

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



IMMUNIZATION AND VACCINE DEVELOPMENT
PROGRAMME



TRAINING MANUAL FOR ROTAVIRUS AND
PNEUMOCOCCAL VACCINES FOR REGIONAL AND
DISTRICT HEALTH MANAGERS

2012



FOREWORD

Globally, Diarrhoea diseases are caused by many different micro-organisms that cause many deaths to children under the age of five years. Diarrhoea due to Rotavirus contributes to 41% of the total diarrhoea cases in developing countries and three quarters of children acquire their first episode of rotavirus diarrhoea before the age of 12 months. In Tanzania diarrhoea diseases are estimated to be responsible for 17% of all deaths in children under 5 years of age.

Although hand washing and improved sanitation has helped to reduce the incidence of diarrhoea, notably those caused by bacteria and parasites, the proportion due to viruses has not been reduced. Prevention options that address other causes of diarrhoea which include good hygiene, sanitation, exclusive breast feeding up to six months, clean and safe water, are significantly less effective for children with rotavirus infections.

Rotavirus vaccines represent the most cost effective intervention for preventing the most severe episodes of rotavirus infection.

Pneumococcal disease is an infection caused by bacteria called Streptococcus Pneumoniae. This disease is the single largest cause of death in children under the age of five years worldwide. The most common types of pneumococcal infections include pneumonia, meningitis, middle ear infections (otitis media), sinus infections and bacteraemia. Other pneumococcal infections include febrile bacteraemia, arthritis, peritonitis, osteomyelitis and bronchitis.

In Tanzania, pneumococcal infection is among the leading causes of deaths in children under the age of five years and contributes to about 14% of overall under five years mortality.

The disease is spread from person to person and spreads fast through breathing, sneezing and coughing by droplets in the air. These diseases are curable if early diagnosed and can be prevented through vaccination. Pneumococcal Conjugate Vaccine (PCV) has been certified for safety by the World Health organization (W.H.O.) to protect against several severe forms of pneumococcal disease.

Tanzania is one of the countries with strong immunization programme for providing vaccinations to under one year old. Considering the importance of protecting children against Vaccine Preventable Diseases the Ministry has added two new vaccines of Rotavirus and Pneumococcal (PCV13) to be provided in the routine Immunization programme.

This manual has been prepared for RHMT and CHMT health workers who are involved in the provision of immunization services so that they can provide quality Rotavirus and Pneumococcal vaccines.

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LISTS OF ABBREVIATIONS AND ACRONYMS

AEFI	-----	Adverse Events Following Immunization
AIDS	-----	Acquired Immunodeficiency Syndrome
ARI	-----	Acute Respiratory Infection
BCG	-----	Bacillus Calmette-Guerin (vaccine against TB)
CCHP	-----	Comprehensive Council Health Plan
CHMTs	-----	Council Health Management Teams
DTP-HepB	-----	Diphtheria Tetanus Pertussis and Hepatitis B vaccine
Hib	-----	Haemophilus Influenza vaccine
EEFO	-----	Earliest Expiry –First –Out (EEFO)
EPI	-----	Expanded Programme on Immunization
FIC	-----	Fully Immunized Children
HIV	-----	Human Immunodeficiency Virus
HMIS	-----	Health Management Information System
IM	-----	Intra muscular route
IMCI	-----	Integrated Management of Childhood Illness
IMR	-----	Infant Mortality Rate
IPC	infection Prevention Control
IVD	-----	Immunization and Vaccines Development
MDG	-----	Millennium Development Goal
MMR	-----	Maternal Mortality Rate
MNCH	-----	Maternal Newborn and Child Health
MOHSW	-----	Ministry of Health and Social Welfare
OPD	-----	Out Patient Department
OPV	-----	Oral Polio Vaccine
PCV 13	-----	Pneumococcal Conjugate Vaccine with 13 antigens
RHMTs	-----	Regional Health Management Teams
TFDA	-----	Tanzania Food and Drug Authority
VVM	-----	Vaccines Vial Monitor
WHO	-----	World Health Organization
UNICEF	-----	United Nation Children Fund

1. ROTAVIRUS

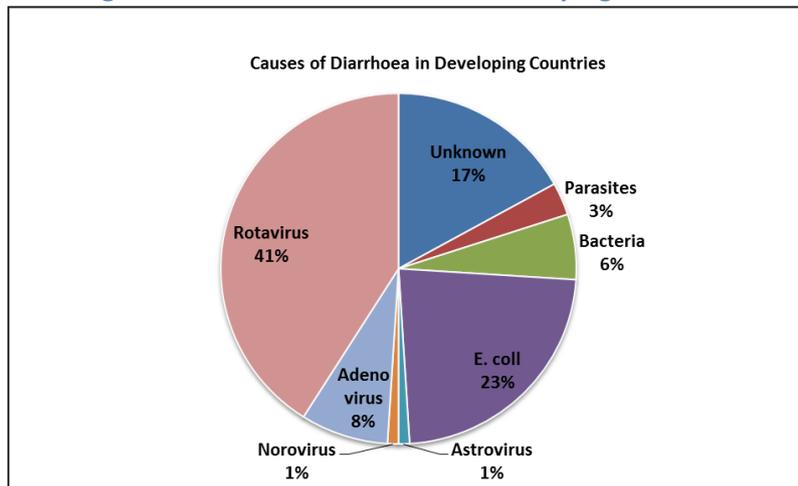
1.1 Epidemiology of Rotavirus

1.1.1 Diarrhoea Diseases

Globally diarrhoea disease is the second leading cause of death in children under five years old, and is responsible for killing 1.5 million children every year. It is estimated that there are about two billion cases of diarrhoea disease every year. Mainly affects children under two years old. It is a leading cause of malnutrition in children under five years old. In developing countries, children under three years old experience on average three episodes of diarrhoea every year.

In 2008, diarrhoea was responsible for approximately 15% of childhood deaths worldwide. Rotavirus contributes 41% of the total diarrhea cases in developing countries as shown in figure 1. In Tanzania diarrhoea diseases are estimated to be responsible for 17% of all deaths in children below 5 years of age.

Figure 1: Causes of Diarrhoea in Developing Countries

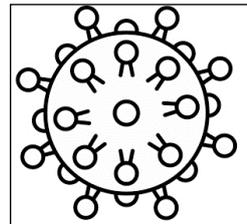


1.1.2 Rotavirus Diarrhoea Diseases

Rotavirus diarrhoea disease is caused by a virus called *rotavirus*. Rotaviruses are the leading cause of severe, dehydrating diarrhoea in children aged below 5 years globally. More than 25 million outpatient visits and 2 million hospitalizations attributable to rotavirus infections each year. In developing countries, three-quarters of children acquire their first episode of rotavirus diarrhoea before the age of 12 months. Severe rotavirus gastroenteritis is largely limited to children aged 6–24 months. In Tanzania several studies indicates that rotavirus is responsible for 30 – 50% of all hospitalised children with diarrhoea.

1.1.3 Causative agent

The name rotavirus comes from the wheel-like appearance of the virus under the microscope. There are five species of rotavirus (A, B, C, D and E) and Rotavirus A causes more than 90% of infections in human.



1.1.4 Modes of transmission

Rotaviruses are shed in very high concentrations ($>10^{12}$ particles/gram) and for many days in the stools and vomitus of infected individuals. Transmission occurs primarily by the faecal–oral route, directly from person to person or indirectly through contaminated fomites. Rotavirus illness follows

an incubation period of 1 to 2 days followed by a progression from asymptomatic to severe diarrhoea. Rotavirus reinfection is common, although the primary infection is usually the most severe clinically. The universal occurrence of rotavirus infections shows that clean water supplies and good hygiene are unlikely to have a substantial effect on virus transmission.

1.1.5 Signs and symptoms

The rotavirus infection affects primarily the small intestinal villi. Destruction of the affected cells reduces digestion and absorption of nutrients, resulting in secretory diarrhoea with a loss of fluids and electrolytes into the intestinal lumen. The rotavirus infection does not cause an inflammatory response, and therefore dysentery does not occur

The clinical spectrum of rotavirus disease is wide, ranging from transient mild diarrhoea to severe diarrhoea which can result in dehydration, electrolyte disturbances, shock and even death. In infants aged >3 months, the first exposure to rotavirus frequently results in gastroenteritis, whereas reinfections are mostly asymptomatic or cause mild disease only. In typical cases, following an incubation period of 1–2 days, the onset of disease is abrupt, with fever and vomiting followed by explosive, watery diarrhea and mucus in stool.

The diarrhoea symptoms normally disappear within 3–7 days, but may last for up to 2–3 weeks. Recovery is in general complete.

1.1.6 Prevention and Control

Although hand washing and improved sanitation has helped to reduce the incidence of diarrhoea, notably those attributable to bacteria and parasites, the proportion due to viruses has not been reduced. Prevention options that address other causes of diarrhoea (i.e., good hygiene, sanitation and exclusive breast feeding) are significantly less effective for children with rotavirus infections.

Rotavirus vaccines represent the most cost effective intervention for preventing the most severe episodes of rotavirus infection.

1.2 Rotavirus vaccines

1.2.1 Registered vaccine in Tanzania

Currently, there are two commercially available vaccines, Rotarix and RotaTeq that are prequalified and recommended for global use by WHO. Rotarix has been registered in for use in Tanzania.



1.2.2 Rotarix vaccine presentation

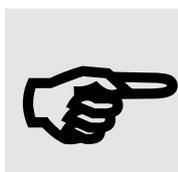
Rotarix vaccine is a solution for oral use. It comes in a tube specially designed for direct oral administration (1 tube = 1 dose; 1 tube has 1.5mL liquid).

