MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

IMMUNIZATION AND VACCINE DEVELOPMENT PROGRAMME (IVD)

TRAINING GUIDELINE FOR REGIONAL AND DISTRICT LEVEL

JUNE 2017

FOREWORD

EPI in Tanzania was established in 1975 with the objective of contributing to reduction of child and maternal mortality and morbidity caused by vaccine preventable diseases. The program was provided with the responsibility to ensure provision of quality immunization services to children under one year and the women of child bearing age, to prevent them from diseases and control vaccine preventable diseases within the country. The program up to 2012 was providing five traditional vaccines which were BCG, OPV, Pentavalent, Measles and Tetanus Toxoid.

Due to expanding roles and increasing workload on immunization services the name of the programme was changed to Immunization and vaccine Development Programme (IVD). The programme currently if dealing with more target group (beyond one year) because more new vaccine targeting various groups has been introduce including Rotavirus vaccine and Pneumococcal conjugate vaccine 13 (PCV 13), Measles Rubella, IPV,MSD and HPV. In addition more vaccines are in pipeline including Malaria, HIV, Men A, Ebola and others. The programme is also striving to increase community access on immunization services and the number of facilities providing immunization has increase from 5027 of 2013 to 6015 of 2017. Furthermore the number of outreach services for immunization has increased from clinic monthly to 2-3 clinics per month for health facilities.

Due to increasing number of vaccine preventable diseases within the country and worldwide, which necessitated introduction of new vaccine which are provided to different target group in the community the ministry decided to develop this guideline which will provide guidance to supervisors, trainers and heath care providers on how to provide quality immunization services and achieving national and global objectives.

The ministry is making a call to all supervisors, trainers and health providers to use knowledge available in this guideline to ensure that all children and other target groups are reached with quality immunization services in order to reduce mortality and morbidity caused by vaccine preventable diseases within the country.

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ACKNOWLEDGEMENT

The Ministry of Health, Community Development, Gender, Elderly and Children wishes to express gratitude to individuals and development partners who worked with the Ministry in the development of this Guideline.

The MOHCDGEC would like to acknowledge partners and stakeholders who contributed in one way or another to the successful development of this document. The Ministry particularly wishes to acknowledge invaluable contributions of the following partners: the World Health Organization (WHO), United States Agency for International Development (USAID) through Maternal And Child Survival Program (MCSP), United Nations Children`s Fund (UNICEF), Clinton Health Access Innitiave (CHAI) for their technical and financial support during the whole process of developing this guideline.

Lastly but not least, The Ministry would also like to acknowledge various contributions made by staff from Immunization and Vaccine Development (IVD) especially the Technical Working Group (TWG) for their tireless effort during the entire process of developing this guideline.

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LIST OF ACRYNOM/ ABBREVIATION

AD ---------- Auto disable syringes

AEFI ---------- Adverse Event Following Immunization

AFP ---------- Acute Flaccid Paralysis

BCG---------- Bacillus Calmette Guerin

CHMT ---------- Council Health Management Team

CHAI----------Clinton Health Access Initiative

CVS ---------- Central Vaccines Store

DIVO ---------- District Immunization Vaccine Officer

DHO ---------- District Health Officer

DMO---------- District Medical Officer

DTP – HB ---------- Diphtheria, Pertussis, Tetanus and Hepatitis B

DRCHCO ---------- District Reproductive and Child Health Coordinator.

DVS---------- District Vaccine Stores

DQA ---------- Data Quality Audit

DQSA ---------- Data Quality Self Assessment

EPI ---------- Expanded Program on Immunization

HMIS ---------- Health Management Information System

IPV----------Inactivated Polio Vaccine

LPG----------Liquefied Petroleum Gas

MCH ---------- Maternal and Child Health

MCSP---------- Maternal Child Survival Program

MR---------- Measles Rubella

MNT ---------- Maternal and Neonatal Tetanus

MUHAS---------- Muhimbili University College of Health and Allied sciences

NBS---------- National Bureau of Statistics

NIDs ---------- National Immunization Days

OPV---------- Oral Polio Vaccine

PHCC---------- Primary Health Care Committee

PIE ---------- Post Introduction Evaluation

RCCO----------Regional Cold Chain Officer

RAS---------- Regional Administrative Secretary

RCHS---------- Reproductive and Child Health Services

REC---------- Reaching Every Child

RMO---------- Regional Medical Officer

RVS---------- Regional Vaccines Store

SIAs---------- Supplemental Immunization Activities.

SNIDs ---------- Sub National Immunization Days

TDHS---------- Tanzania Demographic Health Survey

UNICEF---------- United Nations Children's Fund

VVM---------- Vaccine Vial Monitor

WHA ---------- World Health Assembly

WHO ---------- World Health Organisation

WICR----------Walk-in Cold Room

INTRODUCTION

Tanzania is among the countries which are implementing national and global plans and strategies for reduction of maternal and child mortality. One of the key intervention to achieve the plan is provision of quality immunization services for children and women of child bearing age in order to prevent them from vaccine preventable diseases and hence reduction of mortality and morbidity caused by vaccine preventable diseases. In Tanzania currently children and women are suffering from vaccine preventable diseases including TB, Diphtheria, pertussis, poliomyelitis, measles, Rubella, tetanus, hepatitis B, Meningitis, Pneumonia, Diarrhea and cervical cancer.

The overall objective of National Immunization and Vaccine Development Programme of the Ministry of Health and Social Welfare, working under Reproductive and Child Health Services section is to ensure reduction of women and child Mortality and Morbidity caused by vaccine preventable diseases.

The role of IVD program under, the ministry of health and Social Welfare is to ensure provision of quality immunization services as per national and international standards and guidelines. To ensure quality provision of services capacity building and training for leaders/coordinators and vaccinators in the area of immunization services is of vital important.
The ministry has been from time to time providing training and capacity building program to leaders/coordinators and vaccinators during the campaign, introduction of the new vaccine, supportive supervision, refreshers and new comer's training. In addition various IEC materials and guidelines are also being used to build the capacity of leaders and health workers to ensure provision of quality immunization services according to approved standards.

This guideline was developed specifically for providing training on immunization services for Supervisors/coordinators and health providers at regional, district and health facility level. Supervisors/coordinators and health providers need to use this guideline as a reference while supervising, training and providing immunization services within the country.
The guideline explained in detail the key issues in the provision of immunization services including vaccine quality and supply, vaccine storage, and injection safety practice.
The guideline provides description on the type of vaccine and how all types of vaccines are provided to clients. The component on the health education which is supposed to be provided to client/community before immunization services is also covered. The guideline provided the standard case definition for vaccine

preventable diseases and how to control the effects of the respective diseases. Adverse Event Following Immunization is well addressed in this guideline including the importance of educating the clients/community on possible side effects and the action to be taken by client and health providers.
The guideline also describes surveillance of vaccine preventable diseases for control, elimination and eradication of vaccine preventable diseases.
The aspect of immunization data management is addressed and provides explanation on how to collect, store, analyses and submit immunization data to relevant authority timely for action and decision making.
Finally the guideline describe how to organize fixed, outreach and mobile immunization clinics in partnership with the community and how to ensure effective community participation in planning, implementation and evaluation of immunization services.

The Ministry of Health and Social Welfare expects that, this guideline will be of great support to all supervisors, trainers and health workers dealing with immunization services and adherence to this guide with ensure provision of quality immunization services within the country and achieving the required immunization coverage and control of vaccine preventable diseases.

Objectives of training guideline

The guideline provide a guidance on how to train supervisors and health providers on immunization services at Reproductive and child health clinics. The guideline will provide a guidance to trainers, supervisors and health providers dealing with immunization services as follows;

(a) The guideline will support trainers of immunization services to:

- Understand important issues to train supervisors and health care provider working at RCHS clinics;
- Prepare tropics to use for training supervisors and health care provider with good flow of materials according to accepted national guideline.
    - Use the theme organized in chapters of this guideline as reference for implementation of various immunization

(b) The guideline will support supervisors and health providers to:

- Identify and understand vaccine preventable diseases and the importance of controlling the diseases in the community.
- Understand the importance of reaching the target group for increasing immunization coverage within the country.
- Have clear description on vaccine preventable diseases and the immunity gain to both individual client and the community.
- Have clear knowledge on how to receive, record, store and issue the vaccine and related supplies according to guideline

- To ensure availability and adherence to injection safety standards during immunization session
- Acquire knowledge on how to provide quality immunization services to clients/community
- Understand and ensure availability of functional cold chain system for vaccine storage according to guideline
- To organize and conduct immunization sessions (Fixed, outreach and mobile) according to the agreed immunization schedule at RCHS clinics and the community.
- Be able to provide health education to clients and the community on the type of vaccine provided, disease prevented, AEFI and how to deal with them.
- Strengthening leadership and community participation in planning, implementation and evaluation of immunization services through advocacy, communication and social mobilization.
- Be able to collect, store, analyses and submit data to the required level timely and use their data for actions and decision making.
- Do surveillance for vaccine preventable diseases and report to the required authority.
- Effectively participate in sub immunization days and national campaign

Chapter 1 : Immunity

Immunity is the ability of the body to tolerate material that is indigenous to it and eliminate material that is foreign. The immune system is comprised of organs and specialized cells that protect the body by identifying harmful substances, known as antigens, and by destroying them by using antibodies and other specialized substances and cells.

1.1. There are two basic ways to acquire this immunity (protection)

- Active immunity
- Passive immunity.

Active immunity is provided by a person's own immune system. This type of immunity can come from exposure to a disease or from vaccination. Active immunity usually lasts for many years and often is permanent.

Passive immunity results when antibodies are transferred from one person or animal to another. The most common form of passive immunity occurs when a fetus receives antibodies from his or her mother across the placenta during pregnancy.

Other sources of passive immunity include blood and blood products, immune or hyper-immune globulin, and animal antitoxins. Passive immunity disappears over time, usually within weeks or months. Live microorganisms or antigens bring about the most effective immune responses, but an antigen does not need to be alive for the body to respond.

1.2. Types of Vaccine

Live attenuated vaccines are derived from disease-causing viruses or bacteria that have been weakened under laboratory conditions. They will grow in a vaccinated individual, but because they are weak, they will cause either no disease or only a mild form. Usually, only one dose of this type of vaccine provides life-long immunity, with the exception of oral polio vaccine, which requires multiple doses.

Inactivated vaccines are produced by growing viruses or bacteria and then inactivating them with heat or chemicals. Because they are not alive, they cannot grow in a vaccinated individual and therefore cannot cause the disease. They are not as effective as live vaccines, and multiple doses are required for full protection. Booster doses are needed to maintain immunity because protection by these vaccines diminishes over time.

Inactivated vaccines may be whole-cell or fractional. Whole-cell vaccines are made of an entire bacterial or viral cell. Fractional vaccines, composed of only part of a cell, are either protein- or polysaccharide-based.

Polysaccharide-based vaccines are composed of long chains of sugar molecules taken from the surface capsule of the bacteria. Unless coupled with a protein, pure polysaccharide vaccines are generally not effective in children under the age of two years. This coupling process is known as “conjugation.”

Recombinant vaccines are produced by inserting genetic material from a disease-causing organism into a harmless cell, which replicates the proteins of the disease-causing organism. The proteins are then purified and used as vaccine.

Vaccines used in national immunization programs in developing countries are described in detail in Chapter

CHAPTER 2 :VACCINE PREVENTABLE DISEASES

Vaccination is the administration of agent-specific, but relatively harmless, antigenic components that in vaccinated individuals can induce protective immunity against the corresponding infectious agent
Vaccination is a highly effective method of preventing certain infectious diseases. Immunizations protect people from a number of infectious diseases therefore reduce mortality and morbidity. In Tanzania diseases preventable by vaccine are 12 which include

- Tuberculosis,
- Poliomyelitis,
- Measles,
- Pertussis
- Diphtheria
- Tetanus
- Hepatitis B
- Pneumonia
- Meningitis
- Diarrhea
- Rubella
- Cervical cancer

2.1 Tuberculosis (TB)

2.1.1 Tuberculosis- definition and etiology

- Tuberculosis (TB) is caused by the bacterium *Mycobacterium tuberculosis* that usually attacks the lungs. Tuberculosis can also affect all other parts of the body and the condition is known as extra-pulmonary tuberculosis.

- Few people infected with tuberculosis bacteria may eventually develop the disease

- People who are infected may not feel ill and may have no symptoms and do not spread the infection to others.

- After the infection, the bacteria may lie dormant for life

- It can however cause disease in an event of low immunity such as the **cone** caused by infections including HIV/AIDS, malignancies, or under nutrition.

- **T**B is spread from one person to another through the air often when a person with the disease coughs or sneezes.
- TB spreads rapidly, especially in areas where people are living in crowded conditions and inadequate flow or air, have poor access to health care, and are malnourished.
- Consuming raw milk from infected cattle transmits a variety of animal-transmitted TB, also known as bovine tuberculosis.
- The risk of developing TB is highest in children younger than three years old and in older people. People with TB infection who have weakened immune systems (for example, people with HIV/AIDS) are more likely to develop the disease

2.1.2. Signs and symptoms of TB

The period from infection to development of the first symptoms is usually 4 to 12 weeks, but the infection may persist for months or even years before the disease develop. A person with the disease can infect others for several weeks after he or she begins treatment.

The symptoms of TB include

- General weakness,
- weight loss,
- fever,
- night sweats
- In pulmonary tuberculosis, the symptoms include persistent cough, coughing up of blood, and chest pain.
- In young children, however, the only sign of pulmonary TB may be stunted growth or failure to thrive.
- Other signs and symptoms depend on the part of the body that is affected. For example, in tuberculosis of the bones and joints there may be swelling, pain, and crippling effects on the hips, knees, or spine.
- The complication of TB if untreated may results in debility and death.

2.1.3. Prevention of TB

- Immunization of infants with Bacille Calmette-Guérin vaccine (BCG) can protect against TB meningitis and other severe forms of TB in infants.
- BCG vaccine is given at birth. According to the IMCI guideline, health workers are advised to repeat if no BCG scar is seen.
- Avoid living overcrowding and area with inadequate flow of air

- Treatment of TB in Tanzania is based on the guidelines of management of TB by the IMCI, and TB and leprosy programs. In all circumstances, DOTS is the mainstay treatment method.

2.2. Poliomyelitis (polio)

- Poliomyelitis (also known as polio), is a crippling disease caused by Poliovirus, a single stranded RNA virus and a member of the family Picornaviridae. The virus invades the nervous system and can cause permanent paralysis
- Polio is spread through person-to-person contact and can spread rapidly through a community
- Children are most likely to spread the virus between 10 days before and 10 days after they experience the first symptoms of the disease. The incubation period is 6 to 20 days.
- Most infected people (90%) have no symptoms or very mild symptoms
- However, one in 200 infections leads to permanent paralysis (can't move parts of the body) and even death
- Poliovirus infection is ***highly contagious***
- Poliovirus is spread mostly by the ***fecal-oral route***
    - Primary mode of transmission – passage of the virus in stool to the mouth of another child
    - Can also be spread through saliva or droplets from a sneeze or cough
- There are 3 types of Oral Polio vaccine
    - **Tri**valent OPV (tOPV): types 1, 2 *and* 3 ; most commonly used OPV in routine immunization globally
    - **Bi**valent OPV (bOPV): types 1 *and* 3 ; commonly used in supplementary immunization activities (SIAs)
    - **Mono**valent OPV (mOPV): type 1, 2 *or* 3 ; primarily used for SIAs in areas where only type 1 or type 3 is circulating

Paralysis caused by OPV can be;

- Vaccine virus spontaneously changes and becomes capable of causing disease to the nervous system ,40% of VAPP are from type 2 OPV
- Circulating Vaccine Derived Poliovirus (cVDPV) -Rare outbreaks caused by person-to-person spread of vaccine strain, which mutates/changes to a highly transmissible form capable of causing disease to the nervous system, in areas/countries with low immunity against polio ,97% of cVDPVs are from type 2 OPV
- Therefore the plan is to withdraw type 2 by switch of tOPV to b OPV and introduce Inactivated Polio Virus which contain type 1,2,3 and safe no risk of VAPP and cVDPVs

2.2.2. Sign and symptoms

- Flu-like symptoms
- fever,
- headache,
- loose stools,
- sore throat,
- Stomach-ache.
- The crippling condition begins with mild symptoms and fever and other constitutional ailments followed by severe muscle pain and paralysis of leg and arms, which usually develop during the first week of illness.

2.2.3 Prevention of Poliomyelitis

Poliomyelitis can be prevented by through immunization with oral Polio vaccine at birth, 6, 10 and 14 weeks and Inactivated Polio vaccine at 14weeks

2.2.4 Treatment of Poliomyelitis

- No treatment to cure paralysis from polio with regular physiotherapy as well as orthopedic operation and use of braces, can help reduce long term crippling effect of polio
- Inadequate physiotherapy the paralyzed limbs might not regain full function, often leaving a child seriously crippled and disabled for life.
- Symptomatic treatment to relieve muscle pain and fever

2.3. Pertussis

2.3.1 What is pertusis?

- Pertussis or whooping cough, is a disease of the respiratory tract caused by bacteria known as Bordetella Pertussis that live in the mouth, nose, and throat.
- Many children who contract pertussis have coughing spells that last four to eight weeks. The disease is most dangerous in infants.
- Pertussis spreads very easily from child to child in droplets produced by coughing or sneezing
- Children exposed to the germs become infected. In many countries the disease occurs in regular epidemic cycles of three to five years. The incubation period is five to 10 days

2.3.1 Signs and Symptoms of Pertussis

- Common cold with runny nose
- watery eyes,
- sneezing
- fever,
- Bursts of rapid coughing with a high-pitched whoop.
- The child may turn blue because he or she does not get enough oxygen during a long burst of coughing.
- Vomiting and exhaustion often follow the coughing attacks, which are particularly frequent at night.
- During recovery coughing gradually becomes less intense.

- Complications are most likely in young infants, most common and deadly complication is bacterial pneumonia.
- Other complications such as convulsions and seizures due to fever or reduction in oxygen supply to the brain, loss of appetite, inflammation of the middle ear, and dehydration.

2.3.2 Prevention of Pertusis

Prevention involves immunization with pentavalent vaccine. This is usually given in combination with diphtheria, tetanus, Hepatitis B and *Haemophilus influenzae* type b (Hib).The vaccine is known as Pentavalent which is given at 6 weeks, 10 weeks, and 14 weeks to complete the schedule.

2.3.3. Treatment for Pertussis

Treatment with antibiotic based on IMCI guideline
Children infected with pertussis should get plenty of fluids to prevent dehydration.

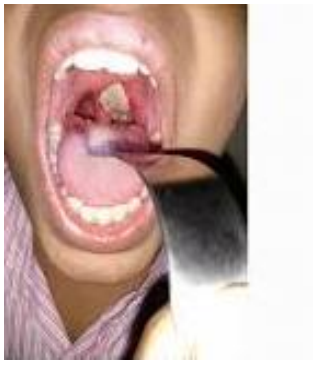
2.4. Diphtheria

2.4.1. What is Diphtheria?

- Diphtheria is caused by the bacterium Corynebacterium diphtheriae. This germ produces a toxin that can harm or destroy human body tissues and organs.
- One type of diphtheria affects the throat and sometimes the tonsils. Another type, more common in the tropics, causes ulcers on the skin.
- Diphtheria affects people of all ages, but most often unimmunized children. In temperate climates, diphtheria tends to occur during the colder months.

- Diphtheria is transmitted from person to person through close physical and respiratory contact. It can cause infection of the nasopharynx, and may lead to breathing difficulties and other complications including death.

2.4.2 Signs and Symptoms of Diphtheria



- sore throat,
- loss of appetite,
- slight fever
- Two to three days a bluish-white or grey membrane forms in the throat and on the tonsils.
- This membrane sticks to the soft palate of the throat and may bleed
- Patients with severe diphtheria do not develop a high fever but may develop a swollen neck and obstructed airway.
- Complication of diphtheria is development of abnormal heartbeats which result in heart failure.

2.4.2. Prevention of Diphtheria

The most effective way of preventing diphtheria is to maintain a high level of immunization in the community. In most countries, diphtheria TOXOID vaccine is given in combination with tetanus toxoid, pertussis, Hepatitis B and Haemophilus influenzae type b (Hib).

2.4.4. Treatment for Diphtheria

Children who develop diphtheria should be given diphtheria antitoxin and antibiotics based on the IMCI guideline.

2.5. Tetanus

2.5.1 What is tetanus?

- Tetanus is acquired through exposure to the spores of the bacterium *Clostridium tetani,* which are universally present in the soil.
- The disease is caused by the action of a potent neurotoxin produced during the growth of the bacteria in dead tissues, e.g. in dirty wounds or in the umbilicus following non-sterile delivery.
- People of all ages can get tetanus but the disease is particularly common and serious in newborn babies called 'neonatal tetanus'.
- Most infants who get the disease die.

2.5.2 How is tetanus spread?

- A person usually becomes infected with tetanus when dirt enters a wound or cut.
- Tetanus is not transmitted from person to person.
- Tetanus germs are likely to grow in deep puncture wounds caused by dirty nails, knives, tools, wood splinters, and animal bites.
- Women face an additional risk of infection if a contaminated tool is used during childbirth or during an abortion.
- A newborn baby may become infected if the knife, razor, or other instrument used to cut its umbilical cord is dirty, if dirty material is used to dress the cord, or if the hands of the person delivering the baby are not clean.
- Infants and children may also contract tetanus when dirty instruments are used for circumcision, scarification, and skin piercing, and when dirt, charcoal, or other unclean substances are rubbed into a wound.
- Tetanus is not transmitted from person to person

2.5.3 Signs and Symptoms of tetanus

- The time between getting the infection and showing symptoms is usually between three and 10 days. But it may be as long as three weeks.
- The shorter the incubation period the higher the risk of death.
- Muscular stiffness in the jaw is a common first sign of tetanus.
- This symptom is followed by stiffness in the neck, difficulty swallowing, and stiffness in the stomach muscles, muscle spasms, sweating, and fever.
- Newborn babies with tetanus are normal at birth, but stop sucking between three and 28 days after birth.

- They stop feeding and their bodies become stiff while severe muscle contractions and spasms occur.
- Death follows in most cases.
- Complications are fracture of spine or bones as result of muscle spasm and convulsions, abnormal heartbeat, coma and death

2.5.4. Prevention of tetanus

- Immunizing infants and children with **pentavalent (DTP-HB-Hib)** and adults with tetanus toxoid (TT) prevents tetanus.
- Pentavalent vaccine is provided at 6 weeks, 10 weeks, and 14 weeks. TT vaccine is given at the age of 15-49 years.
- Neonatal tetanus can be prevented by immunizing women of childbearing age with tetanus toxoid, either during pregnancy or out of gestation period. This protects the mother from tetanus and enables tetanus antibodies to be transferred to her baby.
- Hospital delivery and clean practices are especially important when a mother is delivering a child, even if she has been immunized. People who recover from tetanus do not have natural immunity and can be infected again and therefore need to be immunized.

2.5.5. Treatment for tetanus

Tetanus at any age is a medical emergency best managed in a referral hospital.

Treatment for neonatal tetanus generally includes administration of tetanus antitoxin and muscle relaxants and parenteral feeding.

- **Control of muscle spasms.** The patient should be admitted to a quiet, darkened room where all possible auditory, visual, tactile, or other stimuli are minimized. The first priority in spasm management should be the administration of appropriate drugs to reduce the number and the severity of spasms. Diazepam (Valium) has proved to effectively control spasms and hyper tonicity without depressing the cortical canters.
- **Antitoxin therapy**. After adequate sedation has been achieved, human tetanus immunoglobulin should be given intramuscularly in a single dose (3,000 to 6,000 IU). If human serum immunoglobulin is unavailable, tetanus antitoxin should be given, assuming sensitivity reactions to horse serum are negative. The antitoxin is given intravenously and intramuscularly (half of the dose via each route).
- **Antimicrobial therapy**. The antimicrobial drug of choice is oral (or intravenous) metronidazole (30 mg/kg/day, given at six hour intervals; maximum 4 g/day), which is used to eliminate vegetative forms of C. tetani. Parenteral penicillin G (100,000 U/kg/day) is an alternative. Treatment for 10 to 14 days is recommended.
- **Wound treatment**. After the patient has been sedated and received antitoxin, the wound should be thoroughly cleansed and debrided.
- **Supportive treatment**. Oxygen should be available. During early stages, oral feeding should be avoided because of the danger of aspiration.

2.6. Hepatitis B

2.6.1 What is hepatitis B?

- Hepatitis B is caused by a virus that affects the liver.
- Patients who get hepatitis B usually recover however, most infants infected at birth become chronic carriers i.e. they carry the virus for many years and can spread the infection to others.

2.6.2 Transmission of hepatitis B

The hepatitis B virus is carried in the blood and other body fluids. It is usually spread by contact with blood in the following ways:

- Through an unsafe injection or needle prick injury.
- Unsterilized needles or syringes can contain hepatitis B virus from an infected person, for example from a patient or a needle user
- Transmission of the virus by mothers to their babies during the birth process, when contact with blood always occurs.
- Transmission between children during social contact through cuts, scrapes, bites, and scratches.
- Transmission during sexual intercourse through contact with blood or other body fluids.

2.6.3 Signs and symptoms of hepatitis B

- The incubation period averages six weeks but may be as long as six months.
- Infection in young children usually is asymptomatic. However, a larger proportion of children may become chronic carriers compared to adults.
- People who do show symptoms may feel weak and may experience stomach upsets and other flu-like symptoms.
- They may also have very dark urine or very pale stools.
- Jaundice is common (yellow skin or a yellow color in the whites of the eyes). The symptoms may last several weeks or months.
- A laboratory blood test is required for confirmation.
- Most acute infections are followed by complete recovery however, many children become chronic carriers. People who recover from acute hepatitis B (and who do not become chronic carriers) are protected from becoming infected again throughout their lives.
- Complication of hepatitis B including chronic hepatitis, cirrhosis, liver failure, and liver cancer, occur in people with chronic infection.

2.6.4 Treatment for hepatitis B

- There is no effective treatment for the acute condition.
- Supportive treatment is indicated. In chronic infection the disease can sometimes be stopped with medications.
- Management of hepatitis is based on IMCI guidelines.

2.6.5 Prevention of hepatitis B

- It is recommended that all infants receive three doses of hepatitis B vaccine during the first year of life.
- Hepatitis B vaccine is given in combined form as Pentavalent that includes vaccines for diphtheria, tetanus, pertussis, hepatitis B (HepB) and *Haemophilus inflenzae* type b (Hib). This vaccine is given at 6 weeks, 10 weeks, and 14 weeks to complete the schedule.

2.7. Haemophilus influenzae type b (Hib)

- Haemophilus influenzae type b (Hib) is one of six related types of bacterium causing severe form of pneumonia and meningitis. In 2008, WHO estimated the total number of children who died from Hib to be 199,000 deaths globally, dropping from an estimated number of around 371,000 in 2000, mainly due to meningitis and pneumonia.
- Bacteria are transmitted from person to person in droplets through sneezing, coughing. The Hib bacterium is commonly present in the nose and throat
- Infected children may carry Hib bacteria without showing any signs or symptoms of illness, but they can still infect others.
- The risk of disease is highest for children between six months and two years of age.

2.7.1. Signs and symptoms of Hib

- Pneumonia and meningitis are the most important diseases caused by Hib bacteria. In developing countries, pneumonia is more common than meningitis in children with Hib disease.
- Hib disease should be suspected in the case of any child with signs and symptoms of meningitis or pneumonia.
- Meningitis present with fever, convulsion, neck stiffness, loss of consciousness, bulging fontanel for infants
- Complication of meningitis is blindness, deafness, mental retardation and death
- Sign and symptom for pneumonia see section 2.8.2 below

2.7.2 Prevention of Hib

- Hib is can be prevented by vaccine which is available in the form of Pentavalent. This is given at 6 , 10, and 14 weeks in combination with their vaccines in Tanzania

2.7.3. Treatment of Hib

- Hib disease can be treated with specific antibiotics. However, the Hib has proved to resistant to almost all used antibiotics.

2.8. Pneumococcal disease

2.8.1. What is Pneumococcal disease?

- It is a serious caused by 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, bacteremia, and meningitis. Other pneumococcal infections include febrile bacteremia, arthritis, peritonitis, osteomyelitis and bronchitis.
- The disease is spread from person to person through breathing, sneezing and coughing by droplets in the air.
- The pneumococcal bacteria are common inhabitants of the human respiratory tract.

2.8.2. Sign and symptoms of pneumonia

- cough,
- fever,
- rapid or difficult breathing,
- Chills and loss of appetite.
- In Severe pneumonia, 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 emphysema (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

2.8.2 Prevention of Pneumococcal infection

Pneumococcal infection(Pneumonia, meningitis, pharyngitis) can be prevented by immunization with PCV 13 which is given in three doses at 6, 10 and 14 weeks.

2.8.3 Treatment of pneumococcal diseases

Treatment of pneumonia or severe childhood Acute Respiratory Infection (ARI) and meningitis are managed with antibiotics according to IMCI guideline

2.9 Rotavirus Diarrhoea Diseases

- Rotaviruses are the leading cause of severe, dehydrating diarrhea in children aged below 5 years globally.
- 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 hospitalized children with diarrhea.
- Transmission occurs primarily by the fecal–oral route, directly from person to person or indirectly through contaminated vomits.
- Rotavirus illness follows an incubation period of 1 to 2days followed by a progression from asymptomatic to severe diarrhea
- Rotaviruses are shed in very high concentrations (>10^{12}particles/gram) and for many days in the stools and vomits of infected individuals. Rotavirus re infection 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.

2.9.1. 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 diarrhea with a loss of fluids and electrolytes into the intestinal lumen. The sign and symptoms as follow;

- Fever
- Vomiting
- Explosive watery diarrhea
- dehydration, electrolyte disturbances,
- Shock and even death.
- The diarrhea symptoms normally disappear within 3–7 days, but may last for up to 2–3 weeks. Recovery is in general complete.

2.9.2. Prevention and Control

- Rotavirus vaccines prevent the most severe episode of rotavirus infection which is given at 6 and 10 week
- hand washing and improved sanitation has helped to reduce the incidence of diarrhea,
- Exclusive breastfeeding

2.10. Measles

2.10.1 What is Measles?

- Measles is a highly infectious disease caused by a virus.
- Measles kills more children than any other vaccine preventable disease.
- Because the disease is highly infectious, it tends to occur as epidemics, which may cause many deaths especially among malnourished children.
- Unimmunized children under five years of age, and especially infants, are at highest risk for measles and its complications, including death

2.10.2 How is measles spread?

- The virus is spread by coughing and sneezing, close personal contact or direct contact with infected nasal or throat secretions.
- It remains active and contagious in the air or on infected surfaces for up to two hours.
- An infected person from four days prior to the onset of the rash to four days after the rash erupts can transmit it.
- The incubation period is 10 to 14 days from exposure to onset of rash.

2.10.3 What are the signs and symptoms of measles?

- The first sign of infection is a high fever which begins 10–12 days after exposure
- runny nose
- cough,
- red and watery eyes
- Small white spots inside his or her cheeks.
- Rash
    - Develop after several days, a slightly raised rash, usually on the face and upper neck.
    - Over a period of about three days, the rash spreads to the body and then to the hands and feet.
    - It lasts for five or six days and then fades.

- Complication of measles are severe diarrhea, severe respiratory infection(pneumonia), otitis media may lead to deafness, encephalitis, blindness

2.10.6 How is measles prevented?

Measles is prevented by immunization with measles vaccine which is given in combination with Rubella vaccine (MR) when a child has completed 9 months and 18 months the Second opportunity is provided through mass immunization campaigns conducted every 3 years.

2.10.5 What is the treatment for measles?

- No specific antiviral treatment exists for measles virus.
- Severe complications from measles can be avoided though supportive care that ensures good nutrition, adequate fluid intake and treatment of dehydration.

- This solution replaces fluids and other essential elements that are lost through diarrhea or vomiting.
- Antibiotics should be prescribed to treat eye and ear infections, and pneumonia.
- Vitamin A during treatment of measles have beneficial impact for doses look at IMCI guideline.

2.11 Cervical cancer

2.11.1 What is cervical cancer?

- Cervical cancer is abnormal uncontrolled growth of cell in the cervix .The cell in the cervix change in a way that lead to abnormal growth and invasion of other tissues or organs in the body e.g bladder, vagina rectum, intestine, ureter , liver and kidney.
- Cervix is the lower part of uterus that open into vagina
- Cervical cancer is the leading cause of cancer related morbidity and mortality among women in Tanzania
- Common cause of cervical cancer is Human papilloma virus (HPV) infection and 70% of cervical cancer is caused by HPV type 16 and and 18
- Majority of patients present in late stage of disease at Ocean Road Cancer Institute and 80% die within 5 years of diagnosis
- Higher risk of cervical cancer and more severe cervical cancer disease among women with HIV/AIDS
- Human papilloma infection is spread from infected person to another person through sexual intercourse
- Persistence HPV infection for over 10-20 years result in development of cervical cancer

2.11.2 Sign and symptoms of cervical cancer

- Body weakness
- Irregular vaginal bleeding between menstrual period and after sex
- Foul smelling vaginal discharge
- Back pain
- Pain during sex
- Anemia
- Weight loss
- Loss of appetite
- Complications of cervical cancer are renal failure, severe anemia, renal failure, fistulae (vesico-vaginal) and lymphoedema.

2.11.3. How is cervical cancer prevented?

Cervical cancer can be prevented through immunization with HPV vaccine which prevent HPV infection, the causative of cervical cancer

Other prevention is change of behavior e.g avoiding multiple sexual partners, early age of first sexual intercourse and smoking

Secondary prevention e.g screening for cervical cancer among women age 30-50 to detect and treat early stage of cervical cancer before progressing to cervical cancer.

2.11.4 Treatment of cervical cancer

Cervical cancer if detected early can be treated with cryotherapy and LEEP by destroying the precancerous cell in the cervix.

2.12. Rubella

2.12.1. What is rubella?

Rubella is an acute viral disease transmitted through air from infected person
Children and pregnant women are more at risk to be affected by Rubella
In pregnant women Rubella cause spontaneous abortion, fetal death and congenital defects called Congenital Rubella Syndrome (CRS) which present with;

- Hearing impairment
- Heart defect
- Cataract

2.12.2. Sign and Symptoms

- Fever
- Rash
- Body weakness

2.12.3. Prevention of Rubella

Rubella can be prevented by immunizing children with Rubella vaccine which is given in combination with Measles vaccine at age of 9 months and 18 months.

