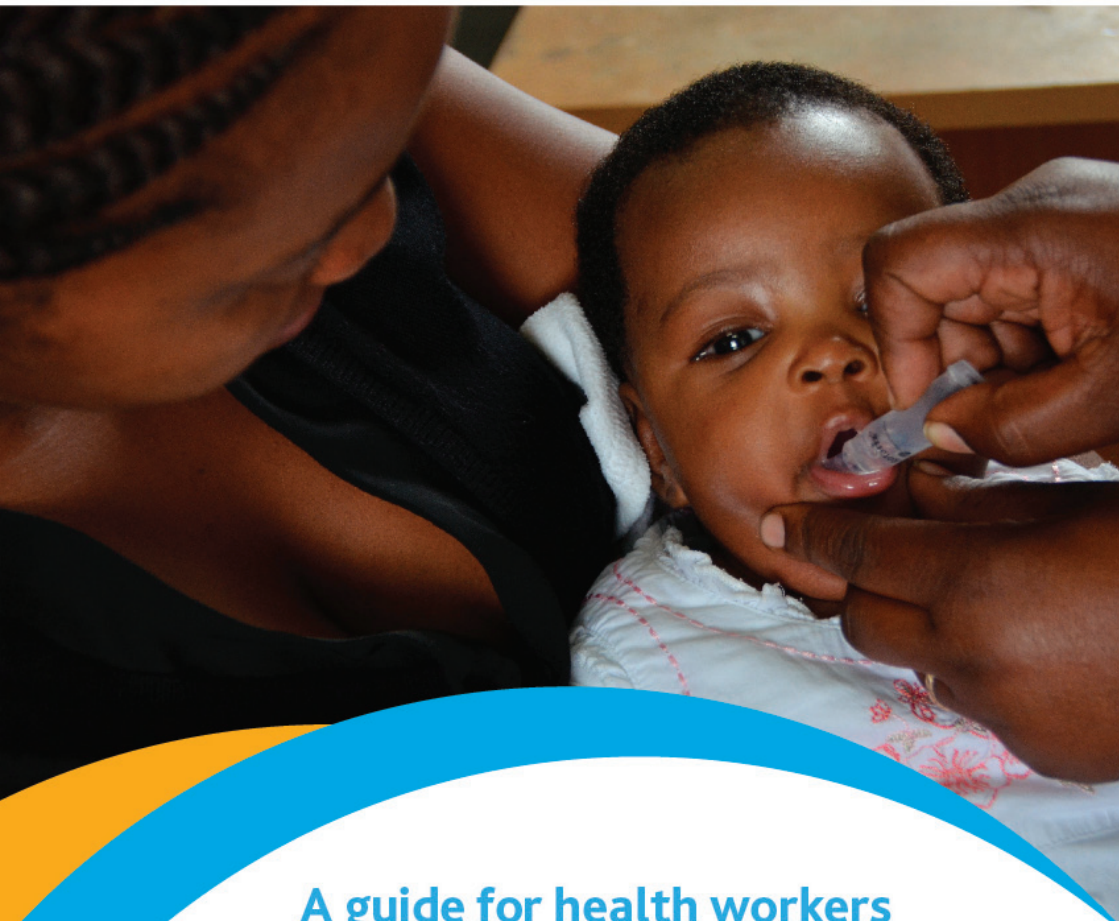


# INTRODUCTION OF ROTAVIRUS VACCINE INTO ROUTINE IMMUNIZATION IN KENYA



**A guide for health workers**





Rotarix™ Vaccine

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# PREFACE

This training guide has been developed primarily for health workers involved in immunization services delivery in Kenya to prepare them for the introduction of the Rotavirus vaccine that will be introduced into the national infant immunization schedule from July 2014. The training guide was adapted from the WHO guidelines for the Rotavirus vaccine introduction and also incorporates product information from the current manufacturer of the Rotarix vaccine – GlaxoSmithKline. As such, all references made to Rotavirus vaccine in this manual refer to ROTARIX, a liquid formulation presented in a single dose-dose tube of 1.5ml.

Although this training guide is being released with the introductory process for the ROTARIX, it will continue to be a useful reference point long afterwards for new health workers being inducted into immunization services delivery.

This guide was developed by the technical committees formed to spearhead the introduction of the ROTAVIRUS vaccine led by the Training Committee. It is a team effort of all of the technical staff of the Unit of Vaccines & Immunization Services and dedicated officers from various partner agencies. Over a period of two months, a remarkable amount of individual time, energy and patience has been committed to the process for which we are truly grateful.

It is the hope of the Ministry of Health, and especially the Unit of Vaccines & Immunization Services that the guide will improve immunization service delivery for all infants in Kenya.



**Dr. Ephantus Maree**  
**Head, Unit of Vaccines & Immunization Services**

# ACKNOWLEDGEMENT

The Ministry of Health through the Unit of Vaccines and Immunization Services is grateful to all partners and individuals whose valuable contributions and technical support made it possible to develop this guide for health workers.

We wish to thank the Head, Unit of Vaccines and Immunization Services, Dr. Ephantus Maree and his team for the exemplary leadership during the process. We wish to acknowledge the collaboration between the Unit and the partners supporting immunization services in Kenya. Special thanks to, WHO, UNICEF, USAID's MCHIP and CHAI for their financial and technical support.

Though not possible to list all who participated in the preparation of this guide individually, the Ministry of Health sincerely appreciates all contributions made and the commitment to the process.

A handwritten signature in dark ink, appearing to read 'Patrick Amoth', is centered on the page.

