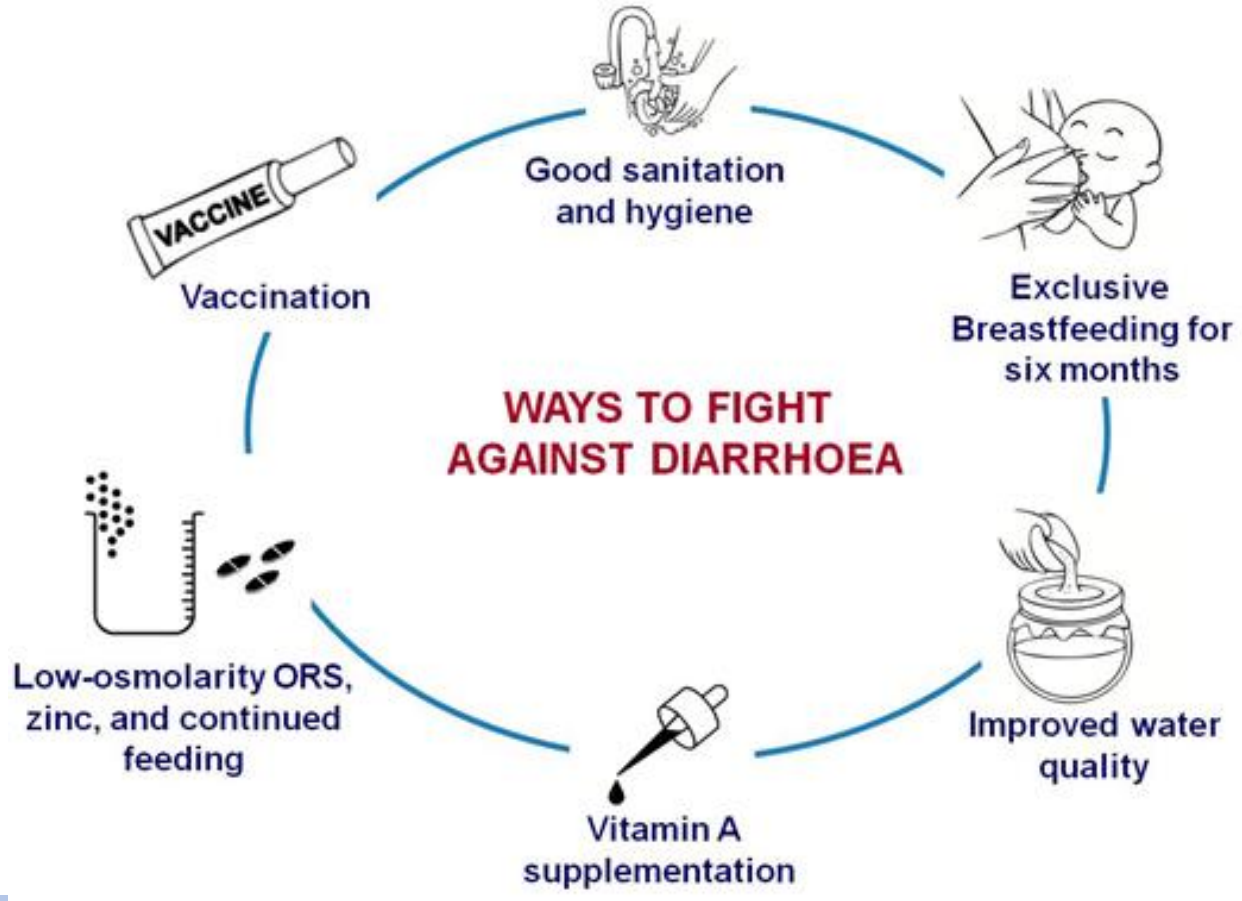
- Rotavirus infection is highly contagious
- Rotavirus spreads by fecal-oral route
  - The primary mode of transmission of rotavirus is the passage of the virus in stool to the mouth of a child

Who is most at risk in the population?

- Two populations are most at risk
  - Infants after the age of 3 months
    - Low to no immunity
    - Vulnerable to dehydration
  - Older children if they are immunocompromised



What can be done to prevent rotavirus and diarrhoeal disease?



Is there a vaccine against rotavirus?

- Currently there are 5 prequalified rotavirus vaccines:
  - Rotateq®
  - Rotarix®
  - Rotavac®
  - Rotavac 5D®
  - RotaSiil®
- Main characteristics
  - Highly effective and safe
  - Protect against severe forms of rotavirus disease
  - Do not protect against diarrhea caused by other agents than rotavirus.

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MODULE: 2
Background and Rationale for Rota vaccine switch

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Background on Rota vaccine

- Kenya introduced Rotavirus vaccine in 2014
- Introduction was supported by Gavi, GoK and Partners
- The vaccine manufactured by GSK has been in use since then (Rotarix®)
- The vaccine is a single dose and is given as a two dose schedule at 6 weeks and 10 weeks
- The Rotarix® tube that occupies 18cm3 per dose

Rationale for Rota switch

- Kenya was informed by GAVI that Rotarix will no longer be available from 2022 hence the need to choose from two different vaccine formulations options.
- MOH-NVIP sought an advisory from KENITAG
- KENITAG recommended switching to a new formulation Rotavac® 5D
- The new vaccine is manufactured by Bharat Biotech (A multi dose vial that occupies less cold chain space (reduction by 61%)
  - Costs less – cost effective (reduction of costs by 25%)
- 3 dose schedule at 6, 10 and 14 weeks

The Rota switch cont;

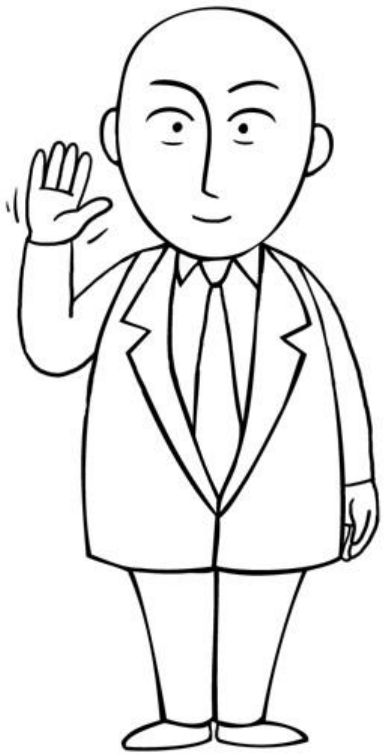
- UNICEF Supply Division (SD) identified further temporary supply delays affecting the supplier of the Rotavirus vaccine Rotavac 5D.
- Due to the supply constraints with Rotavac 5D liquid vaccine, countries were guided on 2 options
  - Accept stockout risk and switch to Rotavac 5D in 2023 (without Rotavac frozen in the interim)
  - Accept Rotavac frozen in the interim and switch twice
- Supply of the liquid Rotavac 5D formulation is expected in the month of **April-May 2023**
- Kenya will now switch to the Rotavac frozen formulation as a stopgap measure

Rotavac

- Our country is about to introduce Rotavac
- Next modules of this training will explain how to:

- ✓ Store the vaccine
- ✓ Determine vaccine eligibility
- ✓ Administer the vaccine
- ✓ Record the vaccine
- ✓ Monitor adverse events following immunization (AEFIs)
- ✓ Communicate with caretakers about the vaccine

End of module



Thank you for your attention!

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MODULE: 3

Rotavirus Vaccine Eligibility

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Learning objectives

- At the end of the module, the participant will be able to:
  - Describe the recommended immunization schedule for rotavirus vaccine
  - Describe when an infant is eligible for rotavirus vaccine and when he/she is not eligible
  - Describe the precautions and absolute contraindications for vaccination

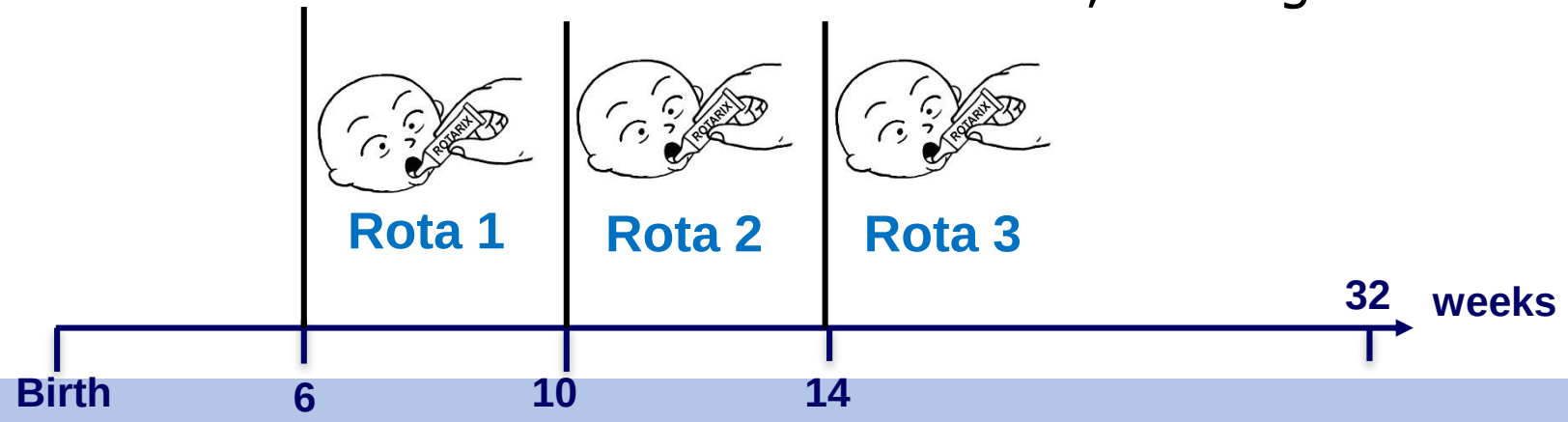
- Duration
  - 60’

Key issues

1. What is the schedule for rotavirus vaccine?
2. What to do for late vaccinations
3. What are the contraindications for vaccination?

What is the rotavirus vaccine schedule?

- Rotavac vaccine is given in a 3-dose schedule at 6, 10 and 14 weeks of age
- Rotavac vaccine can be given at same time as other vaccines in the schedule, such as DTP-HepB-Hib (i.e. Penta1, Penta2 and Penta3)
- Maintain an interval of **4 weeks** between doses, starting 6 weeks



Late vaccination

- If a child misses a rotavirus dose or series for any reason, late vaccination for that child can take place **at any time before** 12 **months of age**
- The interrupted vaccine schedule should be resumed **without repeating the previous dose**
- If the child is older than 12 months of age, the rotavirus vaccine **should not** be given

Product interchangeability

- Studies have found interchangeability of rotavirus vaccine products is **safe and effective**
- WHO recommends that the rotavirus vaccination series for each child be completed with the same product whenever feasible
- However, if the product for the prior dose is unavailable or unknown, complete the series with any available licensed product. **Restarting the series is not recommended**.
- As Rotavac have a 3-dose schedule, continuing with these products following a first dose of Rotarix® means the child will now need **a total of 3 doses for a complete vaccination series**

What should you do in this scenario?

An infant's immunization card shows that he/she is now 17 weeks old and has only received BCG and OPV 1 vaccines.

What should you do?

What to do?

Administer first dose rotavac and advice on second and third dose
Administer the other due vaccines

What should you do in this scenario?

An infant comes for second dose of Rota at 20 weeks, the card indicates he received first dose Rotarix at six weeks .
What will you do?

