

NATIONAL VACCINES AND IMMUNIZATION PROGRAM **ROTAVIRUS VACCINE SWITCH TRAINING** 2022



MODULES

Module 1: Introduction to Rotavirus Disease and Vaccine

Module 2: Background and Rationale for Rotavirus vaccine swit

Module 3: Rotavac® Vaccine Eligibility

Module 4: Rotavac® Vaccine Attributes, Storage conditions

Module 5: Rotavac® Vaccine Administration

Module 6: Recording and Monitoring of Rotavac® Vaccine

Module 7: Rotavac® Vaccine Adverse Events Following Immunization

Module 8: Advocacy Communication and Social Mobilization - ACSM









Ministry of Health

MODULE: 1

Introduction to Rotavirus Disease and Vaccine



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 – 30 Minutes





Key issues

What is rotavirus disease?/Clinical Overview

What are the signs and symptoms of rotavirus?

How is rotavirus spread?

4. Who is most at risk?

What are rotavirus prevention strategies?

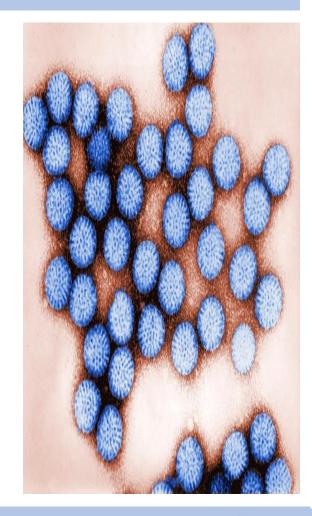






What is Rotavirus Disease?

- Rotavirus disease is a diarrhoea 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 diarrhoea disease in infants and young children worldwide
- Rotavirus is not the only cause of diarrhoea, several other agents may also cause diarrhoea

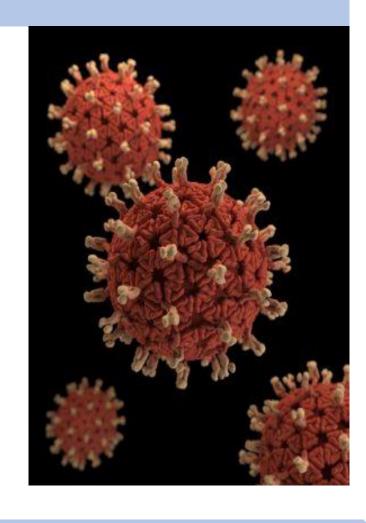






Rotavirus - Clinical Overview

- Rotavirus is the most common cause of severe diarrhoea disease in infants and young children worldwide
- Suspected case definition: A child with diarrhoea (≥3 loose stools in 24 hours) OR vomiting (≥1 episodes in 24 hours).
- Confirmed case definition: A child with clinical symptoms and detection of rotavirus in a faecal specimen by a standard assay (e.g. commercially available enzyme).
- **Dehydration** due to rapid fluid loss is a point of concern hence need for timely, appropriate intervention.







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?

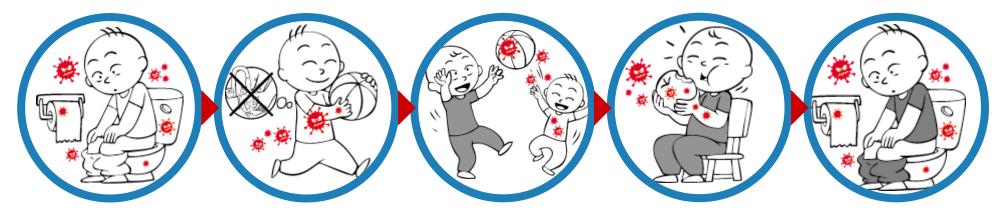
- Confirmation of a diarrhoea illness such as rotavirus requires laboratory testing
- Strains of rotavirus may be further characterized by special testing with enzyme immunoassay or polymerase chain reaction
 - Such testing is not commonly available or necessary





How does rotavirus spread?

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

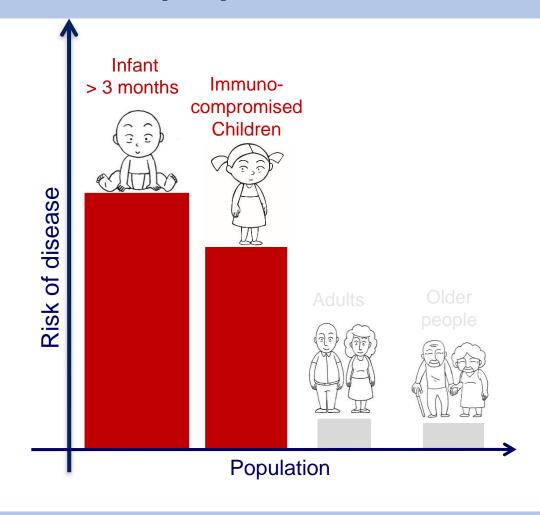






Who is most at risk in the population?

- 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







Is there a vaccine against rotavirus?

- YES: There are 5 prequalified rotavirus vaccines:
 - Rotateq[®]
 - Rotarix[®]
 - Rotavac[®]
 - Rotavac 5D[®]
 - RotaSiil®

Main characteristics

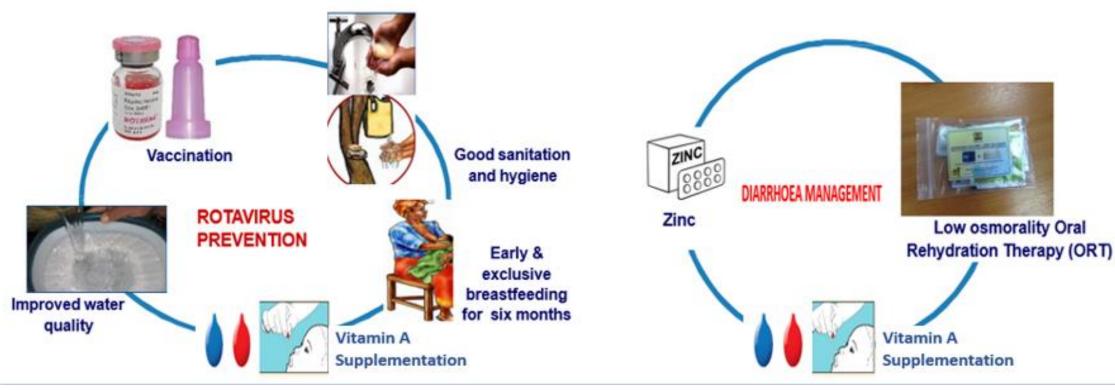
- Highly effective and safe
- Protect against severe forms of rotavirus disease
- Do not protect against diarrhea caused by other agents than rotavirus.





