Government of Malawi

Field Manual

for

Introduction of Rotavirus Vaccine

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Preface

The Ministry of Health, with support from GAVI Alliance and other collaborating partners, is introducing a new vaccine – Rotavirus vaccine, after the pneumococcal conjugate vaccine (PCV13) that was introduced in 2011 and the pentavalent vaccine in 2002. The Rotavirus vaccine protects against rotavirus, the most common cause of severe diarrhoea in children under five and responsible for 25-50% of severe diarrhoeal cases worldwide. Similar to other vaccines that are currently provided through the EPI Programme, the vaccine is only targeting children below one year of age.

Rotarix, the Rotavirus formulation that Malawi will be introducing, provides about 90-100% protection against severe rotavirus disease and about 74-85% protection against rotavirus diarrhoea of any severity. Protection against the most common circulating rotavirus strains has been demonstrated for Rotarix vaccine.

This field manual has been developed primarily for EPI managers. Coordinators and healthcare workers involved in immunization services delivery to prepare them for the introduction of the Rotavirus vaccine that will be introduced into the national infant immunization schedule in October 2012. This field manual will first be used during the training sessions for the introduction of the Rotavirus vaccine, and will subsequentlyalso serve as a reference guide for all healthcare workers, managers, and EPI coordinators involved in providing immunization services. It contains general information on best practices of managing immunization services and specific information for the handling of the Rotarix vaccine.

One of the most important issues with Rotavirus vaccination administration that healthcare workers should know is the schedule. The new 2-dose Rotarix vaccine will be administered at the same time as other existing routine vaccines that are given at the ages of 6 and 10 weeks. The first dose must be administered at 6 to 15 weeks, and the second dose before 32 weeks; vaccination should not be initiated for infants above 15 weeks. The two doses must be given with a minimum interval of 4 weeks between first and second doses.

The Ministry of Health is committed to the prevention and control of vaccine-preventable diseases in the country. We believe that the concerted efforts of all stakeholders involved in the introduction of the Rotavirus vaccine in Malawi will contribute to the achievement of the Millennium Development Goals (MDG 4). We hope that this manual will contribute to a smooth introduction of the Rotavirus vaccine and improve immunization service delivery for the benefit of all infants in Malawi.

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The Ministry of Health through the Expanded Programme on Immunization extends its sincere appreciation to all partners that were involved in the production of this field manual. The following organizations are specifically acknowledged for their leading roles:

- The World Health Organization
- The United Nations Children's Fund
- Clinton Health Access Initiative
- United States Agency for International Development
- Maternal Child Health Integration Program
- Support for Service Delivery Integration - Services

Many partners and individuals have also made valuable contributions towards the development of this manual and their contributions are also appreciated.

The Ministry of Health is grateful to Clinton Health Access Initiative (CHAI) for financial support for the printing of this training manual.

Abbreviations and Acronyms

AD	Autodisable syringe
AEFI	Adverse events following immunization
BCG	Bacillus of Calmette Guiren
CHAI	Clinton Health Access Initiative
DPT-HepB-Hib	Diphtheria, Pertusis, Tetanus, Hepatitis B, Haemophilus influenza type B vaccine
EPI	Expanded Programme on Immunization
FAQs	Frequently Asked Questions
FEFO	First-expiry-first-out
FIC	Fully immunized child
FT	Fridge-Tag
GACVS	Global Advisory Committee on Vaccine Safety
GAVI	Global Alliance for Vaccines & Immunization
GSK	GlaxoSmithKline
IEC	Information, Education and Communication
IM	Intramuscular Injection
MCHIP	Maternal Child Health Integration Program
MoH	Ministry of Health
OPV	Oral Polio Vaccine
ORS	Oral Rehydration Solution
PATH	Program for Appropriate Technology in Health
PCV13	Pneumococcal Conjugate Vaccine with 13 serotypes
SAGE	Strategic Advisory Group of Experts on Immunization
SSDI	Support for Service Delivery Integration - Services
TT	Tetanus Toxoid vaccine
UNICEF	United Nation Children's Fund
USAID	United States Agency for International Development
VVM	Vaccine Vial Monitor
WHO	World Health Organization

Table of Contents

Preface 2
Acknowledgements 3
Abbreviations & Acronyms 4
Table of Contents 5
List of Tables 6
List of Figures 6
List of Annexes 7
1. Rotavirus Disease 8
1.1 Rotavirus 9
1.2 Mode of transmission 9
1.3 Clinical manifestation 9
1.4 Epidemiological characteristics 9
1.5 Diagnosis 12
1.6 Treatment 12
1.7 Prevention 12
1.8 Rotavirus vaccine 13
1.8.1 Efficacy 14
1.8.2 Safety of vaccine 14
1.8.3 Vaccination schedule 14
1.8.4 Vaccine preparation and administration 16
1.8.5 Contraindications 20
1.8.6 Precautions 20
2. Adverse events following immunization (AEFI) 20
2.1 Classification of AEFIs 21
2.1.1 Vaccine reactions 21
2.1.2 Program errors 22
2.1.3 Injection reactions 23
2.1.4 Coincidental AEFIs 23
2.1.5 Unknown causes of AEFIs 23
2.2 Management of vaccine reactions 24
2.2.1 Management of minor common vaccine reactions 24
2.2.2 Management of anaphylactic shock, a rare severe vaccine reaction 24
2.3 AEFI Surveillance 24
2.3.1 Which AEFIs should be reported? 24
2.4. AEFI Investigation 25
3. Cold Chain and Vaccine Management 25
3.1 Vaccine storage 25
3.1.1 Packing the vaccine carrier 27
3.1.2 Conditioning frozen ice-packs 28
3.1.3 Vaccine vial monitor 28
3.1.4 Fridge-Tag 29
3.1.5 Freeze–Tag 29
3.1.6 Shake Test 30
3.2 Vaccine management 31
3.2.1 Estimation of vaccine requirements 31

3.2.2 Estimating vaccine needs on the basis of target population 31
3.2.3 Calculating vaccine wastage 32
3.2.4 Vaccine wastage 32
3.2.5 Stock management 32
3.2.6 Safe waste management 33
4. Communication 34
4.1 Interpersonal communication 34
4.2 Key messages on Rotavirus vaccine 34
4.2.1 For Healthcare Workers 34
4.2.2 For Caregivers 35
5. Monitoring, Evaluation and Supervision 35
5.1 Monitoring 35
5.1.1 Basic recording tools 36
5.2 Supervision 36
5.3 Post-Introduction Evaluation 36
6. Frequently asked questions on Rotavirus disease and vaccine 37
7. Annexes 39
8. References 46

List of Tables

Table 1: Operational characteristics of Rotarix vaccine 13
Table 2: Recommended Schedule of the Rotavirus Vaccine 15
Table 3: Revised Immunization & Vitamin A Supplementation Schedule 16
Table 4: Classification of AEFIs 20
Table 5: Types of Vaccine Reactions 21
Table 6: Common Programme Errors & Associated Events 22

List of Figures

Figure 1 : Causes of under-five year deaths in low income countries 8
Figure 2 : Causes of severe diarrhoea requiring hospitalization of infants and young children 10
Figure 3 : Global mortality due to rotavirus 10
Figure 4 : Seasonality of rotavirus infection in children 11
Figure 5 : Age distribution of children with rotavirus gastroenteritis at QECH, Blantyre, Malawi 11
Figure 6 : Preventative Measures for Diarrhoeal Diseases 13
Figure 7: Sample Rotarix vial and box 14
Figure 8: Timing of Rotavirus Vaccine Doses 15
Figure 9: Recommended Order of Administration of Vaccines When Giving 4 Vaccines at Once 17
Figure 10: Instructions on Oral Administration of Rotavirus Vaccine 18
Figure 11: Example of tube with a broken nozzle lodged inside 19
Figure 12: How to administer the Rotavirus vaccine 19
Figure 13: Diagram Showing How Intussusception Occurs 22
Figure 14: Reportable Incidents 25
Figure 15: Placement of Vaccines in Upright Refrigerator 26
Figure 16: Placement of Vaccines in Chest Refrigerator 26
Figure 17: Foam pad in use 27
Figure 18: How to read a Vaccine Vial Monitor (VVM) 28
Figure 19: VVM on Rotarix tubes 29

Figure 20: Fridge-Tag 29
Figure 21: Freeze-Tag 30
Figure 22: Shake Test Sedimentation Rates 30
Figure 23: Monthly Vaccine Requirements Calculation 31
Figure 24: Vaccine Usage & Wastage Rate Calculations 32
Figure 25: First-Expiry-First-Out (FEFO) Principle 33
Figure 26: Safe Disposal of Sharps 34

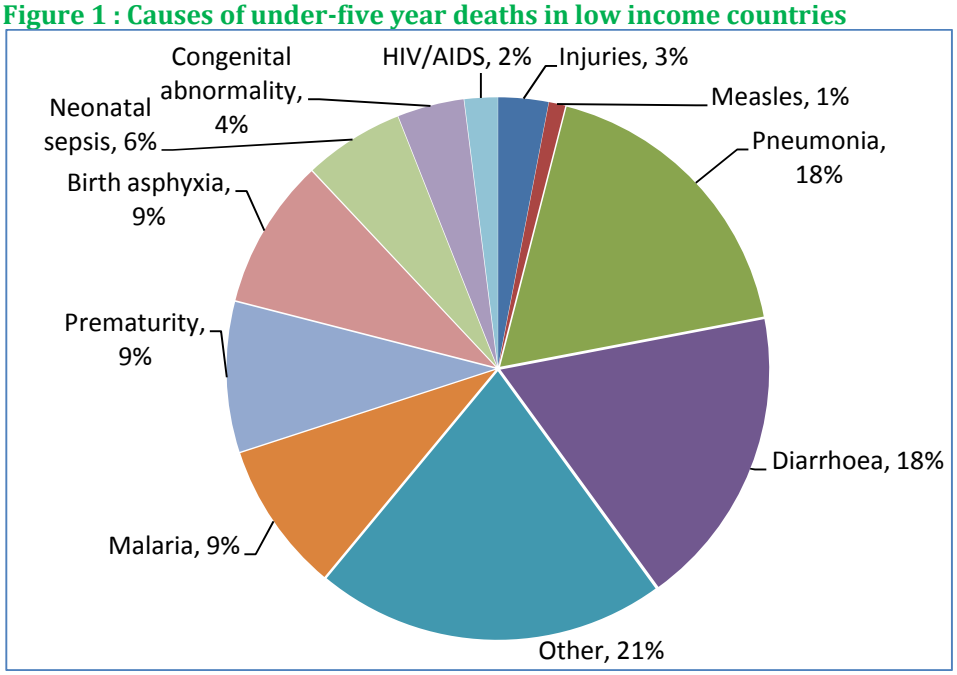
List of Annexes

Annex 1: Adverse Events Following Immunization (AEFI Event Description) Report Form 39
Annex 2: Under 1 Register 40
Annex 3: Daily Temperature Recording & Vaccine Monitoring Tool 41
Annex 4: Monthly Vaccination Performance & Disease Surveillance Report Form 42
Annex 5: Fridge-Tag Guide 43
Annex 6: Steps for Communication During Immunization Session 45

1. Rotavirus Disease

Diarrhoeal disease is one of the leading causes of child mortality, responsible for the deaths annually of an estimated 1.8 million children <5 years of age worldwide. Diarrhoea accounts for 18% of child deaths in low-income countries (Figure 1). Rotavirus, the most common cause of severe diarrhoea in children under five, causes 25%–50% of severe diarrhoeal cases worldwide. While nearly every child is at risk of rotavirus infection, nearly 95% of rotavirus-related deaths occur in developing countries where access to treatment is limited or unavailable.

Figure 1 : Causes of under-five year deaths in low income countries



An estimated 527,000 children die each year from rotavirus infection, and over two million are hospitalized worldwide. The burden of rotavirus disease is substantial throughout the world in both developed and developing countries. Regardless of where they live, nearly every child is infected with rotavirus at least once before the age of five, with the first infection usually occurring before two years of age.

Diarrhoeal diseases are among the top ten causes of under five deaths in Malawi accounting for 7% for under 5 deaths in 2010. It is estimated that deaths caused by rotavirus account for 4.3% of all under 5 deaths in the Malawi (WHO). In the Malawi Demographic Health Survey (DHS) 2010, 18% of the children under 5 years had a diarrhoeal episode in the 2 weeks preceding the survey. The prevalence of diarrhoea varied by age with children aged 6 – 23 months being more prone than children in other age groups. WHO recommends the inclusion of rotavirus vaccination of infants into all national immunization programmes.

