GOVERNMENT OF GHANA

FIELD GUIDE FOR GHANA'S IMMUNISATION PROGRAMME

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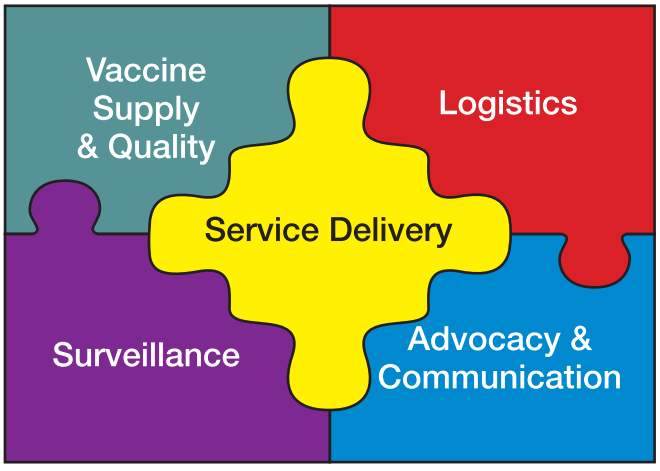
CHAPTER ONE
Introduction

1.1 Introduction
Vaccination is one of the greatest public health achievements of human history. It has led to the eradication of small pox, near eradication of poliomyelitis and elimination of measles in several regions. Globally, an estimated 2-3 million deaths among children under age 5 are prevented annually through immunisation. Immunisation programmes provide opportunities to promote integrated services and improve the overall health of recipients.
The general purpose of the section is to give an overview of vaccines, Ghana's Expanded Programme on Immunisation (EPI), the targeted diseases and the challenges they present.

1.2 Overview of EPI in Ghana
EPI was launched in 1974 by WHO and adopted by Ghana in 1978. Ghana currently has 13 vaccine preventable diseases (VPDs) on its EPI schedule. EPI in Ghana has seen tremendous progress over the years. Using pentavalent vaccine as a proxy indicator, the Programme attained a vaccination coverage rate of 90 per cent in 2014 and has had notable success with regards to some childhood diseases including neonatal tetanus elimination in Ghana in 2011; no reported case of polio since 2008; no death due to measles documented since 2003; and a significant reduction in diarrhoea and pneumonia in children. However, coverage has stagnated, with more than 1 in 10 children not being reached2. Sustained efforts are needed to consolidate the gains made, improve quality of immunisation services and reach the unreached.

1.3 Immunization operations and supportive components
The immunization system is comprised of five key immunization operations, as follows:



- Service delivery – covers the strategies and activities in giving vaccinations
- Logistics – includes delivery of vaccines and equipment to the place of use, transport, management of cold \ chain and waste disposal
- Vaccine supply and quality – consists of forecasting vaccine needs, procurement of vaccines, monitoring of vaccine utilization and safety procedures
- Disease surveillance – includes monitoring of disease incidence, laboratory testing, record keeping and reporting
- Advocacy and communications – covers social mobilization, advocacy, community education on immunization and program promotion

1 WHO 2016. Expanded Program on Immunisation and Integrated Management of Childhood Illness (IMCI) in the African Region: Pocket guide for good practice. WHO/AFRO
2 GDHS 2014

The operations are supported by the following: management, sustainable financing, and human and institutional resources strengthening

- Management includes policy making and standard setting, planning, co-ordination, information collection and sharing, collaboration with other partners, quality assurance, monitoring and evaluation.
- Sustainable financing comprises budgeting, identifying long-term funding sources, actions leading to increased allocation of financial resources for immunization programs.
- Strengthening human and institutional resources includes staffing, training, supervision and institutional support (including supply of technical information, support to research projects

1.4 Vaccines and contraindications[3]

1.4.1 Vaccines

Vaccines may be categorised by the antigen used in their preparation. How vaccines are formulated affect how they are used, how they are stored, and how they are administered. Vaccines used in Ghana's EPI generally fall into four main antigen types shown in Figure 1-1.

Figure 1-1: Types of vaccines

Live Attenuated (LAV)	Inactivated (Killed)	Subunit (Purified antigen)	Toxoid (Inactivated Toxins)
• Tuberculosis (BCG) • Oral Polio Vaccine (OPV) • Rotavirus • Measles • Rubella • Yellow fever	• Whole Cell Pertussis (wP) • Inactivated Polio Vaccine (IPV)	• *Haemophilus influenza* type b • Hepatitis B (HepB) • Pneumococcal (PCV-13) • Conjugate Meningococcal A (MenAfriVac)	• Tetanus Toxoid (TT) • Diphtheria Toxoid

Live vaccines contain a weakened or attenuated form of the germ (virus or bacteria). They are altered so that they ordinarily cannot cause disease. The other main type of vaccine is made of the killed or inactivated germ, or just parts of the germ or the toxins they produce.

Two or more of these vaccines can be combined into multi-valent or polyvalent vaccines. Pentavalent; Measles-Rubella (MR) and Tetanus-diphtheria (Td) are examples of such vaccines used in EPI (Refer Table 1-1).

1.5 How vaccines work

Vaccines stimulate the immune system to develop long-lasting immunity against antigens from specific pathogens. Vaccines contain the same antigens that are found in pathogens that cause the associated disease, but exposure to the antigens in vaccines is controlled.

Figure 1-2: Two ways of acquiring immunity

Vaccination primes (stimulates) the immune system so that when the vaccinated individual is later exposed to the live pathogens in the environment, the immune system can destroy them before they can cause disease. There are two ways of acquiring such immunity: by natural infection and by vaccination. Unlike acquiring immunity through natural infection (e.g. measles), the person who

3 This section is adapted from WHO 2013. Vaccine Safety Basics: learning manual and Vaccine Safety Basics e-learning course www.vaccine -safety-training.org

receives a vaccine does not endure the illness and its potential life-threatening complications. The very low risk of an adverse event caused by a vaccine greatly outweighs the risk of illness and complications caused by natural infection.

Table 1-1: Vaccine-preventable diseases targeted by EPI and associated vaccines, Ghana

Germ	Disease	Associated Vaccine used in Ghana
Mycobacterium tuberculosis	Tuberculosis (TB)	Bacillus Calmette-Guérin (BCG) vaccine
Poliovirus	Poliomyelitis	Oral polio vaccine (OPV),
		Inactivated polio vaccine (IPV)
Corynebacterium diphtheriae	Diphtheria	Diphtheria toxoid vaccine* as a component of Pentavalent (DPT-Hib-HepB) and Td vaccines
Clostridium tetani	Tetanus	Tetanus toxoid vaccine* as a component of Pentavalent (DPT-Hib-HepB) and Td vaccines
Bordetella pertussis	Pertussis or Whooping cough	Pertussis vaccine* in Pentavalent (DPT-Hib-HepB) vaccine
Hepatitis B virus	Viral hepatitis	Hepatitis B (HepB) vaccine (standalone and in Pentavalent (DPT-Hib-HepB vaccine*
Haemophilus influenzae type B [Hib]	Pneumonia, meningitis, Septicaemia etc.	Hib conjugate vaccine as a component of Pentavalent (DPT-Hib-HepB) vaccine
Streptococcus pneumoniae	Pneumonia, meningitis, other IPD†	Pneumococcal vaccine
Rotavirus	Rotavirus diarrhoea	Rotavirus vaccine
Measles virus	Measles	Measles vaccine as a component of Measles-Rubella vaccine
Rubella virus	Rubella & Congenital Rubella Syndrome	Rubella vaccine as a component of Measles-Rubella vaccine
Yellow fever virus	Yellow fever	Yellow fever vaccine
Neisseria meningitidis Serotype A	Meningococcal meningitis	Conjugate Meningococcal A (MenAfriVac) Vaccine
Vitamin A deficiency		Vitamin A supplements¶

*Diphtheria, pertussis and tetanus vaccines are combined as DPT; and as Pentavalent with the addition of HepB and Hib as used in Ghana
†IPD: Invasive pneumococcal diseases
¶Vitamin A deficiency is not a VPD and Vit. A is NOT a vaccine

1.5.1 General Vaccine Contraindications

A contraindication to vaccination is a rare condition in a recipient that increases the risk for a serious adverse reaction. Ignoring contraindications can lead to avoidable vaccine reaction risks. Most contraindications are temporary, and the vaccination can be administered later.

The only contraindication applicable to all vaccines is a history of a severe allergic reaction after a prior dose of vaccine or to a vaccine component

Precautions are not contraindications, but are events or conditions to be considered in determining if the benefits of the vaccine outweigh the risks. Precautions stated in product labelling can sometimes be inappropriately used as absolute contraindications, resulting in missed opportunities to vaccinate. Specific contraindications to individual vaccines are detailed in the appropriate sections in Chapter 2.

Giving multiple vaccinations for different diseases at the same time

A major misconception about immunisation is that "Giving a child multiple vaccinations for different diseases at the same time increases the risk of harmful side effects and can overload the immune system". A number of studies and reviews have been conducted to examine the effects of giving various combinations of vaccines simultaneously. These studies have shown that EPI and other recommended vaccines are safe and effective when given individually or when combined with other vaccines as one vaccine-vial (known as multi-valent or poly-valent vaccine), and that such combinations carry no greater risk for harmful side effects. For example, measles vaccine is as safe and effective as the measles vaccine in the measles-rubella (MR) vaccine.

1.6 Catch-up Immunisation

All children should be vaccinated per Ghana's recommended immunisation schedule. Children with any missed doses should be given "catch-up" vaccines till 5 years of age (except BCG, OPV0 and Rota virus vaccines - refer Table 1 2 for age limits). During any health visit, a child's immunisation status should be assessed and missed doses administered per the recommended "catch-up" schedule as shown in Table 1-2.

However, any child who starts routine immunisation before age 5 must be followed up to ensure all doses are received even if his/her age goes beyond 5 years. Table 1-2 summarizes the catch-up schedule;

Table 1-2: Minimum and Maximum age and intervals for catch-up doses

Vaccine	Minimum Age	Maximum Age	Comments / Interval between doses
BCG	Birth	<1 year	Administered at birth; preferably not beyond 2 weeks
OPV0	Birth	<2 weeks	Administered at birth or within two weeks of delivery
OPV	6 weeks	<5 years	Total of 3 doses, 4 weeks apart
Pentavalent	6 weeks	<5 years	Total of 3 doses, 4 weeks apart
PCV	6 weeks	<5 years	Total of 3 doses, 4 weeks apart
Rota	6 weeks	1st dose: 20 weeks 2nd dose: 24 weeks	Total of 2 doses, 4 weeks apart
IPV	14 weeks	<5 years	Only one dose
MR	9 months	<5 years	Total of 2 doses, If the first dose is given any time between 9 and 17 months the second dose should be given at 18 months If first contact at 18 months or beyond, 4 weeks apart
YF	9 months	<5 years	Only one dose
Men A	18 months	<5 years	Only one dose

4 http://www.who.int/vaccine_safety/initiative/detection/immunisation_misconceptions/en/index6.html

1.7 Intervals between doses of the same vaccine

Pentavalent, OPV, measles-rubella, PCV and rotavirus vaccines require administration of more than one dose for the development of adequate antibody response. A minimum interval of 4-weeks should be maintained between each dose. If a dose is given at less than the recommended 4-week interval, it should be repeated at the appropriate time.

A longer-than-recommended interval between doses does not reduce final antibody response. Therefore, interrupted immunisations need not be restarted, but the remaining dose or doses should be given as if the prolonged interval had not occurred. However, interrupted immunisation extends the time when the child is at risk of contracting the disease so efforts should be made to follow the schedule as prescribed.

Generally, there is no maximum interval between doses of the same vaccine. If a dose of Pentavalent or OPV is missed, vaccination on the next occasion should be continued as if the usual interval had elapsed, and no extra dose is needed, taking into considerations any age limit(s).

1.8 Tetanus-diphtheria Vaccination Schedule

Mothers and newborn babies should be protected against tetanus. A minimum of two doses of TT/Td, at the appropriate interval before delivery, are necessary to attain such protection. Elimination of Maternal and Neonatal Tetanus (MNT) can be achieved by promoting safe delivery practices and ensuring that all pregnant women have been vaccinated with the second dose of tetanus toxoid (TT2/Td2) at least two weeks before delivery. To avoid missed opportunities, pregnant women should be screened at antenatal visits as well as during any other visit to ensure they are provided with the necessary doses per their Td status. The vaccination schedule and the expected duration of protection is as shown in table 1-4.

Table 1-3: Tetanus-diphtheria Vaccination Schedule

Dose of Td (according to card or history)	When to give	Expected duration of protection
TT/Td1	At first contact or as early as possible in pregnancy	None
TT/Td2	At least 4 weeks after Td1	1 - 3 years
TT/Td3	At least 6 months after Td2 or during subsequent pregnancy	At least 5 years
TT/Td4	At least one year after Td3 or during subsequent pregnancy	At least 10 years
TT/Td5	At least one year after Td4 or during subsequent pregnancy	For all childbearing years and possibly longer

Women who have received up-to five doses of TT/Td at the right interval should not be vaccinated. Such a record should however be tallied in the column for women who have received up-to five doses of TT/Td in the tally book.

Table 1-4 details out the schedule for pregnant women who have received previous doses of tetanus containing vaccine (DPT/Pentavalent). Healthcare workers (HCWs) should screen the records of pregnant women in order to know their TT/Td vaccination status.

Table 1-4: Guidelines for immunisation of women who have received previous TT/Td or DPT/Pentavalent doses

Age at last vaccination	Previous immunisations (based on written records)	Recommended immunisation	
		At present contact/ pregnancy	Later (at intervals of at least one year)
Infancy	3 doses of DPT containing vaccine	1 dose of Td	2 doses of Td
School age	3 doses of DPT containing vaccine + 1 TT/Td	1 dose of Td	1 dose of Td
Adolescent	3 doses of DPT containing vaccine + 1 TT/Td + 1 TT/Td	1 dose of Td	None

1.9 Childhood Immunisation and Vitamin A Schedule

Ghana's childhood immunisation schedule is integrated with Vitamin A supplementation and other child health interventions i.e. growth promotion, provision of Long Lasting Insecticide Treated Nets (LLINs) etc. A child needs at least six (6) visits to the Child Welfare Clinic (CWC) or Immunisation Center including a "birth" visit in order to complete the immunisation schedule. Additional visits to the CWC are required for the other child health interventions.

Routine Vitamin A supplementation is recommended in children and children 6-59 months of age. The first dose of Vitamin A supplement is given when the child is six (6) months. The subsequent Vitamin A supplements are given every six (6) months until the child is five (5) years. Vitamin A supplementation does not interfere with EPI antigens. Table 1-5 shows Immunisation and Vitamin A. supplementation schedule for Ghana.

Table 1-5: Routine Immunisation and Vitamin A schedule for Children

Schedule	Vaccines	Doses	Route and Site of Injection
At birth	BCG OPV0	0.05ml 2 drops	Intra-dermal, right upper arm Oral
6 weeks	DPT-HepB-Hib1 OPV1 Pneumo 1 Rota 1	0.5ml 2drops 0.5 ml 1.5 ml vial	Intra-muscular, lateral aspect of left thigh Oral Intra-muscular, lateral aspect of right thigh Oral
10 weeks	DPT-HepB-Hib2 OPV2 Pneumo 2 Rota 2	0.5ml 2drops 0.5 ml 1.5 ml vial	Intra-muscular, lateral aspect of left thigh Oral Intra-muscular, lateral aspect of right thigh Oral
14 weeks	DPT-HepB-Hib3 Pneumo 3 OPV3 IPV	0.5ml 0.5 ml 2 drops 0.5ml	Intra-muscular, lateral aspect of left thigh Intra-muscular, lateral aspect of right thigh Oral Intra-muscular, lateral aspect of right thigh
6 months	Vitamin A	100,000 IU	Oral
9 months	Measles-Rubella Yellow Fever	0.5ml 0.5ml	Subcutaneous, left upper arm Subcutaneous, right upper arm
12 months	Vitamin A	200,000 IU	Oral
18 months	Measles-Rubella Men A Vitamin A	0.5ml 0.5ml 200,000 IU	Subcutaneous, left upper arm Intra-muscular, right upper arm Oral

1.10 Second Year of Life (2YL) Interventions

Immunisation as a health service is highly patronized compared to other child health interventions. It therefore serves as a platform for providing other essential health and nutrition services. However, the use of services drops off after the child has reached age one; and caregivers as well as HCWs very often do not view services beyond age one as a priority.

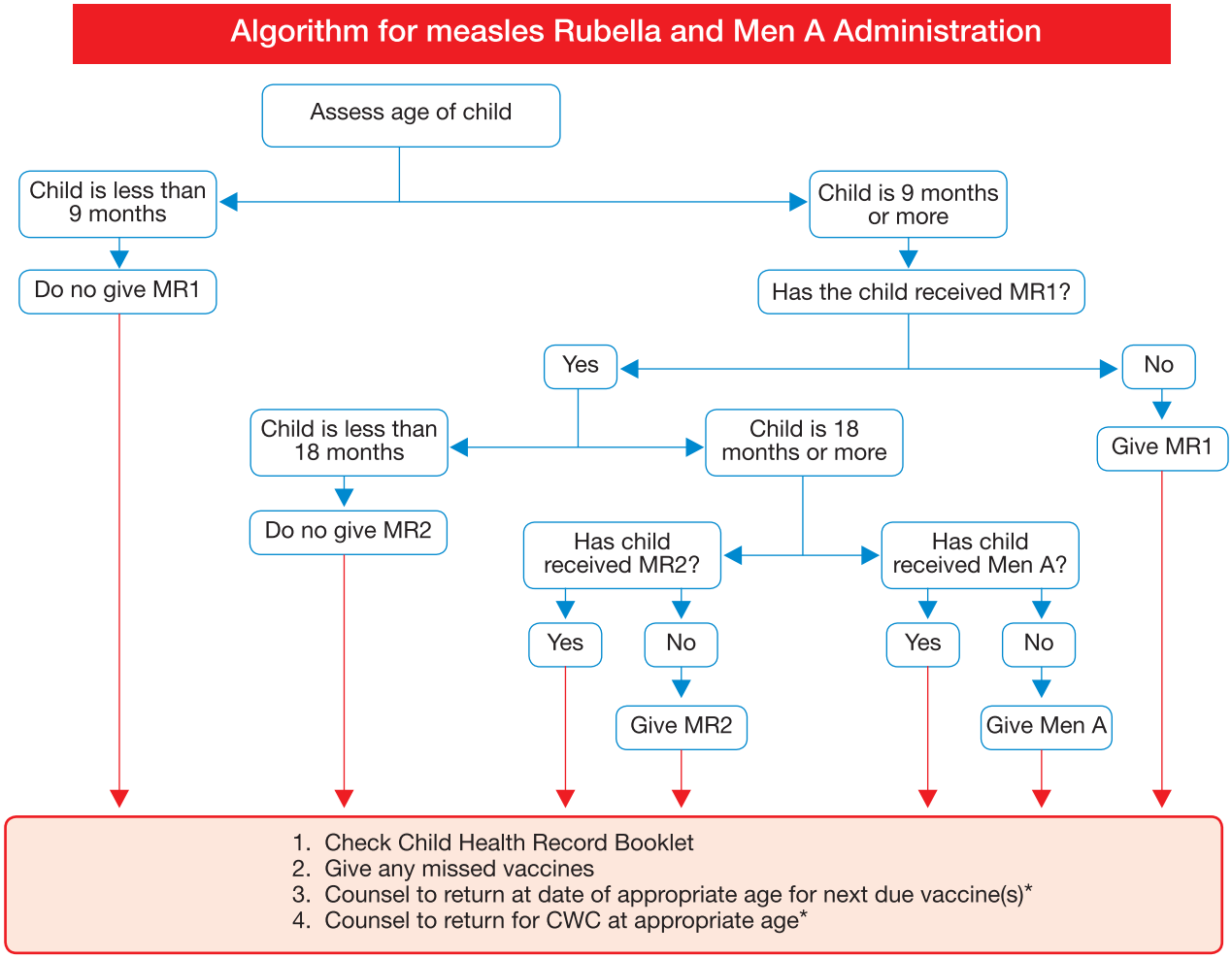
A visit for immunisation scheduled during the second year of life (12-23 months of age) and beyond can encourage caregivers to bring their children for services at a time when the child is still vulnerable. This will afford the health system another opportunity to provide other child welfare services including malaria prevention, nutrition and hygiene interventions.

The major objectives of Second Year of Life (2YL) intervention platform are to:

- Facilitate rapid uptake of Men A and increase coverage of Second Dose Measles-Containing Vaccine (MCV2)
- Increase number of fully immunised children by catch-up of child vaccines (OPV, IPV, Penta, PCV, Yellow Fever)
- Increase equity in immunisation coverage among poor performing districts
- Increase uptake of other child welfare services including malaria prevention through provision of LLINs; Vitamin A supplementation, Growth Promotion and other nutrition interventions.