Rotavirus Prevention and Diarrhoea Management

The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoea diseases with the scaling up of both prevention and Treatment packages









MODULE: 2

Background and Rationale for Rota vaccine switch



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



End of module









MODULE: 3

Rotavirus Vaccine Eligibility



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 ways to determine an infant's eligibility for rotavirus vaccine when a written record is unavailable
 - Describe the absolute contraindications for vaccination





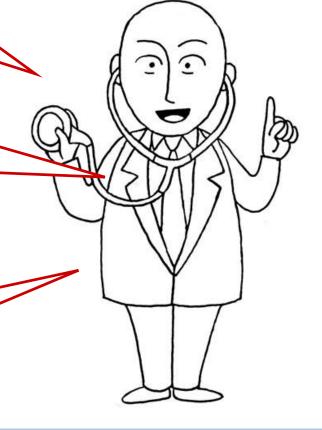


Key Issues

What is the schedule for rotavirus vaccine?

What to do when the exact date of birth (DOB) or immunization card is missing?

What are the contraindications for vaccination?

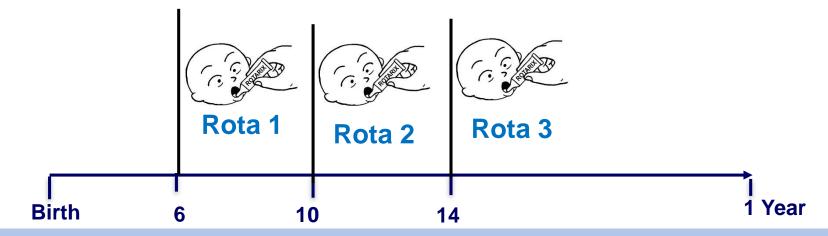






What is the rotavirus vaccine schedule?

- 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 started





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





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 Vaccine Brand	Rotavac®	Rotavac®	3 doses total





What should you do in this scenario?

An infant's immunization card shows that he/she is now 17 weeks old and has received BCG and OPV 1 What should you do?







Answer

- Administer Rotavac first dose and advice on 2nd and

3rd doses

- Administer the other vaccines that are due and

advise on completion of Schedule







What should you do in this scenario?

An infant comes to the clinic at 20 weeks, the card indicates he received first dose Rotarix at six weeks.

What will you do?







Answer

Administer Second dose rotavac and advice on third dose







What should you do in this scenario?

An infant comes for 1st dose of Rota at 11 Months

What will you do?







Answer

Administer Rotavac 1st dose and give return date for second dose in four weeks time and advise on the Third dose to complete the schedule

i.e. 1st Dose – 11 Months 2nd Dose – 12 Months 3rd Dose – 13 Months







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





Contraindications



DO NOT give Rotavirus Vaccine if:

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





Key messages

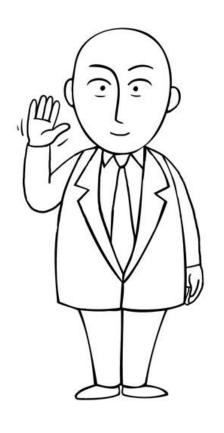


- Routinely First dose of Rotavac should be given at 6 weeks of age
- Second and third dose should be given at 10 and 14 weeks of age, respectively minimum interval of 4 weeks should be maintained between doses
- If infants have missed their rotavirus vaccines, they can receive the vaccine up to 12 months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





End of module



Thank you for your attention!







MODULE: 4

ROTAVAC® Vaccine Attributes, Storage conditions



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

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







Comparison Between Rotarix and Rotavac®



- •One Dose Tube
- Liquid Ready to Use
- VVM on the Cap





ROTAVAC®

- 5 Dose Vial
- Liquid Ready to Use
- · Has a dropper with a Cap
- VVM on the Cap or on the Label







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 on the Cap or on the Label
- Comes with a dropper
- 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

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)

Rotavirus Vaccine (Live, Oral) BP 23 x 25 at hala Vero cell-Derived Portavirus Procedure (Live, Oral) BP 25 x 25 at hala Portavirus Portavirus

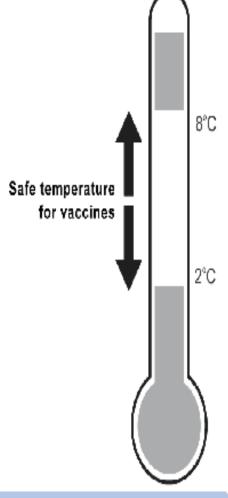
Rotavac® SHOULD NOT BE INJECTED AT ANY CIRCUMSTANCES





Storage Conditions for Rotavac®

- At Central Vaccine Stores, Rotavac[®] should be stored at -20°C
- Shelf life: When stored 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. Once thawed DO NOT Freeze.
- At the Regional Vaccine Stores Rotavac[®] will be stored in Walk in Cold-rooms between +2°C to +8°C
- At Sub County Vaccine Stores and Health Facilities, Rotavac[®] will be stored in the refrigerators between +2°C to +8°C at same level where Rotarix was stored







Rotavac® Storage Cont...