**Dr. Patrick Amoth**  
**Head, Division of Family Health**

The Ministry of Health, through Unit of Vaccines and Immunization Services (UVIS) will be introducing a new vaccine into routine infant immunization schedule nationwide with effect from July 2014. The new Rotavirus vaccine (Rotarix) will be administered to all children eligible for the first dose of pentavalent vaccine (DPT-HEPB+HIB) at 6 and 10 weeks of age.

Rotavirus is the most common cause of severe diarrhea among infants and young children. The Rotavirus vaccine will protect against the most severe forms of diarrhoea disease in childhood. Given that the rotavirus vaccine does not prevent diarrhoea caused by other agents, it is practical that we advocate for scaling up of implementation of other cost effective health and behavioural interventions that control, prevent and protect against all forms of diarrhoeal diseases. These include, hand washing, early and exclusive breastfeeding, proper nutrition and early management of severe dehydration using Zinc tablets and low osmolar ORS.

Although in the past, rotavirus vaccines have been associated with the risk of intussusception (IS), WHO has analysed that risk and has concluded that the risk of IS after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated children. Hence, rotavirus vaccine is strongly recommended to prevent rotavirus disease in infants.

The primary objective of introducing the rotavirus vaccine is to reduce the morbidity and mortality due to severe diarrhoea among infants and young children. It offers tremendous benefits by protecting infants and children from rotavirus disease

This training guide is intended to equip health workers at all levels with sufficient information to ensure smooth integration of the new Rotavirus vaccine into the routine infant immunization schedule.

The Rotavirus vaccine to be provided by the Ministry of Health is an *oral formulation presented in single-dose squeezable tube*.

It is my sincere hope that the Rotavirus vaccine will be introduced successfully and sustained smoothly for the benefit of all Kenyan children.



**Dr. William K. Maina, OGW**  
**Director, Directorate of Preventive & Promotive Health Services**



# ROTAVIRUS DISEASE

## INTRODUCTION

Rota virus is the most common cause of diarrhoeal illness in children worldwide. It is highly infectious with high morbidity and mortality rates, especially in children from developing countries. Rotavirus was discovered by Ruth Bishop in 1973.

## THE VIRUS

Rota virus is a double stranded RNA virus belonging to the Reoviridae family. It has a complex wheel-like structure with a triple-layered icosahedral protein capsid composed of an outer layer, an intermediate layer and an inner core layer. The outer capsid contains 2 structural proteins, the VP4 and VP7 antigens, which are important in classification and vaccine development. There are seven groups of the virus, A-G, with A, B, and C found in humans and animals and D, E, F and G found only in animals. Group A Rota virus is of the greatest clinical significance. There are several serotypes based on the VP4 and VP7 antigens.

## EPIDEMIOLOGY

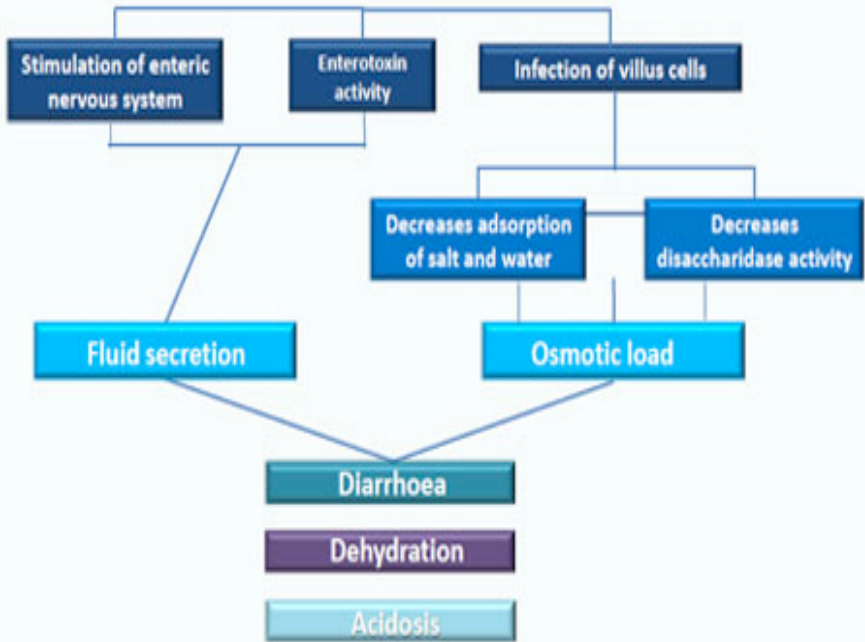
Rota virus gastroenteritis is the leading cause of diarrhoea related illness and death among infants and young children. Rota virus is found throughout the world and it affects both the rich and the poor. 95% of children worldwide are infected within the first 3 to 5 years of life, irrespective of race or socioeconomic status. Most severe infections occur in children under the age of 2 years and nearly half of Rota virus deaths occur in Africa. It is estimated that worldwide, Rota virus results in 25 million outpatient visits/year, 2 million admissions/year and 527,000 deaths/year in children less than 5 years of age. It is the most common diarrhoeal pathogen causing hospitalization in both industrialized and less developed countries, accounting for approximately 40% in both. Rotavirus prevalence in Kenya over the last 3 decades range between 11-56% with G1 being the predominant genotype.

## TRANSMISSION

It is highly contagious. Humans are the main reservoirs although it also affects animals. It is spread predominantly by the faecal oral route by contamination of food, water and environmental surfaces such as toys. This is especially important in infants and young children as they frequently put their hands and toys into their mouths. Rota virus is highly stable and can survive for hours on human hands and for several days on solid surfaces. It remains infective in human stool for up to one week. It is relatively resistant to commonly used disinfectants but is inactivated by high concentrations of alcohol, chlorine or iodine. Transmission can occur before onset of symptoms and can persist for up to 8 weeks after symptoms have subsided.