Use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoeal diseases. A coordinated approach that combines rotavirus vaccines with other prevention and treatment methods, including community-based administration of oral rehydration solution, zinc supplementation, breastfeeding, improvements in water, sanitation, and hygiene, proper nutrition, and overall improvements in case management will achieve the greatest impact on diarrhoeal disease morbidity and mortality (deaths and hospitalizations). It is estimated that 88% of diarrhoeal deaths are potentially preventable using the above measures.

1.1 Rotavirus

First recognized in 1973, rotavirus belongs to the viral family Reoviridae. Scientists called it "rota" virus after its wheel-like shape when seen under an electron microscope. Rotavirus infection has also been detected in many species of domestic animals, and wild mammals and birds, but animal-to-human transmission appears to be rare.

1.2 Mode of transmission

Rotavirus is highly contagious. Individuals suffering rotavirus diarrhoea often shed large amounts of virus in the stool. Rotavirus is spread primarily by the faecal-oral route directly from person-to-person or indirectly via contaminated fomites. Since infection occurs early in life, the majority of older children and adults develop some immunity against rotavirus disease. Humans are the only known reservoir of rotavirus that lead to clinical manifestation of the disease.

1.3 Clinical manifestation

Clinical manifestations of rotavirus infections vary and depend on whether it is the first infection or re-infection. In young children, rotavirus disease is characterized by diarrhoea, vomiting and fever, and may lead to severe dehydration and death. Death is usually caused by dehydration due to rotavirus gastroenteritis. Diarrhoea is defined as watery or loose stools three times per day or more than the usual frequency for the individual.

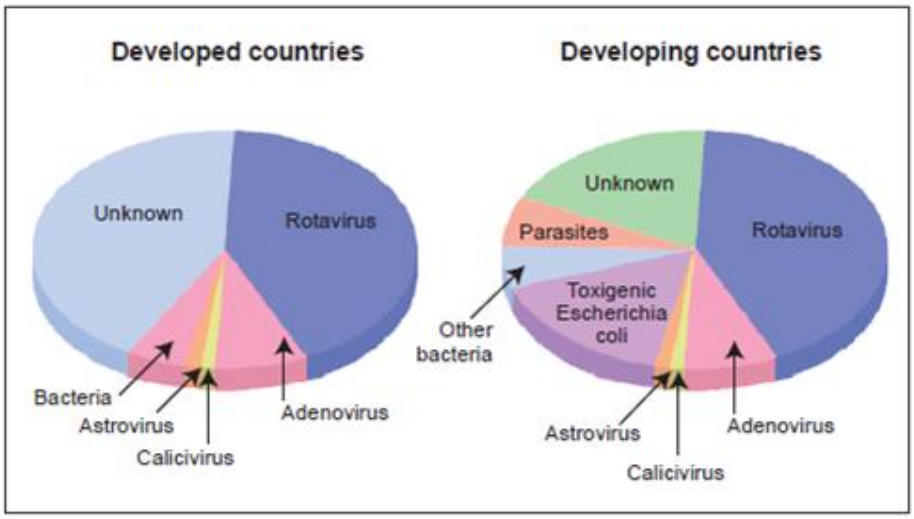
The illness may be asymptomatic, may cause self-limited watery diarrhoea or may result in severe diarrhoea with vomiting and complications like dehydration, electrolyte imbalance and metabolic acidosis and death. Up to one-third of patients may have a temperature greater than 39°C. The incubation period is short, usually less than 48 hours. The gastro intestinal symptoms usually resolve within 3-7 days. Children can spread rotavirus from 2 days before to 10 days after the onset of symptoms.

Children with rotavirus may suffer frequent vomiting that makes it difficult to administer oral rehydration solution (ORS) at home; medical care is then required. Full recovery from the first rotavirus infection usually does not lead to permanent immunity, yet subsequent infections confer progressively greater protection and are generally less severe than the first. The first infection which occurs after three months of age is generally the most severe; later infections may be milder or asymptomatic due to previously acquired cross-immunity.

1.4 Epidemiological characteristics

Human rotavirus is a major cause of severe diarrhoea among infants and young children. Rotavirus consistently outranks other known causes of severe diarrhoea in children <5 years of age.

Figure 2 : Causes of severe diarrhoea requiring hospitalization of infants and young children



Source: *Fields Virology*, 5th ed. Philadelphia, Lippincott Williams & Wilkins, 2007 (8).

The incidence of rotavirus infection is similar in both developed and developing countries. However, more than 80% of rotavirus deaths occur in developing countries, particularly in the poorest countries of Africa, Asia and Latin America, where poverty, malnutrition and limited access to health services exacerbate the problem.

Figure 3 : Global mortality due to rotavirus

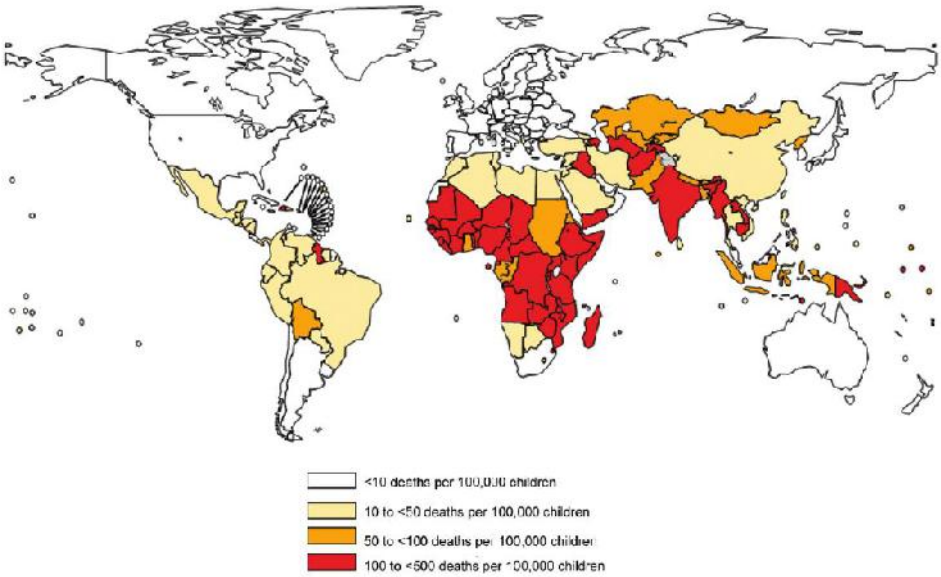
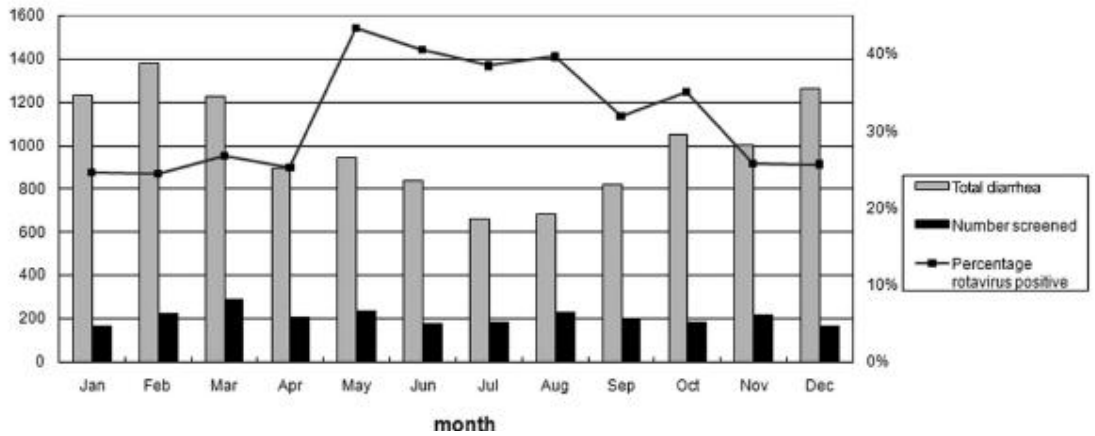


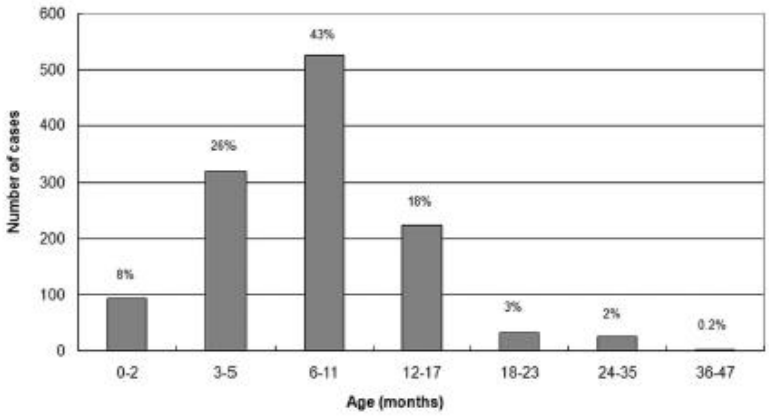
Figure 4 : Seasonality of rotavirus infection in children[1]



Seasonality of rotavirus infection in children (inpatients only) with acute gastroenteritis at the Queen Elizabeth Central Hospital, Blantyre, Malawi, 1997-2007 (each month was combined for the 10 years). Grey bars represent the estimated total number of hospitalizations for diarrhoea per month among children <5 years of age (data extracted from pediatric ward admission book).

Based on data gathered in Blantyre, Rotavirus circulates year round in Malawi with peak detection in dry season, when other types of diarrhoea are less common. Rotavirus was detected in 1/3 of all cases of severe diarrhoea. More than three quarters of rotavirus gastroenteritis cases occurred in infants under the age of 1 with a median age of 7.8 months. Children ages 6-11 months were the most frequently affected.

Figure 5 : Age distribution of children with rotavirus gastroenteritis at QECH, Blantyre, Malawi[1]



Age distribution of children with rotavirus gastroenteritis at the Queen Elizabeth Central Hospital, Blantyre, Malawi, 1997-2007 (combined inpatients and outpatients).

[1] Cunliffe, N., Ngwira, B., Dove, W. et al. *Epidemiology of rotavirus infection in children in Blantyre, Malawi, 1997-2007.* Journal of Infectious Diseases, 2010; 202(S1).

Two populations are most at risk of severe diarrhea caused by rotavirus:

1) Infants older than 3 months; and
2) Older children if they are immunocompromised.

The disease is most severe in infants after the age of 3 months at which age they are likely to get their first infection, have no immunity, and are very vulnerable to dehydration. Older children are also at risk especially if they are immunocompromised. Children who are immunocompromised may experience severe prolonged rotavirus gastroenteritis (persistent diarrhoea lasting more than 14 days) and may have evidence of abnormalities in multiple organs, including the kidneys and liver.

1.5 Diagnosis

Detailed guidelines for the diagnosis and treatment of childhood diarrhoea in Malawi are set out in the manual titled *Management of Diarrhoea in Under Five Children Using Low Osmolarity ORS and Zinc* and in the *Integrated Management of Childhood Illness (IMCI) handbook*. Diagnosis is based on clinical symptoms including the extent of dehydration, the type of diarrhoea exhibited, whether blood is visible in the stool, and the duration of the diarrhoea episode. Laboratory diagnosis is not required to initiate treatment for any form of diarrhoea.

Rotavirus diarrhoea is not possible to distinguish from other causes of gastroenteritis on clinical grounds alone. Laboratory tests to confirm Rotavirus infection can only be done in certain specialized laboratories.

1.6 Treatment

The objectives of treatment are to:

- Prevent dehydration, if there are no signs of dehydration;
- Treat dehydration when it is present;
- Prevent nutritional damage by feeding during and after diarrhoea; or
- Reduce the duration and severity of diarrhoea and the occurrence of future episodes by giving supplemental zinc.

Rotavirus disease cannot be treated with antibiotics or other drugs. The treatment package focuses on three main elements:

1) Fluid replacement to prevent dehydration, including use of oral rehydration solution (ORS) when necessary;
2) Zinc treatment to limit the duration of the diarrhoeal episode; and
3) Counseling on continued feeding for a sick child including breastfeeding.