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

GREEN tray

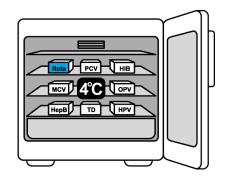
- Vaccine use should follow First Expiry First Out (FEFO) principle.
- Monitor and record refrigerator temperatures twice daily (Morning and Evening)
- Ensure to read and record Minimum and Maximum Temperature for the previous day
- Opened vials should be discarded at the end of 6 hours or at the end of the vaccination session, whichever comes first.



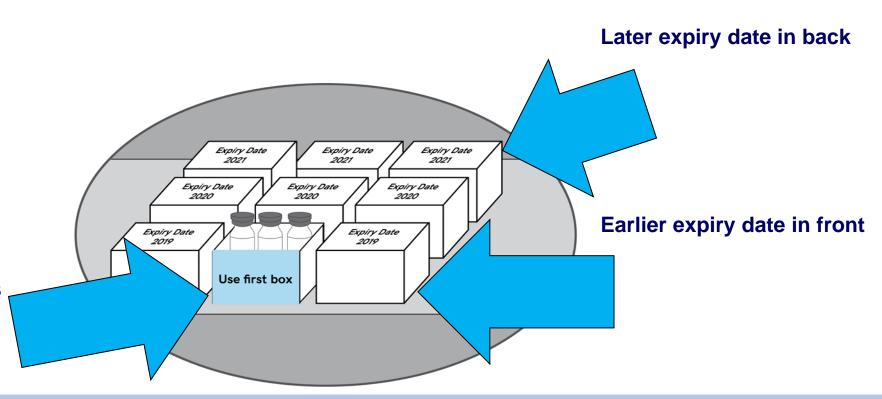


Which vaccine should be stored in front?

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



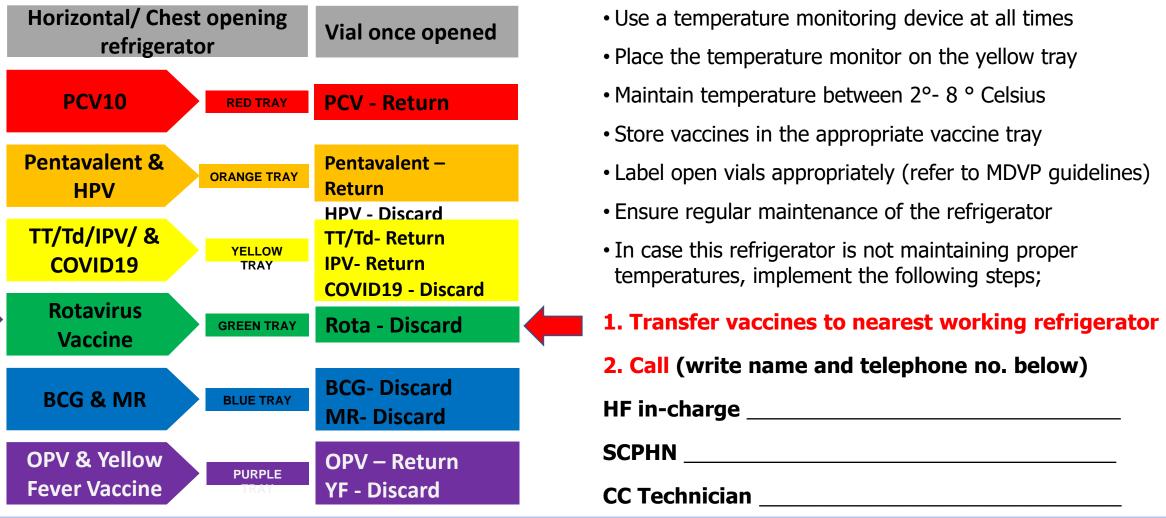
"Use first" box for vaccines brought back unused from fixed or outreach sessions







Place your vaccines correctly in the refrigerator







Transporting Rotavac® vaccine at +2 to +8 ° 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.
- Managers should ensure that all staff doing packing of vaccine(including support staff) understand how to condition ice packs.











How to pack Rotavac[®] in the vaccine carrier



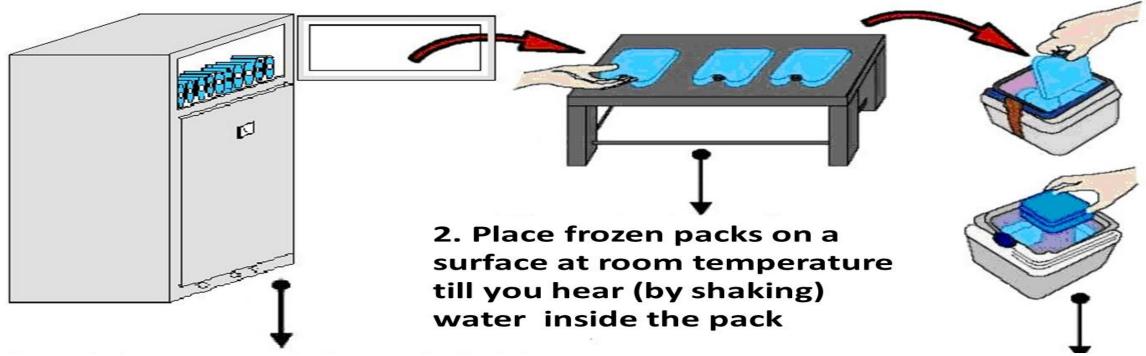
- Wipe the icepacks with a dry cloth before putting them in the vaccine carrier
- Place conditioned ice-packs/cool packs in a clean vaccine carrier
- Place the vaccines and close the lid tightly
- Use Foam pad to keep vaccine inside the carrier cool while providing a place to hold and protect vials in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