# PATHOPHYSIOLOGY

## Pathophysiology of rotavirus diarrhoea



# CLINICAL PRESENTATION

The incubation period of the disease is 2-4 days. The most common clinical features are:

- 1. Vomiting which usually precedes the diarrhoea.**
- 2. Diarrhoea: profuse watery diarrhoea, up to 20 episodes /day that can last for 3-9 days.**
- 3. Fever.**

Other symptoms include abdominal pain, nausea and malaise. Occasionally, the child may have respiratory symptoms and CNS features like headaches and rarely convulsions.

Potential consequences of untreated severe Rota virus gastroenteritis include severe dehydration, metabolic acidosis, electrolyte imbalances, hypovolemic, circulatory collapse and death. The greatest proportions of hospitalizations occur in children 6-24 months of age. The lack of access to



appropriate rehydration therapy during severe Rota virus gastroenteritis results in high mortality rates in the developing world. Natural immunity to Rotavirus infection develops after the first infection, which is usually the most severe. Subsequent infections are less severe.

## DIAGNOSIS

Diagnosis is usually made on clinical grounds and Rotavirus should be suspected in children less than 24 months of age who present with acute onset of vomiting, diarrhoea and fever.

## MANAGEMENT

As it is a viral infection, there is no specific treatment for the disease. Early and appropriate institution of oral rehydration fluids, continued feeding and zinc supplementation are recommended.

## PREVENTION

Since Rota virus affects both the rich and the poor, and is resistant to the common anti-septics, improvement in sanitation and hygiene are unlikely to reduce the incidence of infection. Fortunately, it is now a vaccine preventable disease. Two vaccines against the Rota virus antigen (Rotarix™ and Rotateq™) are licensed by WHO and both have excellent clinical efficacy.

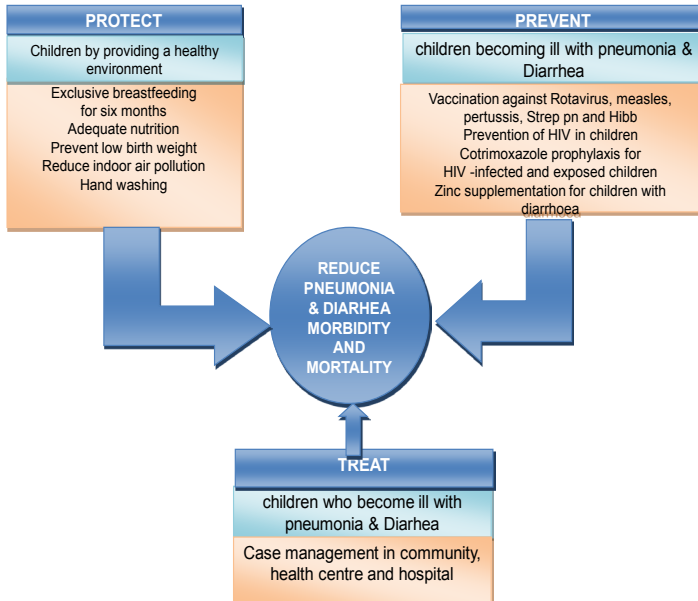
## INTEGRATION APPROACH TO DIARRHOEA PREVENTION AND CONTROL

If planned properly, rotavirus vaccine introduction should provide momentum for scaling up the implementation of the Kenya Action Plan for Pneumonia and Diarrhoea Prevention and Control (KAPPD). The Plan proposes a cohesive approach to ending preventable diarrhoea deaths. It brings together critical services and interventions to create healthy environments, promote practises known to protect children from diseases and ensure that every child has access to proven and appropriate preventive and treatment measures.

In order to achieve this goal, at all levels of the health sector better coordination and integration among programmes that deliver the different interventions is critical. These programmes include:

- *Newborn, Child and Adolescent Health Unit (NCAHU),*
- *Nutrition Unit,*
- *Environmental health Unit*
- *relevant Partners*

## FRAMEWORK FOR COMPREHENSIVE PREVENTION OF PNEUMONIA & CONTROL OF DIARHEAL DISEASES



## Rotavirus vaccines types

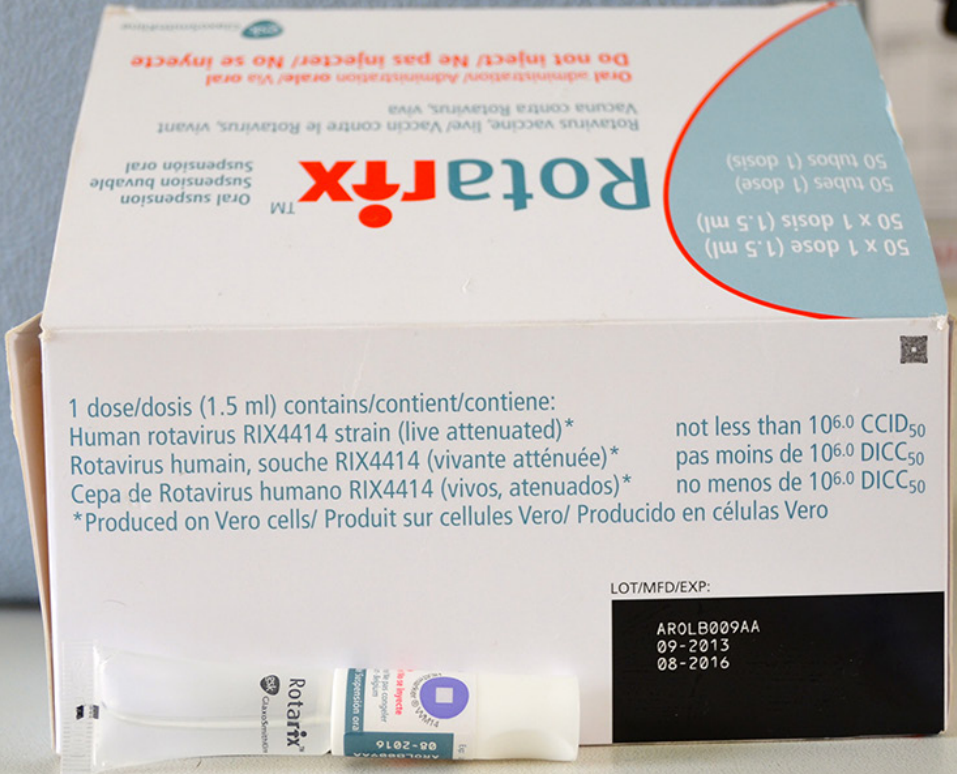
Currently two oral rotavirus vaccines are marketed internationally:

- **The monovalent (RV1) Rotarix® (GlaxoSmithKline Biologicals, Rixensart, Belgium)**
- **The pentavalent (RV5) RotaTeq® (Merck & Co. Inc., West Point, PA, USA).**

Available efficacy and safety data support selection of either of the two vaccines for national use. Although both rotavirus vaccines are efficacious, data show that their efficacy is higher in settings with low mortality in children under five years of age (vaccine efficacy ~ 90%) than, in settings with high mortality in children under five years of age (vaccine efficacy~ 60%). Because the incidence of rotavirus disease is significantly higher in high child mortality settings, the number of severe disease and deaths averted by rotavirus vaccines in these settings is likely to be greater than in low mortality settings, despite the lower vaccine efficacy.

Rotarix and RotaTeq are orally-administered, live, attenuated rotavirus vaccines prequalified by WHO. The vaccines differ in antigen composition and immunization schedule. Rotarix is manufactured by GlaxoSmithKline (GSK) and is available in three presentations, and RotaTeq is manufactured by Merck & Co and is available in one presentation.

It is important to bear in mind that rotavirus vaccine will not prevent or protect diarrhoea or vomiting caused by other germs, but it is very effective at preventing diarrhoea and vomiting caused by rotavirus. This means that even when children are fully immunized against rotavirus, they may still get diarrhoea caused by other agents. For control and prevention of other forms of diarrhoeal diseases refer to the Kenya Action Plan for Prevention and control of Pneumonia & Diarrhoea (KAPPD) strategy.



Oral suspension  
Suspension buvable  
Suspension oral

**Rotarix™**

Rotavirus vaccine, live/ Vaccin contre le Rotavirus, vivant  
Vacuna contra Rotavirus, viva

Do not inject/ Ne pas injecter/ No se inyecte  
Oral administration/ Administration orale/ Via oral

50 x 1 dose (1.5 ml)  
50 x 1 dosis (1.5 ml)  
50 tubes (1 dose)  
50 tubos (1 dosis)

1 dose/dosis (1.5 ml) contains/contient/contiene:  
Human rotavirus RIX4414 strain (live attenuated)\*  
Rotavirus humain, souche RIX4414 (vivante atténuée)\*  
Cepa de Rotavirus humano RIX4414 (vivos, atenuados)\*  
\*Produced on Vero cells/ Produit sur cellules Vero/ Producido en células Vero

not less than 10<sup>6.0</sup> CCID<sub>50</sub>  
pas moins de 10<sup>6.0</sup> DICC<sub>50</sub>  
no menos de 10<sup>6.0</sup> DICC<sub>50</sub>

LOT/MFD/EXP:  
AROLB009AA  
09-2013  
08-2016

Package for Rotarix™

Rotarix™ Vaccine



<b>FORMULATION</b>	<b>ROTARIX VACCINE</b>
Administration	Oral Squeeze tube
Dose size	1.5 mls
Dose per tube	1 (single)
Storage Temperature	Should be kept at +2° C to +8°C, protected from light and should not be frozen
Shelf life	36 months from manufacturing date stored at appropriate temperature
Vaccine Vial Monitor	VVM 14
Packed volume per dose	17.1cm3 per dose

## DIFFERENT TYPES OF ROTARIX IN THE MARKET

GSK Rotarix® - monovalent, human strain, live, attenuated, oral rotavirus vaccine			
Vaccine type	RV1 is a live vaccine		
Route of administration	Oral		
Presentation	Liquid Rotarix™ in oral applicator (single dose)	Liquid Rotarix™ in squeezable polyethylene tube (single dose)	Lyophilized Rotarix™ vaccine reconstituted with CaCO <sub>3</sub> buffer (single dose)
Vaccine picture			
Administration	Administered orally using the applicator	Administered orally using the tube	Administered orally using the applicator
Vaccine Vial Monitor (VVM)	Has VVM 14	Has VVM 14	Has VVM 14
Packaging	1 and 10 oral applicators per pack.	1,10, or 50 tubes of single-dose per pack	1 and 10 single-doses per pack.
Source	GSK Biologicals		

Rotavirus vaccine can be co-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 vaccine first, and then administer other childhood vaccines

## Revised vaccination schedule

Timing is critical for rotavirus vaccine administration. UVIS recommends that infants be given two doses of Rotavirus vaccine at:

**6 weeks,**

**10 weeks.**

Contact	Vaccine dose	Age of child	Dosage	Route
1	BCG OPV birth dose	At birth or at first contact At birth or at first contact (within the first two weeks of life)	0.05 ml 2 drops	Intradermal Oral
2	OPV I DPT-HepB+Hib 1 PCV 10-1	At six weeks of life or at first contact	2 drops 0.5ml 0.5 ml	Oral Intramuscular into the upper outer aspect of the thigh
	ROTA-1	At 6 ( six) weeks or at first contact < 1yr	1.5ml(entire tube)	Oral
3	OPV II DPT-HepB+Hib 2 PCV10-2	At 10 weeks or 4 weeks after OPV I and DPT-HepB-Hib 1	2 drops 0.5 ml 0.5 ml	Oral Intramuscular into the upper outer aspect of the thigh
	ROTA-2	At 10 (Ten) weeks or 4 weeks after Rota 1	1.5ml(entire tube)	Oral
4	OPV III DPT-HepB+Hib 3 PCV 10- 3	At 14 weeks or 4 weeks after OPV II and DPT-HepB-Hib 2	2 drops 0.5 ml	Oral Intramuscular into the upper outer aspect of the thigh
5.	V i t a m i n . A 100,000IU	At 6 months of age	One capsule	Orally
6	Measles 1 <sup>st</sup> dose	At 9 months or first contact after 9 months	0.5 ml	Subcutaneous into the left upper arm (deltoid muscle)
7	Yellow fever	At 9 months or first contact after 9 months – in four special districts	0.5 ml	Subcutaneous into the right upper arm (deltoid muscle)



8.	V i t a m i n . A 200,000IU	At 12 months of age	One capsule	Orally
9	Measles.2 <sup>nd</sup> dose	At 18 months or first contact after 18 months	0.5 ml	Subcutaneous into the right upper arm (deltoid muscle)
10.	Vitamin A 200,000IU	At 18 months of age	One capsule	Orally

**NB: Yellow fever vaccine is currently given routinely to children in Baringo and Elgeyo Marakwet Counties.**

# Rotavirus vaccine storage

Good temperature control during the storage and transport of vaccines is critical to ensure the potency and safety of vaccines.

The rotavirus vaccine should be stored in a refrigerator, **between +2°C and +8°C**. Do not put rotavirus vaccine in the freezer. If the vaccines are frozen, they lose their potency and no longer provide protection against the disease.

## RCW 42 EG & RCW 50 EG

VACCINE TRAY ARRANGEMENT IN A HORIZONTAL (CHEST OPENING) FRIDGE		
	VACCINE	TRAY COLOR CODE
Tray 1	•PCV	•RED
Tray 2	•Pentavalent	•ORANGE
Tray 3	•TT + IPV	•YELLOW
Tray 4	•Rotavirus	•GREEN
Tray 5	•BCG+ Measles	•BLUE
Tray 6	•OPV + Yellow fever	•PURPLE

## SIBIR V170 GE

VACCINE TRAY ARRANGEMENT IN A VERTICAL (FRONT OPENING) FRIDGE		
	VACCINE	TRAY COLOR CODE
Tray 1	•OPV + Yellow fever	•PURPLE
Tray 2	•BCG+ Measles	•BLUE
Tray 3	•Rotavirus	•GREEN
Tray 4	•TT + IPV	•YELLOW
Tray 5	•Pentavalent	•ORANGE
Tray 6	•PCV	•RED

**Rotavirus vaccine should be placed in the GREEN tray in between the BCG and TT vaccines as shown on the tray colour code.**

Do not open the refrigerator door often. Regularly monitor the temperature of the refrigerator

Vaccines with early expiration dates (and/or VVM in stage 2 (or nearing stage 2) if it has a VVM) should be kept in the front of the refrigerator for first use.



# 3

## VACCINE ELIGIBILITY

Timely immunisation is vital, as a vaccine can only protect if given before infection; this is especially critical for rotavirus vaccine, as infections can start from the first weeks of life, and children under 6 months are particularly vulnerable to rotavirus infection.

In Kenya, all children under one year are eligible to receive the rota virus vaccine. However, because the risk of rotavirus infection increases after three months, health workers should encourage caregivers to bring their children before they turn 3 months but preferably at 6 weeks for the first dose and 10 weeks for the second dose.

In the introduction year, rotavirus vaccine shall be administered to children receiving the first dose of pentavalent vaccine. However, rotavirus vaccine shall be administered to eligible children even if the pentavalent vaccine is out of stock or unavailable for whatever reason.

Given the epidemiology of the disease in developing countries, children aged over two year do not benefit from vaccination with rotavirus vaccine. In Kenya, the vaccine will not be administered to children above one year

# 4

## VACCINE ADMINISTRATION

### Vaccine administration

#### Before preparing rotavirus vaccine

Before administering the vaccine, you need to verify and interpret the Vaccine Vial Monitor (VVM) and always check the expiration date marked on the tube cap.

### Prepare for vaccination

#### Step 1:

Pull off the cap from the tube. Clear the fluid from the upper part of the tube by tapping the tube.



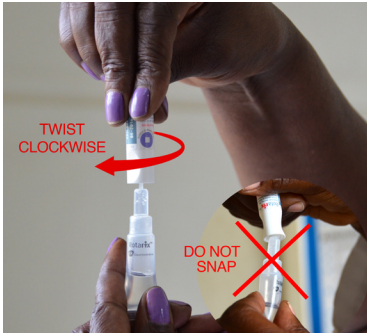
#### Step 2:

Turn the cap upside-down and place the cap vertically onto the tip seal. Insert the tip seal into the small hole in the top of the cap.



### Step 3:

Twist the cap in the direction of the arrow (clockwise) to remove the tip seal. Do not snap off tip seal: It may fall into tube.



### Step 4:

Ensure that a hole clearly appears at the top of the tube and the detached tip seal is inside the top of the cap. It is very important to note that the vaccine must be discarded if the tip seal falls into the tube.



# Administer the vaccine



The child should be seated in a semi reclining position (i.e. normal feeding position) to take the vaccine orally.