The Second Year of Life (2YL) Interventions platform emphasises that routine immunisation does not end at age 1 but goes through the second year of life and beyond. Figure 1-3 is a screenint tool to be used at vaccinatios sites to identify eligible children for the 2YL interventions.

Figure 1-3 Algorithm for 2YL interventions in Ghana



* Consult immunization catch-up schedule for appropriate age intervals between visits

CHAPTER TWO

Target Diseases and Vaccines

The section examines the 13 diseases currently on Ghana's vaccination schedule. It looks at the epidemiology (what, who, when, where, causes and risk factors), signs and symptoms and clinical spectrum of the diseases as well as prevention and treatment. The section also looks at Vit. A supplementation which has been integrated into EPI in Ghana.

2.1 Tuberculosis (TB)

2.1.1 What is TB and what causes it?

- Tuberculosis (TB) is a bacterial infection caused by the Mycobacterium tuberculosis.
- It commonly attacks the lungs (Pulmonary TB), but can also affect any part of the body, including the bones, joints and brain (TB meningitis): TB outside the lungs is called Extrapulmonay TB (ETP)

2.1.2 How is TB transmitted (Spread)?

- TB spreads through the air, when an ill person coughs or sneezes.
- People may be infected without developing the disease. Such persons do not spread the infection to others.

2.1.3 Who is affected, when, where are they affected, what are the risk factors?

- Affects people of all ages but especially persons in extremes of ages (children and older adults) and those whose immune system is weakened by disease etc. (e.g. PLWHA).
- Conditions for rapid spread: crowding, poor access to health care, malnutrition.
- Consuming raw milk of infected cattle can lead to bovine tuberculosis.

2.1.4 Incubation, Signs and Symptoms and Clinical spectrum of TB

Incubation period: 2-12 weeks. Can be many months or even years before the disease develops.
Signs and Symptoms:

- Generalised weakness, weight loss, fever and night sweats, swollen lymph nodes (glands).
- **Children:** failure-to-thrive, stunted growth may be the only sign
- **Pulmonary TB (PTB):** cough, coughing up of blood (haemoptysis), chest pain, fatigue
- **TB meningitis (infection of the covering of brain/spinal cord):** fever, chills, mental status changes, nausea/vomiting, sensitivity to light (photophobia), severe headache, stiff neck
- Other symptoms and signs depend on the part of the body that is affected: e.g. swelling, pain and disabling effects on the hips, knees or spine if bones and joints are affected

2.1.5 How is TB treated?

- Two or more anti-tuberculosis drugs are taken for at least six months under Directly Observed Treatment Schedule (DOTS strategy)

2.1.6 How is TB prevented?

- Vaccination at birth or soon after (but not exceeding 12 months of age) with BCG protects against TB meningitis, TB outside the lungs (extra-pulmonary TB) and other severe forms of TB in children under 5 (miliary TB) but not PTB

2.1.7 TB vaccine and vaccination

- **BCG (Bacillus Calmette-Guérin):** vaccine's name derives from the rod shape of the bacterium (bacillus), and Calmette and Guérin who developed the vaccine.

- The vaccine is a freeze-dried powder (also called lyophilized) form- must be reconstituted
- It must be stored between +2 °C and +8 °C after reconstitution.
- Reconstituted BCG must be discarded after 6 hours or at the end of the session (See Chapters 3 and 4 on opened Multi-Dose Vial Policy (MDVP)
- **Schedule:** 0.05 ml is given at birth or soon after by intradermal route in the shoulder region (DO not give after 12 months of age)
- A small lump usually appears under the skin after injection- disappears within 30 minutes
- A red sore forms after about two weeks- usually lasts for another two weeks and then heals, leaving a small scar about 5 mm across: a sign that the child has been effectively vaccinated
- **Contraindication:** DO NOT give in known HIV infection or other immune deficiency

Box 2.1: Key points about TB
- TB affects the lungs, brain and other parts of the body, including the bones, joints
- It is spread through the air
- Symptoms/signs include general weakness, weight loss, fever and night sweats
- Persons who develop TB disease must complete a course of drug therapy to cure it and to avoid spreading it to others.
- BCG vaccine prevention for children is BCG vaccine given at, or as soon as possible after, birth and before 12 months of age
- PTB should be suspected if a person coughs for 2 weeks or more

2.2 Poliomyelitis (Polio)

2.2.1 What is Polio and what causes it?
- Poliomyelitis (Polio) is a highly infectious viral disease caused by the polio virus
- The virus multiplies in the intestines, enters the blood stream and can damage certain types of nerves (spinal nerves) leading to paralysis or even death

2.2.2 How is polio transmitted (Spread)?
- The virus is found in faeces of infected persons and water contaminated with infected faeces.
- It is transmitted by faeco-oral route i.e. when persons ingest contaminated water and/or food

2.2.3 Who is affected, when, where are they affected, what are the risk factors of polio?
- Polio mainly affects children under 5 but can affect anybody.
- It occurs worldwide, is seasonal-occurs mainly in hot, humid months
- Poor sanitation and non-vaccination are the major risk factors
- The Global Polio Eradication Initiative (GPEI), which was launched in 1988, has contributed to the reduction of Wild Polio Viruses by over 99%: endemic polio is confined to three countries as at 2016

2.2.4 Incubation, Signs and Symptoms and Clinical spectrum of polio
Incubation period: Averagely 7-10 days. Range: 4-35 days
Signs and Symptoms:
- **Asymptomatic** in over 90%
- **Mild illness** in <10% of infected persons: fever, headache and sore throat
- **Paralytic polio** in 0.5 to 1 % of infected persons: sudden onset development of floppy muscles with loss of voluntary movement (Acute Flaccid Paralysis-AFP). May affect any muscle in the body but is primarily seen in those of the limbs (arms and/or legs). Approximately 5–10% of those who develop paralytic polio die due to involvement of the respiratory muscles.

2.2.5 How is Polio treated?
- Polio has no cure: it is treated symptomatically, including rehabilitation to alleviate suffering

2.2.6 How is Polio prevented?

- Vaccination with oral polio vaccine (OPV) and/or inactivated polio vaccine (IPV). Ghana has added one dose of IPV to the routine immunisation (RI) schedule as recommended by WHO.

2.2.7 Polio vaccine and vaccination

- **OPV** is a live attenuated (weakened) poliovirus vaccine containing polio 1, 2 and 3 in isolation or in combination. Ghana currently uses only bOPV containing polio 1 and 3.
- It is supplied in multi-dose vials and administered orally in 2 drops
- It is heat-sensitive and must be kept strictly between +2 °C and +8 °C at the district and facility levels
- **IPV** is an inactivated poliovirus vaccine containing all three types of polio virus.
- It should be stored between +2 °C and +8 °C. It is freeze sensitive (must not be frozen).
- It is supplied in one-, five- or ten-dose vials.
- IPV is injected intramuscularly as a 0.5 ml dose; anterolateral (outer) mid-thigh in children and children
- OPV and IPV are safe:
- There is a small risk of vaccine-associated paralytic polio (VAPP) occurring in approximately 1 in 3 to 4 million doses associated with the first dose of OPV. This risk declines further with subsequent doses.
    - In areas of low vaccination coverage, there is a very rare risk that the weakened viruses contained in OPV can begin to circulate and regain the ability to cause paralytic cases. This is known as circulating vaccine-derived poliovirus (cVDPV).
    - IPV is one of the safest vaccines in routine use. No serious adverse events have been linked to it. Mild events include injection site redness, swelling and soreness.
- **Schedule:** 3 to 4 OPV doses are given in infancy during RI. Birth dose of OPV is given at birth or soon after (Do not give after 2 weeks of age). Subsequent doses (OPV-1, 2 and 3 are given at 6, 10 and 14 weeks respectively). Additional OPV doses are required after the primary doses in children under 5.
    - **IPV is given IM at 14 weeks (with OPV)**
- **Contraindications:** Known hypersensitivity (allergy) or anaphylaxis to a previous dose. Postpone vaccination if the child has moderate to severe illness.

Box 2.2: Key points about Polio

- Polio affects spinal nerves and can cause paralysis and death
- It is spread through faeco-oral route air
- Symptoms/signs include fever, headache, sore throat and sudden onset floppiness of the limbs
- Treatment: Rehabilitation only. No treatment is available to reverse paralytic polio. victims are crippled for life.
- The recommended method of polio prevention for children is OPV and/or IPV vaccine.

2.3 Diphtheria

2.3.1 What is diphtheria and what causes it?

- Diphtheria is serious bacterial infectious disease caused by Corynebacterium diphtheriae
- This bacterium produces a toxin that can harm or destroy human body tissues and organs.
- Patients develop throat (and sometimes, tonsil) infection or ulcers (sores) on the skin.

2.3.2 How is diphtheria transmitted (Spread)?

- Through close respiratory (sneezing, coughing) or physical contact with an infected person.

5 Polioeradication.org
6 Due to the eradication of the type 2 polio virus, tOPV (containing polio viruses 1, 2, 3) was withdrawn globally in 2016
7 OPV is kept frozen at the Regional and National Stores

2.3.3 Who is affected, when, where are they affected, what are the risk factors of diphtheria?

- Can affect anybody but particularly unimmunised children.
- It occurs worldwide: in temperate regions, diphtheria is commoner in the colder months; diphtheria skin ulcers are more common in the tropics

2.3.4 Incubation, Signs and Symptoms and Clinical spectrum of diphtheria

Incubation period: Averagely 2-5 days. May be longer.

Signs and Symptoms:

- **Throat/Tonsils infection:-** mild fever, anorexia (loss of appetite) and sore throat, greyish membrane in the throat that tends to bleed; swollen neck; blocked airway may lead to death. Some may develop chronic heart disease leading to heart failure
- **Skin:-** ulcers

2.3.5 How is diphtheria treated?

- Diphtheria anti-toxin and appropriate antibiotics. Children with diphtheria should be isolated

2.3.6 How is diphtheria prevented?

- Vaccination with Pentavalent vaccine (DPT-Hib-HepB). Achieving high level community immunisation coverage is key to prevention.
- Td in pregnant women offers booster to diphtheria

2.3.7 Diphtheria vaccine and vaccination

- There are several diphtheria-containing vaccines: Pentavalent and Td are used in Ghana's EPI.
- They are freeze-sensitive and must be stored between +2 °C and +8 °C: if freezing is suspected, perform the "Shake Test" to determine whether a vial is safe to use (see Chapters 3 & 4).
- Pentavalent is a multi-dose vial subject to open multi-dose vial policy (see Chapters 3 & 4)
- Penta and Td are administered as 0.5 ml doses: Penta is given IM in the anterolateral (outer) thigh in children and Td in the deltoid muscle (upper arm) of women in reproductive age/pregnant
- Pentavalent and Td vaccines are safe: severe adverse events due to diphtheria vaccine alone have not been reported. Mild events include local reactions– pain, redness and swelling.
- **Schedule:** Penta is given in three-dose primary series at 6, 10 and 14 weeks; two doses of Td are given at least one month apart during pregnancy in unimmunised women (see Chapter 1 on Td Schedule)
- **Contraindications:** Known hypersensitivity (allergy) or anaphylaxis to a previous dose. Postpone vaccination if the child has moderate to severe illness.

Box 2.3: Key points about Diphtheria

- Diphtheria affects throat and skin
- It is spread through respiratory droplets or close contact
- Throat symptoms/signs include fever, lack of appetite, sore throat, swollen neck, airway blockage, heart disease and death; skin infection leads to ulcers
- Treatment: Diphtheria antitoxin and antibiotics
- Can be prevented through high coverage of diphtheria containing vaccine (E.g. Penta, Td).

2.4 Pertussis (Whooping cough)

2.4.1 What is Pertussis and what causes it?

- Pertussis is a bacterial infectious disease caused by Bordetella pertussis
- 3-4 year cyclical epidemics (outbreaks) have been reported in countries with low vaccination coverage

2.4.2 How is Pertussis transmitted (Spread)?

- Through close respiratory contact (sneezing, coughing) with an infected person.

2.4.3 Who is affected, when, where are they affected, what are the risk factors of pertussis?

- It occurs worldwide but commonest in areas with low immunisation coverage
- Can affect anybody but particularly unimmunised children under 6 months.

2.4.4 Incubation, Signs and Symptoms and Clinical spectrum of Pertussis

Incubation period: Averagely 10 days. Range 7-21 days.

Signs and Symptoms:

- **Catarrhal stage:-** similar to a common cold with runny nose, watery eyes, sneezing, mild fever and a mild cough.
- **Paroxysmal stage:-** repeated violent cough (cough spells) with characteristic "whoop" (whooping cough) often accompanied by vomiting, seizures (convulsions) in children; the eyes may redden; may complicate with pneumonia

2.4.5 How is Pertussis treated?

- Pertussis is treated with antibiotics and plenty of fluids to reduce severity and limit spread

2.4.6 How is Pertussis prevented?

- Vaccination with Pentavalent vaccine (DPT-Hib-HepB). Achieving high level community immunisation coverage is key to prevention

2.4.7 Pertussis vaccine and vaccination

- Ghana's EPI has Pentavalent (DPT-Hib-HepB) which contains whole-cell pertussis as the only Pertussis-containing vaccine [See section 2.3.7]

Box 2.4: Key points about Pertussis

- Pertussis is a bacterial infection that affects the respiratory tract
- It is spread through respiratory droplet or close contact
- Symptoms/signs include repetitive cough with characteristic "whoop".
- Usually more severe in children and young children in whom the disease may be fatal
- Treatment: Antibiotics
- Can be prevented through high coverage of pertussis-containing vaccine (Penta).

2.5 Tetanus (Lock-jaw)

2.5.1 What is tetanus and what causes it?

- Tetanus is a bacterial disease caused by the Clostridium tetani (tetanus bacillus).
- A toxin released by the bacterium causes severe, painful muscle spasms that can lead to death.
- Maternal and neonatal (newborn) tetanus (MNT) is a serious problem in areas where deliveries in unclean environment or procedures are common (especially home deliveries): eradication remains difficult because the bacterium is found in the environment everywhere

2.5.2 How is tetanus transmitted (Spread)?

- Transmitted when soil enters a wound or cut (mostly deep/punctured/closed but affects superficial wounds as well).

2.5.3 Who is affected, when, where are they affected, what are the risk factors of tetanus?

- Tetanus spores are present in soil everywhere but infection is more common in Agricultural areas where there is regular contact with animal excreta.

- Can affect anybody but particularly neonates and mothers are at risk during delivery: MNT occurs frequently where there are unclean delivery practices (unclean floors, unclean blade is used to cut the umbilical cord, dirty material-cow dung, charcoal, herbal concoction etc.- is used to dress the cord, or unclean hands of the person delivering the baby.
- Children and children may also contract tetanus when unclean tools are used for circumcision, scarification and skin piercing, and unclean substances are rubbed into a wound

2.5.4 Incubation, Signs and Symptoms and Clinical spectrum of tetanus

Incubation period: Averagely **10** days (**6** days for Neonatal Tetanus-NNT). Range 3-21 days but can take a day to several months

Signs and Symptoms:

- **Neonatal tetanus (NNT):-** neonate sucks and cries well for the first few days after birth but stops feeding at three to 28 days of age due to lock-jaw: then becomes stiff, has severe muscle spasms and arched back (opisthotonus); area around the cord is reddened, sometimes with pus. There may be fever. Death usually follows.
- **Maternal/Adults/Children:-** stiff jaw (trismus or lock-jaw); difficulty swallowing, stiffness in neck, abdomen and/or back, muscle spasms (tetany), sweating and fever.

2.5.5 How is tetanus treated?

- Tetanus immunoglobulins (TIG) or anti-tetanus serum, antibiotics, wound management and supportive care
- Tetanus is a medical emergency; best managed in a referral hospital

2.5.6 How is tetanus prevented?

- MNT: improving maternity care - clean deliveries (**six cleans** at delivery: clean hands of the attendant, clean surface, clean blade to cut cord, clean cord clamp/tie, clean towel to dry and wrap the baby, clean cloth to wrap the mother), emphasis on skilled delivery
- Vaccination with childhood Pentavalent (DPT-Hib-HepB) and Td vaccines in pregnancy

2.5.7 Tetanus vaccine and vaccination

- Tetanus-containing vaccines used in Ghana's EPI are Pentavalent (DPT-Hib-HepB) and Td (See section 2.3.7)
- Non-immunised pregnant women should receive at least 2 doses of Td: first dose as early as possible in pregnancy; second dose at least 4 weeks later, preferably not less than two weeks before delivery (see Chapter 1 on Td Schedule)

Box 2.5: Key points about Tetanus

- Tetanus affects all ages but MNT remains a serious problem in areas with low coverage of tetanus-containing vaccine (Td) in pregnancy, and unclean delivery and cord care practices
- Occurs when bacteria spores contaminate wounds or cord from unhygienic delivery practices and circumcision
- Tetanus presents with poor feeding in neonates, twitching, lock-jaw, and stiffness
- NNT is usually fatal (most neonates with NNT will die)
- Treatment: TIG, anti-tetanus toxin/serum, antibiotics, supportive care in referral hospitals
- Can be prevented through high coverage of Td in pregnancy complemented with high skilled delivery coverage with hygienic and clean cord care practices.

2.6 Hepatitis B

2.6.1 What is hepatitis B and what causes it?

- Hepatitis B is viral infectious disease caused by Hepatitis B virus
- Hepatitis B infection can be acute or chronic and can lead to cirrhosis (liver damage) or liver cancer and death

2.6.2 How is hepatitis B transmitted (Spread)?

- Transmission is through blood and other body fluids
  - sharing infected contaminated sharps (needles, tattooing, circumcision)
  - during social interaction between children with cuts, bites, scratches
  - mother-to-child transmission at birth
  - transfusion of unscreened blood
  - sexual transmission in adults

2.6.3 Who is affected, when, where are they affected, what are the risk factors of hepatitis B?

- Can affect anybody but particularly newborns of infected mothers; intravenous drug use and unprotected sex with multiple sex partners, hospital-based work are risk factors (HCWs, dialysis patients, etc.)
- Occurs worldwide, endemic with little seasonal variation

2.6.4 Incubation, Signs and Symptoms and Clinical spectrum of hepatitis B

Incubation period: Averagely 60-90 days. Range: usually 6 weeks to 6 months. May be as short as 2 weeks to as long as 9 months

Signs and Symptoms:

- Asymptomatic in most cases especially young children; over 90% chronic carriage if infected at birth or early childhood
- **Acute:-** Fever (mild if present), anorexia, nausea, vomiting, abdominal pain, dark urine, jaundice (yellow eyes); raised liver enzymes; may die from liver failure
- **Chronic:-** may be asymptomatic; may lead to cirrhosis and liver failure, liver cancer

2.6.5 How is hepatitis B treated?

- No known treatment--supportive care; chronic hepatitis may sometimes be halted with medication (interferon and anti-viral agents)

2.6.6 How is hepatitis B prevented?

- Risk elimination
- Vaccination: WHO strategy for prevention is based on universal child immunisation. HepB (stand-alone) birth dose is recommended within 24 hours after birth. Pentavalent (DTP+HepB+Hib) vaccine should be given according to schedule.
- Full recovery from hepatitis B infection confers life-long immunity.

2.6.7 Hepatitis B vaccine and vaccination

- HepB vaccine comes as stand-alone or in combination with DPT (quadrivalent) or DPT-Hib (pentavalent)
- Currently, Ghana's RI schedule includes Pentavalent (DPT-Hib-HepB) for HepB prevention in children [See section 2.3.7] and is yet to introduce HepB birth dose. Hib and HepB were added to DPT as Pentavalent (DPT-Hib-HepB) in 2002.

Box 2.6: Key points about Hepatitis B

- Hepatitis B is a viral disease of the liver
- It is spread through exchange of body fluids (mother-to-child, unprotected sex, blood products, sharing of or accidental injury with contaminated sharps)
- Acute infection may manifest with jaundice; chronic carriage may lead to liver damage/cancer
- Treatment: supportive if acute; anti-viral agents are available for halting chronic carriage
- Can be prevented through vaccination (HepB stand-alone, Pentavalent).