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





Rotavac® Vaccine Storage at Different Levels

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

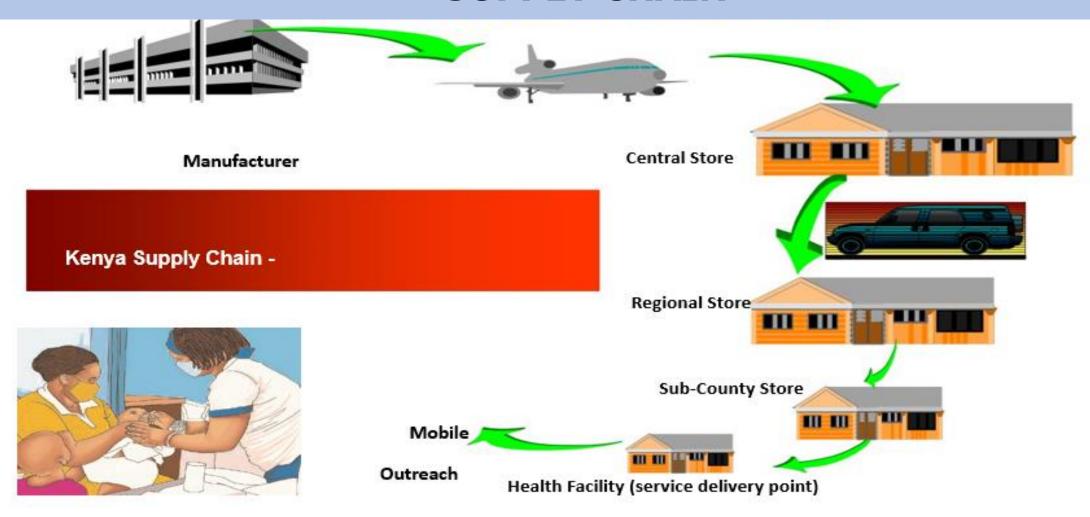




ROTAVAC® Transport and Supply chain Logistics



SUPPLY CHAIN





Calculate Rotavac® vaccine and supplies requirements

- Using target population
 - Target population (TP): (Target Population remains Children under 1yr).
 - Immunization schedule: 3 Dose
 - Immunization coverage target (Coverage)
 - Wastage Factor: 1.33
 - Buffer: 25% of total Vaccine Requirements
 - Formula:

(TP x Immunization schedule x Coverage x WF) +buffer Use vaccine forecasting sheet





2A: VACCINE FORECASTING SHEET

NAME of County/Sub County/ Facility YEAR IPV DPT-PCV YELLOW HPV BCG bOPV ROTA MR TT/Td HEPB+Hib 10 FEVER 1. ANNUAL/QUARTERLY/MONTHLY VACCINE NEEDS (DOSES) BASED ON TARGET POPULATION (ALL CHILDREN UNDER 0-11,12-59 MONTHS OF AGE; ADOLESCENTS 9-14,ALL CHILD BEARING AGE WOMEN) [A] Target population IB1 Doses in immunization schedule [C] Expected Coverage [D] Wastage factor 5 1.25 1.25 1.33 1.25 1.11 1.11 1 05 1.5 [E] Total dose required this year = $(A \times B \times D)$ 2. QUANTITY FOR SUPPLY PERIOD (DOSES) SUPPLY PERIOD: HF = 1 MONTH; SUB COUNTY 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 IMMEDIATELY [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 = $(H \times I)$ 4. MAXIMUM STOCK (DOSES) - YOUR STOCK CEILING, NEVER STOCK MORE THAN THIS AT ANY POINT IN TIME [K] Maximum stock = (H + J)5. QUANTITY TO BE ORDERED (DOSES) YOU MUST CALCULATE THIS EVERY TIME YOU WANT TO ORDER VACCINES [L] Quantity in stock at this time (Physical Count) [M] Quantity to order (doses) = (K-L)

Complied by	Signature





Annex 7:

VACCINE ORDERING SHEET

TOTAL POPULAT	LION										
Children aged 0-	11 months	(under 1 ye	ar)								
Pregnant women											
Antigen	Amount to be Numl Antigen Stocked in Doses child: Vacci			Stock Available			Ordered amount	Amount Received			
	Minimum	Maximum	Since the last order	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 Requesti			Designat	ion	Da	te		Signature			

Dynamic labelling - Sticker

DOTAVIDLE VACCINE (Detayor®)

(Dynamic labeling of vaccine when moved t							
Store vaccine between 2°C and 8°C for up to 18	0 Days from the Date thawing is Done						
Batch No							
Date Thawed							
*Indicate New expiry date Note: If the expiry date calculated new expiry date, only indicate the date thawed and							
New expiry date							
*After this date, do NOT use the Vaccine.							
Name:	Designation:						





Ministry of Health

National Vaccines and Immunization Program

VACCINE STOCK LEDGER

VACCINE STORAGE LEVEL (Health Facility, Sub-county, County, Regional, National	
ANTIGEN/ DILUENT	

Date	Vaccines/Diluents To/from	Vaccine	Quantity in	n 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	





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 and count quantities to ensure consistency with records.



Register all accepted stocks in the vaccine stock ledger/ Chnajo.eLMIS, capturing Date of accepting/ receiving, number of doses, batch/Lot number, VVM, Expiry date





SUMMARY: Rotavac® Vaccine

Administration	Oral
Schedule	3 Doses: 4 weeks apart (6,10, and 14 Weeks)
Temperature Requirements	-20 °C at National – Central Vaccine Store +2 °C to +8 °C at Regional , Subcounty Depots & Health Facilities
Formulation	Liquid, ready to use (NO reconstitution needed)
Dose	0.5 ml - (5 Drops)
Colour	The vaccine colour pink can sometimes change to orange or light yellow without impacting the Vaccine quality
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





Ministry of Health

PRACTICAL SESSIONS



Outline

- ROTAVAC® vaccine Forecasting?
- 2 ROTAVAC® Vaccine Ordering?
- Rotavac® Dynamic Labelling Scenario
- Recording Rotavac® Vaccine in the Ledger Book







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

Use the Vaccine Forecasting Sheet





Vaccine Forecasting Answer

- Minimum Stock
 - 99.75 Round off to 100 Doses (To nearest dose)
- Maximum Stock
 - 498.75 Round off to 499 Doses (To nearest dose)





Vaccine Ordering Session Scenario

Heri NJEMA DISPENSARY (Baraka County, Maji Mazuri Sub County Monthly

Minimum Vaccine Requirement is **100 Doses** and Maximum is **500 Doses**.