## Step 1:

Open the mouth of the child by gently pressing the cheeks.



## Step 2:

Put the tube towards the inner cheek. Make every effort to aim the tube containing the vaccine down one side and toward the back of the child's mouth. Do not put the tube too far back in the mouth. Never place the tube into the center of the mouth to prevent

the risk of choking.



### Step 3:

Administer the vaccine slowly by pressing the tube. Prevent spitting by administering the vaccine in small portions slowly.



### Step 4:

Make sure the child is swallowing the vaccine. Hold the cheeks together and stroke him/her under the chin to help with swallowing. A replacement dose maybe given if the child spits part of the vaccine.

# 5

## ADVERSE EVENTS FOLLOWING IMMUNIZATION

Though rotavirus is safe, no vaccine is devoid of adverse events. Following administration of rotavirus vaccine, some children may experience the following adverse events:

Gastrointestinal:

- *Diarrhoea*
- *Flatulence*
- *Abdominal pain*

Irritability Skin:

- *Dermatitis*
- *Itching*

### Contraindications and Precautions

Rotavirus vaccine should not be administered to children who have:

- ★ History of allergy to either the active substance or any of the vaccine components
- ★ History of adverse reaction after previous administration of rotavirus vaccine
- ★ History of intussusception
- ★ Uncorrected congenital malformation of the gastrointestinal tract that may predispose to intussusception

As with many vaccines, a minor infection is not a contraindication for rotavirus vaccine. However, administration of rotavirus vaccine should be postponed in children suffering from acute severe febrile illness, diarrhoea or vomiting.

With the old Rotavirus vaccine called the Rotashield vaccine, studies suggested that the Rotavirus vaccine may be associated with a slight increased risk of intussusception (IS) in infants after they receive the vaccine, during the first week. However, according to the U.S. Centers for Disease Control and Prevention, the risk of IS after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated children. Hence, rotavirus vaccine is strongly recommended to prevent rotavirus disease in infants.

As a precaution, 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/guardians should be advised to promptly report such symptoms.



# 6

# MONITORING OF ROTA VACCINATION COVERAGE

The introduction of the Rotavirus vaccine has necessitated revision of all recording and reporting tools to conform to the unique requirements of the vaccine as follows:-

## Basic recording tools

Minor adjustments have been made on the following basic recording tools to conform with new vaccine introduction:

- *Mother & Child Booklet – MOH 216*
- *Permanent register – MOH 510*
- *Tally sheet – MOH 702*
- *Monthly summary sheet- MOH 710*

Revisions made include:

### 1. The Mother-Child booklet

- ★ Rotavirus vaccine was included in the 2013 edition. However the age restriction at 32 weeks has been removed and the vaccine can now be given to children under 1 yr

### 2. Immunization permanent register

- ★ Columns for 1<sup>st</sup> and 2<sup>nd</sup> dose of Rotavirus vaccine have been introduced
- ★ Health workers need to review the permanent register weekly to identify children who failed to turn up for doses due and follow up.

### 3. Tally and summary sheets

- ★ Both tally and summary sheets were revised to include Rotavirus vaccine 1 and 2.

**Following the introduction of Rotavirus vaccine, a Fully Immunized Child (FIC) at 1yr is an infant who has received all the routine infant immunization doses based on the revised immunization schedule under 1 yr (surviving infants)**

*The inclusion of Rotavirus vaccine in the definition of FIC commences six months after the introduction*

## **Proper use of recording tools:**

- ★ Record information in the permanent register on first contact with the infant
- ★ Transfer same information to Mother and Child Health Booklet
- ★ Tally the vaccinated infant appropriately as you immunize
- ★ Transfer the information from tally sheet to the summary form on daily basis.
- ★ Summarize facility data and forward to the Sub counties by the 5<sup>th</sup> of the following month.
- ★ Sub counties shall upload the summarised data from MOH 710 on DHIS by 15<sup>th</sup> of every month

## Triple A communication

There are three ways of communicating with parents/caregiver:

**Advice:**

Provide advice to parents/caregivers on what is given: the name of the vaccine, the disease to prevent, etc.

**Alert:**

Alert parents/caregivers of side effects after immunization and how to respond to them

**Arrange:**

Arrange with parents/caregivers the next appointment for administering the second dose of the vaccine

To effectively communicate with parents/caregivers, you must first understand the concerns of parents regarding immunization and understand factors that can lead to misinformation about the safety and effectiveness of vaccines.

You should establish an open, friendly dialogue with vaccine-hesitant parents/caregivers at an early stage and provide clear answers to their questions and accurate information about vaccination.

In summary, you should:

- ★ **Be respectful: Smile often, be friendly**
- ★ **Use simple words** to make sure the caretaker understands your key messages: Look directly at caretakers and try to judge by their body language if they have understood your messages. Reword and simplify if needed.
- ★ **Listen to caretaker's concerns: Do not get angry or irritated** when parents / caregivers ask questions or raise concerns

Ongoing dialogue may successfully reassure vaccine-hesitant parents that immunization is the best and safest option for their child.

## Inform about Rotavirus Disease

Rotavirus is a virus that causes diarrhea, sometimes severe, mostly in babies and young children. It is often accompanied by vomiting and fever and can lead to dehydration.

Rotavirus is not the only cause of diarrhea, but it is one of the most serious. Almost every child in

the world will suffer from at least one infection by the time he or she is three years old. The primary mode of transmission of rotavirus is the passage of the virus in stool to the mouth of another child.