What to do

Administer rotavac second dose and give return date for third dose in four weeks time

Absolute contraindications

- Hypersensitivity after previous administration of rotavirus vaccines or to any of the components of the vaccine
- Previous history of intussusception

Precautions

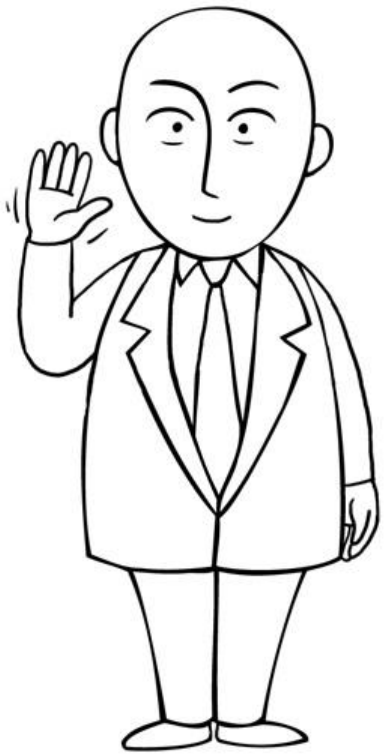
- Acute infection or febrile illness may be a reason to postpone administration of Rotavac
- Rule of thumb: if a person is hospitalized, they should receive vaccination on discharge

Mild illness such as an upper respiratory tract infection or mild diarrhoea is **not** a contraindication

Key messages

- On-time vaccination is very important for rotavirus vaccine
- First dose of Rotavac should be given at 6 weeks of age
- Second and third dose should be given at 10 and 14 weeks of age, respectively – minimum interval of 4 weeks should be maintained between doses
- If infants have missed their rotavirus vaccines, they can receive the vaccine up to 12 months of age
- Rotavirus vaccine can be given simultaneously with other vaccines like pentavalent vaccine, PCV or OPV
- Mild illness such as an upper respiratory tract infection or mild diarrhoea is **not** a contraindication

End of module



Thank you
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MODULE: 4

ROTAVAC® Vaccine Attributes, Storage conditions

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Learning objectives

- At the end of the module, the participants will have learned to:
  - Describe ROTAVAC® vaccine characteristics
  - Vaccine Storage requirements
  - Stock management for Rotavac vaccines

Key issues

1. What is the ROTAVAC® vaccine presentation?
2. At which Temperature should the vaccine be stored?
3. Where in the refrigerator should ROTAVAC® vaccines be stored
4. How do you calculate vaccine requirements and manage your stock?

OLD

ROTARIX

- 1 dose tube
- Liquid: ready to use

NEW

ROTAVAC®

- 5 Dose vial
- Liquid: ready to use
- Dropper with cap

What is rotavirus vaccine (ROTAVAC®) presentation?

- **Rotavac®** is live, attenuated Vaccine
- It is a ready-to-use, oral vaccine in liquid formulation
- **Has a Vaccine Vial Monitor**
- **Comes with a dropper**

DOSAGE

- **Rotavac ®** has 5 doses of vaccine per 2.5 ml vial
- One dose is equivalent to 5 drops orally (**1 dose = 0.5ml = 5 drops)**

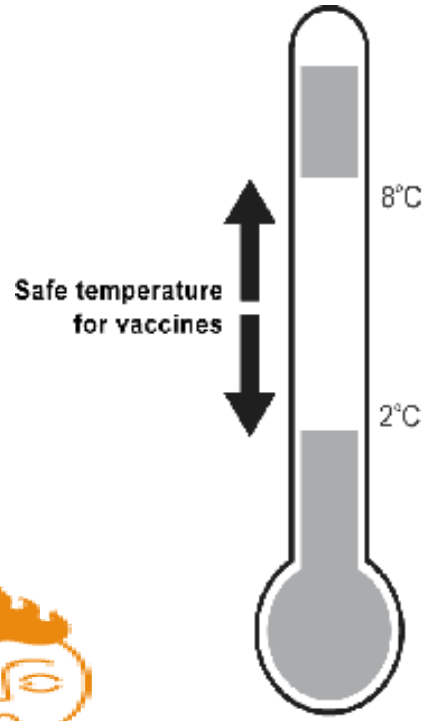
Rotavac® SHOULD NOT BE INJECTED AT ANY CIRCUMSTANCES

STORAGE CONDITIONS FOR ROTAVAC®

- At Central & Regional Vaccine Stores Where walk-in freezers or deep freezers are available, Rotavac® should be stored at **-20°C At Central Vaccine Store.**
  - At -20°C, the shelf life of Rotavac® is **60 months (5 Years)**
  - **Once Thawing has been done** the shelf life of Rotavac® is **180 Days**
- At the **Regional, Sub County Vaccine Stores and Health Facilities**, Rotavac® will be be stored in refrigerators between **+2°C to +8°C** at same level where Rotarix was stored

How should the Rotavac ® vaccine be stored in the refrigirator

- Should be stored between **+2ºC and +8ºC**
- **Shelf life**: The expiry date of the vaccine is indicated on the label and carton of the product
- Opened vials should be discarded at the end of 6 hours or at the end of the vaccination session, whichever comes first.



Where should the **ROTAVAC®** vaccine be placed in the refrigerator?

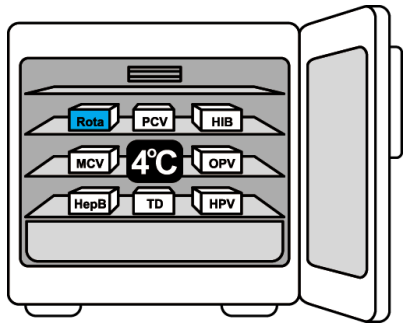
- It will be placed on the same tray as the previous Rotarix Vaccine

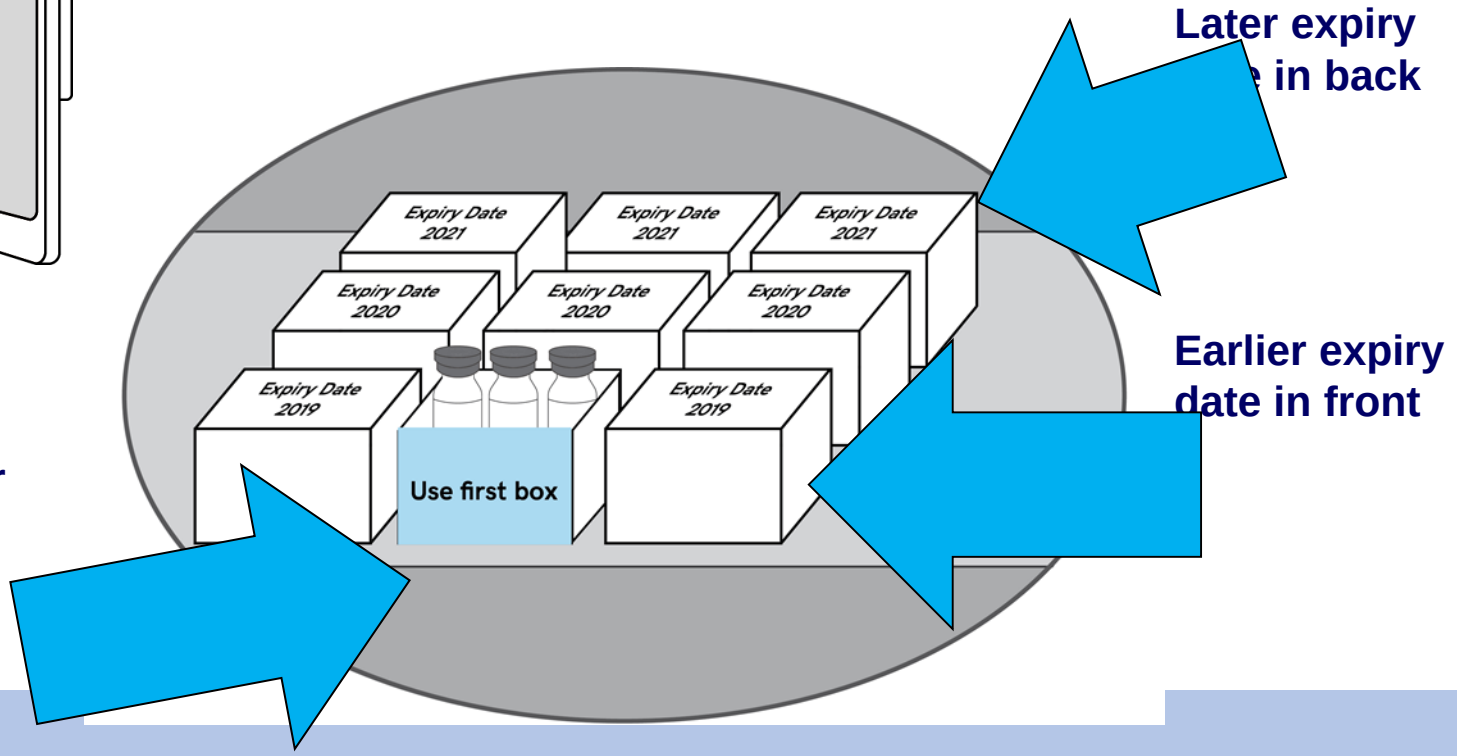
GREEN tray

- Vaccine use should follow First – Expiry – First - Out (FEFO) principle.
- Monitor and record refrigerator temperatures twice daily (Morning and Evening)
- Ensure to read and record Minimum and Maximum Temperature for the previous day

Which vaccine should be stored in front?

- Vaccines with early expiration dates should be kept in front to be used first





Place your vaccines correctly in the refrigerator

Horizontal/ Chest opening refrigerator		Vial once opened
PCV10	RED TRAY	PCV - Return
Pentavalent & HPV	ORANGE TRAY	Pentavalent – Return HPV - Discard
TT/Td/IPV/ & COVID19	YELLOW TRAY	TT/Td- Return IPV- Return COVID19 - Discard
Rotavirus Vaccine	GREEN TRAY	Rota - Discard
BCG & MR	BLUE TRAY	BCG- Discard MR- Discard
OPV & Yellow Fever Vaccine	PURPLE TRAY	OPV – Return YF - Discard

- Use a temperature monitoring device at all times
- Place the temperature monitor on the yellow tray
- Maintain temperature between 2°- 8 ° Celsius
- Store vaccines in the appropriate vaccine tray
- Label open vials appropriately (refer to MDVP guidelines)
- Ensure regular maintenance of the refrigerator
- In case this refrigerator is not maintaining proper temperatures, implement the following steps;

1. Transfer vaccines to nearest working refrigerator

2. Call (write name and telephone no. below)

HF in-charge _____

SCPHN _____

CC Technician _____

ALWAYS MONITOR AND RECORD TEMPERATURES DAILY; MORNING AND EVENING.