2.7 Haemophilus influenzae type b disease

2.7.1 What is Hib disease and what causes it?

- ***Haemophilus influenzae* type b** (Hib) is a member of a family of six sub-types of ***Haemophilus influenzae* (HI)** bacteria identified by their outer coat
- Among the group, **type b** (Hib) is most important in terms of public health because it causes invasive diseases including pneumonia, meningitis and septicaemia (blood infection) especially in children under five years of age.
- HI is normally resident in the nose and throat

2.7.2 How is Hib transmitted (Spread)?

- It is transmitted by droplet infection through sneezing and coughing

2.7.3 Who is affected, when, where are they affected, what are the risk factors of Hib disease?

- Can affect anybody but almost exclusively affects children under five years
- Most at risk group: children 6 months to 2 years;
- Occurs worldwide; healthy carriers (children) can spread the infection to other children

2.7.4 Incubation, Signs and Symptoms and Clinical spectrum of Hib

Incubation period: 2-4 days

Signs and Symptoms:

- **Pneumonia:-** fever, chills, cough, rapid breathing and chest indrawing
- **Meningitis:-** fever, headache, vomiting, sensitivity to light (photophobia), altered consciousness, convulsions; bulging fontanelles is a late sign in very young children. Often complicates in neurological deficit (brain damage/abscess, hearing impairment, mental retardation)
- **Others:-** epiglottitis (inflammation of the laryngeal flap) may present with stridor or noisy breathing; septicaemia (blood infection) can lead to high fever, chills and may be fatal
- May be asymptomatic in many cases. Young children can be healthy carriers and transmit to other children.

2.7.5 How is Hib treated?

- Antibiotics and supportive care. There is widespread antibiotic resistance.

2.7.6 How is Hib prevented?

- Vaccination - Best before end of the 2nd year of life: Vaccine should be given according to schedule.

2.7.7 Hib vaccine and vaccination

- Currently, Ghana's RI schedule includes Pentavalent (DPT-Hib-HepB) for Hib prevention in children [See section 2.3.7]. Hib and HepB were added to DPT as Pentavalent (DPT-Hib-HepB) in 2002.

Box 2.7: Key points about *Haemophilus influenzae* type b (Hib) disease

- Hib is the most important of the six sero-types of *Haemophilus influenzae* bacteria
- It causes meningitis, pneumonia, epiglottitis and other blood-borne infections especially in young children
- It is spread through droplet infection by sneezing and coughing
- Many children can be healthy carriers, infecting other children
- Treatment: Antibiotics but there is widespread resistance
- Can be prevented through vaccination: Pentavalent (DPT-Hib-HepB)

2.8 Pneumococcal disease

2.8.1 What is pneumococcal disease and what causes it?

- Pneumococcal disease is a serious bacterial disease caused by *Streptococcus pneumoniae* (also called pneumococcus) of which there are over 90 sero-types.
- Pneumococcus is normally resident in the nose and throat of healthy individuals worldwide
- Pneumococcus is the commonest cause of community acquired pneumonia (CAP) in all ages. *S. pneumoniae* causes other invasive pneumococcal diseases (IPD) including meningitis and septicaemia (blood infection) especially in children under two years of age.
- Other diseases include otitis media (middle ear infection) and sinusitis (inflammation of the sinuses)
- Certain serotypes are known to cause IPD epidemics e.g. meningitis in Ghana

2.8.2 How is pneumococcus transmitted (Spread)?

- Person to person spread of pneumococcus through sneezing and coughing (droplet infection) is common but disease among casual contacts and attendants is infrequent

2.8.3 Who is affected, when, where are they affected, what are the risk factors for pneumococcus infection?

- Affects all ages but particularly young children (under 5) and elderly (over 55 years of age). Most vulnerable are children and children under 2 years and elderly in institutions
- It occurs worldwide in all climates and seasons but peaks in the colder months (winter in temperate zones and dry harmattan season in sub-Saharan Africa); highest burden in developing countries
- Risk factors for pneumococcal disease in children include low birth weight, lack of breastfeeding and exposure to respiratory irritants e.g. indoor smoke.
- Underlying medical conditions including malnutrition, HIV infection, sickle cell disease, asplenia (lack of a functioning spleen), cancers, other chronic disease (e.g. kidney, heart) and previous influenza virus infection are risk factors for all ages

2.8.4 Incubation, Signs and Symptoms and Clinical spectrum of pneumococcal infection

Incubation period: Varies but may be as short as 1-3 days.; usually preceded by asymptomatic carriage

Signs and Symptoms:

- **Pneumonia:-** fever, chills, cough, rapid breathing and chest indrawing
- **Meningitis:-** fever, headache, stiff neck, vomiting, sensitivity to light (photophobia), altered consciousness, convulsions; bulging fontanelles is a late sign in very young children. Fatality can be very high
- **Others:- septicaemia** (blood infection) can lead to high fever, chills and may be fatal; **middle ear infection** may present with fever, earache and discharge; **sinusitis** may present with fever and catarrhal symptoms (blocked nose, coloured nasal discharge) and facial pain/headaches.

2.8.5 How is pneumococcal disease treated?

- Appropriate antibiotics. Respiratory isolation may be needed for hospitalised patients with antibiotic resistant pneumococcal infection. Contact investigation is of no practical value.

2.8.6 How is pneumococcal disease prevented

- Avoiding crowding in households and institutions; appropriate hand hygiene and cough/sneeze etiquette; physical activity; proper ventilation; adequate nutrition and breastfeeding
- Vaccination with pneumococcal vaccines (e.g. Pneumococcal Conjugate Vaccine-PCV)
- Achieving high level community immunisation coverage can assist herd protection.
- Recovery from infection usually confers lasting sero-type specific immunity to the individual

2.8.7 Pneumococcal vaccine and vaccination

- There are two types of pneumococcal vaccines: Conjugate vaccines and polysaccharide vaccines (pneumococcal polysaccharide vaccine-PPV23). PCV-13 is used in Ghana's RI schedule and is described below.
- PCV-13 is a protein-polysaccharide conjugate vaccine containing 13 of the commonest strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). PCV protects against specific strains contained in the vaccine. It does not protect against non-vaccine strains
- It is highly effective in preventing IPD (meningitis, septicaemia, pneumonia) in recipients (direct effect) and non-recipients (herd effect).
- It is fully liquid, heat and freeze-sensitive and must be stored between +2 °C and +8 °C: if freezing is suspected, perform the "Shake Test" to determine whether a vial is safe to use (see Chapters 3 & 4).
- PCV-13 comes in single dose, 2-dose and 4-dose vials. Ghana **uses the 4-dose vial PCV**
- PCV-13 is administered as 0.5 ml dose and given IM in the anterolateral (outer) thigh in children.
- PCV-13 is safe: severe adverse events are rare. Mild events include fever and local reactions– pain, redness and swelling.
- **Schedule:** PCV-13 is given in three-dose primary series at 6, 10 and 14 weeks of age
- **Contraindications:** Known hypersensitivity (allergy) or anaphylaxis to a previous dose or vaccines containing diphtheria toxoid (Pentavalent; Td). Postpone vaccination if the child has moderate to severe illness.

Box 2.8: Key points about Pneumococcal Disease

- Pneumococcus causes IPD (pneumonia, meningitis, septicaemia), ear and respiratory infection
- It is known to cause outbreaks of meningitis in Ghana
- Many individuals carry the bacterium in their throat and nose but children <2 yrs are most at risk
- It is spread through droplet infection during sneezing and coughing
- Treatment: Antibiotics
- Can be prevented through vaccination: PCV

2.9 Rotavirus gastroenteritis (diarrhoea and vomiting)

2.9.1 What is rotavirus gastroenteritis and what causes it?

- Rotavirus gastroenteritis is a form of diarrhoea and vomiting disease caused by rotavirus, a highly infectious virus that affects mostly in children and young children
- Rotavirus gastroenteritis is associated with severe dehydration and death in young children

2.9.2 How is rotavirus transmitted (Spread)?

- Rotavirus is spread through faeco-oral route. Respiratory spread also been suggested.

2.9.3 Who is affected, when, where are they affected, what are the risk factors of rotavirus gastroenteritis?

- Mostly affects children under five years. By age 2, most children would have had their first or second infection.

- Occurs worldwide, endemic in both industrialised and developing countries; responsible for about two-thirds of severe diarrhoea leading to dehydration
- Peaks during colder seasons (winter in temperate zones and harmattan in sub-Saharan Africa)

2.9.4 Incubation, Signs and Symptoms and Clinical spectrum of rotavirus

Incubation period: Averagely 1-3 days.

Signs and Symptoms:

- Rotavirus gastroenteritis ranges from mild to severe diarrhoea and/or vomiting leading to dehydration, shock and death; may be preceded by fever. Diarrhoea may last 3-6 days

2.9.5 How is rotavirus gastroenteritis treated?

- No known treatment--supportive care: replacement fluids (ORS, homebased fluids, intra-venous infusion-IVF) and zinc therapy. Antibiotics are not recommended; anti-diarrhoeal agents are contraindicated

2.9.6 How is rotavirus disease prevented?

- Breastfeeding and adequate nutrition are recommended; improvements in sanitation and access to safe water are less effective for reducing rotavirus infections.
- Vaccination: Rotavirus vaccination has become important for prevention of severe rotavirus disease

2.9.7 Rotavirus vaccine and vaccination

- WHO has approved two rotavirus vaccines for use in RI: Rotarix® comes in both freeze-dried powder (lyophilised) and liquid forms. RotaTeq® comes only in liquid form. Both are live attenuated and do not protect against diarrhoea caused by other agents.
- Currently, Ghana's RI schedule includes liquid Rotarix for prevention of rotavirus diarrhoea and is described below.
    - Liquid Rotarix® is ready to use in an oral applicator or a squeezable tube.
    - It must be stored between +2 °C and +8 °C without being frozen
    - It is a single dose vial which should be used immediately after opening.
    - Rotarix is administered orally as 1.5 ml dose to children.
- Rotarix is safe and well tolerated. Intussusception (a type of bowel obstruction) is a very are adverse event which may be associated: presents with child becoming irritable, has abdominal pain, cries intermittently, vomits, may have blood in stools and is weak.
    - Intussusception (telescoping of one part of intestine into the next segment) occurs naturally, primarily in children; peak incidence is between four and 10 months of age; may be fatal if untreated. Hospital care is important.
- Mild adverse reactions include irritability, runny nose, ear infection, vomiting and diarrhoea.
- The benefits of the available rotavirus vaccines far outweigh the potential risks.
- **Schedule:** Liquid Rotarix is given in two doses at 6 and 10 weeks of age. To minimise risk of intussusception, the first dose should be given before the child is 20 weeks old and the second dose should be given before the child is 24 weeks old.

Contraindications: History of intussusception: It is practically difficult to obtain such history in many places. Therefore, it is recommended that rotarix be suspended for all children who have had abdominal surgery for unknown reasons.

Box 2.9: Key points about Rotavirus diarrhoeal diseases

- Rotavirus is a highly infectious virus which is associated with severe diarrhoea and vomiting leading to dehydration and death in children and young children
- It is spread through faeco-oral route and affects both developed and developing countries
- Treatment: non- specific; supportive with fluid replacement (ORS, homemade fluids, IVFs), zinc
- Can be prevented through vaccination (Rotavirus vaccines)- vaccination has taken a centre role in prevention as hygiene and safe water measures are ineffective in controlling rotavirus diarrhoea in particular

2.10 Measles

2.10.1 What is measles and what causes it?

- Measles is a highly infectious 'fever-rash' disease caused by measles virus
- It occurs in epidemics, mostly in children and young children
- Measles was widespread in the pre-vaccine era: incidence has drastically reduced due to highly effective measles-containing vaccines (MCV)

2.10.2 How is measles transmitted (Spread)?

- Measles is spread through air-borne droplets when an infected person coughs or sneezes, as well as through contact with items contaminated with nasal and throat secretions.

2.10.3 Who is affected, when, where are they affected, what are the risk factors of measles?

- Mostly affects unvaccinated children and young children (under five years) in under vaccinated communities.
- Occurs worldwide; there has been drastic reduction in measles cases and deaths due to widespread use of measles-containing vaccines.
- Transmission has been interrupted in the Americas but measles is still endemic in Africa and parts of Asia (over 90% of all measles cases are in developing countries).
- Peaks during dry seasons (harmattan in sub-Saharan Africa)
- Most at risk groups include malnourished children, displaced persons (refugee camps), children with vitamin A deficiency, persons with suppressed immune system (e.g. AIDS)

2.10.4 Incubation, Signs and Symptoms and Clinical spectrum of measles

Incubation period: Averagely 10-12 days. Range 7-18 days (Rash typically appears in 14 days but may be as late as 21 days).

Signs and Symptoms:

- *Prodromal or 'fore-warning' stage:* low grade fever, conjunctivitis (red eyes), cough, corhyza (runny nose), whitish spots inside the cheeks (Koplik's spots)
- *Rash stage:* high grade fever, a slightly raised rash on reddened or darkened base (maculopapular)- starts from the head and neck and spreads to the trunks and rest of body. Rash may last 4-7 days and usually peels off (desquamation)
- Measles is usually infectious four days before the first symptoms appear and four days after rash disappears. Up to half of infections may show no signs or symptoms but infected individuals may still be infectious.
- Complications: severe diarrhoea (can lead to dehydration and death); pneumonia, malnutrition, middle ear infection, blindness and encephalitis (brain infection - can take many months to occur)

2.10.5 How is measles treated?

- No known anti-viral treatment--supportive care: Vitamin A (two doses of supplement given 24 hours apart reduces risk of eye damage and blindness, and death); replacement fluids (ORS, homebased fluids, intra-venous infusion) and zinc therapy for diarrhoea; adequate nutrition (including breastfeeding); appropriate antibiotics for ear infection and pneumonia.
- Isolation is required to prevent spread to other children in hospitalised cases.

2.10.6 How is measles prevented?

- Vaccination: Achieving high community coverage of two-doses of Measles-containing vaccine (MCV) schedule and supplementary immunisation activities (SIA) are needed to prevent epidemics.
- Recovery from measles gives life-long immunity.

2.10.7 MCV and vaccination

- There are several MCVs: Measles alone-M; Measles/Rubella-MR, Measles/Mumps-MM, Measles/Mumps/Rubella-MMR, Measles/Mumps/Rubella/Varicella-MMRV
- Currently, Ghana's RI schedule includes measles-rubella (MR) at 9 months and 18 months and is described below.
- **MR** is supplied as freeze-dried (lyophilized) powder with separate diluents: must be reconstituted before use with only the diluent supplied
- Must be stored between +2 °C and +8 °C and protected from light and heat
- It is a multi-dose vial (Ghana currently uses 10-dose vials) which is subject to the opened Multi-Dose Vial policy (See Chapters 3 and 4 on MDVP)
- MR is safe. Rare cases febrile convulsions and of low platelets have been associated
  - Mild adverse reactions include fever, rash, local pain, swelling and redness
- **Schedule:** MR is administered as 0.5 ml dose in a two-dose schedule by subcutaneous injection: at 9 and 18 months in the shoulder region.

Contraindications: Known hypersensitivity (allergy) or anaphylaxis to a previous dose. Postpone vaccination if the child has moderate to severe illness; DO Not give MR to pregnant women or women planning pregnancy within one month

Box 2.10: Key points about Measles

- Measles is a viral 'fever-rash' disease caused by the measles virus
- It is highly infectious and tends to occur in outbreaks in areas with low MCV coverage
- It is spread through airborne droplets
- Infection manifests as rash preceded by fever with cough, red eyes or runny nose
- Complications: diarrhoea, pneumonia, blindness, malnutrition, brain infection
- Treatment: supportive - Vit A, adequate nutrition, fluids, antibiotics for pneumonia, ear infection
- Prevention: vaccination- high RI coverage and SIAs with MR or other MCVs.

2.11 Rubella and congenital rubella syndrome (CRS)

2.11.1 What are rubella and CRS and what causes it?

- Rubella (also called German Measles) is a highly infectious viral 'fever-rash' disease similar to measles but caused by rubella virus
- Rubella is a mild disease and is only important because of the risk of CRS if infection occurs in pregnancy
- *Congenital rubella syndrome (CRS)*: is a group of birth defects that occur when the rubella virus infects a foetus.

2.11.2 How is rubella transmitted (Spread)?

- Rubella is spread through air-borne droplets in coughs and sneezes, contact with items contaminated with nasal and throat secretions and from mother to the unborn child (trans-placental - leads to CRS).

2.11.3 Who is affected, when, where are they affected, what are the risk factors of rubella?

- Can affect anybody but the unimmunised, the immune-suppressed and the unborn child are at most risk
- 90% of children born to mothers who were infected within the first trimester develop CRS. The earlier the infection in pregnancy, the higher the risk.

- Occurs worldwide; there has been reduction in CRS cases due to the use of rubella-containing vaccines.
- Transmission has been interrupted in the Americas and Europe which are pursuing elimination goals. Rubella is still endemic in parts of Africa and other developing countries

2.11.4 Incubation, Signs and Symptoms and Clinical spectrum of rubella

Incubation period: Averagely 14-17 days. Range 14-21 days (May be as late as 23 days).

Signs and Symptoms:

- *Prodromal or 'fore-warning'* symptoms are generally rare especially in children but low grade fever and swollen lymph nodes (behind the ear and neck) may occur in adults; joint pains or arthritis usually occur in young women. If red eyes or runny nose is present, it is usually mild.
- *Rash stage:* high grade fever, a slightly raised rash on reddened or darkened base (maculopapular)- starts from the face and spreads to the limbs; rash may last about a week but unlike measles, do not come together (do not coalesce).
- *Congenital Rubella Syndrome:* manifestations include cataract, congenital glaucoma, heart defects, deafness, microcephaly (abnormally small head and mental retardation), other major organ involvement. Infection in early pregnancy may lead intrauterine foetal death and miscarriage.
- Rubella is usually infectious a week before the first symptoms appear and up to two weeks after rash disappears. Children with CRS may shed the virus for months
- Up to half of infections may show no signs or symptoms but infected individuals may still be spreading the disease.
- Complications: are rare in children but may occur in adults – e.g. brain infection, bleeding problems

2.11.5 How are rubella and CRS treated?

- No known anti-viral treatment: supportive care to reduce suffering
- Isolation is required to prevent spread to other children. Exposed pregnant women should be followed up.

2.11.6 How is rubella prevented?

- Vaccination: a single shot of rubella vaccine gives life-long immunity. Achieving high community coverage of rubella-containing vaccine (above 80%) is important in CRS prevention.
- Recovery from rubella gives long-term immunity.

2.11.7 Rubella and vaccination

- There are several Rubella-containing vaccines: Rubella alone-R; Measles/Rubella-MR, Rubella/Mumps-RM, Measles/Mumps/Rubella-MMR, Measles/Mumps/Rubella/Varicella-MMRV. The goal of any rubella vaccination programme is the elimination of CRS
- Currently, Ghana's RI schedule includes measles-rubella (MR) at 9 months and 18 months, giving a second opportunity to children to be immunised against rubella. (See section 2.10.7).

Box 2.11: Key points about Rubella and Congenital Rubella Syndrome (CRS)

- Rubella is a highly infectious viral 'fever-rash' disease caused by the rubella virus
- It is spread through airborne droplets and through the placenta to the unborn child
- Rubella is a mild disease but when it occurs in pregnancy, it causes CRS
- CRS is a group of birth defects that occur when the rubella virus infects an unborn child
- Treatment: supportive to reduce suffering
- Prevention: vaccination- high RI coverage of MR is important in eliminating CRS

2.12 Yellow fever

2.12.1 What is yellow fever and what causes it?

- Yellow fever is a viral haemorrhagic disease caused by yellow fever virus
- It can occur in epidemics, mostly in forest and humid savanna areas of Africa and forest regions in South America

2.12.2 How is yellow fever transmitted (Spread)?

- Yellow fever is spread through bites of several species of Aedes (Africa, Central and South America) and Haemagogus (Central and South America) mosquitoes. Three transmission cycles have been described.
- **Forest (sylvatic or jungle):** Occurs among non-human primates (monkeys) in the wild but humans get accidentally infected in the forest through the bites of mosquitoes that have previously fed on infected non-human primates (E.g. farmers, loggers visiting the forest and savanna regions in Africa and forest areas in Central and South America)
- **Intermediate:** Occurs when infected semi-domestic mosquitoes feed on both monkeys and humans
- **Urban yellow fever:** Mosquitoes spread the disease from person to person causing large epidemics in crowded urban areas

2.12.3 Who is affected, when, where are they affected, what are the risk factors of yellow fever

- Affects anybody but mainly people in endemic areas of Africa and South/Central America
- Risk factors: persons living in endemic zones; persons with forest occupations e.g. farmers, lumbermen/lumberjacks

2.12.4 Incubation, Signs and Symptoms and Clinical spectrum of yellow fever

Incubation period: Averagely 3-6 days.

Signs and Symptoms:

Many infections go un-noticed or are asymptomatic.

- Of those that show signs/symptoms, most are mild and include fever, headache, chills, anorexia, nausea, vomiting and fatigue. Some develop jaundice (Yellow eyes)
- Toxic phase (15% of clinically apparent infections): Yellow eyes; bleeding tendencies (gums, nose etc.); major organ failure (e.g. liver, kidneys)
- Disease generally lasts two weeks after which patients recovers or dies. Half of those who develop toxic or severe symptoms die.

2.12.5 How is yellow fever treated?

- No known anti-viral treatment--supportive care: Replacement fluids (ORS, intra-venous infusion); adequate nutrition; appropriate antibiotics for additional infection.
- Isolation is not required but patients should sleep in mosquito nets to prevent mosquito bites and spread of the virus.