1.2.3 Vaccine safety

Rotavirus vaccines are generally well tolerated. They do not appear to cause any serious adverse events. Rotavirus vaccine may be given with other vaccines in the infant routine immunization schedule without interfering with their effectiveness.

1.2.4 Side effects

Very common side effects: irritability, loss of appetite. Common side effects: fever, fatigue, diarrhea, vomiting, flatulence, abdominal pain, regurgitation of food. Severe reactions are very rare and may include a slight increased risk of intussusception.

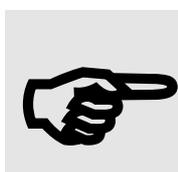
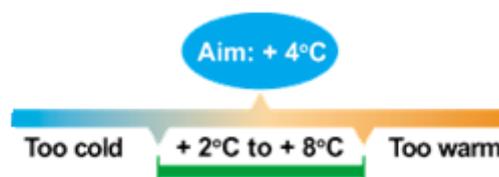


Key messages:

- Rotavirus vaccine has a liquid formulation
- Vaccine comes in a squeezable plastic tube
- Irritability and loss of appetite are very common side effects of rotavirus vaccine

1.2.5 Vaccine storage

The rotavirus vaccine should be stored at temperature between +2°C to +8°C. It should not be frozen. If the vaccines are frozen, they lose their potency and no longer provide protection against the disease.



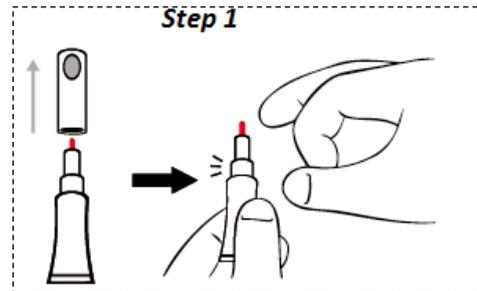
Key messages:

- Store vaccines between +2°C to +8°C
- Do not freeze the vaccine

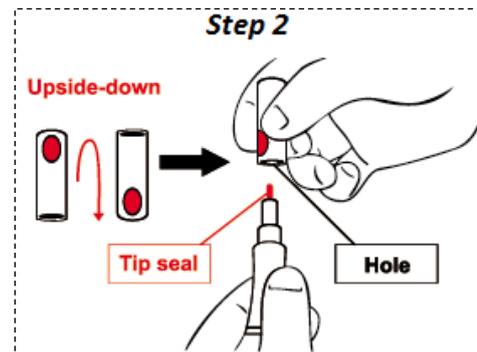
1.3 Regularly monitor the temperature of the refrigerator Administration of rotavirus vaccine

1.3.1 Steps for preparing the vaccine

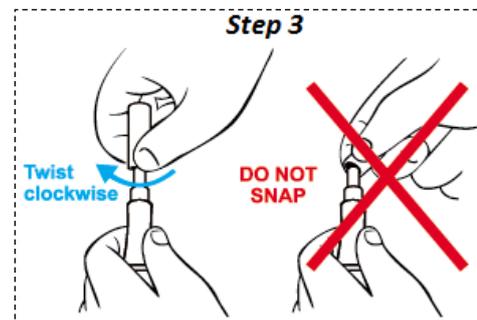
Step 1: Pull off the cap from the tube. Clear the fluid from the upper part of the tube by tapping the tube.



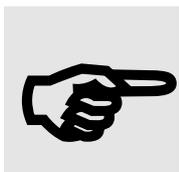
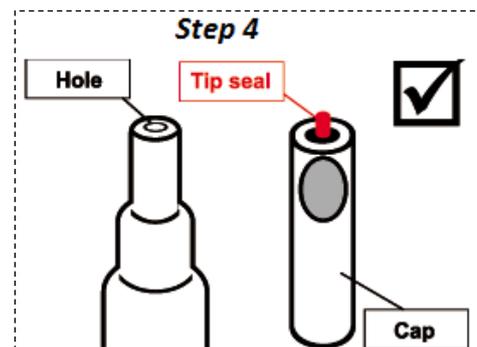
Step 2: Turn the cap upside-down and place the cap vertically onto the tip seal. Insert the tip seal into the small hole in the top of the cap.



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 that the detached tip seal is inside the top of the cap. If the tip seal of the vial falls into the tube discard the vaccine.



Key messages:

- Do not snap off tip seal: It may fall into tube
- The vaccine must be discarded if the tip seal falls into the tube

1.3.2 How to position the child for rotavirus vaccination

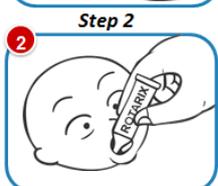
The child should be seated in a semi-reclining position (i.e. normal feeding position).



1.3.3 Administration of the vaccine



Step 1: Gently squeeze the child's cheeks to open the mouth.



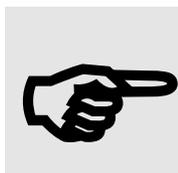
Step 2: Put the tube towards the inner cheek.



Step 3: 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. Administer the entire content of the tube by gently squeezing it several times. Make sure the child is swallowing the vaccine to prevent buildup in the mouth.



Step 4: Gently hold the cheeks together and stroke the child under the chin to help with swallowing.



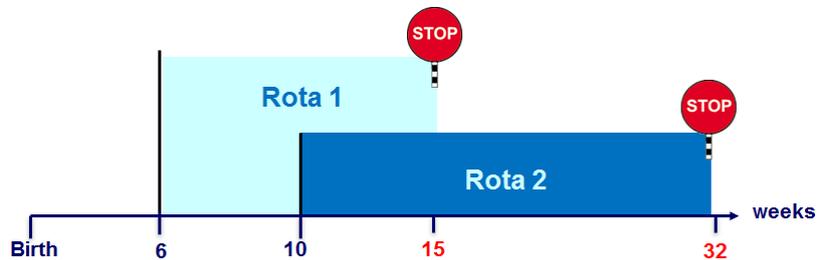
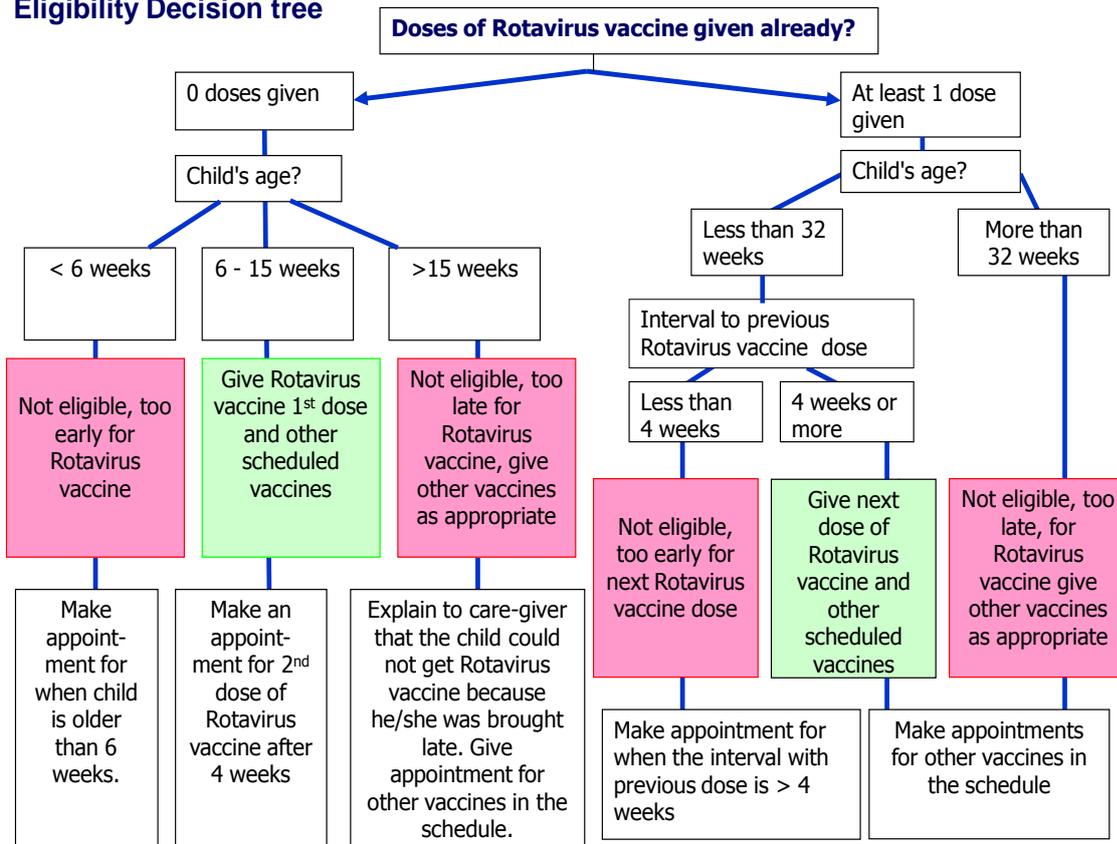
Key messages:

- *The rotavirus vaccine dose quantity is larger than that of oral polio vaccine (Rotarix™1.5 ml) and infants might not take the full dose all at once*
- *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*

1.3.4 Rotavirus vaccine schedule

Rotavirus vaccine is given in a 2-dose schedule: first dose at 6 weeks and second/last dose at 10 weeks of age. Remember that the first dose of vaccine must be given by 15 weeks and second dose by 32 weeks. Maintain the minimum interval of 4 weeks between doses. Infants coming late for vaccination can, however, get other vaccines in the schedule.