During the Month of October 2022 the number of children vaccinated were - 391

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

Batch Number- 61C180445B

Expiry Date -30.01.2023

Date of Last Order: 01.10.2022

Date of this order: 01.11.2022

Calculate the Vaccine Doses to Order

Use the Vaccine Ordering Sheet





Vaccine Ordering Session Answer

ANSWER

Minimum Vaccine -100 Doses

Maximum is **500 Doses.**

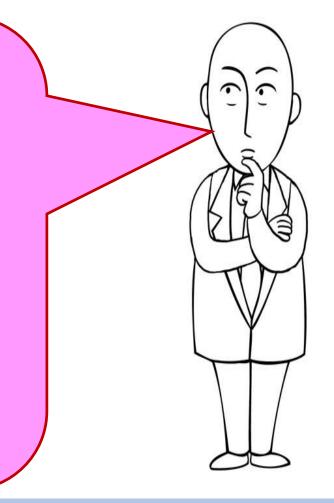
Children vaccinated Since Last Order – **391**

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

Batch Number - **61C180445B**

Expiry Date – **30.01.2023**

Vaccine to Order - 420





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

- Use Manufacturer Expiry Date or Calculated Expiry date whichever comes first
- 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





Rotavac® Dynamic Labelling Scenario

Maji Mazuri - Dispensary received Rotavac Vaccine - on 01.11.2022

Activity one:

Date Thawed: 01.11. 2022

Rota 300 Doses - Batch No - 61FA16021 Manufacturer: Expiry Date - 20.01.2024

VVM – Stage 1

Activity Two

Date Thawed: 30.10.2022

Rota 120 Doses Batch No - 61C18040A Manufacturer :Expiry Date - 30.03.2023

VVM - Stage 2

Use the Sticker





Rotavac® Dynamic Labelling Answer

Maji Mazuri - Dispensary received Rotavac Vaccine – on 01.11.2022

Activity one and Activity Two

Groups	Amount	Batch Number	Manufacturer Expiry Date	Date Thawed	New Expiry Date after
Group A	300	61FA16021	20.01.2024	01.11.2022	29.04.2023
Group B	120	61C18040A	30.03.2023	30.10.2022	NA





Record Rotavac® in the Vaccine Ledger Book

Maji Mazuri - Dispensary
Date Vaccine received: 01.11.2022

Vaccine Received

- -Rota 300 Doses
- -Batch No 61FA16021
- -Date Thawed: 01.11, 2022
- -Manufacturer Bharat Biotec
- -Manufacturer Expiry Date:20.01.2024
- -New Expiry Date 29.04.2023
- -VVM Stage 1

Vaccine Received: Cont....

- -Rota 120 Doses
- -Batch No 61C18040A
- -Date Thawed: 30.10.2022
- -Manufacturer : Expiry Date 30.03.2023
- -Manufacturer Bharat Biotec

VVM - Stage 2



Record Vaccine in the Ledger



End of module



Thank you for your attention!







MODULE: 5

Rotavac® Vaccine Administration



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

How to check the quality of the vaccine?

How to prepare for vaccination?

How to administer the vaccine?

What to do if the infant spits part of the vaccine out?



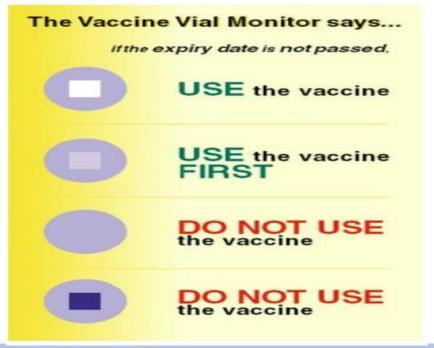




How to check the quality of the Rotavac ® vaccine?

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









How to check the quality of the Rotavac® vaccine?

 Before administering the Rotavac ® vaccine, always check the expiration date on the vial's label and on the Sticker, and use whichever date comes First.





ROTAVIRUS VACCINE (Rotavac®) (Dynamic labeling of vaccine when moved to different storage temperature)										
Store vaccine between 2°C and 8°C for up to 18	0 Days from the Date thawing is Done									
Batch No										
Date Thawed										
*Indicate New expiry date Note: If the expiry d calculated new expiry date, only indicate the date thawed an										
New expiry date										
*After this date, do NOT use the Vaccine.										
Name: Designation:										

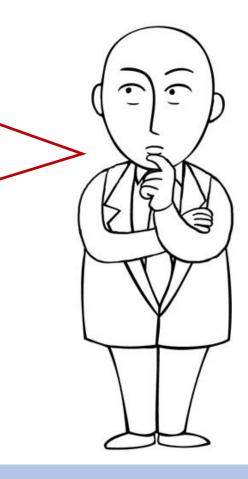




What should you do in this scenario?

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 returned to the refrigerator and inform the supervisor.
- 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?







How to position the infant for rotavirus vaccination?