1.7 Prevention

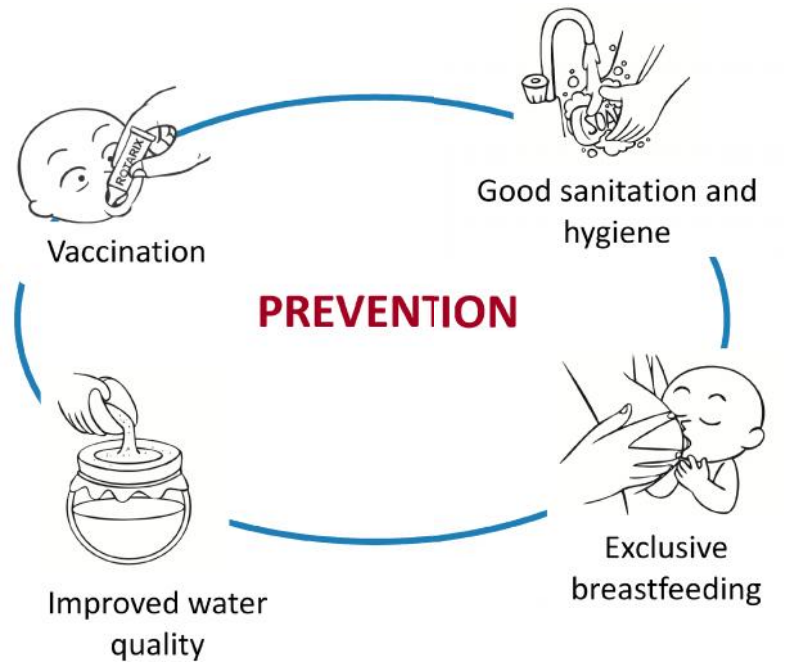
The preventive package highlights main elements that require a concerted approach in their implementation. These are:

- Vaccination against rotavirus;
- Vaccination against measles;
- Promotion of early and exclusive breastfeeding and vitamin A supplementation;
- Promotion of hand washing with soap;
- Promotion of food safety practices;

- Improved water supply quantity and quality including treatment and safe storage of household water; and
- Community-wide sanitation promotion, including use of latrines and safe disposal of stools.

Prevention options, such as improved water hygiene, can reduce the burden of other causes of diarrhoea, but are less effective in preventing rotavirus diarrhoea. Hence rotavirus vaccination represents the best hope for preventing mortality from the most severe episodes of rotavirus infection, particularly in impoverished regions where access to medical care is limited.

Figure 6 : Preventative Measures for Diarrhoeal Diseases



1.8 Rotavirus vaccine

The rotavirus vaccine is used to prevent cases of severe diarrhoea caused by rotavirus. The rotavirus vaccine in use in Malawi is Rotarix. Rotarix is one of the two currently WHO pre-qualified licensed rotavirus vaccines. Rotarix is a live, attenuated vaccine and requires two doses to complete the schedule. The vaccine is given orally at 6 weeks and 10 weeks, at the same time as the first and second doses of oral polio vaccine (OPV), Pentavalent vaccines and PCV 13. Rotarix is stored at temperatures between +2°C and +8°C.

Table 1: Operational characteristics of Rotarix vaccine

Formulation	Rotarix vaccine
Administration	Oral Squeeze tube
Dose size	1.5 mls
Dose per tube	1
Storage Temperature	+2°C to +8°C
Shelf life	36 months from manufacturing date stored at appropriate temperature
Vaccine Vial Monitor	VVM 14
Packed volume per dose	17.1cm^3 per dose

Figure 7: Sample Rotarix vial and box

1.8.1 Efficacy

The live attenuated oral Rotarix vaccine provides about 50%–100% protection against severe rotavirus disease and about 74%–85% protection against rotavirus diarrhoea of any severity, depending on the schedule of administration and the population evaluated. Protection against the most common circulating rotavirus strains has been demonstrated for the Rotarix vaccine. In follow-up studies, the protection against severe rotavirus infection has been shown to extend into the second year. In Malawi, a study of Rotarix vaccine found a protective benefit of 49.5% against severe gastroenteritis – a finding which is consistent with findings that the rotavirus vaccines have lower efficacy in developing countries compared with developed countries. Possible factors that have been suggested include the reduced nutritional status of children in developing countries, co- infections with other gastrointestinal infections, etc.

1.8.2 Safety of vaccine

The vaccine has been evaluated by the WHO using data from research studies (including from Malawi and four other African countries) and experiences of countries that have introduced the vaccine including Australia, the United States, and countries in Latin America. WHO has concluded that the vaccine is safe for administration, including to infants who are HIV-positive or HIV-exposed.

1.8.3 Vaccination Schedule

The efficacy and safety data currently available support selection of either of the two vaccines for national use. The recommended schedule for Rotarix is described in Table 2. See Table 3 for the schedules of the vaccines in the national EPI. WHO recommends that the first dose of Rotarix be administered to infants when they are 6 weeks to 15 weeks of age. The maximum age when administration of the last dose of Rotarix is recommended is 32 weeks of age.

Table 2: Recommended Schedule of the Rotavirus Vaccine

Composition	Rotarix
Number of doses	2
Age of vaccination	First dose: age 6-15 weeks
	Second dose: age 10-32 weeks; 4 weeks interval after first dose
Maximum age for administration of the first vaccine dose	Not later than 15 weeks of age
Maximum age for administration of the second vaccine dose	Schedule should be completed before 32 weeks of age
Need for booster doses	No
Co administration	With OPV, Penta and PCV13

Important Notes:

- **Rotavirus vaccine should be administrated simultaneously with other childhood vaccines, preferably during the 6 and 10-week visit;**
- **Do not start rotavirus vaccination after 15 weeks of age.**
- **Must complete the schedule by 32 weeks of age.**
- **No boosters or catch-up campaigns are recommended for rotarix vaccines.**

Figure 8: Timing of Rotavirus Vaccine Doses

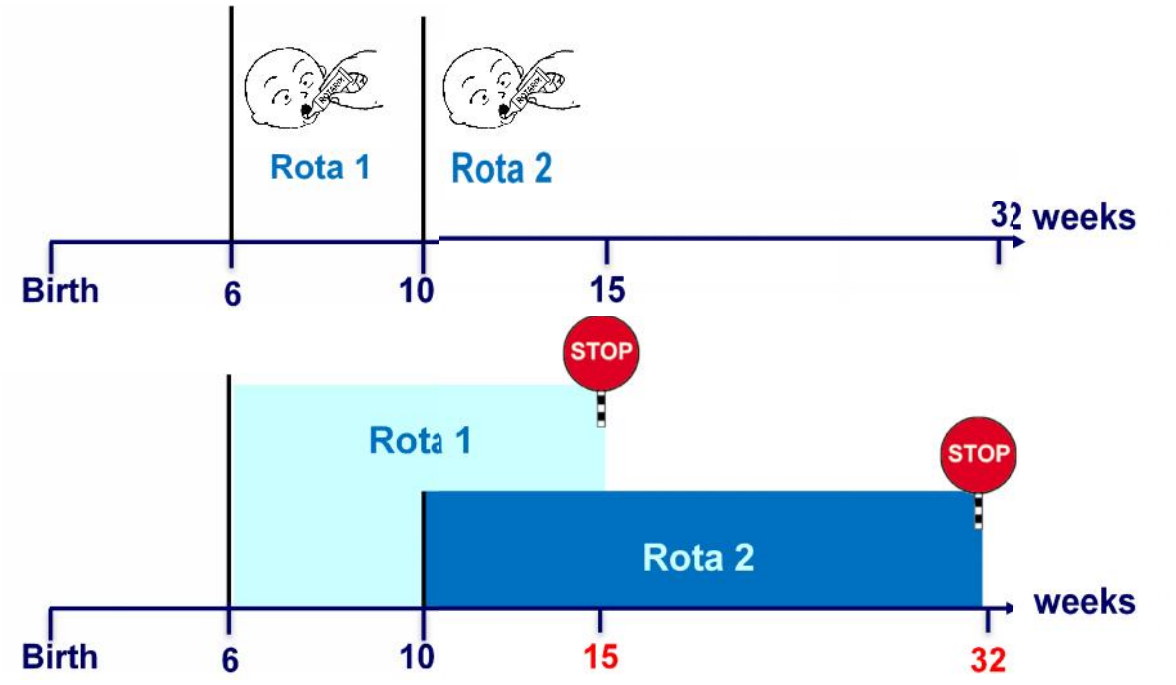


Table 3: Revised Immunization & Vitamin A Supplementation Schedule

Age	Vaccine
At birth or first contact	BCG
At birth up to 2 weeks	OPV 0
At 6 weeks	OPV1, DPT-HepB-Hib1, PCV1 and **Rota1**
At 10 weeks	OPV2, DPT-HepB-Hib2, PCV2 and **Rota2**
At 14 weeks	OPV 3, DPT-HepB-Hib3, and PCV3
At 9 months	Measles
First contact (15-45 yrs and Pregnant women)	TT 1
At 4 weeks after TT1	TT 2
At 6 months after TT2	TT 3
At 1 yr after TT3	TT 4
At 1 yr after TT 4	TT 5
At 6 months and every 6 months up to 59 months	Vitamin A (children)
Within two weeks of delivery (post natal mothers)	Vitamin A

Steps to ensure that an infant is vaccinated on time:

- ✓ It is important to offer vaccines at every available opportunity.
- ✓ Whenever infants visit the health centre, their immunization record should be screened, and they should be given all of the vaccines they are eligible to receive.
- ✓ When an infant is brought to the health centre, his/her age and previous immunization status should be determined using the child's health passport before deciding which vaccine doses to provide. If the child did not get the first dose of rotavirus vaccine on time between the age of 6 to 15 weeks, the child is not eligible for rotavirus vaccine. Children should not receive a second dose of rotavirus vaccine after 32 weeks of age.
- ✓ It is therefore, very important to implement accurate recording of the child health passport, and to remind the parent of the next visits and the importance of completing the full immunization schedule.
- ✓ One can also follow-up with children who are overdue for their vaccine. Even if infants come too late to receive their rotavirus dose(s), they can get other vaccines in the schedule.

Defaulter tracing system using village health registers can assist by providing a record for each health centre of which immunizations are due by month, and healthcare workers can send reminders to parents of those children who are due for immunizations. For this to be effective, defaulters need to be tracked regularly every month.

1.8.4 Vaccine Preparation & Administration

Prior to conducting an immunization session, you need to complete certain tasks explained below:

1) Check the VVM and expiry date of vaccines for validity.
2) Inspect visually if the vaccines are frozen. The vaccine should present as a clear, colorless liquid, free of visible particles, for oral administration. In the event of being frozen, discard the vaccine(s).
3) Pack sufficient vaccines for the session in the vaccine carrier with conditioned ice packs. During the first 3 months, you should pack Rotavirus vaccine of at least 1.5 times the amount of PCV 13/Pentavalent required for an immunization session due to anticipated higher demand.

During an immunization session:

4) Vaccines are protected from heat for a longer period of time if they are inserted in a foam pad in the vaccine carrier.
5) Confirm the age of the child.
6) When an eligible child is ready for immunization, take the vaccine out of the vaccine carrier and place it on a conditioned ice pack.
7) The vaccine should be well shaken before use.

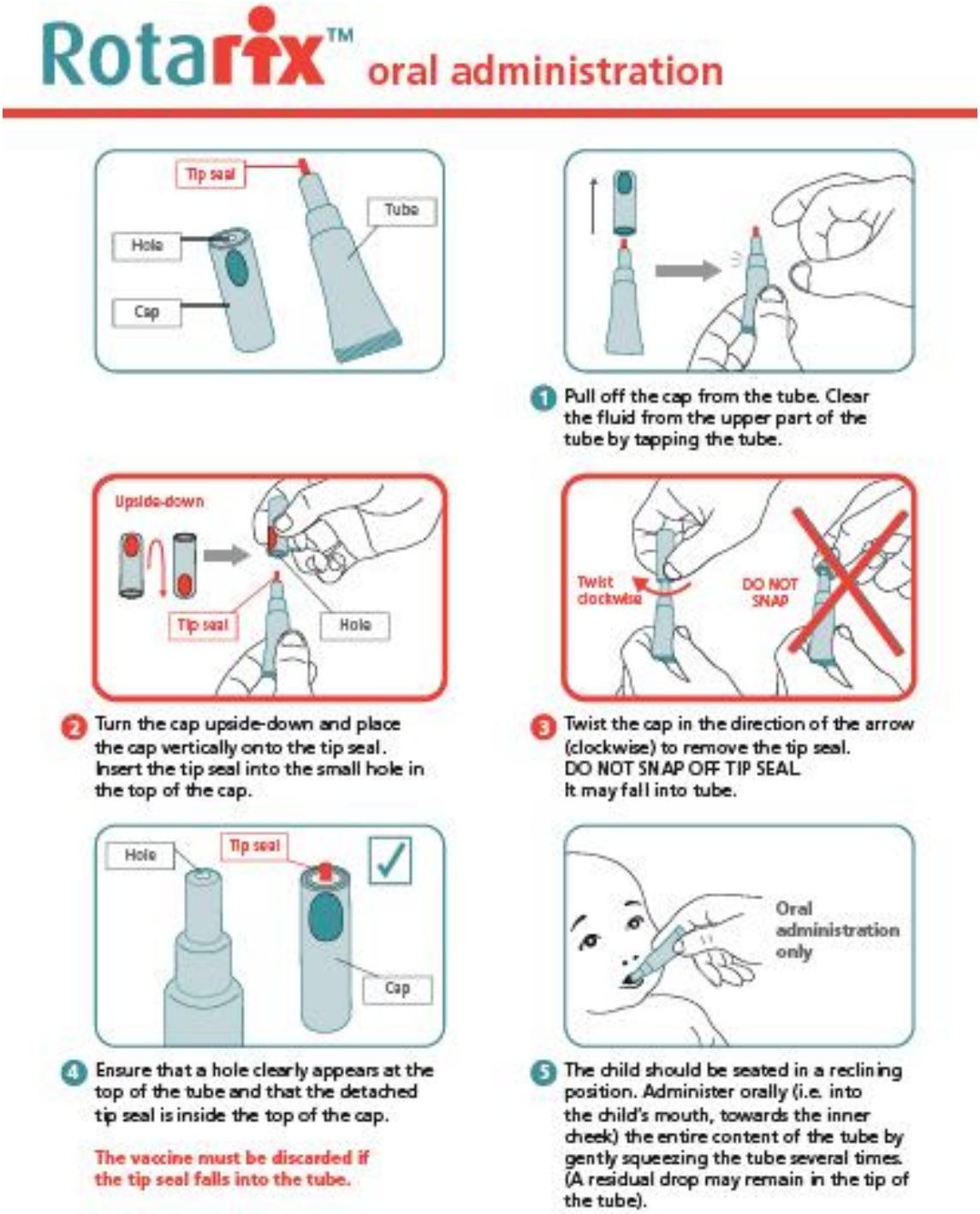
Rotarix vaccine is prepared for oral administration, do not inject!
Rotarix is a liquid vaccine in a one-dose squeezable tube and the opened tube should be used immediately. You should squeeze out the entire contents of the tube (1.5ml).