2.12.4. Treatment of Rubella

No specific treatment for Rubella only supportive treatment by relieve of fever and rehydration

Chapter 3: Vaccines supply and quality

The availability of an adequate supply of vaccines, diluents and safe-injection

Equipment of assured quality is critical to every immunization service.

i. 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.
ii. This chapter will comprise of
iii. Estimation of vaccines and related supplies
iv. Distribution and transport of vaccines and related materials
v. Storage
vi. Receiving of immunisation materials
vii. Monitoring temperature
viii. Multi-dose vial policy
ix. Monitoring vaccines use and wastage

3.1 Estimating vaccines and related materials

Methods for estimating vaccines (and related materials) needs

Two methods are commonly used to estimate vaccine and related materials

a) Using target population
b) Consumption methods

3.1.1. Estimation based on target population

The parameter needed in estimating immunisation supplies using this method are

a) The target population of the area such as infants or pregnant women
b) Number of doses for each vaccine
c) Expected wastages (this will be important in calculation of the wastage factor)
d) Expected coverage

Amount of vaccines needed=

$$Population * Coverage * Number\ of\ doses * wastage\ factor$$

$$\text{Wastage factor} = 100/(100 - wastage\ rate)$$

For example;

Calculate the number of BCG vaccines needed for Buhigwe district with live birth of 10,000 (The wastage of BCG in Buhigwe is 65% and expected coverage is 95%)

Solution

Amount of BCG needed per year=

$$annual\ target\ population * Coverage * Number\ of\ doses * wastage\ factor$$

=10,000 X 0.95 X1 X (100/(100-65))

=27,143 doses need

When ordering 25% should be added as buffer

Amount to order=27,143 + (0.25X27, 143)
=27,143 + 6786
=33929 doses

Estimating injection materials

Total number of auto-disable syringes = Total number of injectable vaccine doses needed (wastage and buffer are included in calculation of vaccine needs)
Total number of reconstitution syringes = Total number of lyophilized doses needed divided by number of doses per vial
Total number of safety boxes = Total number of auto-disable and reconstitution syringes / 100
(10% buffer might be added)

3.1.2. Using consumption method

This method uses the information from previous consumption of the vaccines and related materials
The parameter needed in the calculation of the vaccines needs are

a) Initial stock at the begining of the given period
b) Stock received during the period
c) Closing stock at the end of the period
d) Unopened wastage example expiry, frozen, stolen etc
e) Any additional special activity for the forthcoming supply period

Example
Let assume Buhigwe district receive vaccines from Kigoma region every three month (January, April, July and October). It is now the end of September 2015 and the district want to estimate OPV vaccine needs for the next three month and no OPV campaign expected.
The data from the vaccines ledger are
OPV on 1st July 2015 = 10,000 doses
OPV received during July-Sept 2015= 50,000 doses
OPV on 30th September 2015 =20,000

Calculate the amount of vaccines needed for October-December 2015

Vaccine needs=$Starting\ balance + stock\ received + new\ plans - Closing\ stock$
= 10,000 + 50,000 +0 -20,000
= 40,000 doses
So the number of OPV vaccines needed for the October-December 2015 is 40,000 doses

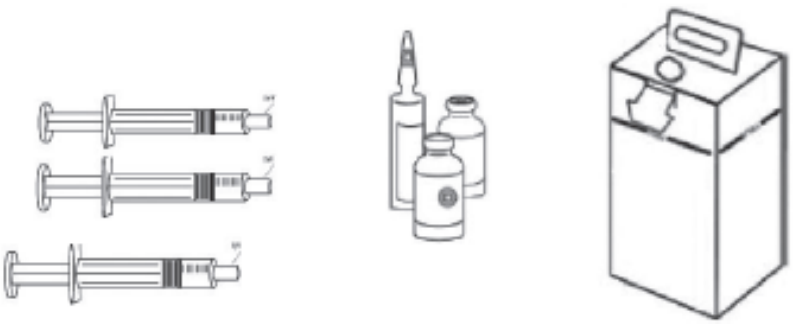
Table 1: Comparative advantage of the two methods

Method	Advantage	Constraints	Comment	Preferred application
Target population	Facilitate active planning Assist in monitoring vaccines wastage	Unreliable demographic data	Can be used for short and long term planning	Supplementary immunisation services, national level plannning
Consumption	Adequate for short period	Difficult to apply for long period Planning data difficult to apply	For estimation of future needs an advance control of quarterly needs is important	Convinient at facility level

3.2 Distribution and transport of vaccines and other materials

Distribution of vaccines and related supplies from higher to lower level should make sure the temperature of the vaccines are maintained at +2 - +8^{o}C and whenever possible bundled. Cold boxes and vaccine carrier should be used.

In immunisation bundling defines the concept of theoretical bundle which must comprise good quality vaccines, auto-disable syringes and safety boxes. Bundling has no physical connotation and does not imply the item be packaged together.



For example

If the population of district X has the live birth of 10,000 a year the number of BCG vaccines (with 10% wastage) and syringes (with 10% wastage) and syringes should be as shown in the table below;

Table 2: calculation of vaccine and supplies needed

	Target population	BCG	0.05ml AD syringes	5ml AD syringes	Safety boxes
District **X**	10,000	20,000	11,000	2,200	146

Several steps needs to be taken to ensure that vaccines and safe injection equipment are delivered to the health facilities, districts and regions in the correct quantities, on time and under correct transportation conditions.

Depending on the storage capacity the frequency of distribution per year at the health facilities is 12, district level is 4-6 and regional level is 4.
DIVO and RIVO should prepare distribution plan and estimates of the quarterly quantities of vaccines and injection materials to be supplied to the health facilities and district respectively.

3.3. Storage of vaccines and related materials

Each vaccine has its own specific storage and distribution temperature requirements so it is important to know how long and at what temperature each vaccine can be stored.
Depending on the level of service each vaccine can be stored at positive temperature (+2-+8^{o}C). However, only some vaccines can be stored at negative temperatures (-15 ^{o}C- -25 ^{o}C)
Vaccines that have been exposed to temperatures above +8 ^{o}C may lose their potency over time. The vaccine vial monitor (VVM) on the vaccine vial guide the decision of the use on the vaccine. VVM does not indicate if the vaccine is frozen.

3.3.1. Table 3A; Recommended vaccines storage temperature at all levels

<table>
<tr><th>Vaccines</th><th>National vaccines store</th><th>Regional vaccines store</th><th>District vaccines store</th><th>Health Facility</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>OPV</td><td colspan="3">Store at -15oC- -25oC
OPV is the vaccine that can safety be frozen and unfrozen repeatedly</td><td rowspan="3"></td></tr>
<tr><td>BCG</td><td rowspan="2">Store at -15^{o}C- -25^{o}C</td><td rowspan="2">Store at +2-+8^{o}C</td><td rowspan="2"></td></tr>
<tr><td>MR</td></tr>
<tr><td>HepB</td><td colspan="3">Store at +2-+8^{o}C</td><td>Store at +2-+8^{o}C</td></tr>
</table>

DTP-HepB-Hib		
IPV		
TT/Td		
PCV 13		
Rota vaccines		
HPV		

Diluents must be stored outside the cold chain until one day before its use at health facility where it will be stored in the refrigerature.

Each vial shows an expiry date and should not be used beyond that even when VVM show no heat demage. Always employ earliest-expiry-first-out principle.

3.3.1.1. Freezing

DPT-Hib-HepB, TT, HepB, IPV, rotavirus and PCV13 should always be stored in positive temperatures (+2-+8^{o}C) as they are damaged by freezing. HepB vaccine is the most sensitive to freezing temperatures.
The most common cause of exposure to freezing temperatures is the failure to correctly condition ice packs prior to transport.
If freezing is suspected DIVO or other designated officer should conduct shake test.

Note: Shake test should not be done on IPV vial. This is because the vaccine is not an adsorbed as it does not contain alluminium adjuvant. When there is suspicion of freezing it should be discarded.

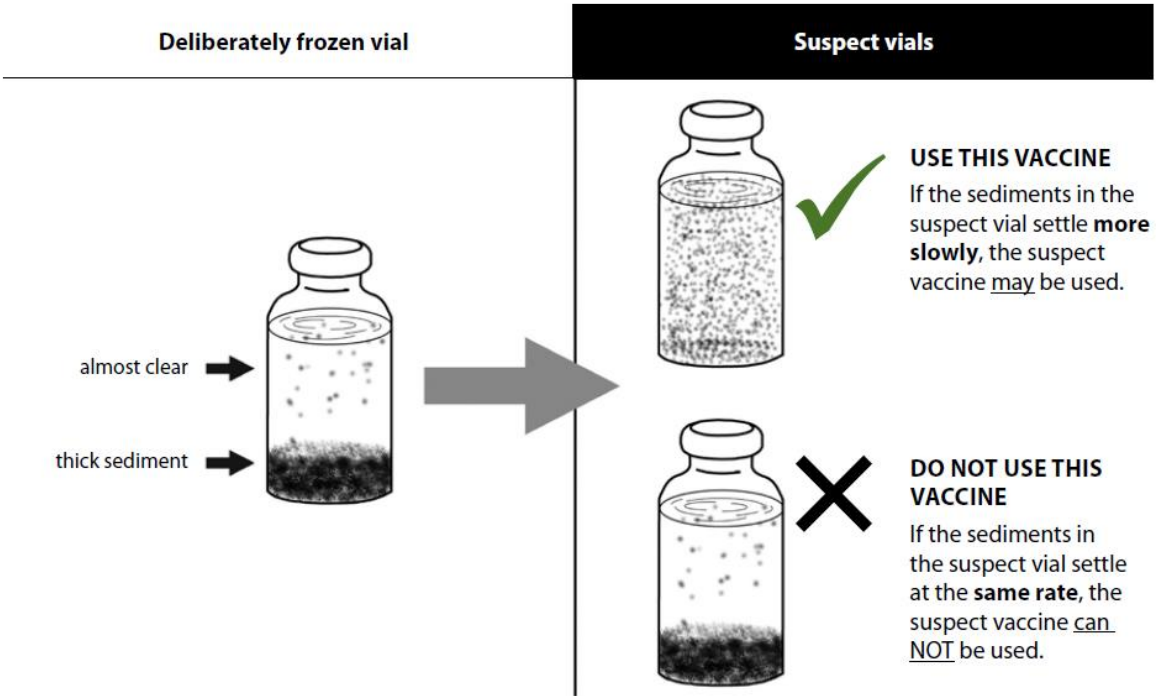
Shake test

The “Shake test” can help give an idea whether adsorbed vaccines (Pentavalent, PCV and TT) have been subjected to freezing temperatures likely to have damaged them. After freezing, the vaccine no longer has the appearance of a homogenous cloudy liquid, but tends to form flakes, which settle at the bottom of the vial after shaking.
Sedimentation process is faster in a vial which has been frozen than in a vial, from the same manufacturer, which has not been frozen.
The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.
A health facility staff, whenever suspect a vaccine being frozen, should inform the DIVO immediately.
Shake test should be done by the DIVO or other designated officer only.

Procedure for doing shake test

Step 1 — Prepare a frozen control sample: Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and from the same manufacturer. Freeze the vial until the contents are solid (at least 10 hours at -10°C) and then let it thaw. This vial is the control sample. Mark the vial clearly so that it is easily identifiable and will not be used by mistake.
Step 2 — Choose a test sample: Take a vial (s) of vaccine from the batch (es) that you suspect has been frozen. This is the test sample.
Step 3 — Shake the control and test samples: Hold the control sample and the test sample together in one hand and shake vigorously for 10–15 seconds.
Step 4 — Allow to rest: Leave both vials to rest by placing the vials on a table and not moving them further.
Step 5 — Compare the vials: View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample has most probably not been frozen and can be used. If the sedimentation rate is similar, the vial has probably been damaged by freezing and should not be used.

Figure 1; Frozen vial



Note that some vials have large labels, which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the control and test vials upside down and observe sedimentation taking place in the neck of the vial.
If the shake test procedure indicates that freezing has damaged the test sample, you should notify your supervisor immediately. Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

Note:

Frozen samples can be used for shake tests only when testing the same vaccine from the same manufacturer and the same lot number. A new sample is needed for each manufacturer and lot number.

Photosensitivity

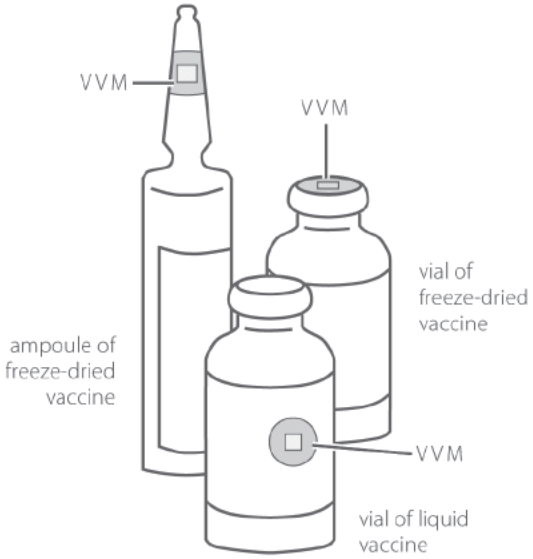
Some vaccines are very sensitive to light and their exposure to ultraviolet light causes loss of potency. BCG and MR vaccines are equally sensitivitive to light and must be protected from sunlight and fluorescent light.

3.3.1.2. VVM

A vaccine vial monitor is a label on a vaccine vial which changes colour on exposure to heat over a period of time.
Before opening a vaccine vial VVM must be checked to see whether the vaccine has been demaged by heat.
All vaccines used in Tanzania have a VVM attached on a vial or cap. It looks like a square inside a circle.
As a vaccine vial is exposed to more heat, the square becomes darker.

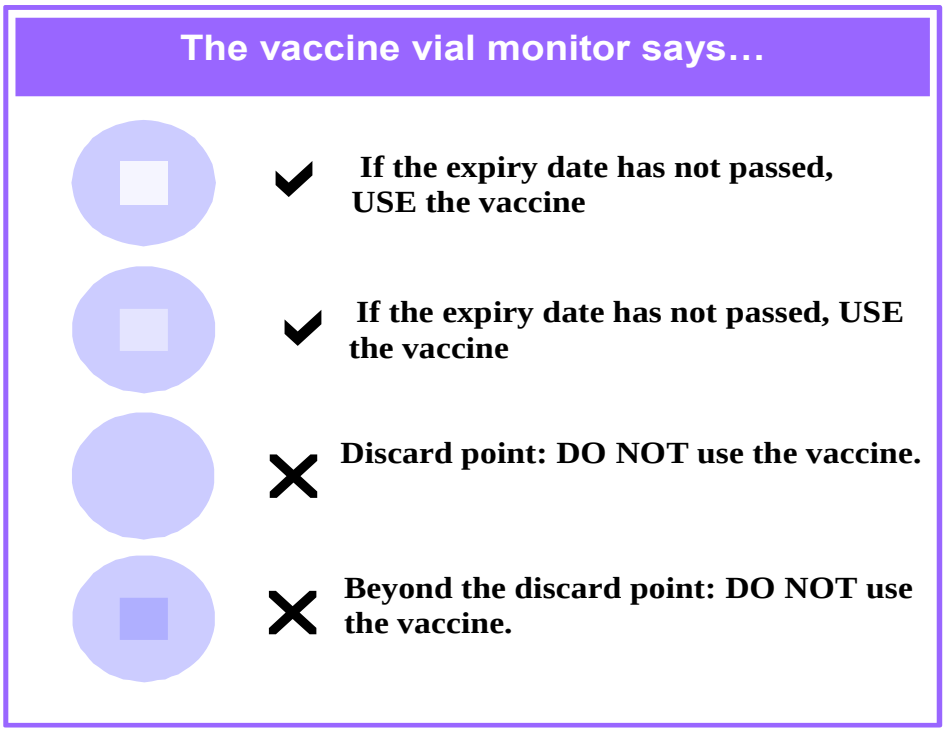
Figure 2 VVM LABEL

VVM on vial label or cap



For liquid vaccines, the VVM is permanently attached to the vaccine vial, even after the vial has been opened and remains readily observable before, during and after use.
For freeze dried vaccines: The VVM is attached to the vaccine vial or ampoule and remains readily observable until the vial or ampoule is opened but not observable after opening.

Figure 3; VVM stage



There are four different types of VVMs designed for different types of vaccines depending on their heat stability; VVM2, VVM7, VVM14 and VVM30.

Table 3B; Types of VVM

VVM category	# days to end point at +37°C	# days to end point at +25°C	Time to end point at +5°C
VVM 30 (High stability)	30	193	>4 years
VVM 14 (Medium stability)	14	90	>4 years
VVM 7 (Moderate stability)	7	45	>4 years
VVM 2 Least stability)(	2	n/a	225 days

3.4. Ordering vaccines

All health facilities / stores should use stock ledger and/or BIN card for vaccines and injection materials monitoring. For the district and regional level web-based stock management system is now in use which generates the order automatically. This will

i. Avoid stock shortage
ii. Avoid overstock
iii. Avoid expiry
iv. Ensure all necessary commodities like syringes and safety boxes are ordered accordingly (bundling).

When ordering the ordering store should make sure the amount ordered is sufficient for the maximum stock allowed for that store.

The allowed amount of vaccines and other supplies depending on the availability of the cold and dry space is shown in the table below

Location of the store	Supply period (months)
Central vaccines store	6
Regional vaccines store	3
District vaccines store	2-3
Health facilities	1

3.4.1 Minimum stock

This is the minimum number of doses that should be in stock when the next supply is made, usually 25% of the total vaccines needs for the supply period. The minimum stock takes into account the possible delays in supply as well as unexpected increase in population to be immunised.

For example;
The number of doses required per quarter for Buhigwe district for OPV is 10,000
Percentage desired as minimum stock is 25%
The minimum stock is hence 0.25 X 10,000= 2500 doses

3.4.2 Maximum stock

Maximum number of vaccines that should be in stock when the new supply has been collected

$$S_{max} = q_{period} + s_{min}$$

For the above example the maximum stock = 10,000+ 2500=12,500 doses

3.4.3 Re-order level

Number of vaccines available when it is necessary to place order.

Re-order level=$q_{delivery} + s_{min}$

$q_{Delivery}$= Number of doses needed during delivery period
= (Qperiod x (Lead time / D_{period})

Lead time = Time taken to receive order, weeks
D_{period} = Duration of the storage period, weeks

= (10,000 X2/ 12) + 2500

Re-order level=4167 doses

3.5 Receiving of immunisation materials

At all levels only qualified personnel should receive vaccines and all other related materials.

a) Check if the content is the same as written invoice, issue voucher and accompanying document
b) Check if diluent is correct and corresponds to the amount of vaccines
c) Check if the packaging condition are met
d) Check for expiry and VVM status

3.5.1 Recording vaccines movement

In stock management all operations should be recorded to trace them back when necessary. The tools used have to be filled by immunisation focal person or designated person. The tools used are stock ledger and/or BIN cards, web-based stock management tool or vaccines management information system. These tools contain the following parameters which should be completely filled

i. Name of the antigen or item
ii. Minimum and maximum stock of the antigen/item in store
iii. Date of the operation
iv. Destination of the outward or origin of the inward stock
v. Quantities raised (entry/issue)
vi. Batch number
vii. Balance
viii. Comment/observation which should include VVM status

3.6 Temperature sensitivity of vaccines

Vaccines lose their effectiveness when they are exposed to extreme temperature. Once vaccine lose their potency through heat it will not regain it.

More sensitive to heat		
	OPV	
	MR	
	BCG	
	DPT-HepB-Hib	
	TT	
	HepB	

Less sensitive to heat

More sensitive to freezing	
	HepB
	DPT-HepB-Hib
	TT
Less sensitive to freezing	

3.5. 1 Monitoring temperature in the refrigerator

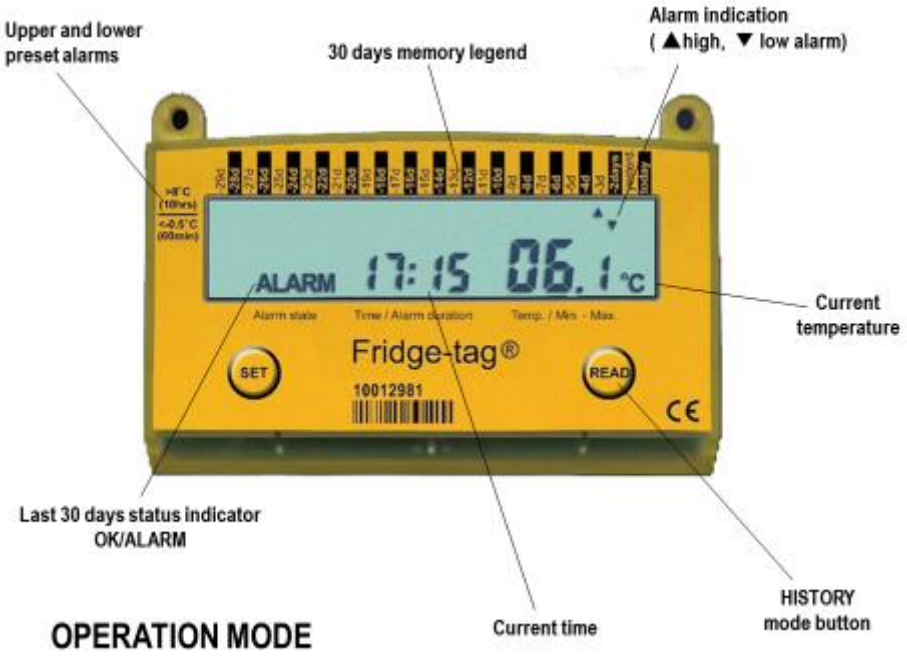
The objective is to use the temperature records for three purposes:

a) To verify whether the storage temperature is within the acceptable temperature ranges of +2°C to +8°C in cold rooms and vaccine refrigerators and - 25°C to -15°C in the freezer room and freezers.
b) To detect temperature alarm conditions1 which may have caused vaccine damage and to take appropriate action.
c) To assess the performance over time of vaccine handling at each link of the cold chain and to monitor the performance of cold chain equipment.

3.6. 1 Fridge tags

Monitors vaccine temperature during storage
Displays actual storage temp
Provides and safe-keeps previous 30 day history of storage temperatures
Shows visual indicators (alarms) for temperatures & times outside +2°C to +8°C
Direct Read-out with or without Software or PC
Requires replacement after approximately 2 years (Low battery indicator)

Figure 4; Fridge tag and freeze tag



3.5.2 Freeze tags

Freeze-Tag is an irreversible temperature indicator that shows if a product, such as vaccine has been exposed to freezing temperatures. It consists of an electronic temperature measuring circuit with associated LCD-display. If the indicator is exposed to a temperature below -0.5°C ±0.5°C for more than 60 minutes the display will change from **OK** status to **ALARM** status.

3.7 Multi-dose vial policy

The use of open multi-dose vials of vaccine in subsequent immunization sessions

a. Liquid Multi-dose vials contain preservatives that prevent growth of bacterial contamination: Vials of OPV, DTP-HepB-Hib (Penta), PCV10, TT and Rota

vaccines, from which one or more doses of vaccine have been removed during a static immunization or outreach session, may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met:

- the expiry date has not passed;
- the vaccines are stored under appropriate cold chain conditions;
- the vaccine vial septum has not been submerged in water;
- aseptic technique has been used to withdraw all doses;
- the vaccine vial monitor (VVM) has not reached the discard point; and
- the vial has been marked with the date-of-opening

Because of the increase in number of liquid vaccines and the need to improve safety the policy has been revised accordingly. The revised text states that;

All opened WHO-prequalified multi-dose vials of vaccines should be discarded at the end of the immunization session, or within six hours of opening, whichever comes first, UNLESS the vaccine meets all four of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening. The criteria are as follows.

1. The vaccine is currently prequalified by WHO.
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
3. The expiry date of the vaccine has not passed.
4. The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer- recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

3.8 Monitoring vaccines use and wastage

Monitoring vaccines use is the priority of the immunization manager (DIVO, RIVO etc) so as to detect problem and find appropriate solution and contribute to planning by providing data on vaccines use and wastage.

3.7. 1 Vaccines wastage

Vaccines wastages can occur as unopened vial or sacrified doses.
Wasted doses in unopened doses can occur due to expiry, VVM change, freezing and multi-dose vial that has been thrown by vaccinator.
Sacrified doses are those that have been wasted deliberately for the sake of immunization to take place as in BCG when less than 20 children are vaccinated.

Chapter 4: Cold chain

The cold chain is a combination of people and equipments with the task of insuring that vaccines are kept in an ideal environment and temperature to preserve their quality during transportation from the site of their production to the site of storage or application.

The cold chain is a system used for keeping and distributing vaccines in good condition. It ensures potency of vaccines from the time they are manufactured to the time they are used at a service delivery point. Since vaccines are sensitive to heat and freezing, they must be stored at recommended/appropriate temperature ranges throughout the immunization supply chain.

The cold chain consists of a series of storage and transportation links designed to keep vaccines within an acceptable range until it reaches the user.

Generally, the cold chain has five most important aspects to ensure vaccine quality including:-

- Transportation of vaccine
- Storage of Vaccine
- Recommended temperature
- Point of manufacture
- Point of use

The cold chain maintenance **requires vaccines and diluents** to be:-

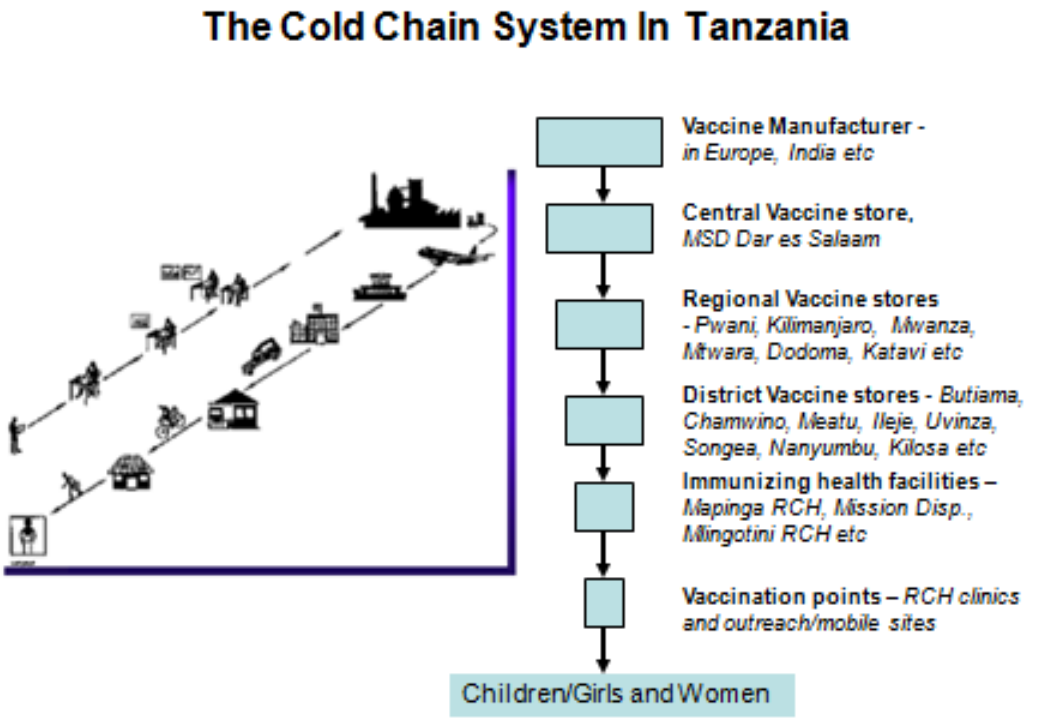
- Collected from the manufacturer or an airport as soon as they arrive or become available;
- Transported between 2ºC and 8ºC from the airport and from one store to another depending on the storage structure of a country;
- Stored at the recommended temperature (see **Figure 4A**) at all level of the cold chain - central, regional and district vaccine stores and in health facilities;
- Transported between 2ºC and 8ºC to outreach sites and during mobile sessions;
- Kept between 2ºC and 8ºC range during immunization sessions; and
- Kept between 2ºC and 8ºC during return to health facilities from outreach sites.

After vaccines have arrived at the health facility they must be:-

- Kept between 2ºC and 8ºC in health facility's refrigerator.
- Carried to the immunization session in a vaccine carrier with cooled-water packs.

The figure below illustrates the general immunization cold chain.

Figure 4A: The cold chain in Tanzania



4.1 Cold chain options

Effective vaccine management assessment and cold chain mapping can be used to determine the most appropriate cold chain system. Two options are proposed her under as: “fast” cold chain and “slow” cold chain.

Table 4: Cold chain options

	Slow cold chain	Fast cold chain
Definition	The slow cold chain relies on cold generating equipment (e.g. cold rooms, refrigerators, freezers, etc), will reduce the costs of vaccine distribution, but increase the quantity in circulation.	The fast cold chain option is based on the use of passive containers (not cold generating but maintaining it), e.g., cold box, vaccine carrier, etc. used for temporary storage of vaccines. The fast cold chain relies on speed to minimize the gaps in vaccine storage, distribution and handling. The fast cold chain can lead to higher transportation costs, but these are compensated partly by cheaper storage costs.
Conditions	• Refrigeration at the health facility level is reliable. • Stock management system is adequate. • Good warehousing practices are in place. • Vaccine distribution system/transport is expensive and unreliable. • Distances between levels of	Refrigeration at health facility level is not reliable. • Stock management system is inadequate. • Poor warehousing practices; • Vaccine distribution system/transport in place is reliable and quite cheap; • Distances between two storage points are short;

	the health systems are long. • Vaccines costs are moderate. • This system uses equipment such as refrigerators, freezers or cold rooms.	• Vaccines to distribute and use are costly (e.g. Pentavalent, HPV, HepB, PCV, Rota, etc.).

It is not necessary to choose one cold chain option for the entire country, region or council. Based on the specific situation in each locality, some will choose the fast cold chain and others the slow cold chain. A combined plan can also be made: slow cold chain between the central and regional/district stores, fast cold chain between the district stores and the health centers.

When planning this, you should take note that outreach services and immunization campaigns are implemented using mainly fast cold chain.

4.3 Cold chain equipment used in immunization services in Tanzania

Different levels within the health care system need different equipment for transporting and storing vaccines and diluents at the correct temperature.

- **Central/National** vaccine store need cold or freezer rooms, freezers, refrigerators, cold boxes, and sometimes refrigerator trucks for transportation.
- **Regional and District** vaccine stores, depending on their size/capacity, and population to serve need cold and freezer rooms, and/or freezers, refrigerators, and cold boxes.
- **Health facilities** need refrigerators with freezing compartments, cold boxes and vaccine carriers.

The cold chain equipment used in the health care system includes the following:-

4.3.1 Walk-in-Cold rooms (WICR)

The Walk-in-cold room is a pre-fabricated and pre-painted modular Polyurethane (PUF) insulated panels with two identical Refrigeration units and are available in different sizes - 30 cubic meters and 40 cubic meters.

These are connected with standby generator sets with automatic start and stop facilities. These are also provided with a temperature meter and alarm system. These are normally used for storage of large quantities of vaccines at the Central and Regional levels. In Tanzania, these are located at the Central stores in Dar es Salaam and the Regional Vaccine stores all over the country.

WICRs stores bulk quantities of DTP-HepB-Hib, TT, BCG, Measles, PCV, Rota vaccine, IPV and HPV at the regional level. At the Central store OPV, BCG and Measles Rubella are kept in the WIFRs. Storage temperature of these equipment is: +2 to +8 degree Centigrade.

4.3.2 Walk-In-Freezer Rooms (WIFR)

The Walk-in-freezer is a pre-fabricated and pre-painted modular Polyurethane (PUF) insulated panels with two identical Refrigeration units and are available in two sizes of 32 cubic metres and 15 cubic metres. These are connected with standby generator sets with automatic start and stop facilities. WIFR are also provided with a temperature meter and alarm system.

In Tanzania, Walk-in-freezers are only installed at the Central Vaccine Stores in Dar es Salaam. They are capable to:-

- Store bulk quantity of OPV.
- Freezes ice packs.
- Operating storage temperature of: -25 degree Celsius.

4.3.3 Refrigerators

Refrigerators are used to store vaccines at district vaccine store and immunizing health facilities. Vaccine refrigerators may be powered by electricity, gas, kerosene, or solar energy. Electric refrigerators are usually the least costly to run and the easiest to maintain, but their functionality is highly jeopardized by frequent power failures. In Tanzania, district refrigerators are commonly using electricity.

District vaccine stores are using ice-lining refrigerators to overcome electricity unreliability. These refrigerators can maintain appropriate vaccine storage temperature for about 16 hours without power. Modern refrigerators are designed to reduce the risk of accidental freezing of vaccines and to eliminate the need for thermostat adjustment.

Ice-lined refrigerators (ILR) are supplied with the top opening lid and are used to store vaccines at district level. ILRs are so designed with an ice bank which keeps the internal temperature at a safe level despite electricity failure. Keep thermometer hanging on the baskets and maintain temperature between +2 to + 8° C (monitor morning and evening)

Currently solar direct drive (SDD) refrigerators are installed at facility level to reduce operation costs of running gas operated RCW50EG which are mostly installed in health facilities starting early 2000s.

Liquefied Petroleum (LP) gas refrigerators like RCW50EG keep vaccines at correct temperatures and are easy to maintain. These refrigerators have different capacities for storing vaccines and for freezing and storing ice packs. A refrigerator in a health facility should be able to hold:-

- A one-month supply of vaccines and diluents in the refrigerator compartment;
- A two-week reserve stock of vaccines and diluents (an additional of 50% of the one-month supply);
- Frozen ice-packs in the freezer compartment; and
- Cooled-water packs in the refrigerator compartment (to act as a buffer to temperature changes, especially if there is a power failure).

In addition, half the total space in the refrigerator should be left empty to allow air to circulate around the vaccines and diluents to keep them cool.

Figure 4B: The three most common refrigerators used in Tanzania

Vestfrost, MK404, Icelined refrigerator

Dometic, TCW 3000, Icelined refrigerator

Dometic, RCW 50 EG

4.3.4 Deep Freezers (DF)

Under the immunization program, most deep freezers have been supplied with the top opening lid. Deep freezers maintain a cabinet temperature between -15°C to -25°C. They are mostly used to store OPV (at the Regional and District levels) and prepare ice packs during immunization campaigns which uses ice-packs. If adequate minus temperature storage capacity is available, BCG followed by Measles Rubella can be frozen at both Regional and District vaccine stores.

Deep freezers vaccine storage capacity ranges from:- 300 liters, 286 liters, 135 litres etc. The mostly used deep freezer in Tanzania is a TCW1152, with currently TCW3000AC being used interchangeably as a refrigerator and freezer.

The holdover time of ideal deep freezer is 18 hours at 43° C or 22 hours at 32° C.

4.3.5 Cold boxes

A cold box is an insulated container that can be lined with ice-packs or cooled-water packs to keep vaccines and diluents cold during transportation and/or short period storage (from two to seven days). **Figure 4C**

At the minimum, a district vaccine store must have at least 4 cold boxes for vaccine collection, temporary storage and transportation to lower health facilities.

Cold boxes are also used to store vaccines when the refrigerator is out of order or being defrosted and for outreach and mobile sessions in addition to vaccine carriers.

Different models of cold boxes have different vaccine storage capacities ranging from 8 liters, 12 liters and 25 liters. In addition, cold boxes are selected according to their cold life. Different models have a cold life of two to seven days depending on the environmental/outside temperature.

Cold life with frozen water packs *(used for transporting OPV and single antigen freeze-dried (lyophilized) vaccines)* is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C, at a constant ambient temperature of 43°C. For example, the cold life of a RCW25 at 43°C is 134.6 hours.

Cool life with cooled-water packs at +5°C *(for transporting or storing freeze-sensitive vaccines like Pentavalent)* is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches +20°C, at a constant ambient temperature of +43°C. The cool life of RCW25 at +43°C is 34.4 hours.

Health facilities usually need two cold boxes that can hold:-

- A one-month supply of vaccines and diluents; and
- A one–to–two-week reserve stock of vaccines and diluents.

Figure 4C: Vaccine cold boxes

Dometic, RCW25,
Long range cold box

Apex International, ICB-11F (Grey),
Long range cold box

The most suitable cold boxes for a particular vaccine store/immunizing health facility are determined by:-

- The vaccine storage capacity needed by that store or facility;
- The cold life needed i.e., the longest time that vaccine will be stored in the box;
- The weight and the volume of the box, which depends the transportation vehicles available i.e., vans, motorcycles, bicycle or hand; and
- The ice packs compatible with size of the cold box.

4.3.6 Vaccine carriers

Like cold boxes, vaccine carriers are insulated containers that, when lined with frozen ice-packs or cooled-water packs, keep vaccines and diluents cold during transportation and/or temporary storage.

They are smaller than cold boxes and are easier to carry if walking. Unfortunately, they do not stay cold as long as a cold boxes - their hold over time goes to 48 hours with their lids closed.

These are mostly used at vaccinating health facilities where as every facility is supposed to have 2 vaccine carriers. Vaccine carriers are used to transport vaccines and diluents to outreach sites and for temporary storage during immunization sessions at the health facility. Vaccine carriers are also used to store vaccines when the refrigerator is out of order or is being defrosted.

Different models of vaccine carriers have different storage capacities.

Figure 4D: Vaccine carrier

Apex International, AIVC-44, Long range vaccine carrier

Giostyle, Long range vaccine carrier

The type of a vaccine carrier at a particular health facility needs depends on:-

- The type of vaccines and diluents to be transported;
- The number of vaccines and diluent vials, and ice-packs to be carried;
- The cold life required;

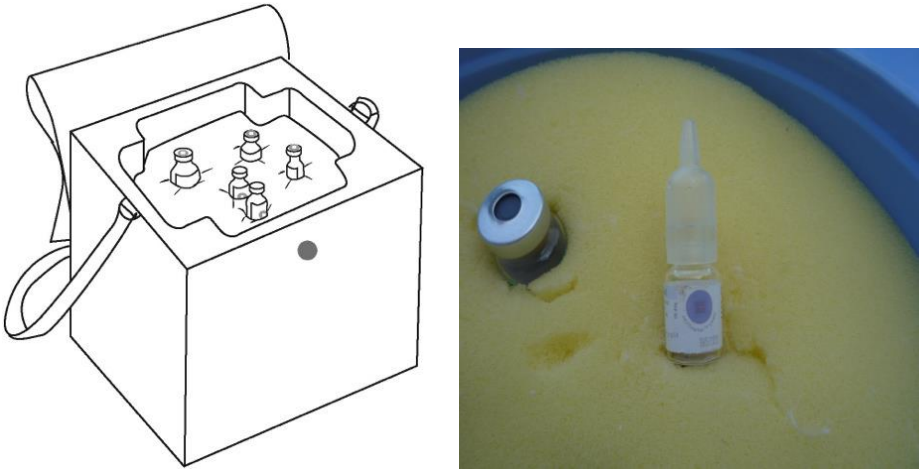
- Cooled-water packs compatible with the size of vaccine carrier;
- The means of transport to be used.