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







Vaccine Administration

- 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 and vaccine before administering to subsequent infants
- 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

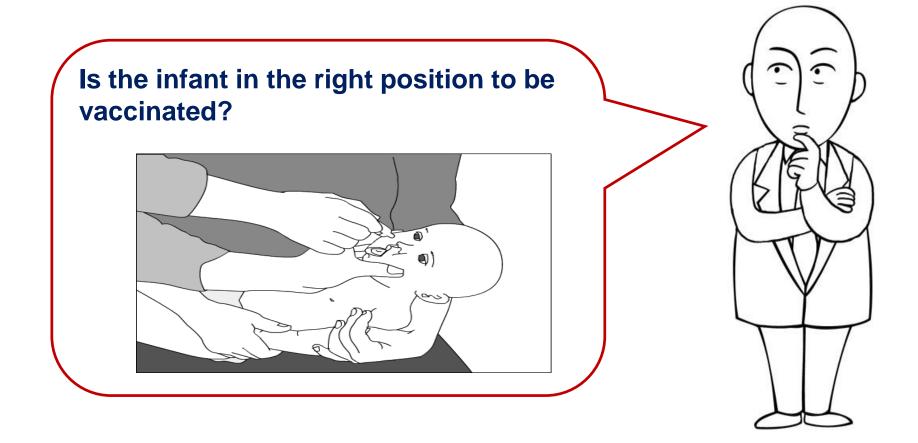
NB: A dose of rotavirus vaccine (Rotavac ®) is larger than a dose of oral polio vaccine Rotavac ® = 0.5 mL (5 drops); Polio = 0.1 mL (2 drops)







What should you do in this scenario?







How many vials to take for outreach?

- Rotavirus vaccines can be given at the same time as other vaccines in the routine programme and Outreaches
- 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.





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 Vaccine Brand	Rotavac®	Rotavac®	3 doses total





Key messages



- Check and interpret vaccine vial monitor and check expiry date on the vial and Beyond Use Date Sticker 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 Rotavac ® and OPV first, then administer the injectable vaccines
- 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





End of module



Thank you for your attention!







Ministry of Health

MODULE: 6

Recording and Monitoring of Rotavirus Vaccines



Learning objectives



- At the end of the module, the participant Will bé able to:
 - Record vaccination MCHB
 - Record vaccination on the immunization register in the tally sheet and monthly summary report
 - Use Immunization register to record rotavirus vaccination



- How to monitor performance and track defaulters
- How to calculate Rota virus vaccination coverage





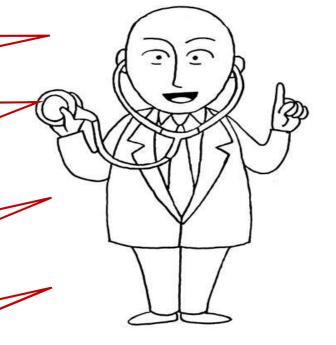
Key issues

Basic Recording Tools

How to record MOH 510 vaccination 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?









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
- Defaulter Tracing Register





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 the infants who don't return for next vaccination on time
- Useful to conduct coverage surveys





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

What should you do?







Answer?

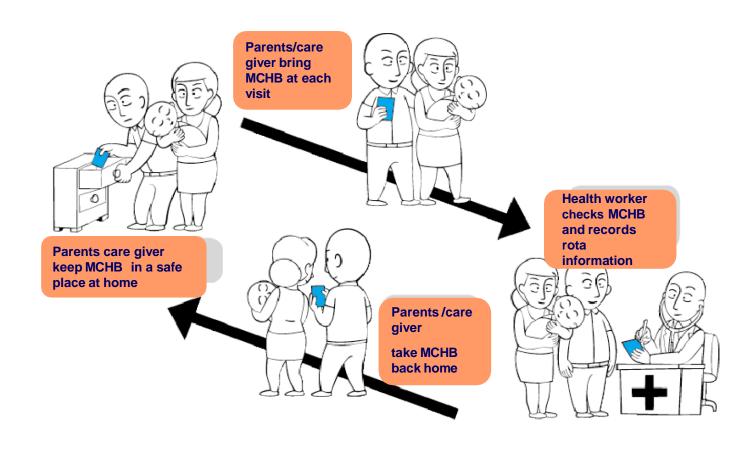
The health workers shall Record by adding the rotavirus vaccination third dose (Rota 3) information writing on the MCHB indicating date when the dose was given.







How to use the MCHB?







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





How to screen and track infants for rotavirus vaccine?

- Identify newborns for the first dose
 - Screen the child permanent register /MCHB or other records
- Health care worker to Inform parents/ caregiver of the next vaccination appointment.
- Use volunteers to track infants due for subsequentrotavirus vaccination





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.
- List the defaulters
- Use Community Health Volunteers (CHV)/ Community Health Assistants(CHA) to follow up defaulters.





Defaulter tracing Register

MINISTRY OF HEALTH NATIONAL VACCINES AND IMMUNIZATION PROGRAMME IMMUNIZATION DEFAULTER TRACKING REGISTER



			MON	TH		YEAR						Vaccinate to Protect.
Serial No.	Date	Name of the child	Date of Birth	Name of Parent/Caregiver	Age in months of the child	No.	Physical address/Landmark/ Estate	Name of village	Vaccines defaulted	Traced-/B- Not traced-)	Outcome(C- vaccinated at the facility D-Vaccinated elsewhere, E- Refered to other facility ,F-not traced)	e.t.c)
A	В	С	D	E	F	G	Н	1	J	К	L	М
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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





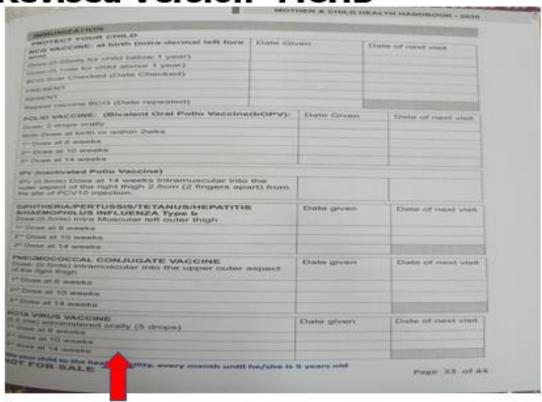
Mother & Child Health Booklet – MOH 216

Old Version - MCHB

DIPHTHERIA/PERTUSSIS/TETANUS/HEPATITIS B/HAEMOPHILUS INFLUENZA Type b Dose: (0.5mls) Intra Muscular left outer thigh	Date given	Date of next visit
1 st Dose at 6 weeks	15	3
2 rd Dose at 10 weeks		
3rd Dose at 14 weeks	1	
PNEUMOCOCCAL CONJUGATE VACCINE Dose: (0.5mls) intramuscular into the upper outer aspect of the right thigh	Date given	Date of next visit
1* Dose at 6 weeks		1 8
2 nd Dose at 10 weeks		
3 rd Dose at 14 weeks		
ROTA VIRUS VACCINE 1.5mls administered orally, slowly	Date given	Date of next visit
1" Dose at 6 weeks	1.5	
2 [™] Dose at 10 weeks		

Record the third dose of Rota vaccine in the space just below the second dose.