Eligibility Decision tree



Key messages:



- First dose of rotavirus must be given between 6 to 15 weeks only,
- Second dose should be given between 10 to 32 weeks,
- Do not start the rotavirus vaccination to children older than 15 weeks
- Do not give the second dose of rotavirus vaccine to children older than 32 weeks of age.
- Rotavirus vaccine doses can be given at the same time as first and second dose of OPV and DTP-HepB-Hib (i.e. OPV1, and OPV2, Penta1 and Penta2)

1.3.5 Contraindications

- Hypersensitivity after previous administration of rotavirus vaccines
- Previous history of intussusception
- The administration of rotavirus vaccine should be postponed in children suffering from diarrhea or vomiting and in need of rehydration therapy
- Note that mild illness such as an upper respiratory tract infection is not a contraindication.

1.4 Communication for Rotavirus vaccine

1.4.1 Background

Healthcare workers should establish an open, friendly dialogue with parents at an early stage and provide easily comprehensible answers about known vaccine adverse events and provide accurate information about vaccination.

1.4.2 Triple A communication

Triple A communication is a mnemonic system that allows health workers to remember the three ways of communicating with parents.

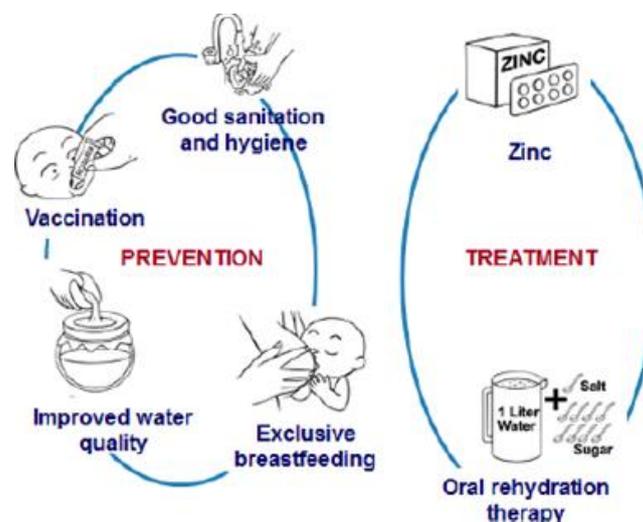
- **Advice** parents on what is given (disease prevented, vaccine used, etc.)
- **Alert** on side effects after immunization and how to respond to that possible side effects
- **Arrange** and fix with parents the next appointment for administering the second dose of the vaccine

1.4.3 What to communicate about the 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.

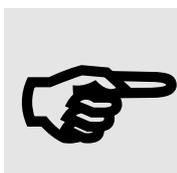
1.4.4 Messages on diarrhea prevention and treatment

Prevention methods against rotavirus disease include breastfeeding, improvements in nutrition, hygiene, and water quality; they 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 most effective way to prevent the severe episodes of rotavirus infection. Treatment for diarrhea disease includes zinc and oral rehydration therapy.



Key messages:

- Rotavirus infection is highly contagious
- Vaccination is the only way to prevent the severe episodes of rotavirus infection.

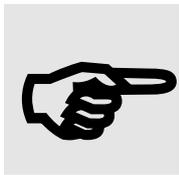


1.4.5 Message on rotavirus vaccine

- Rotavirus vaccine is very safe and effective
- The rotavirus vaccine is given orally at the same time as pentavalent vaccine; therefore no extra visit is required to get Rotavirus vaccine separately. . Rotavirus vaccine prevents the most common cause of diarrhoea, but your child can still get diarrhea due to other agents.

1.4.6 How to advice on the rotavirus vaccine schedule

- Explain to the caretakers 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.
- Rotavirus vaccine is given orally in 2 doses at ages 6 and 10 weeks. Children should be vaccinated with the first dose of rotavirus by 15 weeks and the second (last) dose by 32 weeks. There should be an interval of at least 4 weeks between the 2 doses.



Key messages:

- *Vaccination is the only way to prevent the severe episodes of rotavirus infection,*
- *A child immunized with rotavirus vaccine can still get diarrhea from other agents*
- *On-time vaccination is very important.*

1.5 Summary on Rotavirus diarrhoea and vaccine

1.5.1 General

- Rotavirus Vaccine (RV) prevents the **leading cause of severe diarrhoea in children** (~40% of diarrhoea hospitalizations).
- Unlike other infectious causes of diarrhoea, **rotavirus remains common with access to clean water and sanitation**; nearly **all children are exposed to rotavirus in their first five years**
- For a vaccine to work, it must be given before exposure to the infection. **Timely immunization is vital for all vaccines, especially Rotavirus Vaccine** as children get infected from the first weeks of life.
- In Tanzania, children are exposed earlier in life; it is estimated that , half of all children get infected before the age of 32 weeks .
- Most of the children die from diarrhoea diseases; efforts are needed to vaccinate these children.

1.5.2 Administration of vaccine

- Rotavirus Vaccine will **prevent many but not all causes of diarrhoea**. When a vaccinator gives Rotavirus Vaccine, it is a great opportunity to remind caregivers about (1) other healthy actions to prevent diarrhoea - especially breast-feeding and hand-washing with soap; (2) home treatment of diarrhoea, and give or advise how to get ORS and Zinc; and (3) danger signs for seeking health care.
- It is important to remind the caregiver of the need to complete the **full immunization schedule (all antigens)**, date of the next visit and the importance of **timely receipt for all vaccines**.
- The vaccine is given orally, like OPV – however, this is a bulkier dose of vaccine (1.5cm³ compared to two drops for OPV). Rotavirus vaccine takes more time to fully administer, and the method of giving is different to OPV (given on the inside of the cheek)
- It is important to **open the vaccine tube correctly** to prevent the small nozzle being dropped inside the tube and possibly inhaled by the child.

1.5.3 Targeting of most vulnerable

- Communities with infants who are currently un or under-vaccinated are the ones with most to benefit from Rotavirus Vaccine. Special focus on reaching these populations should be part of the RV introduction planning
- For communities who are only reached four times (or less) per year with immunization services, timely vaccination is not feasible. As infants in these communities are also the ones at greatest risk, additional resources may be needed to provide more frequent immunization sessions and/or modified schedules to ensure timely vaccination with all antigens, including all Rotavirus Vaccine doses.

1.6 ROTAVIRUS: FREQUENTLY ASKED QUESTIONS

What is rotavirus?

Rotavirus is the most common cause of severe diarrhea in young children worldwide. It can result in acute dehydration, vomiting, and fever and is responsible for more than 500,000 deaths each year, mostly in developing countries.¹

How is rotavirus spread?

Rotavirus is highly contagious and is typically transmitted by the faecal-oral route. Contaminated water, hands, or objects pass the virus. The virus can survive well on toys or other surfaces. It may also be spread through droplets in the air.

What are the symptoms of rotavirus infection?

After an incubation period of 18 to 36 hours, a child may develop diarrhea that lasts for 3 to 7 days. The illness often begins with explosive vomiting and may be accompanied by fever. With severe diarrhea and vomiting, a child can become dehydrated from acute loss of fluid and electrolytes, which can lead to shock, cardiac arrhythmia, and death.

Where does rotavirus infection occur?

Rotavirus is found in every country. Regardless of where they live, virtually all children become infected in the first 3 years of life. Because of greater access to medical care, children in industrialized countries are at lower risk of death. However, in the United States alone, rotavirus causes an estimated 50,000 hospitalizations each year.

Why haven't we heard of rotavirus before?

Rotavirus is a relatively "new" disease, only clinically discovered in 1973. Since then it has taken many years to get a sound estimate of the disease burden, and complete, accurate data from Asia and Africa are still needed.

What can be done to prevent rotavirus and diarrheal disease in general?

In the past 20 years, diarrhea mortality has decreased significantly due to improvements in sanitation and nutrition and the availability of oral rehydration solution (ORS). Mortality due to rotavirus remains a stubborn exception. Improvements in water, sanitation, and hygiene do not significantly reduce its spread. Vaccination is the only way to prevent severe episodes of rotavirus infection, and rotavirus vaccines will be an important new addition to a portfolio of interventions to prevent and manage diarrheal disease. This portfolio should include rotavirus vaccines, as well as ORS, zinc, breastfeeding, and improvements in nutrition, hygiene, and water quality.

Why does clean and safe water reduce diarrhea but not rotavirus?

Rotavirus is so contagious and resilient that providing safe water and promoting good hygiene do not significantly impact incidence. Incidence is nearly the same around the world, regardless of water quality and hygiene practices.

What is the treatment for rotavirus?

ORS is a common intervention for managing diarrhea, and it can be effective in treating mild rotavirus infections. In severe cases when rapid dehydration occurs, however, ORS is not sufficient, and urgent medical care is required.

What are the symptoms of intussusception?

Intussusception is a rare type of bowel obstruction that occurs when one portion of the bowel slides into an immediately adjacent segment (also known as telescoping or prolapse). Complications of this can lead to intestinal swelling, inflammation and decreased blood flow to the part of the intestines involved.

Symptoms of intussusception include abdominal pain with severe crying (which may be brief); several episodes of vomiting; blood in the stool; or a baby may act weak or become very irritable. Intussusception is very rare.

What is the risk of intussusception following Rotarix™?

Studies have suggested that the Rotarix™ vaccine may be associated with a slight increased risk of intussusception in infants after they receive the vaccine, especially during the first week. Whether Rotarix™ affects the overall incidence of intussusception has not

been established. The rotavirus vaccine offers tremendous benefits by protecting infants and children from rotavirus disease. Rotavirus is the most common cause of severe diarrhea among infants and young children. The risk of intussusception after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated children.

2. PNEUMOCOCCAL

2.1 Epidemiology of pneumococcal diseases

2.1.1 Pneumococcal Diseases

Pneumococcal disease is an infection caused by the *Streptococcus pneumoniae* bacterium, also known as pneumococcus. It is commonly found in the nose and throat of healthy people without causing disease. It can spread to different parts of the body to cause a variety of diseases, one of which is pneumonia. The most common types of pneumococcal infections include pneumonia, middle ear infections (otitis media), sinus infections, bacteraemia, and meningitis. Other pneumococcal infections include febrile bacteraemia, arthritis, peritonitis, osteomyelitis and bronchitis.