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Transporting ROTAVAC® vaccine at +2 to +8 º C

- Use only **recommended transport** boxes with adequate and appropriately prepared coolant-packs

- Monitor temperature, preferably using **fridge tags**, as this allows monitoring throughout the transport period and check the reading at end of trip and download of data

- Managers should ensure that all staff doing packing of vaccines (including support staff) understand how to condition ice packs

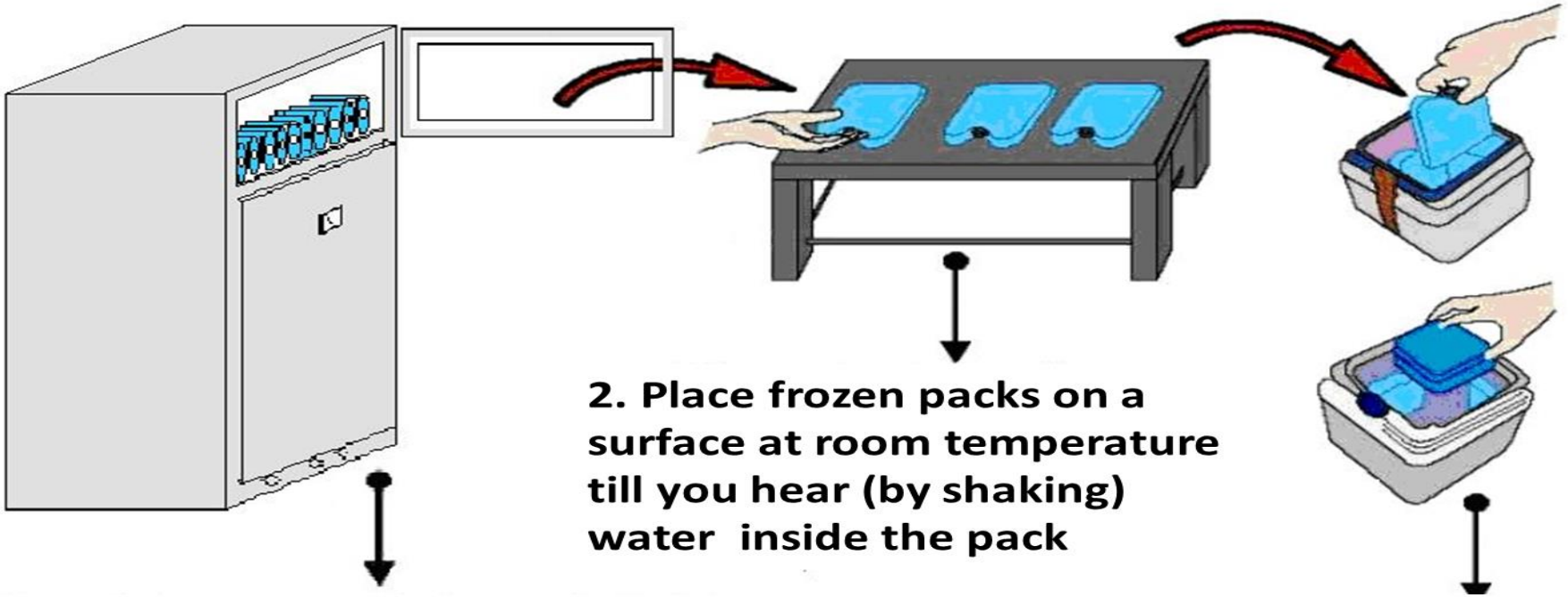
©WHO/PQ website

How to pack **ROTAVAC®** vaccine in the vaccine carrier

- Place conditioned ice-packs/cool packs in a clean vaccine carrier
- Wipe the icepacks with a dry cloth before putting them in the vaccine carrier
- Place the vaccines and close the lid tightly
- Foam pad keeps vaccines inside the carrier cool while providing a place to hold and protect vials in use

Use cool packs or conditioned ice packs

Frozen packs conditioning



1. Frozen packs from freezer could be at very low temperature (-5C to -20C)

2. Place frozen packs on a surface at room temperature till you hear (by shaking) water inside the pack

3. Place the conditioned packs in vaccine carrier / cold box, then put the vaccine

SUMMARY
Rotavac® Vaccine Storage at Different Levels

Central Vaccine Store (National)	Regional Vaccine Store (RVS)	Sub County Vaccine Stores	Heath Facility
-20ºC	+2ºC to +8ºC	+2ºC to +8ºC	+2ºC to +8ºC

What should you do?

The refrigerator stops functioning.

What should you do?

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ROTAVAC, Transport and Supply chain Logistics

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COLD CHAIN SYSTEM

Manufacturer

Central Store

Kenya Supply Chain -

Regional Store

Sub-County Store

Mobile

Outreach

Health Facility (service delivery point)

DOSES NEEDED FOR A COMPLETE SCHEDULE

- While Rotarix® is given in a 2-dose schedule, Rotavac® are given in a **3-dose schedule**
- A schedule started with Rotarix ® can continue with Rotavac® but requires **3 doses in total** for a complete series **(Give an Interval of Four Weeks Between Doses)**

Dose 1	Dose 2	Dose 3	Complete series
Rotarix®	**Rotarix®**		**2 doses total**
Rotarix®	**Rotavac®**	**Rotavac®**	**3 doses total**
Rotavac®	**Rotavac®**	**Rotavac®**	**3 doses total**
Unknown	**Rotavac®**	**Rotavac®**	**3 doses total**

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Calculate vaccine and supplies requirements for ROTAVAC® Vaccine

- Using target population
  - Target population (TP):
  - Immunization schedule: 3 Dose
  - Immunization coverage target (Coverage)
  - Wastage Factor:1.3

  - Formula:

    TP x Immunization schedule x Coverage x WF +buffer

    Use vaccine forecasting sheet

2A: VACCINE FORECASTING SHEET

LEVEL: (COUNTY/SUB COUNTY/ HEALTH FACILITY) NAME _____

		BCG	OPV	IPV	DPT- HEPB-HIB	PCV10	ROTA	MR	YELLOW FEVER	HPV	TT/Td
	1.ANNUAL /QUARTELY/MONTHLY NEEDS (DOSES) BASED ON TARGET POPULATION (ALL CHILDREN 0- 11, 12-59 MONTHS OF AGE; ADOLESCENTS 9-14 , ALL CHILD BEARING AGE WOMEN)										
A	Target Population										
B	Doses in immunization schedule	1	4	1	3	3	3	2	1	2	3
C	Expected Coverage										
D	Wastage factor	5	1.25	1.111	1.25	1.111	1.3	2	1.05	1.5	1.25
E	Total doses required this year= (A x B x D)										
	2. QUALITY FOR SUPPLY PERIOD (DOSES) SUPPLY PERIOD: HF= 1MONTH, SUBCOUNTY STORE=3 MONTHS REGIONAL STORE = 3 MONTHS										
F	Supply Period (months)										
G	Supply Period (Years) = (F/12)										
H	Total doses required for supply period= (E x G)										
	3. MINIMUM STOCK(DOSES)ANY TIME YOUR STOCK REACH THIS LEVEL, YOU MUST REORDER IMMEDIETLY										
I	Reserve stock proportion = (25%)	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
J	Minimum or Reserve stock = (H X I)										
	MAXIMUM STOCK (DOSES) YOUR STOCK CEILING , NEVER STOCK MORE THAN THIS AT ANY POINT IN TIME										
K	Maximum Stock = (H + J)										
	QUANTITY TO BE ORDERED (DOSES) YOU MUST CALCULATE THIS EVERY TIME YOU WANT TO ORDER										
L	Quantity in stock at this time (Physical Count)										
M	Quantity to order (doses) = (K- L)										

Vaccine Forecasting Scenario

Heri NJEMA Dispensary is serving Under One year Population of year 2022 is 1200

Calculate Heri NJEMA's monthly Rotavac vaccine Minimum and Maximum requirement

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Vaccine Forecasting Scenario

Answer:

- **Minimum Stock**
  - **97.5 Round off to 100 Doses (*To get Full Vial*)**

- **Maximum Stock**
  - **487.5 Round off to 490 Doses (*To get Full Vial*)**

How do you order ROTAVAC® vaccines?

- Like other vaccines, the ROTAVAC® vaccine will be forecasted once a month at health facility level
- **Quantities to order =** Annual vaccine requirements (including buffer) ÷ 12 months
- Orders should be placed using Vaccine Requisition voucher/S11
- All vaccines received should be recorded in the designated stock ledger book

Annex 7: **VACCINE ORDERING SHEET**

LEVEL: Central: ☐ **Regional:** ☐ **Sub County:** ☐ **Health Facility:** ☐

Name of the County: …… Sub County: …… …… Health Facility……

Date of Last Order: …… Date of this order: ……Expected date of next order……

TOTAL POPULATION	
Children aged 0-11 months (under 1 year)	
Pregnant women	

Antigen	**Amount to be Stocked in Doses**		**Number of children Vaccinated Since the last order**	**Stock Available**			**Ordered amount**	**Amount Received**			
	Minimum	Maximum		Amount in Doses	Batch Number	Expiry date	Amount in Doses	Amount in Doses	Batch Number	Expiry date	VVM Stage
Pneumococcal											
DPT-HepB-HiB											
HPV Vaccine											
Td											
IPV											
Rotavirus											
BCG											
Measles Rubella											
Oral Polio											
BCG Diluent											
MR Diluent											

The Officer Requesting……Designation……Date……Signature……

Issued by……Designation……Date……Signature……

Received by……Designation……Date……Signature……

Vaccine Ordering Session Scenario

Heri NJEMA DISPENSARY (Baraka County, Maji Mazuri Sub County Monthly Minimum Vaccine Requirement is **100 Doses** and Maximum is **490 Doses.**

During the Month of June 2022 the number of children vaccinated were – **391**

Physical County at the end of the month is – **80 Doses**

Batch Number- 61C180445B

Expiry Date -30.10.2022

Date of Last Order: 01.05.2022

Date of this order: 01.06.2022

Calculate the Vaccine to Order

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Vaccine Ordering Session Scenario

ANSWER

Minimum Vaccine -**100 Doses**

Maximum is **490 Doses.**

Children vaccinated Since Last Order – **391**

Physical County at the end of the month is – **80 Doses**

Batch Number - **61C180445B**

Expiry Date – **30.10.2022**

Vaccine to Order - 410

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Received Session Scenario

Order Day – 01. 06.2022

Received – 410 Doses

Batch - 61C180447J

Expiry Date – 30.11.2022

VVM Stage 1

Received By……. Stamp and Date

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Dynamic labelling of ROTAVAC® Vaccine that has been thawed or transported at 2 – 8° C

- Once Vaccine is thawed, cross out the expiry date printed by the manufacturer
- The New expiry dates after thawing is **180 days**
  - Indicate the date ROTAVAC® vaccine was thawed and the new expiry date using **a sticker** and transfer the same information to the Vaccine Ledger Book

Note: If the expiry date printed by manufacturer is earlier than the calculated new expiry date, only indicate the date thawed and do not cross out the expiry

Dynamic labelling

ROTAVIRUS VACCINE (Rotavac®) *(Dynamic labeling of vaccine when moved to different storage temperature)*	
Store vaccine between 2°C and 8°C for up to 6 Months from the Date thawing is Done	
Batch No	
Date Thawed	
***Indicate New expiry date**	
New expiry date	
***After this date, do NOT use the Vaccine.** **Note:** *If the expiry date printed by manufacturer is earlier than the calculated new expiry date, only indicate the date thawed and do not cross out the expiry*	
Name:	**Designation:**

ROTAVAC® Dynamic Labelling Scenario

PRACTICAL - DYNAMIC LABELLING – Divide the Class In two Groups
Group A Do Activity one & Group Two Do Activity Two

Maji Mazuri - Dispensary received Rotavac Vaccine – on 01.06.2022

Activity one:
Date Thawed: 30.06.2022
Rota 300 Doses - Batch No - 61FA16021
Manufacturer: Expiry Date – 28. 02 .2023

Activity Two
Date Thawed: 30.06.2022
Rota 90 Doses Batch No - 61C18040A.
Manufacturer :Expiry Date – 30.11.2022

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Bundling

- Bundling ensures that vaccines are always supplied with **droppers** corresponding quantities, at each level of the supply chain.