Revised Version- MCHB



MCHB has third dose of Rota indicated





MOH 510 Immunization Permanent Register

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

OLD Version – MOH 510

Revised Version – MOH 510

PCV 10 Pneumococ cal) 3 Rota1 Rota2 Rota2 W X Yellow Fever Ch Rota2 AA AB A

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	BCG	Polio birth Dose	OPV 1	OPV 2	OPV 3	IPV	DPT / Hep.B / Hib.1	DPT / Hep.B / Hib.2	DPT / Hep.B / Hib.3	PCV 10 (Pneumoc occal) 1		(Pneumoc	Rota 1	Rota 2	Rota 3	Vitamin A(6-11 months)	MR1	Yello v Fever	Fully Immunized Child.	MR2
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MOH 702 Tally sheet

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

Old Version – MOH 702

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	000	
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	00000	
Rola 3— Vitamin A	At 6 -11 Months (100,000IU)	00000	00000	00000	00000	00000	00000	00000	00000	0000	00000	
	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	00000	0000	0	
Yellow fever		00000	00000	00000	00000	00000	00000	00000	00000	0000	00	
	Above 1 Year		00000	00000	00000	00000	00000	00000	0000	0000	00	
MR 1	Under 1 Year	00000						00000	0000	000	00	
	Above 1 Year	00000	00000	00000	00000	00000			2000	000	00	

Revised – MOH 702

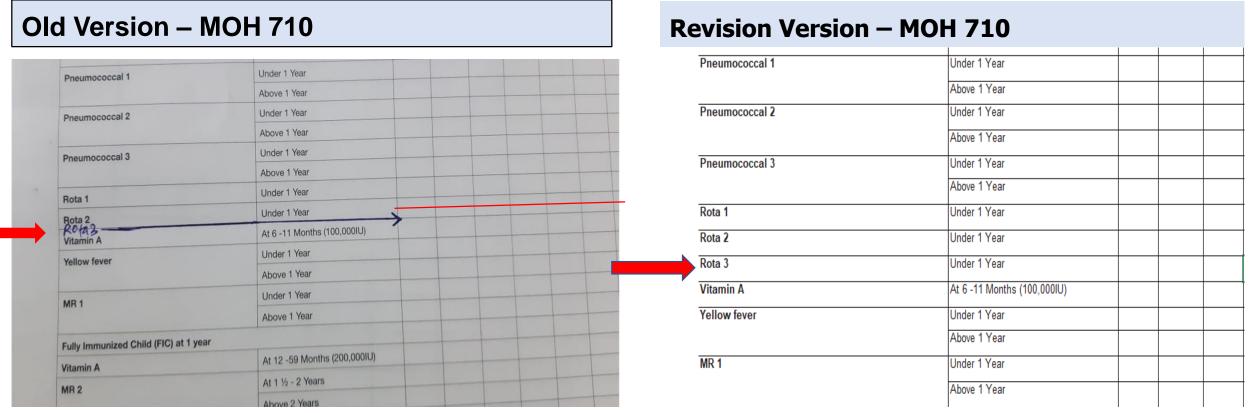
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		Above 1 Year	00000	00000	00000	00000	00000	00000	00000	
	Pneumococcal 2	Under 1 Year	00000	00000	00000	00000	00000	00000	00000	
		Above 1 Year	00000	00000	00000	00000	00000	00000	00000	
	Pneumococcal 3	Under 1 Year	00000	00000	00000	00000	00000	00000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





MOH 710 Summary sheet

- Transfer the tallies for third dose of Rota from the Tally sheet to the Summary sheet
- Using a ruler, divide the Rota 2 row into two and record Rota3







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 (%) = Number vaccinated in 2021 X 100
 # of surviving infants in 2021
- Q2. Calculate the drop-out-rate.
- Drop-out-rate = <u>Dose 1 Dose 3</u> X 100 Dose 1
- Q3. Calculate the number of unvaccinated children.
- Unvaccinated children = Target population/Surviving infant Total vaccinate dose 3





Answer

• Q1. 76.4%

• Q2. 14%

• Q3. 262

• <u>Note:</u>

• Discuss on Health facility X performance and their mitigation measure to increase their coverage and reduce their drop-out-rate.





End of module



Thank you for your attention!







MODULE: 7

Rotavac® Vaccine Adverse Events Following Immunization



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

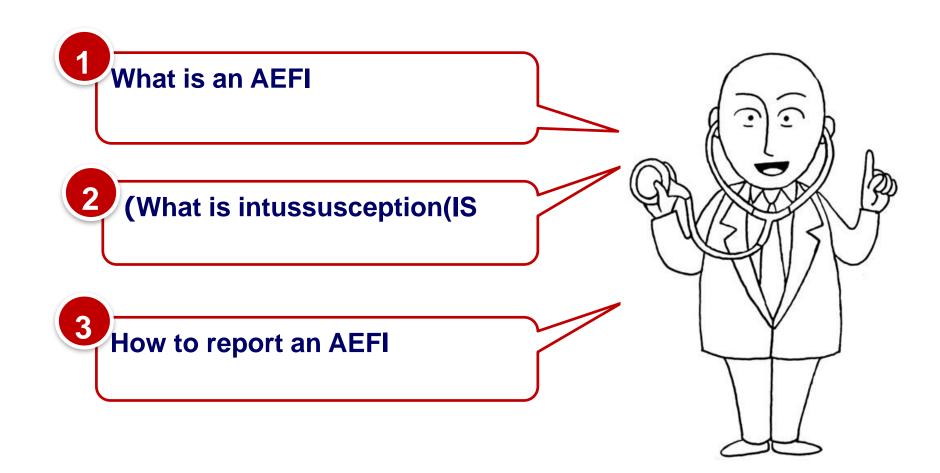


- Duration
 - 15mins





Key issues







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
- Diarrhoea- Risk is lower than that of severe rotavirus disease