2.12.6 How is yellow fever prevented?

- Vaccination: One dose is protective for life. Achieving high routine child vaccination and preventive vaccination in high risk areas is important in achieving herd immunity.
- Mosquito control can reduce the risk of yellow fever in urban areas.
- Epidemic preparedness and response: Early detection of outbreak and prompt reactive vaccination prevents further spread of yellow fever

2.12.7 Yellow fever and vaccination

- Ghana's RI schedule includes YF at 9 months
- **YF vaccine** is supplied as freeze-dried (lyophilized) powder with separate diluents: must be reconstituted (only with its own supplied diluent) before use.

- Must be stored between +2 °C and +8 °C and protected from light and heat
- It is a multi-dose vial (Ghana currently uses 10-dose vials) which is subject to the opened Multi-Dose Vial policy (See Chapters 3 and 4 on MDVP)
- **YF vaccine** is safe. Rare cases of severe adverse events including anaphylaxis, acute neurotropic disease (AND) and acute viscerotropic disease (AVD) have been associated (See section on Vaccine Safety: AEFI).
  - o Mild adverse reactions include fever, local pain, swelling and redness
- **Schedule:** YF vaccine is administered as a single 0.5 ml dose schedule by subcutaneous injection in the shoulder region from 9 months in routine immunisation and to adults. No booster is needed (per new WHO guidelines).
- **Contraindications:** Known hypersensitivity (allergy) or anaphylaxis to a previous dose; severe egg allergy; people with severe immunodeficiency due to symptomatic HIV/AIDS or other causes (e.g. thymus disorder)
- Postpone vaccination if the child has moderate to severe illness;
- DO Not give YF vaccine to pregnant or lactating women or women planning pregnancy within one month except in outbreak when the risk of infection is high.

Box 2.12: Key points about yellow fever

- Yellow fever is a viral haemorrhagic disease
- It is spread by infected mosquitoes primarily in tropical zones of Africa, Central and South America.
- YF symptoms and signs can range from none to toxic liver and kidney failure that leads to death
- No specific antiviral treatment is available: treatment is supportive-adequate nutrition, fluids, antibiotics for superinfection
- Prevention: YF vaccine is effective as a single dose and should be given to all eligible people aged nine months or more living in or travelling to endemic areas

2.13 Meningococcal disease

2.13.1 What is meningococcal disease and what causes it?

- Meningococcal disease commonly manifests as meningitis, an inflammation of the meninges (membranes covering the brain and spinal cord)
- It is caused by the bacterium *Neisseria meningitidis* (also known as the meningococcus).
- Each *Neisseria meningitidis* bacterium has a capsule (or outer coat) and, depending on the type of this capsule, it is put in a serogroup.
- *Neisseria meningitidis* serogroups A, B, C, X, W and Y cause most cases of meningococcal meningitis.
- Before mass preventive vaccination campaigns, 8 to 9 out of 10 cases of meningitis occurring in the meningitis belt were due to group A meningococcus, with huge epidemics occurring at intervals of 7–14 years. After mass Men A vaccination campaigns, the proportion of the A serogroup has declined drastically.
- The meningococcus bacterium also causes septicaemia (bloodstream infection), which is more severe and often fatal (leads to death) but is less common.

2.13.2 How is meningococcus transmitted (Spread)?

- Meningococcus is spread from person to person through sneezing and coughing (droplet infection) during prolonged contact with carriers

2.13.3 Who is affected, when, where are they affected, what are the risk factors for meningococcus infection?

- Affects all ages but particularly young children. Children are the most vulnerable

- It occurs worldwide in all climates and seasons but peaks in the colder months (winter in temperate zones and dry harmattan season in sub-Saharan Africa;
- In the sub-Saharan Africa meningitis belt (which extends from Senegal to Ethiopia), epidemics occur every two to three years.
- Risk factors for meningococcal disease include crowding and exposure to respiratory irritants e.g. indoor smoke.

2.13.4 Incubation, Signs and Symptoms and Clinical spectrum of meningococcal disease

Incubation period: Usually 3-4 days but can range from 2-10 days usually preceded by asymptomatic carriage

Signs and Symptoms:

- **Meningitis:-** fever, headache, stiff neck, vomiting, sensitivity to light (photophobia), altered consciousness, convulsions; bulging fontanelles is a late sign in very young children. Fatality can be over 50% without treatment. Even with prompt treatment, 10-15% of patients will die and 10-20% of survivors will live with complications including hearing impairment, mental retardation, brain abscess.
- **Septicaemia** (blood infection or meningococcaemia) can lead to high fever, chills; petechial haemorrhages (bleeding into the skin) and may precede meningeal signs.
- **Others:-** pneumonia and other infections are rare but can occur

2.13.5 How is meningococcal disease treated?

- Appropriate antibiotics and supportive treatment. Meningitis is a medical emergency and needs prompt treatment. Respiratory isolation may be needed for hospitalised patients.

2.13.6 How is meningococcal disease prevented?

- Avoiding crowding in households and institutions; appropriate hand hygiene and cough/sneeze etiquette; physical activity; proper ventilation; adequate nutrition including breastfeeding
- Vaccination with meningococcal vaccines (e.g. Meningococcal Conjugate Vaccine)
- Achieving high level community immunisation coverage can assist herd protection.
- Recovery from infection may confer sero-type specific immunity to the individual but with uncertain duration
- Effective surveillance and response including contact tracing is key to prevention and control.

2.13.7 Meningococcal vaccine and vaccination

- Vaccines are available to protect against meningococcal serogroups A, C, W and Y in combination (e.g. tetra or quadrivalent ACYW, trivalent ACW or bivalent AC) or monovalent (A or C).
- There are two types of meningococcal vaccines: Conjugate vaccines and polysaccharide vaccines (Conjugate vaccines are preferred because they confer herd immunity; polysaccharide vaccines are usually used for outbreak response).
- Men A Conjugate Vaccine (MenAfriVac) has recently been introduced into Ghana's RI schedule and is described below.
- MenAfriVac (Men A) vaccine is a protein-polysaccharide conjugate vaccine containing type A meningococcus
    - It is highly effective in preventing Men A disease in recipients (direct effect) and non-recipients (herd effect). It does not protect against other serotypes
    - It is lyophilized (powdered) and must be reconstituted with its own diluent.
    - It is heat sensitive and must be stored between +2 °C and +8 °C
    - Men A comes in 10-dose vials and is subject to the open MDVP
    - Men A is safe: severe adverse events including anaphylaxis, are rare. Mild events include fever and local reactions– pain, redness and swelling.
- **Schedule:** Men A is administered as 0.5 ml dose and given deep IM in the shoulder region in children at 18 months in Ghana.

- **Contraindications:** Known hypersensitivity (allergy) or anaphylaxis to a previous dose or vaccines containing tetanus toxoid (Pentavalent; Td). Postpone vaccination if the child has moderate to severe illness.

Box 2.13: Key points about Meningococcal Disease

- Meningococcal disease is caused by *Neisseria meningitidis* or meningococcus
- It most commonly shows as meningitis but can also manifest as septicaemia
- Meningococcal meningitis is known to occur as outbreaks in Africa's meningitis belt which includes northern parts of Ghana; children and young children are most at risk but it affects all ages
- It is spread through droplet infection during sneezing and coughing by carriers
- Meningococcal meningitis typically presents with sudden-onset severe headache, fever, stiff neck., vomiting, and sensitivity to light; children may not show typical symptoms but may be irritable and feed poorly; a petechial rash is a sign of meningococcal septicaemia.
- Treatment: Antibiotics; meningitis is a medical emergency and needs prompt treatment
- Common types can be prevented through vaccination. Conjugate vaccines are prefered due to herd immunity. Men A (MenAfriVac) vaccine is used in RI in Ghana for preventing type A infection in children

2.14 Vitamin A

- Vitamin A is essential for normal body function
- Vitamin A deficiency (VAD) is prevalent in Ghana.
- EPI offers an opportunity to offer Vitamin A supplementation and prevent VAD.

2.14.1 What are the uses of Vitamin A and the consequences of Vitamin A defificiency VAD?

- Vitamin A is an important vitamin for the human body.
- It is essential for the functioning of the immune system, the healthy growth and development of children and is required for proper vision (eyesight).
- All the Vitamin A the body needs must come from the food we take in
- Lack of vitamin A, or VAD can result in poor night vision and reduced immune function leading to all kinds of diseases.

2.14.2 What are the sources of Vitamin A?

- The sources of Vitamin A include the following:
  - Animal sources: breast milk; liver, eggs, meat, fish liver oil, milk, cheese and other dairy products
  - Plant sources: yellow and orange fruits and vegetables: e.g. mangoes, papayas, 'dawadawa', pumpkins and carrots; green, leafy vegetables e.g. 'kontomire', 'alefu'; red palm oil
  - Foods can be fortified with Vitamin A during processing. Such foods include sugar, vegetable oil and wheat flour.

2.14.3 Who is affected by VAD, when and where are they affected, what are the risk factors?

- Vitamin A deficiency occurs when a person does not eat enough food containing vitamin A or when the body uses it up too fast; such as during illness, during pregnancy and lactation, and when children's growth is most rapid – from six months to five years of age
- VAD is common in lower income countries e.g. Ghana

2.14.4 How is VAD prevented?

- Eating (feeding the child) Vitamin A rich foods (See Section 2.14.2)

- Provision of Vitamin A supplements every six months to children is an effective way to prevent VAD and reduce child morbidity and mortality
- In Ghana, Vitamin A is given to children from 6 months of age and is repeated every 6 months until the child is 5 years. This is linked with routine immunisation

Box 2.14: Key points about Vitamin A

- Vitamin A is essential for normal body function. Lack of Vitamin A causes illnesses and blindess
- Green leafy vegetables, yellow and orage fruits/vegetables, liver, poultry and dairy products are rich sources of Vitamin A
- Vitamin A deficiency occurs when a person does not eat enough food containing vitamin A or when the body uses it up too fast e.g. when the child is growing rapidly or during illness
- VAD is prevented by food fortification with vitamin A and/or Vitamin A supplementation
- In Ghana, Vitamin A supplementation is linked with EPI and is given to children from 6 months of age and is repeated every 6 months until the child is 5 years.

CHAPTER THREE

Cold Chain and Logistics

3.1 Introduction

The cold chain or the vaccine (immunisation) supply chain is the system used for storing vaccines to keep them in good condition. It consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges, from the point of manufacture to the point of administration.

Some vaccines are sensitive to freezing, some to heat and others to light. Vaccine potency can reduce when the vaccine is exposed to inappropriate temperatures. To maintain quality, vaccines must be protected from temperature extremes because lost potency cannot be regained.

Table 3-1 shows the temperature sensitivity of vaccines on the immunisation schedule.

Table 3-1: Vaccine sensitivity

Freeze sensitive	Light sensitive	Heat sensitive
Pentavalent Hepatitis B Inactivated polio vaccine (IPV) Pneumococcal conj. Vaccine Rotavirus Tetanus-diphtheria	BCG Measles-rubella	Oral polio vaccine (OPV) Measles-rubella Yellow Fever BCG Meningitis A conj. vaccine

3.2 How to Monitor the Cold Chain

All vaccines should always be stored and transported in the cold chain at a temperature between +2° C and +8° C at all levels of service delivery. The only exception is oral polio vaccine (OPV), which must be stored at freezing temperatures at the national and regional levels ONLY.

The freezing compartment of vaccine refrigerators should be used for freezing ice packs only. The transportation and storage of vaccines must be monitored at all levels to ensure vaccines given to children and women are potent. The recommended vaccine storage temperatures and arrangement is shown in Figure 3-1.

Figure 3-1: Vaccine storage temperatures per for service delivery levels

<table>
<tr><td rowspan="2">Vaccine</td><td rowspan="2">National</td><td colspan="2">Intermediate</td><td rowspan="2">Health Centre</td><td rowspan="2">Static Clinic/ Outreach</td></tr>
<tr><td>Region</td><td>District</td></tr>
<tr><td>6 months</td><td>3 months</td><td>1 month</td><td>1 month</td><td>Daily Use</td></tr>
<tr><td>OPV</td><td colspan="5">-15°C to -20°C</td></tr>
<tr><td>BCG
Measles-Rubella
Yellow Fever
DPT-HepB-Hib (Penta)
Pneumococcal Conj. Vaccine (PCV)
Meningococcal A Conj. Vaccine
Rotavirus
Tetanus-diphtheria (Td)
Inactivated Polio Vaccine (IPV)</td><td colspan="5">+ 2°C to +8°C</td></tr>
<tr><td>Diluent</td><td colspan="3">Store at Room Temperature</td><td colspan="2">Cool to same temp as vaccine a day before use</td></tr>
<tr><td colspan="6">Penta, PCV, Td and diluents must NEVER be frozen. Always store them in the top basket in the refrigerator</td></tr>
</table>

3.3 Monitoring the temperature in the Refrigerator

The temperature monitoring devices that are used at all levels are stem thermometer, fridge tag and vaccine vial monitor (VVM).

3.3.1 Using stem thermometers

Always hang the stem thermometer in the middle of the fridge to monitor the temperature in it. Check and record the temperature in your fridge twice daily (morning and evening), including weekends and holidays and record the reading on the appropriate temperature monitor chart. If the vaccines have been exposed to too high (more than +8° C) or too low temperatures (less than +2° C), take immediate action as necessary.

One temperature monitor chart should be used for every month. File the completed temperature monitor chart and keep it for at least three years.

Figure 3-2: Stem thermometer

3.3.2 Fridge Tags

This is a continuous temperature-monitoring device that shows daily minimum and maximum temperatures over a period of 30 days and the current temperature in the refrigerator. The temperatures for the last 30 days are read directly from the fridge tag.

3.3.3 Features of a Fridge tag

- It provides an LCD display of temperature
- Stores up to 30 days temperature recordings that can be checked in history mode
- Has a pre-set alarm which sounds when the temperature goes above 8ºC for more than 10 hours continuously or when the temperature goes below -0.5ºC for more than 1 hour continuously
- Displays highest and lowest temperatures reached in a day as well as alarm episodes (if it occurred)

Figure 3-3: Fridge Tag (operation mode)

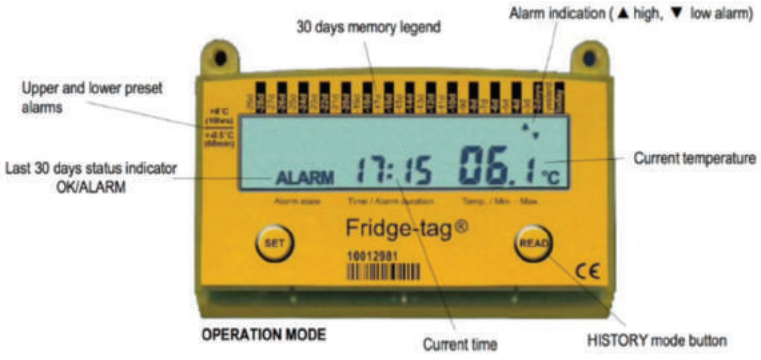
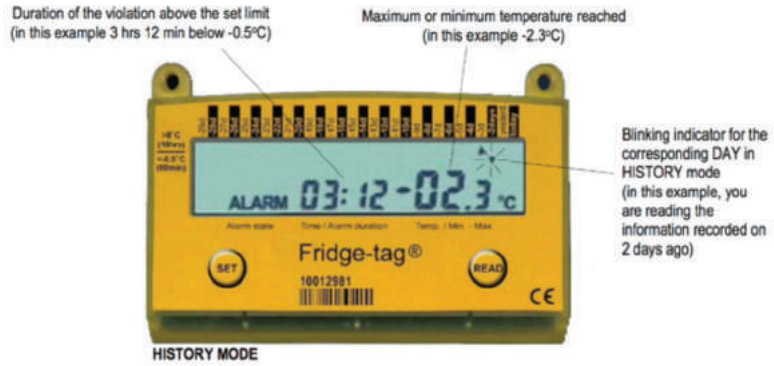


Figure 3-4: Fridge Tag (history mode)



3.3.4 How to use the fridge tag

Activating the device

The device comes in “sleep mode”. The LCD screen is blank. To activate the device press the SET and the READ buttons simultaneously for more than 2 seconds. Four zeros will appear on the screen. The first zero will flash.

Setting the time

Use the READ button to adjust the time. Each time you press the READ button, the number in the flashing digit will increase by 1. For example, if you want to set the time to 12:42 you have to perform the following steps:

1. The first digit is flashing: Press READ once. “1” will appear as the first digit. Press SET to save.
2. The second digit will start flashing. Press READ two times, when “2” appears as the second digit press SET to save. The third digit will start flashing. Press READ four times to set the digit as “4”. Press SET to save.
3. The last digit will start flashing. Press READ two times to obtain “2”. Press SET to save.

If during this operation, you press READ more then you were supposed to, continue pressing the READ button until you obtain the desired number, then press SET button to save your settings.

When you finish setting the time, the “°C” sign (degree celsius) will appear and blink at the right bottom corner. Press SET to record and read temperatures in Celsius. This will complete your activation.

3.3.5 The Vaccine Vial Monitor (VVM)

A vaccine vial monitor (VVM) is a 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 exposed to heat.

All vaccines used in the EPI Programme have VVM attached to them. The VVM is printed on the vial label, cap or on the conical tip. It normally appears as a white square inside a purple circle. As the vaccine vial is exposed to more heat, the square becomes darker.

Figure 3-5: VVM on vial label or cap

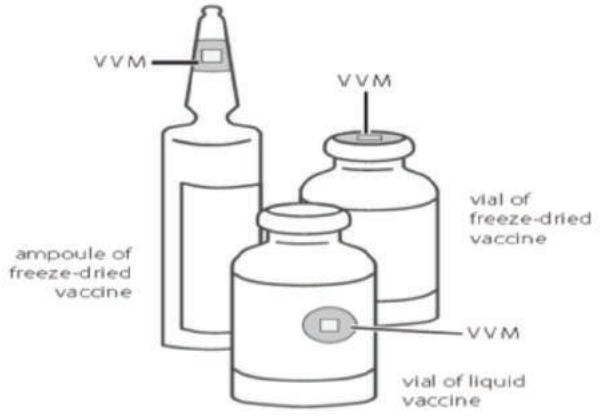


Figure 3-6: Interpretation of VVM

3.4 Dealing with suspected heat exposure

Check and record the VVM status when receiving vaccines. If the VVM indicates stage 2 accept few quantities and use them first. Do not accept any vaccine in VVM stages 3 and 4.

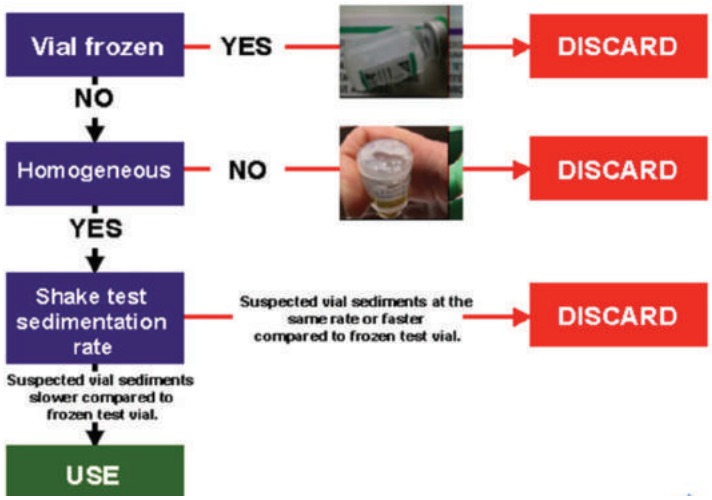
If a cold chain manager finds vaccines in VVM stages 3 or 4 in his/her refrigerator, these vaccines should be removed from the refrigerator, recorded in the vaccine stock ledger and sent to the next higher level through to the national level for disposal.

If the ice packs in your vaccine carrier have melted but the VVM has not reached discard point, return the vaccines into the refrigerator and indicate 'use first' so that they will be used first during the next session.

3.5 Dealing with suspected exposure to freezing: the shake test

The shake test is designed to determine whether a vaccine has been previously frozen. If freezing of any vaccine is suspected, use the algorithm below to determine whether a shake test is necessary or the vaccine can be discarded without needing a shake test.

Figure 3-7: Algorithm for determining the need to discard or conduct shake test



After freezing, the vaccine is no longer a uniform cloudy liquid (Homogenous), but tends to form flakes, which gradually settle at the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial which has been frozen compared to a vaccine vial from the same manufacturer that has never been frozen.