4.3.6 Foam pads

A foam pad is a piece of soft foam that fits on top of the cooled-water packs in a vaccine carrier. Incisions are made on it to allow vaccine vials to be inserted in the foam during vaccination.

During immunization sessions, the foam pad serves as a temporary lid to keep unopened vaccines inside the carrier cool while providing a surface to hold, protect and keep cool opened vaccine vials. In addition, vaccine vials are protected from heat for a longer period of time if they are inserted in a foam pad.

Figure 4E: Foam pad in use during immunization session



4.3.7 Water packs

Water packs are flat, square plastic bottles that are filled with water and kept cool in a refrigerator. Cooled-water packs are used to keep freeze sensitive vaccines cool inside the vaccine carriers or cold boxes, whereas ice-packs are used for heat sensitive vaccines. The number of water packs required for a cold box or vaccine carrier varies depending on the size container.

Conditioning of ice packs for vaccine storage or transportation is no longer recommended in Tanzania, due to high the risk of freezing some vaccine - Hepatitis B, DTP-HepB-Hib, TT, PCV13 which are very costly.

In addition, do not use pre-filled water-packs which normally come with vaccines or other laboratory items, they often contain additives, which may lower the freezing point to below 0°C and hence they can risk freeze-sensitive vaccines like DTP-HepB-Hib etc.

Figure 4F: Cooled-water/Ice packs storage and/or transportation of vaccines

Note:

Taking cooled-water packs or ice-packs out of the cold box or vaccine carrier will shorten its cold life. During immunization sessions, opened vaccine vials must be placed into the foam pad to keep them cool and to protect them.

4.4 Cold chain performance monitoring equipments

The cold chain equipment performance monitoring is used to track the functionality by monitoring temperature to which vaccines and diluents are exposed to during storage and transportation.
The commonest equipment used in Tanzania include fridge-tags, freeze-tags, Vaccine Vail monitor (VVM), and stem thermometers. In addition, the central vaccine store and all regional vaccine stores are remotely monitored using Fridgefones™ from the national level. District vaccine stores of Lindi, Geita, Arusha, Dodoma, Njombe and Ruvuma are piloted with Fridgefones™ to monitor CCEs performance and vaccine quality.

4.4.1 Fridgefones™

Is a Remote GSM Temperature Monitoring Device manufactured by BeyondWireless Technology (Pty) Limited, South Africa.

They are used to provide automatic remote data logging, real time monitoring and alarming for cold chain storage facilities and assets such as warehouses, fridges, freezers, walk in cold rooms and vehicles.

Fridgefones™ are capable of monitoring up to 16 different temperature inputs as well as mains power status and door positions.

They automatically logs temperature data which is then wirelessly transmitted via the local cellular network to the ColdCloud™ portal. In the event of a temperature excursion being detected, the system can automatically send the alarm to multiple recipients via both SMS and e-mail.

Detailed excursions' reports and real time dashboards are accessible via the ColdCloud™ portal showing all alarms at a national, regional, site and asset level, displaying the date and time of the alarms, the duration and the alarm recipients.!!

4.4.2 Fridge-tags

These are electronic devices which continuously record and displays temperature and time of the vaccine fridge. Fridge-tags maintains a 30 day history of:-

- Daily maximum temperature
- Daily duration of time when temperature was above 8° C
- Daily minimum temperature

- Daily duration of time when temperature was below -0.5° C

The fridge-tags have visual alarms after exposure of vaccines to over 10 hours above 8° C or 1 hour below -0.5° C. Normally they have a shelf life of 2 years and the batteries are not replaceable. The current market price is USD 25/unit.

The fridge-tags have a continuous 24hrs temperature monitoring, rather than the traditional twice daily spot checks. So, they provide “at a glance” history of occurrences of temperature excursions over the last 30 days. The new invention of fridge-tags enable a 60 days review when connected to the computer. Fridge-tags are mostly applicable at District Vaccine stores and immunizing health facilities.

These records, permits assessment of cumulative time vaccines are stored outside of WHO recommended temperatures which enables supervisors to verify accuracy of reports over preceding 60 days period.

Figure 4G: Fridge-tag temperature monitoring device

4.4.3 Freeze-tags

Freeze-tag consists of an electronic temperature measuring circuit with associated LCD-display. If the indicator is exposed to a temperature below 0°C ± 0.3°C for more than 60 minutes ± 3 minutes the display will change from the “good” status into the “alarm” status as indicated on the picture below.

The indicator is used to warn of freezing and is packed with DTP-HepB-Hib, PCV13 and TT vaccines during storage and transportation. The shelf life of freeze-tags is 5 years.

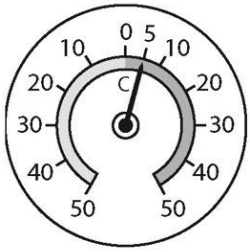
Figure 4H: Freeze-tag temperature monitoring device

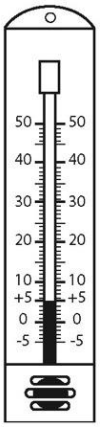
Vaccines OK **Do shake test**

4.4.4 Thermometers

Health facility staff use stem thermometers to monitor the temperature of refrigerators. On a stem or bulb thermometer, coloured fluid in the bulb moves up the scale as it becomes warmer, and down the scale as it becomes colder.

Figure 4I: Two types of thermometers *(dial and stem thermometer)*





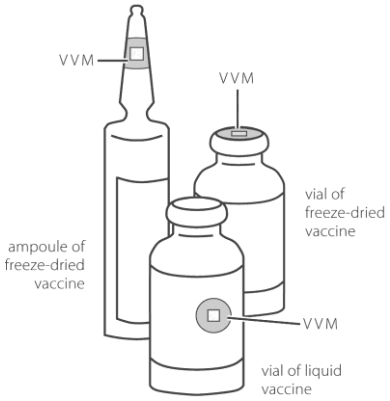
Dial thermometer Stem thermometer

4.4.5 Vaccine vial monitors

A vaccine vial monitor (VVM) is a heat-sensitive label that changes colour when the vaccine vial has been exposed to heat over a period of time. Before opening a vial, the status of the VVM must be checked to see whether the vaccine has been damaged by heat.

Vaccine manufacturers attach VVMs to vials of all vaccines. The VVM is printed on the vial label or cap. It looks like a square inside a circle. As the vaccine vial is exposed to more heat, the square becomes darker.

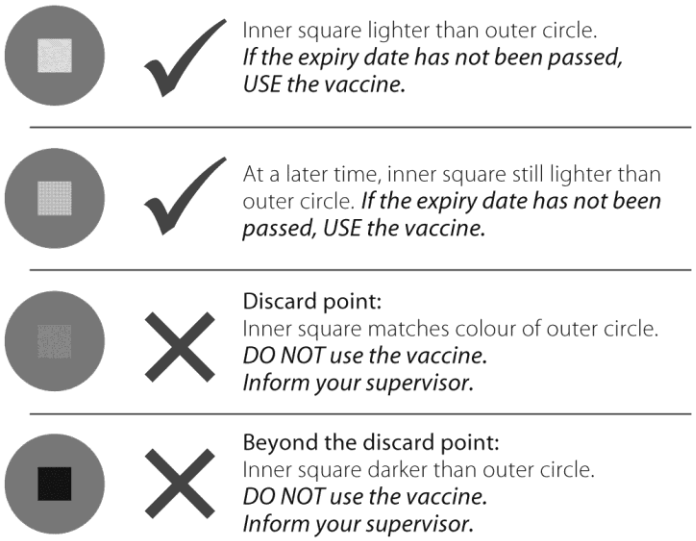
Figure 4J: VVM on vial label or cap



Note:

- Use only vials with inner squares that are lighter in colour (at VVM stages 1 and 2 only) than the outside circle (at VVM stages 3 and 4).
- Vials with VVMs in which the inner square has begun to darken but is still lighter than the outer circle should be used before the vials with a lighter inner square.

Figure 4K: How to read a vaccine vial monitor (VVM)



It should be noted that:-

- VVMs do not measure exposure to freezing temperatures (freeze-sensitive vaccines).
- A VVM not at discard point does not exclude the possibility that the vaccine was frozen.

- Before use, make sure that the freeze-sensitive vaccine with good VVM has not been frozen.

4.5 How to load a cold chain equipment

Cold chain equipment, including refrigerators, cold boxes, and vaccine carriers, must be loaded correctly to maintain the temperature of the vaccines and diluents inside.

Note:

There should be one person at each health facility responsible for the vaccine refrigerator. This person's responsibilities should include:-

- Storing vaccines, diluents, and cool-water packs.
- Checking and recording the refrigerator temperature twice daily, even on weekends.
- Maintaining the health facility's cold chain equipment.

All health workers in a health facility, however, should know how to monitor the cold chain and what action to take if the temperature is too high or too low.

4.5.1 Loading chest refrigerators (a top opening)

1. Put OPV, Measles Rubella and BCG vaccines in the bottom part; and
2. Freeze-sensitive vaccines (Hep B, DTP-HepB-Hib, TT, PCV13 etc) in the top part.

4.5.2 Loading cold boxes and vaccine carriers

Load vaccines into cold boxes and vaccine carriers as follows:-

Step 1: Take the frozen ice-packs you need from the freezer and/or cooled-water packs, and close the door of cold chain equipment.

Step 2(a): Put ice-packs against each of the four sides and on the bottom of the cold box.

Step 2(b): Put cooled-water packs against each four sides and on the bottom of the cold box or the sides of a vaccine carrier.

Step 3(a): Put the *heat-sensitive* vaccines (like OPV, BCG, Measles Rubella etc) in the cold box or vaccine carrier.

Step 3(b): Put the *freeze-sensitive* vaccines (like Hepatitis B, Pentavalent, TT etc) in the cold box or vaccine carrier.

Step 4: In the vaccine carriers, place a foam pad on top of the cooled-water packs. In cold boxes, place frozen ice-packs on top of the vaccines.

Step 5: Close the cold box or vaccine carrier lid, tightly.

Step 6: Never put cold boxes or vaccine carriers in direct sunlight, like using open, un-shaded vehicles during transportation.

4.6 How to monitor and adjust the refrigerator temperature

4.6.1 Monitoring the temperature in vaccine refrigerators

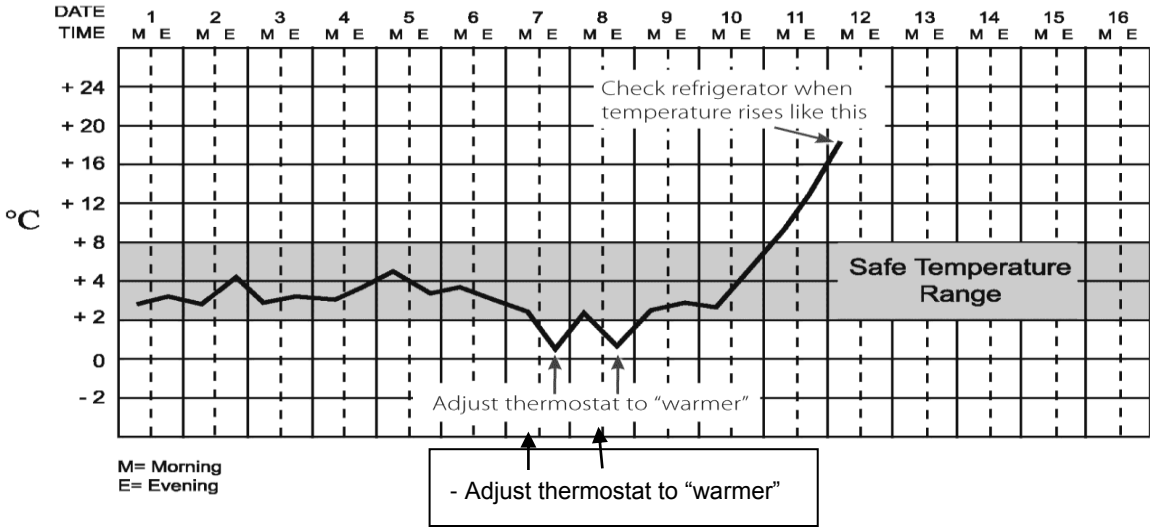
To monitor the temperature of a refrigerator you might need:-

- A FridgeFone™, Fridge-tag or thermometer, and
- A temperature monitoring chart, which you should tape to the outside of CCE door.

To monitor the temperature, proceed as follows:-

- Set the refrigerator thermostat during the coldest part of the day to around +2ºC to +4ºC.
- Monitor temperatures first thing in the morning and before you leave the health facility in the afternoon. If the temperature is between +2ºC to +8ºC, do not adjust the thermostat.
- Continue to monitor the temperature first thing in the morning and before you leave the health facility in the afternoon, including workdays, weekends, and holidays.
- Record the temperature for the day and time on the refrigerator temperature chart, as shown below.
- When a chart has been completed, replace it with a new one.
- Keep the completed charts in a record book for future reference.
- **Actions should be taken when the temperature goes out of range.**

Figure 4L: Refrigerator temperature monitoring chart



4.6.2 How to adjust the temperature of vaccine refrigerators

If the temperature is too **LOW** (below +2°C):

- Turn the thermostat knob so that the arrow points to a lower number. This will make the refrigerator warmer.
- Check whether the door of the refrigerator closes properly. The gasket may be broken.
- Check freeze-sensitive vaccines (TT, DPT-HepB-Hib, PCV13 vaccines) to see whether they have been damaged by freezing by conducting a shake test
- Take note that, heat exposure is as damaging as the freezing of vaccines.
- It is obligatory to maintain the refrigerator temperature at +2ºC to+ 8ºC

If the temperature is too **HIGH** (above +8ºC):

- Make sure that the refrigerator is working. If not, check if gas or power supply is present.
- Check whether the door of the refrigerator or the freezing compartment closes properly. The gasket may be broken.
- Check whether frost is preventing cold air in the freezing compartment from entering the refrigerator compartment. Defrost if necessary.
- Turn the thermostat knob so that the arrow points to a higher number. This will make the refrigerator cooler.
- If the temperature cannot be maintained between 2ºC and 8ºC, store vaccines in another place until the refrigerator is repaired.

Warning:

Do not adjust thermostat to a higher (cooler) setting after a power cut. This could freeze the vaccines.

Do not adjust thermostat to a higher setting when vaccines arrive. This could freeze the vaccines.

4.7 How to maintain cold chain equipment

4.7.1 Maintaining vaccine refrigerators

A refrigerator works well only if it is properly installed, cleaned and defrosted regularly.

Thick ice in the freezer compartment does **not** keep a refrigerator cool. Instead, it makes the refrigerator work harder and use more power or gas. You should defrost the refrigerator when ice becomes more **than 0.5 cm thick**, or once a month, whichever comes first.

To defrost and clean a refrigerator:-

- Take out all the heat sensitive vaccines (OPV, Measles, BCG, etc) and transfer them to a cold box lined with frozen ice-packs.
- Take out all the freeze sensitive vaccines (Hep B, Pentavalent vaccine, TT,) and transfer them to a cold box lined with conditioned ice-packs.

- Turn off the power supply to the refrigerator.
- Leave the door open and wait for the ice to melt. Do not try to remove the ice with a knife or ice pick, since doing so can permanently damage the refrigerator. You can place a pan of boiling water inside and close the door.
- Clean the inside of the refrigerator and door seal with a clean wet cloth.
- Turn the refrigerator on again.
- When the temperature in the main section falls to +8°C or lower (but not less than +2°C), return the vaccines, diluents, and ice-packs to their appropriate places.

4.7.2 What to do when a vaccine refrigerator is out of order

If your vaccine refrigerator stops working, first protect the vaccines and then repair the refrigerator. Ensure that the cold box with ice is available for the transfer to a facility with working refrigerator. Always report the malfunctioning cold chain equipment to the web-based SMT/CCIT.

Protecting the vaccines

Move the vaccines to another place until the refrigerator is repaired. If you think that the problem will last only a short time, you may use a cold box or vaccine carrier lined with cooled-water packs for temporary storage. For a longer storage durations, use another refrigerator. Always keep a freezer indicator with the freeze-sensitive vaccines to monitor eventual freezing.

Restoring the refrigerator to working order

Check the power supply. If there is no power, make other arrangements (e.g. store the vaccine in a household refrigerator) until power is restored. If there is no gas, get it as soon as possible.

If a lack of power or gas is not the problem, repair the refrigerator or report to your repair technician or supervisor (web-based SMT/CCIT.

Record the breakdown on the daily temperature-recording chart.

It is important to have a contingency plan (an alternative rescue plan) on power failure, cold chain or transport breakdown in your area. A standby power generator though expensive to run, but can be used in cases of emergency power outage.

4.7.3 Maintaining cold boxes and vaccine carriers

Vaccine carriers and cold boxes must be well dried after their use, otherwise they will become mouldy. Mould may affect the seal of the cold boxes and vaccine carriers. If possible, store cold boxes and vaccine carriers with their lids open, when not being used.

Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. If this happens the vaccines inside will be exposed to heat.

4.8 Estimating required net storage volume of vaccines

Demographic and immunization coverage data for the last year from EPI strategic five-year plan can be used to calculate the storage volume of vaccines store.

To estimate the net volume, the following information is needed:-

- Number of target population to be served
- Expected target coverage of the area
- National immunization schedule (number of doses of each vaccine needed for full immunization)
- Packed volume - volume of storage packaging per dose in cubic centimetre (cm^3)
- Vaccine wastage rate - this rate is used to calculate the wastage factor
- Supply period, and
- Minimum stock

The above, are basic data for calculation of the net volume for vaccine storage, which can be determined using two methods based on:-

- Estimated vaccine doses needed
- Vaccine volume per fully immunized child (FIC), usually used when introducing new vaccines.

4.8.1 Calculation based on vaccine doses needed

This method consists of estimating the needs for vaccines for a given supply period. A district store needs a projection of coverage data for a given year (as stated in the five-year plan).

For each vaccine, multiply the needs for a given supply period by the packed volume per dose. The result is recorded in either the positive temperature (+t°) or the negative temperature (-t°) column in line with the required storage conditions (+2°C to +8°C or -15°C to -25°C) for each vaccine.

The sum for each column will give you the net storage volume of vaccines at positive or negative temperature.

Table 4B: Calculation of the net storage volume of vaccines

S/No.	Vaccines	Presentation (doses/vial)	Estimated vaccine needs as per target coverage (doses)	x	Packed volume* (cm3 /dose)	=	Storage volume according to required temperature of vaccines (cm3)	
							+2°C to +8°C	-15°C to -20°C
1	BCG	20			1.2			
2	OPV	20			2.0			
3	DTP-HepB-Hib	10			2.6			
4	Rotavaccine	1			17.1			
5	TT	20			2.5			
6	PCV13	10			4.8			
7	HepB	10			10.0			
8	HPV	1			15.0			
9	MR	10			3.5			

Note:

* These numbers in this column are indicative and depend on the manufacturer.

Estimate your needs based on the vaccine volumes available in the market. Remember that diluents for freeze-dried vaccines must be chilled at least one day (24 hours) in advance, before use. Space must also be set aside for cooled-water packs too. You should also foresee any significant increase in immunization activities that would raise vaccine requirements and any other supplies that need to be refrigerated.

4.8.2 Calculation based on fully immunized child (FIC)

This method consists of calculating the net storage volume of vaccine per fully immunized child. **Table 7** contains information for this purpose. The total net storage volume is obtained by multiplying the volume per fully immunized child and the total number of expected children during the course of the year.

Table 4C: Calculation of the storage volume per fully immunized child

S/No.	Vaccines	Presentation (doses/vial)	Number of doses per target	Target coverage	Packed volume (cm3/dose)	Wastage		Storage volume (cm3)
						Wastage rate (%)	Wastage factor	
	A	B	C	D	E	F	G	H
1	OPV	20	4	95%	2.5	10	1.11	
2	IPV	5	1	95%	15.0	1		
3	MR	10	2	95%	3.0	18	1.22	
4	BCG	20	1	95%	1.2	70	3.33	
5	DTP-HepB-Hib	10	3	95%	19.2	10	1.11	
6	TT	20	4	95%	2.5	10	1.11	
7	PCV-13	10	3	95%	12.0	5	1.05	
8	Rotavirus	1	2	95%	17.1	5	1.05	
9	BCG Diluent	10	1	95%	1.2	70	3.33	
10	MR Diluent	10	2	95%	4.0	18	1.22	

It should be noted that:-

At the Central/National and sub-national levels, the net storage volume per fully immunized child (cm^3) is without OPV & diluents; because OPV are stored separately (in freezers) and diluents in a dry store.

At the district level, the net storage volume per fully immunized child (cm^3) is without diluents because diluents are stored in a dry store.

At a service delivery point, the net storage volume per fully immunized child (cm^3) is with OPV & diluents.

N.B:-

a) Wastage factor (G) = 100/(100-F)

b) Storage volume (H) = C x D x E x G

Required storage volume in litres = net volume per fully immunized child (in cm^3) x number of children.

The volume per fully immunized child corresponds to the vaccines used in the programme. Therefore, for each vaccine used in the national immunization programme calculations should be based on specific package size.

It is equally important that diluents for freeze-dried vaccines, which must not be refrigerated at national, regional, and district levels, are refrigerated at health center level before their intended use (24 hours in

advance). Subsequently, their volume must be taken into account, multiplying freeze-dried vaccine volume by 2 at the health center level.

The wastage rates in the tables are merely for orientation purposes. They can be used whenever data from the field are not available.

The introduction of VVM on vaccine vials as well as implementation of opened vial policy for liquid vaccines may have great influence on their wastage rates. Countries should ensure monitoring of the vaccine wastage and adjust their estimations accordingly.

CHAPTER 5: DELIVERY OF IMMUNIZATION SERVICES

In order to reduce mortality, morbidity, and disability, safe delivery of potent vaccines to susceptible children and women before they are exposed to vaccine-preventable diseases is of paramount importance. This chapter outlines the procedures for delivery for immunization services and describes some of the barriers that prevent people from using immunization services and overcoming some of these problems that all levels should adhere in order to improve immunization services.

Immunization Schedules in Tanzania

The schedule for delivering vaccine in Tanzania for primary series of vaccines to children and adults is shown on the table below. This schedule reflects a balance between epidemiology and practicality.

Table 5: Immunization schedule

Antigen	Tanzania Mainland
BCG , OPV 0	At birth or first contact
OPV1, DTP-HepB-Hib1,PCV 1, Rota 1	6 Weeks of age
OPV2, DTP-HepB-Hib2, PCV 2, Rota 2	10 Weeks of age
OPV3, DTP-HepB-Hib3 , PCV3, IPV	14 Weeks of age
MR 1	9 Months of age
MR 2	18 Months of age
Vitamin A: 1st dose	9 Months of age
Vitamin A: 2nd dose	15 Months of age
Vitamin A: 3rd dose	21 Months of age
TT 1	First contact
TT 2	1 Month after the 1st dose
TT 3	6 Months after the 2nd dose
TT 4	1 Year after the 3rd dose
TT 5	1 Year after the 4th dose
HPV 1	9 years
HPV 2	6 months after 1st dose

5.1. Strategies for Provision of Routine Immunization Services

There are several strategies for the routine delivery of immunization services in or from health facilities in Tanzania as explained below/

- **Fixed facility**

This refers to the regular delivery of vaccinations in a health facility on specified days of the week and hours of the day. It is recommended that immunization serviced be delivered five (5) days a week from Monday through Friday. Moreover, delivery should be done whenever eligible clients come.

- **Outreach**

Outreach is the delivery of services to people who cannot get to health facilities or who can do so only with difficulty. Outreach should be delivered in villages more than 5km from the health facility but not more than 10km.Trips to outreach sites are usually completed within a day and are made by health care worker that is competent in delivering immunization. It is done on foot or using motorized vehicles, bicycles, or pack animals or boats. Monthly visits provide the timeliest protection for children, although less frequent visits may be necessary where distances are far, travel is difficult, or staff resources are limited.

- **Mobile strategy**

This is usually describes trips of more than one day by district or regional health workers for the purpose of delivering services to people living in remote areas. Mobile teams may spend several days traveling to reach the people. Some of the services provided include Immunization, antenatal care, deworming, Vitamin a supplementation, HIV screening etc. Mobile services are conducted in villages that are more than 10km from the facility

It should be understood that, the cost per vaccination is higher when services are provided through outreach and mobile strategies than through fixed services, because health workers spend more time to reach each child and because there are transportation and per diem costs involved. However, some people cannot be reached in any other way.

Importance of Routine Immunization Services

In Tanzania great majority of parents view immunization as a worthwhile and relatively easy health practice. Childhood immunization only requires parents to take action about five times in the first year of a child's life and is generally accepted by families and communities. This contrasts with other practices, such as exclusive breastfeeding, which require repeated and frequent actions on the part of mothers and which are sometimes contrary to cultural norms and beliefs.

Giving proper information in good environment gives confidence
Of immunization services to mothers

Mothers will use immunization services at least once if they know what services are offered and where and when they are available. They will return if:

- They know when to come back
- They have been treated respectfully
- They have confidence that they will receive the vaccinations that they come for

Obstacles of in utilizing Routine Immunizations Services

- **Lack of information**

Many families lack accurate information about immunizations and immunization services. In fact, this is often the primary obstacle to achieving full immunization of children and women who have good access to services. They do not know when and where immunizations are available or when their next vaccination is due. They often are unaware that if they miss a scheduled immunization date, they can still be immunized; so they should come as soon as they can.

- **Poor services**

Some people receive one or more immunizations, but are unwilling to return because they are dissatisfied with the services they have received for such reasons as:

- Long waits
- Rudeness or insensitivity on the part of health workers
- Poor vaccination techniques that cause abscesses or other discomfort
- Unauthorized fees charged by health care providers

- Unscheduled facility closures
- Shortages of personnel, vaccines, drugs, or other supplies

Long waits and queue are some of obstacles to immunization services

- **Time constraints**

Making a trip to a health facility with a healthy child may not be the first priority for people with other important things to do. For many parents, particularly women, collecting and preparing food for daily meals requires working from dawn to dusk. Others have agricultural work that takes them far from home, inflexible working hours, other family obligations, or they lack child care.

- **Social, cultural, or political barriers**

Many people who live within geographic reach of health facilities do not use them because of social, cultural, or political barriers. Migrants, people from minority ethnic groups, urban squatters, and illegal residents often try to avoid contact with any public authority. People will not return to health facilities where they feel unwelcome.

- **Misinformation**

False beliefs or malicious rumours also keep people from using services. Common misconceptions include the following:

- Children are safe from vaccine-preventable diseases because a religious or supernatural being protects them.
- Children are fully protected because they have received some immunizations.
- Sick children cannot be vaccinated.
- Immunizations commonly cause sterilization, disease, or dangerous side effects.
- Vaccinators would come to their homes or communities if the vaccinations were truly important because they have done so before during immunization campaigns.

- **Distance**

Some people simply do not live within reach of health services. Some of these people live in permanent communities, and others are on the move (e.g., nomads and seasonal migrants).

Strategies for Increasing the Use of Routine Immunization Services

The reasons why people never use immunization services or stop using them after one or two encounters differ from place to place, but most strategies focus on one or more of the following goals:

- Reaching Every Child (REC)
- Reducing drop-outs
- Limiting missed opportunities

5.2. Reaching Every Child (REC)

Reaching Every Child (REC) is a health facility and community focused approach which ensures that all children in a specified community are immunized against vaccine-preventable diseases.

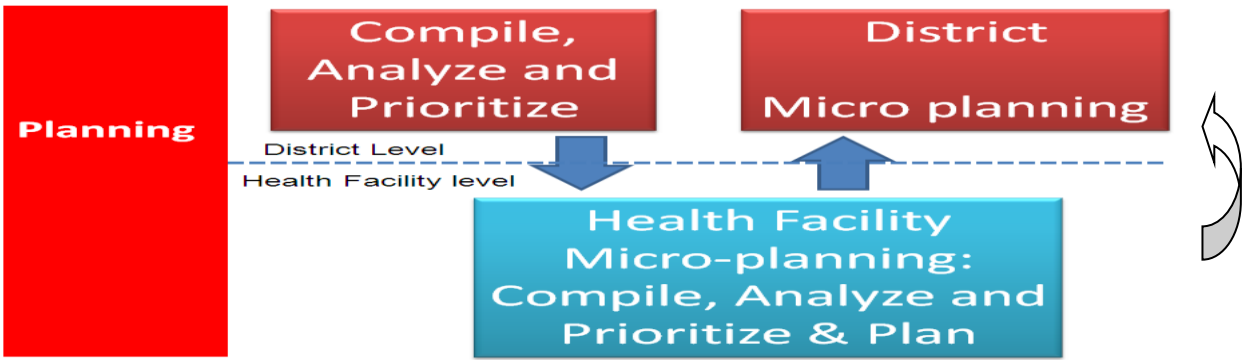
Basic principles of management cycle need to be followed in the process of implementation of Reaching Every Child approach. The basic principles of management cycle include:

- Planning,
- Implementation
- Monitoring and evaluation.

Planning			Implementation	Monitoring and Evaluation
COMPILE (population and coverage data)	ANALYZE (problems, causes and solutions)	PRIORITIZE (Where First, What First)	IMPLEMENTATION (Service delivery)	MONITOR, REVIEW AND ACT (Progress, Issues and Next Steps)

Council micro plan cycle

- The Council should start the process by compiling and analyzing health facilities data, and prioritize facilities to be focused. Health facilities identified will compile and analyze their immunization data, and plan how to reach every child in their service area.
- The council should then collate the health facility plans and develop the council micro planning.



District prioritization of health facilities

Step 1: Review routine immunization data

Council Health Management Team needs to review the available routine immunization administrative data –one year data. Line list all health facilities which are providing vaccination services in the council and indicate the following;

- Routine immunization target population of each health facility
- Children vaccinated with Pentavalent 1, Pentavalent 3 and Measles Rubella in each health facility in that specified period

Exercise: Calculate children unvaccinated with Pentavalent 1, under vaccinated with Pentavalent 3 and unvaccinated with Measles Rubella for the specified period using tool below.

Problem Identification and Priority Setting

Regions: _____ **Council:** _____

No.	Health Facilities	Compile data on population, doses of vaccine administered. Calculate immunization coverage in the current year							Analyse problem						
		Target Pop.	Children vaccinated			Immunization coverage (%)			Un-vaccinated (No.)		Dropout rate (%)		Identify problems*		Categorise problems **
		<1yr	Penta 1	Penta 3	Measles	Penta 1	Penta 3	Measles	Penta 3	Measles	Penta 1 - Penta 3	Penta 1- Measles	Access	Utilisation	Category 1,2,3,4
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1															
2															
3															
4															

Step 2: Council map with health facilities

Get the council map showing health facilities services area with all villages and major settlements. Indicate on the spreadsheet the target population of each village.

Step 3: Prioritize health facilities contributing to unvaccinated and under-vaccinated children

Identify health facilities which are contributing more than 75% of unvaccinated and under-vaccinated children in the council.

For effective supportive implementation, identify a maximum of 10 priority health facilities to be involved in the reach every child approach in the council.

Step 4: Planning session with priority health facilities

The CHMT after identification of priority Health Facilities will invite one HCW who is fully involved in immunization activities to attend a five days' workshop. The CHMT gives clear instruction to the health facility to bring Routine Immunization data, vaccine ledger, health facility map showing the village and major settlement indicating target population of each village or settlement, and any relevant data to help in the micro planning process. The five days' workshop objectives are to assist the health facility workers to:-

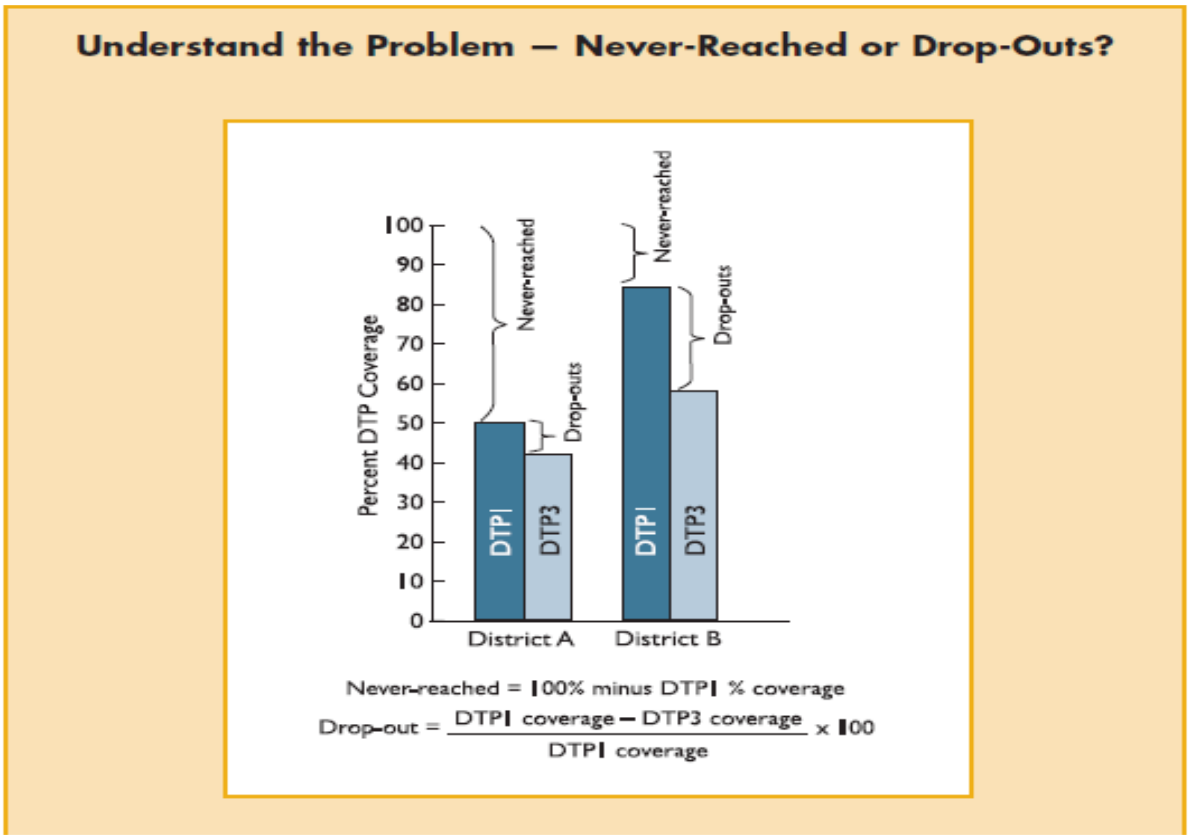
- Compile and analyse their immunization data
- Identify immunization problems
- Identify appropriate solutions
- Develop a health facility work plan to improve immunization coverage in their work areas

Step 5: Monitoring and Evaluation of REC approach

The CHMT should establish immunization monitoring procedures so as to assess the success or failure of the district/facility in improving immunization coverage. Specific monitoring indicators should be established and monitored timely.

1.4.2 Reducing Drop-Outs

- Children who begin the vaccination schedule but do not complete it are referred to as drop outs.
- If a child does not receive all of the doses required for full protection, the resources that have been used to partially vaccinate that child are mostly wasted.
- RHMT and CHMT have to decide where their efforts will result in the greatest benefit.



Example exercise

District A

50% of children have access to immunization services using DTP1 coverage as an indicator. 42% complete the three-dose series of DTP. The drop-out rate therefore is 16% :(50% – 42%) x 100 = 16%

In District A, planners should give priority to raising DTP1 coverage by reaching the 50% of children who have never been reached. Reducing drop-outs would, at best, result only in a gain in DTP3 coverage from 42 to 50%.

District B

85% of children have received DTP1. 58% complete the three-dose DTP series. The drop-out rate is 32% :(85% – 58%) x 100 = 32%

In District B, reaching the last 15% of the population that has never been reached is likely to be labour-intensive and expensive. On the other hand, following up on dropouts and persuading them to complete the series could raise coverage of DTP3 from 58% to 85%. Unless additional information indicates otherwise, District B should give priority to reducing drop-outs.

1.4.3 Limiting Missed Opportunities

- When a child come for immunization session and does not receive all of the vaccines for which he or she is eligible that will be a missed opportunity.
- This delay protection and prolong the risk of getting the disease. Most of the reasons are system related, i.e. health workers do not have sufficient quantities of vaccine or the appropriate equipment.
- More commonly, missed opportunities can be corrected by health workers themselves.