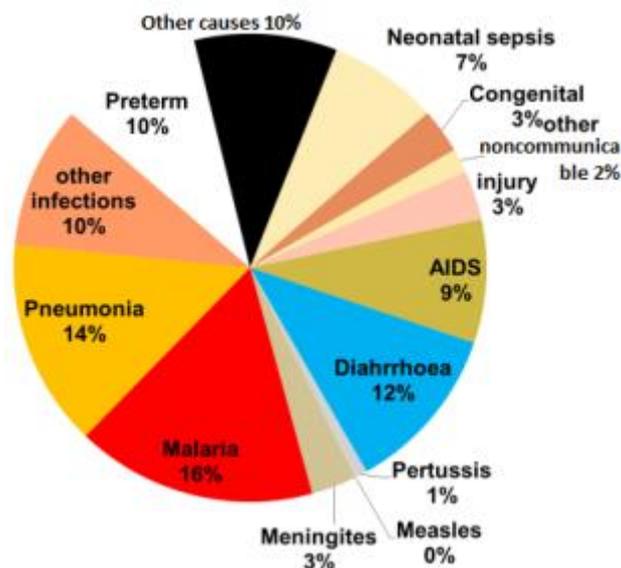
2.1.2 Disease Burden

Pneumonia is the single largest cause of death in children worldwide. Every year, it kills about 1.4 million children under the age of five years. In Africa, it is responsible for 18% of below 5 years mortality. Infants have the highest rates of pneumococcal disease, while the most at-risk group are children below two years of age.

In Tanzania, pneumococcal infection is among the leading causes of deaths in children under the age of five years and contributes to about 14% of overall under five years mortality. WHO estimates that the number of severe illness cases and deaths from Hib and *Streptococcus pneumoniae* (Spn) in children from one month to less than five years of age in Tanzania are:

- About 104,095 cases of *Haemophilus influenzae* type b with 6,459 deaths
- Whereas *Streptococcal pneumoniae* cases are 222,256 with annual estimated deaths among under 5 children is 15,206

Figure 1: Causes of under five years mortality in Tanzania



2.1.3 Mode of Transmission

The disease is spread from person to person. It spreads through breathing, sneezing and coughing by droplets in the air. The pneumococci bacteria are common inhabitants of the human respiratory tract. They may be isolated from the nasopharynx in 5–70% of normal, healthy adults.

2.1.4 Signs and symptoms

The symptoms of pneumonia include cough, fever, rapid or difficult breathing, chills and loss of appetite. When pneumonia is severe, children may experience lower chest in-drawing. Infants may be unable to feed or drink and may also lead to loss of consciousness, hypothermia and convulsions.

Complications of pneumococcal diseases include empyema (pus in the pleural space), pericarditis (inflammation of the sac surrounding the heart), endo-bronchial obstruction with atelectasis (collapse of lung tissue) and lung abscess formation.

2.1.5 Control, Prevention and management

Adequate nutrition is important in improving child's natural defences. Exclusive breastfeeding for the first six months of life prevents pneumonia and helps to reduce the length of the illness if a child does become ill.

In reducing risks of spread of infection in children encourage good hygiene; avoid overcrowded houses and indoor air pollution. In children infected with HIV, cotrimoxazole when given daily will decrease the risk of contracting pneumonia.

Management of severe childhood Acute Respiratory Infection (ARI) and meningitis are managed with antibiotics according to IMCI guideline. Hospitalization is recommended for severe cases and infants aged two months or younger. In many countries however, strains of pneumococcus are becoming increasingly resistant to some commonly used antibiotics. Pneumococcal infections which are resistant to the commonly used antibiotics require treatment using other broad spectrum and expensive antibiotics.

Immunization against pneumococcus, Haemophilus Influenza B, measles and whooping cough (pertussis) is the most effective way to prevent pneumonia. Preventing pneumonia in children is an essential component of a strategy to reduce child mortality.

2.2 Pneumococcal Vaccine

2.2.1 Pneumococcal Conjugate Vaccine

Pneumococcal Conjugate Vaccines (PCV) protect against several severe forms of pneumococcal disease, such as meningitis, pneumonia and bacteraemia. PCV will not prevent pneumonia caused by other agents or other strains of pneumococcus that are not contained in the vaccine. The vaccine that will be introduced in Tanzania in 2013 will protect against 13 common types of pneumococcal serotypes and is therefore referred to as Pneumococcal Conjugate Vaccine 13 (PCV13).

2.2.2 Vaccination schedule

PCV13 is given by intramuscular injection in a dose of 0.5 ml. The primary series consists of three doses at minimum intervals of four weeks, starting at the age of 6 weeks, then 10 weeks and 14 weeks.

PCV13 will be administered along with other IVD vaccines. The vaccine should not be mixed with other vaccines in the same syringe or given on the same site with other injectable vaccines. The vaccine will be given on the anterior lateral aspect of the right thigh.

Integrating PCV13 vaccine into the routine immunization schedule

Children who will be below one year of age and have not started pentavalent vaccine during the introduction period will be eligible for the three doses of the pneumococcal Conjugate Vaccine with a 4 weeks interval between each dose. Those children who have started pentavalent vaccine should continue with the old schedule and will not be eligible for the pneumococcal vaccine.

2.2.3 Steps to ensure that an infant is vaccinated on time

It is important to offer vaccines every day of the year, to reduce missed opportunities for vaccinating children. Whenever infants visit the health facility their immunization record should be screened, and they should be given all the vaccines they are eligible to receive. If children did not get a second or third dose of PCV13 vaccine on time, do not restart: they should continue with the remaining doses, given 4 weeks apart from the previous dose. Children should receive all the three doses of PCV13 vaccine by their first birthday. It is therefore very important to record accurately all necessary information, including date of the next visit in the child health card. The care taker should be reminded on the importance of completing the full immunization schedule and date of the next visit.

2.2.4 Safety of pneumococcal vaccine

Pneumococcal conjugate vaccine has been proven to be safe and well tolerated even among children infected with HIV, malnutrition and sickle cell disease. Severe adverse reactions due to the vaccine are extremely rare. Mild side effects such as soreness and redness at the injection site and transient fever of $\geq 39^{\circ}\text{C}$ have been reported in less than 5% of children vaccinated.

It is important to note that pentavalent will be given at the same visit as pneumococcal vaccine, thus the child may also be reacting to the pentavalent vaccine.

2.2.5 Contraindications to pneumococcal conjugate vaccine

Infants with moderate or severe illness (temperature $\geq 39^{\circ}\text{C}$) should not be vaccinated until they improve. Mild illness such as upper respiratory tract infection is not a contraindication. PCV13 should not be given to anyone who has had severe allergic reactions to a previous dose.

2.3 Administration of the vaccine

2.3.1 PCV 13 packing

This section outlines general information on safety of vaccine administration with specific recommendations for the PCV13 single dose liquid vaccine presentation. PCV13 is a liquid vaccine in a single dose vial and is packed in boxes of 50 vials.



2.3.2 Storage of PCV13 vaccine

Like most other vaccines, PCV13 should be stored and transported between +2 to +8 ° C at all levels. Do not freeze or place PCV13 vaccine on a frozen icepack. PCV13 vaccine loses potency and provides no protection if frozen. If there is doubt, the “shake test” should be performed to check whether the vaccine has been frozen.

To avoid exposure of the vaccine to freezing, cool water packs should be used. To condition an ice-pack, leave the ice pack at room temperature until there is some liquid water in it.

3.3.3 Administration of Pneumococcal Conjugate Vaccine 13

- Instruct the mother on how to hold the baby for vaccine administration.
- Shake the vaccine well and only use if the vaccine is a homogenous white suspension
- Draw up 0.5 ml with a new sterile needle.
- Administer the vaccine on the right anterior lateral aspect of the mid-thigh intramuscularly (syringe at 90⁰).
- In case of bleeding Press the injection site firmly using dry cotton wool for a few seconds. Do not massage



Key messages:

- *PCV13 should be given on the anterior lateral aspect of the right mid- thigh and Pentavalent on the anterior lateral aspect of the left mid-thigh.*
- Frozen PCV 13 should be discarded

2.4 Communication strategies

2.4.1 Background

Healthcare workers should establish an open, friendly dialogue with parents at an early stage and provide easily comprehensible answers about known vaccine adverse events and provide accurate information about vaccination.

2.4.2 Triple A communication

Triple A communication is a mnemonic system that allows health workers to remember the three ways of communicating with parents.

- **Advice** parents on what is given (disease prevented, vaccine used, etc.)
- **Alert** on side effects after immunization and how to respond to that possible side effects
- **Arrange** and fix with parents the next appointment for administering the second dose of the vaccine

2.4.3 What to communicate about the disease

- What diseases does Pneumococcus cause?
 - Pneumonia
 - Meningitis
 - Bacteremia
 - Others: middle ear infection (otitis media), sinusitis and bronchitis.
- Pneumonia is a leading killer of children under 5 years old. In Tanzania, one in every five deaths in children is attributed to pneumonia.
- Pneumonia is an airborne disease that is spread from person to person e.g. through coughing and sneezing.
- Pneumonia can be prevented by vaccinating children with the pneumococcal vaccine (PCV 13).
- The vaccine is safe, effective and provided free of charge in all health facilities in Tanzania.
- It is important that your child receives all three doses of PCV 13 vaccines before the age of one year at 6, 10, 14 weeks.
- In addition to immunization, pneumonia can be prevented by exclusive breastfeeding during the first 6 months of the child's life, good nutrition, reducing overcrowding and hand-washing with soap.
- Although it may be uncomfortable for the child to receive two injections at the same time, the benefits outweigh the risk of contracting and managing pneumococcal diseases.
- PCV 13 vaccine is safe but occasionally this vaccine may cause a mild reaction, including a fever or a local reaction (swelling, hotness and redness where the child had the injection). Serious side effects are rare but should they occur, the child should be taken to the nearest health facility

2.4.4 Common concerns of caretakers

- Pain from injection
- Fear that already sick and weak children will become worse for too many vaccines given.