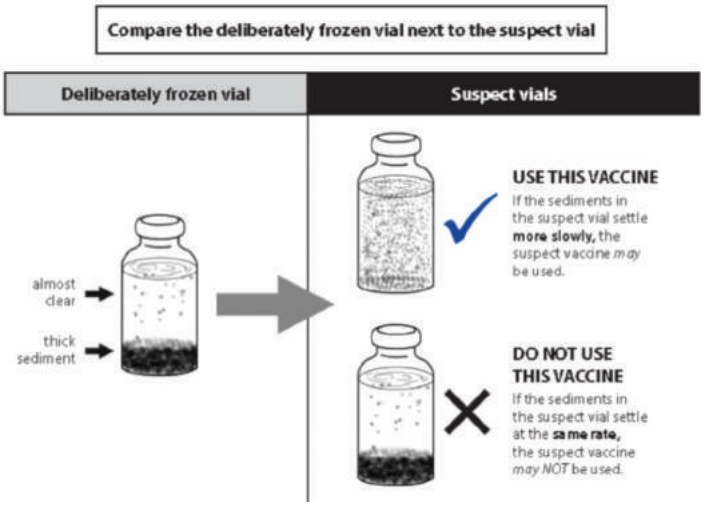
Note that individual batches of vaccine may behave differently from one another. Therefore the test procedure described below should be repeated with all suspected batches[8].

Test procedure:

- Prepare a frozen control sample: Take a vial of vaccine of the same type and batch (made by the same manufacturer) as the vaccine you suspect to have been frozen. Clearly mark the vial to differentiate it from the test vial as well as other vaccines. Intentionally freeze this vial until the contents are solid, and then allow it to thaw. This vial is the control sample.
- Choose a test sample: Take a vial of vaccine from the batch that you suspect to have been frozen. This is the test sample
- 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
- Allow to rest: Leave both vials to rest.
- Compare the vials: compare the rate of sedimentation between the two vials. If the test sample shows a much slower sedimentation rate than the control sample, the test sample is probably potent and may be used. If the sedimentation rate is similar and the test sample contains flakes, the vial under test has probably been damaged by freezing and should not be used. 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 sample and reference vials upside down and observe sedimentation taking place in the neck of the vial

8 In the case of international arrivals, the shake test should be conducted on a random sample of vaccines. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.

Figure 3-8: Shake test



Subsequent action: If the test procedure indicates that, freezing has damaged the test sample, you should notify your supervisor immediately. Standard Operating Procedures should then be followed to ensure that all damaged vaccines are identified and that none of this damaged vaccine is distributed or used.

3.6 Transportation of vaccines

Transportation of vaccines for duration of more than 4 hours should be done with a refrigerated van. The temperature of the refrigerated van should be monitored with a dial thermometer.

3.7 Adjusting the temperature of refrigeration equipment

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 freezer closes properly. The seal may be broken.
- Check freeze-sensitive vaccines to see whether they have been damaged by freezing by using the shake test
- Make sure that the refrigerator is working. If not, check if kerosene, gas or power supply is present.
- Check whether the door of the refrigerator or the freezing compartment closes properly. The seal may be broken.
- Check whether frost is preventing cold air in the freezing compartment from entering the refrigerator compartment. Defrost if necessary.

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

Turn the thermostat knob so that the arrow points to a higher number. This will make the refrigerator cooler. Once you can see that the daily temperature range remains consistently between +2 °C and +8 °C, the thermostat is correctly adjusted and the setting should not be changed, even if electrical power is lost.

If the temperature cannot be maintained between +2ºC and +8ºC, store vaccines in another place until the refrigerator is repaired.

Any time the refrigerator is not cooling at all, is not cold enough (above +8°C) or is too cold (below +2°C), please report immediately to your supervisor. Be ready to transfer the all vaccines to a different refrigerator or next level. For health facilities ensure that vaccines are immediately transferred into vaccine carriers or cold boxes.

3.8 Routine maintenance of the refrigerator

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. 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 most heat-sensitive vaccines (OPV, measles-rubella, BCG, yellow fever) and transfer them to a cold box lined with frozen ice-packs.
- Take out all the freeze-sensitive vaccines (Penta, Td, PCV, Men A, IPV, Rotarix) and diluents, 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 hot 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.

NOTE: if you have to defrost your refrigerator more than once a month, the door is probably opened too often. If this is not the case, contact your supervisor for technical check-up by a cold chain technician.

If the refrigerator fails:

Be prepared for an emergency. National and Regions must always identify in advance another refrigerator where vaccines can be sent for storage in case of emergency. Districts and facilities must always have cold boxes and enough frozen icepacks ready for storage. Report immediately to your supervisor whenever there is any problem with the refrigerator.

Packing a cold box or a vaccine carrier

A cold box or a vaccine carrier cannot make vaccines cold. It only keeps them cold. Before use, check them for cracks and broken hinges or lids. If correctly packed and used, the cold life in cold boxes is usually 2-7 days and 24-36 hours in vaccine carriers. There is inadequate cold life if the icepacks have completely melted by the end of the first day.

Icepacks should be conditioned before use. Before putting the icepacks inside the cold box or the vaccine carriers, place them on a table for 20 to 30 minutes until the outside frost has melted. Place OPV, measles-rubella, yellow fever and BCG vaccines at the bottom. Above them, place DPT-HepB-Hib, PCV (Pneumo), Men A, Rota and Td vaccines and diluents. Close the lid tightly, and keep it closed as much as possible.

Foam pads in Vaccine Carriers

A foam pad must fit precisely on top of the ice packs inside a vaccine carrier while still permitting the lid of the vaccine carrier to fully close. It usually has slits in which vaccine vials can be inserted snugly and protected. It should be used during an immunisation session as a temporary lid to securely hold opened vials while protecting unopened vials in the cool chamber below inside the carrier.

Note that opened vials of heat- sensitive vaccines can be protected from heat damage for longer periods during

immunisation sessions if they are pushed into the foam pad. Even with a foam pad, however, it is important to keep the hard vaccine carrier lid closed whenever possible to maintain the inner temperature.

3.9 Cold Chain Inventory

Cold rooms, refrigerators, freezers, cold boxes, vaccine carriers, ice packs and thermometers used in managing vaccines are all called cold chain items. Cold rooms, refrigerators and freezers are known as major cold chain items while cold boxes, vaccine carriers, icepacks and fridge thermometers are minor items.

All facility and sub-district managers are to compile a list of these equipment. District Health Directorates should compile a list of these equipment in all their health facilities and update it biannually (January and July every year) and send it through the Region Health Directorate to the National level. They are also to compile a list of health facilities offering EPI services that will require any particular cold chain equipment and update the list biannually and share with region.

An example of cold chain inventory format is provided in Figure 3-9.

Some 'DOs' and 'DON'Ts' of a vaccine friendly fridge

Dos

- Always plan before opening the fridge
- Aim to only open fridge door 2 or 3 times a day
- Arrange vaccines to allow air to circulate between boxes

Don'ts

- Never store food or drink in a vaccine refrigerator.
- Do not open the door or lid unless it is essential to do so. Frequent opening raises the temperature inside the refrigerator.
- If there is a freezer compartment, do not use it to store vaccines and diluents.
- Do not keep expired vaccines in the refrigerator[9].
- Do not keep vaccines with VVMs that have reached, or are beyond, their discard point9.
- Do not keep reconstituted vaccines for more than six hours, or after the end of an immunisation session9.
- Do not store vaccines in the door of the fridge
- Do not overstock the fridge

Figure 3-9: Major cold chain Inventory format

No.	EPI Asset Tag #	Region	District	Sub District	Facility	Facility Code	Type of Facility	Facility Longitude (GPS)	Facility Latitude (GPS)	Facility Electricity Source	Facility Gas	Facility Kerosene	Facility Electricity Availability (hrs)	Facility Vaccine Carriers	Facility Cold Boxes	Model	Working Status	Equipment Utilisation	Energy Source of Equipment	Year of Acquisition	Size	Designation	Make / Manufac-turer

9 Discard all these items immediately according to your national guidelines. Refer any questions to your supervisor.

Table 3-2: Minor cold Chain inventory format
Date updated:

TYPE-HF	NAME OF FACILITY	QUANTITIES OF UNDERLISTED EQUIPMENT				No. of outreach sessions in a week / No. of NID teams
		Cold Boxes	Vaccine Carriers	Ice Packs	Thermometers	

3.10 Vaccine Management

Adequate supply of vaccines, diluents and safe-injection equipment of assured quality is critical to every immunisation service. These must be bundled. Effective management and storage of supplies can help save on programme costs, prevent high wastage rates and stock-outs, and improve the safety of immunisations. This section outlines two methods that are commonly used to estimate vaccine and safe-injection equipment needs;

- Estimating vaccine and injection equipment needs based on the target population
- Estimating vaccine and injection equipment needs based on previous consumption

3.10.1 Estimating vaccine and injection equipment needs based on the target population

The following paraameters are needed:

- The size of the target population of the area (such as children or pregnant women);
- Details of dose schedules of vaccines in the routine mmunization programme, and the number of doses per vial;
- The wastage factor (WF) for each vaccine and the AD syringes
- Expected coverage

Table 3-3 illustrates the steps in estimating vaccines and safe injection supplies based on the above parameters. The table is constructed as follows.

Column A: List all vaccines currently in the immunisation schedule

Column B: Insert the target population for each vaccine

Column C: Number of doses needed per vaccine that each child and pregnant woman should receive

Column D: Number of doses per vial

Column E: Percent wastage rate for each vaccine.

Column F: Calculate the wastage factor for each vaccine (100/ (100-wastage rate)

Column G: Calculate the number of doses needed, based on size of target population, 100% expected coverage, the number of doses and the wastage factor (B x C x F x 100)/100.

Column H: Calculate the number of vials needed (F/D)

Column I: Indicate wastage factor for syringes (estimated to be 1.11 for all types).

Column J & K: Calculate the number of AD syringes needed, based on the target population, the number of doses, expected coverage of 100% and the wastage factor for syringes (B x C x G x100)/100. (Only BCG vaccine uses a 0.05 ml syringe.)

Column L and M: Calculate the number of syringes needed for reconstitution, based on the number of doses needed and the number of doses per vial (G/D).

Column N: Calculate the number of safety boxes required, based on the total number of syringes (J+K+L+M)/100. This method provides a way of planning your needs; however, during distribution you must ensure that each facility (especially the smaller ones) has enough boxes.

Table 3-3: Spreadsheet for estimating vaccine needs

Vaccines	Target Population	No. of doses in schedule	Doses per vial	Wastage Rate	Wastage factor	Doses needed	Vials needed	Wastage factor (syringes)	0.05ml AD syringes	0.5ml AD syringes	2ml reconstitution syringe	5ml reconstitution syringe	Safety boxes
A	B	C	D	E	F = (100/(100-E))	G = (B*C*F*100)/100	H = F/D	I	J = B*C*I	K = B*C*I	L = G/D	M = G/D	N = (J+K+L+M)/100
BCG	2500	1	20	50	2.00	5,000	250	1.11	2,775		250		30
OPV	2500	4	20	25	1.33	13,333	667	1.11					
IPV	2500	1	10	25	1.33	3,333	333	1.11		2,775		333	31
Penta	2500	3	10	25	1.33	10,000	1,000	1.11		8,325		1,000	93
PCV	2500	3	4	10	1.11	8,333	2,083	1.11		8,325		2,083	104
Rota	2500	2	1	5	1.05	5,263	5,263	1.11					
Measles -Rubella	2500	2	10	25	1.33	6,667	667	1.11		5,550		667	62
Yellow Fever	2500	1	10	25	1.33	3,333	333	1.11		2,775		333	31
Men A	2500	1	10	25	1.33	3,333	333	1.11		2,775		333	31
Td	2500	2	10	25	1.33	6,667	667	1.11		5,550		667	62
Total									2,775	36,075	250	5,417	445

3.10.2 Estimating supplies based on previous consumption

Estimating needs based on previous consumption may not be as reliable as the method based on target population because the parameters change with programme performance. At the lower levels, vaccine and safe-injection equipment are supplied regularly.

Consider the following measurements when estimating vaccine and safe injection equipment needs based on previous consumption:

- Stock at the beginning of the period
- Quantity received during the period
- Stock at the end of the period

Example: Let us assume that a CHPS zone with a vaccine refrigerator, receives vaccine and safe-injection equipment supplies every month. It is now the end of June and the incharge wants to estimate OPV vaccine needs for the next month, based on previous consumption. No supplementary immunisation activities using OPV are planned during this period.

The data required for estimating needs on the basis of previous consumption are:
OPV vaccine balance at the beginning of June = 20 doses;
OPV vaccine received in June = 60 doses;
OPV vaccine balance at the end of June = 20 doses.

Vaccine needs = starting stock balance + stocks received MINUS wastage MINUS balance at end of June = 20+ 60 -20
= 60 doses
= 3 vials
60 doses should be ordered and should be converted to vials by dividing the number of doses required by number of doses in a vial (ie 60/20 =2.4 assumung using the 20 dose OPV vial

Note: This method automatically considers vaccines that have been wasted during the previous period so there is no need to include the wastage factor

3.10.3 How to Estimate Vaccine Wastage Rate

Vaccine wastage rate in order to calculate wastage factor. The vaccine wastage is the doses of vaccines used, including unfinished and unopened but destroyed vaccine, minus the total number of people who receive the vaccine. The acceptable vaccine wastage rates vary among vaccines. Wastage rates also vary between levels and within levels as the rates are influenced by local conditions.
Wastage rate (WR) = (vaccine used – Persons vaccinated) x 100 / vaccines used
Wastage factor = 100 / (100- WR)

3.10.4 How to Order for Vaccines

Always use the standard requisition and delivery forms when ordering and receiving vaccines. Keep the receipts in a dedicated vaccine file. Do not receive vaccine without labels. Do not receive vaccine which has expired or will expire before you use or vaccine in VVM stages 3 or 4. Always rotate your stock by moving old stock to the front (or the top) and apply the first in, first out principle for vaccines with same expiry date or first to expire first out principle (FEFO) if otherwise.

3.10.5 How to keep track of vaccine stock and consumption

Keep careful records. Standard stock ledgers with separate sheets for each batch of vaccine must be used and updated at the end of each issue. These records will show how much vaccine is in the refrigerator, the expiry date of each vaccine batch, and the dates and the doses of vaccine received and used.

Ensure all vaccine arrivals and dispatches are recorded within one working day (24hrs) of completion of transaction

3.10.6 Vaccine Physical Stock Taking

Vaccines physical stocktaking means making a total count of quantities of vaccines in stock. The physical stock should cover all vaccines and should be carried out every month in all districts, sub districts and facilities before ordering for supply. The stocks balance should be adjusted according to the physical stocks done. If the actual quantity counted is more than the balance in the vaccine ledger, the difference should be recorded in the vaccine ledger book and the remarks written as extra doses. If the actual quantity is less than the balance in the vaccine ledger, the difference should be recorded and remarks written as missing doses.

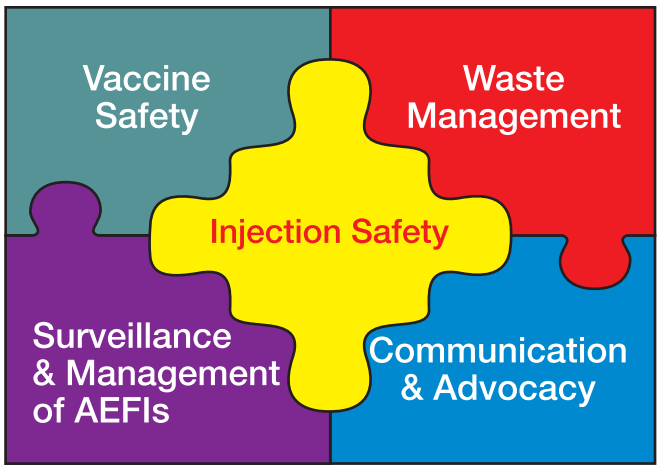
CHAPTER FOUR

Ensuring Immunisation Safety

4.1 Introduction

As the number of injections increase due to global initiatives to reach more people, new vaccine introduction and mass campaigns with injectable vaccines, immunisation safety including Adverse Events Following Immunisation (AEFIs) has taken a centre stage in immunisation programmes. Assurance of safe immunisations is an important measure of quality of care. Managers and health-care workers (HCWs) should therefore, adhere to EPI policies[10]. The purpose of this section is to enhance the skills of managers and HCWs in ensuring safe immunisations.

Figure 4-1: Components of Immunisation Safety[11]



Immunisation safety has five main components:
Injection Safety;
Vaccine Safety;
Health Care Waste Management;
Adverse Events Following Immunisation (AEFI), and Advocacy and Communication in relation to safety.

4.2 Vaccine Safety

4.2.1 Ensuring safe and quality vaccines

Vaccine production is a biological process using live organisms, or their toxins, as raw material. Thus, the characteristics of each batch (or lot) are subject to variation depending on growth conditions. The quality of the finished product cannot be determined solely by laboratory testing. Quality control requires full compliance with Good Manufacturing Practice (GMP) and with Good Laboratory Practice (GLP) as recommended by WHO standards.

It is essential that quality be ensured from the first step in the production process to the final packing of the product. Vaccine quality control is a complex and careful process and not all suppliers can assure quality. Many producers make vaccines under manufacturing conditions and product quality which do not meet the WHO pre-qualification standards.

Vaccines are heat sensitive and must be stored and transported in a cold chain. Certain vaccines also are damaged by freezing and light. Again, vaccines have a very limited shelf life (a maximum of two years in most cases).

10 See National Policy Guidelines on Immunisations in Ghana, 2016
11 Adapted from 2011 MLM Training, Nairobi-Kenya

4.2.2 The role of Food and Drugs Authority- the National Regulatory Authority

A major World Health Organization's goal in immunisation is to ensure that "100%" of vaccines used in all national immunisation programs are of assured or high quality. **"Assured quality vaccines"** means that

1. There should be a **National Regulatory Authority (NRA)** which is independent of vaccine manufacturers.
2. The NRA must be functional. In order words, the NRA must have a system of performing its regulatory functions as required
3. **All** reported problems with vaccines should be resolved

BOX 4.1: Before health-care worker uses any vaccine, he or she must observe the following rules:

1. Check the labels of the vaccines and diluent. If the label is not attached, discard the vaccine or diluent or both.
2. Check for any particulate matter. If present, discard the vaccine or diluent or both.
3. Check the expiry dates. If the expiry date has already passed, the health-care worker must discard vials or diluent or both.
4. Check the vaccine vial monitor (VVM). If it indicates that the vaccine has reached discard point (VVM Stages 3 and 4), it must be discarded immediately.
5. If you suspect that a freeze-sensitive vaccine has been frozen, the shake test should be performed (see Chapter 3).
6. For each vaccine used, health-care workers must know the:
   a. Age at which each dose should be given;
   b. Number of doses required and minimum intervals between doses;
   c. Correct dosage (never inject or give less than required dose of vaccine to any recipient).

In Ghana, the Food and Drugs Authority (FDA) is legally mandated to perform the functions of the NRA for vaccines. Thus, the FDA serves as a "referee" between producers and importers on one hand, and consumers/clients on the other. FDA works in conjunction with EPI to ensure that vaccines purchased are in compliance with international and national standards. All vaccines in Ghana's EPI are sourced through the UNICEF and are WHO pre-qualified. The FDA performs mainly licensing functions and assists with AEFI surveillance (monitoring). The UN (WHO/UNICEF) performs other regulatory functions before vaccines are procured. The quality and efficacy of the vaccine should be maintained throughout its arrival, transportation, storage and use.

4.2.3 The importance of the cold chain in vaccine safety

Vaccines are heat sensitive so must be stored and transported in adequate cold chain at all times (see Chapter 3). During immunisation sessions, vaccines must be kept at +20C to +80C temperature all day. A break in the cold chain (i.e. storage in wrong temperatures) may result in loss of vaccine potency by reducing the strength of the immune response or result in an AEFI once administered. This renders the vaccine unsafe. There are some indicators to monitor if vaccines have been exposed to heat or freezing conditions (e.g. VVM, freezing indicator, continuous temperature monitoring with alarms, Shake test etc.). All managers and HCWs should attach high priority to the maintenance of the cold chain (conditions of cold rooms, refrigerators, freezers, cold boxes, back-up generators, etc.) to maintain vaccine potency while assuring vaccine safety. Storekeepers and repair technicians should be adequately trained to ensure proper functioning of the cold chain (See Chapter 3).

4.2.4 Multi-Dose Vial Policy (MDVP) and vaccine safety

The MDVP provides for reduction in vaccine wastage while assuring vaccine safety. WHO developed guidelines on how to use vials of certain vaccines (not all vaccines) once they have been opened (see Chapter 3). All opened **WHO-prequalified multi-dose vials of vaccines** should be discarded at the end of the immunisation session, or within six hours of opening, whichever comes first, UNLESS the

vaccine meets **all four** of the criteria listed in BOX 4.2. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening.

BOX 4.2: Criteria to be met for opened vials to be kept and used for up to 28 days after opening

1. The vaccine is prequalified by WHO.
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO (or manufacturer)
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 reached its discard point, and the vaccine has not been damaged by freezing.