The Following should be done to limit missed opportunities

- **Improve screening.**

Make sure children's and women's vaccination status is checked on RCH card every time a client visits a health facility or outreach site, regardless of the reason for the visit. Sick children should always be screened for vaccination, as recommended by Integrated Management of Childhood Illness (IMCI) guideline.

Screening for missed opportunity by checking RCH card

- **Give all vaccines due.**

Ensuring a child receive all immunization as scheduled to that day in important in reducing missed opportunities.

- **Eliminate false contraindications.**

Children with low-grade fever, a cold, diarrhea, vomiting, or other mild illness can safely and effectively be vaccinated. Moreover, prematurity, low birth weight, and breastfeeding are not reasons to withhold a vaccination

The issue of vaccination and HIV status is summarized below:

Children with compromised immune systems. Live attenuated vaccines are a particular risk because the vaccines can cause a form of the disease, and children with weakened immune systems may not be able to fight off even a mild infection. This risk, however, must be balanced against the threat of the disease that the vaccine is intended to prevent. Such diseases can be very severe in HIV-infected children.

The problem is that most infants who have been infected with the HIV virus do not show symptoms, and it is difficult to know if they should be excluded from vaccination. With respect to the vaccines that may present the greatest threat to HIV-infected children, WHO recommends the following:

- BCG – BCG should be given to all infants, even if their mothers have HIV, unless the infant shows HIV/AIDS symptoms, which is highly unlikely. Since testing infants for HIV before they are vaccinated is generally not feasible, virtually all new-borns should receive BCG. This practice will protect HIV-positive and -negative children who are at high risk of exposure to tuberculosis because their mothers are HIV-infected.
- OPV – In highly HIV-endemic countries, as in other countries, individuals without HIV/AIDS symptoms should be immunized with OPV according to standard schedules.
- Measles – Measles can be very severe in HIV-infected children. WHO currently recommends that an early dose be given at six months followed by the scheduled dose at nine months to children who are known to be infected with HIV. For children with AIDS disease, the potential risks and benefits must be evaluated on an individual basis. The overall risk of adverse events from the vaccine is relatively low compared with the risk of measles infection in HIV-infected children. Children should not be screened for HIV antibody status before receiving measles vaccine.

1.5 Supplemental Immunization Activities (SIA`s)

- Supplemental Immunization Activities should be used to reach children who have not been vaccinated or have not developed sufficient immunity after previous vaccinations.
- The mode of such activities should differ according to the epidemiology of the disease.
  - Examples include Measles Rubella campaigns.

1.6 Accelerated Disease Control

Accelerated disease control strategies differ by disease. For polio, population immunity levels must be increased quickly in order to interrupt chains of poliovirus transmission and prevent the emerging cVDPV. In the few remaining polio-endemic countries, NIDs are held two or more times annually to vaccinate everyone in the target population (usually children under five years of age) in a one- to- three-day period. In non-endemic countries with low population immunity, NIDs are needed approximately every three years. In addition to NIDs, polio eradication planners use sub-national immunization days (SNIDs) and even local immunization days (LIDs) to reach children who were missed in previous campaigns and are not reached by routine services.

With respect to tetanus, supplemental immunization activities also focus on high-risk areas; however, they cannot interrupt transmission because tetanus is not a contagious disease.

- **Catch-up campaigns** for accelerated measles control are conducted during a period of several days or a week over wide geographic areas. Follow-up campaigns are held after catch-up campaigns to reach children in a narrower age range. Measles catch-up and follow- up strategies provide a "second opportunity" because all children in the target population are included, regardless of immunization status. For those who were missed before, such strategies provide a second opportunity to be vaccinated. For those who were vaccinated earlier but failed to develop immunity, these strategies provide a second opportunity to be immunized. (See the measles section in Chapter 12 for more information.)

5.3. Outbreak Response

Respond to outbreak timely and effectively is important as far as diseases control initiatives is concerned. Outbreak investigations should include the following;

- The health facility surveillance focal person (health facility in charge) notifies the district team about the occurrence of clusters of cases using the quickest available means of communication.
- The health facility surveillance focal person or Council Health Management Team (CHMT) completes case investigation forms and takes blood specimens from the first five suspected cases only.
- The CHMT notifies all clinicians and surveillance coordinators in nearby areas of the outbreak and the need for intensified surveillance.
- The CHMT team creates a line-listing of all subsequent cases to record place of residence, date of onset of rash, age, sex, vaccination status, outcome and EPID number (to be assigned at National level).
- The CHMT conducts active case searches in health facilities and in surrounding villages to determine the extent of the outbreak.
- The CHMT analyses and interprets surveillance data (date of onset of rash, vaccination status, age, geographic location) in order to determine the extent of the outbreak and the reason: whether the outbreak was a result of failure to vaccinate or vaccine failure.
- The CHMT team should then monitor the evolution of the outbreak by keeping track of the number of cases and dates of onset of rash of reported cases using an epidemic curve.
- The CHMT completes and sends to the regional and national level the district outbreak investigation report (within 2 weeks of the investigation) summarizing the findings, the response, evaluation and feedback processes.
- A more comprehensive documentation needs to be done at the end of the outbreak. An outbreak of measles in a district is said to have come to an end when there has not been any new suspected case of measles seen for more than 4 weeks, and when all neighboring districts have also not reported any case for a similar period of time.

Special Populations

- Refugees and people in other emergency situations are often more susceptible to infection because of unsettled conditions, lack of services, population movements, and crowded living conditions.
- Measles poses a particular risk in emergencies because measles case fatality can be as high as 50%.
- Minimum immunization target should be to rapidly reach all children up to 15 years of age with measles vaccine and vitamin A supplementation.
- Campaigns to vaccinate people in emergencies can prevent outbreaks and may also supplement routine immunization services.
- Generally refugees should be follow Tanzania immunization schedule once they are in the country.
- Special immunization delivery strategies should be deployed to migrant's population depending on the area.

CHAPTER 6: VACCINES DELIVERED IN TANZANIA

The EPI program in Tanzania was established in 1975 with delivery of vaccines against Tuberculosis and Poliomyelitis. Later on the program expanded to include vaccines against Pertussis, Diphtheria, Tetanus and Measles during the 1980`s.Currently the program is offering vaccines against the following diseases:

- *Measles*
- *Poliomyelitis*
- *Diptheria*
- *Pertussis*
- *Tetanus*
- *Hepatitis B*
- *Pneumonia*
- *Meningitis*
- *Rubella*
- *Diarrhoea*
- *Tuberculosis*

Moreover, the program has the following diseases targeted for new vaccines in the pipeline of introduction in routine immunization services:

- *Human Papilloma Virus*
- *Epidemic Meningitis*
- *Yellow fever*
- *Malaria*

This chapter describes the vaccines available and in the pipeline of IVD Tanzania following. Vitamin A deficiency (VAD), which is being addressed as part of national immunization programs in many developing countries, is then discussed.

BCG Vaccine

- BCG vaccine protects infants infected with TB from progressing to more dangerous forms of the disease and gives them some protection against recurrence at a later age.
- BCG does not prevent TB itself and provides little protection against the pulmonary forms.
- BCG is not recommended for adults.

Form and Presentation

- BCG vaccine is freeze-dried, so it must be reconstituted with BCG diluent made by the same manufacturer as the vaccine.
- BCG has a short life span and, once reconstituted, must be used or disposed of within six hours.

Efficacy

- Vaccination of uninfected children with BCG vaccine can provide protection for more than 90%, but the protective effect varies.

Side Effects

- An injection of BCG vaccine normally results in a small sore approximately the diameter of a pencil.
- The sore usually heals by itself and leaves a small round scar, which health workers look for to determine whether a child has been effectively immunized.
- Absence of a scar does not mean that the BCG vaccination did not work.
- When given properly, BCG vaccine has no side effects other than the ulceration described above.
- Local reactions, such as abscesses and inflammation of the lymph glands, may occur if too much vaccine is given or the vaccine is injected under the skin instead of in its top layer.

Contraindications

- BCG should be given to all infants, even if their mothers have HIV, unless an infant shows HIV/AIDS symptoms.
- All newborns should receive BCG. This practice will protect HIV-positive and -negative children who are at high risk of exposure to tuberculosis because their mothers are HIV-infected

Schedule and Target Age Group

- Single dose of BCG should be given at birth.
- If not given at birth, BCG may be given at the infant's first contact with the health system.

Administration

- The 0.05 ml dose of BCG is injected intradermal into the upper arm, just below the deltoid insertion site.
- Health workers should administer BCG in the same place on every child so that their colleagues know where to look for the BCG scar.
- The presence of such a scar should be used as evidence for prior BCG vaccination

Table 6A: Summary of BCG vaccine

Type of vaccine	Live attenuated bacteria
Number of doses	One
Schedule	At or as soon as possible after birth
Booster	None
Contraindications	Symptomatic HIV infection
Adverse reactions	Local abscess, regional lymphadenitis; rarely, distant spread to osteomyelitis, disseminated disease
Special precautions	Correct intradermal administration is essential. A special syringe and needle is used for the administration of BCG vaccine
Dosage	0.05ml (For those with no scar if comes before 12months give 0.1ml.)
Injection site	Right shoulder
Injection route	Intradermal
Storage	Store between 2°C–8°C (vaccine maybe frozen for long-term storage at National, Regional and District level. but not the diluent)

Polio Vaccine

- Note: Immunization is the only protection against polio infection.

Form and Presentation

- OPV, unlike other vaccines, is given orally and therefore, can be given by people with limited training.
- Inactivated polio vaccine (IPV) is an injectable vaccine and is relatively expensive.
- IPV produce less immunity in the intestines than OPV,

Efficacy

- In more than 95% of recipients, three doses of OPV produce immunity for all three of the poliovirus types in the vaccine.

Side Effects

- Reactions to OPV are rare. Vaccine-associated paralytic polio (VAPP) is a rare adverse event that occurs following the administration of OPV. It is estimated that there is one case of VAPP per 2.4 million doses given to both healthy and immunodeficient individuals.

Contraindications

- There are no contraindications to polio vaccination. However, if a child has diarrhea when OPV is given, an extra dose should be administered four weeks later.

Routine Schedule and Target Age Group

- Children receive four doses of OPV before one year of age
- These doses should be given at least four weeks apart, usually at the same time as DTP
- If the OPV0 dose is not given within 14 days of birth, it should not be given at all, and the primary series should begin with OPV1 at six weeks of age.

Administration of OPV

- OPV is dropped into the mouth. Usually two drops are given

Table 6B: Summary of OPV vaccine

Type of vaccine	Live oral polio vaccine (OPV)
Number of doses*	Four doses (including birth dose)
Schedule*	At birth, 6, 10, 14 weeks
Booster	Supplementary doses given during polio eradication activities
Contraindications	None
Adverse reactions	VAPP very rarely (approximately 2 to 4 cases per million children vaccinated)
Special precautions	None
Dosage	2 to 3 drops depending on the manufacturer instructions
Injection site	–
Injection type	–
Storage	Store between +2°C to +8°C (maybe frozen for long-term at National, regional and district levels).

IPV

- Inactivated polio vaccine comprises of three serotypes that decreases polio incidence and interrupt wild polio virus transmission
- The primary purpose of the IPV dose is to maintain immunity against type 2 poliovirus during and after the planned global withdrawal of OPV2 and switch from tOPV to bOPV.
- IPV will be administered in addition to OPV at the same health visit where OPV3/Penta3 is given.

MEASLES RUBELLA (MR) VACCINE

- This is a combined vaccine that is in one vial having dual antigen of protecting against Measles and rubella Infection.
- It is a live attenuated virus and freeze- dried (lyophilized) vaccine.
- The vaccine is safe and highly effective.
- It is sensitive to ultra violet light such as sunlight hence it is kept in amber-colored glass vials

Vaccine Schedule

- The vaccine is given in two (2) doses. The First dose is given at the age 9 months and the Second dose is given at the age of 18 months.
- Following reconstitution it must be stored in the temperature between +2° C and +8° C and used within 6 hours, thereafter, it should be discarded.
- Vaccine reconstitution must be performed by a health worker and should only be reconstituted with the diluent provided by the same manufacturer to avoid unnecessary Adverse Events Following Immunization.

Administration

- Measles Rubella vaccine is administered subcutaneously on the left upper arm.

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component
- Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy5 or patients with human immunodeficiency virus [HIV] infection who are severely immunocompromised)
- Pregnancy

PENTAVALENT VACCINE (DTP- Hep B - Hib)

- Pentavalent vaccine provides protection to a child from 5 life-threatening diseases – Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib.
- DPT (Diptheria+Pertussis+Tetanus) was the first to be introduced in Tanzania and later Hep B and Hib were introduced.
- Hib vaccine can prevent serious diseases caused by Haemophilus influenza type b like pneumonia, meningitis, bacteremia, epiglottitis, septic arthritis etc.
- Giving pentavalent vaccine reduces the number of pricks to a child and provide protection to all five diseases.

Form, Presentation and Administration

- Pentavalent vaccine comes in a liquid form in a vial which contains 10 doses.
- Each dose is 0.5 ml to be given by intra muscular injection in anterolateral aspect of the mid-thigh using AD syringes.

- Discard injection waste as per guideline for immunization waste management.
- Pentavalent vaccine is a freeze sensitive vaccine, and should be stored and transported at +2 to +8 degree Celsius in ice lined refrigerators and vaccine carriers with conditioned ice packs
- Discard if vaccine is frozen or VVM reaches discard point.

Pentavalent schedule

- Three doses are given. The first dose is given as pentavalent vaccine only after a child is 6 weeks old. The second and third doses are given at 10 and 14 weeks of age respectively also in the form of pentavalent vaccines

Table 6 C: Summary of Pentavalent vaccine

Type of vaccine	DTP-HepB-HiB vaccines
Number of doses*	Three doses
Schedule*	6, 10, 14 weeks
Booster	Not recommended
Contraindications	Anaphylaxis to previous dose
Adverse reactions	Mild local or systemic reactions are common
Special precautions	Do not use at birth and over six years
Dosage	0.5ml
Injection site	Lateral to left thigh
Injection type	Intramuscular
Storage	Store between +2°C to +8°C never freeze.

Pneumococcal Vaccine (PCV)

- Pneumococcal vaccine prevents severe form of 13 strains of Pneumococcus serotypes including pneumonia, bacteremia, and meningitis.
- The vaccine doubled as Pneumococcal conjugate 13 (PCV13).

Vaccination administration and schedule

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

Safety

- 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 ≥ 39oC 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.

Contraindications

- PCV13 should not be given to anyone who has had severe allergic reactions to a previous dose.

Table 6 D: Summary of PCV

Type of vaccine	Conjugate Pneumococcal vaccine (PCV 13)
Number of doses	Three
Schedule	6, 10, 14 weeks of age
Booster	None
Contraindications	Severe allergic reaction to previous dose
Adverse reactions	Mild local and systemic reactions are common
Special precautions	Discard opened vial after six hours.
Dosage	0.5ml
Injection site	Outer mid right-thigh
Injection route	Intramuscular
Storage	Store between +2°C to +8°C. Never freeze

Rotavirus Vaccines

- Rotavirus is a live attenuated ready to use oral vaccine used to prevent against rotavirus gastroenteritis.
- A rotavirus vaccine used in Tanzania is Rotarix.

Presentation and administration

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

Side Effects

- Rotarix is safe to use, it does not cause serious adverse reaction.
- Irritability and loss of appetite are most common 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 slight increased risk of intussusception.

Table 6E: Summary Rotarix

Type of vaccine	Live attenuated oral vaccine
Number of doses	Two
Schedule	6 and 10weeks of age
Booster	None
Contraindications	Previous history of intussusception and hypersensitivity to previous dose
Adverse reactions	Irritability and loss of appetite
Special precautions	First dose should not be given after the age of 15 weeks and second dose should not be given after the age of 32 weeks
Dosage	1.5ml
Vaccine administration	Oral
Storage	Store between +2°C to +8°C. Never freeze

Tetanus toxoid (TT) vaccine to pregnant Women

- Tetanus toxoid (TT) vaccine protects women against tetanus, but also prevents neonatal tetanus in their new-born baby.
- It is provided as a liquid in vials and also in prefilled auto-disable injection devices.
- A three-dose course of TT provides protection against maternal and neonatal tetanus for at least five years.
- A maximum of five doses will protect women throughout their childbearing years.
- When tetanus toxoid stand for a long time, the vaccine separates from the liquid and looks like fine sand at the bottom of the vial.
- Shake the vial to mix the vaccine and liquid again before giving the vaccine

Table 6F: schedule for pregnant women and duration of protection:

Dose of TT	When to give	Expected duration of protection
1	At first contact or as early as possible in pregnancy	None
2	At least 4 weeks after TT 1	1–3 years
3	At least 6 months after TT 2 or during subsequent pregnancy	At least 5 years
4	At least 1 year after TT 3 or during subsequent pregnancy	At least 10 years
5	At least 1 year after TT 4 or during subsequent pregnancy	For all childbearing years and possibly longer

Safety

- Tetanus toxoid vaccine cause very few serious reactions but quite frequent mild reactions which include soreness, mild pain, redness, warmth, and swelling at the injection site for about one to three days after the injection. Moreover, about one in ten people may develop a mild fever after receiving the vaccines.

Vitamin A Supplementation

- Vitamin A supplementation for infants, children, and postpartum women is used as a preventive strategy until all members of the population are certain to get an adequate intake of vitamin A through breastfeeding, improved diet with dark green or yellow vegetables, and food fortification.
- Two 200,000 IU doses of vitamin A should be given to women within six weeks after delivery at least 24 hours apart. This will benefit the woman, replacing the losses from her vitamin A stores caused by pregnancy and lactation. It will also benefit the infant by increasing breast milk and infant serum retinol concentrations.

Table 6G: Schedule for Vitamin A

9 months	Measles (Surua)	Subcutaneous lateral to the left shoulder	0.5ml
	Vitamin A-1st	Oral	*
15 months	Vitamin A-1st	Oral	*
18months	Measles 2nd dose	Subcutaneous left lateral shoulder	0.5ml
21months	Vitamin A	Oral	*

Form and Presentation

- Vitamin A is usually given in an oil-based solution in soft gelatin capsules that contain 50,000, 100,000, or 200,000 IU.
- The capsules should be kept dry and out of direct sunlight, but it is not necessary to keep them in the cold chain.
- They should not be frozen.

Side Effects

- High-dose vitamin A supplements cause nausea, vomiting, and headache in 3 to 9% of children aged one to four years, but these side effects resolve spontaneously within 48 hours.
- In neonates and young infants under the age of 6 months, about the same percentage may develop a transient bulging fontanel; this also subsides within 24 to 72 hours.

Contraindications

- Women who are pregnant, or who may become pregnant, should not consume more than 10,000 IU per day or 25,000 IU per week.

6.1. New vaccines introduction

- Introduction of new vaccine is in line with the Global Vaccine Action Plan (GVAP) 2011-2020 in reaching **Decade of Vaccines** goals. It require countries and their partners to

"Develop and introduce new and improved vaccines and technologies". Hence new vaccines will be introduced in Tanzania whenever the need arise.

- Carefully managed is of paramount importance during the process of introducing new vaccines. The introduction process provides an opportunity to affirm the importance of immunization, motivate health workers and members of the community, improve services, and ultimately serve broader health objectives.

The following diseases are targeted by new vaccines

- Hepatitis B infection
- Yellow fever infection
- Human papilloma virus disease
- Epidemic meningitis
- Malaria
- Ebola
- Human Immunodeficiency Virus (HIV)

Several decisions and factors need to be considered at regional and Council level before the introduction of new vaccine making the process a complex scenario. These are discussed below

Policy

- Introduction of new vaccine or technology may require changes in policies as well as guidelines to support the implementation of those policies.
- Regional and Councils should be engaged in development and adaptation these policies for implementation
- For example, the immunization schedule usually has to be amended and guidelines introduced on vaccine storage, injection techniques, reconstitution, and the use of open vials, among other matters. Guidelines if health personnel are to take on different responsibilities; for example, if traditional birth attendants are to administer the birth dose of Hep B vaccine.

Target Population

- When a new vaccine or vaccine combination is added to the routine schedule, the national EPI in collaboration with Regions and Councils must identify the age group to receive the vaccine
- Two cohorts to be considered:
  - Children between 0 and 11 months of age at the beginning of the year.
  - Children born during the start-up year (the birth cohort).

Service Delivery Strategies

- Regions and Councils should deciding best approach approach helps minimize confusion and inconvenience for both caretakers and health workers during the introduction of new vaccine
- The creation of an optimal service delivery schedule for vaccination sessions is best determined at the district level, taking into account the typical vaccination session size and the times and places that caretakers find most convenient.
- These factors can help reduce drop-out rates, contributing to full immunization and the efficient and effective use of all vaccines.

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Vaccine Supply, Cold Chain and Logistics

- The phasing out of an old vaccine and introduction of a new combination vaccine has to be timed carefully to avoid over- or under-stocking of either vaccine.
- Contingency plans should be developed in the event that the anticipated vaccine formulations do not arrive in the required quantities at the specified time.
- Immunization logistic personnel should decide the vial size to be introduced.
- The most appropriate vial size should be based on the number of children at a typical immunization session, the cost of various presentations, storage requirements, and other operational factors.

Staff at all levels of the system (including the drivers who deliver the vaccines) may need new instructions about vaccine storage. These instructions should include the protection of both freeze-sensitive and heat-sensitive vaccines.

- The need for cold and dry space equipment must be estimated and delivery schedules planned to ensure continuous supplies.
- More space may be needed to store auto-disable syringes and needles and safety boxes.
- Vaccine arrival reports, stock control records, and requisition forms may have to be revised.

Exercise

You are the RIVO in Tanzania. The MoHSW has decided to introduce a new vaccine (PCV) into the routine childhood immunisation programme. You have been asked to develop an introduction plan. The last programme review took place 5 years ago. Below is the basic information from the review you have to use.

Service delivery

- *The Regional DTP3 coverage was 60%, but in half of rural districts the coverage was < 50%.*
- *Outreach services were irregular and infrequent in remote districts.*
- *Standard disposable needles and syringes were used for all vaccination injections. 80% of staff reported needle sticks in the previous 12 months.*
- *75% of injections observed were done with sterile needles.*

- *50% of health facilities burned and buried used-injection materials, 25% disposed of used materials in opened dumpsites, and other 25% used incinerators to dispose of used injection materials.*

Logistics

- *The EPI Review also revealed that 98% of health facilities had refrigerator; 85% of the refrigerators were in good working condition and almost all of the refrigerators were used for vaccine storage only.*
- *The average age of the refrigerators was 7.5 years.*
- *The overall strengths of the cold chain remain somewhat questionable, but the system had sufficient capacity for at least one additional vaccine.*

Vaccine management

- *Findings of the review showed that stock management was very poor district and facility level.*
- *Based on the consumption rate, the estimated quantity of measles vaccine in the region was adequate for 40 months, but the vaccine would expire in 12 months.*
- *There were sufficient supplies of all other vaccines for 8-25 months.*
- *50% of rural health facilities reported at least two DTP stock outs in the previous six months, each lasting for about 4 weeks.*
- *Vaccine wastage rate for DTP (10-dose vial) was estimated at 40%. Vaccine wastage was not monitored routinely.*
- *Open vial policy was not implemented in many health facilities and outreach sites.*

The MoHSW support of the introduction. They have requested you to come up with a realistic plan for the introduction of the new vaccine

Your tasks:

- *Outline the key activities you would have to undertake to develop a realistic introduction plan based on Regional data*.
- *If you choose to do a situation analysis, list the components of EPI you would give special attention to and provide reasons for your choice.*
- *Form small working groups to prepare various components of the plan and present the consolidated plan to the plenary session*

Disease Surveillance

- Arrangement will be done by MoHSW with support of epidemiologists to decide what should be reported about the "new" disease, that the vaccine is introduced, who should report such information, and how often.
- Special training should be provided to enable health workers to recognize and discuss the symptoms of diseases that are not often seen or diseases that cannot be diagnosed on the basis of symptoms alone.

Communication

- Health workers need to be given technical information on the disease and vaccine so that they can administer it correctly and can provide essential information to caretakers.

- Parents or other caretakers need more concise information, including the name of the vaccine, its benefits (in brief), the vaccination schedule, and possible side effects.

Training

- All of these changes mean that health workers, supervisors, and others need new information and, sometimes, new skills.
- Ministry of Health and Social Welfare will identify who needs training, in what, for how long, and by whom.
- Job aids and supervisory skills should be developed or upgraded to reinforce the training.

Financing

- Capital and recurrent costs related to the introduction of new vaccines should be estimated and included in the annual immunization budget.
- Additional capital costs might include investment in cold chain equipment. Recurrent costs include vaccines, A-D syringes and needles, training, safe disposal of waste, advocacy/social mobilization, monitoring, supervision and evaluation of the impact of immunization

SPECIFIC NEW VACCINES

Yellow fever vaccine

- Yellow fever Vaccine is scheduled for introduction in Tanzania in 2019.
- Immunization of children who are nine months of age or older with 17D yellow fever vaccine will be the best protection.
- Inclusion of older age groups may be appropriate among populations and within areas at high risk of epidemics.
- A single dose provides protection against the disease for at least 10 years and often for 30 years or more.

Form and Presentation

- Yellow fever vaccine is freeze-dried, so it must be reconstituted with yellow fever diluent made by the same manufacturer.
- Once the vaccine is reconstituted, it must be used or disposed of within six hours.

Efficacy

- An injection of yellow fever vaccine is effective in almost 99% of recipients.

Side Effects

- Children may get fever, headache, or mild muscle and joint pain after an injection of yellow fever vaccine

- Encephalitis has been reported following yellow fever vaccination of a few infants younger than six months, leading to the recommendation that the vaccine not be given before that age, even in an outbreak.

Contraindications

- There are no contraindications for giving yellow fever vaccine to children older than six months of age, except for HIV.
- Yellow fever vaccinations should not be given to patients with symptomatic HIV infection or to pregnant women.

Schedule and Target Age Group

- One dose should be given to children at nine months of age, at the same time as measles vaccine.

Administration

- The 0.5 ml dose is given subcutaneously in the upper right arm.

HPV vaccine

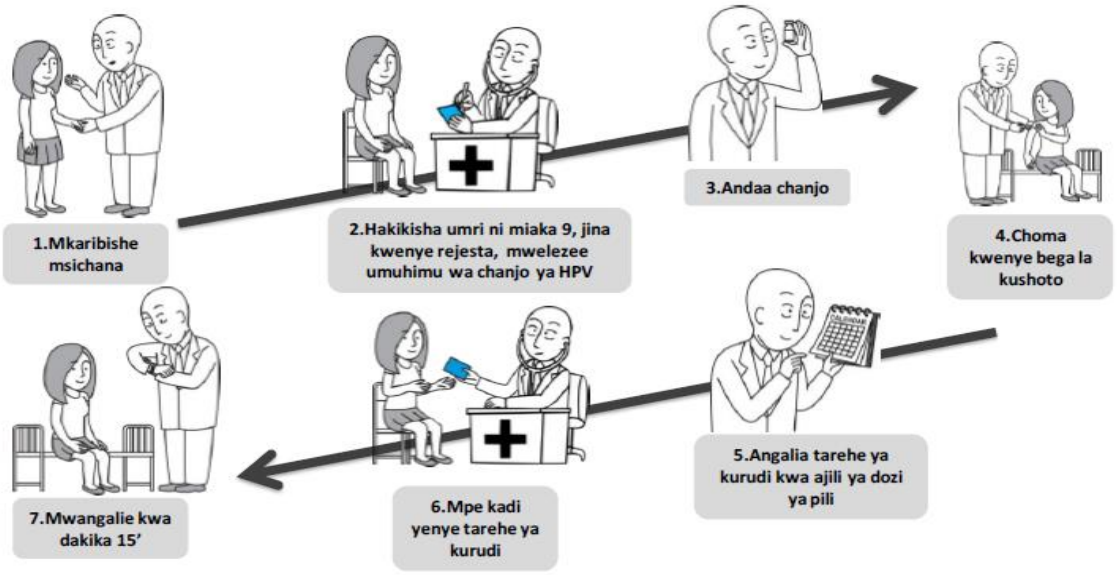
- The primary preventive method for cervical cancers caused by HPV infection is through the use of HPV vaccine.
- It prevents women from acquiring HPV infection in the first instance, so there is no risk of an infection progressing to cervical cancer later in life.
- This vaccine will be available countrywide as part of routine immunization in Tanzania in 2017.

Target group and Schedule

- The target age group for HPV vaccination is girls aged 9 years who are at school and those out of school (community).
- The vaccine will be provided in two (2) doses for attaining full immunity against cervical cancer.
- The interval between the two doses will be six (6) months.

- It is important to ascertain that the target age girls have received both two doses by keeping records of those who have been vaccinated.

- This records will help to determine whom have been vaccinated and the number of doses received.
- All the targeted girls must be recorded on the register and soon after vaccination should be given HPV card indicating the next scheduled dose.



MenA vaccine

- Two types of meningococcal vaccines are available in the market:
  - Polysaccharide vaccine
  - Conjugate vaccine.

- A low cost conjugate group A meningococcal vaccine (MenAfriVac) was developed, and if introduced in well planned programmes, will prevent the epidemics of group A meningococcal disease.
- The recently introduced meningococcal group C conjugate vaccines have also proved to be safe and efficacious in all age groups including infants, and are easily adapted to the timing of routine childhood immunization services.
- As with Hib and pneumococcal conjugate vaccines, group A, C, Y and W-135 meningococcal polysaccharides have been chemically conjugated to carrier proteins.
- Conjugate vaccines induce a T cell-dependent response, resulting in an improved immune response in infants and young children and a priming of immunologic memory leading to a booster response to subsequent doses. These vaccines are expected to provide long-lasting immunity even when given as a series in infancy, and to enhance herd immunity by decreasing nasopharyngeal carriage and thus transmission of the causing bacteria

CHAPTER 7: SAFE INJECTION AND DISPOSAL OF SHARPS, SYRINGES AND NEEDLES

Injection safety is the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment, and correct disposal of contaminated injection equipment.

- **Why Injection Safety?** It is well known that giving injections using non-sterile procedures can cause abscesses and transmit life-threatening infectious diseases, including hepatitis B, hepatitis C, and HIV/AIDS in recipients, health workers and the community.

7.1 Selecting Safe Injection Equipment

- Auto-disable (AD) syringes are recommended for administering vaccines in routine immunization and mass campaigns.
- It is no longer recommended to use standard plastic disposable injection equipment and sterilized syringes and needles for immunization, with the exception of reconstitution syringes used for reconstitution of freeze-dried vaccines. Until AD (Auto-Disable) syringes for reconstitution become widely available, standard disposable equipment should be used for reconstitution of vaccines.

Main characteristics of AD syringes are that they:

- Are designed to ensure a single use only
- Have a pre-set volume limit
- Have a fixed needle of an appropriate gauge for immunization
- Are automatically rendered unusable after they have delivered a full dose
- Are available as 0.5ml and 0.05ml units, while other sizes are available for reconstitution purposes
- Once the vaccine is administered by the syringe, it is impossible to refill by drawing back the plunger forcibly or by applying back pressures to the needle of the syringe

7.2 Safe Injection Practices

Vaccines must be administered using safe injection practices and safe injection equipment. To avoid harm to the recipient and to health workers, the following safe injection practices should be implemented.

1. Use a new sterile AD syringe and needle for every injection.
2. Use a new sterile syringe and needle each time a lyophilized vaccine is reconstituted.
3. Discard an AD syringe that has touched any non-sterile surface (e.g. hands, environment surfaces) before injection.

4. Prepare the injection materials on a designated surface (table or tray) that is clean and where blood and body fluid contamination is unlikely
5. Protect fingers with a small gauze pad before opening glass ampoules.
6. For multi-dose vials, always pierce the septum with a sterile needle. Never leave a needle in place in the stopper of the vial.
7. Never re-cap the AD syringe, but dispose of it immediately into the safety box after use.

Summary of unsafe Injection Practices- Pictorial Illustration

Do not overfill the safety box

Do not recap the needle

Do not leave the needle attached to or inside the vial

Do not touch the needle

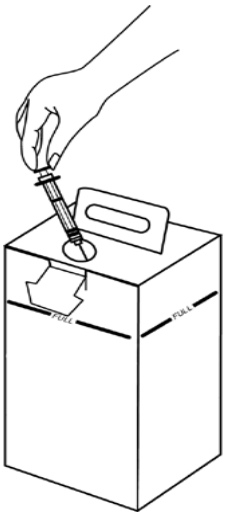
Do not dispose of used needles in an open cardboard box

7.2.1 Using Safety Boxes

Sharps, and more specifically needles, are considered the most hazardous category of health-care waste for health-care workers and the community at large if they are not properly handled and disposed of; needle-stick injuries can easily occur and carry a high potential for infection, including hepatitis B and hepatitis C, human immunodeficiency virus (HIV) and sepsis.

- To prevent risk of infection to the community and to health workers, the safe disposal of used needles and syringes is a critical component of any immunization program.
- Without recapping, vaccinators should place needles and syringes in safety boxes immediately after administering vaccines.

Figure 5: Safety box



- Different safety boxes are assembled in different ways, but appropriate instructions are always printed on each box.
- The safety boxes should be within immediate reach of your work station so that you can dispose of the used syringe promptly after giving the injection. Many needle-stick injuries happen after the injection, but before the syringe is placed in a safety box.

- If providing immunizations away from the clinic (during an outreach session, for example), be sure to take the safety box, even if the box already has some used syringes in it.

- Keep an extra, empty safety box nearby at all times, in case the box you are using fills up.

7.3 Positioning Children for Injection

Unexpected motion at the time of injection can lead to accidental needle-stick injuries. To prevent this, position the child securely before giving the injection. Adults may tuck the child's legs between theirs to secure them, or hold the child's legs. The adult should also hold the child's free arm. Health workers cannot hold the child because they need both hands for the injection. Even though the child is securely positioned, always tell him/her when you are about to give them an injection.

7.4 Safe Disposal of sharps syringes and needles.

All safety boxes with used sharps, syringes and needles must be disposed by incineration method or burning and burring.

Incineration Method

- This involves burning at high temperatures using Small Scale Incinerators (SSI) which can attain 800°C and above.
- All sharps to be completely burned and the remaining ashes and vaccine vials to be buried in pits designed for this purpose.
- This method is common in most hospitals and health centers in Tanzania.

Advantages

- Complete combustion of syringes and needles
- Reduce risks of toxic emissions
- Reduce volume of wastes

Disadvantages

- Building materials not readily available e.g. firebricks
- Relatively expensive to build, operate and maintain
- Require trained personnel to operate
- May require fuel or dry wastes to start the burning

Figure 6A: Incinerator

Burn and Bury

- Where there is no incinerators the burn and bury method can be used.
- This involves burning at low temperature in pits one meter deep.
- The remains/ashes and vaccine glass vials to be covered with soil/sand.

Figure 6B: Burning safety box

Advantages

- Relatively inexpensive
- Minimum training is required
- Reduction in wastes volume
- Reduction in infectious materials

Disadvantages

- Pollution toxic emissions i.e. dioxins and furans
- May not completely burn

CAUTION: Do not put the following material in a safety box, discard with other medical waste:

-Empty vials;

-Discarded vaccine vials;

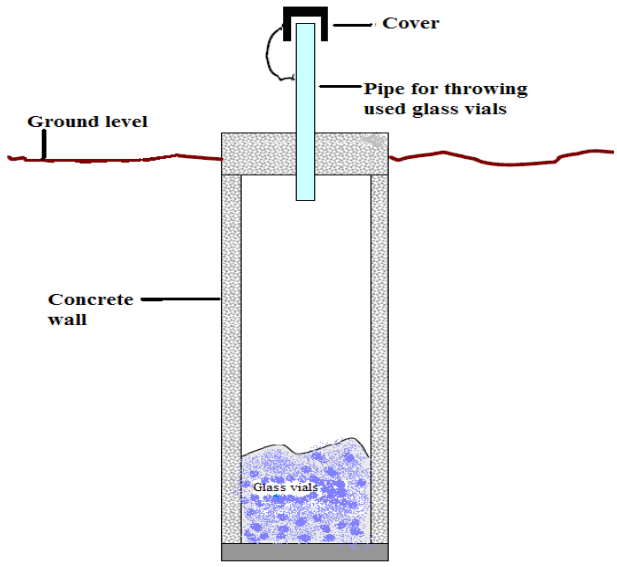
-Gloves or any kind of plastic materials or waste products.