2.4.5 Messages to give the caretakers

- Pain is usually short-lived
- A new vaccine against Pneumonia disease has been added to our country's schedule. The Vaccine will greatly reduce the child's risk of contracting pneumonia and meningitis.
- It is extremely important to protect your child from these diseases as early in life as possible.
- The vaccine will not make the child worse

- If your child is not vaccinated today he/she will be left unprotected and risk getting sick from Pneumonia.
- All children under one year who have not started immunization will be eligible for PCV 13.

2.4.6 Advice on the PCV 13 immunization schedule

Explain to the caretakers that it is important to get vaccinated on time.

- PCV 13 is given through injection in three doses at 6, 10 and 14 weeks. There should be a minimum interval of at least 4 weeks between the doses. The vaccine is give at the same session with Pentavalent vaccine.
- Child who has already started Pentavalent 1 and now coming for second dose is no longer eligible for PCV13
- Pain and discomfort for the child receiving two injections at the same time in two different sites might be experienced. But the benefits of the two injectable vaccines outweigh the risk of contracting and managing the disease.
- PCV 13 may cause a mild reaction which include fever and or local reaction (swelling, hotness at the injection site). Serious side effects are rear but should they occur, the child should be taken to the nearest health facility



Key messages:

- *Vaccination is among the ways to prevent the severe pneumonia and meningitis.*
- *A child immunized with PCV 13 can still get pneumonia and meningitis from other agents*
- *On-time vaccination is very important.*
- *If child had had its first dose of Pentavalent vaccine, on coming for subsequent doses should not start (be given) PCV13.*

2.4.7 Messages for care givers

- Pneumonia and meningitis (infection of the membranes covering the brain) are among the most common causes of death and disability in children.
- Vaccines can help to greatly reduce your child's risk of contracting pneumonia and meningitis.
- The pneumococcal vaccines are very safe and effective for protecting against one of the most common and serious bacteria causing childhood pneumonia and meningitis.
- It is important that your child receives all three doses of PC V13 vaccines before the age of one year at 6 weeks, 10 weeks and 14weeks.
- In addition to immunization, children can be protected from pneumonia by exclusive breastfeeding during the first 6 months of the child's life, good nutrition, reducing overcrowding and hand washing with soap.
- Although it may be uncomfortable for the child to receive two injections at the same time, the benefits outweigh the risk of contracting and managing pneumococcal diseases.
- PCV13 vaccine is safe. Occasionally this vaccine may cause a mild reaction, including a fever or a local reaction (swelling, hotness and redness where the child had the injection). Serious side effects are rare but should they occur, the child should be taken to the nearest health facility.

2.5 Frequently Asked Questions

Why is it that only children below one year of age are receiving this vaccine?

Despite the fact that children aged below 5 years are most vulnerable to pneumococcal diseases, the burden of pneumococcal disease is highest in children below one year. In introducing this vaccine, the government has decided to vaccinate children at the earliest opportune time.

Can older children and adults receive this vaccine?

No, the PCV13 vaccine that is being introduced is specifically formulated for younger children.

Is it safe to give my child two vaccine injections at the same time?

Yes, it is safe to give pentavalent and PCV13 vaccines at the same time.

Are there any side effects for this vaccine?

This vaccine is relatively safe. Occasionally children vaccinated with this vaccine may develop a mild fever or a local reaction (swelling, redness, hotness, where the child had the injection). Notably, most children get better quickly. However, if the side effects persist, please take them to the nearest health facility.

Will it make a difference if my child isn't immunized at 6, 10 and 14 weeks?

Your child must receive all the vaccinations necessary at the time when they most need them. Not having the vaccinations as scheduled may put your child at risk of contracting diseases. However, do not hesitate to bring your child for vaccination even if late, as long as the child is still eligible.

My child is sick today. Is it okay for she/he to have the immunization?

Mild conditions like a common cold should not be regarded as contraindications for vaccination with this vaccine. Only children with severe illness, as determined by a health worker (e.g. fever $\geq 39^{\circ}\text{C}$) should wait until their condition improves before being vaccinated.

How do I know if my child has pneumonia?

Symptoms of pneumonia may include cough, fever, difficulties in breathing. Always take your child immediately for assessment by a qualified health professional. Early treatment of pneumonia can prevent serious complications and death, even in children who have received all their vaccines.

After my child is vaccinated with this vaccine, can he/she still contract pneumonia?

There are many organisms that cause pneumonia. This vaccine will protect your child against the most severe types of pneumonia. There is a small risk of your child contracting other forms of pneumonia but this risk is lower compared to children who are not vaccinated with this vaccine.

My child is HIV positive, should he/she be vaccinated with this vaccine?

This vaccine is safe to be administered to HIV positive children.

I always ensure my child is warm. Isn't this enough to protect against pneumonia?

Keeping the child warm is important but it is not enough to prevent pneumonia. Pneumonia is an airborne disease that is transmitted from person to person. It is important that your child is vaccinated against pneumonia.

My child was previously treated for pneumonia, should he/she receive this vaccine?

Yes, there are several causes of pneumonia; therefore it is still possible for your child to get pneumonia again. PCV13 vaccine protects against the most severe forms of pneumonia and can reduce the chances of your child having another episode of pneumonia.

2.6 Waste management

2.6.1 Introduction

Injection sharps pose a serious health and environmental problem. 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 health workers from mishandling of equipment.

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.

2.6.2 Ensuring safe disposal of injection

All used syringes and needles must be disposed of immediately after use throughout the immunization procedure by dropping them into the safety boxes. These boxes reduce the risk posed by contaminated needles and syringes to both the health staff and the general public.

Close the nearly (approximately 3/4) full box securely shut and store the box in a safe place until it can be properly disposed of, so as to prevent infecting health care workers and the community. To avoid an occupational hazard, safety boxes should not be over-filled. One box can hold 90 to 100 syringes and needles.



2.6.3 Handling of boxes

Contaminated sharps should not be transferred from container to container, and must not be left in a public area of the health facility. Do not transfer filled safety boxes from one place to the other if you expect any damage to the containers to allow spill or uncontrolled drop of used sharps.

2.6.4 Disposal of Contaminated Sharps

Used syringes and needles at immunization posts will be discarded in the safety boxes provided for the purpose. At the end of each implementation day, safety boxes will be disposed of as follows:

3.4.4.1 Incineration

- **The best method of disposing of contaminated sharps is by means of Incineration.**
- **Incineration provides high temperatures and destroys microorganisms and therefore is the best method for disposal of used syringes, sharps and other medical wastes.**
- **Incineration also reduces the bulk size of wastes to be buried.**
- **Incinerators of the type Mark I and III De Montfort are recommended**
- **Ash and remains from incineration should be buried in a pit as described below.**

3.4.4.2 Pit Burning

- Where incineration is not possible, choose an unused area for the burning site, as far from buildings as possible. The area should be cleared and fenced.
- Dig a pit at least 1.5 meter wide and 2 metres deep
- Place the filled safety boxes in the pit. Mix paper, leaves, or other flammable materials among the boxes to help them burn.

- Warn people to stay away (fencing) and avoid smoke, fumes, and ash from the fire.
- Burn until all boxes and contents are destroyed
- Use the pit on subsequent implementation days, covering completely each layer of burned waste with a thin layer of soil till the last day.

2.6.5 Disposal of other wastes

Any other waste should NOT be put into the safety boxes. Instead, other waste should be disposed of in a bin and burned regularly along with the safety boxes by incineration or pit burning

3. ANNEX 1. ROUTINE IMMUNIZATION SCHEDULE

Age of administration	Vaccine	Dose	Route
At birth	BCG	0.05 ml	Intradermal deltoid muscle right arm
	OPV 0	2 drops	Oral
6 weeks	OPV 1	2 drops	Oral
	Pentavalent 1	0.5 ml	Intramuscular anterior-lateral aspect of the left mid-thigh
	PCV 1	0.5 ml	Intramuscular anterior-lateral aspect of the right mid- thigh
	Rotarix 1	1.5 ml	Oral
10 weeks	OPV 2	2 Drops	Oral
	Pentavalent 2	0.5 ml	Intramuscular anterior-lateral aspect of the left mid-thigh
	PCV 2	0.5 ml	Intramuscular anterior-lateral aspect of the right mid- thigh
	Rotarix 2	1.5 ml	Oral
14 weeks	OPV 3	2 Drops	Oral
	Pentavalent 3	0.5 ml	Intramuscular anterior-lateral aspect of the left mid-thigh
	PCV 3	0.5 ml	Intramuscular anterior-lateral aspect of the right mid- thigh
9 months	Measles	0.5 ml	Subcutaneous anterior-lateral aspect of left upper arm

*BCG: In case the child was not vaccinated at birth can be vaccinated anytime the child attends the clinic for the first time