Failure to strictly adherence to the MDVP means that the vaccines could be avoidably wasted, damaged or contaminated in which case the safety is compromised.

4.3 Injection Safety

4.3.1 Consequences of unsafe injections

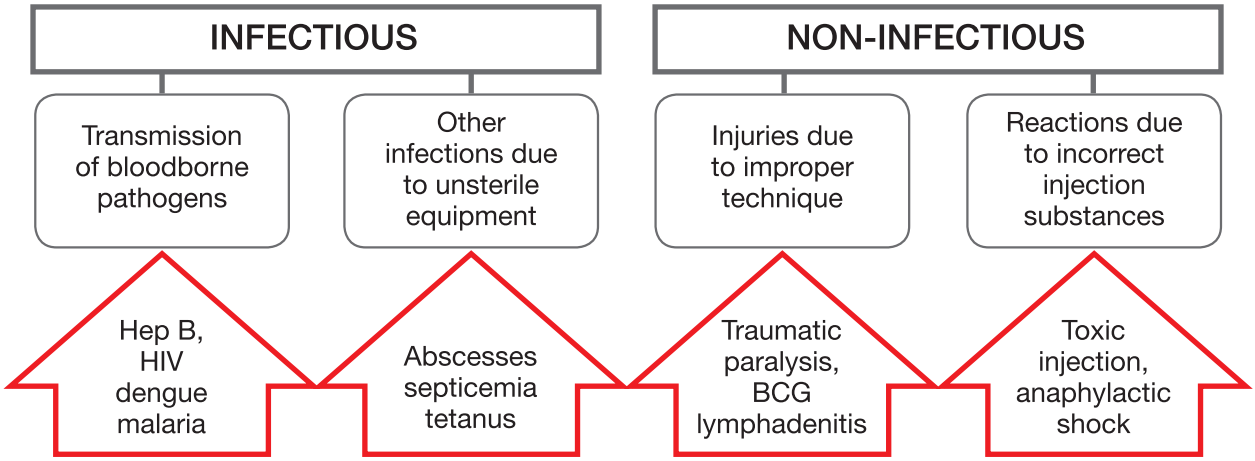
The results of unsafe injections can be dire for both HCWs and non-HCWs. Unsafe injections can lead to both infectious (e.g. Hepatitis B and HIV/AIDS transmission) and non-infectious consequences [e.g. traumatic paralysis, anaphylactic shock] (See Figure 4-3).

Figure 4-2: Unsafe injection practices[11]

4.3.2 What is injection safety in immunisation?

Immunisation injections are safe only when the correct **and effective vaccine is properly administered with sterile equipment that is subsequently disposed of safely**[11].

Figure 4-3: Consequences of unsafe injections[11]



This implies that there is **no potential harm to the recipient, the health-care worker** and **the community. Safe injections** also mean that a **package of measures and practices are in place** to make sure that **100% of injections are safely administered**.

4.3.3 Ensuring Injection Safety

Safe injections involve the use of safe injection equipment as well as the right injection procedures and techniques. Assuring the safety of injections should be a top priority for immunisation managers and HCWs at all times. This involves

- Assessment of injection safety practices
- Adhering to Policy on injection safety (EPI Policy)
- Following an injection safety plan including the designation of focal persons at all levels and defining activities, roles and responsibilities.
- Ensuring safe disposal of used injection equipment by training/orienting HCWs about the method and procedures for waste disposal
- Provision of appropriate equipment and supplies
- Supervising HCWs to ensure injection safety practices
- Monitoring and evaluation of injection safety using standardised tools

Figure 4-4: Left: AD syringe Right: Safety Box

4.1.1.1 *Safe injection equipment*

To ensure that immunisation injections are safe, the United Nations (notably WHO, UNICEF and UNFPA) recommend that sufficient quantities of auto-destruct [auto-disable] (AD) syringes and safety boxes (SB) are provided for all immunisations sessions (including every fixed, temporary or outreach posts). The proper use of AD syringes in immunisation greatly reduces the risk of person-to-person transmission of blood-borne infections.

4.3.3.1 *Use of auto-disable syringes in immunisation services*

The AD syringe, which is now widely available at low cost, presents the lowest risk of person-to-person transmission of blood-borne pathogens (such as hepatitis B or HIV) because it cannot be reused. The AD syringe is therefore, recommended as the equipment of choice for administering vaccines both in routine immunisation and mass campaigns (See Box 4.3).

Ghana adopted the use of AD syringes for routine immunisation and immunisation campaigns in the mid-1990s. All immunisation injections in Ghana must be administered with a new AD syringe/needle. AD syringe/needle shall also be used for re-constitution of vaccines as they become available. All used syringes/needles should immediately be put in a SB without recapping.

BOX 4.3: Use of AD syringes in immunisation services

- AD syringe and safety boxes should be supplied as a bundle* for all immunisation sessions
- All partners are requested to finance not only vaccines but also the safe administration of vaccines, AD syringes and safe management of waste

12 WHO/V&B/99.25. WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunisation services. 1999

* The term bundling is theoretical and must consist of each of the following 3 items: (i) Good quality vaccine; (ii) Diluent specific to vaccine, Auto-disable syringes, Reconstitution syringes; (iii) Safety boxes. Bundling means each component of these items must be considered as part of a bundle containing the other two. It does not necessarily mean that the items are actually packaged together in the same container.

4.3.3.2 *Using the right injection procedures*

Only qualified health professionals who are mandated to provide vaccination should provide same. The following proper injection procedures should be followed to vaccinate children:

- Keep vaccines at +20C to +8 0C at all times during the immunisation session
- Wash hands under running water and dry them using a clean towel before all immunisation sessions
- Use matching diluent (supplied only by the manufacturer) for each vaccine – check the labels and keep the diluent at +20C to +8 0C temperature before reconstituting freeze-dried vaccines: BCG, YF, MR, Men A
- Prepare each dose immediately before its administration – do not pre-fill syringes in advance

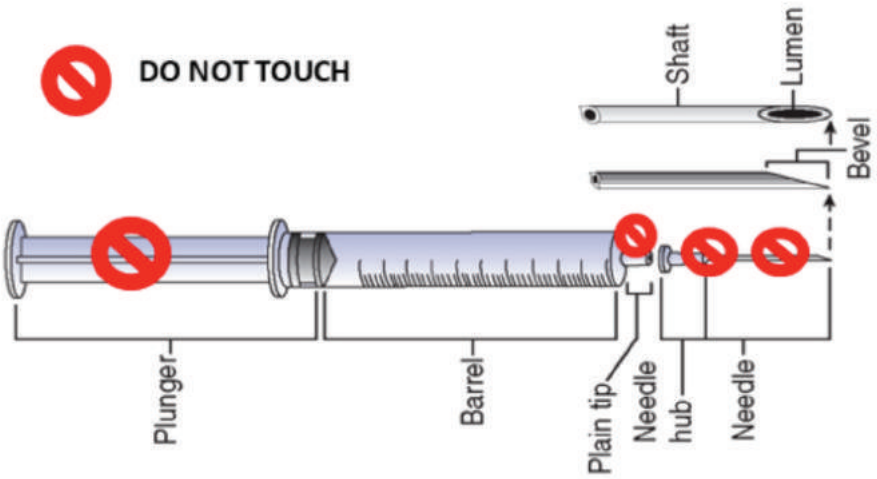
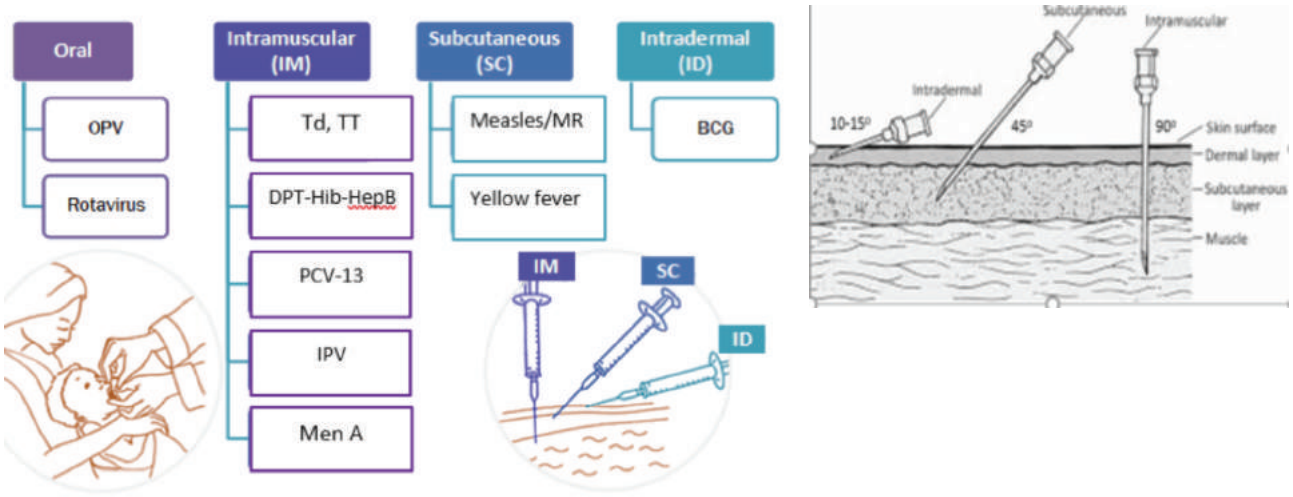


Figure 4-5: Parts of the Syringe-Needle not to be touched

- Never leave the needle in the top of the vaccine vial
- Follow the MDVP for opened vials.
- Minimize handling of syringe: do not touch the plain tip (collar) of the syringe, any part of the needle or the needle adapter (see Figure 4 5)
- Position the child carefully to minimize risk of movement and injury while administering an injectable vaccine
- The injection site should be cleaned with cotton wool dipped in clean water to remove visible dirt as necessary.
- Adhere to the recommended routes and techniques of administration at all times (see Figure 4-6):
  - o Intradermal: BCG
  - o Subcutaneous (SC): MR, YF
  - o Intramuscular (IM): PCV, Penta, IPV, Men A, TT/Td
- Withdraw the needle and press with cotton wool over the injection site. If there is any bleeding, keep pressing with the cotton wool until the bleeding stops.
- **DO NOT recap needles!!!!**
- Always use a safety box (see Figure 4-4) positioned nearby: put sharp waste immediately into the SB and **seal when three-quarters full**.
- Final disposal of sharps from immunisation sessions should be by incineration or recommended burning procedures (see section 4.4).

Figure 4-6: Recommended routes of administration of EPI vaccines
(inset: recommended angles for injections)



Modified from WHO Vaccine Safety Basics: e-learning course: Available on http://vacine-safety-training.org/vaccine-reactions.html. Assessed 17 January 2017. DPT-Hib-Hep = Pentavalent vaccine

4.4 Immunisation Waste Disposal

Immunisation managers and HCWs are responsible for safe immunisation waste disposal. The proper disposal of used equipment is an important component of immunisation safety. At the end of each immunisation session, teams should inspect and clean the surroundings of the immunisation post to maintain safe environment.

4.4.1 Why worry about sharps waste?

With increasing injections and use of AD and other safety syringes for immunisation, inadequate management of sharps wastes can cause serious health and environmental problems. Unsafe disposal can spread some of the very same diseases the immunisation program tries to prevent[13].

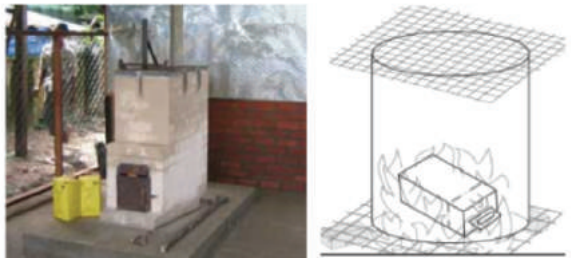
Used needles are likely contaminated and can lead to:

- Patient-to-patient transmission of infection due to the re-use of syringes
- Patient-to-HCW transmission due to needle-stick injuries
- Patient-to-Community transmission due to unsatisfactory final disposal

4.4.2 Final Disposal of Injection Waste

HCWs should guard against needle-sticks by carefully and professionally handling syringes and needles. They should refrain from recapping needles after use. Used syringes and needles (including reconstitution syringes and needles) should be placed immediately, without recapping, into a SB as recommended. There should be no attempt to reuse either the injection syringe, or the reconstitution syringe and needle.

Figure 4-7 Left: de Monfort Incinerator Right: Metal Drum

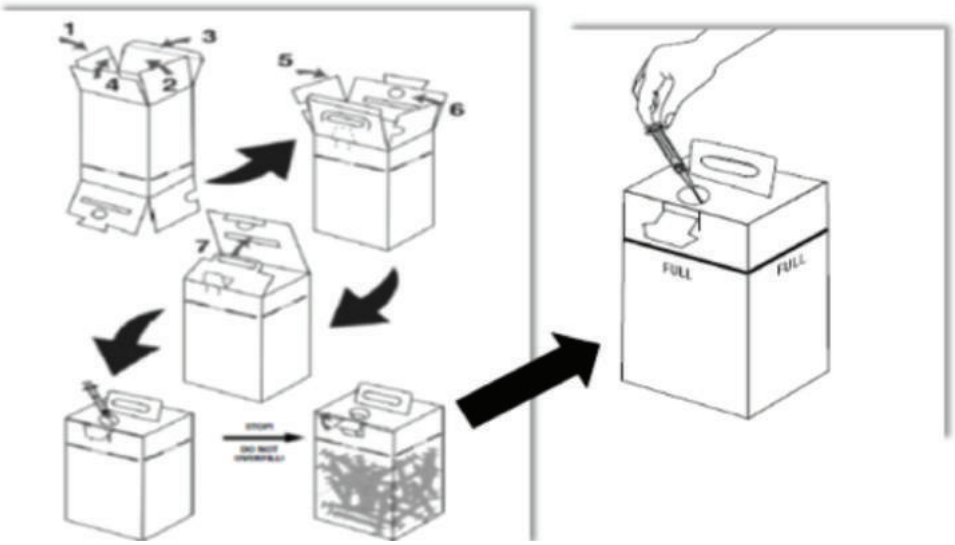


The SB should be filled to about three-quarters and then sealed by closing the lid to avoid spillage of the contents (see Figures 4.8 for assembly and use). These filled safety boxes should be transported to an appropriate site by a designated officer (focal person) to ensure final disposal and destruction. Other injection waste including syringe wrappers and cotton

13 World Health Organization 2015, Immunisation in Practice: A practical guide for health staff: Stylus Pub Llc,

wool should be put in a separate carrier bag during the session and disposed of safely after. The recommended method of final disposal is incineration. There are a number of models of incinerators on the market. Ghana uses the de Monfort type or a modification of it. If there is no incinerator available, the alternative is burning in a metal drum as shown in Figure 4.7. Open pit burning is not recommended because it can scatter waste.

Figure 4-8 Assembly and use of Safety Box



4.5 Advocacy and communication on Immunisation safety

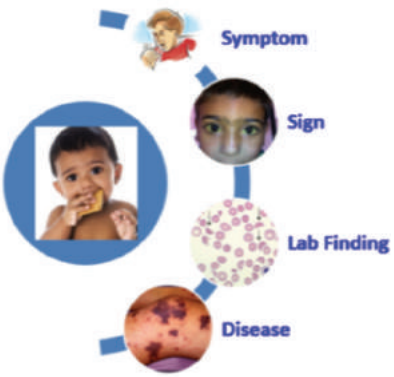
All immunisation managers should emphasize the importance of safe disposal of waste to HCWs and the community. HCWs should be sensitized on the potential risks related to recapping needles after vaccination and refrain from it, and the need to use safety boxes systematically. The community should be aware of the risks of manipulating used needles and syringes and of the efforts made by the HCWs to prevent accidents.

The public should know that used material is stored and disposed of regularly and safely. Well-informed community members should spread the message on prevention of accidents caused by sharps among other community members, especially preventing children to play with used sharps. HCWs should ensure the inclusion of safe waste disposal in school health programmes.

4.6 Monitoring Adverse Events Following Immunisation

4.6.1 Introduction

Immunisation has been a great public health success. The goal is to protect the individual and communities from vaccine-preventable diseases (VPDs). Vaccines used in national programmes are safe and effective when used correctly. Careful procedures are followed before vaccines are registered for use. However, no vaccine is “perfect” and entirely without risk.



After immunisation, some people may experience reactions ranging from mild local to life-threatening symptoms or in rare cases-illnesses. These adverse events following immunisation (AEFI) may be true reactions caused by the vaccine or its products or by an error in the administration of the vaccine or in most cases, may be unrelated to the vaccine or its administration (i.e. there is no causal relationship at all).

Whatever the cause, AEFI upsets people to the extent that they refuse further immunisations for their children and themselves. As a result they, especially the children are put at risk of VPDs. Public

trust in vaccine safety is key to the success of vaccination programmes. HCWs should therefore, be able to diagnose, treat and report AEFIs, and differentiate between mild, non-significant reactions and serious events which need prompt attention.

4.6.2 Definition of AEFI

An AEFI is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease (see 4.6.1).

4.6.3 Classification of AEFI

There are two systems of classification: Regulatory and Causes-specific

4.6.4 Regulatory Classification

Based on this classification, an AEFI can either be serious or non-serious. A serious[14] AEFI is one that

- is life-threatening, or
- requires in-patient hospitalization or prolongation of existing hospitalization, or
- results in persistent or significant disability/incapacity, or
- results in a congenital anomaly (birth defect), or
- results in death

Non-serious AEFI: This includes mild and moderate temporary adverse events following immunisation that are not classified as serious.

4.6.5 Cause-Specific Classification

Based on specific causes, AEFI is categorized into **five** types or unknown as follows.

Vaccine product-related reaction	Vaccine defect-related reaction	Immunization error-related reaction	Immunization anxiety-related reaction	Coincidental event	Unknown
• Due to inherent properties of the vaccine: Eg. Anaphylaxis due to reaction to some vaccine component(s)	• Due to manufacturing defect:Eg. Failure to attenuate a live-attenuated vaccine properly leading to infection (polio, yf, measles etc.)	• Due to errors in handling prescribing, storage or administration of the vaccine: essentially, a program-related error E.g. Agscess at the site following injection	• Due to anxiety to vaccination or the processes of vaccination: E.g. Fainting attacks among teenagers in a queue during a mass vaccination campaign exercise	• Unrelated to vaccine or vaccination: E.g. Malaria occuring after vaccination	• Cause cannot be determined

4.6.6 Objectives of AEFI Surveillance

The main objective is to ensure public safety. Specifically, AEFI surveillance aims to;

- Detect, manage and report AEFIs
- Investigate specific AEFIs
- Assess the extent (magnitude) of AEFIs
- Analyse AEFI reports by person place and time
- Prevent immunisation error-related AEFI
- Prevent and/or manage rumours
- Assure public confidence in vaccination programmes

14 A serious adverse event or reaction is a regulatory term as defined above. A severe reaction is a broader term, which includes serious reactions, but also other reactions that are severe but do not necessarily lead to long term problems that qualify to be serious e.g. an uncomplicated abscess.

4.6.7 Types for AEFI surveillance

Different strategies exit for AEFI surveillance but in Ghana, two types are usually employed: Spontaneous reporting and active follow-up.

4.6.8 Spontaneous and active AEFI reporting

Spontaneous: Either client (or care-giver) comes back to complain after receiving vaccine or the health worker links a client's condition to vaccination (not necessarily caused by the vaccine[15]). This is the sole strategy for routine immunisation.