Receiving vaccines - SUMMARY

- Check Quantity against the parking slip & Type of vaccines and other supplies
- Check VVM, Expiry Date ,(Manufacturer or New Expiry date After Thawing and record
- Check for damages, opened packaging
- Count quantities to ensure consistency with records
- Register all accepted stocks in the vaccine stock ledger

  Date, Number of doses, Batch/Lot number, VVM, Expiry date

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VACCINE STOCK LEDGER

VACCINE STORAGE LEVEL (Health Facility, Sub-county, County, Regional, National)_____

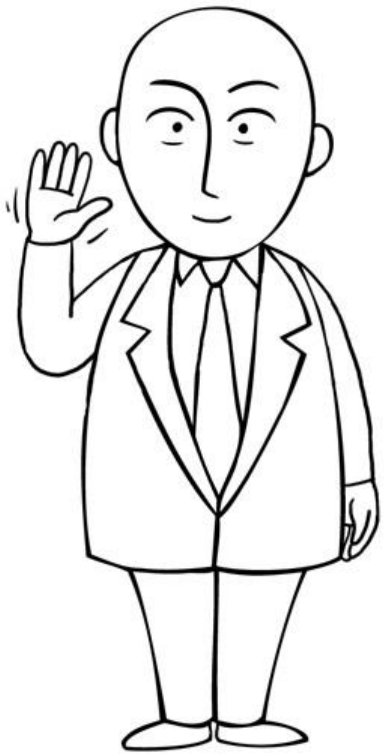
ANTIGEN/ DILUENT_____

Date	Vaccines/Diluents To/from	Vaccine Quantity in doses			Vaccine Information				Diluent Quantity in doses			Diluent information			Remarks
		Receipts /Returns	Issues	Losses					Receipts /Returns	Issues	Losses				
	Source/Destination name	Received	Issued	Discarded	VVM Stage (1,2,3,4)	Lot/Batch No.	Expiry Date	Vaccine Balance in doses	Received	Issued	Discarded	Lot/Batch No.	Expiry Date	Diluent Balance in doses	

SUMMARY: ROTAVAC® Vaccine

Administration	Oral
Schedule	3 Doses: 4 weeks apart (6,10, and 14 Weeks)
Temperature Requirements	-20 °C at National/Regional Vaccine Depots +2 °C to +8 °C at Subcounty Depots & Health Facilities
Formulation	**Liquid, ready to use** (NO reconstitution needed)
Dose	0.5 ml - (5 Drops)
Special Instructions	Discard any unused ROTAVAC® vaccine vial at the end of 6 hours of Opening or at the end of the Vaccination session, whichever comes first.
Doses per vial	5 Doses per Vial
Dynamic Labelling	Indicate date thawed and new expiry date on **both the ledger book** and **the carton**

End of module



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MODULE: 5

ROTAVAC® Vaccine Administration

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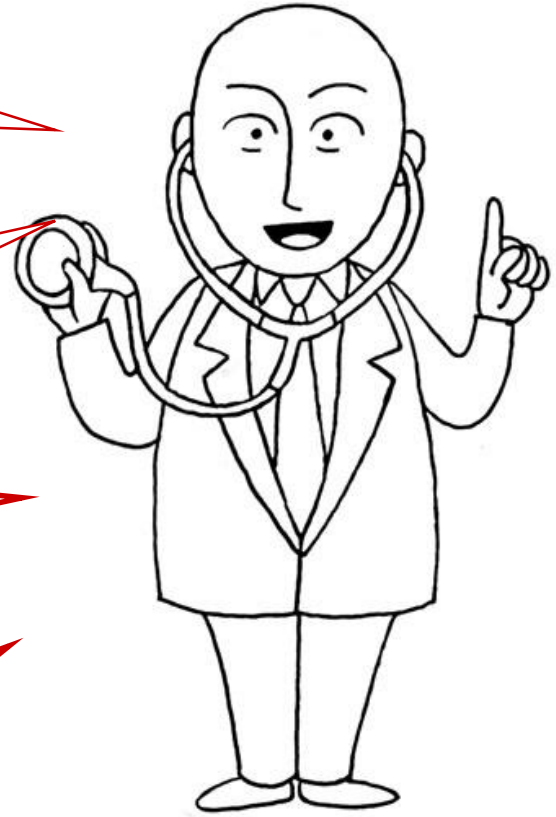
Learning objectives

- At the end of the module, the participant will be able to:
  - Identify the necessary steps to assure good vaccine quality
  - Describe the method to administer the vaccine
  - Describe special considerations for outreach

- Duration
  - 45minutes

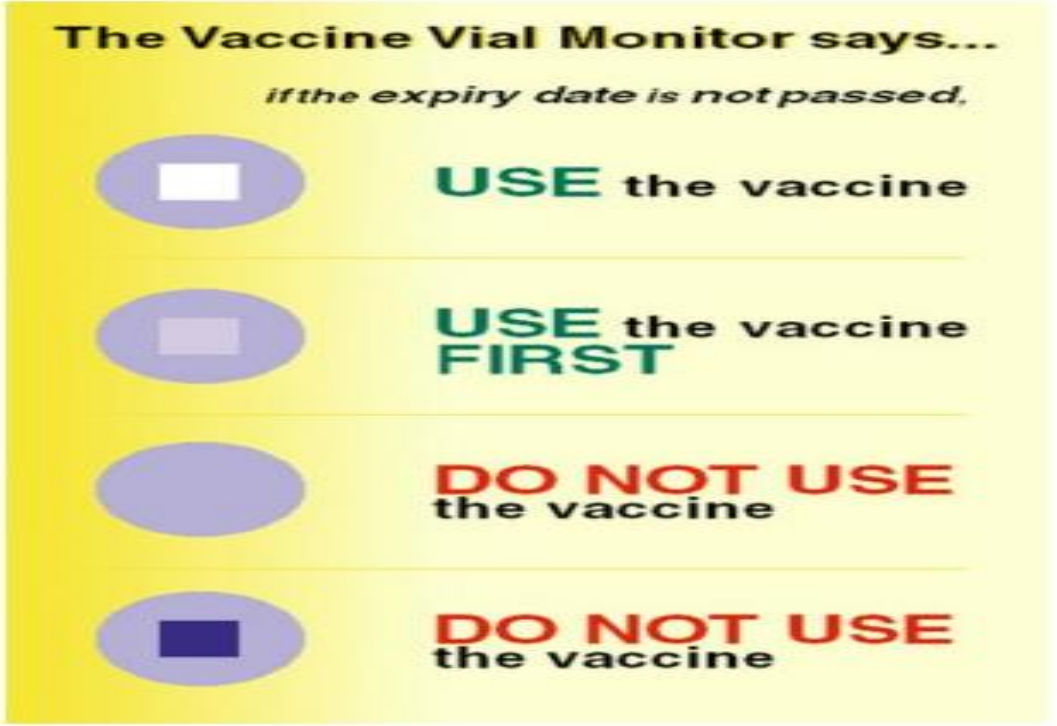
Key issues

1. How to check the quality of the vaccine?
2. How to prepare for vaccination?
3. How to administer the vaccine?
4. What to do if the infant spits part of the vaccine out?



How to check the quality of the Rotavac ® vaccine? (1/2)

- Before administering the Rotavac ® vaccine, you need to check the Vaccine Vial Monitor (VVM) on the vial cap



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How to check the quality of the Rotavac ® vaccine? (2/2)

- Before administering the Rotavac ® vaccine, always check the expiration date on the vial's label

What should you do in this scenario?

The vaccine vial monitor shows that the inner square is lighter than the ring, but it is already darker than the initial color.

What should you do?

How to prepare for vaccination with the Rotavac® presentation?

How to prepare for vaccination with the Rotavac ® presentation? (2/3)

- Make sure the Rotavac ® vaccine is not frozen prior to administration – visually check there are no ice crystals. If frozen, the vial should be discarded.
- The vaccine is generally pink in colour but can sometimes change to orange or light yellow. This change in colour does not impact the quality of the vaccine
- Use only the droppers provided with the vaccine. Do not use OPV droppers.
- Dropper should be discarded with the used vaccine vial. Do not re-use droppers.

How to prepare for vaccination with the Rotavac ® presentation? (3/3)

- Opened vials of Rotavac ® vaccine should only be used within 6 hours of opening; they **must** be discarded after 6 hours or at the end of the vaccination session, whichever comes first

Can rotavirus vaccine (Rotavac ®) be given at the same time as other childhood vaccines?

- Rotavac ®, as well as other rotavirus vaccines, can be administered with any of the following routine childhood vaccines without interfering with their effectiveness:
  - Diphtheria–tetanus–pertussis vaccine (DTP)
  - *Haemophilus influenzae* type b vaccine (Hib)
  - Inactivated polio vaccine (IPV)
  - Hepatitis B vaccine
  - Pneumococcal vaccine
  - Oral polio vaccine (OPV)

- Give the rotavirus (and OPV) vaccine **first**, then administer other injectable childhood vaccines

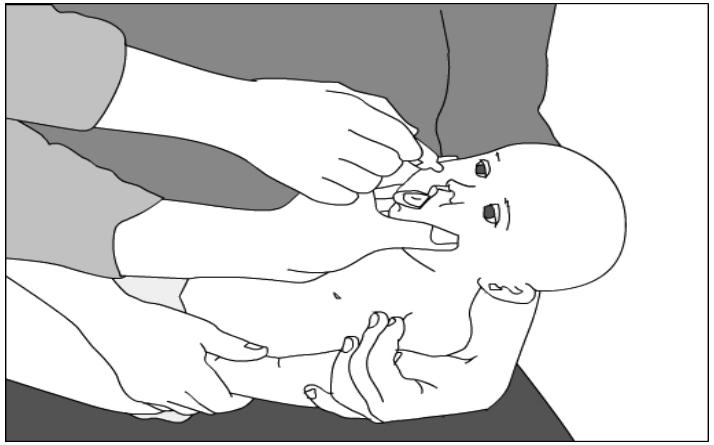
What should you do in this scenario?

The infant is 6 weeks old. You give him/her OPV, rotavirus and pentavalent vaccines.

In which order should you give the vaccines?

What should you do in this scenario?

Is the infant in the right position to be vaccinated?

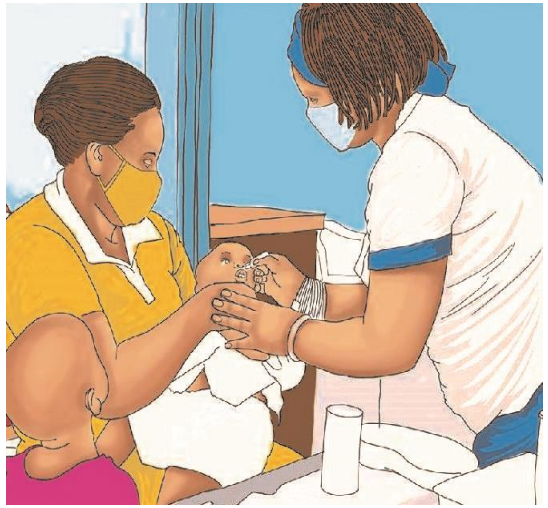


How to position the infant for rotavirus vaccination?

- The infant should be seated in a semi reclining position to take the vaccine orally

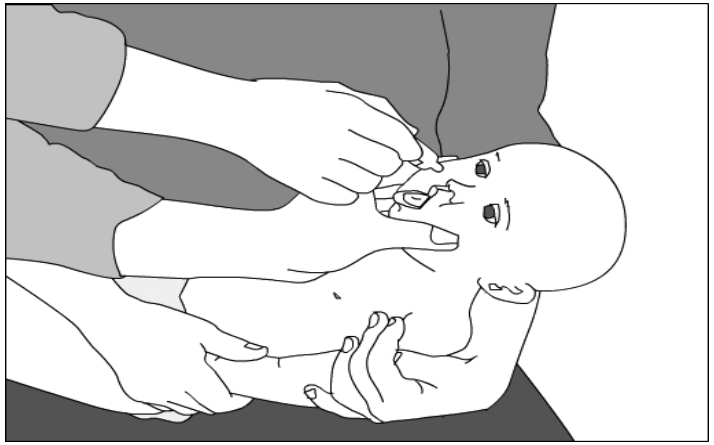
How to position the vaccine?

- Open the infant's mouth by gently pressing the cheeks together
- Position the dropper at 45° angle
- The dropper should not touch the mouth of the infant
  - if it does, discard dropper & vaccine before administering to subsequent infants
- Administer 5 drops into the mouth of the infant



What should you do in this scenario?

Is the infant in the right position to be vaccinated?



What to do if the infant spits out part of the rotavirus vaccine (Rotavac®)?

- A dose of rotavirus vaccine (Rotavac ®) is larger than a dose of oral polio vaccine
  - Rotavac ® = 0.5 mL (5 drops); Polio = 0.1 mL (2 drops)
- To prevent spitting
  - Open the infant's mouth by gently pressing the cheeks together
  - Angle the dropper at a 45° angle
  - The dropper should not touch the mouth of the infant (discard dropper & vaccine before administering to subsequent infants if it does)
  - Administer 5 drops into the mouth of the infant
- A replacement dose is not needed if an incomplete dose is administered for any reason
  - e.g. infant spits or regurgitates the vaccine

How many vials to take for outreach?