-Fence the Pit site used for burn and bury, and should not be an open space, accessible to children

Disposal pits

Disposal pit can be used in long-term measures. This type of pit is specifically designed for the disposal of vaccine glass vials. This pit will not allow for excavation of the glass vials. This method is being applied in Zanzibar and some of the region in Tanzania mainland eg Kigoma whereby circular pits with a depth of 4 meters and diameter of 5meters are constructed using concrete and covered at the top with a small opening enough to allow for depositing glass vials. Empty or expired vials if not recycled for glass manufacturing should be crushed into a pit for volume reduction. Glass should never be incinerated as it may clogged incinerator or may explode.

Figure 7: Disposal pit



NOTE:

Used syringes and needles must NEVER be dumped in open areas where people might step on them or children might find them.

Protective clothing to health care waste handler is crucial i.e. overalls, rubber gloves, boots or closed-toe shoes, rubber aprons, goggles

IMPORTANT: The remains of the needles and safety box should be buried after burning, whether burning is done in a metal drum or in an open pit. Bury them deeply in a disposal pit, controlled landfill, or a similar location where people do not have access to them.

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CHAPTER 8: ADVERSE EVENTS FOLLOWING IMMUNIZATION TANZANIA

The overall goal of immunization is the protection of the health and well-being of infants, children and pregnant women who depend on vaccines to protect them from serious vaccine preventable diseases (VPD). Such products are relatively safe and can rarely cause adverse events following immunization (AEFI). Because serious adverse events are very rare and occur primarily in children who were apparently healthy, monitoring vaccine safety is of paramount importance in a healthcare system of any country.

The most common AEFIs in Tanzania are immunization error related, which occur as a result of inappropriate storage, handling, preparation and administration of vaccines. It is important that these AEFIs are reported, investigated and corrective measures taken to prevent additional incidents.

8.1. What is an Adverse Events Following Immunization?

An **"Adverse Event Following Immunization"(**AEFI) is a medical incident that takes place after an immunization, causes concern, also is an adverse event following immunization is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

Reported adverse events can either be true adverse events - i.e. resulting from the vaccine or immunization process - or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

The Adverse Events may be any unfavorable or unintended sign or disease that causes concern to client, parent, community and public. It is important that these AEFIs are reported, investigated and corrective measures taken to prevent additional incidents.

Trigger event, A medical incident following immunization that stimulates a response, usually a case investigation.

Injection safety The public health practices and policies dealing with various aspects of the use of injections (including adequate supply, administration and waste disposal) so that the provider and recipient are not exposed to avoidable risks of adverse events .

Immunization safety The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse events surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.

Safe injection practice, Practices which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.

Contraindication, A situation where a particular treatment or procedure, such as vaccination with a particular vaccine, must not be administered for safety reasons.

Contraindications can be permanent (absolute), such as known severe allergies to a vaccine component, or temporary (relative), such as an acute/ severe febrile illness.

Surveillance, The continuing, systematic collection of data those are analyzed and disseminated to enable decision-making and action to protect the health of populations

Vaccine reaction, an event caused or precipitated by the active component or one of the other components of the vaccine,

Vaccine reactions may be grouped into two broad categories:

A. Cause-specific vaccine reactions:
   - vaccine product-related reaction and
   - vaccine quality defect-related reaction
B. Vaccine reactions by seriousness and frequency:
   - common or minor reactions;
   - Rare or serious reactions.

Severe vaccine reaction, it refers to the intensity of vaccine reactions. A severe reaction refers to the high grade intensity of its grading such as mild moderate and severe. Severe reactions may include both serious and non-serious reactions.

Cause-specific vaccine reactions

Vaccine product-related reaction: This is an individual's reaction to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. Most often the exact mechanism of a vaccine product-related reaction is poorly understood. The reaction may be due to an idiosyncratic immune mediate reaction (e.g. anaphylaxis) or to replication of the vaccine-associated microbial agent (e.g. vaccine-associated poliomyelitis following OPV which contains attenuated live virus).

Vaccine quality defect-related reaction: This is a due to a defect in a vaccine (or its administration device) that occurred during the manufacturing process. Such a defect may have an impact on an individual's response and thus increase the risk of adverse vaccine reactions. Insufficient inactivation of wild-type vaccine agent (e.g. wild polio virus) during the manufacturing process or contamination introduced during the manufacturing process could cause the vaccine quality defect-related reactions.

Vaccine reactions by seriousness and frequency

Most vaccine reactions are minor and subside on their own. Serious reactions are very rare and, in general, do not result in death or long-term disability.

8.2. Generally Causes of Adverse Events are:

- **Vaccine reaction,** an AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer)
- **Vaccine quality defect related reaction,** an AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer
- **Programme error**, an AEFI that involves incorrect handling, reconstituting the vaccine, wrong site and drug dosage, improper storage and handling, unsterile syringe and needles.
- **Adverse Events due to destruction of Parasites** are the consequence of the death of parasite upon the action of the medicine.
- **Coincidental,** an AEFI which happens after immunization but not caused by something other than drug product/vaccine or vaccination process,
- **Injection reaction,** an Adverse Events is anxiety about or pain caused by the injection not vaccine, usually a case investigation.
- **Unknown caused**-the cause cannot be determined

A robust AEFI surveillance system in a country will help authorities detect, manage and prevent AEFIs.

Table 7: Immunization error-related reactions

Immunization error		Related reaction
Error in vaccine handling:	Exposure to excess heat or cold as a result of inappropriate transport, storage or handling of the vaccine (and its diluents where applicable)	Systemic or local reactions due to changes in the physical nature of the vaccine, such as agglutination of aluminium-based excipients in freeze-sensitive vaccines
	Use of a product after the expiry date	Failure to protect as a result of loss of potency or no viability of an attenuated product
Error in vaccine prescribing or non-adherence to recommendations for use	Failure to adhere to a contraindication	Anaphylaxis, disseminated infection with a LAV e.g. Disseminated BCG
	Failure to adhere to vaccine indications or prescription (dose or schedule)	Systemic and/or local reactions, neurological, muscular, vascular or bony injury due to incorrect injection site, equipment or technique

Error in administration	Use of an incorrect diluent or injection of a product other than the intended vaccine	Failure to vaccinate due to incorrect diluent, reaction due to inherent properties of whatever was administered other than the intended vaccine or diluents
	Incorrect sterile technique or inappropriate procedure with a multi dose vial	Infection at/beyond the site of injection

An immunization error-related reaction may sometimes lead to a cluster of events associated with immunization. For instance; freezing vaccine during transport may lead to an increase in local reactions

8.3. Classification of Adverse Events Following Immunization (AEFI)

- **Common, Minor Adverse Events**, an event that is not serious and does not pose a potential risk to the health of the recipient. They are caused when recipient's immune system reacts to antigens or the vaccine's components, Most AEFI are minor and settle on their own, could be local or systemic. Non-serious AEFIs also should be carefully monitored because they may signal a potentially larger problem with the vaccine or immunization, or have an impact on the acceptability of immunization in general.

- **Rare, Serious Adverse Events**, an event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious. They are caused by the body's reaction to a particular component in a vaccine. The term "severe" is used to describe the intensity of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance. All serious AEFI should be reported, investigated and the causality assessed

8.4. Prevention and management of AEFI

Vaccines are very rarely contraindicated. However, it is important to check for contraindications to avoid serious reactions. Vaccine anaphylaxis is very rare. it is recommended to conduct:

1. Prevention and management of immunization error-related reactions
2. Prevention and management of immunization anxiety-related reactions
3. Management of suspected anaphylaxis or collapse after vaccination

Specific prevention and management are;

- ❖ Preparedness to provide emergency treatment for anaphylaxis is necessary in all clinic settings.
- ❖ All immunization providers need to be trained and develop competence in recognizing and managing anaphylaxis and have epinephrine (adrenaline) available.
- ❖ For parents, advice should be given on managing the common minor reactions, in addition to instructions on seeking proper medical care if there are more severe symptoms.
- ❖ Avoiding Programme error by
    - By using sterile syringe and needle for every injection
    - Reconstitute vaccine with specific diluents
    - Discard reconstituted vaccines after six hours
    - Do not store drugs and other medicine in the same fridge with vaccine and diluents.
    - Always check the validity of the vaccine, diluents, by observing expiry date, VVM status and batch number
    - Use of clean and safe water while administering drugs/vaccine.
    - Train and supervise and health workers to ensure safety injection
    - Careful epidemiological investigation of an AEFI is needed to pinpoint the cause and to correct immunization practices.
    - Prior to immunization, adequate attention must be given to contraindications.
    - Monitor ,and investigate and act when AEFI occurs

- ❖ To minimize AEFIs, health workers should follow instructions including contraindication
    - History of allergic reaction to previous dose
    - Severe illness with temperature ≥ 39°C

- ❖ All vaccination staff must be able to recognize AEFIs and report them.
- ❖ Health care providers also have the additional responsibility to manage AEFI and, if necessary, refer such patients for any required treatment.

8.5. AEFI surveillance in Tanzania

- Surveillance for adverse events following immunization (AEFI) is an integral part of the Tanzanian National Immunization and Vaccine Development (IVD) Program, and reinforces the safe use of all vaccines in the country while also helping to maintain public confidence in its immunization program.

- **Why AEFI Surveillance**

- Adverse Event Following Immunization (AEFI) surveillance helps to preserve public confidence in the immunization programme
-
- **The objectives of AEFI surveillance are to**:
  - ❖ To identify, correct and prevent immunization error related reactions
  - ❖ To trigger further investigations regarding a possible causal relationship between a vaccine and AEFI.
  - ❖ To provide descriptive epidemiologic data on national numbers of reported (AEFI)
  - ❖ To closely monitor the safety of newly Introduced vaccines
  - ❖ To detect previously unrecognized reactions from both existing and newly licensed vaccines
  - ❖ To detect apparent increases or decreases of AEFIs
  - ❖ To detect preexisting conditions that may promote AEFIs & precautions to additional doses
  - ❖ Rapidly detect and respond on time to the occurrence of an AEFI
  - ❖ To detect vaccine lots associated with unusual numbers and types of reported events
  - ❖ Generate information with which to effectively communicate with parents, the community media and other stake holders, regarding the safety of vaccines used in Tanzania

- Vaccine recipients themselves and/ or parents of immunized infants/children, health care providers at immunization facilities and staff in immunization facilities are most likely to recognize or detect AEFIs when they first occur. Any AEFI case that is therefore notified to any health care provider working within the health care system, should be reported to the District Immunization and Vaccine Officer (DIVO) using the standard reporting form. The DIVO should in fact be informed of any Serious AEFI cases by telephone and this should be followed up by completion and submission of the reporting form.
- The reportable AEFI include serious AEFI, as a result of potential immunization errors, clusters, AEFI causing parental or community concern, those that are unexpected, and any that are known but occur with unexpected frequency, it needs to be stressed that health workers should report all cases that are notified to them.

Table 8A: Case definitions of the reportable adverse events.

AEFI	**Case definition**	**Vaccine**
Anaphylaxis	A clinical syndrome characterized by sudden onset (within one hour), rapid progression of signs and symptoms involving multiple (more than two) organ systems - Skin – urticaria (Hives), angioedema	All

AEFI	Case definition	Vaccine
	(swelling of face/body), Respiratory – persistent cough, wheeze, stridor, Cardiovascular – low blood pressure (hypotension) or reduced circulation (fast weak pulses), Gastrointestinal – vomiting, abdominal pain.	
BCG Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of Mycobacterium bovis BCG strain.	BCG
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain. Usually in immuno-compromised individuals.	BCG
Encephalopathy	Acute onset of major illness characterized by ▪ Depressed or altered level of consciousness and/or distinct change in behavior lasting for one day or more	Measles, Pertussis
Fever	The fever can be classified (based on rectal temperature) such as ▪ Mild fever: 100.4 ^{0}F to 102 ^{0}F (38 to 38.9oC), ▪ Moderate fever: 102 ^{0}F to 104.7^{0}F (39 to 40.4^{0}C) and ▪ Severe fever: 104.7^{0}F or higher (>40.5^{0}C).	All
Hypotonic, Hypo responsive Episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12] hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: ▪ limpness (hypotonic) ▪ reduced responsiveness (hypo responsive) ▪ pallor or cyanosis – or failure to observe/ recall	Mainly DPT, rarely others
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, positive bacterial culture), Sterile abscess if no evidence of bacterial infection on culture. Sterile abscesses are usually due to the inherent properties of the vaccine.	All injectable vaccines

AEFI	Case definition	Vaccine
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph nodes enlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	BCG
Persistent inconsolable screaming	Inconsolable and continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	DPT, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >100.4 ^{0}F or 38 ^{0}C (rectal) Afebrile seizures: if temperature is normal	All, especially Pertussis, Measles
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture.	All injectable vaccines
Severe local reaction	Redness and/or swelling centered at the site of injection and one or more of the following: ▪ Swelling beyond the nearest joint ▪ Pain, redness and swelling of more than 3 days and interfering with daily activities ▪ Requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.	All injectable vaccines
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization. Often leading to death within 24 to 48 hours.	All injectable vaccines
Vaccine Associated Paralytic Poliomyelitis (presenting as AFP)	Acute onset of flaccid paralysis and neurological deficits, compatible with diagnosis of poliomyelitis, with isolation of vaccine virus and absence of wild virus in stool.	OPV
Serious AEFI: Any AEFI causing		No time limit, if they are

AEFI	Case definition	Vaccine
	• Death • Hospitalization • Disability, congenital anomaly • Other severe and unusual events	thought by health workers or the public to be related to immunization

- All vaccination staff must be able to recognize AEFIs and report them. However, accurate diagnosis of AEFIs requires staff training and education. Health care providers also have the additional responsibility to manage AEFI and, if necessary, refer such patients for any required treatment.

Stakeholders in AEFI reporting and investigation;

In Tanzania, the subnational stakeholders in AEFI reporting and investigation are

1. Health workers
2. The District Immunization and Vaccine Officer (DIVO)
3. The Regional Immunization and Vaccine Officer (RIVO)

National stakeholders in AEFI investigation
In Tanzania, the national stakeholders are

1. Tanzania IVD and Tanzania Food and Drugs Authority (TFDA)
2. National AEFI committee

Field investigation of AEFI

The purpose of investigating AEFI cases are:

- To confirm the reported diagnosis and/or propose other possible diagnoses as well as clarify the outcome of the medical incident comprising the AEFI.
- To ascertain the particulars, circumstances and procedures around the vaccine used to immunize the affected recipient. Most importantly, identify any potential vaccine related link to the given AEFI.
- To examine the operational aspects of the programme. Even if an event seems to be vaccine product induced or coincidental.
- To determine whether a reported event was a single incident or one of a cluster and if it is a cluster, confirm that the suspected immunizations were indeed given and the individual vaccines that were used.
- To determine whether unimmunized people are experiencing the same medical incidents.

Role of the Subnational stakeholders

As outlined earlier in this chapter, the main role of the health worker is to provide primary medical care and report the basic details about the patient and the adverse event to the district by completing the AEFI reporting form (preceded if appropriate with a preliminary report by telephone if a serious event).

Role of stakeholders at the district and the regional level

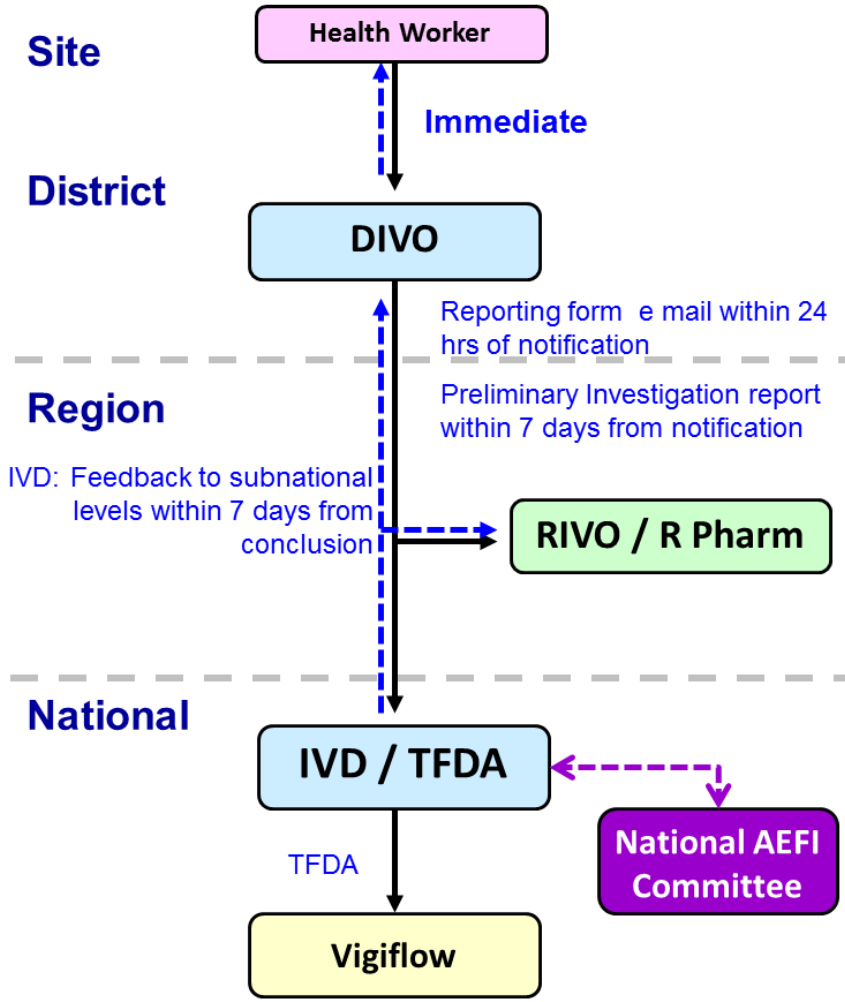
When and AEFI report is received by the DIVO, he should review the report and determine if the reported AEFI case meets the criteria required for a detailed investigation. If necessary he should contact the primary reporter and visit the locality of the event and interview relevant stakeholders for additional information. If the DIVO considers the case as

The specific activities conducted at this point will include the following

- Confirm the AEFI, assign a unique report identifying number, complete ALL details in the AEFI reporting form (in case any of them were missing when reporting) and initiate AEFI investigation.
- Convene a Council Health Management Teams (CHMT) planning meeting prior to the investigation.
- With the CHMT, the DIVO should visit as required the patient, the care provider(s) and the hospital; interview relevant stakeholders (parents, health worker, treating doctor, vaccine supply focal person); and conduct the investigation of the AEFI case.
- Complete the AEFI investigation form.
- Initiate collection of medical reports, a post-mortem report (if available), vaccine vials , logistic samples, and laboratory reports e.g. CSF, Serum (or other biological products).

Figure 8B Tanzania AEFI reporting

Tanzania AEFI Reporting – Routing, Timeline and Actions



Complete the report form

- On receipt of reporting form, to take a decision on detailed investigation and if "yes" discuss with the CHMT and plan investigation
- Initiate field investigation if there is capacity,
- Complete investigation form
- Initiate collection of Medical report, vaccine, logistic samples, Laboratory report eg CSF, Serum (or other biological products)

- Review sub regional situation to determine if there are similar problems in other districts
- If needed, plan and conduct field investigation
  - ✓ With the district team, investigate the AEFI case (ask IVD/ TFDA for help only if necessary)
  - ✓ Complete the investigation form
  - ✓ Initiate collection of Medical report, vaccine, logistic samples, Laboratory report eg CSF, Serum (or other biological products)

IVD/ TFDA: Support field investigation if needed & function as secretariat to National AEFI committee

IVD:
Immediately review reporting form and see if addl cases occurred in other places of the country

TFDA:
- With report form, create national linelist and national database
- Analyze the investigation form, consult with AEFI expert committee if needed.
- Upload data to Global database (Vigiflow)
- If needed
  - ✓ Inform UNICEF and MAH
  - ✓ Inform manufacturer and authorized importers

8.6. Action and response to AEFI

Responding to AEFI may involve immediate short-term activities or/and long-term follow-up activities. Follow-up activities should be based on findings of investigations, causality assessments and recommendations by the investigation/expert committees.

Proper and early treatment should be provided to patients regardless of the diagnosis. Case management and referral will vary depending on the seriousness. Mild symptoms such as mild fever and pain are likely to be of short duration and can be managed by assuring and educating parents during immunization. If parents return to seek medical attention, these cases should be documented and reported in the standard form. In case patients need hospitalization, a clear system for referral should be in place.

Table 8B; Actions to be taken upon completion of the investigation/causality assessment

Type of AEFI	Follow-up action
Vaccine-related reaction	If there is a higher reaction rate than expected from a specific vaccine or lot, obtain information from the manufacturer and consult with the WHO regional office to consider: ▪ withdrawing that lot; ▪ investigating with the manufacturer; ▪ Obtaining vaccine from a different manufacturer.
Immunization error related	Correct the cause of the error. This may mean one or more of the following: ▪ changing logistics for supplying the vaccine; ▪ changing procedures at the health facility; ▪ training of health workers; ▪ Intensifying supervision. Whatever action is taken, it is important to review at a later date to check that the immunization error related events have been corrected.
Coincidental	The main objective is to present the evidence showing that there is no indication that the AEFI is a vaccine-related reaction or immunization-related error and, that the most likely explanation is a temporal association between the event and vaccine/vaccination. This communication can be challenging when there is widespread belief that the event was caused by immunization. Sometimes, it may be useful to enlist further expert investigation to ensure that the event was truly coincidental. The potential for coincidental events to harm the immunization programme through false attribution is immense.

CHAPTER 9: SURVEILLANCE OF VACCINE PREVENTABLE DISEASES

9.1. Principles of disease surveillance

9.1.1 What is disease surveillance and why we need it?

Disease surveillance is the systematic collection, analysis and dissemination of data on diseases of public health importance so that appropriate action can be taken to either prevent or stop further spread of disease. It guides disease control activities and measures the impact of immunization services.

9.1.2 Why is disease surveillance necessary?

- Disease surveillance is used to :
- Predict or detect disease outbreaks with a view to investigation and containment ;
- Identify high risk populations requiring Special Attention;
- Monitor Impact and progress towards diseases eradication and elimination and control; identify areas in which system performance is poor, so that corrective measures can be taken
- Determine the frequency and burden of disease in the community.
- Monitor program effectiveness by documenting short- and long-term effects of immunization on disease burden and epidemiology ;
- Identify circulating strains, including serotypes, Genotypes and Subtypes

Table 9A: The type of surveillance for a specific vaccine-preventable disease depends on the attributes of the disease and the objectives of the disease control program —control, elimination or eradication

Vaccine-preventable disease*	Disease Control Objective	Surveillance activity			
		Find all cases or chains of transmission	Monitor trends, predict and detect outbreaks and identify att risk	Provide evidence on disease burden, epidemiology of disease and impact of	Identify circulating strains

			populations	immunization	
Diphteria	Control		X		
Haemophilus influenzae type b	Control			X	X
Hepatitis B	Control		X	X	X
Measles	Elimination				
Neonatal tetanus	Elimination	X	X		
Pertussis	Control		X		
Pneumococcal disease	Control		X		
Poliomyelitis	Eradication	x			X
Rotavirus				X	
Congenital Rubella Syndrome	Elimination	X	X		
HPV	Control			X	

9.1.3 DEFINITIONS OF CONTROL, ELIMINATION AND ERADICATION

- Control: the reduction of disease incidence, prevalence, morbidity or mortality to an acceptable level through deliberate efforts.E.g diphtheria, pertussis

- Elimination: reduction to zero incidence of a specified disease in a defined geographical area through deliberate efforts. *Continued intervention measures are required E.g Measles and MNT*

- Eradication: the complete interruption of transmission and the extinction of the causative agent so that it no longer exists in the environment. *Intervention measures no longer needed. E.g Polio*

9.2. Types of disease surveillance and their purpose

9.2.1 PASSIVE SURVEILLANCE

Passive surveillance is regular notification and reporting of disease data by all institutions that see patients (or test specimens) and are part of a reporting network. These are hospitals, health centres, dispensaries, private facilities and laboratories. It is the commonest and cheapest surveillance method used to detect vaccine preventable diseases. The advantage is that it covers a very wide area (the whole country).

But depends on the cooperation of health providers, this has the limitation of not ensuring timeliness and completeness of reports.

Passive surveillance requires that every health facility to send a monthly (sometimes weekly) report of all cases of vaccine-preventable disease (and sometimes other diseases of interest) on a standard form (IDSR/IDWE). This includes zero reporting if there are no cases.

9.2.2 ACTIVE SURVEILLANCE

Designated active surveillance staff regularly visit health facilities in person to search for suspected cases among persons who might have attended the facility.

It involves physical review of medical records and registers, interviews with health workers and visits to relevant outpatient clinics and hospital wards.

When a case is found, the active surveillance staff investigate it, document clinical and epidemiological data, arrange to send appropriate laboratory specimens and report the information rapidly, according to IVD guidelines

This method is usually used for the diseases targeted for eradication or elimination in Tanzania (AFP, Measles), when every possible case must be found and investigated. It is also used for outbreak investigations.

Advantages of Active Surveillance

1. Help to improve timeliness and accuracy of case detection and reporting
2. Enables rapid case investigation including taking laboratory specimen
3. Enables timely action to be taken in response to the detected case

9.2.3 Active search

There are two types of Active search

1. The term ‘active search’ is used to describe searches for cases in the community.
2. There is also ‘retrospective record search’, which is used to search hospital and clinic records and is used for diseases under elimination or eradication.

This is a very resource-intensive way of finding cases, requiring many people and large amounts of money, and is used only in certain situations, e.g. during outbreaks to locate unreported cases and during polio immunisation campaigns to find cases of acute flaccid paralysis.

9.2.4 SENTINEAL SURVEILLANCE

- **Sentinel Surveillance**: Collection and analysis of data by designated institutions selected for their geographic location, medical specialty and ability to accurately diagnose and report high quality data.
- A sentinel surveillance system is used when high-quality data are needed about a particular disease that cannot be obtained through a passive system.
- Selected reporting units, with a high probability of seeing cases of the disease in question, good laboratory facilities and experienced well-qualified staff, identify and notify on certain diseases.
- A sentinel system deliberately involves only a limited network of carefully selected reporting sites. For example, a network of large hospitals might be used to collect high-quality data on various diseases and their causative organisms, such as invasive bacterial disease caused by *Haemophilus influenzae* type b, meningococcus or pneumococcus.

Use of Sentinel Surveillance

- Data collected in a well-designed sentinel system can be used to signal trends,
- identify outbreaks
- Monitor the burden of disease in a community,
- Providing a rapid, economical alternative to other surveillance methods.

Because sentinel surveillance is conducted only in selected locations it may not be as effective for detecting rare diseases or diseases that occur outside the catchment areas of the sentinel sites.

Table 9B: Type of surveillance

	Type of		
	Nationwide routine/passive surveillance	Sentinel surveillance	Active surveillance
Population under Surveillance	Whole country	Cases seen and treated at selected health	All cases attending selected health facilities

Outcome measures	Cases and deaths Incidence rates Trends in epidemiology	Cases and deaths in selected health facilities	Cases and deaths in selected health facility Full case investigation with details on each case
Advantages	Can provide accurate rates and data on burden if reporting is complete and supported by reliable laboratory Results	Requires limited resources Can be managed easily Can contribute to basic understanding of disease burden	Can represent the whole country Directs eradication or elimination programmes Can be expanded to include additional diseases as required Rapid detection of outbreaks
Disadvantages	Needs extensive clinical and laboratory capacity and resources Reporting is rarely complete and timely Heavy demands on data management	Cannot be used to calculate incidence rates Is not representative of the whole country	Resource-intensive Requires dedicated staff, transport, management Heavy demands on data management

9.2.5 Case-based surveillance

Case-based surveillance data provide details of individual cases of vaccine preventable diseases. Case-based surveillance requires the use of a standard case definition and a case investigation form to record information, such as the patient's name, age, immunization status, date of last immunization against the suspected disease, address, date of disease onset, suspected diagnosis and laboratory results (when available).

Case-based data are often used for diseases that require urgent public health action or are subject to accelerated disease control goals (e.g. polio, measles, and neonatal tetanus) or during suspected outbreaks of epidemic-prone diseases, such as measles or cholera

9.3. Implementing surveillance.

9.3.1. CORE FUNCTIONS OF SURVEILLANCE

There are steps that you need to follow for an effective surveillance

- **Step 1** - Identify cases and events (e.g. deaths). Using standard case definitions, identify priority diseases, conditions and events.
- **Step 2** – Report or notify to the next level all suspected cases or conditions or events. If this is an epidemic-prone disease or a potential Public Health Emergency of International Concern (PHEIC), or a disease targeted for elimination or eradication, respond immediately by investigating the case or event and submit a detailed report.
- **Step 3** - Investigate and confirm suspected cases, outbreaks or events. Take action to ensure that the case, outbreak or event is confirmed, including laboratory confirmation wherever it is feasible. Gather evidence about what may have caused the outbreak or event and use it to select appropriate control and prevention strategies.
- **Step 4** - Analyse and interpret findings. Compile the data, and analyse it for trends. Compare information with previous periods and summarize the results.
- **Step 5** – Respond Coordinate and mobilize resources and personnel to implement the appropriate public health response.
- **Step 6** - Provide feedback. Encourage future cooperation by communicating with levels that provided data, reported outbreaks, cases and events about the investigation outcome and success of response efforts.

9.3.2. ENSURING AND MANAGING A SURVEILLANCE SYSTEM IN REGIONS AND DISTRICTS

9.3.2.1. Implementing a Passive surveillance

Know all your health institutes, hospitals, Facilities and Laboratories in your Region and district

Identify the following

- Passive surveillance sites(All)
- Sentinel sites as discussed with the National people
- Active search give priority as directed by the National level

The Region will appoint a surveillance designated Officer for the Region and district.
The designated surveillance Officers should visit the various surveillance sites and persons to brief about case definition, frequency of reporting, reporting format, deadlines for each report and the address to which the report should be sent. They should be instructed to send a periodic report even if no cases are seen during the reporting period.

When no cases are seen, 'zero reporting' is used, with a '0' in the report.
This is important to ensure the completeness of reporting for monitoring the quality of the surveillance system and gives regional and national authorities confidence that the surveillance system is operational, even if no disease is identified. A simple table should be maintained to track the completeness of reporting, such as in the example given below (in August of that year).

Table 9C; To track the completeness of reporting - 2015

Reporting	Jan	Feb	Mar	Apr	Ma	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Hospital 'A'	3	3	3	3	3	3	3					
Health centre 'B'	3	3		3			3					
Practitioner 'X'	3		3		3	3						

See the example above. Follow up is needed with Health centre B and Practioner "x" on why they did not report in March, May, June, February and April respectively. What was the problem??

A similar table with dates (shown below) should be maintained to track whether the reports came in within the agreed time limit, thus monitoring the **timeliness** of reporting.
A time limit should has been set in Tanzania for reporting time from one level to another. From the health facility to the districts reports should be at the district by the 5th of the preceding month. From the districts to the regions it should 15th of the preceding month. From the nation to the national level it should be ------
After the above mentioned dates reports will be considered to have been reported late.

Table 9D: Table to track timeliness of reporting

Reporting unit	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Hospital 'A'	02 Feb	03 Mar	06 Apr	07 May	04 Jun	07 Jul	09 Aug					
Health centre 'B'	15 Feb	08 Aug		08 Aug			08 Aug					
Practitioner	05 Feb		05 Mar		10 Aug	10 Aug						

In this example, health center 'B' sent the reports for February, April and July in August, and practitioner 'X' sent the reports for May and June in August. Such grossly delayed reports, although received, have very little usefulness.

9.3.2.2. Implementing an Active surveillance system

The following steps are involved in an active surveillance system.

9.3.2.2.1. Identify Surveillance Officers

1 Senior Management at Region and district level will manage the active surveillance, train staff at district and health facility level and supervise them.
2 Together with the National surveillance Officer the designated regional surveillance officer will select the reporting sites.
3 Surveillance officers are the focal points responsible for visiting designated active surveillance sites in the network, conducting core investigations and making follow-up visits.

9.3.2.3. Seek the Cooperation health facilities

1. The choice of active surveillance reporting sites depends on several factors, including the disease under surveillance and the behavior of the community towards illness (Where do they go??). The selection should be made in consultation with persons at the senior management level, and they may include hospitals, clinics, private practitioners and traditional healers.
2. The surveillance focal person will make an introductory meeting at which the hospital staff, clinicians and health workers are provided with information, such as booklets or posters, to improve their knowledge about the disease and to explain the rationale for conducting active surveillance. At the meeting, the standard case definitions should be introduced, and it should be emphasized that all cases that fit the case definition must be reported, even if the diagnosis is uncertain. Clinicians must be assured that the results of laboratory investigations will be sent to them as soon as they are available.
3. One staff member in each facility should be identified who will be the focal point for that institution, responsible for assisting in active case detection and reporting.

9.3.2.4. Frequency of visits to selected sites

1 The surveillance officer will conduct regular surveillance visits to the reporting site

2 The frequency of visits to any particular site is determined by the likelihood of suspected cases being admitted, so that timely epidemiological investigations can take place. If the likelihood of a suspected case being seen at the institution is high, the surveillance officer should make weekly visits; if the likelihood is medium, the visits can be monthly, and if the likelihood is low, the visits can be quarterly.

9.4. Disease specific case based surveillance

9.4.1 AFP Surveillance

9.4.1.1 Definitions

AFP case definition (What are we looking for?):

Acute Flaccid Paralysis (AFP) is defined as any child under 15 years of age with acute (sudden onset), flaccid paralysis (weakness of the limb – arm, leg or both), or any person of any age when paralytic illness if polio is suspected by a clinician

REMEMBER: WE ARE NOT LOOKING FOR POLIO, BUT ACUTE FLACCID PARALYSIS, A SYNDROME!

Answer Three (3) Questions:

1. Is the case less than 15 years old? If older, does a clinician suspect polio?

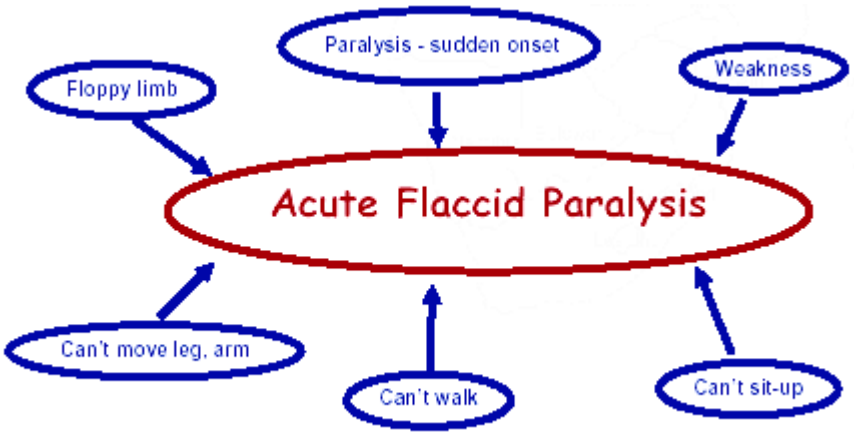
2. Does (s) he have Paralysis/weakness (of the limb – arm, leg or both)?

3. Is the Paralysis/weakness sudden (appeared within the last week) and Flaccid (Weakness or Floppiness)?

YES to ALL Three = should be investigated as an AFP CASE *

* In case of doubt, REPORT the case to your supervisor

Figure 9A: SYMPTOMS OF ACUTE FLACCID PARALYSIS



9.4.1.2. Types of AFP surveillance

1. **Active Surveillance**: This is the most important strategy for AFP surveillance.
    - **The Regional or district surveillance Officer will make regular visits to health** care facilities (clinics, hospitals, rehabilitation centers, traditional healers premises.)
    - **T**o search for and investigate unreported AFP cases through a review of health facility records, interviews with health workers and/or visit to wards to review cases.
    - Surveillance sites should be prioritized according to their probability of seeing AFP cases i.e. those sites, which have a higher probability of seeing an AFP case, should be visited more regularly.
    - Every surveillance officer should have a list of surveillance sites and a schedule of how these sites are visited. Each surveillance visit should be documented. Monitoring of active surveillance visits is a certification requirement
    - **The sites according to priority**
        - **HIGH Priority**

          A Surveillance site and community contacts (informant, focal person, resource person), where an AFP case would **MOST LIKELY** seek care. This can be any surveillance site, including traditional healers, **reputed/famous** for the treatment of paralysis. **MUST** be visited **ONCE A WEEK**.

            - **MEDIUM Priority**

              A Surveillance site and community contacts where an AFP case would **LIKELY** seek care. This can be any health institution where patients with paralysis would go, even if the institution is not famous for treating paralysis. Surveillance sites classified as medium priority MUST be visited at least **ONCE EVERY TWO WEEKS**.