Rare

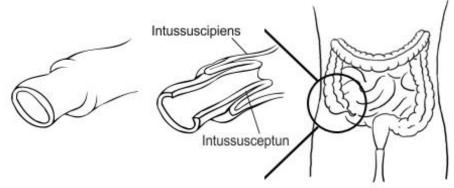
- Intussusception rare type of intestinal obstruction
- Risk is lower than that of severe rotavirus disease
- Whether the rotavirus vaccine effects the overall incidence of IS has not yet been established





What about Intussusception (IS)?

 In the past, the first rotavirus vaccines (RotashieldTM) caused Intussusception (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 intussusception 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

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...

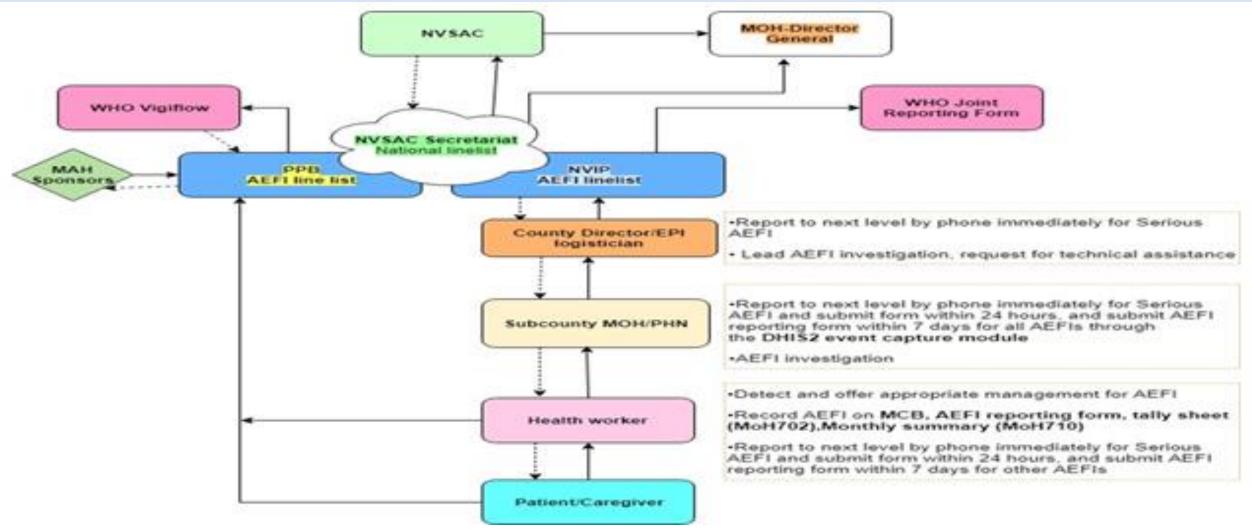
- Type of vaccine(s) administered
- Route of administration
- Associated event(s)
- Reporter details fully filled for assistance in follow up of client during investigation
- Investigations to be completed for serious events

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AEFI Reporting Pathway







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







MODULE: 8

Advocacy Communication and Social Mobilization -ACSM



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 techniques

- Effective communication maintains respect and trust between health workers, families and communities.
- Asking questions in order to understand and listen to community members experiences and perspectives.
- 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.
- Providing simple, practical information about who will receive the vaccine, why
 and where





Discussion

What are the most common concerns or questions you receive from the caregivers in your health facility on

Rota vaccine switch

Give a few examples.







ACTIVITY: Role Play

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 6 weeks

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

- a) subsequent Rota vaccine doses
- b) Measles Rubella second dose





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 Pneumococcal 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
- Given at 6 weeks, 10 weeks and 14 weeks
- Interval of 4 weeks between the 3 doses
- 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 expected Vaccine Reaction

- 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

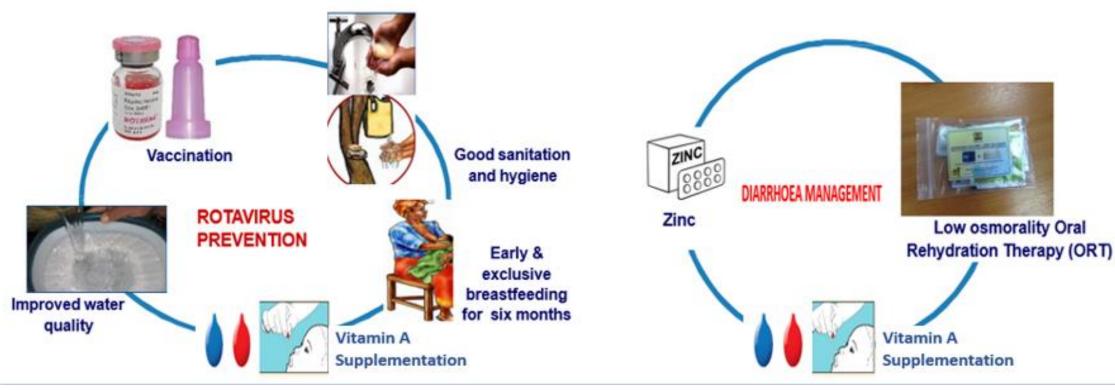






Rotavirus Prevention and Diarrhoea Management

The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoea diseases with the scaling up of both prevention and Treatment packages







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 diarrhoea caused by other agents therefore it is important to continue practicing good hygiene and sanitation behavior; and other related behaviours
- On-time vaccination is very important
- Ongoing dialogue may successfully reassure vaccine-hesitant parents that immunization is the best and safest option for their infant





Key messages Cont..



- 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
- 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





End of module