- Rotavirus vaccines can be given at the same time as other vaccines in the routine programme
- For outreach take the same number of doses of rotavirus (Rotavac ®) vaccine as for OPV
- Unopened rotavirus vials brought back from outreach should be immediately kept in the refrigerator for use in the next session, provided that the VVM and expiry date have not passed the discard point and date
  - Opened vials of Rotavac ® should be discarded after 6 hours of opening or at the end of session.

Key messages

- Check and interpret vaccine vial monitor and check expiry date on the vial before giving the vaccine
- Prepare for administration, making sure that the vaccine has not been frozen, and the correct dropper is used
- Give the oral vaccines - OPV and Rotavac ® - first, then administer the injectable vaccines
- Give OPV before Rotavac ® so the “sweeter” vaccine (Rotavac ®) takes away the taste of the “bitter” OPV vaccine
- Rotavac ® vaccine dose quantity is larger than that of OPV (5 drops vs. 2 drops). To make sure that infants take the full dose at once:
  - Seat the infant in a semi-reclining position, open the infant’s mouth by gently pressing the cheeks together and angle the dropper at a 45° angle
  - If the infant spits out some or all of the vaccine, the dose does not need to be given again during that visit

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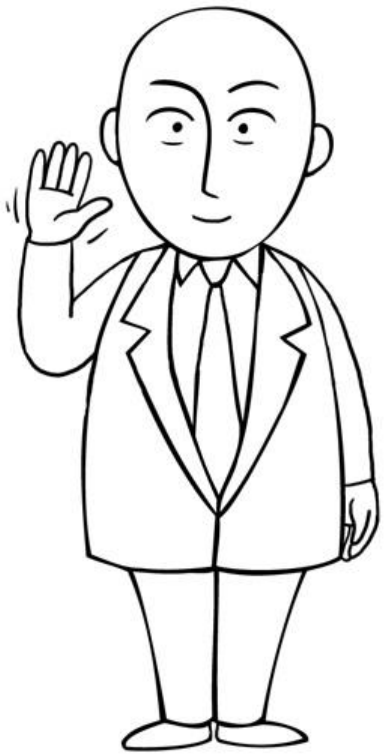
End of module



Thank you
for your attention!

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Ministry of Health

MODULE: 6

Recording and Monitoring of Rotavirus Vaccines

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MODULE: 6

Recording and Monitoring of Rotavirus Vaccines

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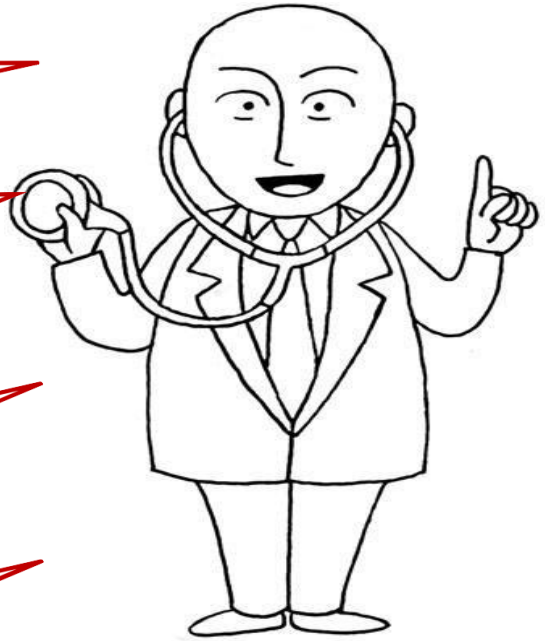
Learning objectives

- At. the end of the module, the participant Will bé able to:
  - Record vaccination MCHB
  - Record vaccination on the immunization register , tally sheet and monthly summary report
  - How to monitor performance and track defaulters
  - How to calculate rota virus vaccination coverage

Key issues

- How to fill the Mother Child Health Booklet (MCHB)
- How to record antigens on MOH 510 ,on the tally sheet (MOH 702) and summary sheet (MOH 710)
- How to monitor uptake of rotavirus vaccine ?
- How to screen eligible infants and track defaulters?



What are the main purpose of the MCHB?

- Informs health worker and parents/caregiver of:
  - Vaccines already received and those due for completing the immunization schedule for the infants
  - Next appointment for vaccination
- Can assist to identify infants who don't return for next vaccination on time
- Useful to conduct coverage surveys

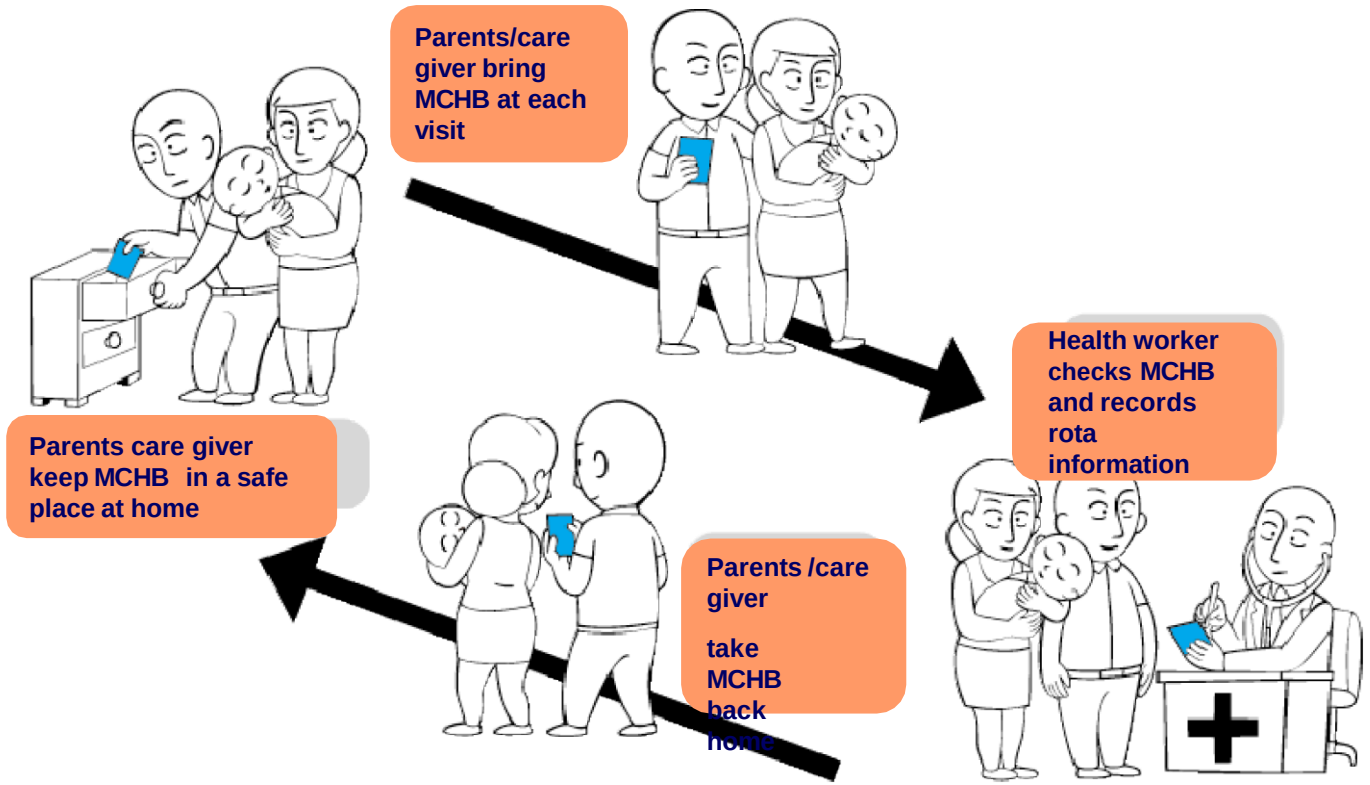
How to record and report rotavirus vaccine (Demo)

- Provide the participants with hard copy of the Immunization register, tally and monthly summary sheet
- Report Rota1, Rota2 and Rota3 doses given each month, along with other series vaccine doses

Defaulter tracing for the subsequent doses of rotavirus vaccine?

- Follow up with infants who have received the first dose and have not come back for the second/ third dose as per the schedule.
- Mother and child health booklet (MCHB) or permanent immunization register could be used to follow up the defaulters.
- Use Community Health Volunteers (CHV)/ Community Health Assistants(CHA) to follow up defaulters.

How to use the MCHB?



Basic recording tools

Minor adjustment has been made on the following tools to conform with current switch revised EPI schedule 2019 :

Mother & Child Health Booklet – MOH 216

Permanent register – MOH 510

Tally sheet – MOH 702

Monthly summary sheet MOH - 710

What should you do in this scenario?

The parents of a child provide you with an MCHB where the third dose of rotavirus vaccine is not included in this card and its due

How should you record the vaccination given?

Response:

The health worker may add the rotavirus vaccination third dose (Rota 3) information by writing on the MCHB indicating date when the dose was given

How to monitor uptake of rotavirus vaccine?

- Health facility should monitor rotavirus vaccine performance on monthly basis against the target.

Rotavirus vaccine recording and reporting

- Record child information in the permanent register
- Transfer same information to Mother-Child Booklet
- Tally the vaccinated child appropriately
- Transfer the information from tally sheet to the summary form at the end of the session or daily.
- All facility data should be summarized and forwarded to the sub county by the 5th of the following month.
- Sub-counties uploads on DHIS by 15th of the same month

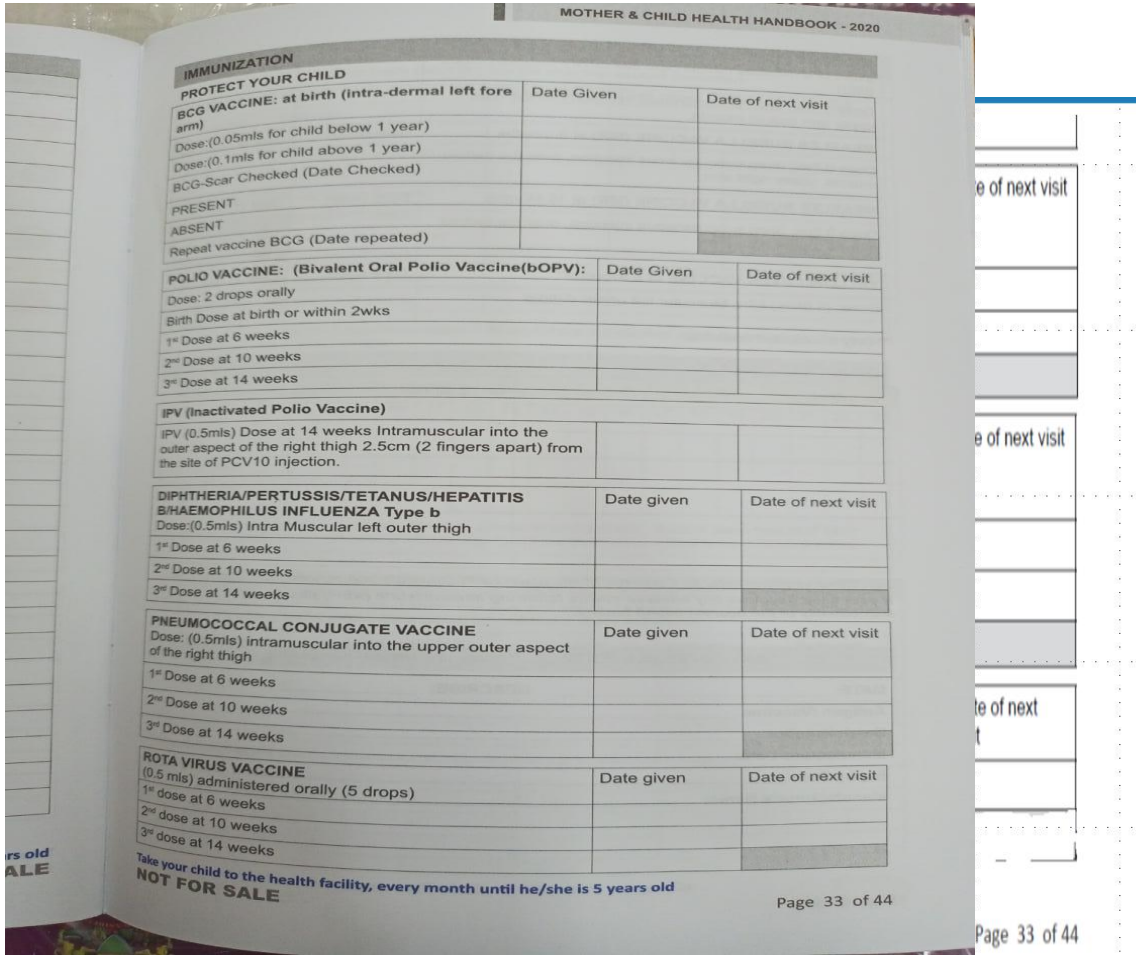
Revised EPI tools

- MOH 702 Tally sheet
-
- MOH710 summary sheet

- MOH 510 Child Permanent Register

- MOH 216 – Mother child booklet

Mother & Child Health Booklet – MOH 216



MOTHER & CHILD HEALTH HANDBOOK - 2020

IMMUNIZATION

PROTECT YOUR CHILD

BCG VACCINE: at birth (intra-dermal left fore arm)	Date Given	Date of next visit
Dose:(0.05mls for child below 1 year)		
Dose:(0.1mls for child above 1 year)		
BCG-Scar Checked (Date Checked)		
PRESENT		
ABSENT		
Repeat vaccine BCG (Date repeated)		