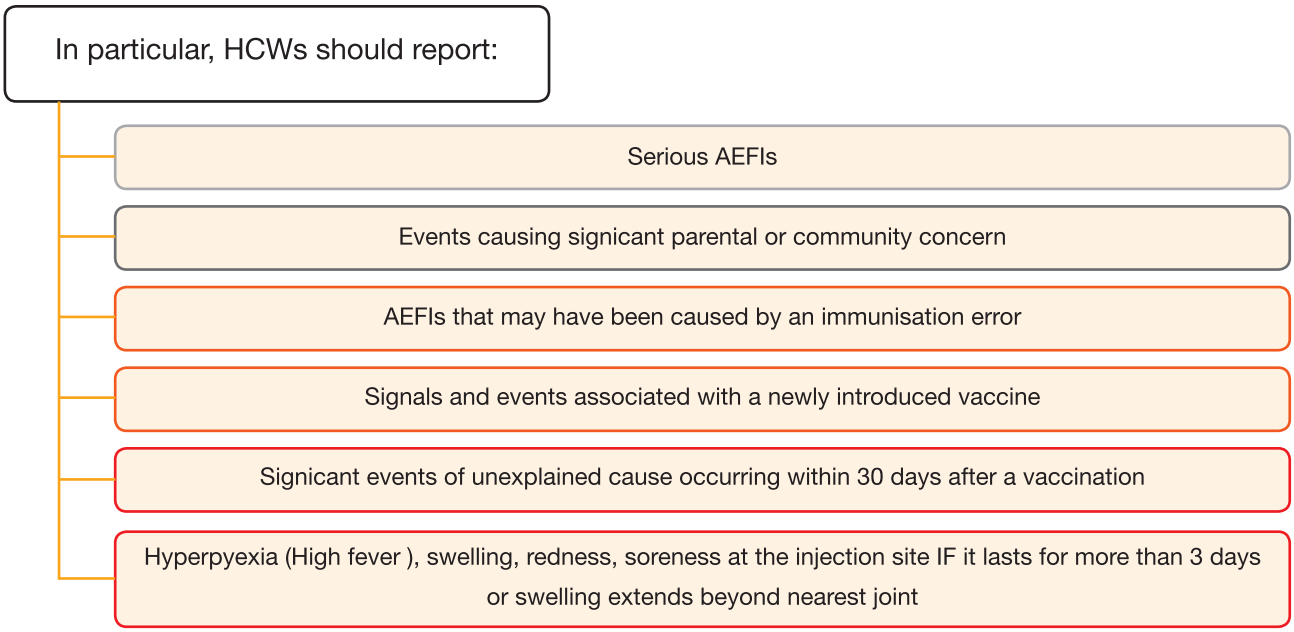
Active: In active reporting, selected conditions are actively looked for in health facilities and/or communities. This strategy is normally used to complement spontaneous reporting during specific immunisation campaigns or when a new vaccine is being introduced. The conditions selected, for which specific definitions are provided, depend on the type of vaccine/campaign.
Guidelines/Standard Operating Procedures (SOPs)[16] have been developed specifically for AEFI surveillance and HCWs and managers are encouraged to use it as a complementary tool.

4.6.9 Detection and reporting

Clients of immunised children/children, HCWs at immunisation centers and hospitals are most likely to recognize and/or detect AEFIs when they first occur. HCWs have the responsibility to report AEFIs when appropriate. They also have the responsibility to treat or refer patients for treatment. All vaccination staff must be able to diagnose adverse events. Managers are responsible for effective staff training and education to ensure accurate diagnosis of AEFIs based on case definitions, which are included on the AEFI reporting form[17] and in the national AEFI guidelines.

4.6.10 Who should report and what should be reported

Any AEFI that is of concern to the parents or to the HCW should be reported whether the AEFI is previously known or unknown, including local reactions, systemic events, serious or non-serious events.



An AEFI reporting form should be completed for all cases and clinical notes (clinical investigation form, laboratory form) completed for all serious AEFIs to enable causality assessment by the National Expert Committee (NEC). Ensure adequate specimen collection and handling (when necessary). Only regulatory classification (serious or non-serious) should be done at the facility, district and regional levels.

15 Causal association can only be determined at the level of the National Expert Committee (NEC) based at Food and Drugs Authority
16 Guidelines for surveillance of adverse events following immunisation in Ghana, April 2013
17 See Annex 4.4

4.6.11 Case management

Cases should be managed according to the National AEFI Guidelines including establishing appropriate diagnosis and providing care to the patient (see Table 4-1 for minor vaccine reactions and treatment)[18]. **Anaphylaxis** following injection is rare but a serious medical condition which requires emergency procedures (See Annex 4.3 for emergency procedures for ANAPHYLAXIS)

> Note: The foremost responsibility towards any client presenting with AEFI is treatment. All AEFIs should be treated free of charge. If in doubt, consult your supervisor.

All serious AEFIs should be seen by a clinician (after initial treatment), preferably in a hospital setting because clients may require admission. Cases of serious AEFIs should, therefore, be referred to hospital for further management as appropriate.

Table 4-1: Common minor vaccine reactions and treatment

Vaccine	Local Reactions	Systemic Reactions	
	(Pain, swelling, redness)	Fever > 38ºC	Irritability, malaise and systemic symptoms
BCG*	90-95%	-	-
HepB	Adults: up to 15%; Children: up to 5%	1-6%	-
Hib	5-15%	2-10%	
Measles/MR	~10%	5-15%	5% (Rash)
OPV	None	<1%	<1%†
Pertussis^	Up to 50%	Up to 50%	Up to 55%
PCV	~20%	~20%	~20%
TT/Td/DT	~10%‡	~10%	~25%
Treatment	1. Cold cloth at injection site 2. Paracetamol	1. Give extra oral fluids 2. Wear cool clothing 3. Tepid sponge or bath 4. Paracetamol**	• Give extra oral fluids

*Varies with brand †diarrhoea, headache and/or muscle pain ‡Rates may be higher with booster doses
^reaction rates are lower for acellular pertussis (DaPT) compared with whole cell pertussis (DwPT)
**Paracetamol Dose: up to 15ng/kg every 6-8 hours, maximum of 4 doses in 24 hours

4.6.12 When should AEFIs be reported and what is the route of reporting?

All AEFIs are immediately notifiable (within 24 hours of detection). Serious AEFIs in particular should be reported **immediately** to the Central/National level. Reporting should be through both electronic and paper-based means. Electronic reports from district should simultaneously be sent to Regional and National levels while corresponding paper-based reports go through the pathway as shown in .

Table 4-2: AEFI Reporting Pathway

18 See Annex for Reported Severe Reactions

4.6.13 Immunisation-error related reaction (Programme-related error)

Immunisation-error related reactions (iERR) may constitute the greatest proportion of AEFIs. They are usually person-based and can include deaths associated with the reconstitution of vaccines with an incorrect diluent or a drug (e.g. insulin, oxytocics, and anaesthetic drugs). Health care workers tend to under-report such errors for fear of reprimand. The purpose of reporting iERR is for corrective action and not reprimand. Therefore, HCWs and managers are encouraged to document all such errors and report appropriately.

The main errors include:

- Non-sterile injections
- Reconstitution errors
- Incorrect injection sites, route or technique
- Cold chain breakdowns
- Ignored true vaccine contraindications (See Chapters One & Two)

The consequences of Immunisation-errors are as summarized below:

Consequences of immunisation-error related reactions					
Local reactions	Injection site abscess	Sepsis	Toxic Shock Syndrome	Blood bone infections	Lymph-adenitis

4.1.1.2 Basic rules to avoid immunisation-error related reaction

The following steps (Box 4.4) should be taken by HCWs to avoid immunisation errors.

Box 4.4: Basic rules to avoid immunisation-error related reaction

- Use the diluent supplied by the manufacturer
- Ensure adherence to MDVP (Multi-Dose Vial Policy)
- Do not keep 'drugs' other than vaccines in the vaccine fridge
- Use AD syringe for each injection
- Practice one sterile reconstitution syringe and needle for each vial to be reconstituted
- Investigate AEFI fully and correct errors

CHAPTER FIVE

Micro planning for reaching every community

5.1 Introduction

It is essential that we reach every district and every child with all the benefits of vaccination. This chapter discusses the Reaching Every District (RED)/ Reaching Every Child (REC) strategy and the process of microplanning to ensure immunisation services reach every community and child.

Microplanning is one of the tools used by health workers to ensure that immunisation reaches every community.

It starts with maps at district and health centre level, which should be updated to include all population centres and groups in the catchment area and to flag high-risk areas. It next describes how to identify priority, high-risk subdistricts and communities based on numbers of unimmunised children. It then describes how to clarify barriers and bottlenecks to service access and utilization in priority subdistricts, and communities and to make a workplan for solutions. It concludes with making a session plan.

Planning is the most basic component of the Reaching Every District (RED) strategy. All the other elements of the Reach every District (RED) strategy cannot be implemented if the planning process has not been conducted properly. At each level, (district, subdoistrict, CHPS zone, and facility) planning should identify what resources are needed to reach all those targeted

5.2 What is Reaching Every District/Child (RED/REC)?

RED/REC is a strategy that offers opportunity for districts and sub-districts as well as CHPS zones to use immunisation coverage data to analyze the spread of unimmunised children, to prioritize districts with poor access and poor utilization of immunisation services, and to make micro-plans at district or sub-district level to address the identified problems. Implementation of the RED/REC strategy should support disease control efforts. The focus now should be on **Reaching Every Community** in order to **reach every child.**

5.3 Operational components of the RED strategy

The RED approach encompasses five operational components aimed at improving coverage in every district by strengthening capacity at the district and facility levels through addressing common immunisation bottlenecks.

These are:

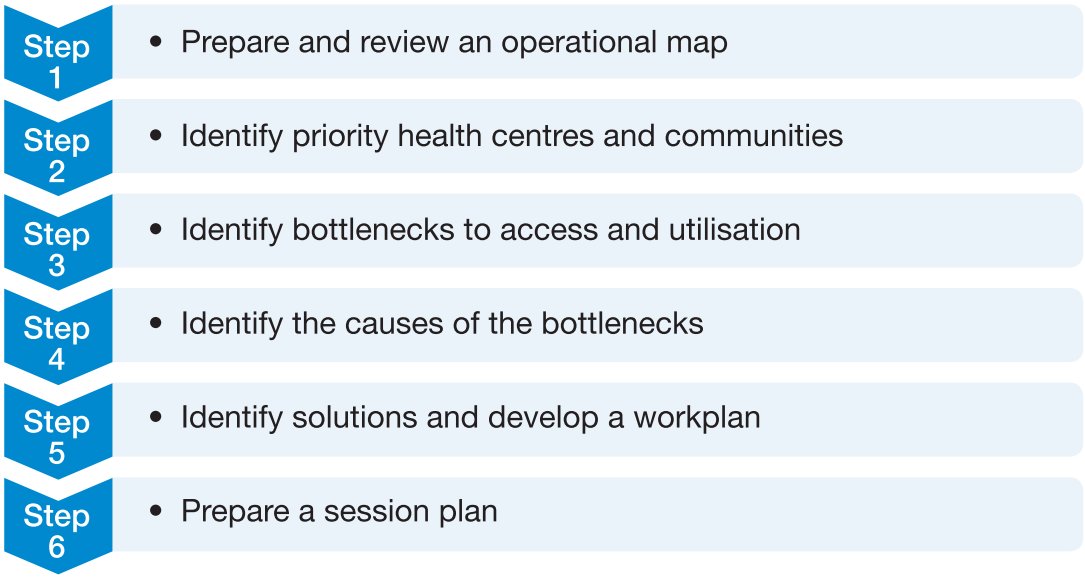
- Effective planning and management of resources: ensuring better management of human, financial, and material resources at every level.
- Reaching all target populations: reaching out to previously underserved, unreached communities, in giving support and access to services.
- Linking services with communities: partnering with communities to promote and deliver services through regular meetings between communities and health staff.
- Supportive supervision: providing local staff with on-site training, feedback, and follow-up by supervisors.
- Monitoring for action: using tools and providing feedback for continuous self-assessment at all levels.

5.4 Micro-planning Process

A good formulated EPI plan should propose solutions to the following critical issues, which all managers are confronted with at all levels:

- How to increase immunisation coverage and reach every child
- How to maintain the quality of immunisation services
- What can be done to reduce dropout rates and missed opportunities
- How to improve the quality of immunisation coverage data
- How to ensure effective supervision

Micro-planning steps



Step 1. Prepare and review an operational map

Depending on the level,

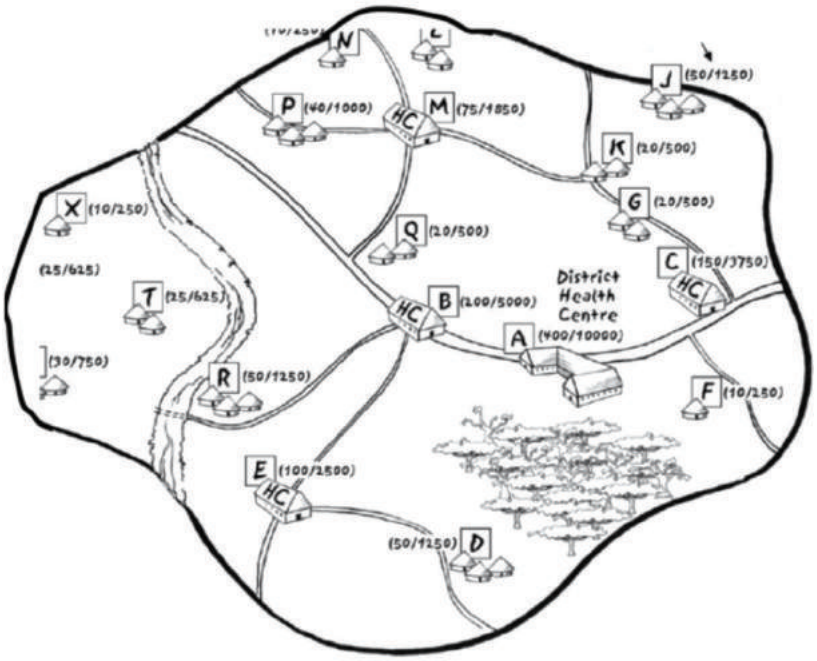
1. A district level map with sub-districts, health facilities and their catchment populations;
2. A sub-district map with CHPS zones, health facilities and community populations;
3. A CHPS zone map with health facilities and community populations

Every district, subdistrict, CHPS zone and health centre should display a map that shows the current location and relative size of the population groups in their catchment areas. The communities in the catchment area should be listed and updated regularly.

The district and subdistrict, and health facility catchment area maps should include:

- Locations of every village and/or community in the catchment area, including those that are not reached and/or are new
- The total population and target populations in each community in the catchment area
- Indicate which populations will be served by static, outreach, mobile or camp out strategy.
- Landmarks and significant buildings, for example, religious centres, markets, schools, lorry parks
- Settlements of urban poor, migrants and displaced persons within towns and cities
- Location of nomadic populations
- Roads and geographical landmarks (rivers, streams, and mountains)
- Areas with seasonal accessibility
- Community volunteer names and their mobile phone numbers.

A sample map of a catchment area



At the district level display a table indicating the information below by the map:

- the total population and target population in the catchment area of each health centre
- approximate distances and travel times to each health centre health centre
- contacts and any other information that may be useful in coordination and supervision efforts.

Table 5-1: District-level list of peripheral health centres and their catchment area populations

Health centre name	Total population in health centre catchment area	Population <1 year of age in health centre catchment area	Distance between health centre and main district facility (km and travel time)	Name of health centre contact person	Phone number of health centre contact person

At the health centre a display the information in table 2 by the map

- the total population and target population in each community in the catchment area
- approximate distances and travel times to each community
- community volunteer names and their mobile phone numbers.

Table 5-2: Health centre-level list of catchment area communities and populations

Community name	Total population in community*	Population <1 year of age in community	Distance between community & health centre (km & travel time)	Name of community contact person	Phone number of Community contact person

Step 2: Identification of priority health centres and communities

Two levels of analysis lead to the identification of priority subdistricts and communities:

1. At district level, the analysis of subdistrict immunisation data for the past year should identify those subdistricts in need of priority support

2. At Sub-district or CHPS zone level, the analysis of community immunisation data for the past year should identify those in need of priority visits. Visits may be needed for evaluating low coverage and the reasons behind it

Analysis of immunisation data

Table 5-3 shows a format for the analysis of district immunisation data from the preceding 12 months using the RED categorization tool. The format identifies and prioritizes subdistricts where immunisation performance is problematic. Rank and prioritize subdistricts by the number of unimmunised children in their catchment areas.

How to prioritize subdistricts using district immunisation data

- Use all available information to complete the analysis of immunisation data. Rank subdistricts by the number of unimmunised children; the one with the highest number of unimmunised children is ranked first (1). The subdistrict ranked 1 has the highest priority.
- Subdistricts that have inaccurate data; for example, a subdistrict that shows negative values for unimmunised children due to inaccurate population data or negative vaccine wastage rates may need to be given priority.

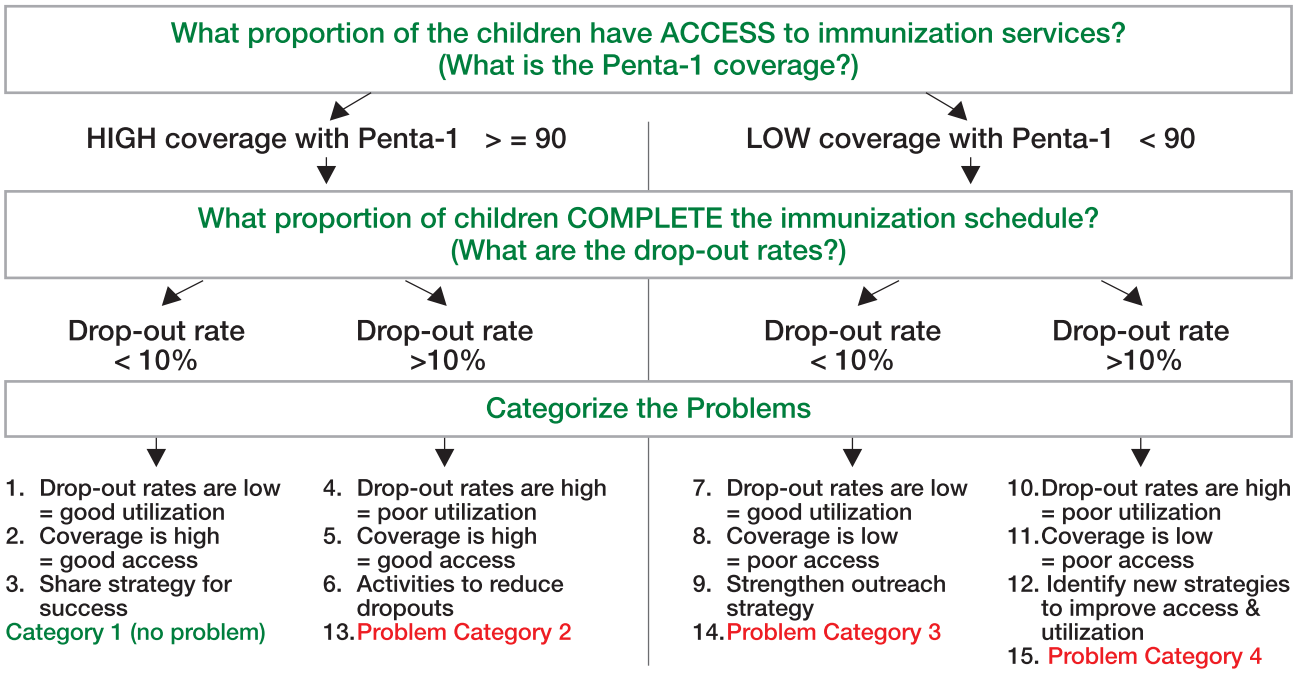
How to prioritize communities using CHPS zone immunisation data

- Use all available information to complete the analysis of CHPS zone data.
- List every community, including new ones and those that do not have regular access to services (for example, urban slums, and distant rural communities).
- Rank communities by number of unimmunised children; the one with the highest number of unimmunised children is ranked first (1) and has the highest priority.

Table 5-3: Red Categorization tool

	Complie population, immunisation coverage data in previous in 12 months									Analyze Problems							Prioritize areas
District/ Subdistrict/ CH PS Zone	Annual Target Popu-lation	Doses of vaccine administered				Immunization coverage (%)				Unimmunized		Drop out Rate (%)		Identify Problems		Categorize the problem	Priority
	<1 year	Penta 1	Penta 3	MRI	MR2	Penta 1	Penta 3	MRI	MR2	Penta 3	MR2	Penta1-Penta3	MR1-MR2	Access	Utilisation	Category1,2,3,4	1,2,3,4
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r

Figure 5-1: Access/ drop-out chart



The main categories are:

Observation in a district/subdistrict/CHPS	Diagnosing a problem
High Penta1 coverage, low drop-out rate	No Problem (Category 1)
High Penta1 coverage, high drop-out rate	Utilization problem (Category 2)
Low Penta1 coverage, low drop-out rate	Access problem (Category 3)
Low Penta1 coverage, high drop-out rate	Utilization and access problems (Category 4)

Step 3: Identification of bottlenecks to access and utilisation:

The analysis of bottlenecks uses a set of key determinants related to enabling environment, supply, demand and quality of the Expanded Programme on Immunisation (EPI) service delivery and utilisation, to identify and analyse barriers and bottlenecks that obstruct reaching effective coverage rates. It allows for a comprehensive in-depth analysis of the performance of the EPI and leads to more evidence-based solutions with the aim of improving broader maternal, new-born and child health outcomes.