Rotavirus vaccine is administered together with three other vaccines during the 6-week and 10-week visits. To avoid accidentally missing any of the vaccines, it is a good practice to always administer the vaccines in the same order. Oral vaccines should always be administered first because injected vaccines usually cause the children to cry, making oral administration more difficult. The order of administration of vaccines in Malawi is described in the following table.

Figure 9: Recommended Order of Administration of Vaccines When Giving 4 Vaccines at Once

Order	Antigen	Mode of administration
First	OPV	Oral
Second	Rota	Oral
Third	Penta	Intramuscular injection to **left** upper outer thigh
Fourth	PCV13	Intramuscular injection to **right** upper outer thigh

Figure 10: Instructions on Oral Administration of Rotavirus Vaccine



Warning – Important:

- If the tube is inappropriately opened, the nozzle can either fall into the tube or get lodged in the opening of the tube. If this happens, discard the vaccine.
- If the nozzle falls into the tube or gets lodged in the opening of the tube, then the child may risk inhaling the nozzle when the vaccine is administered, and this could lead to either a collapsed lung or aspiration pneumonia in a young infant, either of which could be potentially life-threatening, if not detected and treated in a timely manner

Figure 11: Example of tube with a broken nozzle lodged inside

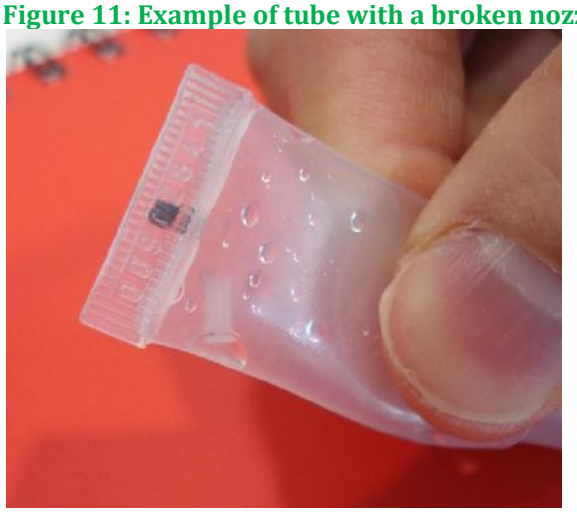
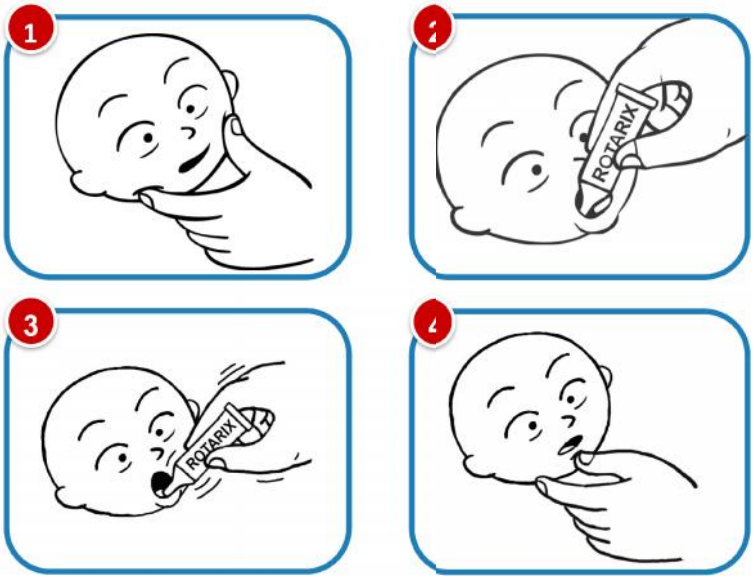


Figure 12: How to administer the Rotavirus vaccine



<u>How to Position & Administer the Rotavirus Vaccine (Refer to Figure 12 above)</u>

The child should be seated in a semi-reclining position (i.e. normal feeding position).

<u>Step 1:</u> Gently squeeze the child's cheeks to open the mouth.
<u>Step 2:</u> 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.
<u>Step 3:</u> Administer the entire content of the tube by gently squeezing it several times. Make sure the child is swallowing the vaccine to prevent build-up in the mouth.
<u>Step 4:</u> Gently hold the cheeks together and stroke the child under the chin to help with swallowing.

Key messages:
1) The rotavirus vaccine dose quantity (Rotarix 1.5 ml) is larger than that of oral polio vaccine and infants might not take the full dose all at once. It is important to ensure that the child receives the entire contents of the tube.
2) To prevent spitting, slowly administer the vaccine in small amounts and properly place the tip of the tube towards the inside of the child's cheek.

1.8.5 Contraindications

Hypersensitivity following previous administration of rotavirus, or previous history of intussusception will be a contraindication. Rotavirus vaccine should therefore not be administered to children presenting with these conditions..

1.8.6 Precautions

Vaccination in infants with ongoing severe gastroenteritis or serious febrile illnesses should be postponed until the child completely recovers. The presence of minor infections, however, is not a contraindication for vaccination.

2. Adverse Events Following Immunization (AEFI)

An adverse event following immunization (AEFI) is a medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization. AEFIs are usually classified into five categories as described in the table below.

Table 4: Classifications of AEFIs

Causes of AEFI	Description
Vaccine reactions	Events caused or precipitated by vaccine and is caused by the inherent properties of the vaccine
Programme error	Event caused by an error in vaccine preparation, handling or administration
Injection reaction	Event from anxiety about, or pain from the injection itself rather than the vaccine
Coincidental	Event that happens after immunization but is NOT caused by the vaccine (i.e. a chance association)
Unknown	Event's cause cannot be determined

In order to know what AEFIs need reporting, healthcare workers should follow the national guidelines and list of AEFIs that are to be reported. At a minimum, serious AEFIs defined according to standard WHO classification must be reported. These are those that:

- are life-threatening,
- result in hospitalization (or prolonged hospitalization),
- result in disability (or have the potential to result in disability), or
- result in death.

In addition, WHO recommends that certain types of AEFIs should be considered serious enough to warrant urgent investigation and proper management. These include:

- AEFIs that may have been caused by programme error (e.g. clusters of AEFIs, bacterial abscesses, severe local reactions, high fever or sepsis, toxic shock syndrome);

- Serious events (including deaths) of unexplained cause occurring within 30 days after a vaccination; and
- AEFIs causing significant parental or community concern.

The healthcare worker should fill the AEFIs reporting form shown in *Annex 1*. It should be noted that some AEFIs are coincidental events and adequate investigation of causality should be conducted for each reported case in line with national regulations. The results of the investigation should then be clearly communicated to various actors in the immunization community, including paediatric associations, mothers, healthcare workers, media etc. to avoid rumours that may affect confidence in the immunization programme.

2.1 Classification of AEFIs

2.1.1 Vaccine reactions

Vaccine reactions are adverse events caused or precipitated by the vaccine and may be classified into (a) common, minor reactions or (b) rare, more serious reactions. Most vaccine reactions are minor and resolve on their own. The more serious reactions are very rare and in general and do not result in long-term problems.

Table 5: Types of Vaccine Reactions

Common, minor vaccine reactions	Rare, more serious vaccine reactions
1. Local reactions a. Redness at injection site b. Pain c. Swelling 2. Fever < 38.5°C 3. Irritability 4. Malaise 5. Generalized apathy These symptoms result from normal body immune response reaction to a vaccine or its components.	1. Convulsions 2. Anaphylactic shock 3. Severe allergic reactions 4. Adenopathy 5. Encephalopathy

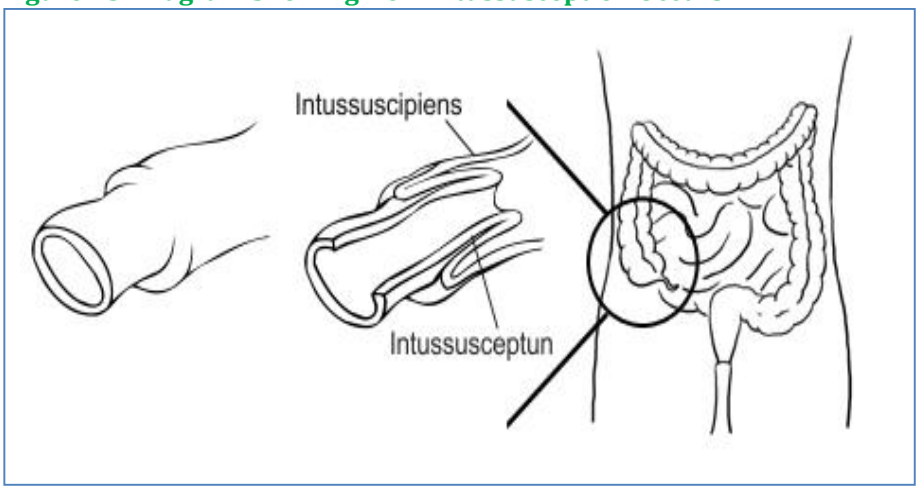
There are two types of reactions to rotavirus vaccine:

1) Mild reactions
A small proportion of infants receiving the vaccine may suffer short episodes of mild diarrhoea, vomiting or fever in the week following vaccination.

2) Severe reactions:
Marketing surveillance of the new rotavirus vaccines is still recommended to evaluate any potential association between rotavirus vaccines and potential adverse events, including intussusception.

Intussusception
Intussusception is one of the causes of acute bowel obstruction in infants and young children, however, it is rare. It occurs when one segment of the bowel becomes enfolded within another segment. If this obstruction is not relieved, the vascular supply to the bowel is compromised, resulting in bowel ischemia that can lead to death. Incidence of intussusception peaks among infants 4-10 months of age, and the baseline rates may vary annually from 0.5 to 4.3 per 1000 live births (18). In the majority of cases, the cause is unknown.

Figure 13: Diagram Showing How Intussusception Occurs



The new rotavirus vaccines (Rotarix and Rotateq) have been tested in the largest Phase III vaccine trials ever conducted and the studies have not indicated any increased risk of intussusception or other serious adverse events associated with the use of the new rotavirus vaccines. However post-marketing surveillance will continue to assess the increased risk of this extremely rare reaction, which can also occur naturally in young children. The association between natural rotavirus infection and intussusception has not been confirmed with rigorous epidemiologic studies.

2.1.2 Program Errors

Most of the reported AEFIs are related to programme errors than any other cause. The causes of errors are listed in Table 6. Vaccines are very rarely contraindicated. However, it is important to check for contraindications to avoid serious reactions. For example, vaccines are contraindicated if there is serious allergy to the vaccine or its components.