POLIO VACCINE: (Bivalent Oral Polio Vaccine(bOPV):	Date Given	Date of next visit
Dose: 2 drops orally		
Birth Dose at birth or within 2wks		
1st Dose at 6 weeks		
2nd Dose at 10 weeks		
3rd Dose at 14 weeks		

IPV (Inactivated Polio Vaccine)		
IPV (0.5mls) Dose at 14 weeks Intramuscular into the outer aspect of the right thigh 2.5cm (2 fingers apart) from the site of PCV10 injection.		

DIPHTHERIA/PERTUSSIS/TETANUS/HEPATITIS B/HAEMOPHILUS INFLUENZA Type b Dose:(0.5mls) Intra Muscular left outer thigh	Date given	Date of next visit
1st Dose at 6 weeks		
2nd Dose at 10 weeks		
3rd Dose at 14 weeks		

PNEUMOCOCCAL CONJUGATE VACCINE Dose: (0.5mls) intramuscular into the upper outer aspect of the right thigh	Date given	Date of next visit
1st Dose at 6 weeks		
2nd Dose at 10 weeks		
3rd Dose at 14 weeks		

ROTA VIRUS VACCINE (0.5 mls) administered orally (5 drops)	Date given	Date of next visit
1st dose at 6 weeks		
2nd dose at 10 weeks		
3rd dose at 14 weeks		

Take your child to the health facility, every month until he/she is 5 years old

NOT FOR SALE

Page 33 of 44

- Record the third dose of Rota vaccine in the space just below the second dose for clients who presents with old version of MCHB
- New version of MCHB has third dose of Rota indicated

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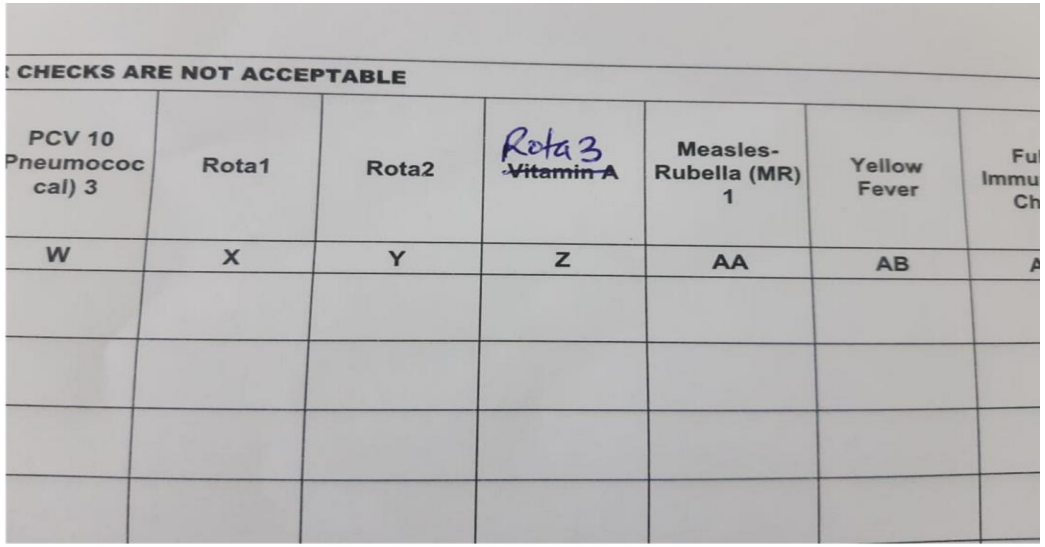
MOH 510 Immunization Permanent Register



CHECKS ARE NOT ACCEPTABLE

PCV 10 Pneumococcal) 3	Rota1	Rota2	~~Vitamin A~~ Rota 3	Measles-Rubella (MR) 1	Yellow Fever	Fu Immu Ch
W	X	Y	Z	AA	AB	A

- Record the third dose of Rota in the space provided for Vitamin A 6-11 months in the immunization register
- Write Rota 3 below Vit. A and CANCEL Vit. A 6-11m

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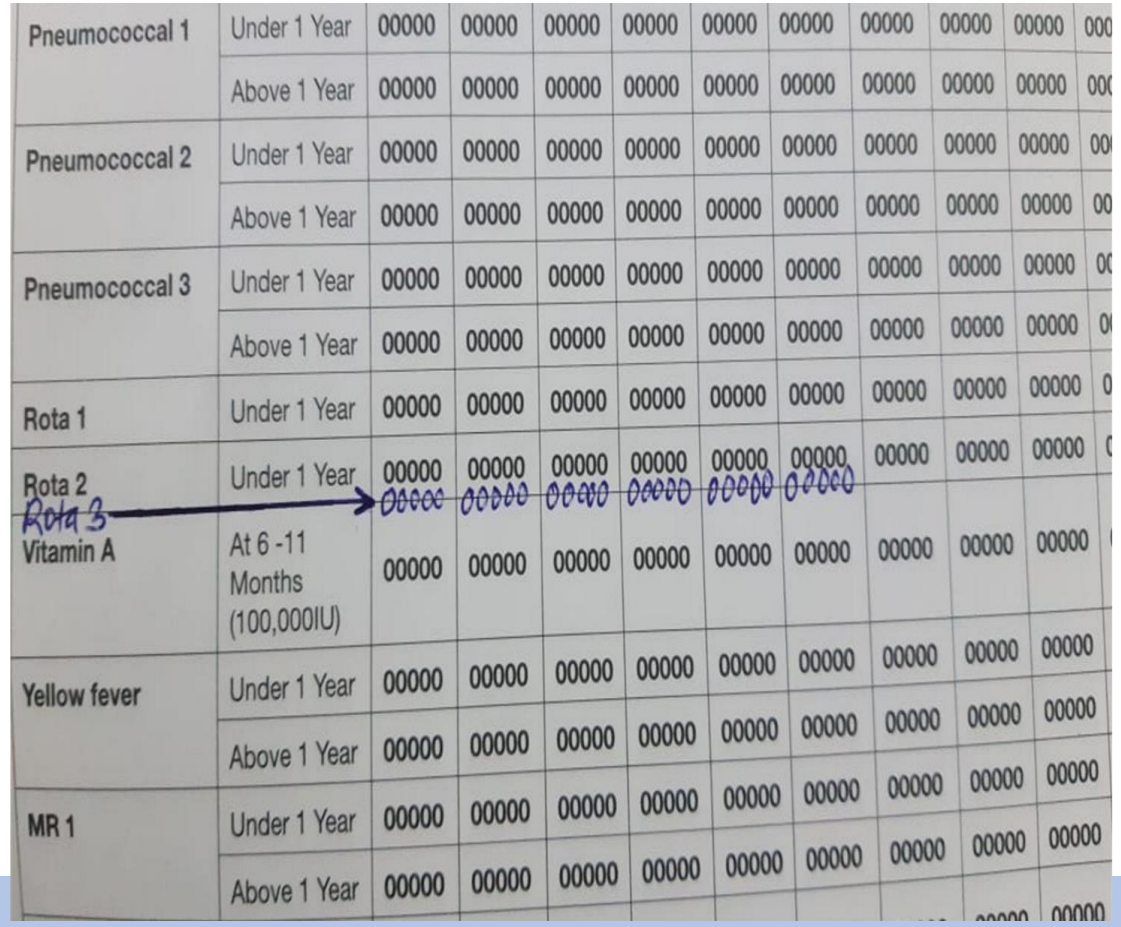
MOH 702 Tally sheet



Pneumococcal 1	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	000
	Above 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	00
Pneumococcal 2	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	00
	Above 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	00
Pneumococcal 3	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	00
	Above 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	0
Rota 1	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	0
Rota 2	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	
Rota 3		00000	00000	00000	00000	00000	00000				
Vitamin A	At 6 -11 Months (100,000IU)	00000	00000	00000	00000	00000	00000	00000	00000	00000	
Yellow fever	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	Above 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	
MR 1	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	Above 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	00000	

- Indicate and Tally the third dose of Rota vaccine below Rota 2

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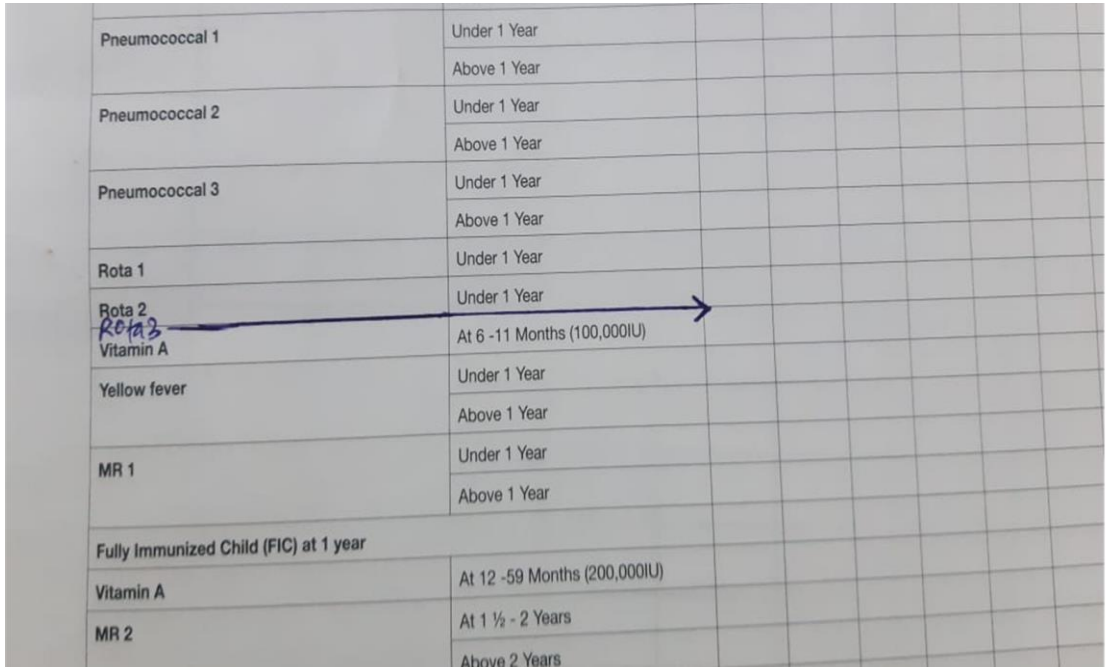
MOH 710 Summary sheet



Pneumococcal 1	Under 1 Year
	Above 1 Year
Pneumococcal 2	Under 1 Year
	Above 1 Year
Pneumococcal 3	Under 1 Year
	Above 1 Year
Rota 1	Under 1 Year
Rota 2	Under 1 Year
Rota3 Vitamin A	At 6 -11 Months (100,000IU)
Yellow fever	Under 1 Year
	Above 1 Year
MR 1	Under 1 Year
	Above 1 Year
Fully Immunized Child (FIC) at 1 year	
Vitamin A	At 12 -59 Months (200,000IU)
MR 2	At 1 ½ - 2 Years
	Above 2 Years

- Transfer the tallies for third dose of Rota from the Tally sheet to the Summary sheet
- Using a ruler, divide the Rotta2 row into two and record Rota3

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How to calculate rotavirus vaccine Coverage

Example:

- Number of surviving infants for sub county XYZ in 2021 extracted from DHIS e.g. 1,112

- The denominator (1,112) for surviving infants will apply to all series antigens as per immunization schedule.