            - **LOW:**

              All the rest of Surveillance sites and community contacts in the area. These are all this institutions that were not classified (high or medium Priority). Surveillance sites classified as low priority **MUST** be visited at least **ONCE A MONTH**.

Conducting a Visit to Health Facilities:

- Meet with your focal person at the health facility.
- Ask if any cases with AFP have been identified at the facility since the last visit.
- Look at the registry books (admission, outpatients) for any of these diagnoses listed below which can be associated with AFP (record review).
- Ask for the **medical records** (if records are kept) for any person who has one of the above diagnoses listed with their name in the registry books.

- Look at the medical records of any of these cases with medical person based in the health facility (nurse, medical assistant, Community Health Worker, Doctor, other); are they cases of AFP?
- If cases are identified in the records but are no longer there get contact information and try to find them in the community.
- Discuss **Case definition of AFP and procedures** with staff of facility at **each visit**.
- Record on active case search monitoring tool (visitors' book, register) where and with whom you visited; and have your focal person sign off on reporting form.

***Important:** Look out for these clues in your search for AFP cases in the registry book (record review), Paralysis, paresis (weakness), flaccid (floppy) paralysis (in combination with any other words). Weakness (of limb, of unclear origin, etc.), **"**Frequent falls", "gait disturbance", "cannot walk", "cannot stand", etc.

2. **Passive Surveillance**:
    - All health facilities are expected to send a report to the district level at the end of each month, including "zero reporting".
    - The district also submits routine surveillance reports monthly to the regional level and regions also submit these reports to the national level.
    - Routine surveillance reports at all levels should be regularly reviewed to detect any AFP cases that may have been missed by the active surveillance system;
    - The monitoring of completeness and timeliness of routine reporting by district is a certification requirement.

3. **Surveillance by community focal points**:
    - Community focal persons, who are likely to know about the occurrence of AFP in the community are regularly sensitized to recognize an AFP case and report such cases to the surveillance officers.
    - Community focal persons include CHWs, traditional birth attendant, chief, traditional healer, drug-shop attendants…etc.
    - Surveillance officers usually visit their community focal points, but at less frequency than the active surveillance sites e.g. once monthly or once every 2 months.

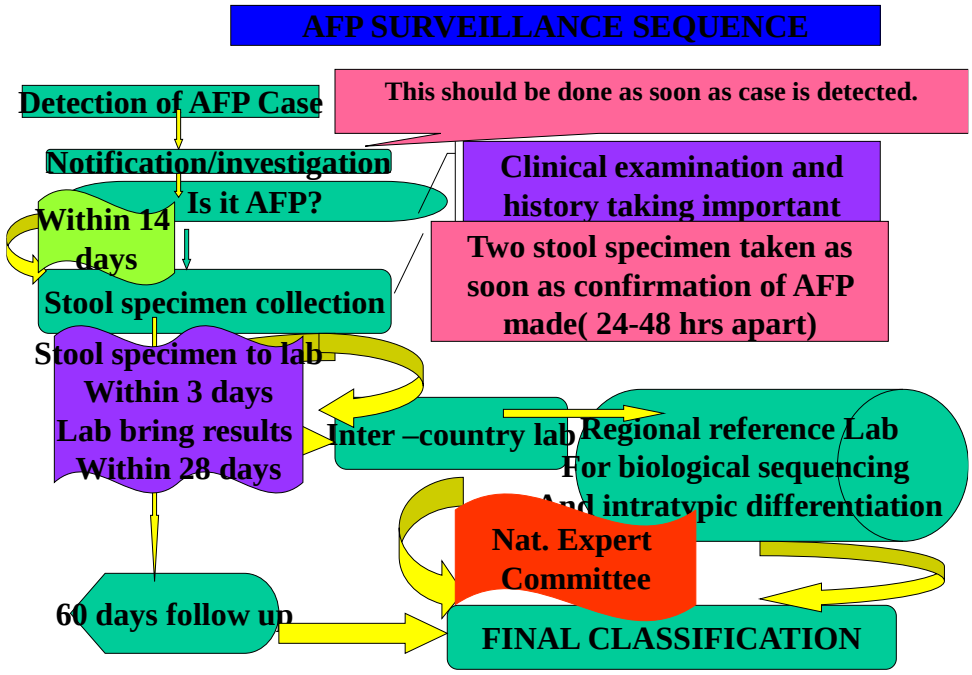
    - Make sure you are visiting contacts in all parts of your District.
    - At each visit take time to teach people the basic facts about polio, AFP and the importance of immunization.
    - Ask if your contact has heard about any cases of AFP.
    - If you are told about any cases of AFP **immediately investigate**!
    - Record on the Reporting Form where and with whom you visited. Have your contact sign on the Reporting Form.

9.4.1.3 Major steps of AFP surveillance

The AFP surveillance includes the following major steps
(Case detection using the Standard AFP Case Definition)

1. IMMEDIATE AFP Case Notification/reporting
2. Prompt Case Investigation, within 48 hours of notification
3. Collection of TWO-stool specimen, 24 to 48 hours apart in the first 14 days following the onset of paralysis
4. Maintaining reverse cold chain with appropriate stool storage in the dedicated carries
5. Immediate transport of the samples to the national laboratory of reference for eventual poliovirus isolation
6. Obtaining laboratory results and providing feedback to the program, family & community
7. Conducting 60 day Follow up
8. Obtaining Final classification by the NPEC
9. Providing epidemiologic situation report and sharing information

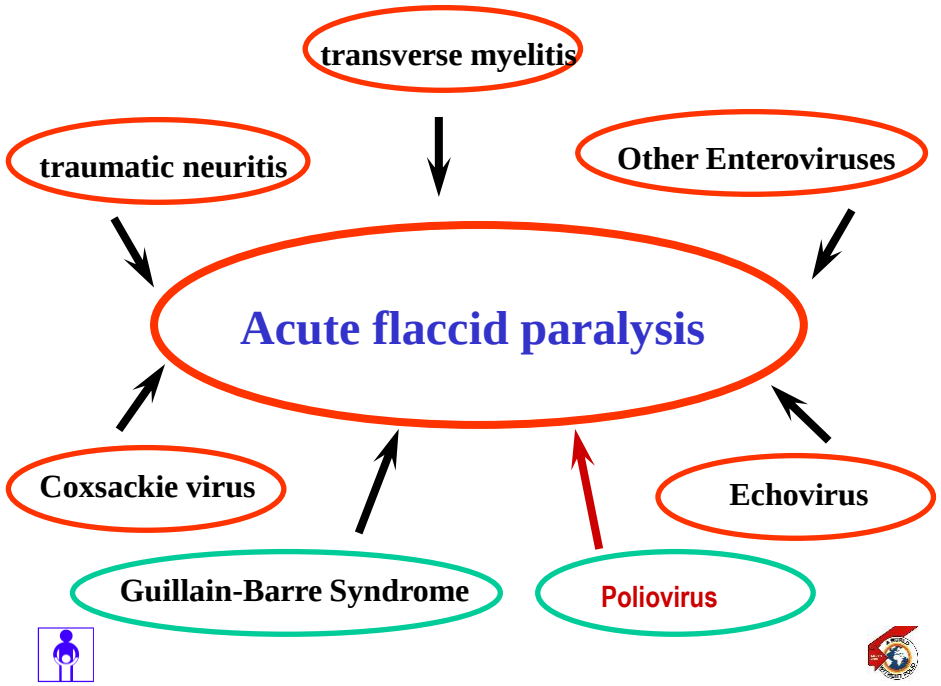
Figure 9C: Steps of AFP surveillance



9.4.1.4. Case Detection

Using the case definition, AFP cases may be detected during day-to-day clinical exercise, during active cases search, retrospective reviews and voluntary reporting from the community. Supervision or any visit to the health institution is an opportunity to inquire about AFP cases not yet reported.

Figure 9D: POLIO DIFFERENTIAL



DIAGNOSIS

9.4.1.5. DIAGNOSES: (ALWAYS PRESENT WITH AFP)

- **Poliomyelitis**, rule out polio, suspect polio (polio causes rapidly progressing floppy paralysis of usually ONE leg or ONE arm)
- **Guillain-Barré Syndrome** (illness causing slowly progressing floppy paralysis for **BOTH** legs)
- **Transverse myelitis** (rare illness causing floppy paralysis of **BOTH** legs)
- **Traumatic neuritis** (usually due to an incorrect intramuscular injection)

DIAGNOSES: **(SOMETIMES PRESENT WITH AFP)**

- (Muscle) **Hypotonia** (hypotonia means loss of muscle tone due to some other cause)
- **Hypokalemic paralysis** (weakness due to low potassium in the blood; this often happens during diarrhea, and is quickly reversible)

- **POTT's** disease (this is TB affecting the vertebrae of the spine)
- **TB meningitis** (all other meningitis; meningitis is an infection of the spinal cord cover; encephalitis: an infection of the brain)
- **Osteomyelitis** (i.e., bone infection of arm or leg, child may not move limb because of pain)

9.4.1.6. Case Notification / Reporting

Each AFP case must be notified and investigated IMMEDIATELY, after detection. AFP Surveillance reports must be sent immediately, even if IDWE is reported weekly.

9.4.1.7. Case Investigation

The focal person should investigate cases of AFP in each health facility prioritized as active AFP surveillance sites. A clinician should examine all cases with inadequate stool specimen.

It is, essential that a trained health worker re-examine all reported AFP cases as a quality control measure to ensure that what is reported as AFP is truly AFP.

An AFP case investigation form is the tool used to collect the data on each case of AFP. The form enables the collection of personal data on the case that will allow for the case to be traced as well as data on the clinical presentation of the case, and risk factors for polio. All data fields must be filled during the initial investigation and 60 days follow-up.

"Hot" AFP Case: An AFP case likely to be paralytic polio, either on clinical grounds (polio or suspected polio based on history and clinical impression) and/or AFP case with direct contact to a confirmed case. Investigation, stool collection and laboratory processing of specimens should be prioritized for "hot" cases.

9.4.1.8 Specimen Collection and Transportation

9.4.1.8.1. Collection Kit: Supplies to be prepared are:

1. Carrier (Big "AFP" sign marked on dedicated carrier)

2. *Frozen* ice packs ("AFP" sign)

3. AFP Case Investigation Form
4. Water-resistant felt-tip pen (to complete form and label the container)

5. Container labels

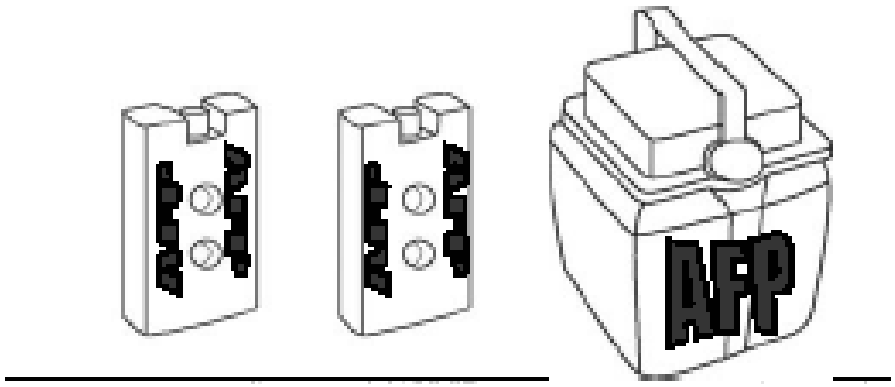
6. Leak-proof specimen container with a screw cap

7. Absorbent material (cotton wool)

8. Plastic bags

Remember to maintain ice packs *frozen* for immediate use.

Figure 9E: FROZEN ICEPACKS AND CARRIER



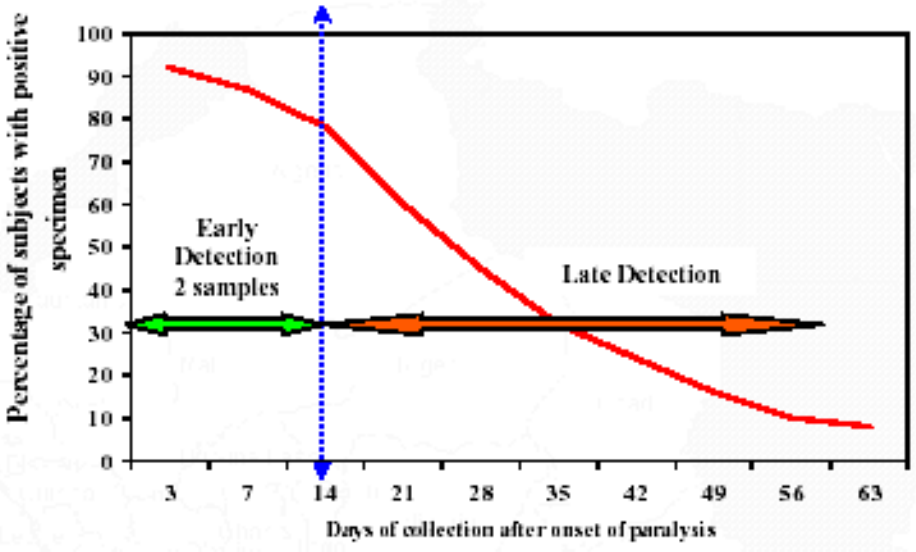
9.4.1.8.2 Rational for collection of stool specimen

Two stool specimens are required from each AFP case. The 1st stool specimen is collected on the 1st day of investigation, and the 2nd stool specimen is collected 24-48 hours after the 1st specimen. This is due to the intermittent excretion of the wild poliovirus, and the 2 stool specimens increase the chances of collecting at least one of the specimens during the peak period of viral excretion (Fig.3.5)

Why do we have to collect Stool Specimen within 14 days after onset of Paralysis?

Note: There is a dramatic fall of percentage of subjects with positive (virus recovered from the specimen) specimen on the 14th day after onset of paralysis. After 14 days from onset of paralysis (late detection) the detection rate of poliovirus becomes difficult. Furthermore, there is no need to collect stool samples once 60 days have passed since onset of paralysis.

Figure 9F: Percentage of paralyzed subject's excretion of the virus in the feces with time



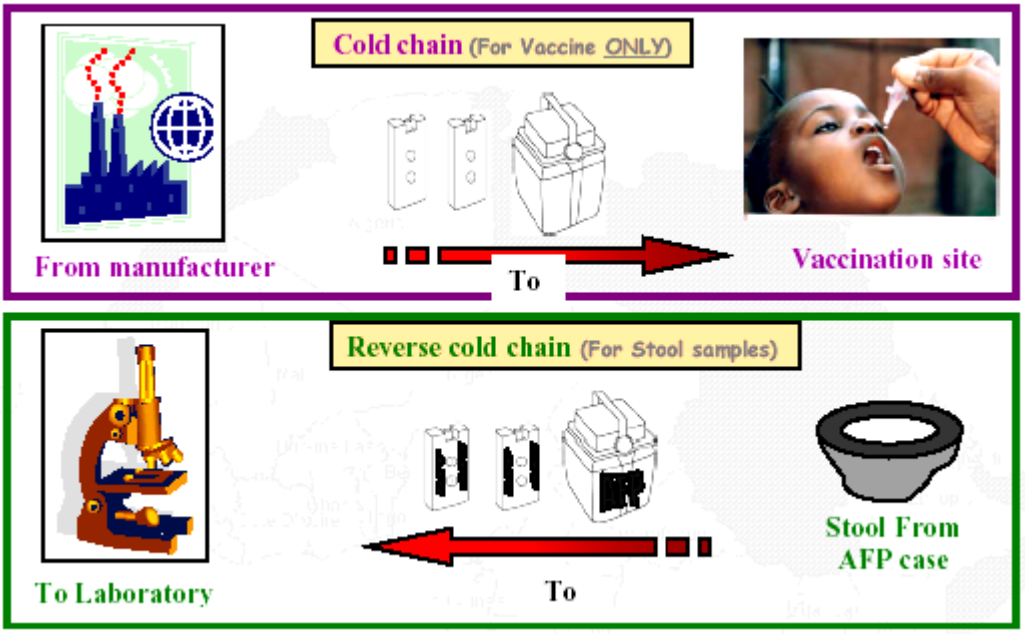
9.4.1.8.3 Stool Collection Procedures

1. Collect at least 1 adult "thumb sized" (8 g) amount of stool
2. Place in clean plastic container, such as wide mouthed plastic bottle with an external screw-on cap
3. Side of container should be labeled with name, identification number of the case, number of specimen (1or 2), and date of collection using a water-resistant pen
4. Place specimen container wrapped in cotton wool in sealed plastic bag
5. Store separately from vaccines and other clean items
6. Store in refrigerator or any container that can maintain temperature below 8°C until shipment has been arranged

9.4.1.8.4 Stool Storage and Transport

The stool specimens should immediately be kept at 4-8°C after collection. A dedicated vaccine carrier with 2 or 4 well frozen ice packs should be used. This is called "reverse cold chain", basically meaning the stool specimen is kept cold (4-8°C) from the collection, from the AFP case, to the Laboratory. If for any reasons stool cannot be transported to the national Lab, it should be stored at – 20°C. The ice packs should be changed just before transporting the specimens to the laboratory so as to maintain the temperature in the vaccine carrier.

Figure 9G: Cold chain and reverse cold chain



Vaccine carrier and ice packs dedicated to AFP must NEVER be used for transportation of vaccines and Stool Samples should ONLY be transported using an AFP DEDICATED vaccine carrier

9.4.1.9. Sixty-Day Follow up

Approximately 60 days, i.e. 8-9 weeks, following the onset of paralysis, all surviving patients must be re-examined for residual paralysis. The importance of this re-visit is even greater for cases with inadequate stool specimen, whose lab results are negative. The presence of residual paralysis at this time is further evidence that the cause of paralysis is most likely poliovirus.

It is preferable that the re-examination be conducted by the same person who conducted the first investigation of the cases (filled out the case investigation form)

To conduct the follow up examination, the investigator must:

- Use the 60-day follow up exam complementary form (Annex…)

- Verify with the parent that the information on the case investigation form is correct

- Ask the parent if the paralysis has changed

- Observe how the child moves limbs or areas of the body that were paralyzed (look for areas of muscle atrophy and, if possible, watch the child walk)

- Verify whether the paralysis is flaccid (i.e. floppy)

- Verify that sensation is normal

- Fill in all the parts of the 60-day follow up exam complementary form

- Send the form to EPI, according to established local procedures.

The following situation can be expected, during the 60-day follow up visit:

1. Weakness or residual paralysis: 60 days after date of onset, paralysis persists (no improvement or slight improvement)
2. No residual paralysis: 60 days after date of onset, paralysis has receded, the limb recovers all functions
3. Lost follow up: case missing for whatever reason
4. Cases deceased.

9.4.1.10 AFP Case Classification

National Polio Expert Committee (NPEC)

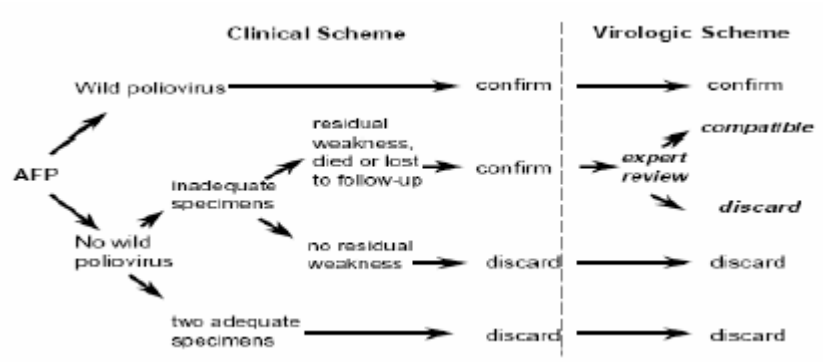
The NPEC is a group of independent technicians working closely with the EPI team at country level. The NPEC is comprised of leading scientists/senior physicians/academics, independent of polio initiative and EPI. Their role include determining the final classification of all AFP cases and assessing, verifying (field visit if deemed necessary) the certification documentation prepared by national staff. 3 or 5 members are required in the NPEC supported by 2 or 3 persons for the secretariat (including WHO, Lab and EPI personnel).

In Tanzania, the National Polio Expert Committee that conducts the final classification, of AFP case, by meeting regularly to review the AFP cases. Within ninety days (twelve weeks) of onset of paralysis, all suspected cases are classified as **confirmed polio**, **polio-compatible** or **discarded** (i.e. non-polio) by the NPEC.

Given that the lab has isolated cases in which wild poliovirus are automatically confirmed (straight forward) cases, only cases with inadequate specimen are reviewed by the NPEC, usually. So, NPECs do not need to review/classify all AFP cases but should concentrate on detailed review of those AFP cases that are 'difficult to classify' because of limited available data (i.e. those with inadequate specimens and either no follow-up or with residual paralysis), with the goal to either discard them or classify them as 'polio-compatible'

Every case that is classified as polio-compatible should have an explanatory note, e.g. Inadequate specimens and no follow up or death child can be classified as compatible because of zero evidence versus Inadequate specimen and residual paralysis compatible with polio clinically.

Figure 9H: Flow chart of AFP case classification



9.4.2. MEASLES CASE BASED SURVEILLANCE

9.4.2.1 .Measles is a notifiable disease in our country; a suspected case of measles should be reported and investigated with a serological specimen at first contact within 28 days of the onset of rash.

In the accelerated control of measles towards elimination of measles the intensified surveillance helps to:

- ✓ Detect outbreaks early
- ✓ Identify high risk populations /areas
- ✓ Estimate how many people become sick or die from measles
- ✓ Monitor progress of measles control measures
- ✓ Determine impact of vaccination campaigns

In Tanzania measles surveillance is integrated with AFP surveillance. Use the same system (passive, active surveillance, case reporting, feedback, coordination, etc.), resources and structures.

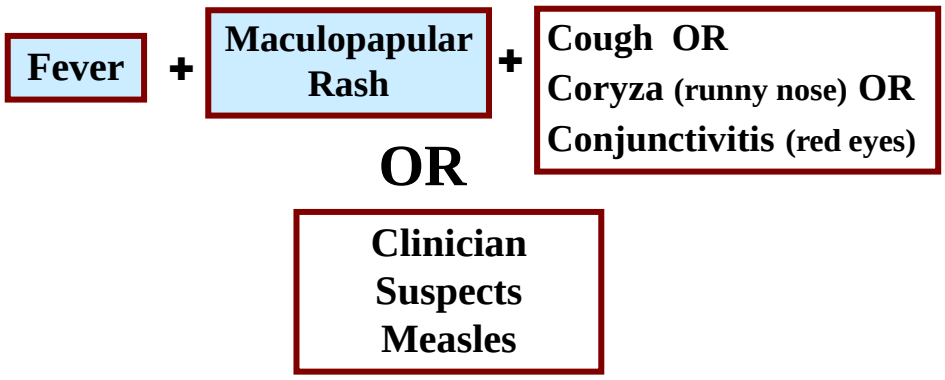
When you are collecting data for on patients with measles in active surveillance you will use the same procedure and activities as for AFP including identifying cases using a standard case definition, extraction of data from registers, and reporting.

Measles case definition:

- **A suspected case of measles**:
  - any person with maculo-papular rash and fever PLUS cough/ coryza/ conjunctivitis
  - Any person in whom a clinician suspects measles

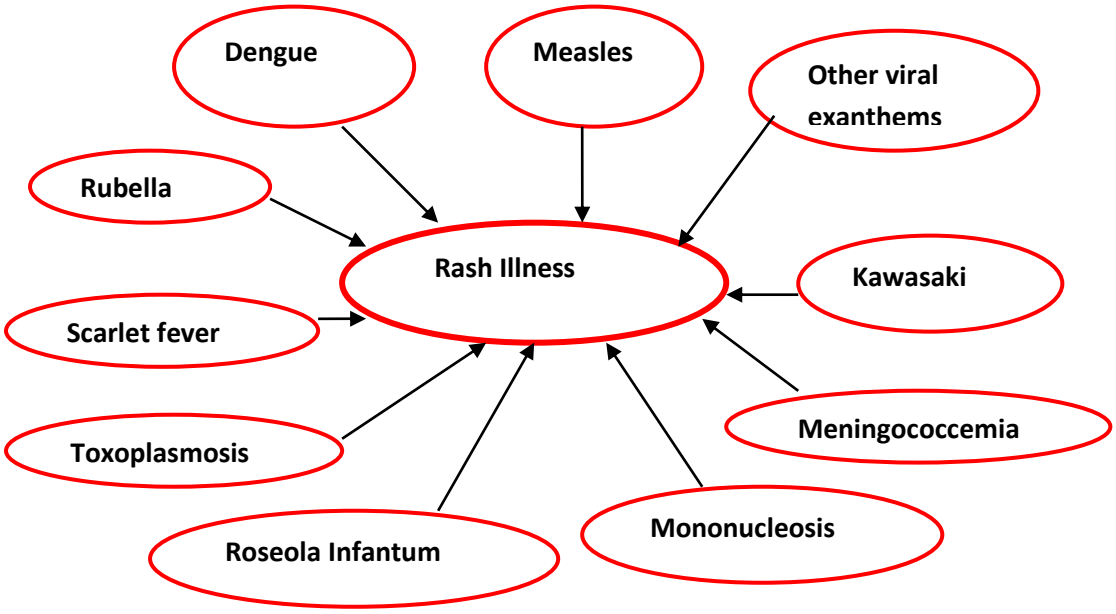
- **A measles death**: any death from an illness that occurs in a confirmed case of measles (lab or epi link) within one month of the onset of rash.

Standard Case Definition Suspected Measles



The case definition given has a high sensitivity for measles. However, suspected cases may not be “true measles cases” particularly in areas of low measles prevalence. For these reasons, it is very important to wait for serological confirmation (take blood specimen from suspected cases) .

Figure 9I: Other rash illnesses

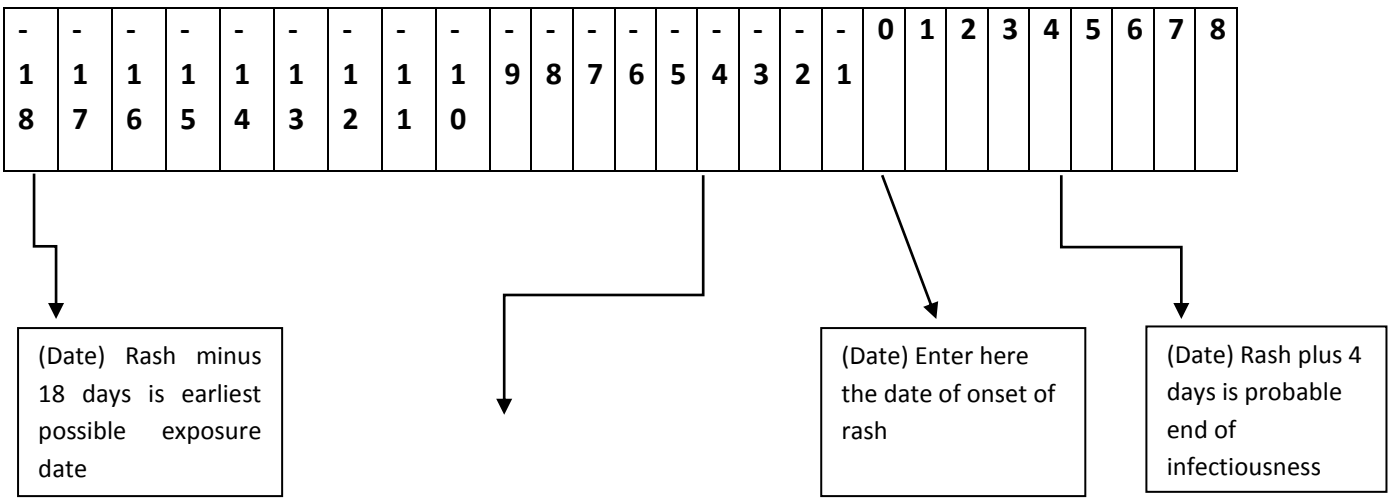


9.4.2.2 The Process of Measles Case Based Surveillance

Surveillance Focal persons should investigate all measles suspected cases on case by case basis and confirm all outbreaks by collecting blood specimens from the first five reported cases.

***Collection of nasopharyngeal swabs from 5 cases within 5 days of rash onset to isolate viruses and document viral strains during outbreaks, will be done with the assistance of the National level.**

Clinical course of measles and active case finding



(Date) Rash minus 4 days is probable start of infectiousness

The roles and responsibilities of health workers and authorities at different levels of the health care system are described below.

9.4.2.2.1 Health facility:

- Detect and report cases and outbreaks using the standard case definition
- Investigate suspected cases of measles, and manage cases appropriately
- Collect, consolidate, analyze and interpret surveillance data,
- Provide feedback to appropriate families and communities

9.4.2.2.2 District level:

- Ensure that blood specimens are collected for serological confirmation from all suspected
  Cases of measles and from the first five cases in outbreaks.

- Ensure that nasopharyngeal swabs are taken from five suspected measles cases during
  Outbreaks for purposes of determining the circulating viral strains with the assistance of
  Regional and national level.

- Conduct good quality measles outbreak investigation; includes prompt investigation once
  The outbreak threshold is reached, conducting active case finding in the community and line listing of all cases with essential variables like age, vaccination status and address.

- Analyze disease patterns and trends, interpret data, and produce routine reports,

- Feed data forward

- Feed back to health facilities and communities in time

9.4.2.2.3 Regional level:

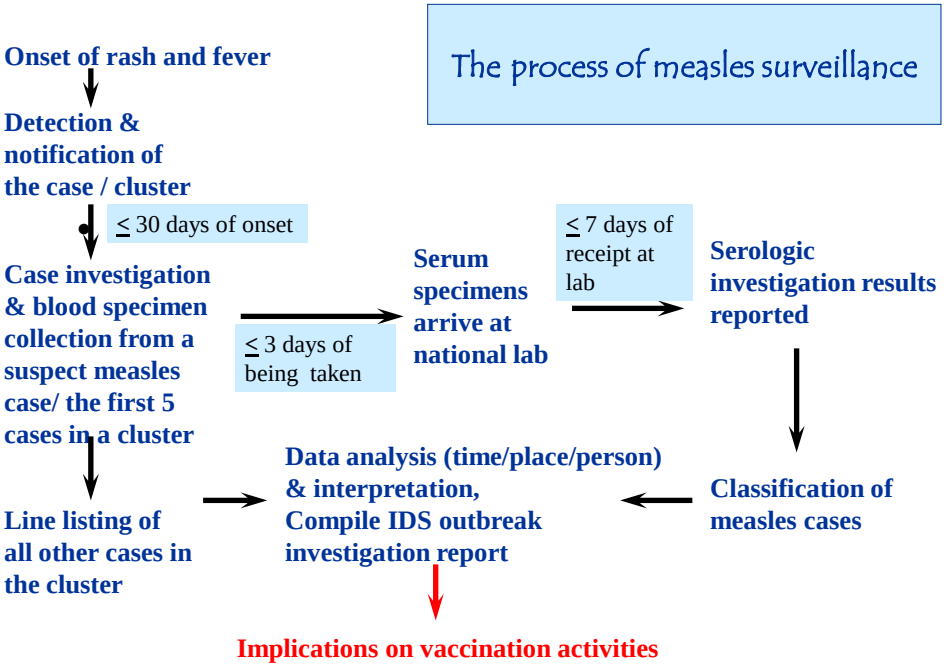
- Analyze disease patterns and trends, interpret surveillance data in conjunction with routine immunization coverage data, and produce routine reports

- Monitor the surveillance performance using standard indicators
- Feed data forward to the next level,
- Provide feedback (information) to district levels
- Supervise and provide technical support to district level activities

9.4.2.2.4 National level:

- Confirm cases and outbreaks using IgM serological testing (the National Measles laboratory), and organize possible shipment of specimens for viral isolation and genotyping.
- Analyze disease patterns and trends, interpret surveillance data in conjunction with the routine immunization coverage data, and produce routine reports
- Monitor the surveillance performance using standard indicators
- Provide feedback (information) to regional levels and feed data forward
- Supervise and provide technical support to district and regional level activities
- Use data to evaluate national objectives and to direct the control program
- Review technical and programmatic issues regularly

Figure J: Process of measles surveillance



9.4.2.3 Measles surveillance as part of the routine reporting of communicable diseases

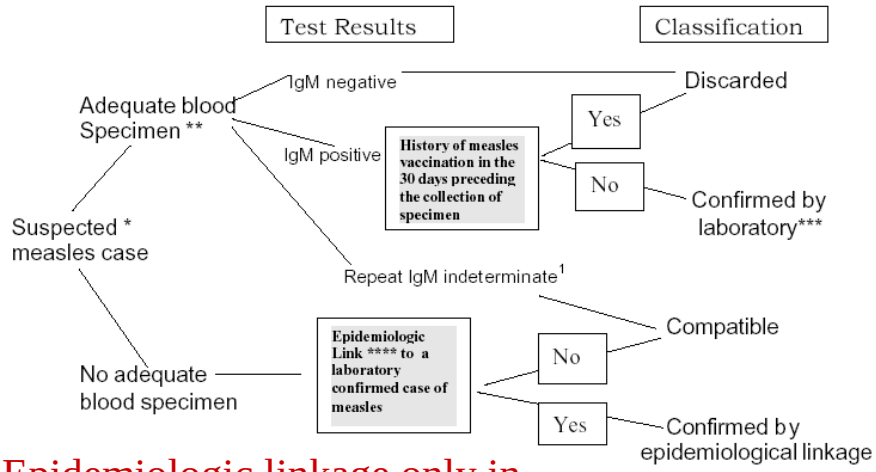
1. Routine weekly summary reporting of measles cases (as part of the infectious notifiable disease surveillance system)-IDWE is the first step of measles surveillance.
2. IDSR reporting on a monthly basis as passive reporting by health facilities and districts.
3. The routine weekly surveillance report form should be used for regular reporting of cases seen.
4. Health facilities should record all suspected measles cases in a register with place of residence, date of onset of rash, age, sex, vaccination status and outcome. This information should be compiled each month and sent to the district. If no cases were seen, zero cases should be reported. Timeliness and completeness is monitored
5. Harmonization of data is very important. The Surveillance Focal Person should work together with other reporting systems to ensure consistent of reports and data from the health facilities up to the National level.

9.4.2.4 Measles Surveillance- Case Based

Steps for investigating and reporting a suspected measles case at health facility/district level

1. The Health Facility worker will welcome the patient and get the history of the illness from the patient or caretaker.
2. The confirmation of suspected measles will be made. If in doubt get the help of your Supervisor.
3. Complete an individual case investigation form for each patient
4. Collect a specimen for serological confirmation of measles infection at the first contact with the case anytime between the days of onset of rash up to the 28th day of illness. Arrange for transport of the specimen to be sent to the EPI national level.
5. Ask the family if there are other persons with similar signs and symptoms at home or in the neighborhood. If any, ask family for new cases to be brought to the health care facility.
6. Update the suspected measles case line listing
7. Notify the district health team. This can done from the beginning when you first suspect the measles case.

WHO-AFRO measles case classification scheme



Epidemiologic linkage only in confirmed outbreaks!

9.4.2.5

Filling the form and specimen Collection

- **The form will be filled by the facility worker at all the areas needed to be filled.**
- **Procedure for collection, handling and transport of blood specimen for serological confirmation**

1. Collect 5 mls (infant 3 mls) blood by venipuncture into a sterile tube
2. Label the tube with patient identification and collection date.
3. To separate the serum from red cells, one of the following three methods described below can be employed. To prevent bacterial over-growth, ensure that the serum is poured into a clean glass test tube. The test tube does not to be sterile, just clean.

- Let the blood sit at an angle for at least 60 minutes (without shaking or being driven in a vehicle), then pour off the serum into a clean glass tube.

- If a refrigerator is available, put the sample in a refrigerator for 4 - 6 hours until the clot retracts, then pour off the serum the next morning.

- If a centrifuge is available, let the blood sit for 30-60 minutes, then centrifuge the specimen at 2000 RPM for 10 - 20 minutes and pour off the serum into a clean tube.

Do not freeze whole blood.

- Store serum at 4 - 8°C until it is ready for shipment.
- In case of problems serum can be stored in the refrigerator for a maximum of 7 days,
- Serum must be frozen at –20°C if it is going to be stored for longer periods.
- It is strongly recommended specimen delivery to the lab should be within three days of date of specimen collection.
- Freezing and thawing should be avoided.

Three dates are very important

- Date of rash onset
- Date of collection of sample.
- Date of last measles vaccination

Transporting the Blood specimen

- Place specimens in plastic bags.
- Specimens from different patients should never be sealed in the same bag.
- Place specimen form and investigation form in another plastic bag and tape to inner top of the specimen transport box.
- Just as for AFP stool specimen, blood for suspected measles cases is transported under the reverse cold chain. See above.
- Place ice packs at the bottom of the box and along the sides, place samples in the centre, then place more ice packs on top.
- When shipping arrangements are finalized, inform receiver of time and manner of transport.