Table 6: Common Programme Errors & Associated Events

Programme Error	Possible AEFIs
Non-sterile injection Reuse of disposable syringe or needle Improper handling of mixing syringes Contaminated vaccine or diluents	Infections Local suppuration at injection site Abscesses Cellulitis Systemic infections Toxic (septic) shock syndrome Blood-borne infections
Improper vaccine preparations Vaccine prepared incorrectly, including reconstitution with wrong diluents Drugs substituted for vaccine Wrong amount of diluents used Inadequate shaking of vaccines before use Breakage of nozzle during opening for oral applicator.	Local reaction or abscess Effects of the drug (e.g. muscle relaxant, insulin) Aspiration of oral applicator

Programme Error	Possible AEFIs
Improper vaccine injection technique Subcutaneous instead of intra dermal BCG Toxoid vaccines (TT, DPT etc.) not administered deep enough (IM) Injections into buttocks Injection of too much vaccine	Local reactions Sciatic nerve damage
Improper vaccine handling Improper transport/storage Use of frozen vaccine Vaccine expired VVM stage III/IV	Local reaction from frozen (and ineffective) vaccine
Contraindications ignored	Avoidable severe vaccine reactions

Programme errors can be avoided by observing the following:

- Reconstitute vaccines with the appropriate volume of diluents from the same manufacturer.
- Correct application of multi-dose vial policy. (Discard measles and BCG vaccines after six hours or at end of session, whichever comes first)
- Do not store anything else in the vaccine fridge except the vaccines and diluents
- Use only AD-syringes and needles and one mixing syringe per vial for reconstitution of measles and BCG vaccines.
- Inject vaccine in the proper site and depth (intradermal, subcutaneous, or intramuscular) at all times.

In addition to the above-mentioned measures, the following should be observed to avoid Rotavirus vaccine-related program errors:

- Adhere to recommended age for 1st and 2nd dose;
- Avoid providing the vaccine to children with reported hypersensitivity reaction to Rotarix;
- Store vaccine +2° to +8°C;
- Postponed rotavirus vaccine administration to children with severe gastroenteritis and/or high grade fever (+39°C); and
- If the nozzle becomes lodged inside the tube during opening, do not use.

2.1.3 Injection Reactions

Injection reactions are reactions associated with anxiety related to injection. These can occur prior, during or after the injection. Caregivers should be assured that these reactions are normal. **NB: Rotavirus is an oral vaccine and should never be injected.**

2.1.4 Coincidental AEFIs

These are events caused by something other than programme errors and individual reactions to vaccine. A coincidental event means that the medical incident would have occurred even if the individual had not been immunized. Coincidental events are unrelated to immunizations or vaccines in any way except for the time that they occur. The best evidence to support a conclusion that a medical incident is coincidental is that the same event has been diagnosed in people who have not been immunized.

2.1.5 Unknown causes of AEFIs

Another classification, "Unknown" is helpful for categorizing events with an unknown cause after investigation by appropriate authorities.

2.2 Management of Vaccine Reactions

2.2.1 Management of minor common vaccine reactions

Healthcare workers should give advice on managing common reactions to parents, as well as instructions to return if there are more serious symptoms. This will help to reassure parents about immunization and prepare them for these common reactions.

Paracetamol, at a dose of 10-15mg/kg every four hours with a maximum of four doses in 24 hours, is useful for the common minor reactions. It eases pain and reduces fever. A feverish child can be cooled with a tepid sponge or bath, and by wearing cool clothing. Extra fluids need to be given to feverish children. For a local reaction, a cold cloth applied to the site may ease the pain.

2.2.2 Management of anaphylactic shock, a rare severe vaccine reaction

Anaphylaxis is a very severe reaction which may occur rarely after any injection including an immunization. The client collapses with signs of shock and breathing problems. Follow the steps described below immediately:

1) Call out for help and assist patient immediately.
2) Check breathing and heartbeat.
3) If the victim is not breathing, secure the airway and ventilate (mouth-to-mouth or use Ambu-bag).
4) If there is no heartbeat: Do CPR (cardio-pulmonary resuscitation).
5) Give adrenaline 1 : 1000 dilution:
    - 0-3 years : 0.1ml subcutaneous at once
    - 4-7 years : 0.2ml subcutaneous at once
    - 8-<15 years : 0.3ml subcutaneous at once
6) Then give adrenaline 1 ampoule diluted with normal saline to 10ml in small amounts slowly IV or through the endo-tracheal tube. The heart rate should not exceed 160 per minute.
7) Finally, give Hydrocortisone sodium succinate slowly IV in the following doses:
    - Under 1 year : 100 mg
    - 1-3 years : 200mg
    - 4-7 years 300 mg
    - 8-9 years : 400 mg
    - 10 years and above 500mg
8) If available, run normal saline (0.9% drip fast).

2.3 AEFI Surveillance

The major goal of immunization safety surveillance is early detection, and appropriate and quick response to adverse events in order to lessen the negative impact on the health of the individuals and on the immunization programme. AEFIs are a key indicator of programme quality and enhances programme credibility by providing actual country data on vaccine risks.

2.3.1 Which AEFI should be reported?

It is unnecessary to report common minor reactions such as local reactions, fever, and self-limiting systemic symptoms. These are expected to occur and if reported, the volume of reports would overwhelm the system while contributing information of limited value. It is therefore important for healthcare workers to advise the caregiver at the time of vaccination that these reactions are expected, and to advise them on how to manage these common minor reactions (e.g. paracetamol to treat fever).

For more serious problems, the caregiver should be advised to return or seek medical attention. More importantly, they should be advised not to delay treatment of a coincidental illness falsely attributed as a vaccine reaction.

Severe local reactions (e.g. swelling beyond the nearest joint; pain, redness, and swelling of more than 3 days duration; or requiring hospitalization), especially if occurring in clusters, should be reported. Local reactions occurring at increased frequency, even if not severe, should also be reported. They can be markers for programme errors or for problems with specific vaccine lots.

Figure 14: Reportable Incidents

The following incidents should be reported and investigated:

1. All injection site abscesses;
2. All cases of BCG lymphadenitis;
3. All deaths that occur within one month of an immunization;
4. All cases requiring hospitalization that occur within one month of an immunization; and
5. All medical events believed to be caused by immunization and about which people are concerned.

Deaths and hospitalizations should receive immediate attention and should be reported as soon as they are detected. Abscesses, lymphadenitis, and other AEFIs should also be reported immediately if they are causing community concern. Immediate reports may be made by telephone, which gives supervisors an opportunity to assess the validity of data without delay. The AEFI reporting forms should also be filled immediately; if forms are not available at the facility, then they should be requested from the District EPI Office and the first report should be submitted immediately by telephone. All AEFIs, including those reported immediately during the month, should be counted in routine, written, monthly surveillance reports.

Healthcare workers must report adverse events without fear of penalty. It should be clear to both the supervisors and the healthcare workers that the aim of reporting is to improve systems or provide further training and not to blame individuals.

2.4 AEFI Investigation

The ultimate goal of a case investigation is to find the cause of an AEFI or cluster of AEFIs and correct it. Investigation should begin as soon as possible; ideally within 24 hours of detection by a healthcare worker, to identify any programme errors that might be present, to correct them before other people are exposed to the same error, and to show members of the community that their health and concerns are taken seriously.

3. Cold Chain and Vaccine Management

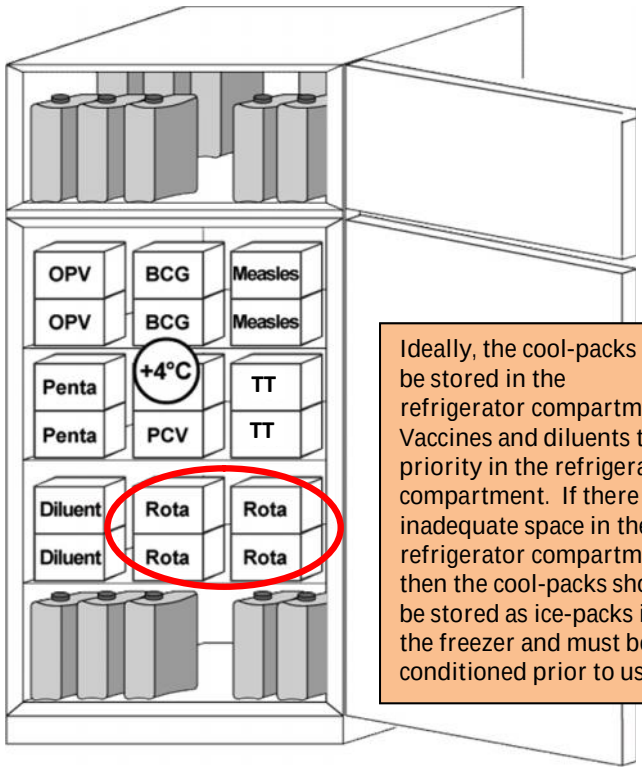
3.1 Vaccine Storage

Vaccines are sensitive to heat and freezing and must be kept and transported at the correct temperature from the time they are manufactured until they are administered. Therefore, it is essential to store vaccines at every stage of the cold chain properly.

Evidence suggests that excessive cold or freezing could occur at any level and the vaccine handlers should take precautionary steps to prevent vaccine freezing and discard vaccines that are damaged due to freezing. To safeguard the potency of vaccines in the cold chain system, health workers should closely monitor the VVM and freeze indicators (freeze-tag or fridge-tag) to avoid unnecessary vaccine wastage.

Figure 15: Placement of Vaccines in Upright Refrigerator

Placement of vaccines		Items	Refrigerator compartments
Freezer compartment		Ice-packs	
Refrigerator compartment	Upper level	OPV BCG, Measles	
	Mid-level	DTP-HepB-Hib PCV13, TT	
	Lower level	Diluents, Rota Cool-packs	



Ideally, the cool-packs will be stored in the refrigerator compartment. Vaccines and diluents take priority in the refrigerator compartment. If there is inadequate space in the refrigerator compartment, then the cool-packs should be stored as ice-packs in the freezer and must be conditioned prior to use.

Rotarix vaccine should be stored between +2°C and +8°C. Freezing is not recommended for storage. Store Rotarix vaccine in the original package, in order to protect from light.

Figure 16: Placement of Vaccines in Chest Refrigerator

In an icelined chest refrigerator, vaccines should not be placed on the bottom of the refrigerator but in trays, as shown in Figure 16.

Fridge-Tag

While storing the vaccine, the following should be noted:

- Keep the packets containing the vaccines in a neat row;
- For easy identification, similar vaccines should be stored in the same area, and different vaccines should be kept separately;
- Keep about 2 cm space between rows of vaccines for circulation of air;
- In upright refrigerators, vaccines with the earliest expiry date, open vials, and vaccines with VVM stage 2 should be placed towards the front of the fridge for first use. Rotarix, freeze-sensitive vaccines and diluents should be kept on the lower shelves;
- In chest refrigerators, store diluents, Rotarix, freeze-sensitive vaccines and vaccines with early expriy dates towards the top of the fridge; heat-sensitive and late expiry date vaccines should be placed towards the bottom of the fridge shelves;
- Expired vaccines should be removed from the refrigerator;
- Nothing other than EPI vaccines, diluents, and cold packs should be stored in the refrigerator;
- Fill the daily temperature recording forms twice daily, using a functioning thermometer .

3.1.1 Packing the vaccine carrier

Vaccine carriers are insulated containers that keep vaccines cold during transportation and/or temporary storage. They are smaller than cold boxes and are easier to carry if walking. However, they do not stay cold as long as a cold box - they stay cold for a maximum of 48 hours with the lid closed.

You should put conditioned ice-packs or cool-packs against each of the four sides of a vaccine carrier and put the vaccines in the middle of the carrier. Before packing the vaccines check for their VVM status, expiry date and inspect if the vaccine is not frozen. Finally, place a foam pad, if available, on top of the conditioned ice-packs, and close the lid tightly.

Figure 17: Foam pad in use

During an immunization session, opened vials are protected from heat for a longer period of time if they are inserted in a foam pad as shown in Figure 17. In the absence of a foam pad, you can place the vaccines directly on a cool-pack during the immunization session to ensure that they stay cold. Note that Rotarix must be administered immediately after it is taken out of the vaccine carrier.

3.1.2 Conditioning frozen ice-packs

Ice-pack conditioning or use of cool-packs[2] is necessary in packing freeze-sensitive vaccines for clinics and during vaccine collection/distribution from one location to another. The use of cool-packs is preferable to conditioning frozen ice-packs prior to each immunization session. Cool-packs should be maintained by keeping them in a cooling compartment for at least 24 hours at a temperature of +2° to +8°C.