- Dummy Exercise for participants

Exercise

- A facility X have vaccinated 990 infants with their first dose and 850 infants with their third dose of Rotavirus vaccine from the 1,112 surviving infants they have in their catchment for the year 2021.
- ***Q1. Calculate the coverage for third dose.***

- Coverage (%) = $\frac{\text{Number vaccinated in 2021}}{\text{\# of surviving infants in 2021}}$ X 100

- ***Q2. Calculate the drop-out-rate.***

- Drop-out-rate = $\frac{\text{Dose 1} - \text{Dose 3}}{\text{Dose 1}}$ X 100

- ***Q3. Calculate the number of unvaccinated children.***

- Unvaccinated children = Target population/Surviving infant – Total vaccinate with dose 3

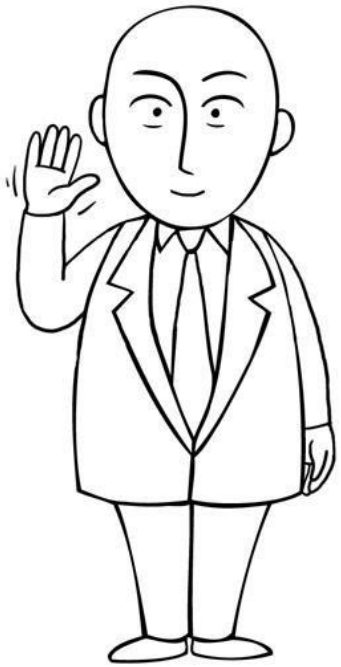
Answer

- Q1. 76.4%
- Q2. 14%
- Q3. 262
- ***Note:***
- *Discuss on Health facility X performance and their mitigation measure to increase their coverage and reduce their drop-out-rate.*

Key Messages

- Ensure all tools used for data recording and reporting are up to date as per the program (Latest version)
  - i.e. Improvise tally sheet, Immunization summary sheet and the old MCHB to accommodate the new schedule of Rotavac where need be. (3rd Dose of Rotavirus vaccine)
- All fields should be well filled, complete and signed for ownership.
- All reports should be submitted on time to the next level
- Monitor performance- compute coverage, drop out rate and unvaccinated children, discuss results and take action.

End of module



Thank you
for your attention!

Ministry of Health

MODULE: 7

ROTAVAC® Vaccine Adverse Events Following Immunization

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Learning objectives

- At the end of the module, the participants will be able to:
  - Identify adverse events following immunization (AEFIs), including intussusception (IS)
  - Explain how to manage AEFIs
  - Explain how to report AEFIs

- Duration
  - 15mins

Key issues

1. What is an AEFI
2. (What is intussusception(IS
3. How to report an AEFI

What is an AEFI?

AEFI = An adverse event following immunization is

- Any unwanted or unexpected medical occurrence
  Which FOLLOWS immunization
- May or may not be caused by the vaccine
- May be an unfavorable or unintended sign, abnormal
- laboratory finding, symptom or disease

- AEFI can be categorized into
  - Vaccine product related reaction
  - Vaccine Quality Related reaction
  - Immunization Error Related Reaction
  - Immunization Anxiety Related Reaction
  - Coincidental Event

Expected Reactions

Commonly reported

- Fever
  Intussusception

Gastrointestinal- Rare type of intestinal obstruction

Diarrhoea- Risk is lower than that of severe rotavirus disease

Other

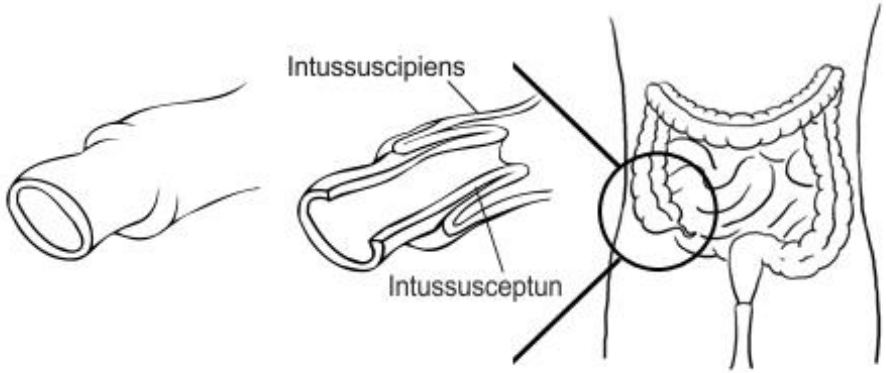
Intussusception Rare type of intestinal obstruction

Risk is lower than that of severe rotavirus disease

Whether the rotavirus vaccine effects the overall incidence of IS has not yet been established

What about Intussusception (IS)?

- In the past, the first rotavirus vaccines (Rotashield™) caused IS, a serious but very rare bowel obstruction



- With the new rotavirus vaccines, there seems to be a very small increased risk of IS in infants following rotavirus vaccination
- The increased risk appears to occur mainly in the first 1- 7 days following the first dose of rotavirus vaccine

Risk of IS against risk of rotavirus infection

- Data from India (where Rotavac® was introduced in 2016) support no increased risk of intussusception. Data continue to be monitored globally.
- The risk of IS after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated infants and young children!

Contraindication/precautions

You should not give rotavirus vaccine to babies with:

A severe(life-threatening)allergic reaction to a previous dose of rotavirus vaccine

A severe (life threatening)allergy to any component of rotavirus vaccine,

Severe combined immunodeficiency (SCID)or

A previous episodes of intussusception

Precautions Cont

Healthcare professionals should follow up on any symptoms indicative of intussusception

- Severe abdominal pain
- Persistent vomiting
- Bloody stools

Abdominal bloating and/or high fever

Parents/caregivers should be advised to promptly report such symptoms

How to manage an AEFI

Manage the AEFI according to immunization guidelines and refer where necessary

Reassure the caregiver as treatment is being given

Report all AEFI (serious and non serious) on AEFI reporting form and submit to the supervisor who reports to Sub-county public health nurse/SCMOH

Record in Mother Child Booklet,Tally sheet and Summary Sheet

Reporting can also be electronically on the online AEFI reporting form https://pv.pharmacyboardkenya.org

In case of Serious AEFIs let the caregiver know the AEFI will be investigated to establish the cause

How to report an AEFI? (2/2)

- AEFI report should contain
  - Client information
  - Immunization event(s) well described
  - Indicate the dose number and not the quantity administered (e.g. dose 1,2,3,4)
  - Adverse event(s) description
  - Relevant medical and treatment history and relevant medical/clinical reports attached(if any)

How to report an AEFI? CONT…

- Type of vaccine(s) administered
- Route of administration
- Associated event(s)
- Reporter details fully filled for assistance in follow up of client during investigation
- Investigations to be completed for serious events

MINISTRY OF HEALTH
NATIONAL VACCINES AND IMMUNIZATION PROGRAM
AEFI Reporting Form

(To be filled in triplicate) ☐ Initial Report ☐ Follow-up report

NAME OF REPORTING INSTITUTION ..... INSTITUTION MFL CODE .....

COUNTY ..... SUB-COUNTY .....

Patient Details

PATIENT'S NAME ..... IP/OP NO ..... DATE OF BIRTH (or age) .....

GENDER ..... NAME OF GUARDIAN (If patient is a child) .....

ADDRESS ..... PHONE NUMBER (self or nearest contact) .....

VILLAGE ..... WARD ..... SUB-COUNTY ..... COUNTY .....

VACCINATION CENTRE ..... COUNTY OF VACCINATION CENTRE .....

TYPE OF VACCINATION SERVICE (static, mass, outreach) .....

Type of AEFI	Please tick:			Brief details on the event (including timeline of occurrence)
BCG Lymphadenitis	☐	Anaphylaxis	☐	.....
Convulsion	☐	Encephalopathy, Encephalitis/Meningitis	☐	.....
Generalized urticaria (hives)	☐			.....
High Fever	☐	Paralysis	☐	.....
Injection site abscess	☐	Toxic shock	☐	.....
Severe Local Reaction	☐	Others (specify)	☐	.....

Onset of event: Date ...../...../..... Time .....

Suspected vaccine(s)

Name of Vaccine (e.g. BCG, DPT-Hib-HeB)	Dose No.	Date vaccinated	Time vaccinated	Route, site of vaccination (i.m., s.c.)	Details of Vaccine			Details of Diluents		
					Lot/Batch No.	Manufacturer's Name	Expiry Date	Lot/Batch No.	Manufacturer's Name	Expiry Date

Past medical history (including history of similar reaction or other allergies, concomitant medication/vaccine, concomitant illness, other cases, pregnacy status and other relevant information *(continue on separate sheet if necessary)*

.....

.....

.....

Action taken ☐ Treatment given (specify) .....

☐ Specimen collected for investigation (specify type(s) of specimen) .....

AEFI Outcome ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Died

Name of Person Reporting ..... Phone number .....

Designation ..... Signature: ..... Date: .....

Final Classification of AEFI (*to be filled at national level*):

(See overleaf for guidelines on how to complete the form)

HARAMBEE

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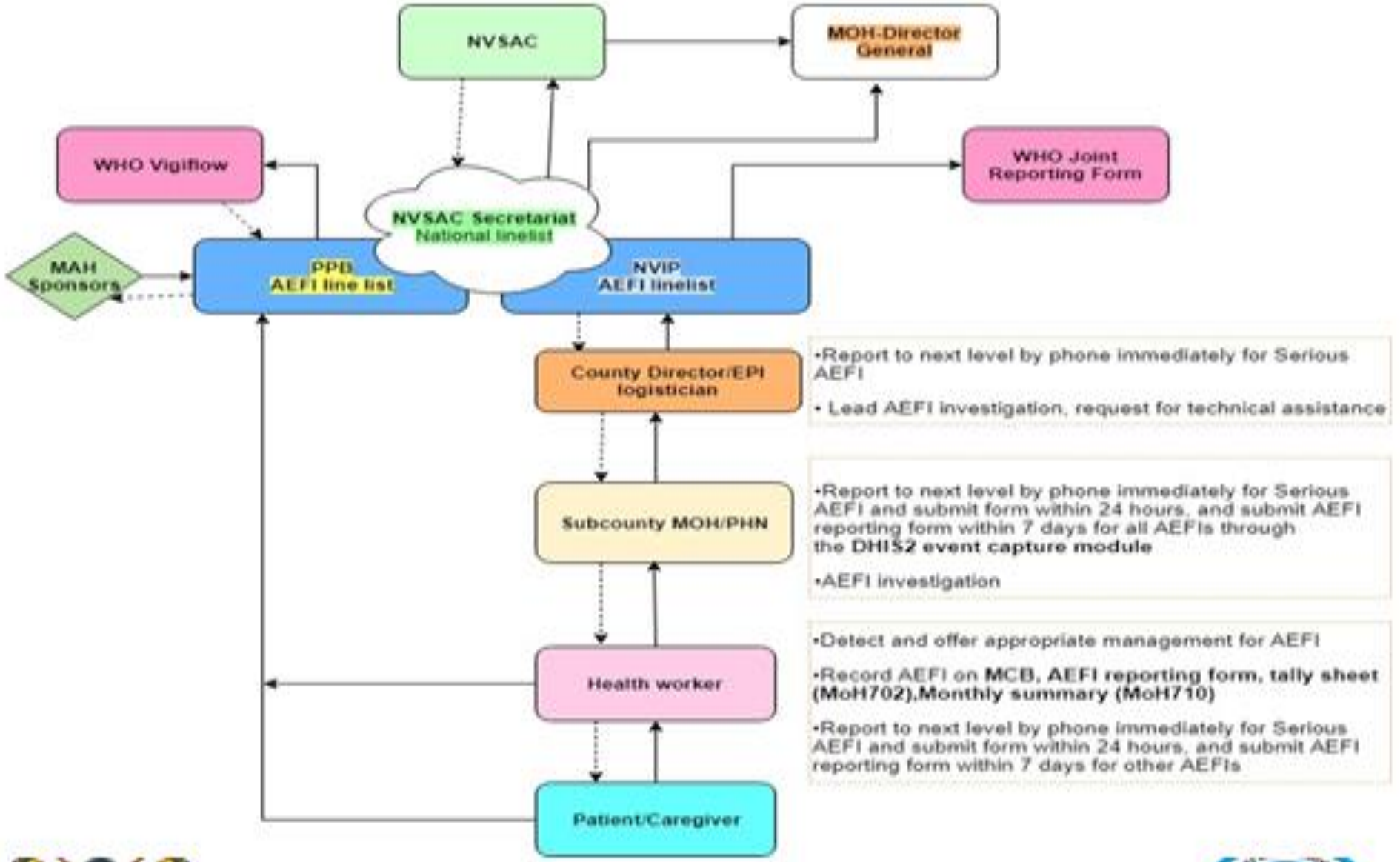
Reporting pathway