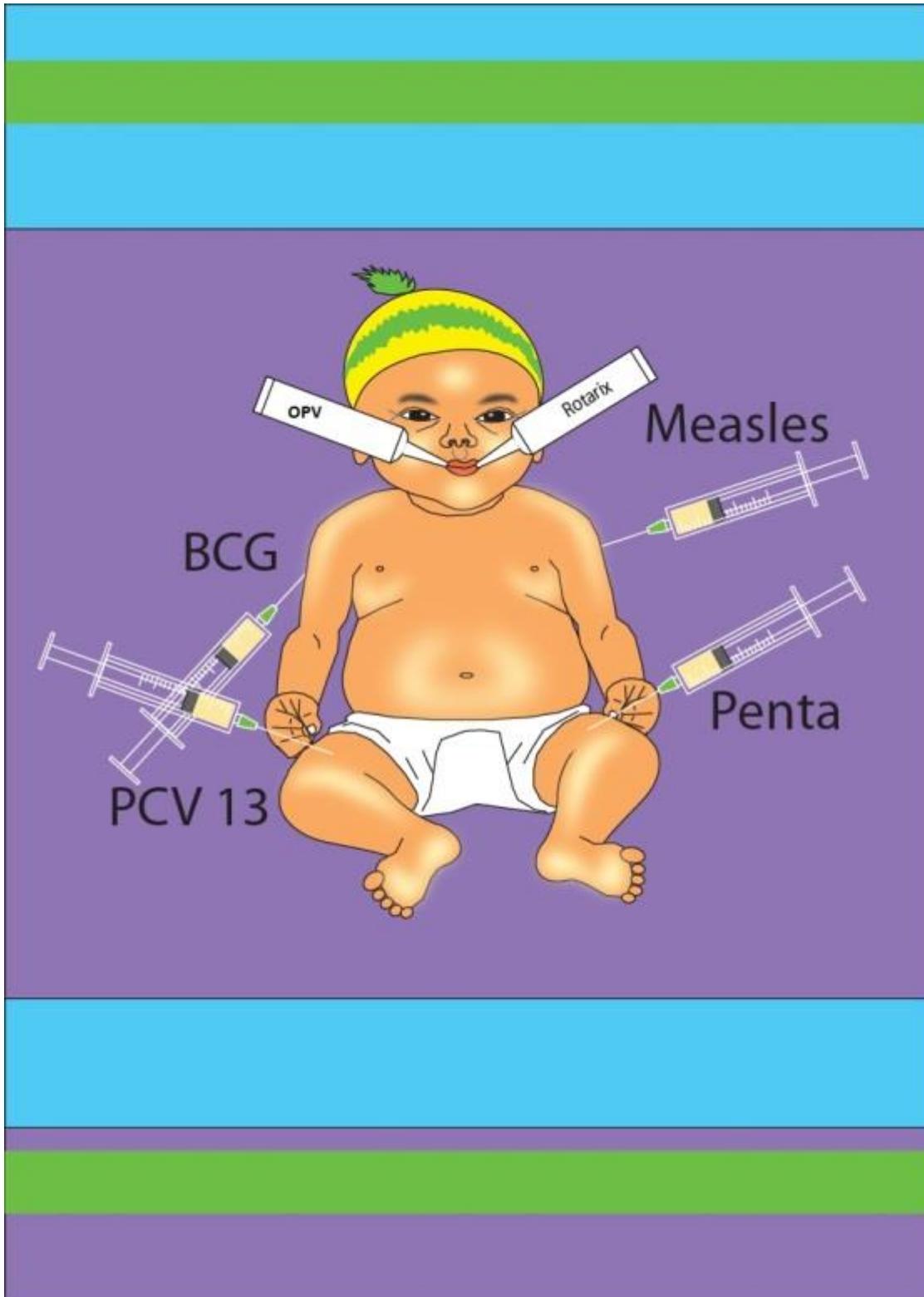
**OPV 0: In case the child was not vaccinated at birth can be vaccinated within 14 days after birth. After 14 days there is no need to give OPV 0.



Key messages

- *It is important to follow immunization schedule*
- *It is important to receive all vaccines*
- *Vaccines are safe and can be given together*
- *Inform the caretaker the date to come next dose or vaccination*

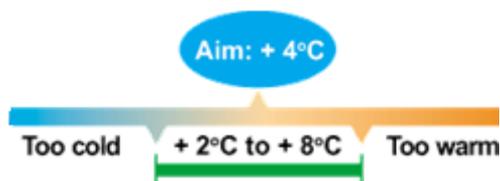
4. ANNEX 2. VACCINATION SITES FOR ALL ANTIGENS CURRENTLY BEING PROVIDED IN TANZANIA



5. ANNEX 3. STORAGE AND TRANSPORTATION OF VACCINES

5.1 Cold chain, transportation and storage of vaccines

Vaccines must be transported and stored at + 2°C to + 8°C either in the vaccines carrier, cold box or fridge. Vaccines should not be frozen.



5.2 Use of chilled packs

Frozen ice packs are not allowed to be used while transporting vaccines at all levels because they can cause the vaccines to be frozen. While transporting vaccine either in vaccine carrier or cold boxes use the chilled packs.



Key message

Frozen vaccines should not be used even if the expired date has not been reached.

5.3 Freeze-tag

Freeze-tag must be used to ensure the vaccines are safe and not frozen during transportation or in the fridge.

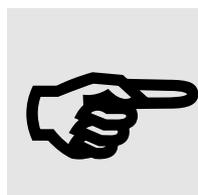
Freeze-tag is a gadget which helps to monitor the temperature in the vaccine carrier, cold boxes and fridge not to be below -0.5°C for more than 1 hour.

In case the temperature goes below -0.5°C for more than 1 hour the (v) sign will change to (x) sign as shown in the two pictures.

Vaccine are safe



Do shake test



Key message

- *Ensure all fridges keeping vaccines have a freeze tag*
- *Once you receive vaccines check the freeze-tag if it is still with (v) sign*
- *Ensure that when you transport vaccines put the active freeze-tag in the vaccine carrier or cold box. Never transport vaccine without a freeze tag.*

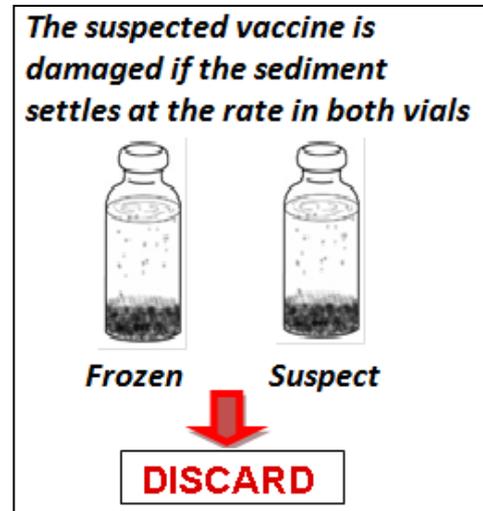
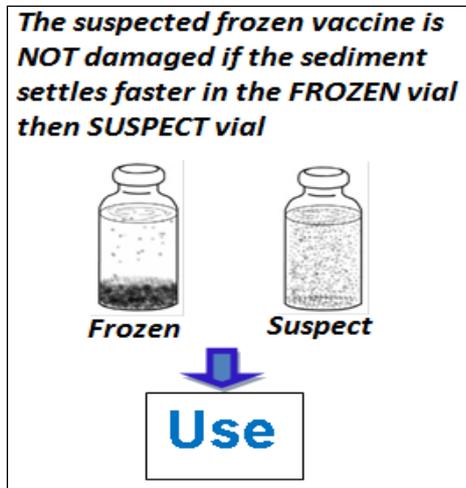
5.4 Shake test

The shake test can be conducted to check whether any vial has been frozen. The "shake test" is performed as follows:

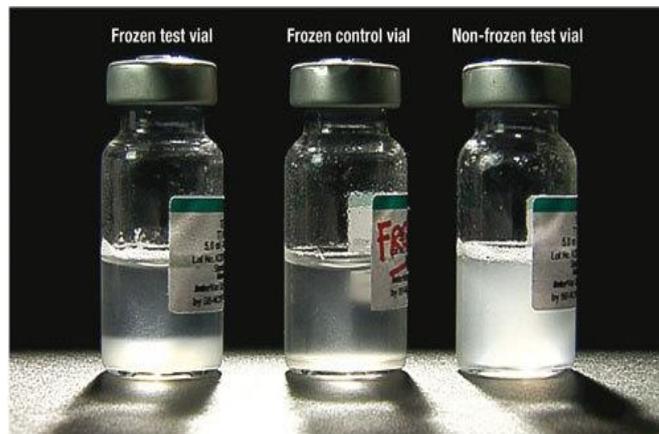
- Deliberately "freeze" a "control sample" of the same vaccine and batch number until the contents are solid - at least 10 hours at -10°C.
- Take a vial of vaccine from the batch that you "suspect" has been frozen - this is your "test sample".
- Hold the control sample and the test sample together in one hand and shake vigorously for 10-15 seconds.

- iv. Allow to rest by placing both vials on a table and not moving them further.
- v. View both vials against the light to compare the sedimentation rate.
- vi. If the "test sample" shows much **slower sedimentation rate** than the "control sample", the "test sample" has **probably not been frozen**.
- vii. If the "test sample or suspect" has a **similar sedimentation rate** as the "control sample or frozen", the vial has probably been damaged by freezing and **should not be used**.

The Shake Test Sedimentation Rates



Practical shake test result



Results

- **IN CASE**, the vial which is suspected to be frozen the sediments settle down slowly than the Control Frozen Vial. **USE THAT VIAL**.
- **IN CASE**, the vial which is suspected to be frozen the sediments settle down faster or the same rate with the Control Frozen Vial. **DON'T USE THAT VIAL**.