9.4.2.6 Case Management

It is very important to manage measles suspected cases in your facility

- Vitamin A supplementation
    - Isolation of cases
    - Supportive treatment
    - Treatment of complications as needed

9.4.2.7. DEFINITIONS OF MEASALES CASES

- A suspected case of measles:
    - any person with maculo-papular rash and fever PLUS cough/ coryza/ conjunctivitis
    - Any person in whom a clinician suspects measles
- A measles death: any death from an illness that occurs in a confirmed case of measles (lab or epi link) within one month of the onset of rash.
- Lab confirmed: Suspected case of measles with positive serum IgM antibody, and not vaccinated in the preceding 4 weeks.

In confirmed measles outbreaks:

- Confirmed by epidemiologic linkage: A suspected case of measles not investigated serologically but has possibility of contact with a laboratory-confirmed case whose rash onset was within the preceding 30 days* (same / adjacent districts with plausible transmission)

    * corresponds to about two generations of infection with an average incubation period of 14 days

Compatible Measles (Clinical Measles): A suspected measles case that has not had a blood specimen taken for serologic confirmation (or has spoilt specimen) and is not linked epidemiologically to any lab confirmed case of measles.

- Suspected measles cases with measles IgM test results that are indeterminate twice may also be classified as compatible.
- Compatible measles cases Suggests “failure of the system” to investigate properly and adequately.

9.4.3. NEONATAL TETANUS SURVEILLANCE

9.4.3.1. Neonatal tetanus (NNT) is targeted in Tanzania for **elimination** as a major public health burden along with maternal tetanus.

Elimination for NNT is defined as less than one NNT case per 1000 live births at district level per year.

Why NNT surveillance?

- Effective surveillance is critical for identifying areas or populations at high risk for NNT
- Monitoring the impact of interventions.

9.4.3.2 Standard Case definition

Clinical case definition and case classification

Suspected case:

- Any neonatal death between 3 and 28 days of age in which the cause of death is unknown; **or**
- Any neonate reported as having suffered from neonatal tetanus between 3 and 28 days of age and not investigated

Confirmed case:

Any neonate with normal ability to suck and cry during the first 2 days of life **and**
- who, between 3 and 28 days of age, cannot suck normally **and**
- becomes stiff or has spasms (i.e. jerking of the muscles)

Note: The basis for case classification is entirely clinical and does not depend on laboratory confirmation. NT cases reported by physicians are considered to be confirmed. However, investigators should examine NT case records during annual hospital record reviews

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9.4.3.3 Surveillance of NNT

- **Passive routine monthly surveillance:** the number of confirmed NT cases should be included in all routine reports and should be reported separately from other (non-neonatal) tetanus
- **Zero reporting:** designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as "zero reporting")
- **Active surveillance:** The surveillance Focal person will as part of AFP and Measles case based surveillance visit major health facilities regularly (at least monthly) to identify any NNT case admitted or diagnosed in them.
- During these visits, hospital inpatient and outpatient registers should be checked and key clinical staff (e.g. in paediatric and emergency wards) should be asked whether any new NNT case or death has been identified in the hospital since the previous visit.
- If it is a death effort should be made to find the reason of the death and rule out signs and symptoms for NNT
- **Retrospective record review:** hospital records should be reviewed for NNT cases at least once annually in major hospitals to identify previously unreported NNT cases

- **Community sensitization:** in "silent areas" areas (i.e. where routine reporting is not functional but where other indicators suggest that neonatal tetanus could be a problem) the community should be sensitized about NNT and the need to bring suspect cases/deaths to the attention of the health authorities

- **Case investigation**
  suspected neonatal tetanus cases should be investigated *as soon as* reports are received from the health facility. Health facility staff should be part of case investigation and case response activities.
  Use a Standard Case Definition – See above
- Confirm the diagnosis of neonatal tetanus.
- Determine why the case occurred.
- Plan and take action to prevent cases in the future.
- Identify where to strengthen immunization activities.
- Take corrective action on the possible factor which contributed to occurrence of NNT

Community NNT Surveillance

- In remote areas and in areas where disease reporting is known to be unreliable or incomplete, gather disease information from key informants in the community.
- Sensitize communities
- Use Community informants

9.5. Principles of outbreak investigation

9.5.1. What is outbreak?

- Outbreaks occur when the accumulated number of susceptible individuals is greater than the critical number of susceptible individuals, or epidemic threshold, for a given population to sustain transmission.
- Outbreaks may occur in the area where there is low coverage, which are likely to occur in certain geographic areas, such as urban slums, squatter communities, remote rural areas, border communities, and in certain population groups with habitually low vaccination coverage rates such as nomadic peoples, marginalized population groups.

9.5.2. The steps for conducting an outbreak investigation

- The health facility surveillance focal person (health facility in charge) notifies the district team about the occurrence of clusters of cases using the quickest available means of communication
- The CHMT led by the DMO,DIVO and the surveillance Focal person prepare for field work (collect available data by province/district/ward also for bordering areas; job aids, data collection forms; drugs for case management; material for specimen collection, etc.)

- Verify the diagnosis –- The health facility surveillance focal person or Council Health Management Team (CHMT) completes case investigation forms and takes blood specimens from the first five suspected cases only. laboratory confirmation of cases when applicable

- Establish the existence of an epidemic – compare trends with the past, and describe clusters against the outbreak definitions
- The CHMT notifies all clinicians and surveillance coordinators in nearby areas of the outbreak and the need for intensified surveillance
- The CHMT conducts active case searches in health facilities and in surrounding villages to determine the extent of the outbreak. Do record reviews in case of missed cases.
- Continuously line-listing additional cases. The CHMT team creates a line-listing of all subsequent cases to record place of residence, date of onset of rash, age, sex, vaccination status, outcome and EPID number (to be assigned at National level).
- Monitor the outbreak (epidemic curve) overtime

  The CHMT team should then monitor the evolution of the outbreak by keeping track of the number of cases and dates of onset of rash of reported cases using an epidemic curve.

  The CHMT analyzes and interprets surveillance data (date of onset of rash, vaccination status, age, geographic location) in order to determine the extent of the outbreak and the reason: whether the outbreak was a result of failure to vaccinate or vaccine failure.
- Report writing using the IDSR framework

  The CHMT completes and sends to the regional and national level the district outbreak investigation report (within 2 weeks of the investigation) summarizing the findings, the
- response, evaluation and feedback processes
- Dissemination of findings
- Intensify surveillance and routine immunization activities

9. 5.3. Interpreting outbreak data

- Data analysis: by time, place and person, to describe the outbreak
- Identify persons affected by the outbreaks (location, age, vaccination status, etc.) to guide response activities

- Formulate and test hypothesis regarding the cause of the outbreak (e.g failure of vaccination or failure to vaccinate by routine immunization and/or SIAs)
- Risk analysis to prevent extension of outbreak to other areas

9.5.4. MEASLES OUTBREAKS

8.4.4.4.1 An outbreak of measles occurs when the number of cases observed is greater than the number normally expected in the same geographic area for a given period. The epidemic threshold of measles is low because of the high level of communicability of measles.

Suspected outbreak of measles is defined as the occurrence of 5 or more reported suspected cases of measles in a health facility or district in one month.

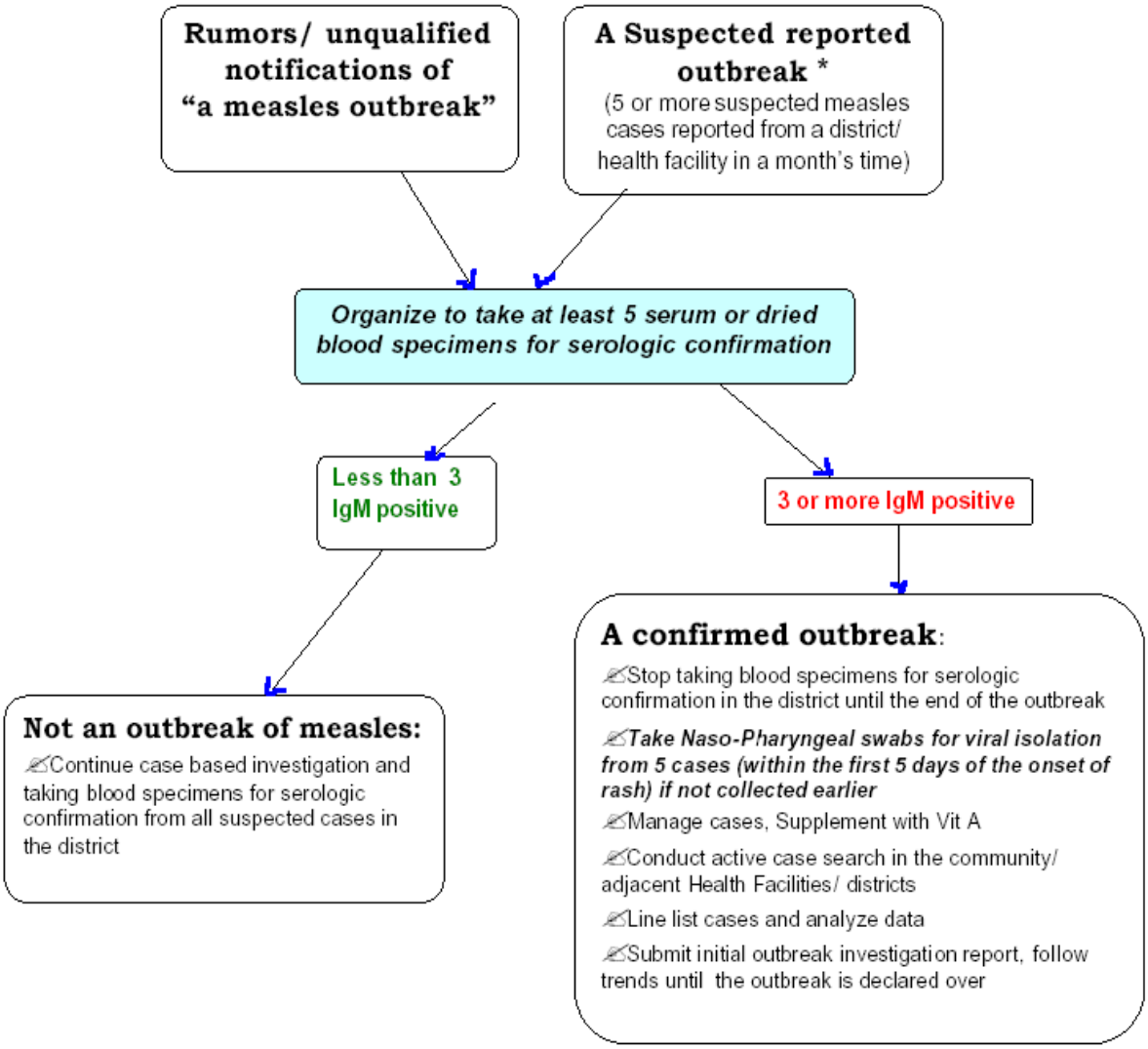
A confirmed outbreak of measles is defined as 3 or more measles IgM positive

(Laboratory confirmed) cases in a health facility or district in one month.

8.4.4.4.2 It is important to investigate and document suspected measles outbreaks for the following reasons:

- To assess the magnitude of the outbreak (severity of illness, potential for further spread
- To develop guidance on control measures needed (to prevent further spread and minimize disabilities and deaths).
- To prevent future outbreaks
- To respond to political pressure/ legal obligation, public concern.
- As a research opportunity to understand the epidemiological situation better

Figure 9K: Outbreak investigation flow chart


Rumors/ unqualified notifications of "a measles outbreak"
A Suspected reported outbreak *
(5 or more suspected measles cases reported from a district/ health facility in a month's time)
Organize to take at least 5 serum or dried blood specimens for serologic confirmation
Less than 3 IgM positive
3 or more IgM positive
Not an outbreak of measles:
Continue case based investigation and taking blood specimens for serologic confirmation from all suspected cases in the district
A confirmed outbreak:
Stop taking blood specimens for serologic confirmation in the district until the end of the outbreak
Take Naso-Pharyngeal swabs for viral isolation from 5 cases (within the first 5 days of the onset of rash) if not collected earlier
Manage cases, Supplement with Vit A
Conduct active case search in the community/ adjacent Health Facilities/ districts
Line list cases and analyze data
Submit initial outbreak investigation report, follow trends until the outbreak is declared over

CHAPTER 10: SUPPORTIVE SUPERVISION

10.1. Definition:

Supportive supervision is "a process that promotes quality at all levels of the health system by strengthening relationships within the system, focusing on the identification and resolution of problems, and helping to optimize the allocation of resources—promoting high standards, teamwork, and better two-way communication". It is carried out in a respectful and non-authoritarian way with a focus on using supervisory visits as an opportunity to improve knowledge and skills of health staff.

A cornerstone of supportive supervision is working with health staff to establish goals, monitor performance, identify and correct problems, and proactively improve the quality of service.
Together, the supervisor and health workers (Supervisees) identify and address weaknesses on the spot, thus preventing poor practices from becoming routine. Supervisory visits are also an opportunity to recognize good practices and help health workers to maintain their high-level of performance.

The important factors in this definition are as follows:

1. Supervision is a ***"process"***. It is not a one-time event, but is a connected series of events over a period of time.
2. Supervision involves ***"guiding, helping and encouraging staff"***. This recognizes that the only way to improve staff performance over the long term is to promote in them the wish to perform well and to give them guidance to perform well.
3. Supervision helps staff to ***"meet the defined standards of their organization"***.
    a. Service delivery standards, such as the IVD guidelines or management standards, define how and when work should be done.

Supportive supervision is aiming at making things work, rather than checking to see what is wrong

10.2 Supportive supervision approaches:

- Focus on improving performance and building relationships.
- More like a teacher, coach, mentor.
- Use local data to monitor performance and solve problems.
- Follow up regularly
- Only support provided

10.3 Types of Supervision

Generally, supportive supervision takes one of three forms: integrated supportive supervision, technical supervision, and emergency technical supportive supervision.

10.3.1 Integrated Supportive Supervision

Integrated supportive supervision is the periodic assessment of *all* the activities for which a particular facility is responsible. Whilst not all activities can be supervised at one time, every activity should have been supervised
Integrated supportive supervision is most effectively carried out by multi-disciplinary teams which have expertise in clinical practice, public health, administration and finance.
Integrated supportive supervision allows for the sharing of scarce resources (e.g. vehicles) to support a wide range of activities. It also enables the different supervisors to develop a broad understanding of all the different programs and to be able to offer integrated guidance.
During an integrated supportive supervision visit, problems may be found that cannot be dealt with during the current visit. This may be due to inadequate time, lack of the necessary expertise or lack of the necessary equipment or tools required to deal with the problem. In such cases, the supervision team will need to report back to their management committee and seek the necessary experts or materials to return to the facility to provide technical support.

10.3.2 Technical Supervision

Specific programs may require program-specific supervision. For example, the communicable disease control officer at a district Health Office may be required to conduct supervision of the health facilities in the council to follow up on IVD activities specifically. In other instances, as described above, a need for program-specific technical support may be identified during an integrated supportive supervision visit to a facility. In these cases, one or more program specialists in question can be sent to supervise program implementation and to offer expert guidance. Program-specific supervision may also be provided in response to a request from the facility itself.
Program-specific technical supervision can provide needed specialist support, however its use should be carefully controlled since there is the danger that supervision will revert to parallel, non-integrated efforts which lead to duplication of efforts and waste of scarce resources.

10.3.3 Emergency Technical Support

Supervisors may be required to provide support in the case of emergencies such as an outbreak or disaster.

10.4 Key Elements of Effective Supervision

For a supervision system to be effective, there are a number of elements that need to be present:

- Management Commitment: Managers must be committed to supervision. If managers do not demonstrate their belief in the value of supervision and fail to ensure that supervision is carried out as intended, staff will recognize this and will not take supervision seriously.

- Standards of Performance: There must be documented and well-known standards of expected performance, since standards are a baseline against which actual performance is measured and compared.

- Planning for Supervision: Advance planning before supervision allows proper preparation and ensures that all key individuals are present and well-informed.

- Preparation for Supervision: Careful preparation needs to be carried out by both supervisors and supervisees before supervision takes place.

- Stakeholder Involvement: Supervision should involve preferably many of the key staff of the facility or office being supervised. These staff members should optimally be in the same room to ensure wide involvement, good understanding of the issues being discussed and commitment to the results.
- Supervisory Tools: Use of a supervisory tool such as a checklist helps to ensure that all key areas are covered. It also provides a record of the findings for all participants.

- Documentation of Supervisory Findings: The results of the supervision and the agreements reached on next steps should be documented. This allows for review of progress at a later date.

- Preparation of an Action Plan: A key part of supervision is the agreement of the supervisors and supervisees to a follow-up action plan which lays out how the issues identified during the supervision are to be addressed by both parties.

- Sharing of Supervision Findings: The results of the supervision should be shared with key officers from the supervisor's office and from the supervised site. This ensures that all staff are aware of results, including actions to be taken.

- Self-assessment: Improved performance can only be sustained when sites take responsibility over their own performance. Individual sites should conduct self-assessments with the same

tools used by their external supervisors, and measure their performance against established standards.

10.5 Organizational structure for Supervision:

This results in the supervisory structure in which each level is responsible for supervision of the level directly below, from the Central Ministry of Health and Social welfare to the Region and District Health Office.
Supervision refers to regular visits, performance monitoring and support of a facility. Of course, a higher level always has the right to visit facilities – at any time – to confirm the supervisory reports, but this is a sporadic check, not regular supervision.

Figure 10A: Supervisory Structure and levels in point of Immunization service delivery

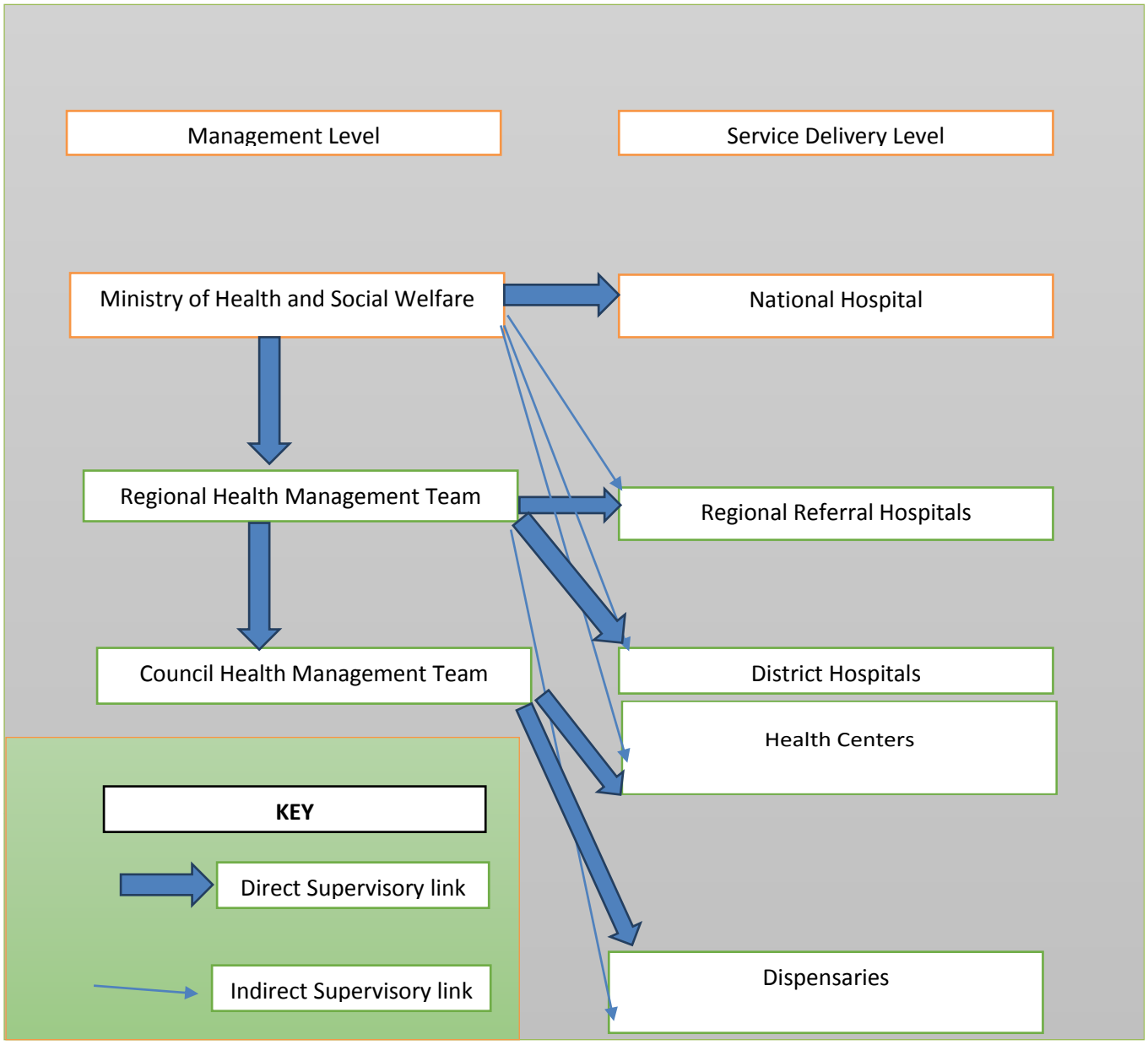


Table 10A: Preparation of supervision

Description	National	Regional	District
Who performs supervision	IVD Officers from different units	RHMT RMO RDO RRCHCO RIVO RP RNO RLT RMHCO Etc	CHMT DMO DDO DRCHCO DIVO DP DNO DLT DMHCO Etc
When supervision Happens	Quarterly	Quarterly	Monthly
How do supervisors prepare	Review immunization performance data to identify Facilities/Councils/Regions need to be visited Prepares a matrix listing the months and dates of all the supervisory visits The routes and vehicles for each trip The facilities to be visited The members of the supervision team Ensures logistics and supplies needed for the visit Supervisors review previous supervisory	Review immunization performance data to identify Facilities/Councils need to be visited Prepares a matrix listing the months and dates of all the supervisory visits The routes and vehicles for each trip The facilities to be visited The members of the supervision team Ensures logistics and supplies needed for the visit	Review immunization performance data to identify Facilities need to be visited Prepares a matrix listing the months and dates of all the supervisory visits The routes and vehicles for each trip The facilities to be visited The members of the supervision team Ensures logistics and supplies needed for the visit Supervisors review

	reports Supervisors review reported achievements Supervisors decide before the supervision visit on what they need to focus on	Supervisors review previous supervisory reports Supervisors review reported achievements Supervisors decide before the supervision visit on what they need to focus on	previous supervisory reports Supervisors review reported achievements Supervisors decide before the supervision visit on what they need to focus on
What happens during supervision encounters	Use standardized supervision checklist Observation of performance and comparison to standards Immediate feedback from supervisor Joint problem solving on possible solutions to performance problems Provision of technical updates and guidance On-the-job training (Mentoring) where necessary Use of data to help identify opportunities for improvement Check the availability of stock and the condition of equipment Check cold chain and vaccine quality Observe immunization sessions and note strengths and weaknesses	Use standardized supervision checklist Observation of performance and comparison to standards Immediate feedback from supervisor Joint problem solving on possible solutions to performance problems Provision of technical updates and guidance On-the-job training (Mentoring) where necessary Use of data to help identify opportunities for improvement Follow-up on the previously identified problems Check the availability of stock and the condition of equipment	Use standardized supervision checklist Observation of performance and comparison to standards Immediate feedback from supervisor Joint problem solving on possible solutions to performance problems Provision of technical updates and guidance On-the-job training (Mentoring) where necessary Use of data to help identify opportunities for improvement Follow-up on the previously identified problems Check the availability of stock and the condition of equipment

	Review health facility records, including coverage and dropout rate monitoring charts Use information gathered during the visit to discuss progress with the health facility team Follow-up on the previously identified Problems	Check cold chain and vaccine quality Observe immunization sessions and note strengths and weaknesses Review health facility records, including coverage and dropout rate monitoring charts Use information gathered during the visit to discuss progress with the health facility team	Check cold chain and vaccine quality Observe immunization sessions and note strengths and weaknesses Review health facility records, including coverage and dropout rate monitoring charts Use information gathered during the visit to discuss progress with the health facility team
What happens after supervision encounters	Actions and discussions are recorded Ongoing monitoring of weak areas and improvements Follow-up on prior visits and problems	Actions and discussions are recorded Ongoing monitoring of weak areas and improvements Follow-up on prior visits and problems	Actions and discussions are recorded Ongoing monitoring of weak areas and improvements Follow-up on prior visits and problems

9.6 Stay motivated

Staying motivated to use supportive supervision can be a challenge. Staff can become discouraged when performance planning is burdensome.

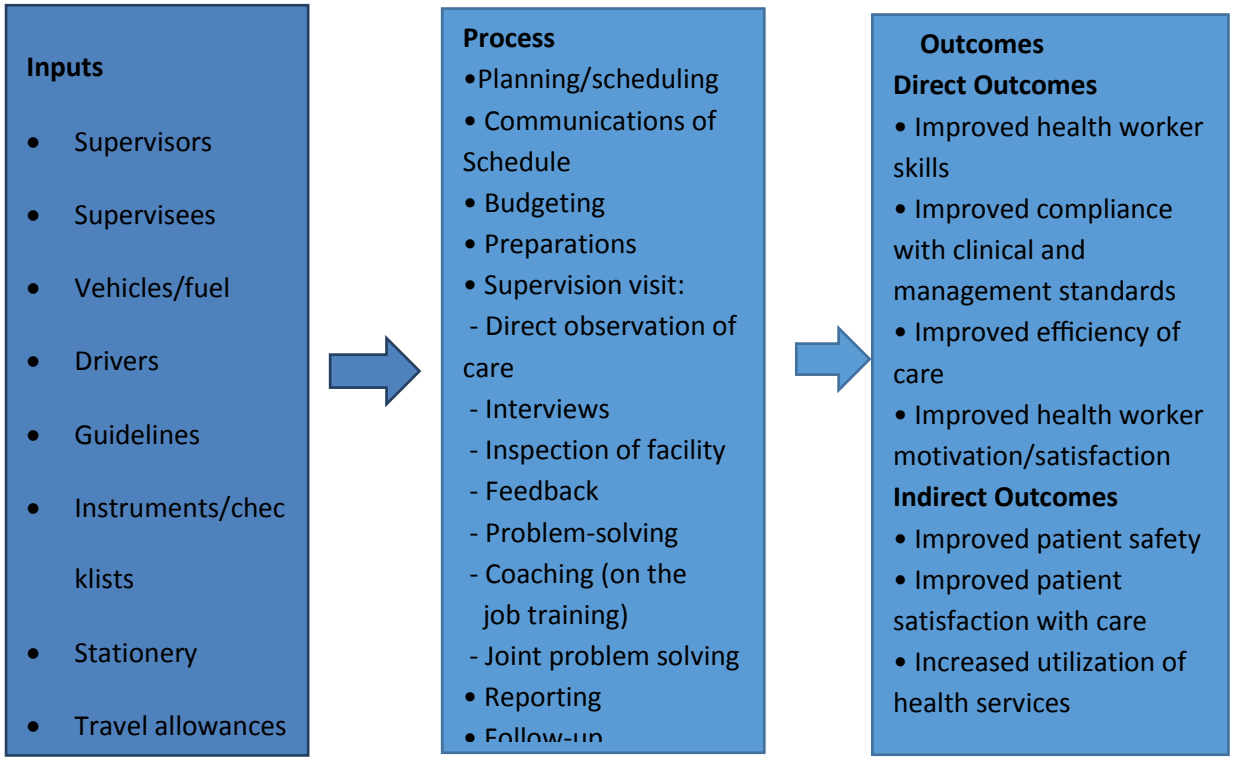
The following suggestions may help:

Give praise and recognition to health workers for what they are doing right

Identify career growth or leadership opportunities and provide guidance and training needed for advancement.

Involve health workers in the planning process and encourage supervisors to work together with health facility staff and the community to develop checklists, job aids, monitoring tools, etc.
Act on feedback from the health workers. For example, if a health center needs a new refrigerator and a supervisor is able to lobby the central-level authorities to procure one, health workers will feel valued and that they have an impact.

Figure 10B:Framework for Supervision in the Health System



9.7 After the supervision visit

The team goes back to the headquarters, writes a full report, and discusses results with the whole team core and co-opted members at that specific level.

- Action items are listed for remaining challenges that were not resolved during the facility visit.
- A copy of the full supervision report is sent back to each visited level (facility/region/council)
- Difficult issues that could not be resolved by the supervising levels are referred to the higher level
- The process then continues until all health facilities in the councils have been reached.

CHAPTER 11: ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION

The main goal of this chapter is to inform, educate and create awareness to the community, parents and other care givers in older to help them understand and increase demand for immunization services on a routine basis. It is also to help planners, decision makers, managers and service providers understand and work better. This can be done through culture, political system and all governance structure in a country. If this guide is implemented effectively it will empower communities and care givers to access accurate

and timely information, resulting in greater public awareness, acceptance and guide appropriately public/community involvement and participation in immunization services.

DEFINITION OF TERMS

Advocacy

Is a communication process geared at soliciting support of leaders, managers, planners, an individual and any key organization responsible for policy decisions, legislations and resource allocation .Also aims at changing the way decision makers behaves.

Communication

Is an interactive process that seeks to increase awareness, influences social norms and create behavior change among selected individuals or sub population (audiences). It can also improve interpersonal interactions including counseling, between families, communities and among health providers. Communication activities might include media campaigns to disseminate accurate information on routine immunization services, public educational materials or community education events to encourage parents, care takers and families to be actively involved in immunization services. This approach is very effective in disseminating messages to areas which are hard to reach.

Social mobilization

Is the process of bringing together, all feasible and practical inter-sectrol social allies to raise people's awareness of and demand for routine immunization services, to assist in soliciting and delivery of resources, and to strengthen community participation and its' sustainability. In Social Mobilization the concept of "Community "goes beyond householders, villagers/ hamlets to include various stakeholders: such as political leaders, Regional and District heads, NGO, Civil societies, Media houses, Religious leaders e.c.t. In campaigns social mobilization is often used to mobilize internal resources for the planed intervention.

Objectives of Advocacy, sensitization and Social Mobilization in this chapter are to:

Main objective

Enhance communication advocacy and social mobilization knowledge and skills to trainers of health service providers at different levels (from National, Regional, District)

Specific objectives:

- coordinate, monitor and supervise social mobilization activities
- Mobilize resources for routine and campaign
- Create awareness in the community
- Communicate/disseminate messages from national to facility level
- Distribute IEC Materials to all levels

11.1. Organization of Advocacy, and Social Mobilization Committees

Management of advocacy and social mobilization is important for success. Committee need to be multsectoral and from pre-existing government administrative structures from national to village level. At each level there must be clear roles and functions.

Advocacy and Social Mobilization Committees

The advocacy and Social mobilization committees include:

- National advocacy and social mobilization committee
- Regional advocacy and social mobilization committee
- District advocacy and social mobilization committee
- Ward advocacy and social mobilization committee
- Village advocacy and social mobilization committee

Composition of the committees and their role at each level

National level:

At national level there is a Multispectral Advocacy and Social mobilization committee.

- Ministry of Health and Social Welfare
  RCHS/ IVD, Health Education and Promotion Unity
- Ministry of Education
- Ministry of Finance
- Faith based Organization
- Media
- TPHA
- PAT
- APHTA Political leaders of all registered parties

- Non-governmental Organization
- Development Partners
- Civil society Organizations (optional)

Roles and functions at National level:

- To oversee the planning and implementation of advocacy and social mobilization activities
- To identify needs and mobilize resources
- To identify possible partners
- To coordinate all the efforts among the partners
- To conduct press release, conference and launching
- To develop, print and disseminate messages for TV, Radio, Newspapers and Posters
- Monitoring of advocacy and social mobilization activities.

Regional level

At regional level there is a multispectral Advocacy and social mobilization committee whose composition is in line with the Regional PHC committee.

Roles and Functions

- To oversee the planning and implementation of advocacy and social mobilization activities in the region
- To coordinate social mobilization activities at regional level
- To supervise and support social mobilization efforts at district level
- To disseminate advocacy and social mobilization materials in the region
- To disseminate messages through TV, Radio, Newspapers and posters
- Monitoring of advocacy and social mobilization activities in the Region
- Identify and respond to rumors then report to national level

District level

Composition of Council advocacy and social mobilization committee is in line with the PHC Committee**.**

Roles and functions

- To conduct District advocacy meeting for resource mobilization
- To oversee the development of micro planning and implementation of advocacy and social mobilization activities in the district
- To coordinate social mobilization activities at district level
- To supervise and support social mobilization activities in the district

- To supervise distribution of advocacy and social mobilization materials in the district
- Monitoring of advocacy and social mobilization activities in the district
- To identify and respond to rumors then report to region level

Ward level:

Ward advocacy and social mobilization committee has the composition of the existing ward development Committee under local government

Roles and functions

- To conduct advocacy meeting at ward level
- To oversee the development of micro planning and implementation of advocacy and social mobilization activities in the ward
- To coordinate social mobilization activities at ward level
- To supervise and support social mobilization activities in the village level
- To supervise distribution of advocacy and social mobilization materials in the ward.
- Monitoring of advocacy and social mobilization activities in the village
- To identify and respond to rumors then report to district level

Village level

Village advocacy and social mobilization committee has the composition of the existing village committee under local government.

Roles and functions

- To conduct advocacy meeting at village level
- To oversee the development of micro planning and implementation of advocacy and social mobilization activities in the village/ Health Facility.
- To coordinate social mobilization activities in the level
- To supervise and support social mobilization efforts at village level
- To supervise distribution and display of advocacy and social mobilization materials in the village.
- Monitoring of advocacy and social mobilization activities in the village
- To identify and respond to rumors then report to village level

11.2. Dealing with Rumors

Rumor is an unverifiable assertion that is circulating or General talk, gossip or hearsay of doubtful accuracy.

Process of dealing with rumors

- Find where do rumors or negative publicity starts
  -Those with vested interests: e.g. traditional healers
  -panic reaction to stories in the press
  -Religious beliefs or fundamentalists: Ban followers from receiving vaccines
  -Ant-vaccines lobby (parents who believe their child was damaged by vaccines)
  -Is the rumor based on the management of the vaccines e.g. policy, service, process or service provider
  -Is the rumors based on the product e.g. manufacture

Responding to rumors or negative publicity

After analyzing the situation:

- Move quickly to respond to rumors without a delay using existing government channels.
- Clarify the rumor or misinformation (Type of messages circulating, source, person or organizations) spreading the rumor.
- Determine the motivation behind the rumor (lack of information, question of authority, religious opposition
- Communicate a benefit focused on audience expectation
- Provide facts that create trust
- Disseminate the correct information through mass media
- Use chain command in reporting the rumors, know the spokes person

Key communication messages

- Vaccines are extremely safe and cause no side-effects, they have been approved by WHO and Ministry of Health and Social welfare.
- Vaccines protect your child from vaccines preventable diseases like polio, measles e.c.t.
- Document in the immunization card the date of next visit.
- Tell parent / care taker when and where to take the child for his or her next immunization.
- Tell parent / care taker that for a child to get full protection against diseases,

  - Children need to have some vaccines repeated even more than three times.

  Tell the parent / care taker that her/his child must complete the schedule of immunizations.
- Tell parents / care taker that some injections may cause mild side-effects such as:

  - Light fever, soreness and redness. If it happens give advice about what to do.

Chapter 12: Data Management, Monitoring and Evaluation

12.0. Introduction

Data collection is an important aspect of monitoring and evaluation of the Immunization program for the future improvement. Quality data can help to show how a district is performing as far as immunization is concerned. Immunization data flow can tell the following:

- Whether immunization services are accessible to the target population.
- How many individuals in the target population are being vaccinated
- Who is not being vaccinated, and why.
- Whether the quality of services meets program standards.
- Whether resources are used efficiently.
- Whether service strategies are meeting objectives.
- Whether mortality and morbidity from vaccine-preventable diseases are being reduced

12.1 Basic recording tools

There are several basic monitoring tools that could benefit health workers, CHMT and RHMT throughout the system but they are neglected because people don't know how to use them. This is true despite the fact that many have been available at every level. The most important of these are maps, patient registers, vaccination cards, tally sheets, and immunization monitoring charts. Making records systematically and regularly after each session will help to follow up on defaulters and solve other problems. These tools are each of which is described below.