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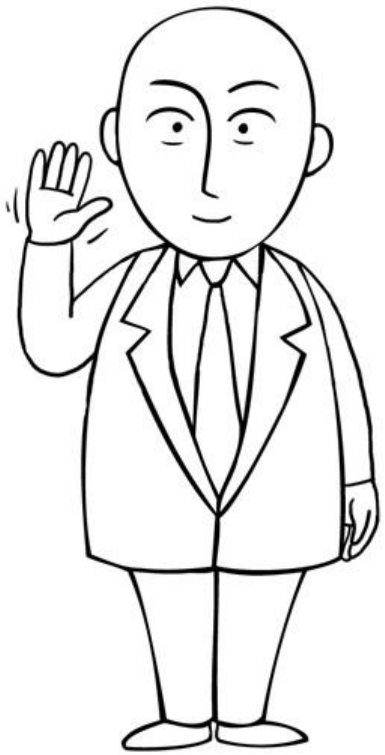
Key messages

- The current safety profile of rotavirus vaccines is good
- Many infants who get the rotavirus vaccine do not experience any side effects
- The risk of IS after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated infants and young children
- AEFIs should be reported through the existing AEFI reporting systems/forms
- The forms/systems to be fully filled and clinical reports attached for investigation.
- Feedback of the AEFI investigated to be communicated to the caregivers
- Reassure the caregiver- admit uncertainty and keep the community informed

End of module



Thank you for your attention

Ministry of Health

MODULE: 8

ACSM

Vaccinate to Protect.
Ministry of Health

Presentation Outline

- Learning Objectives
- Caregivers concerns
- Effective communication techniques
- The Triple A communication approach
- Key messages
- Summary

Learning objectives

- At the end of the module, the participant will be able to:
  - Inform communities to support rotavirus vaccine switch
  - Describe how to communicate with parents/caregivers
  - Advise caregivers on rotavirus disease and prevention methods particularly on the need for timely vaccination
  - Alert caregivers of potential side effects and how to respond to them
  - Provide other messages to caregivers before they leave the session

- Duration: 20mins

Effective communication maintains respect and trust between health workers, families and communities.

Effective communication entails:

- **Asking questions** in order to understand and listen to community members experiences and perspectives.
- **Providing simple, practical information** about who will receive the vaccine, why and where
- Responding to questions and concerns **with empathy and respect** to increase trust and address refusals.
- Acknowledging local challenges and show **respect for customs and cultures**.

Discussion

What are the most common concerns or questions you receive from the caregivers in your health facility on Rotavaccine switch Give a few examples.

ACTIVITY:ROLEPLAY

Ask for two volunteers (1 is a caregiver and the other is a health worker):

Caregiver presents in the health facility with a baby girl 9 months old who had received 1 dose of Rota vaccine at 12 weeks

How do you communicate as a health worker to the caregiver on

a) subsequent Rota vaccine doses
b) need to complete second dose of Measles Rubella

How to communicate with caregivers?

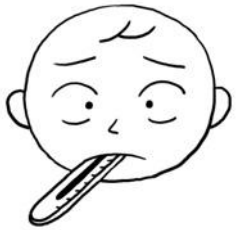
- Be respectful
- Use simple words and avoid technical terms
- Listen to caregiver's concerns
- Make sure the caregiver has understood your key messages
- Need to complete all Rota vaccine doses

Inform caregivers/communities on Rotavirus vaccine

- Emphasize on the importance of Rotavirus vaccine in prevention of diarrhoea
- Informing the caregivers that the vaccine require 3 doses given at 6 weeks, 10 weeks and 14 weeks together with Penta valent, polio and Pneumo vaccine
- Inform the caregiver of any other vaccines the child is due or have missed out

What is “triple A” communication with parents?

Advise
on what is given



Alert
on side effects and how to respond

Arrange
for when to return

Advise: How to inform about the disease?

- Rotavirus vaccine helps to prevent Rotavirus disease
- Getting vaccinated on time is important
- Require 3 doses of Rotavirus vaccine
- Interval of **4 weeks** between the 3 doses
- Given at 6 weeks, 10 weeks and 14 weeks The vaccine will be given at the same time as pentavalent vaccine, therefore no extra visit is required for this vaccine

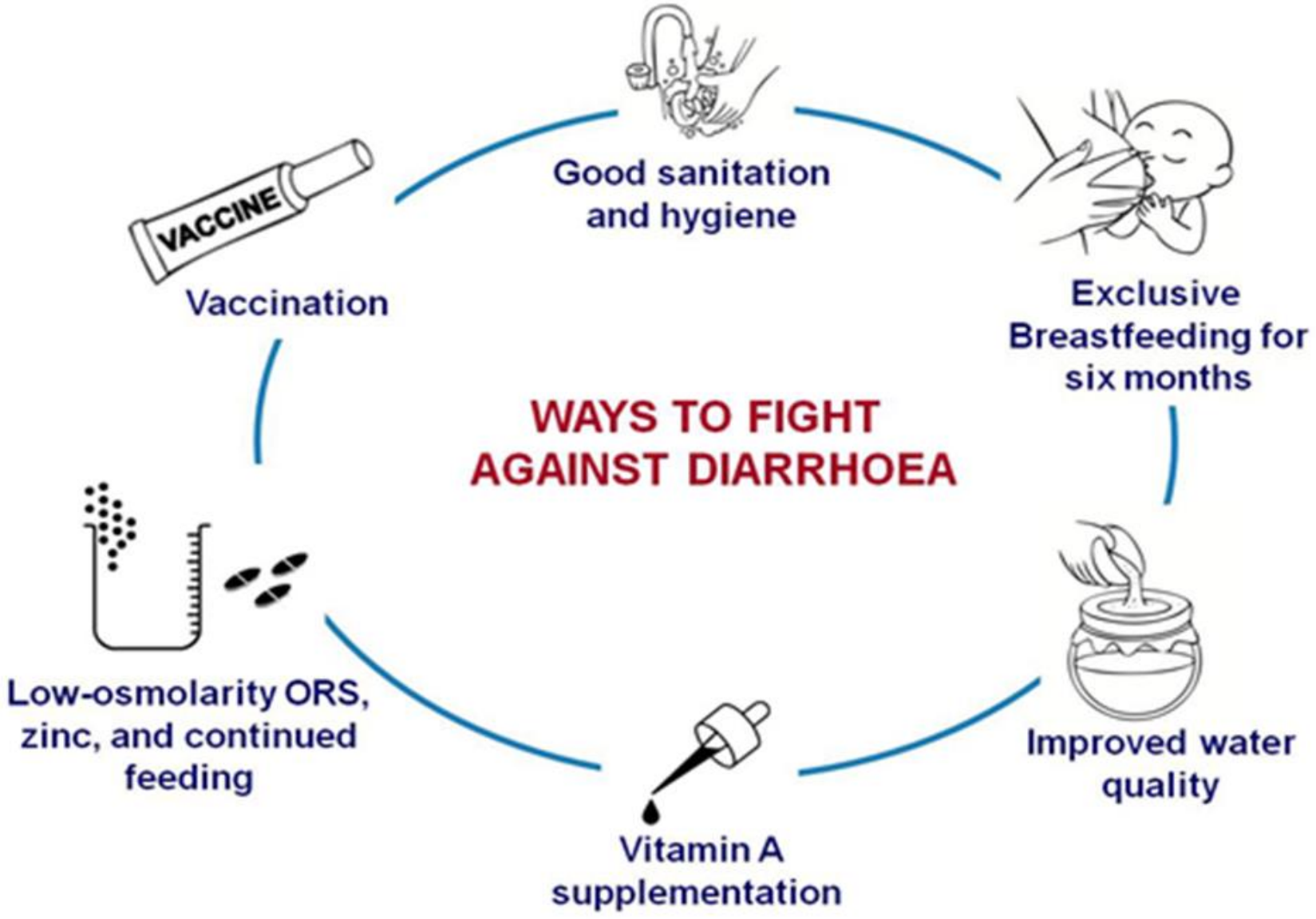
Alert: How to respond to side effects

- Inform the caregiver that common mild reactions might occur but are of short duration: fever, irritability, crying, swelling and tenderness at injection site
- Tell the caregiver if there are any unexpected side effects, to return to the nearest health facility
- Be prepared to communicate with communities in case of any rumors by providing factual messages

Arrange: When to return?

- Write the date of the next visit on the mother child booklet
- Remind the Caregiver to keep the Mother and Child booklet safe and to bring it in the next visit

Other prevention interventions



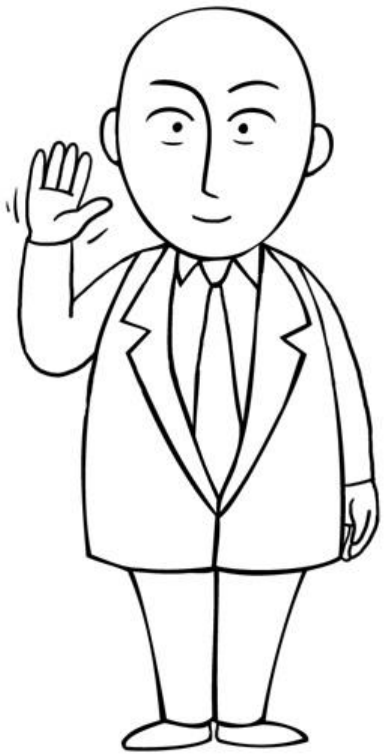
Key messages

- Vaccination is the most effective prevention measure of severe episodes of Rotavirus infection
- A child immunized with rotavirus vaccine can be protected against diarrhea caused by rotavirus
- A child may still get diarrhea caused by other agents therefore it is important to continue practicing good hygiene and sanitation behavior; and other related behaviours
- Ongoing dialogue may successfully reassure vaccine-hesitant parents that immunization is the best and safest option for their infant
- On-time vaccination is very important
- Keep the Mother and Child Booklet safe and remember to bring it in the next visit
- Contact caregivers of children who have missed out of Rotavirus vaccine using phone numbers in the register

HARAMBEE

Vaccinate to Protect.

End of module



Thank you
for your attention!

Summary

- Effective communication is essential for the successful Rotavirus vaccine switch
- It is necessary to reassure caregivers on the safety of the new formulation

Need to trace and vaccinate all children who have been missed out before the switch

- Overall effective communication will lead to increased utilization of vaccination services