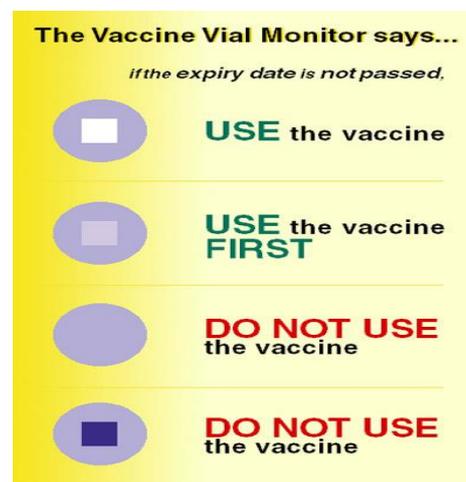
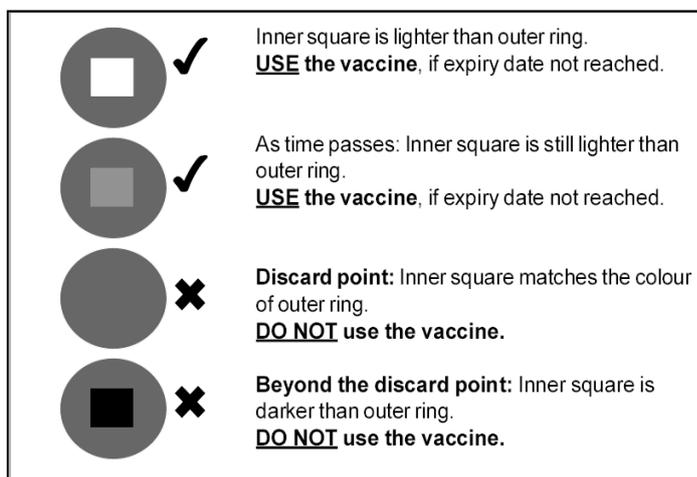


Key message

- *If the health facility suspect the vaccines are frozen they must immediately inform the CHMT*
- *CHMT are the one responsible to conduct shake test*

5.5 Vaccine Vial Monitor (VVM)

Vaccine Vial Monitors (VVMs) are heat sensitive chemicals applied to the vaccine vial label or cap. Every vaccine vial used in Tanzania has a Vaccine Vial Monitor to monitor the heat exposure of the vaccines since leaving the factory. The VVM on liquid vaccine is on the label, while the VVM on reconstituted/dried vaccine is on the caps.



Key message

- Use the vaccine is in stage one and two only.
- Do not use vaccines in stage three and four.
- Vaccine in stage three and four must be removed from the fridge immediately.

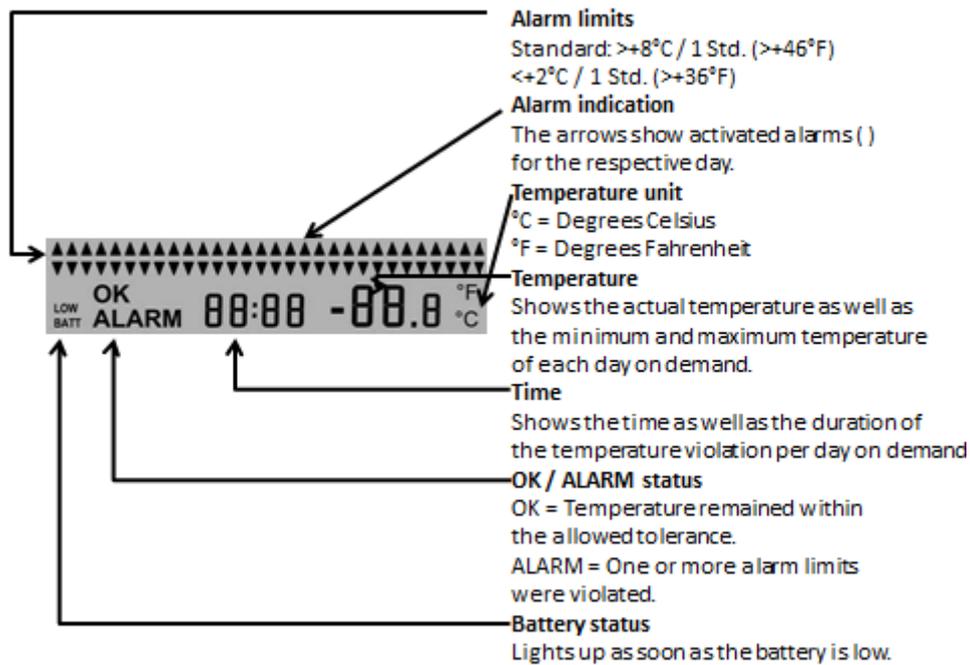
5.6 Fridge tag

Fridge tag is reliable temperature monitoring tool used to monitor the environmental temperature of sensitive goods reliably during storage in refrigerators or cold rooms. Due to its big display, all relevant data can be checked effortlessly at any time and temperature violations are discovered immediately.

- actual temperature in degrees Celsius or Fahrenheit
- all alarm violations over the previous 30 days at a glance
- daily minimum and maximum temperature over the last 30 days
- time duration of the temperature violation per day



All data can be read out easily and precisely without any further software or computer.



Correct storage temperature

- OK sign is visible when the alarm limit has never been violated during the previous 30 days.
- Display shows actual time and temperature.
- By pressing the READ button, the minimum and maximum temperature of each day appears.

Violation of the alarm limits

- ALARM sign appears when the alarm limits have been violated at least once during the previous 30 days.
- Display shows actual time and temperature.
- Arrows show at a glance, which alarm was violated on which day.
- By pressing the READ button, the detailed data of each day can be shown.

Easy read out of the data

By pressing the READ button the following data can be read out for each day:

- Minimum / Maximum temperature
- Duration of the time outside the permitted storage temperature
- OK sign when storage conditions have been kept
- ALARM sign by violated limits



Key message

- Upward arrow will appear if the temperature will be above 8°C for more than 10 hours
- Lower arrow will appear if the temperature will be below -0.5°C for more than 1 hour

6. ANNEX 4. ADVERSE EVENTS FOLLOWING IMMUNIZATION

What is Adverse Events Following Immunization?

The goal of immunization is to protect the individual and the public from vaccine-preventable diseases. Although modern vaccines are safe, no vaccine is entirely without risks. An “Adverse Event Following Immunization” (AEFI) is a medical incident that takes place after an immunization and is believed to be caused by the immunization. Although people often think that a medical incident after an immunization must be caused by the immunization, many such incidents are coincidental. “*Serious AEFI*” are extremely rare and are defined as those events that result in death or hospitalization. “*Mild AEFI*” is defined simply as one that is not serious.

Adverse reactions following immunization can undermine an immunization programme by causing parents and the community to lose confidence in the benefits of immunization. Therefore, it is important that immunization programmes monitor serious adverse events following immunization and that appropriate action is taken to correct any programmatic errors.

Identifying adverse events

Four “trigger events” which must be monitored during the immunization process are as follows:

- Any injection site abscess following immunization
- Any case requiring hospitalization that is thought by health workers or the public to be related to immunization
- Any other severe or unusual medical incidents believed by health workers or the public to have been caused by, or related to, immunization
- Any death thought by health workers or the public to be related to immunization

Causes of AEFI

Programmatic errors

Programmatic errors involve incorrect handling, reconstituting or administering the vaccine. This is the most frequent cause of adverse events. Examples include:

- Injecting vaccine at the wrong site
- Improper immunization site or route
- Syringes and needles not sterile
- Vaccine reconstituted with incorrect diluent or wrong amount of diluent used
- Inadvertently substitution of vaccine or diluent with other preparations i.e. Normal Saline, Water for injection and others
- Vaccine or diluent contaminated
- Vaccine stored incorrectly
- Contraindications ignored, e.g. a child who experienced a severe reaction after a previous dose is immunized with the same vaccine
- Reconstituted vaccine not discarded six hours after reconstitution or thrown out at the end of an immunization session and used in subsequent session

Nature of the vaccine or individual response to the vaccine

Examples of adverse events associated with the vaccine or individual response are: lymphadenitis following BCG administration, fever or febrile convulsions following measles or whole-cell pertusis immunization, and paralysis following administration of oral polio vaccine.

Coincidence

Medical incidences that occur after immunization can be purely coincidental. There is no association between the immunization and the medical incident following the immunization. Sometimes illness

appears to be more frequent following immunization, due to parental concern or more intense observation for illness following immunization.

Unknown cause

With continued research, unknown causes will hopefully be classified in one of the above two categories.

Incidence of AEFI

The current vaccines are very safe vaccine. Nevertheless, there are some rare reactions that may occur following immunization. Pentavalent, PVC and Measles vaccination are normally associated with mild AEFI including soreness at the vaccination site and fever, all of which resolve spontaneously without permanent damage. Other rare events which may occur include rash, febrile convulsions, encephalitis/encephalopathy and sub-acute sclerosing pan encephalitis.

Handling AEFI during the immunization process

AEFI must be monitored up to 4 days after administration of the vaccine. Identified focal persons, training, logistics requirements, and communication are key issues to be addressed in handling AEFI during the immunization process.

Focal persons and Training in handling of AEFI

During the planning and training sessions for the immunization process, the focal persons for handling AEFI in each Council and at each health facility should be designated. These are the persons who should be alerted immediately when an AEFI is reported, and who should assist in the handling and investigation of the case. All health workers who are involved in the immunization process and who see sick children at vaccination post should know who the focal persons are. These people need to be with clinical background. All health workers who are involved in the immunization must be trained in the detection and handling of AEFI, which should include procedures for dealing with the public.

Logistics requirements

Each health facility should have an emergency kit . The emergency kit should consist of adrenalin (1:1000), hydrocortisone, analgesics, anti- inflammatory agents, normal saline, and injection equipment (2 mls and 10 mls syringes and needles and intravenous giving set). Every health facility must have a supply of AEFI case investigation forms. (Annex 12)



Key message

- *The AEFI Focal Person at the health Facility level is the Clinician In-charge*
- *At Council level is the DMO or clinician designated for AEFI*
- *At the Regional Level is the RMO or clinician designated for the same purpose*

Treatment of AEFI during the immunization process

Treatment

Treatment must always be the first response to an AEFI. All severe AEFI cases should be referred immediately to the nearest health facility or hospital for treatment. The case investigation form must be quickly filled in as far as possible and accompany the patient being referred, otherwise the investigation may not be followed up. Case investigation forms should be filled for every case of a severe AEFI.