## Communicate about diarrhea prevention methods

Prevention and treatment methods against rotavirus disease include

- ★ Early and exclusive breastfeeding for first 6 months and continued breastfeeding up to 2 years,
- ★ Improvements in nutrition, hygiene, and water quality,
- ★ ORS/Zinc
- ★ Vaccination with rotavirus vaccine

These can reduce diarrheal disease and child mortality where diarrheal disease is a serious burden. But enhancing sanitation and hygiene is not enough to prevent the disease and stop the spread. Currently, vaccination is the only way to prevent severe episodes of rotavirus infection.

## Communicate about the new rotavirus vaccine

- ★ Millions of children have received rotavirus vaccine in the last 8 years and the vaccine is considered very safe and effective.
- ★ The rotavirus vaccine must be given to babies orally, which means swallowed and not injected. This vaccine is given at the same time with pentavalent vaccine; therefore no extra visit is required for this vaccine. Rotavirus vaccine does not prevent diarrhoea caused by other agents. Therefore it is important to practice hand washing, sanitation and other hygienic behaviours
- ★ Explain to the parents/caregivers that it is important to **get vaccinated on time**. If the infant is brought in late for vaccination, he/she may not get rotavirus vaccine. Worse still, he/she may suffer from the disease with fatal consequences.
- ★ Rotavirus vaccine is given orally in 2 doses at ages **6 and 10 weeks**. There should be an interval of at least **4 weeks** between the 2 doses.

## Communicate about side effects and how to respond

- ★ Current rotavirus vaccines are generally safe.

- ★ Following vaccination, children may be more irritable and have loss of appetite. Some children may also experience fever, fatigue, diarrhea, and vomiting
- ★ If the child has a high fever ( $>39^{\circ}\text{C}$ ), advice parents/caregivers to expose and tepid sponge the child and bring the child back.
- ★ Parents/caregivers should be advised to promptly report the following symptoms. Severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever.
- ★ Parents/caregivers have to understand that the risks of the side effects after rotavirus vaccination are much lower than the risk of severe rotavirus disease in unvaccinated children.

## Arranging for a return visit



Make an appointment for the next dose of rotavirus vaccine and other vaccines according to the immunization schedule.

Ensure that a minimum gap of 4 weeks is maintained.

Ensure that there is a session on the given date (no public holiday, weekend, etc.)

- ★ Write the date of the next visit on the **immunization card** and remind the parent / caregivers to come on the due date and to **bring the card**.

## Annex 1: Advocacy and communication

### ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION

Advocacy, communication and social mobilisation are key components of the successful introduction of Rota Virus vaccine into national childhood immunisation schedule. The introduction of Rota virus vaccine will ensure availability to children to a vaccine that protects them from the major causes of diarrhoea – a disease that is one of the leading causes of morbidity and mortality among children less than 5 years in Kenya. Recently more vaccines has been introduced in the national immunization schedule and therefore making effective, clear and consistent communication for healthcare workers and caregivers is critical to the uptake of Rota virus vaccines and adherence to this life-saving vaccination. With effective well planned strategies for advocacy, communication and social mobilisation before, during and after the introduction phase will make an impact on the burden of Rota virus disease. Focussed effective advocacy with decision makers, social mobilisation, communication with parents and caregivers, and training healthcare workers regarding the introduction of the new vaccines will ensure smooth introduction of Rota virus vaccine. Correct information on Rota virus disease, vaccination regime, side effects, vaccine safety and potential advantages of rota vaccine vaccination will lead to high and sustained demand of the vaccine by caregivers. Mis information may lead to mistrust or lack of confidence in the vaccine hence, the need to inform families and communities of the potential benefits of immunization, the safety of vaccines, and where and when services can be accessed. Health workers must be knowledgeable and skilled in communicating with service users. At minimum, every adult who leaves a place of immunization should know about Rota disease, vaccine, the possibility of side effects and what to do if they arise, and when and where the child has to return for the next immunization. In addition, the health worker should encourage the caregivers to make a return visit according to schedule and ensure that the services are available. A mix of communication strategies will be employed to ensure the public is mobilized for the Rota vaccines. This will include: 1. Sensitization meetings for stakeholders at central, county and sub county levels 2. National, County and Sub county launches 3. National and regional mass media (Print & Electronic) 4. Social institutions especially schools, religious places and market places 5. Community based organizations, civil societies and Non governmental organizations 6. Information, education and communication materials for targeted audiences

# Annex 2:

MINISTRY OF HEALTH																													
UNIT OF VACCINE AND IMMUNIZATION SERVICES (UVIS)																													
IMMUNIZATION AND VITAMIN A TALLY SHEET ( MOH 732 )																													
Name of Health Facility (Static or Outreach)					Constituency					District					County					Month					Year				
Tally all the Vaccine and Vitamin A as you Administer (The Tally Sheet should be available in all immunizing health facilities)																													
Antigen	Age	Days of the month /Name of facilities																		Total									
BCG	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
OPV (Birth dose)	Within 2 weeks	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
OPV1	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
OPV2	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
OPV3	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
IPV (Given with OPV 3)	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
DPT+HB+HEPB 1	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
DPT+HB+HEPB 2	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
DPT+HB+HEPB 3	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Pneumococcal 1	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Pneumococcal 2	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Pneumococcal 3	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Rotax 1	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Rotax 2	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Vitamin A At 6 Months (100,000 IU)	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Yellow fever	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Measles 1	Under 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 1 Year	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Fully Immunized Child (FIC) at 1 year		0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Vitamin A At 1 Year (200,000 IU)	At 1 Year (200,000 IU)	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	At 1 To 2 Years (200,000 IU)	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Measles 2	At 1 ½ - 2 Years	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Above 2 Years	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Tetanus Toxoid for pregnant women	1st Dose	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	2nd Dose	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
	3rd Dose	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
	4th Dose	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
	5th Dose	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Adverse Events Following Immunization		0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Vitamin A 2 Years to 5 Years (200,000 IU) Including Mothers (200,000 IU)	2 Years to 5 Years (200,000 IU)	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000								
	Including Mothers (200,000 IU)	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									
Signs/Write E: no reflexion (Under 1 Year)		0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000									