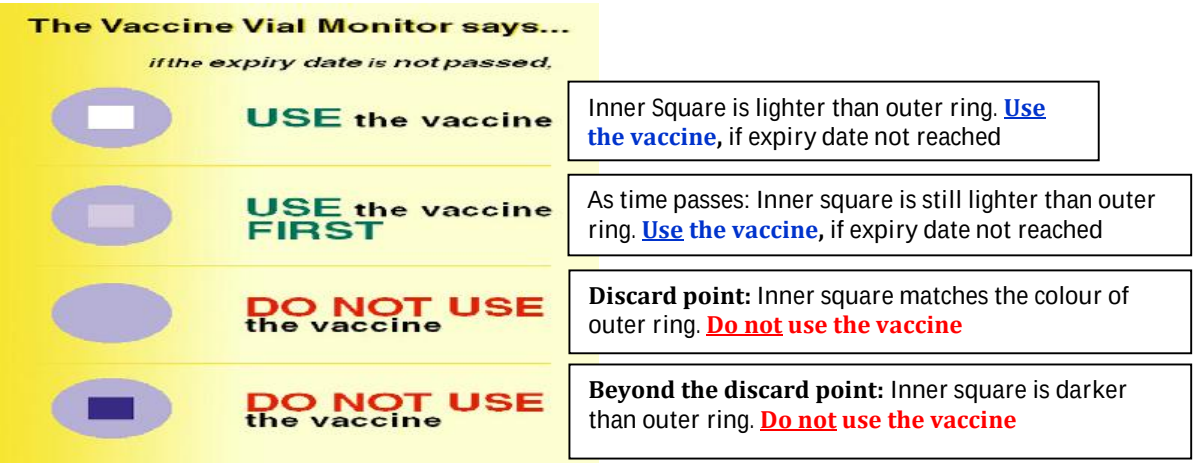
To convert a frozen ice-pack to a cool-pack, the frozen ice-packs should be conditioned by performing the following activities:

1) Allow the frozen ice-packs to stay at room temperature until ice has completely melted but pack is still cold. This can take several hours at an ambient temperature of +20°C and less time at higher temperatures.
2) Check to see if the ice-pack has been conditioned by shaking it and listening for water to ensure it has completely melted. This will prevent the freeze-sensitive Rotarix, TT, and Pentavalent vaccines from freezing.

3.1.3 Vaccine Vial Monitor

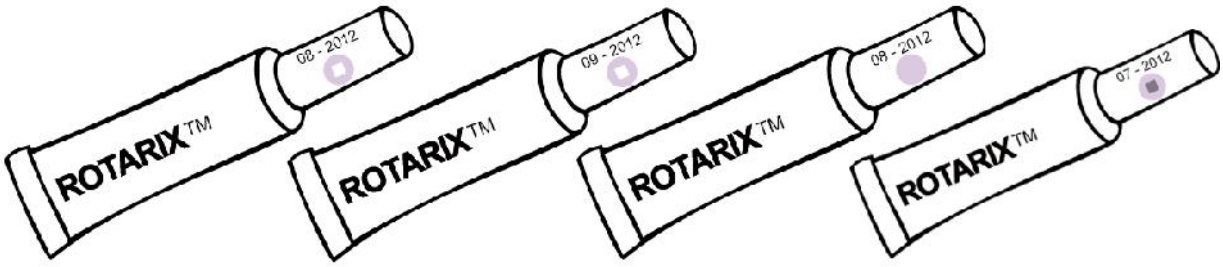
Besides freezing, exposure to heat can also reduce a vaccine's potency. Therefore, protect the vaccine from exposure to heat >+8°C. A VVM is a heat-sensitive label on the side of or on top of a vaccine vial. The white square inside the light purple (violet) circle changes color (darkens) irreversibly when the vaccine is exposed to heat over a period of time. By comparing the color of the inner square to that of the outer circle, users can determine the extent to which the vaccine has been exposed to heat and can decide whether to use the vaccine or not. Using the appearance of the white square of the VVM, a vaccine can be in any of the four stages indicated below in Figure 18. Vaccines in stage II should be used first before they reach the discard point. Only vaccines in stages I and II should be used. Vaccines that have reached stages III and IV should never be used, but should be discarded.

Figure 18: How to read a Vaccine Vial Monitor (VVM)



[2] Cool-packs are ice-packs which are chilled, not frozen.

Figure 19: VVM on Rotarix tubes



3.1.4 Fridge-Tag

The Fridge-Tag (FT) is a temperature monitoring device for refrigerators. A FT displays information on the temperature inside the refrigerator during the past 30 days. The FT shows which days had temperature alarms. A freeze alarm occurs when the temperature drops **below +0.5°C** for more than 60 minutes, and a heat alarm occurs after 10 hours at **above +8°C**. A Fridge-Tag also displays current temperature and time. This information can tell you how a refrigerator is performing. However, even with a FT in place, temperature must still be monitored daily and recorded on the temperature monitoring sheet, and the person managing the refrigerator must take action when alarms occur. Shelf life is 2 years, unless it has a mechanical fault. The Fridge-Tag should be kept in the refrigerator, together with freeze-sensitive vaccines.

Figure 20: Fridge-Tag

Compared to the regular thermometers, the Fridge-tag has the following advantages:

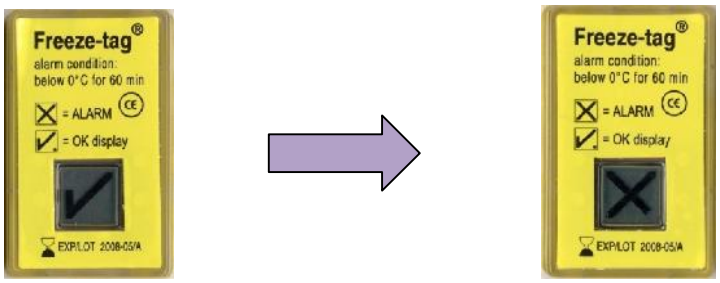
- Uninterrupted temperature monitoring in the refrigerator;
- Data retention for the last 30 days;
- Pre-set alarms to warn healthcare workers if there are any violations;
- Detailed information on violations (minimum and maximum temperatures reached and the duration of violation in hours and minutes) for each days for the last 30 days;
- Healthcare workers have can make more informed decisions, if there are any temperature alarms;

3.1.5 Freeze-Tag

A freeze indicator tag is an irreversible temperature indicator which shows if a product, such as vaccine, has been exposed to freezing temperatures. If the indicator is exposed to a temperature **below 0°C ± 0.3°C** for more than 60 minutes ± 3 minutes, then the display will change from the "**Tick**" status into

the "**Cross**" status as indicated in Figure 21 below. The indicator is used to warn of freezing and should be packed with Pentavalent, TT, Rotavirus and PCV 13 vaccines. Shelf life is 5 years, unless it has a mechanical fault.

Figure 21: Freeze-Tag



Not Activated (Vaccine is okay)

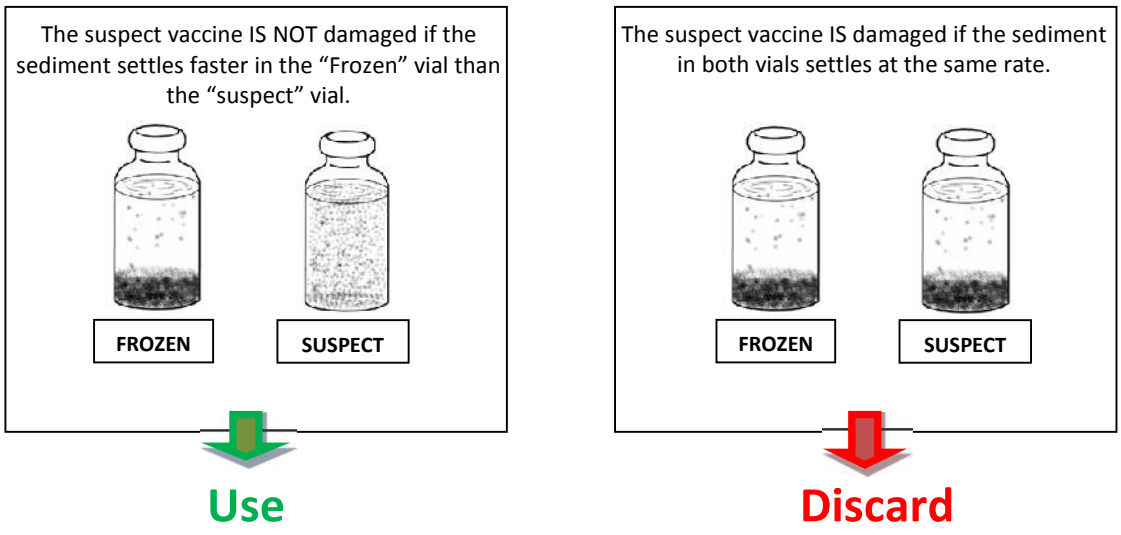
Activated (Do shake test for freeze sensitive vaccines)

3.1.6 Shake Test

The shake test can be conducted to check whether any of the vials have been frozen. The "shake test" is performed as follows:

1) Deliberately "freeze" a "control sample" of the same vaccine and batch number until the contents are solid - at least 10 hours at -10°C.
2) Take a vial of vaccine from the batch that you "suspect" has been frozen - this is your "test sample ".
3) Hold the control sample and the test sample together in one hand and shake vigorously for 10-15 seconds.
4) Allow to rest by placing both vials on a table and not moving them further.
5) View both vials against the light to compare the sedimentation rate.
6) If the "test sample" shows much **slower sedimentation rate** than the "control sample", the "test sample" has **probably not been frozen.**
7) If the "test sample or suspect" has a **similar sedimentation rate** as the "control or frozen sample", the vial has probably been damaged by freezing and **should not be used**.

Figure 22: Shake Test Sedimentation Rates



3.2 Vaccine management

3.2.1 Estimation of Vaccine Requirements

The availability of adequate and quality vaccine is critical to immunization services. Effective management and storage of supplies can help save on programme costs, prevent high wastage rates and stock-outs, and improve immunization safety.

Estimating vaccine needs for the Rotavirus vaccine should be based on the number of children to be vaccinated, target coverage and wastage factor (wastage factor for Rotavirus vaccine is 1.05). The most common method for estimation of vaccine requirements is based on target population.

3.2.2 Estimating vaccine needs on the basis of target population

To estimate vaccine needs on the basis of target population, basic parameters such as target population (the number of children within the targeted age), planned annual immunization coverage, immunization schedule and wastage rate are necessary.

Figure 23: Monthly Vaccine Requirements Calculation

Monthly Vaccine Requirements (including reserve) = Target population x Number of doses x Desired immunization coverage x Wastage factor / 12 months x 1.25 reserve stock

Example:

If the target (surviving infants) population of the area is 1,750 and planned coverage 100%, what will be the monthly requirement of the Rotarix vaccine?

Target population – 1750; Rotarix vaccine doses per child – 2; Planned coverage – 100%;

Wastage rate for Rotarix – 5%; Reserve stock – 25%

Therefore the monthly vaccine need is:

= 1750 x 2 x 100/100 x 1.05 / 12 months x 1.25

=383 doses of Rotarix vaccine

Each level has to calculate, monitor vaccine stock and report to avoid vaccine stock-outs and over-stock:

1) *Maximum Monthly Stock (125%):* At any given time, facilities should not have more than their maximum stock level, which is their monthly vaccine requirements plus reserve stock of 25% (see above for calculation).
2) *Minimum Stock (25%):* Facilities should not have less than their minimum stock level, which is recommended to be 25% of their regular shipment (e.g. most facilities receive shipments monthly, therefore this minimum stock level would be one week's supply). Once this level is reached, facilities should contact their District Vaccine Store for resupply.
3) *Stock-outs (no vaccine) and below-minimum stock levels* are unacceptable at all levels.
4) All levels should monitor vaccine *wastage*.

During the first six months of the introduction period, healthcare workers and program managers will need to be more vigilant of the number of Rotavirus vaccine doses administered, as well as other vaccines.

3.2.3 Calculating vaccine wastage

To calculate the vaccine wastage, first one needs to calculate the vaccine usage, and then the vaccine wastage can be obtained by deducting the vaccine usage rate from 100%.

Figure 24: Vaccine Usage & Wastage Rate Calculations

Vaccine Usage Rate = $\frac{\text{Doses administered}}{\text{Beginning balance + Received during the month – Ending balance}}$ x 100%

Vaccine Wastage Rate = $\frac{\text{No. Doses used and wasted - No. Children vaccinated}}{\text{No. Doses used and wasted}}$ x 100% - vaccine usage rate

3.2.4 Vaccine Wastage

Some degree of vaccine wastage is expected in any immunization service. Wastage can occur at any stage. It can occur in the cold store at central level, at various intermediate levels, at the point of use at an immunization session and during transportation. Reducing wastage depends upon better management at all levels. The factors associated with vaccine wastage can be classified as unavoidable and avoidable.