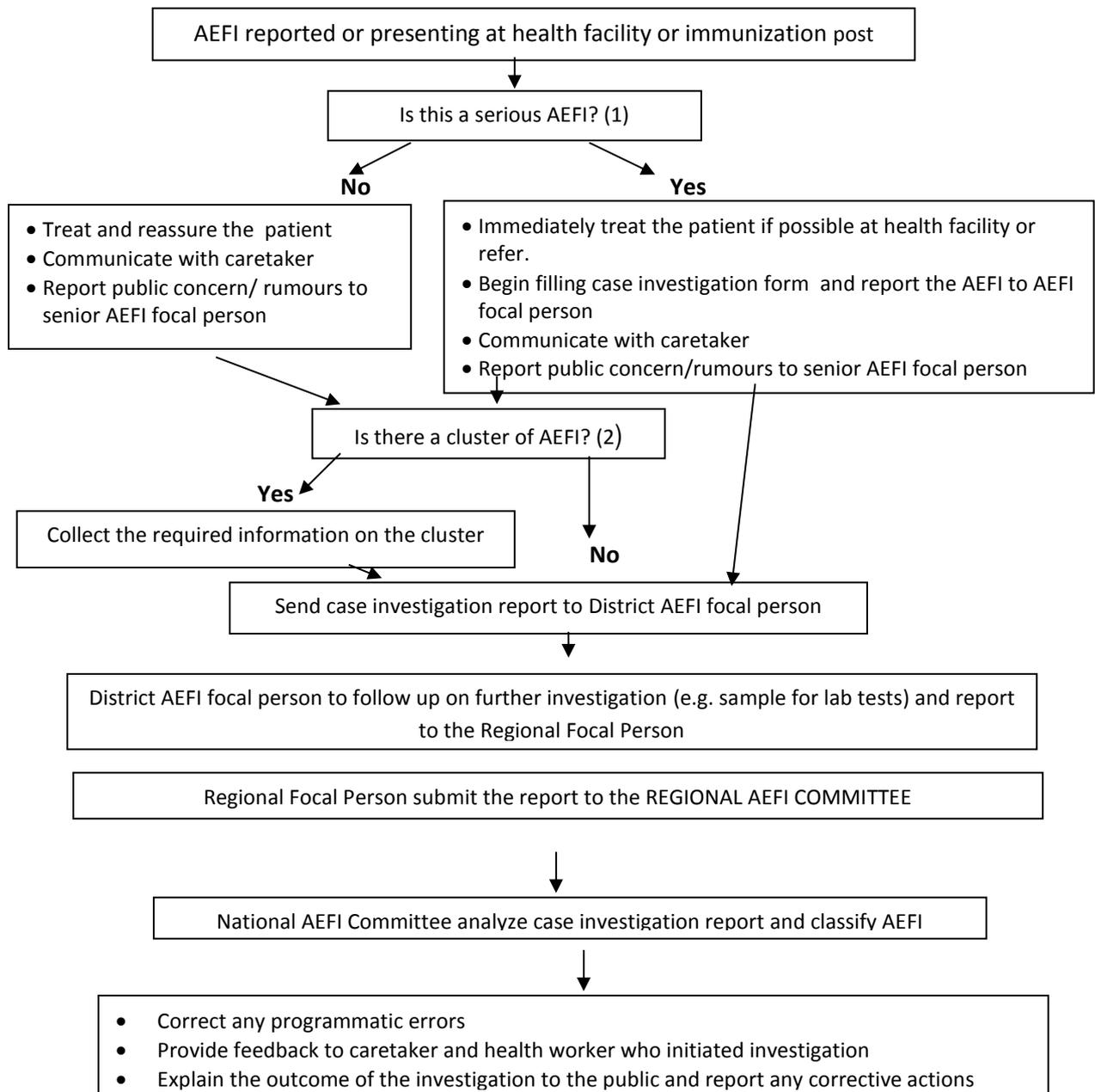
- Cases of anaphylaxis should be treated at the health facility where the immunization took place or at the facility with an emergency kit that is closest to the fixed post.
- Mild symptoms such as fever can be treated at home or by health workers. Health workers must be able to decide which AEFI to treat and which to refer...
- Treatment for AEFI should be free of charge.



Key message

- Any anaphylaxis require immediate attention)
- Do not PANIC! Reassure the client

ACTIONS TO BE TAKEN IN THE CASE OF AEFI



Notes

1. Defined as **Serious** if it results in hospitalization or death.
2. A Cluster is defined as AEFI that occur with unusual frequency, by vaccine, by batch number, by type of reaction, or by health facility/ community.

EMERGENCY PROCEDURE IN THE CASE OF ANAPHYLAXIS

Anaphylaxis is a very severe reaction, which may occur rarely after any injection including a vaccination. The patient collapses with signs of shock and breathing problems. If this occurs, follow the steps described below immediately.

1. Call for help and attend to patient immediately.
2. Check breathing and heartbeat.
3. If the patient is not breathing:
 - Secure the airway and ventilate
 - If there is no heartbeat:
 - Do CPR (cardio-pulmonary resuscitation)
4. Give adrenalin 1:1000
 - Children under 3 years: 0.1 ml subcutaneous at once
 - Children 4-5 years: 0.2 ml subcutaneous at once
 - Children 5- 10 years 0.3 ml subcutaneous at once
5. Give adrenalin as follows: 1 ampoule diluted with normal saline to 10 ml in small amounts slowly IV. The heart rate should not exceed 160/minute.
6. Give hydrocortisone sodium succinate slowly IV in the following doses:

Children under 1 year:	100 mg
Children 1- < 3 years:	200 mg
Children 3- < 5 years:	300 mg
7. Set IV drip and run the Normal saline drip fast

Recommendations to Minimize AEFI

- Measles vaccine must be reconstituted only with the diluent supplied by the manufacturer.
- Always check the validity of the vaccine, diluents, syringes and needles by observing Expiry date, batch number and VVM Status
- Reconstituted vaccines must be discarded at the end of each immunization session or after six hours of reconstitution and NEVER retained for use in subsequent sessions.
- In the refrigerator of the immunization centre, no other drugs and substances should be stored beside vaccines.
- Training of immunization workers and their close supervision to ensure that proper procedures are being followed are essential to prevent deaths or injury following immunization.
- Careful epidemiological investigation must be carried out in the event of adverse events following immunization. Complete investigation of AEFI is of critical importance to pinpoint the cause of the incident and to correct immunization practices so that future AEFI is prevented.

7. ANNEX 5. 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 the safety of immunizations.

Estimating vaccine and injection equipment needs for vaccines should be based on the number of children to be vaccinated, target coverage and wastage rate. At regional and District Vaccine Stores buffer stocks should be 25% and 50% at health facility levels

Estimating vaccine needs on the basis of target population

To estimate vaccines 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.

$$\text{Annual need of vaccines} = \text{Target population} \times \text{Number of doses} \\ \times \text{expected immunization coverage} \times \text{Wastage factor} + \text{Buffer Stock}$$

Storage of vaccine

It is very essential to store vaccines at every stage of the cold chain properly. While storing the vaccine, the following should be noted:

- Keep the packets containing the vaccines in a neat row;
- Similar vaccines should be stored in the same area, different vaccines should be kept separately to facilitate easy identification;
- Keep about 2 cm space between rows for circulation of air;
- The period of time in which any vaccine remains in cold chain stores without being used should be recorded,
- In chest type (top opening) refrigerators, store diluents and freeze sensitive/early expiry date vaccines on the top and heat sensitive/late expiry date vaccines on the bottom. In vertical (front opening) refrigerators freeze sensitive vaccines and diluents must be kept on the lower shelves.

The suggested maximum length of storage at health-facility level is 1.5 months. Also keep in mind that the **VVM status and expiry dates** of vaccines must be monitored and acted upon.

Each vial shows an expiry date. Never use vaccines when the expiry date has passed, even if the VVM shows no heat damage. In general, always apply the earliest-expiry-first-out (EEFO) principle. Keep separate (date-wise) records of vaccine receipts, distribution and balance sheet for each type of vaccine and each size of vial.

Vaccines should be stored and transported between +2 to +8 ° Celsius at all levels. Do not freeze or place Pentavalent, PCV13 and TT vaccines on a frozen icepack. Some of vaccine loses potency and provides no protection if frozen. If there is doubt, the “shake test” can be performed to check whether the vaccine has been frozen.

To avoid exposure of the vaccine to freezing, ice packs should 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.

Preparation for the vaccination session

In a fixed immunization session you need to complete certain tasks explained below:

- Condition the ice-packs (*Before the infants come for the immunization session*) by allowing ice-packs to stay at room temperature until ice begins to melt and water starts to form. This can take several hours at an ambient temperature of +20° C and less time at higher temperatures. Check to see if an ice-pack has been conditioned by shaking it and listening for water. This will prevent the freeze-sensitive PCV from freezing. The use of chilled water packs is preferable to conditioning frozen ice packs. Prepare the vaccine carrier *with conditioned ice packs or chilled water packs (Before the infants come for the immunization)*
- Check the VVM and expiry date for validity.
- Inspect if the vaccine is frozen, if you suspect the vaccine is frozen, conduct a shake test before use.

Protecting vaccine from heat during the session

During an immunization session, vials are protected from heat for a *longer period of time if they are stored in a vaccine carrier at temperatures between 2°C - 8°C inserted in a foam pad as shown in Figure 4.*



Note: *It is recommended that all opened vials should be kept on the foam pad during vaccination session.*