Revised March 2014





# Annex 3: Immunization Summary Sheet (MOH 710)

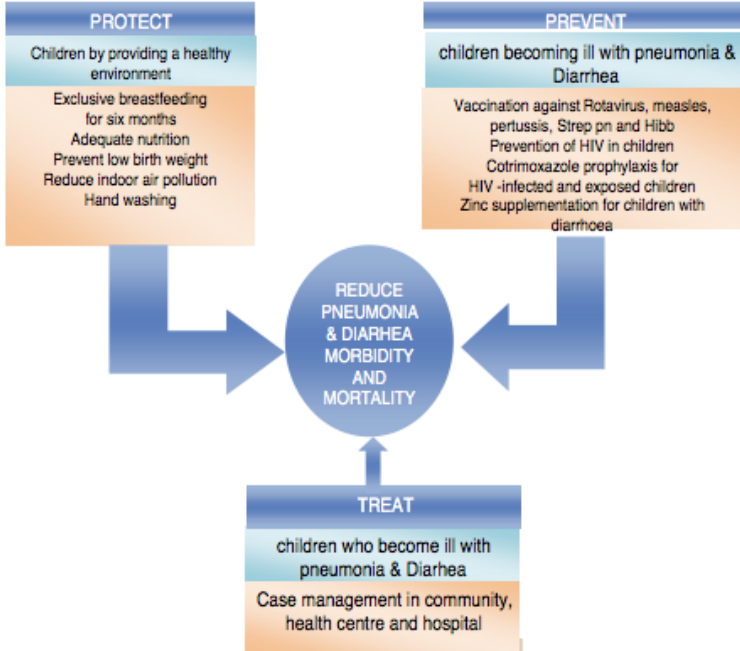
MINISTRY OF HEALTH														
UNIT OF VACCINE AND IMMUNIZATION SERVICES (UVIS)														
INTEGRATED IMMUNIZATION, VITAMIN A, OPHTHALMOLOGY AND EPI LOGISTICS SUMMARY SHEET (MOH 710)														
Facility Name _____		Constituency _____		Sub-constituency _____		County _____		Month _____		Year _____				
Number of Immunizing health facilities (During the month) _____						Total Number of Reporting EPI health facilities (For the month) _____								
Complete Section A and B, then in Section B only monthly total to be filled at the Health facility level														
SECTION A														
ARTICLEN	AGE	FACILITY/DATE OF MONTH										Total out reach	Grand Total	
BCG	Under 1 Year													
	Above 1 Year													
OPV (Birth dose)	Within 2 weeks													
OPV1	Under 1 Year													
	Above 1 Year													
OPV2	Under 1 Year													
	Above 1 Year													
OPV3	Under 1 Year													
	Above 1 Year													
IPV	Under 1 Year													
	Above 1 Year													
DPTwB+H+EPB 1	Under 1 Year													
	Above 1 Year													
DPTwB+H+EPB 2	Under 1 Year													
	Above 1 Year													
DPTwB+H+EPB 3	Under 1 Year													
	Above 1 Year													
Pneumococcal 1	Under 1 Year													
	Above 1 Year													
Pneumococcal 2	Under 1 Year													
	Above 1 Year													
Pneumococcal 3	Under 1 Year													
	Above 1 Year													
Rotax 1	Under 1 Year													
Rotax 2	Under 1 Year													
Vitamin A	All 6 Months (100,000 IU)													
Yellow fever	Under 1 Year													
	Above 1 Year													
Measles 1	Under 1 Year													
	Above 1 Year													
Fully Immunized Child (FIC) at 1 year														
Vitamin A	All 1 Year (200,000IU)													
	All 1 1/2 Year (200,000IU)													
Measles 2	All 1 1/2 - 2 Years													
	1st Dose													
	2nd Dose													
	3rd Dose													
	4th Dose													
	5th Dose													
Tetanus Toxoid for pregnant women														
	1st Dose													
	2nd Dose													
	3rd Dose													
	4th Dose													
	5th Dose													
Adverse Events Following Immunization														
Vitamin A	2 Years to 5 Years (200,000IU)													
	Lasting Mothers (200,000IU)													
Squid/White Eye reflexion	Under 1 Year													
SECTION B COLD CHAIN LOGISTIC AND VACCINE STOCK OUTS. FILL MONTHLY TOTALS AT FACILITY LEVEL EVERY COLUMN SHOULD HAVE COLD CHAIN INFORMATION AND VACCINE'S & VITAMIN A STOCK OUT														
<b>IMMUNIZATION LOGISTICS</b> (NB: If more than one equipment, separate each entry with a slash e.g Model: PCV420G-SIBR VITD2C Serial No. 39482648 )	<b>Cold Chain Equipment</b>													
	Type (Freezer or Refrigerator)													
	Model													
	Serial No.													
	Working Status (Y/N)													
	Energy Source (E/G/S)													
	Equip. age in Yrs													
	<b>Vaccines and Vitamin A stock-out and age</b>													
	Type (Vaccine)													
	No. Days													
	Type (Vaccine)													
	No. Days													
	Type (Vitamin A)													
	No. Days													

Revised March 2014



# Annex 5: KAPPD FRAMEWORK

## FRAMEWORK FOR COMPREHENSIVE PREVENTION OF PNEUMONIA & CONTROL OF DIARHEAL DISEASES



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