12.1.1 Immunization register

The immunization register helps health workers keep track of the immunization services they offer to each infant and to pregnant women. A health facility should have two separate registers, one for recording infant immunizations (HMIS Book 7) and another for recording TT given to women (HMIS Book 6).

12.1.2 The immunization card (RCH)

The infant immunization card contains the immunization history and status. The immunization card is important for many reasons:

- It serves as a reminder for parents to return to the clinic for the next dose. It helps the health worker to determine an infant's immunization and vitamin A status.
- It is useful when conducting coverage surveys and any related assessments.

The card may be the only record of immunization history and status available for health workers if immunization registers are not well maintained or if clients move from one health facility to another.
Each infant should have a card with immunizations marked correctly. Similarly, a separate card should be given to each woman having received TT vaccine

12.1.3 Tally sheets

Tally sheets are forms on which health workers make a mark every time they administer a vaccination. These are used as a basis for reporting to the district level. Supervisors use them to monitor the accuracy of reporting from health facilities to districts

Health worker should mark soon after administering a vaccine to the appropriate vaccine on the tally sheet. Use a new tally sheet every month. Several mistakes can arise during tallying as shown below

- Tallying before the vaccine is administered
- Tallying at the end of a session according to number of doses contained in the used vials
- Tallying all vaccines under one age group (to include those outside the targeted age)

All these should be addressed during supervisions because they have huge implications on immunization data.

The health facility should keep the tally sheet for records for at least two years. At the end of the month a copy of the tally sheet should accompany the monthly report to the district.

Table 11: "Common mistakes to be avoided in tallying"

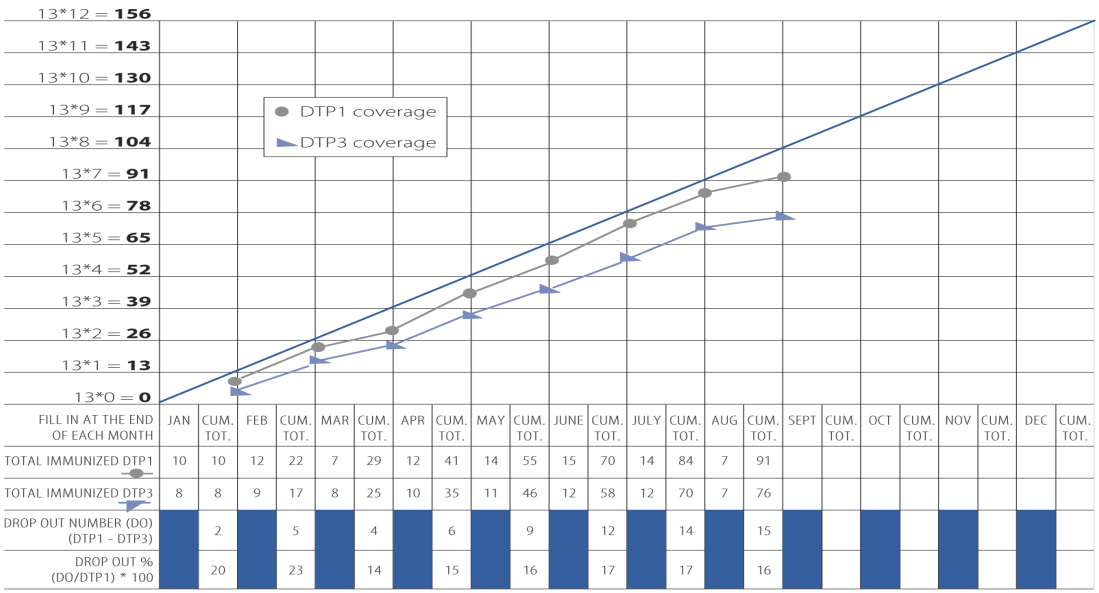
Mistake in tallying	**Possible problem that may occur**	**Correct practice**
Tallying before the vaccine is administered	The child may not receive the vaccine	Give the dose first then tally using the tally sheet
Tallying at the end of a session according to number of doses contained in the used vials	"Wasted" doses may be counted	Tally each dose given (as above)
Tallying all vaccines under one age group (to include those outside the targeted age)	Will result in inaccurate coverage data	Separate tally for under 1 and over 1 year old

12.1.4 Immunization performance monitoring charts

Every health facility that offers immunization services needs to monitor progress toward coverage objectives. Providing tools such as monitoring charts and ensuring that health workers have the skills to use them can motivate health workers, enhance performance, and improve the quality of data.

Immunization monitoring charts should be posted in every health facility for inspection by health facility staff, clients, and supervisors. The charts can be shared with political and community leaders.

Such charts provide a visual reminder of both the overall immunization objective and a gauge of the facility's progress in achieving it. If all goes well, the chart could also foster a sense of accomplishment.



FILL IN AT THE END OF EACH MONTH	JAN	CUM. TOT.	FEB	CUM. TOT.	MAR	CUM. TOT.	APR	CUM. TOT.	MAY	CUM. TOT.	JUNE	CUM. TOT.	JULY	CUM. TOT.	AUG	CUM. TOT.	SEPT	CUM. TOT.	OCT	CUM. TOT.	NOV	CUM. TOT.	DEC	CUM. TOT.
TOTAL IMMUNIZED DTP1	10	10	12	22	7	29	12	41	14	55	15	70	14	84	7	91								
TOTAL IMMUNIZED DTP3	8	8	9	17	8	25	10	35	11	46	12	58	12	70	7	76								
DROP OUT NUMBER (DO) (DTP1 - DTP3)		2		5		4		6		9		12		14		15								
DROP OUT % (DO/DTP1) * 100		20		23		14		15		16		17		17		16								

Figure 11: Shows DTP1 and DPT3 coverages

12.1.5 Monthly summary report

The immunization data collected needs to be consolidated into a monthly report manually for health facility use and transmission to the district. The district compiles data electronically for use and transmission to the region and eventually to national. At each level the data should be charted, analysed and used to improve the programme.

A copy of the report is send with date and signatures to the next level but also a copy of the report is stored for use at the health facility. Efforts need to be ensured such that reports are completed, accurate and submitted

12.1.6 Maps

In addition to geographical distribution of cases, maps can show access to services, particularly in rural areas. For example, local maps can show population distribution in relation to the location of health facilities. Maps should indicate geographical features (e.g., mountains and rivers) and infrastructure (e.g., roads and bridges), because these are important considerations for improving access.

For immunization programs, coverage and drop-out rates are used as indicators of the availability, accessibility, and use of services, as well as of other program characteristics. As the name implies, an indicator describes one or more aspects of services and shows only that there may be a problem. A mix of indicators, as shown in the table, should be used to get a more complete picture of services and to identify problems that should be investigated

Table 12A: Immunization Indicator

Immunization Coverage and Drop-out Indicators		
Indicator	**What it may Indicate**	**Limitations**
DTP1 Coverage	**Availability of, Access to, and initial use of Immunization services by children**	**Measures only the first in a three-dose series** **BCG, although the first vaccination in the schedule, is not an effective indicator for where births take place at home and no BCG is given.** **When BCG is given to babies born in hospitals, it may be recorded in a different information system, if at all**
DTP3 Coverage	**Continuity of use by parents, client satisfaction with services, and capability of the system to**	**Shows only completion of DTP series and not other antigens.**

	deliver a series of vaccinations	
Measles Coverage	**Protection against a disease of major public health importance.**	**Does indicate the capability of the system to deliver a series of vaccines.** **Supplementary doses may be confused with routine doses**
DTP1 to DTP3 **(Difference in the number of children who received DTP1 and the number who received DTP3, expressed as rate)**	**Quality of service as perceived by parents and the quality of communication between parents and health workers – this is a classic drop-out indicator.**	**Does not stand on its own; must be interpreted in light of actual coverage levels.** **Does not give a complete picture of drop-outs that may be occurring between other antigens.**
TT1 Coverage	**Available of, access to, and use of immunization services by pregnant women**	**Measures only the first dose in a multi-dose series**
TT2+(TT2,TT3,TT4, and or TT5) Coverages	**Continuity of use, client satisfaction, and capability of the system to deliver a series of vaccinations to women.**	**The series of five TT doses is given at different intervals over the course of many years.** **Once a woman has received five doses, she should no longer counted in the denominator as member of the target population.**
Fully immunized child (FIC)	**Capability of the system to provide all vaccines in the**	**Generally not available from routine service**

	childhood schedule at the appropriate age and the appropriate interval between doses in the first year of life; also measures a public demand and perceived quality of services.	**statistics.** **Information can usually be derived from population-based surveys analyzed by WinCOSAS or other software.** **Absence of vaccination cards limits the reliability of this indicator.** **The definition of FIC may vary among countries.**

12.2 Analysis and Use of Data

Regional, Council and Health facility staff must be to analyze and use data themselves and by their supervisors to monitor performance in general and, specifically, to monitor immunization coverage and the drop-out rate

12.2.1 Making monthly reports

The immunization data collected needs to be consolidated into a monthly report manually for health facility use and transmission to the district. The district compiles data electronically for use and transmission to the region and eventually to national. At each level the data should be charted, analysed and used to improve the programme.

The copy of report should be sent date and signatures to the next level but also store a copy of the report for use at the health facility.

12.2.1.1 Preparing reports

Health workers should ensure that the reports prepared are:

- **Complete**: All the sections of the reports have been completed; no parts have been left blank and all reports from reporting sites have been received.
- **Timely**: Check the deadline for report submission. Reports should be submitted to the next level before the deadline. When reports are sent and received on time, the possibility of a prompt and effective response is greater.

- **Accurate**: Before sending the reports, double-check entries, totals and all calculations. Make sure that the reported figures correspond to the actual figures.

The district, regional, national levels should keep track of the completeness and timeliness of reporting by the lowest level, and remind those levels of missing or late reports.

What to include in the monthly report of the health facility?

1. **Reporting on vaccinations given to infants and women and vitamin A**

   Data collected on the tally sheets needs to be consolidated into a monthly report, manually for use by the health facility and transmission to the district.

2. **Reporting on Priority vaccine-preventable diseases. (Measles, NNT and AFP)**

   Write the number of cases of each vaccine-preventable disease.

3. **Reporting on any adverse event following immunization (AEFI)**

   If there have been any adverse event during the month, details must be provided to the district. Serious events should be reported immediately. Serious events are defined as:

   - Those that are **life threatening** and
   - Those that result in **hospitalization** (or prolonged hospitalization)
   - Those that result in **disability** (or have the potential to result in disability)
   - Or those that result in death.

4. **Reporting vaccine usage and wastage patterns**

   The usage and wastage of vaccine will vary greatly from one session to another. However it is useful to monitor wastage and usage patterns regularly at all immunization points to improve supply and avoid stock outs. This is done by recording vaccine vial start and end balances, and vials received each month. This information should be compiled at the facility level, where the following calculation can be made.

$$\text{Vaccine usage (rate)} = \frac{\text{Number of infants immunized during the period}}{\{\text{Number of usable doses at beginning of period}\} + \{\text{Number of oses received during period}\} - \{\quad\}} \times 100$$

   Vaccine wastage rate = 100 *minus* vaccine usage rate

5. Any specific problems encountered during the reporting period (e.g. stock-outs, transportation problems, cold chain failure etc.)

This is an opportunity to report supply problems and record supervisory visits.

6. Additional information for example:
    - The sex of infants immunized (M/F) and the sex of disease cases;
    - Campaign activities during the reporting period

12.2.2 Storing data and reports

For purposes of verification and also retrieval whenever needed, data must be stored at all the different levels. Storage of data should be done in hard copies or electronically. At the health facility, tally sheets, registers and reports should be stored for at least three years. Higher administrative levels use computers, however it is important that back-ups (hard copies and/or electronic copies) be available to avoid the loss of data in the case of system failure.

The following types of data should be stored at each health facility for a period of **at least three years**:

1. Immunization registers
2. Tally sheets
3. Copies of monthly reports
4. Target population data
5. Immunization monitoring charts
6. Case/outbreak charts and reports(case investigation form)
7. Supervisory visit reports
8. Daily temperature records forms
9. Cold chain maintenance record
10. Village Register
11. Ledger Book
12. Line list form

Important note:

Data collection is only useful if the data are regularly analyzed and the result of the analysis is used to improve service delivery. Data analysis is the responsibility not only of supervisory levels, but also that of health workers at all levels.

The following section will guide you through the most common ways to analyze the data at the health facility and higher administrative levels

12.3. Monitoring performance

Data collected (Section 10.1) and compiled (Section 10.2) are only useful if they are used to improve the programme performance.

This section will provide guidance through some common ways to use the data at all levels.

12.3.1 Making and using charts to monitor vaccination coverage

A performance-monitoring chart shows trend of vaccination performance over a period of time for every antigen. The monitoring chart graphically shows doses given compared to the number of infants eligible to receive them.

Every health facility should display a current year monitoring chart on the wall, where it can be seen by all staff every day and past 3 years must be well filled and stored. This chart is used at all levels and the principles are the same.

How to prepare the chart for monitoring doses administered in infants less than one year of age

This chart has been developed to track the monthly progress you are making towards immunizing infants under one year of age each month and throughout the year. It also helps you to determine whether your target population is completing the series of vaccines.

1. Calculate the annual and monthly target population to receive immunization services

   a) Annual target population

   You should aim to reach every infant in your catchment area, especially those who are hard to reach. Use existing population figures for infants under one year of age obtained from official census data or your own community census. If you do not have these numbers, obtain an estimate by multiplying the total population times 4%. This document uses 4% as the estimated percentage of infants less than one year of age and of pregnant women in a population. If you have a more precise percentage for your region or district, use this number instead (If the total population is 3900 then infants under one year would be 3900 x 4/100 = 156).

   b) Monthly target

   To get a monthly target population, divide the number of infants under one year of age by 12 (If annual target under one year is 156, monthly target is 156/12 = 13).

2. Label the chart well

3. Draw a diagonal line from zero to the top right-hand corner to show the ideal rate of progress if every infant is immunized on time.

4. Plot immunization data on the chart.

5. Calculate the total number of dropouts between subsequent vaccinations

6. Calculate the cumulative drop outs as a percentage of point 5 over a total cumulative

12.3.2 Compiling coverage data

In order to analyse data, it is necessary to compile data properly by area.

1. List each geographic area or community that you serve.
2. List the target population numbers for infants <1 year.
3. Enter the number of doses of vaccine administered to the target age group during the preceding month period, for example for Penta1, Penta3, and Measles

12.3.2.1 Calculate Immunization Coverage

Calculate immunization coverage in the preceding month period, for example for Penta1, Penta3, and Measles. You can also add coverage for other vaccines administered including TT1, TT2+ etc.

To calculate immunization coverage, divide the total number of immunizations given over the preceding month period by the target population.

Use the formula below:

Annual coverage for childhood immunizations (BCG, Penta3, OPV3, measles) and vitamin A			
Percentage coverage With the vaccine or vitamin A	=	Number of infants under one year of age receiving all required doses for selected vaccine or vitamin A during the last months Target population of infants under one year of age or live births	X 100

12.3.2.2 Calculate number of unimmunized infants

Calculate the number of unimmunized infants for a specific vaccine or pregnant women for TT 2+, for example: number of infants who have not received Measles vaccine

Unimmunized infants with measles vaccine = *target population - infants who received measles vaccines*

Calculate annual dropout rates, for example: Penta1–Penta3, Penta1–Measles, or for any other combination of vaccines you have selected.

Penta1–Penta3 dropout rate:

$$\frac{\text{Doses of Penta1 administered - doses of Penta3 administered}}{\text{Doses of Penta1 administered}} \times 100$$

Penta1–measles dropout rate:

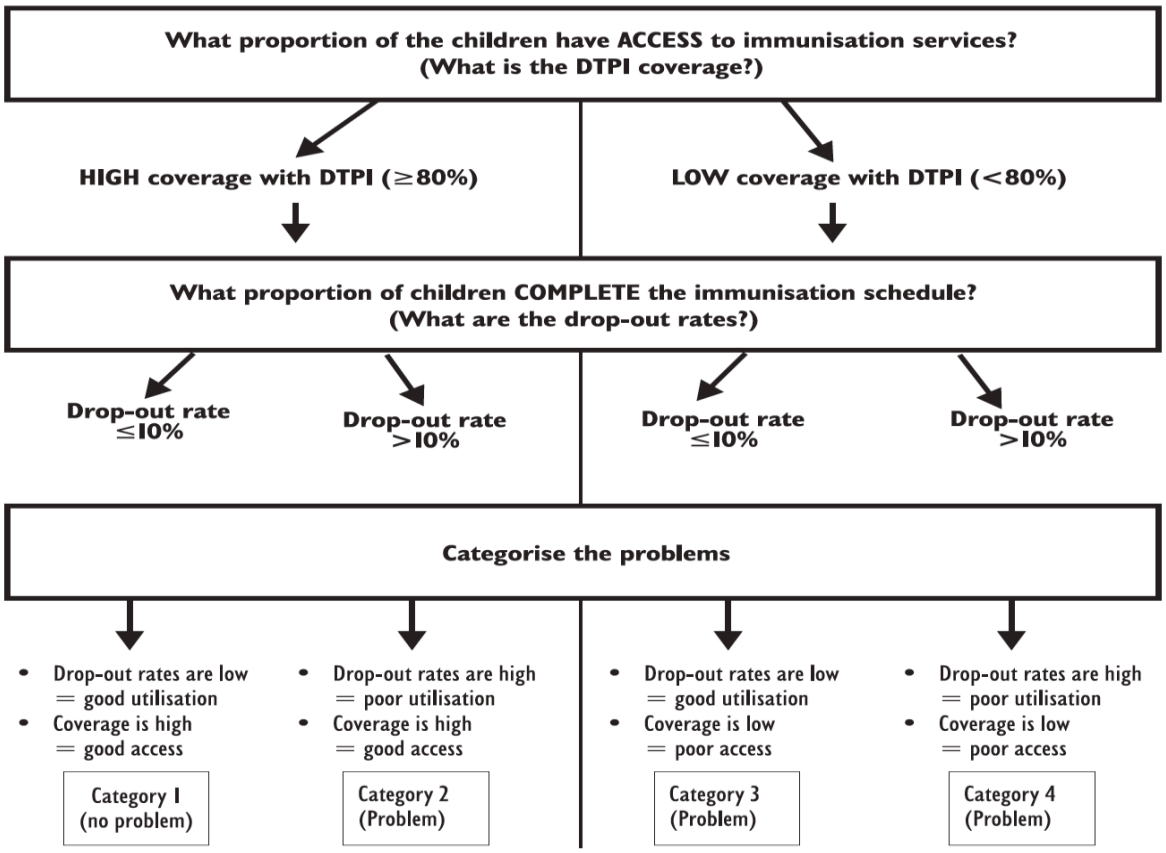
$$\frac{\text{Doses of Penta1 administered - doses of measles vaccine administered}}{\text{Doses of Penta1 administered}} \times 100$$

10.3.2.4 Identify and categorize problem for each area you serve

Specify in the quality of access (good or poor) depending on the Penta1 coverage ("good" is defined in this exercise as Penta1 coverage ≥ 80% in the target age group, and "poor" corresponds to a Penta1 coverage in the target age group of < 80% ; however, you may decide to use lower or higher cut-off coverage rates).

Specify in the quality of "utilization" (good or poor) depending on the dropout rates ("good" is defined in this exercise as a dropout rate in the target age group < 10%, and "poor" corresponds to a dropout rate in the target age group ≥10%; however, you may decide to use lower or higher cut-off dropout rates).

Figure 12; Category of problem



10.3.2.5 Use your data to prioritize areas

Assign the highest priority to the area that has the most unimmunized infants, and not necessarily the lowest coverage. Refer to REC strategy

12.4. Taking corrective action

In this section, you will identify problems and plan corrective action in your area.

12.4.1 Identification of problems

Problems can be broadly associated either with access or with utilization. A problem may be related to one or more villages/areas or may apply to the entire district.

12.4.1.1 Problems related to poor access to service

Infants and pregnant women do not attend immunization sessions. The reasons may be:

- Sessions not conducted as planned
- Session site and times inconvenient or not advertised
- Cultural, financial, racial, gender or other barriers preventing use of immunization services.

12.4.1.2 Problems related to poor utilization of services

Parents do not bring infants back to complete the full series of immunizations. The reasons maybe:

- Parents lack information about the complete immunization schedule
- Supply shortage
- Incorrect contraindications applied
- Problems of relationship between health workers and community
- Tetanus toxoid not available for women at all sessions (according to national policy).

12.4.2 Finding solutions and adding corrective actions to your work plan

The purpose of this section is to help you decide what corrective action is needed. Follow the steps given below to list corrective actions that can be added to the work plan as part of your coverage improvement plan.

Step 1: Health facility level: Review your health facility work plan

- Look at your work plan for the last quarter and identify the sessions that were not held.
- Identify the problem that led to each of these sessions not being held. List these problems.
- Suggest appropriate solution(s) for each problem

Step 2: District level: Discuss the problems and possible solutions at a meeting

- Discuss the problems faced in the last quarter and suggested solutions. Together with district staff decide corrective action(s) to address each problem.
- Categorise the problems according to whether they affect all areas or only some areas.

Step 3 Prioritization of activities

- Solutions for those problems that impact the whole district should be implemented before area-specific solutions.
- Prioritize the order in which you will implement the area-specific solutions.

Step 4 Adding corrective actions to the work plan

After developing a list of solutions and prioritizing them, the next step is to add these to the work plan for the next quarter

Some problems will result in all work plans (district and all health facilities) to be modified, while others will be specific to work plans of one or more health facilities and/or the district

- Include at least one priority solution per month in the work plan and implement it during that month.
- The problems that cannot be realistically addressed during one quarter should be addressed in the following quarter.

12.4.3 Ensure quality of sessions

Sessions should be completed as planned but they must also be of good quality. Decide what corrective action is needed to ensure the quality of every session. The following chapters provide further guidance on:

- Adequate safety measures regarding immunization practices
- Adequate safety measures for safe waste disposal
- Community involvement in providing immunization services.

Remember: *All solutions should be activities that can be done with existing resources. These can be added to the work plan. The work plan needs to be reviewed every quarter*

Table 12B: Sample Problems and Solutions to improve Immunization Coverage

	Examples of commo problems	**Examples of solutions: activities to be included work Plan**

Supply quantity	**Stock-outs of vaccine(s), AD syringes, diluents, safety boxes; immunization Cards**	**Request immediate supplies from district level.**
		Review stock recording system.
		Review vaccine usage and wastage rates and tak action.
		Review method of estimating needs.
Supply quality	**Expired vaccine(s) in stock**	**Review stock recording system.**
	VVMs show that vaccine has reached the discard point	**Review method of estimating needs.**
	Frozen Penta vaccines in refrigerator	**Review management of cold chain equipment.**
Staffing quality	**Some staff have not had recent training**	**Inform supervisor and select subjects for "on-the-job" training/supportive supervision, fo example:**
		Using AD syringes
		New vaccines
		Reading Vaccine Vial Monitors (VVM)
		Implementing Multi dose vial policy (MDVP)
	Irregular supervisory visits	**Include supervisory visits' schedule in district work plan**
Staffing quantity	**Vacant position of health worker, general staff shortage**	**Inform supervisor and district authorities and take steps for recruitment.**
		Request temporary assignment from district level and consider volunteers for some duties.
		Ensure staff available for each session.

Service quality and Demand	**Poor attendance at sessions and poor utilization in some areas**	**Meet with the community to discuss possible reasons for low attendance and suggested solutions.**
		Consult the community and change work plan t make sessions more convenient for the communit
		Check whether all planned sessions have bee held, aim to improve reliability by holding a planned sessions.
		Screen all infants for immunization whenever the visit the health facility and give all of the vaccines they ar eligible to receive
		Review use of true contraindications to ensure tha infants are not missed
	Mothers lose or do not bring the immunization cards	**Set up a defaulter tracking system to keep complete records (Register, reminder cards) at the health facility and take these along during outreach sessions. Provide new cards and update from other records. (Do not restart schedule because of lost cards)**
	Parents fear side-effects and there are rumours that Injection practices are not 100% safe	**Inform parents about benefits of immunization an reassure about side effects.**
		Review safe injection practices: ensure AD syringe supply, use safety boxes, and use safe disposal practices.
		Meet community to discuss rumors
		Review information on AEFI and how to report AE cases

Service quantity ar demand	**Unreliable information abo catchment population**	**Request community to list of all household families,** **new-born**
		Map your catchment area to include all populatio
		Compare population data from various sources including data from National Immunization Days **(Use the NID <5 population and divide by 5 for infant target).**
	Inaccurate coverage data	**Check record keeping and reporting systems for completeness**
		Review all tally sheets and reports does numerato include all areas?
	Some areas distant ar underserved	**Discuss with supervisor and organize mobile team approach from district/province, minimum 4 sessions per year.**
		Discuss service with the communities and arrange adequate sessions, dates and timings
	Transport not available f some	**Identify which sessions were not held due to lack transport**
	outreach sessions	**Look for alternative transport e.g. public transport sharing with other programs**
		Request next level for vehicle for outreach/mobile
	Poor attendance at antenat care (ANC) clinics and/or po TT2+ coverage	**Promote value of antenatal care including TT immunization during any contact with pregnant women.**
		Inform the community about dates of ANC clinics. **Find out if session timing or venue is inconvenient if so make appropriate changes in next quarter's work-plan.**
		Use all opportunities to give TT immunization

		including when mothers accompany infants for childhood immunizations.

ANNEXES

ANNEX 1: AEFI RREPORTING FORM

AEFI Reporting ID Number:

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Patient name: ***Patient's full Address:*** Telephone: Sex: ☐M ☐ F ***Date of birth (DD/MM/YYYY):*** __ __ / __ __ / __ __ __ __ *OR Age at onset:* ☐☐ *Years* ☐☐ *Months* ☐☐☐ *Days* *OR Age Group:* ☐ *< 1 Year* ☐ *1 to 5 Years* ☐ *> 5 Years*	***Reporter's Name:*** Institution / Designation, Department & address: Telephone & e-mail:

Health facility (or vaccination centre) name:

Name of Vaccines Received	***Date of vaccination***	***Time of vaccination***	Dose (e. g. 1st, 2nd, etc.)	***Batch/Lot number***	Expiry date

Adverse event (s):	Describe AEFI (Signs and symptoms):
☐ Severe local reaction ☐ *>3 days* ☐ *beyond nearest joint* ☐ Seizures ☐ *febrile* ☐ *afebrile* ☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Fever≥38°C ☐ Other (specify)..... Date & Time AEFI started (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ ☐☐ Hr ☐☐ Min Was the patient hospitalized? ☐ Yes ☐ No Date patient notified event to health system (DD/MM/YYYY): __ __ / __ __ / __ __ __ __	
Outcome: ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown ☐ Died If died, date of death (DD/MM/YYYY): _____ / _____ / _____ Autopsy done: ☐ Yes ☐ No ☐ Unknown	
Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). *Use additional sheet if needed:*	

First Decision making level to complete:

Investigation needed: ☐ Yes ☐ No	If yes, date investigation planed (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

National level to complete:

Date report received at national level (DD/MM/YYYY): __ __ / __ __ / __ __ __ __	AEFI worldwide unique ID :
Comments:	

**Compulsory field*

ANNEX II: AEFI INVESTIGATION FORM

AEFI INVESTIGATION FORM

(Only for Serious Adverse Events Following Immunization – Death / Disability / Hospitalization / Cluster)

Section A — Basic details

Province/State **District** **Case ID**

Place of vaccination (✓): ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____
Vaccination in (✓): ☐ Campaign ☐ Routine ☐ Other (specify) _____

Address of vaccination site:

Name of Reporting Officer:

Date of investigation: __ __ / __ __ / __ __ __ __
Date of filling this form: __ __ / __ __ / __ __ __ __

Designation / Position:

This report is: ☐ *First* ☐ *Interim* ☐ *Final*

Telephone # landline (with code): Mobile: e-mail:

Patient Name Sex: ☐ M ☐ F

(use a separate form for each case in a cluster)

Date of birth (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

OR Age at onset: __ __ *years* __ __ *months* __ __ __ *days* *OR Age group:* ☐ *< 1 year* ☐ *1–5 years* ☐ *> 5 years*

Patient's full address with landmarks *(Street name, house number, locality, phone number etc.)*:

Name of vaccines/diluent received by patient	Date of vaccination	Time of vaccination	Dose (e.g. 1st, 2nd, etc.)	Batch/Lot number	Expiry date
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent

Type of site (✓) ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____

Date of first/key symptom *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ Time of first symptom *(hh/mm)*: __ __ / __ __
Date of hospitalization *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __
Date first reported to the health authority *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __

Status on the date of investigation (✓): ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely ☐ Unknown

If died, date and time of death *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ *(hh/mm)*: __ __ / __ __
Autopsy done? (✓) ☐ Yes (date)_____ ☐ No ☐ Planned on (date)_____Time_____
Attach report (if available)

Section B — Relevant patient information prior to immunization

Criteria	Finding	Remarks (if yes provide details)
Past history of similar event	Yes / No / Unkn	
Adverse event after previous vaccination(s)	Yes / No / Unkn	
History of allergy to vaccine, drug or food	Yes / No / Unkn	
Pre-existing illness (30 days) / congenital disorder	Yes / No / Unkn	
History of hospitalization in last 30 days, with cause	Yes / No / Unkn	
Patient currently on concomitant medication? (If yes, name the drug, indication, doses & treatment dates)	Yes / No / Unkn	
Family history of any disease (relevant to AEFI) or allergy	Yes / No / Unkn	

For adult women

- Currently pregnant? Yes (weeks) _____ / No / Unknown
- Currently breastfeeding? Yes / No

For infants

The birth was ☐ full-term ☐ pre-term ☐ post-term. Birth weight:

Delivery procedure was ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum etc.) ☐ with complication (specify)

Section C	Details of first examination** of serious AEFI case	
Source of information (✓ *all that apply*): ☐ **Examination by the investigator** ☐ **Documents** ☐ **Verbal autopsy** ☐ **Other**_____ *If from verbal autopsy, please mention source* _____		
Name of the person who first examined/treated the patient:_____ Name of other persons treating the patient: _____ Other sources who provided information (specify): _____		
Signs and symptoms in chronological order from the time of vaccination:		
Name and contact information of person completing these clinical details:	Designation:	Date/time

****Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, laboratory reports and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents, i.e.**

- ***If patient has received medical care*** – attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available) and write only the information that is not available in the attached documents below
- ***If patient has not received medical care*** – obtain history, examine the patient and write down your findings below (add additional sheets if necessary)

Provisional / Final diagnosis:

Section D	Details of vaccines provided at the site linked to AEFI on the corresponding day									
Number immunized for each antigen at session site. Attach record if available.	Vaccine name									
	Number of doses									

a)	When was the patient immunized? (✓ the ☐ below and respond to ALL questions)	
	☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown	
	In case of multidose vials, was the vaccine given ☐ within the first few doses of the vial administered? ☐ within the last doses of the vial administered? ☐ unknown?	
b)	Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes* / No
c)	Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes* / No / Unable to assess
d)	Based on your investigation, do you feel that the vaccine's physical condition (e.g. colour, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes* / No / Unable to assess
e)	Based on your investigation, do you feel that there was an error in vaccine reconstitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	Yes* / No / Unable to assess
f)	Based on your investigation, do you feel that there was an error in vaccine handling (e.g. break in cold chain during transport, storage and/or immunization session etc.)?	Yes* / No / Unable to assess
g)	Based on your investigation, do you feel that the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	Yes* / No / Unable to assess
h)	Number immunized from the concerned vaccine vial/ampoule	
i)	Number immunized with the concerned vaccine in the same session	
j)	Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations: _____	
k)	Is this case a part of a cluster?	Yes* / No / Unkn
	i. If yes, how many other cases have been detected in the cluster?	
	a. Did all the cases in the cluster receive vaccine from the same vial?	Yes* / No / Unkn
	b. If no, number of vials used in the cluster (enter details separately)	

**It is compulsory for you to provide explanations for these answers separately*

Section E	Immunization practices at the place(s) where concerned vaccine was used *(Complete this section by asking and/or observing practice)*			
Syringes and needles used:				
• Are AD syringes used for immunization?		Yes / No / Unkn		
If no, specify the type of syringes used: ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other _____				
Specific key findings/additional observations and comments:				
Reconstitution: (complete only if applicable, ✓ NA if not applicable)				
• Reconstitution procedure (✓)		Status		
	Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
	Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
	Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
	Separate reconstitution syringe for each vaccination?	Yes	No	NA
• Are the vaccines and diluents used the same as those recommended by the manufacturer?		Yes	No	NA
Specific key findings/additional observations and comments:				

Section F Cold chain and transport *(Complete this section by asking and/or observing practice)*	
Last vaccine storage point:	
• Is the temperature of the vaccine storage refrigerator monitored?	Yes / No
o If "yes", was there any deviation outside of 2–8° C after the vaccine was placed inside?	Yes / No
o If "yes" provide details of monitoring separately?	
• Was the correct procedure for storing vaccines, diluents and syringes followed?	Yes / No / Unkn
• Was any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	Yes / No / Unkn
• Were any partially used reconstituted vaccines in the refrigerator?	Yes / No / Unkn
• Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator?	Yes / No / Unkn
• Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes / No / Unkn
Specific key findings/additional observations and comments:	
Vaccine transportation:	
• Type of vaccine carrier used	
• Was the vaccine carrier sent to the site on the same day as vaccination?	Yes / No / Unkn
• Was the vaccine carrier returned from the site on the same day as vaccination?	Yes / No / Unkn
• Was a conditioned ice-pack used?	Yes / No / Unkn
Specific key findings/additional observations and comments:	

Section G Community investigation (Please visit locality and interview parents/others)

Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality?
Yes / No / Unknown If yes, describe:

If yes, how many events/episodes?

Of those effected, how many are
- Vaccinated:_____
- Not vaccinated:_____
- Unknown:_____

Other comments:

Section H Other findings/observations/comments

Annex 3

AEFI – LABORATORY REQUESITION FORM (LRF)

(To be completed by XXX. LRF should be accompanied with specimens)

(For Serious Adverse Events Following Immunization)

AEFI category (Encircle): **Death / Hospitalized / Cluster / Disability**

Province		**Case ID**	
District			
Sub District			

Name of person sending the specimen: Date of filling LRF :

Designation:

Phone Number :

Case Name	

Date of Birth	D	D	M	M	Y	Y	Y	Y		Age (in months)				Sex	Male	Female

Complete Address of the patient with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*

P	**H**	**O**	**N**	**E**	**-**																				

Date of vaccination	D	D	M	M	Y	Y	Y	Y	Date of Onset	D	D	M	M	Y	Y	Y	Y

Date of collection of specimen	D	D	M	M	Y	Y	Y	Y	Time of collection of	H	H	M	M	(	AM	PM	)

								specimen									

. Precise description of samples:

a) For vaccine/diluents specimens: (to be transported in reverse cold chain)

Mention vaccine/diluent	Quantity Sent	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date

b) For logistics specimens: (AD, Reconstitution, Disposable syringes)

Mention Logistics	Quantity Sent	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date

c) For Biological product specimen: (CSF, Blood, Urine, etc)

2. Test requested:
3. Preliminary clinical diagnosis (working hypotheses):

4. Name & complete address of officials to whom laboratory results should be sent:

Send to	Complete address	Phone/Fax	Mobile	Email-ID

National Level				
Province/ State level				
District level				
Others (specify)				

To be completed by lab officials after receiving the specimen

Date of receipt of specimen at laboratory	D	D	M	M	Y	Y	Y	Y

Name of person receiving specimen(s) at laboratory	

Condition of specimen upon receipt at lab (*encircle*)	Good	Poor	Unknown

Comments by pathologist, virologist or bacteriologist:

Date specimen results sent from this lab	D	D	M	M	Y	Y	Y	Y

Name of laboratory professional	

Signature

Phone number:	Email Id:

Annex 4

AEFI Line listing

													Name/ID
													Village/Town/District
													Date of birth (dd/mm/yyyy) and age
													Date of immunization(dd/mm/yyyy)
													Reaction type (code) [1] Minor [2] Severe/Serious
													Outcome (Recovered disability/Died)
													Suspect vaccine (name and dose, e.g. Penta-2)
													Vaccine batch/Lot number
													Diluent batch number
													Onset time interval (hours, days, weeks)
													Date reporting (dd/mm/yyyy)
													Investigated? (If yes, date)
													Cause (code)

Establishing codes for area, reaction type, cause of AEFI, and certainty of cause will facilitate recording, data entry and analysis. Because of the potential for coding errors, the code should be double-checked.

Coding for cause of AEFI:

[A1] Vaccine-related	[A2] Immunization error-related	[A3] Immunization anxiety-related	[B] Indeterminate	[C] Coincidental	[D] Inadequate information to classify