1. Unavoidable vaccine wastage factors

The most important unavoidable wastage factors include:

- The use of reconstituted vaccines that have to be discarded at the end of the session or 6 hours after drawing the first dose.
- Manufacturer defects
- Damage in transit from the manufacturer

2. Avoidable vaccine wastage factors

The following are some factors that can be controlled by improving vaccine management:

- Poor stock management resulting in over-supply and vaccines reaching expiry before use
- Cold chain failure that exposes vaccines to unacceptably high or low extremes of temperature.
- Incorrect dosage (e.g. the administration of more than the recommended drops of OPV).
- Failure to comply with the multi-dose vial policy.
- Vials lost, broken or stolen.

3.2.5 Stock Management

Wherever vaccines are stored, a system of stock management must be in place to record vaccines received, and vaccines dispatched or used. This ensures that vaccines are used before their expiry date, that the status of VVM is recorded at receipt and issue, and that there are no stock-outs or over-stocking.

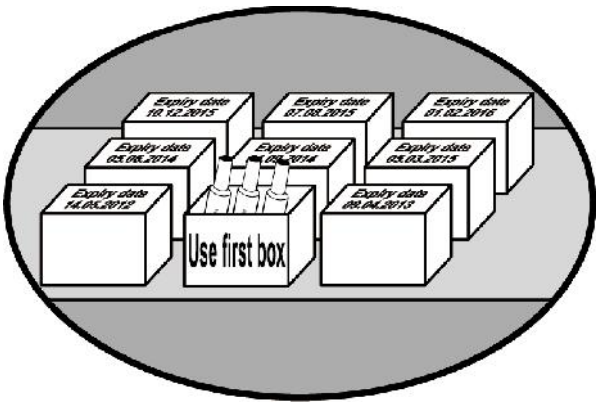
Keep separate (date-wise) records of vaccine receipts, distribution and balance in the stockbook for each type of vaccine and diluent. You should be able to track the movement of different batches of vaccine once it arrives at your health facility. If you need to send your vaccines to a nearby health facility for temporary storage, then you should properly record this movement in vaccines as well.

It is important to distinguish between different batches of vaccine because they may have different expiry dates, and the vials with the earliest expiry dates should be used first (FEFO principle) as long as the VVM is in Stage 1. Also, in the rare situation that there is a serious adverse event, it is important to know the exact description of the vaccine (e.g. manufacturer, batch number).

Regular monitoring for adequate stock levels is necessary. Once your health facility reaches its minimum stock level[3], you should contact the District Vaccine Store for resupply.

The VVM status and expiry dates of vaccines must be monitored and acted upon. Each Rotavirus vaccine tube shows an expiry date and VVM status. Never use vaccines when the expiry date has passed, even if the VVM shows no heat damage.
In general, always apply the First-expiry-first-out (FEFO) principle. When vaccines expire, dispose the vaccine.

Figure 25: First-Expiry-First-Out (FEFO) Principle



To avoid exposure of the vaccine to freezing, ice-packs must be 'conditioned' prior to use. To condition an ice-pack, leave the ice pack at room temperature until there is some liquid water in it. Refer to *Section 3.1.2* for instructions on conditioning ice-packs.

3.2.6 Safe Waste Management

Sharps' waste poses a serious health and environmental risk. Unsafe disposal can spread some of the very same diseases that we are trying to prevent. Leaving used syringes and needles in the open or on the ground puts the community at risk. Most frequently, children are the unfortunate victims of needle-stick injuries from haphazard disposal of needles and healthcare workers from mishandling of equipment.

Therefore, all used injection equipment (syringes and needles) should be discarded in a safety box immediately after use. These safety boxes should be leak-proof and tamper-proof and needles cannot easily pierce them. Used vials should be disposed in a separate container.

Used Rotavirus vaccine tubes and cap should be disposed properly like sharp waste materials in the safety box. However, paper cartons, inserts, syringe wrappers and other non-hazardous waste can be disposed in a separate container during the immunization session.

[3] The minimum stock level is recommended to be 25% of its regular shipment (e.g. most facilities receive monthly resupplies, therefore their minimum stock level is one week's supply).

The recommended method of disposal is incineration. If incinerators are not available, another recommended method is open burning in designated pits. Such pits should be dug in an unused area as far from building as possible. The pit should be at least 1 meter deep and the waste must be burnt until the boxes are destroyed. Once the burning is over, the residual must be buried or covered with soil.

Figure 26: Safe Disposal of Sharps

Safety first
DO NOT throw filled safety boxes in unprotected open area.
Follow disposal guidelines for collection or burn and bury.

4. Communication

4.1 Interpersonal Communication

Interpersonal communication is very important during vaccination sessions. Healthcare workers should spend time with the caregiver at the vaccination session to explain the following:

1) Immunization schedule;
2) Re-assure them about the benefits of immunization;
3) Explain possible side-effects and what to do in the event of a side effect;
4) When to return for the next vaccine; and
5) Answering any questions they may have.

Three basic skills are needed for interpersonal communication during vaccination sessions:

1) Communication to clients in a caring manner
2) Problem-solving skills
3) Counseling

See "Recommended Steps for Communication During an Immunization Session" in *Annex 6*.

4.2 Key messages on Rotavirus Vaccine

4.2.1 For Healthcare workers

- Diarrhoea is one of the most common causes of Under 5 Mortality.
- Rotavirus is the most common cause of severe diarrhoea in infants and young children in Malawi. It can lead to severe dehydration and death.
- Rotavirus is spread primarily by the faecal-oral route, directly from person-to-person, or indirectly via contaminated fomites.
- Rotarix vaccine is a live, attenuated vaccine against rotavirus infection and has been demonstrated to be safe and highly effective.

- Oral Rotavirus vaccine must never be injected or frozen.
- Each Rotarix vial contains one dose— the full amount must be administered to one infant.
- Rotavirus vaccines may be given at the same time as other childhood vaccines at 6 weeks and 10 weeks of age.
- All children should receive two oral doses of rotavirus vaccine in infancy. The 1st dose should not be given after 15 weeks of age and the 2nd dose should not be given after 32 weeks of age (8 months). **The recommended age for administration of Rotarix vaccine should be strictly followed**.
- Any serious adverse events related to the vaccine should be reported through the existing AEFI Reporting System.

4.2.2 For Caregivers

- Rotavirus is the leading cause of diarrhoea among children. It can lead to severe dehydration and death. Death from rotavirus is most common where there is no quick access to medical care, so vaccination is the most effective way to prevent severe cases and deaths.
- Oral rehydration solution (ORS) is an accessible means to treat dehydration and save the child from severe illness or death.
- If your child experiences severe diarrhoea, it is important to ensure they have a lot of fluids and to take them to a clinic if they show signs of dehydration.
- Rotavirus vaccine is safe and effective against rotavirus disease.
- All children should receive two doses of rotavirus vaccine before eight months of age.
- Even after your child is vaccinated, improvements in sanitation, safe water supply, children's nutrition and breastfeeding, use of ORS and zinc, are still important for prevention and control of diarrhoea.
- Side effects of the vaccine are rare; mild reactions such as fever, vomiting and diarrhoea may occur in some children.

5. Monitoring, Evaluation and Supervision

5.1 Monitoring

Monitoring is required to assess data, procedures and practices in order to identify problems, develop solutions and guide interventions and document the overall new vaccine introduction process.

Routine monitoring should include:

- Proportion of children who have completed the rotavirus vaccination schedule at the appropriate age.
- Proportion of the target population receiving the first dose of rotavirus vaccine. This indicator is important to monitor, as some children will be denied the rotavirus vaccine if their first contact with the health system was after 15 weeks of age.
- Number of fully immunized children (FIC), which will now be defined as including a complete schedule of a rotavirus vaccine, as well as the other vaccines provided in the immunization schedule.
- Drop-out rate from first to second dose of rotavirus vaccine.

5.1.1 Basic Recording Tools

Recording tools are necessary to ensure that each child receives the appropriate number of doses of vaccine; health facilities are maintaining adequate stock levels in cold chain; and tracking performance. The introduction of Rotavirus vaccine will require reporting on the standard EPI recording tools:

- Child Health Passport
- Under 1 Register
- Monthly Vaccination Performance Reporting Form
- Daily Temperature & Vaccine Stock Recording Form
- Vaccine Stock Books
- Village Health Registers

5.2 Supervision

Supervision increases quality of implementation of activities by guiding, supporting and assisting service providers to carry out their duties to achieve the programme objectives. The supervisor should review the monitoring data, injection practices, social mobilization, logistics, stock management and vaccine handling practices at the health facility.

5.3 Post-Introduction Evaluation

Evaluation activities provide an opportunity to assess the overall program status and new vaccine introduction efficiency — performance, effectiveness and efficiencies — in order to improve the current and future new vaccine introduction processes. In the initial stage of vaccine introduction, it may be good to monitor the proportion of children who were not vaccinated with rotavirus vaccine because of late presentation, and the proportion not vaccinated for other reasons.

The EPI Unit will conduct a post-implementation evaluation (PIE) after 6 months of introduction in selected districts and facilities. Where possible, districts are encouraged to conduct their own PIEs 6 to 12 months after introduction.

6. Frequently Asked Questions on Rotavirus Disease & Vaccine

1) What is the incidence of Rotavirus disease in the developing world?

In less than five years age group rotavirus is the leading cause of childhood mortality in developing countries causing more than 500,000 deaths per year. In Malawi, it is estimated that deaths caused by rotavirus account for 4.3% of all under 5 deaths.

2) What is the Rotavirus vaccine? Why it is needed?

The Rotavirus vaccine protects children (under 5 years of age) from the diarrhoeal diseases caused by rotavirus. Rotavirus is the leading cause of severe dehydrating diarrhoea in infants and young children. Therefore, the vaccine is critical in Malawi to reduce childhood mortality caused by rotavirus.

3) How is the vaccine given?

Rotavirus liquid vaccines are given by mouth (orally) to young infants.

4) At what age should children receive rotavirus vaccine?

Rotarix is administered in a 2-dose series, with the first dose being administered at 6-15 weeks and the second dose before 32 weeks. The minimum interval between doses of rotavirus vaccine is 4 weeks. Vaccination should not be initiated for infants above 15 weeks.

5) How well does rotavirus vaccine work to prevent rotavirus disease?

Efficacy studies have demonstrated that rotavirus vaccine is 85%-98% protective against severe rotavirus disease and 74%-87% protective against rotavirus disease of any severity in the first year after vaccination. In Malawi, a study of Rotarix vaccine found a protective benefit of 49.5% against severe gastroenteritis (a finding which is consistent with findings that oral vaccines are often found to have less efficacy in developing countries compared with developed countries). Possible factors suggested for this are reduced nutritional status of children in developing countries, co- infections with other gastrointestinal infections, etc.Therefore, even after vaccination, it is important to practice exclusive breastfeeding for children under 6 months, wash hands after using the bathroom and before feeding the child, and use improved sanitation facilities.

6) Is the rotavirus vaccine safe?

The vaccine has been evaluated by the WHO using data from research studies and experiences of countries that have introduced the vaccine. The vaccine has been concluded to be safe.

7) Are there any side effects associated with the vaccine?

A small proportion of infants receiving the vaccine may suffer short episodes of mild diarrhoea, vomiting or fever in the week following vaccination.

An earlier version of Rotavirus vaccine (Rotashield) was noted to have increased risk of intussusception in children post immunisation and was withdrawn from the market. The new rotavirus vaccines (Rotarix and Rotateq) have not indicated any increased risk of intussusception.

8) Who should not be vaccinated?

Any child who is above 15 weeks before receiving the first dose should not receive the vaccine. The last dose should be given before 32 weeks. Children with reported hypersensitivity following previous administration of rotavirus vaccine should not be vaccinated.

9) What should you do if a child regurgitates the Rotarix dose?

A replacement dose maybe given if, for any reason, an incomplete dose is administered (e.g. infant spits or regurgitates the vaccine).

10) Can the vaccine be given with other vaccines?

Rotavirus vaccine can be administered together with other routine vaccines. In the Malawi schedule, rotavirus vaccine will be given at the same time as DPT-HepB-Hib, pneumococcal conjugate vaccine (PCV 13), and OPV. Available evidence suggests that Rotavirus vaccine does not interfere with the immune response to these vaccines.

11) How is a serious side effect of Rotarix or other vaccines reported?

Parents who observe a serious adverse reaction to the vaccine should bring their child back to the health center. Adverse reactions and other problems related to vaccines should be reported through the Adverse Event Reporting System, which is maintained by the filling an AEFI form and sending it to the EPI Unit through the DHOs.

7. Annexes

Annex 1: Adverse Events Following Immunization (AEFI Event Description) Report Form

Reported by	Health facility	Address	
Vaccinator's Name	Date of Report (day) (month) (year)	Telephone Number	
Name of Patient (Surname), First Name)	Age at Immunization	Date of Immunization	
Type of vaccine	Manufacturer	Batch number	Expiry date
Suspected Adverse Events			
Local Reaction	Systemic Reaction		
•Lymphadenitis •Injection site abscess •Severe local reaction (Swelling extending more than 5 cm from the injection site, or redness and swelling of more than 3 days	**•All cases of hospitalization thought to be related to the immunization** •Collapse/shock-like state with 48 hours •Encephalopathy within 7 days •Fever of 40.5°C within 48 hours •Seizures within 3 days. Any death thought to be related to the immunization		

NB: Send form immediately to National EPI Unit, P. O Box 30377, Lilongwe 3. Tel: 725637, within 24 hours of the event through the District Health Officer.

Annex 2: Under 1 Register

Month:_____ Fiscal Year__ _____

Date	Monthly serial number	Registration number		First visit		Sex M/F	Date of birth	Immunization given																Vitamin A given	Growth Status	
				Child's																		Fully Immunized				
		New	Revisit	Name	Address			BCG	Pentavalent-I	Pentavalent-II	Pentavalent-II	Polio-0	Polio-I	Polio-II	Polio-III	PCV 1	PCV 2	PCV 3	ROTA 1	ROTA 2	Measles	< 1 Yr	> 1 Yr		Normal	Under Weight
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27

Annex 3: Daily Temperature Recording & Vaccine Monitoring Tool

Ministry of Health Daily Temperature Recording and Vaccine Monitoring Tool

Name of Health Facility_____ **Month**_____ **Year**_____ **Source of power: Electricity/Paraffin/Gas/Solar (circle one)**

Date	Temperature				Fridge Tag		BCG doses				OPV doses				DPT-HepB-Hib doses				PCV10 doses				Rota doses				Measles doses				TT doses			
	Fridge		Freezer		Alarm																													
	AM	PM	AM	PM	>8°C	<2°C	Stock at beginning	Received	Used & wasted	Balance	Stock at beginning	Received	Used & wasted	Balance	Stock at beginning	Received	Used & wasted	Balance	Stock at beginning	Received	Used & wasted	Balance	Stock at beginning	Received	Used & wasted	Balance	Stock at beginning	Received	Used & wasted	Balance	Stock at beginning	Received	Used & wasted	Balance
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Annex 4: Monthly Vaccination Performance & Disease Surveillance Report Form

MINISTRY OF HEALTH

FORM NO. EPI/VAC/011

HEALTH FACILITY MONTHLY VACCINATION PERFORMANCE AND DISEASE SURVEILLANCE REPORT FORM

Health Facility: _____ **District:** _____ **MONTH:** _____ **YEAR:** _____

Total population_____ **Annual target population**_____

A. Immunization sessions

	Number	%		Number	%
Planned immunization sessions (Static)			Cancelled immunization sessions (Outreach)		
Cancelled immunization sessions (Static)			Reasons for cancellation		
Planned immunization sessions (Outreach)					

B. Childhood Vaccinations

Age	Monthly Target	BCG				OPV 0				Monthly Target	Measles				Overall dropout rate
		Static	Oireach	Total	Cov	Static	Oireach	Total	Cov		Static	Oireach	Total	Cov	
Under 1															
Over 1															
Total															

Age	Monthly Target	OPV1			OPV2			OPV3				Dropout rate
		Static	Oireach	Total	Static	Oireach	Total	Static	Oireach	Total	cov	
Under 1												
Over 1												
Total												

Age	Monthly Target	DPT-HepB-Hib1			DPT-HepB-Hib2			DPT-HepB-Hib3				Dropout rate
		Static	Oireach	Total	Static	Oireach	Total	Static	Oireach	Total	cov	
Under 1												
Over 1												
Total												

Age	Monthly Target	PCV1			PCV2			PCV3				Dropout rate
		Static	Oireach	Total	Static	Oireach	Total	Static	Oireach	Total	cov	
Under 1												
Over 1												
Total												

Age	Monthly Target	ROTA 1			ROTA 2			Dropout rate
		Static	Oireach	Total	Static	Oireach	Total	
Under 1								
Over 1								
Total								

Age	Monthly Target	Fully immunized children			
		Static	Outreach	Total	Cov
Under 1					
Over 1					
Total					

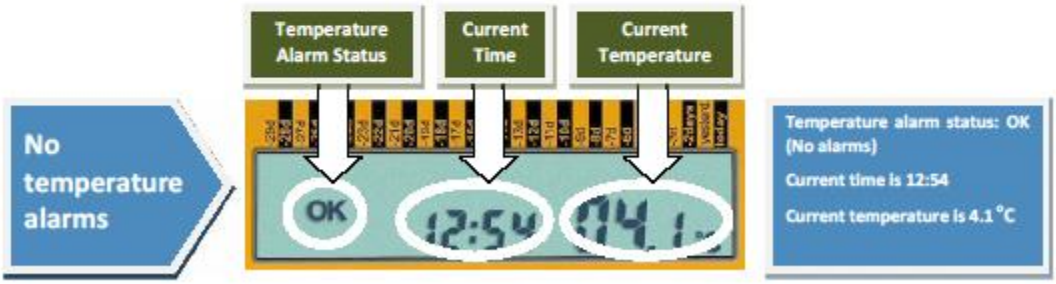
Annex 5: Fridge-Tag Guide

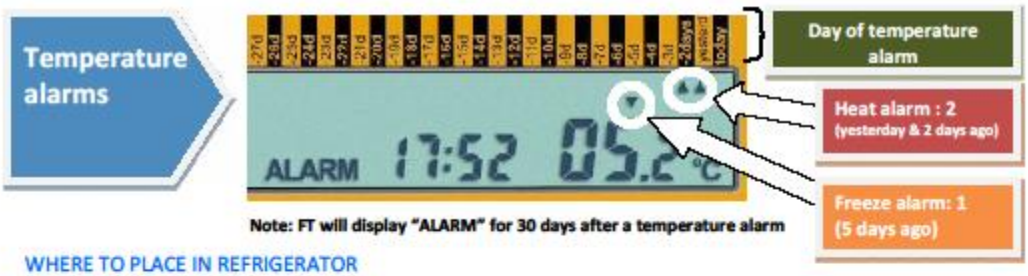
Fridge-Tag™: Users' Guide

The Fridge-Tag™ (FT) is a temperature monitoring device for refrigerators. **Do not place in freezers.** A FT displays information on the temperature inside the refrigerator during the past 30 days. The FT shows which days had temperature alarms. A freeze alarm occurs when the temperature drops below 0.5°C for more than 60min. A heat alarm occurs after 10 hours at above 8°C. A Fridge-Tag™ also displays current temperature and time. This information can tell you how a refrigerator is performing.

HOW TO READ THE FRIDGE-TAG

FT displays provide 3 basic pieces of information: temperature alarm status for the past 30 days, current time and current temperature. When there are temperature alarms, the FT shows what day they happened and if they were heat or freeze alarms.





Note: FT will display "ALARM" for 30 days after a temperature alarm

WHERE TO PLACE IN REFRIGERATOR

FTs should be placed in the REFRIGERATOR where the pentavalent vaccine (or other freeze-sensitive vaccine) is stored. Also consider safety (avoid keeping it in the door to minimize likelihood of FT falling out) and the ease of reading the FT. Do NOT place FTs in the freezer.

WHAT TO RECORD

Twice a day record the temperature on the Fridge-Tag™ recording sheet – once in the morning (AM) and once in the afternoon (PM) at the end of the day. Leave the remaining fields blank for the rest of the day. The next day, record the readings for the previous day (and weekend readings) in the fields that were previously left blank. This should be repeated each day.

WHAT TO DO IF THERE IS AN ALARM

An alarm indicates a serious problem with the fridge and you should immediately contact your supervisor for help.

Heat Alarm	Check all vaccine vial monitors (VVMs) and discard any vaccines with VVMs at stage 3 or 4.
Freeze Alarm	Conduct a shake test on any freeze-sensitive vaccines (eg. penta, TT) stored in the refrigerator. Use at least 3 vials from different locations in the fridge.

Fridge-Tag™: Supervisors' Guide

Review users guide containing basic information on Fridge Tags (FT) prior to reading the Supervisor's guide.

ACTIVATING THE FRIDGE-TAG

- FT must be activated within 1 year of the manufacturing date (written on the back of the FT)
- Firmly press the **'SET'** and **'READ'** buttons **together** for a few seconds until "00:00" flashes on the screen
- Set the time using the **'READ'** button to change a number and the **'SET'** button to save the number and move to the next digit.

Example: Set time to 13:47

- Press **'READ'** once to see "10:00", then press the **'SET'** to save and move to next digit.
- Press **'READ'** 3 times to get "13:00"; then press **'SET'**
- Press **'READ'** 4 times to get "13:40", then press the **'SET'**
- Press **'READ'** 7 times to get "13:47" and then press the **'SET'**. **The time is now set**

- After the time has been set, the 'C' sign will flash in the right bottom corner. Press **'Set'** to record temperatures in Celsius.
- **The FT is now activated**: write the date of activation on the back of the FT. Note it will read 'LoC' for 10 minutes after activation before showing a temperature reading.
- The FT has a shelf life of approximately 2 years from the date of activation.

RE-SETTING THE TIME

If you make a mistake or want to adjust the time after the device is activated, you can reset the time.
First press **'SET'** and keeping that button held down, press the **'READ'** button: "00:00" will flash and you can then repeat the time setting procedure, as above.

DISTRIBUTING FRIDGE-TAGS

The FT must be activated at the health facility where it will be used and it should be immediately into the fridge.

HOW TO READ MAXIMUM AND MINIMUM TEMPERATURES

- Press the **'READ'** button once
- The FT will have a blinking "▲" under "today" and displays the maximum temperature reached today. If a heat alarm was triggered it displays the duration (in hours and minutes) the FT was above 8° C where time usually appears.
- Press **'READ'** again, and FT will have a blinking "▼" and display the minimum temperature. If a freeze alarm was triggered it displays the duration (in hours and minutes) the FT was below 0.5°C.
- Each time you press **'READ'**, the FT will show you first the maximum and then the minimum for each previous days, all the way back to 30 days prior.
- *Remember: the blinking triangle shows you which day and whether it is maximum ▲ or minimum ▼.*

No temperature alarms

Maximum Temperature shown for: Today

Alarm status: OK (No alarms)

Maximum temperature displayed: 6.1°C

Temperature alarm

Minimum Temperature shown for: 2 days ago

Alarm status: Alarm

Minimum temperature displayed: -2.3°C, for 3 hours and 12 minutes below 0.5°C

Annex 6: Steps for Communication During Immunization Session

Steps for interpersonal communication during a vaccination session*:*

Welcome:

1) Greet the mother and infant when they come for vaccination. Ask her about the general health condition of her child and advise accordingly.

Before vaccination:

2) **Ask and confirm the child's age using the Child Health Passport.**
3) Inquire about severe gastroenteritis or serious febrile illness ongoing at the time of the session.
4) Inquire about hypersensitivity reactions to any previous rotavirus vaccine given.
5) Inform the mother about the vaccines the child is going to receive and the diseases they protect against.
6) Explain that there is no harm in giving multiple vaccines at the same time.

After vaccination:

7) Thank the caregiver for the patience and support during the vaccination(s).
8) Inform the caregiver when and where to bring the child for the next vaccination session.
9) Ask the caregiver if she/he has any questions or concerns
10) Advise the caregiver to keep the Child Health Passport in a safe place and to bring it to the next scheduled vaccination session for her child.

Remin*d:*

- ✓ Tell the mother that if the child is not getting complete series of the vaccination, he/she will be left unprotected and risk getting sick from Diarrhoea.
- ✓ The vaccine(s) given may cause mild reactions, including fever, mild diarrhoea and vomiting or a local reaction (e.g. fever, vomiting and swelling, hotness and redness where the child had the injection) for injectable vaccines.
- ✓ Reassure her that serious side effects are rare, but should they occur, the child should be taken to the nearest health facility.

Additional tips on communication

- Listen carefully, demonstrating that you are interested in what the mother has to say.
- Summarize what the client said to show you have understood and answer all her questions.
- Use simple and non-technical words when giving information and answering questions.
- Make the mother/child comfortable while administering the vaccine or recording it. Show loving and caring gestures to her child.

8. References

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Fields Virology, 5th ed. Philadelphia, Lippincott Williams & Wilkins, 2007 (8).

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