The bottleneck analysis is a structured approach utilised to reveal at what level obstructions in the delivery and utilisation of key interventions occur and the reasons behind these obstructions that prevent these interventions from reaching high effective coverage rates. For this, the bottleneck analysis proposes a framework of 10 determinants, or critical conditions, that need to be fulfilled to ensure an adequate coverage of each intervention. The **10 determinants** are grouped into 4 main domains:

1) **Enabling environment, *comprising 4 determinants*:**
    1. *Social norms:* assessing the widely followed social rules of behaviour pertaining to the intervention or service
    2. *Management and Coordination:* describing the management structures, roles, accountability, coordination mechanisms and partnerships in place to support the service delivery
    3. *Legislation and Policy*: describing the presence, adequacy and relevance of laws, policies and guidelines to support and govern the delivery of the intervention.
    4. *Budget and Expenditures*: verifying the allocation and disbursement of required resources to deliver the intervention or service
2) **Supply, *comprising 3 determinants related to:***
    1. *Commodities*: reflecting the availability of essential commodities required for the delivery of the intervention or service eg vaccines

2. *Human resources*: reflecting the presence of trained human resources to perform the intervention or service
3. *Geographical accessibility*: verifying the physical accessibility to the intervention or service

3) **Demand, *comprising 2 determinants related to:***
   1. *Initial utilisation*: reflecting the financial accessibility (can users afford the service?) and the individual beliefs and practices that convince or prevent someone from using the intervention or service for the first time
   2. *Continued utilisation*: reflecting the continuity or completion in use of the intervention or service by beneficiaries
4) **Quality, *comprising one determinant:***
   1. *Effective coverage*: reflecting the adherence to required quality standards for the delivery of the intervention or service for those beneficiaries that continued or completed using the intervention or service

Before starting the bottleneck analysis process, **a tracer intervention** is selected to which the 10 determinants will be applied. These tracer interventions from which to choose are:

1) Immunisation with DPT HepB+Hib (Penta) vaccine,
2) Immunisation with measles-rubella vaccine,
3) Immunisation with tetanus-diphtheria toxoid vaccine,

For each tracer intervention, the 10 determinants framework is applied to identify and prioritise the key bottlenecks to effective coverage of the intervention. A bottleneck analysis graph will be produced for the supply, demand and quality determinants. The bottleneck analysis uses the same **sources of information** and data available at all levels

Table 5-4: Definition of indicators for analyzing bottlenecks in vaccination coverage.

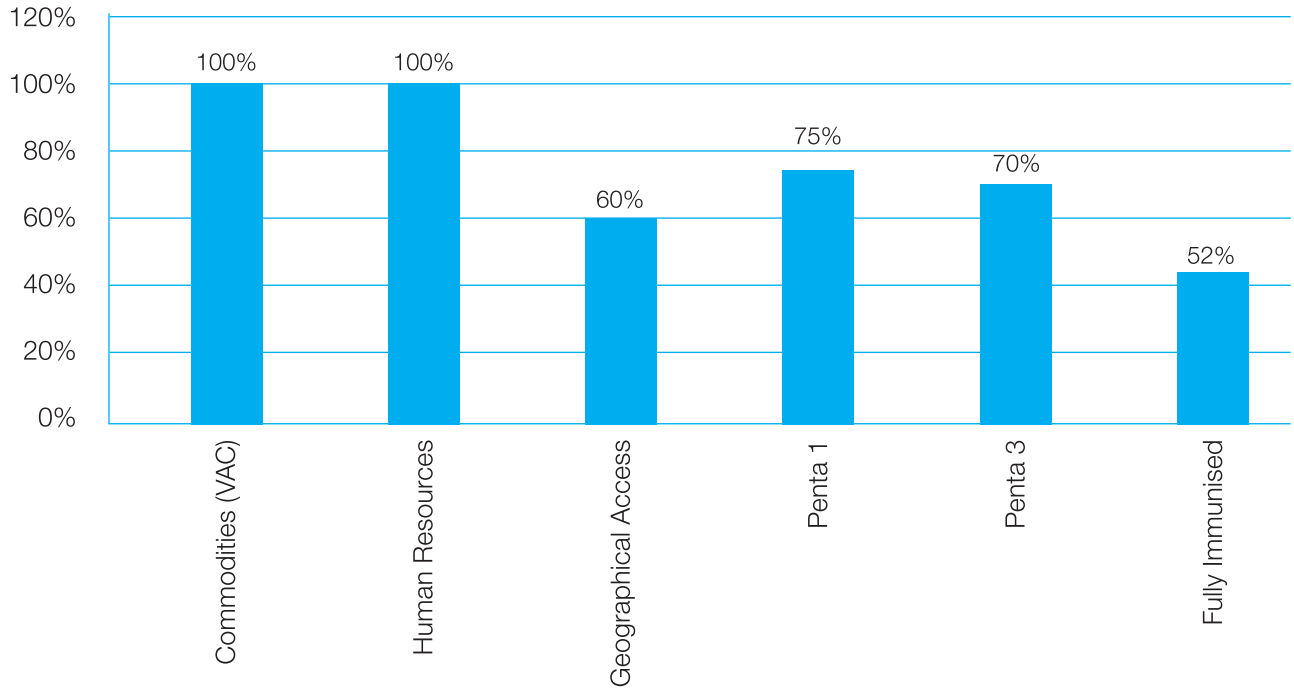
Determinant	Indicator	Definition (numerator and denominator)
Commodities	% of health facilities without stock-outs of any vaccines in the past 6 months	Num. Number of health facilities with no stock-outs of any vaccine/injection materials in the past 6 months Den. Total number of health facilities offering vaccination
Human Resources	% of health facilities with at least 2 qualified health workers for vaccination	Num. Number of health facilities with at least 2 qualified health workers for vaccination Den. Total number of health facilities offering vaccination
Geographic Access	% of EPI target population having access to immunisation services through fixed and/or outreach services	Num. Number of children 0-11 months living within 5 km / 1 hour from vaccinating centre Den. Total number of children age 0-11 months
Initial Utilisation	% of EPI target population that received 1st dose of Pentavalent vaccine	Num. Number of children 0-11 months who received 1st dose of Pentavalent vaccine Den. Total number of children age 0-11 months
Continued Utilisation	% of EPI target population that received 3rd dose of Pentavalent vaccine	Num. Number of children 0-11 months who received 3rd dose of Pentavalent Den. Total number of children age 0-11 months
Quality	% of EPI target population that is fully immunised	Num. Number of children age 0-11 months fully immunised by 12 months of age Den. Total number of children age 0-11 months

1) Exercise: Bottleneck analysis to identify key bottlenecks for low second dose measles coverage

The exercise requires the **6 determinants** related to supply, demand and quality to be monitored. A list of proposed indicators and their definition for the determinants of the selected tracer interventions can be found in Table 5-4. In this exercise use routine Measles/Rubella-1 coverage as the indicator for continuous utilisation and Measles/Rubella-2 as for quality. In addition, an **assessment of financial bottlenecks** and **managerial issues** can also be done.

Enter the data on the six coverage determinants into the excel based bottleneck analysis (BNA) tool (found in a separate document) to generate the bottleneck chart. Figure 5 2 shows an example output chart from the BNA tool.

Figure 5-2: An example output chart from Bottleneck Analysis Tool



Step 4: Identify causes of problems

To identify the causes of the problems or bottlenecks you should hold discussions with the community and health staff. For promoting completion of the full immunisation schedule, include community members by asking them how the service can be made more accessible to them. Other surveys, such as Household surveys of immunisation status, Knowledge Attitude and Practices (KAP) surveys and focus group discussions on immunisation can be used to give further explanations to some of the observed bottlenecks.

In addition, health staff should discuss why children do not begin or complete the immunisation schedule. Exit interviews and observations during sessions by the supervisor provide important hints too.

The key **bottlenecks are then analysed to uncover the root causes** of these obstructions from the local perspective, using the **"5 Why"-method.** The 5 Whys as shown in Table 5 5 is a technique to explore the root causes of a particular problem. It starts by asking why a problem exists. The team uses the answer as the basis for a subsequent "why," and continues to dig deeper until the cause is identified. The number "5" in the name is used because typically five "why questions" are needed to resolve the problem. Based on the results from the causal analysis, **corrective actions** to alleviate the root cause are proposed.

Table 5-5: The "5 Why" Method of analysis to uncover the root causes of bottlenecks

Problem: Children are not fully immunised	
1	Why are children not fully immunised? Their families have negative beliefs about immunisation.
2	Why do families have negative beliefs about immunisation? They are afraid of side effects.
3	Why are families afraid of side effects? They do not have correct information about typical side effects and how to manage them if they occur.
4	Why have families not been adequately informed? CHOs do not take the time to tell families about side effects.
5	Why do CHOs not tell families about side effects? CHO training, supervision, and behavior change communication materials and skills do not reinforce the importance of telling families about side effects.

Step 5: Identify solutions and prepare workplan

Hold a brainstorming session with key people from the district, health facility, partners and community to gather ideas. Get consensus on the main problems and list the priority ones. Choose practical and feasible activities to solve the prioritized problems.

- Health centre problem solving activities should be within existing capacity and resources
- Community activities should be limited to the capacity of the volunteers
- District level activities may provide support to health centres with extra technical and financial resources

Table 5-6: Example of identified solutionsError! Not a valid link.

After assessing the various solutions proposed, choose one to three solutions to test through Plan-Do-Act-Study (PDSA) cycles. The PDSA is a problem-solving cycle used for carrying out changes or making improvements. Change ideas are tested within a short period and measured to determine if improvements occurred. PDSA cycles may also lead to the identification of additional problems, which can then be tested through more PDSA cycles. Or, they may suggest that new solutions to existing problems should be tested. The use of the PDSA is cyclical ans is as follows

a. Make a plan of action that includes:

- Objectives
- Predictions about what will happen when the test is carried out
- Who will do what task, when he or she will do it, and how and where
- Responsibilities and plan for data collection

b. D- Do (carry out) the plan:

- Implement the "change idea"
- Document changes, problems, and unexpected observations
- Check data quality and begin data analysis

c. S- Study the results of implementing the plan:

- Complete data analysis
- Review run charts or line graphs. Run charts are line charts which show variation in data over time
- Consider qualitative data and other Information
- Compare data to predictions
- Summarize lessons learned

d. A- Act on the findings—decide:

- Did the change lead to an improvement?
- Was the improvement significant?
- Did the change produce any unintended effects? Did any other factors affect the outcomes?
- What changes will we test in the next PDSA cycle?

Step 6: Make a session plan

A session plan lists all communities served by the health centre and specifies how frequently each community will be reached based on such factors as distance, target population, and workload. It is based on a maximum workload of about 30 children per vaccinator per session. It uses an immunisation schedule that requires a minimum of four contacts during the first year of life. The aim is to plan sessions so that staff time is used efficiently.

Immunisation session plan

Table 5-7 shows an example immunisation session plan format. It compiles a list of communities and the distances from the health centre that is responsible for their immunisation services. The type of session needed – fixed (at the health centre) or outreach (at a site in the community) – for rural communities usually depends on the distance of the community from the health centre or on the travel time needed if the terrain is difficult. The type of session needed for urban communities may depend on social factors or convenience for the groups being served. The frequency of sessions needed depends on the number of children expected at each session. The number of children an immunisation programme should expect to serve in a community depends on its total population. Table 5-8 is a simplified guide to choosing session frequency based on total population – it gives the end result of calculations based on total population and estimated proportions of children in the total population.

Table 5-7: A sample immunisation session plan format

Community name	Distance from HC in km	Type of session (fixed or outreach)	Total population	Session frequency

Note that all communities are included, some of which may be scheduled for fixed sessions (at the health centre) and some for outreach

How to choose session frequency

Table 5-8 estimates the best use of staff time based on the number of vaccinators expected to be available for each session in a range of population sizes using workload of 30 children per vaccinator per session. Use the total population of the community to be served to choose the session frequency based on the number of vaccinators available for the immunisation team. The following are some examples:

- for a community with a total population of 6000 and an immunisation team with two vaccinators per session, session frequency should be every two weeks
- for a community with a total population of 3000 and an immunisation team with one vaccinator per session, session frequency should be monthly
- for a community with a total population of 500 and an immunisation team with one vaccinator per session, session frequency should be quarterly.

CHAPTER SIX

Managing and immunisation session

6.1 Preparing for the session

Introduction:

Planning and preparing for immunisation sessions should be part of the health facility micro plan. This should be well in advance of the immunisation session. Planning should continue throughout the session to help provide feedback to improve the next sessions.

The purpose is to make the community aware of the sessions in advance and to plan for the needed resources including adequate quantities of vaccines, vaccine carriers and/or cold boxes, AD syringes, safety boxes, reporting tools and any other important materials.

6.2 Plan the immunisation session

Each health center should have an immunisation session plan on file or displayed showing where and when immunisations will be conducted. The session plan should be developed and communicated to the community as part of the microplanning. Immunisation sessions may be held daily, weekly, every two weeks or monthly depending on whether it is a fixed or an outreach site.

For an outreach site, the frequency of the sessions depends on the size of the community being served and the workload. Health staff should plan with community leaders, volunteers and members. Staff should solicit support from the community and agree on arrangement of the session, including choosing a suitable time (e.g. market or community resting days) and track children who are due for immunisation. The actual day for the immunisation session should be communicated early enough for the community to be aware.

Prepare the workplace

Whether you are conducting an outreach or fixed session, there is need to have the following stations:

- Waiting area for caregivers
- Registration and screening area
- Place for vaccination
- Health education place, where care givers can be educated on the health of the child through interpersonal communication.

An ideal immunisation site should:

- be easily accessible and identified with a sign post stating “Immunisation Clinic or child welfare clinic
- be located in the same place each time in a clean area, out of the sun and rain;
- have shelter where those needing vaccination can wait;
- be large enough to provide space for registration and assessment; immunisation and record keeping; screening and education on other health issues

Overcrowding should be avoided at all times as large crowd may cause safety concerns for the health worker and everyone else. Careful preparation is therefore, necessary to ensure a successful immunisation session.

Logistics and equipment needed

The following items are needed and should be reviewed before all sessions using a checklist:

- vaccines and diluents
- Vaccine carrier
- AD syringes
- Mixing syringes
- Safety box
- Cotton wool
- Metal file to open ampoules, if needed
- Emergency drugs (hydrocortisone and adrenaline)
- Immunisation tally book
- CWC Register
- Maternal and Child Health Books
- Container for rubbish that does not go into a safety box
- Note pad pencils and pens
- Table and chairs (may be provided by the community)
- Water container, basin, and soap, towel for hand washing and drying
- A record indicating the expected target population to be vaccinated

When conducting immunisation session at the health facility, vaccines required should be taken from the fridge beforehand to reduce the number of times the fridge is opened.

For an outreach site, additional 10% of all vaccines should be added to the estimated requirement to meet unexpected demand at the session. When number of persons to be vaccinated is not known, the quantity of vaccines can be estimated based on the previous immunisation session demand.

Verify that vaccines are safe to use

The number of each vaccine needed for the session should be estimated before opening the vaccine refrigerator. When opening the fridge, first check the temperature. If there has been exposure to freezing, do the Shake Test on freeze-sensitive vaccines as described in Chapter 3 on vaccine cold chain.
When selecting vials from the refrigerator, check each vaccine and diluent vial/ampoule and remember to:

- Use only vials or ampoules in good condition; discard vials or ampoules that are damaged or have no label
- Discard any vials or ampoules that have passed their expiry date and those with VVMs past the discard point. Vaccines should be discarded based on the procedure prescribed in the EPI policy
- Do not use any vials or ampoules with vaccine that has changed colour or contains particles: seek the advice of your supervisor if any are found.

Vaccines should be used in the order given below:

1. Vaccines whose expiry dates are close.
2. Opened vials kept in the refrigerator with date written on the bottle and labelled “USE FIRST” (in accordance with multi-dose vial policy).
3. Unopened vaccine vials that have been returned from outreach sessions or have been outside of the refrigerator and returned (usually also labelled USE FIRST).
4. Vaccine vials with vaccine vial monitors (VVMs) that have started to change to a darker colour but have not reached or gone past the discard point

Auto-disable syringes and safety boxes

One AD syringe should be taken for each dose of injectable vaccine with an additional 10% as buffer stock. Quantities of syringes required for BCG vaccination and those for other vaccines should be estimated separately.

Take one reconstitution syringe and needle for each vial of vaccine to be used. Take one safety box for every 100 AD syringes.

Ensure correct use of ice packs and vaccine

- Use conditioned ice packs to avoid freezing vaccines.
- Open vials should be inserted in the foam pad of the vaccine carrier during immunisation sessions.
- Do not keep opened vials on ice

Communicating with caregivers

Communication is an essential skill needed throughout a vaccination session. Interaction with each child and caregiver during immunisation encounter is also important for giving out health education. The actual content of communication depends on what caregivers want to know (their own questions) and the key information that must be given, including when to return for the next immunisation. (Refer Chapter 9 for detailed discussion on communicating with care givers at the vaccination center).

Assessing children for vaccination

Before administering vaccines, it is important to check the following:

- Assess eligibility for immunisation by screening for immunisation received and give all the vaccines needed
- If the child is not due that day, appointment should be made and explained to the caregiver
- Verify the child's age on the Maternal and Child Health Book or ask the caregiver for the child's age.
- If the caregiver does not know the child's age, it should be estimated by asking if the child was born during or around a notable community or other event
- Verify which vaccines the child has received by reviewing the Maternal and Child Health Book
- If the child does not have a Maternal and Child Health Book but has been to the health facility before, check the register and fill out a booklet. If the child is new to the health facility, ask the caregiver questions to prompt recall of each vaccine the child should have received and fill out a new card.
- Check for a BCG scar (usually right upper arm/shoulder) if there is no record or recall
- Proceed to the next step with or without the card, recall or a scar. If immunisation status is in doubt and there are no known contraindications vaccinate the child

6.1 Giving vaccinations

Use aseptic technique to prepare vaccines at all times:

- Start with handwashing – use soap and water and dry your hands thoroughly
- Work on a clean table
- Prepare vaccines individually for each child. **DO NOT PREFILL SYRINGES**

Whenever possible, prepare the vaccine away from the child and caregiver; be aware that injection materials may cause anxiety. If this is not possible, turn away slightly to shield the preparation. Try to interact with the caregiver while preparing injections as showing interest in the caregiver is reassuring.

6.1.1 Reconstituting vaccines

Some vaccines need to be reconstituted before use. For such vaccines (BCG, Yellow Fever, Measles-Rubella and Meningococcal A), the correct diluent must be used.

Points to note about diluents

- Always use diluent from the same manufacturer as the vaccine.
- Diluents are not interchangeable: different vaccines have different diluents. Administering a vaccine with the wrong diluent has led to serious adverse events, including death.
- Diluents should be cooled to the same temperature as the vaccine at least 24 hours before reconstitution.

Steps for reconstitution vaccines

- Check each vial/ampoule to make sure it is not past its expiry date, and read the label carefully
- Check if VVMs has not reached discard point. Do not use if VVM is in stage 3 or 4
- If a vial has a metal cap, use a file to lift the pre-cut centre and bend the cap backwards; for a plastic cap, flip it off with your thumb or slowly twist it depending on the specific instructions for the type of vial
- Open the glass ampoule by holding the ampoule between the thumb and middle finger and supporting the top with the index finger; scratch the ampoule neck with a file, then gently break off the top, taking care to avoid injury from the sharp glass (use a piece of gauze for protection)
- If you injure yourself, discard the ampoule since the contents may have been contaminated. Cover the wound before opening a new ampoule.
- Remove the reconstitution needle and syringe and discard them in the safety box.
- Put the reconstituted vaccine vial in the foam pad of your vaccine carrier

6.1.2 Positioning the child for vaccination and how to give vaccinations

How to give intradermal injection (BCG)

- Positioning: Cuddle-position on caregiver's lap is recommended for a child receiving BCG vaccination as shown in Figure 6-1.
- Administration: Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards.
- Lay the syringe and needle almost flat along the child's skin.
- Insert the tip of the needle under the surface of the skin just past the bevel

Figure 6-1: Giving BCG (intradermal) injection

- Keep the needle close to the skin at the same angle as you inserted it.
- Place your other thumb on the lower end of the syringe near the needle to hold the needle in position, but do not touch the needle.
- Hold the plunger end of the syringe between the index and middle fingers. Press the plunger in slowly with the thumb. If you feel no resistance to the plunger, you are not in the right place and should reposition (see figure Figure 6 1).
- A pale flat-topped swelling with small pits like an orange peel should appear on the skin.
- Remove the needle smoothly at the same angle as it went in.
- The caregiver may hold a clean swab gently over the site if it is bleeding. Do not rub or massage the area.
- Calm the child.
- Disposal: Discard the needle and syringe straight into the safety box.

When an intradermal injection is given correctly, the syringe plunger is hard to push. If the plunger goes in too easily, the injection may be too deep. Stop injecting immediately, correct the position of the needle, and give the remainder of the dose.

If the whole dose has already gone in, count the child as having received a dose of vaccine, even though it was given subcutaneously rather than intradermal. Do not repeat the dose immediately.

The risk of side effects, such as abscesses or enlarged glands, is greater if the vaccine is given incorrectly, so the technique is very important. It is better to ask for help from a supervisor or other colleague than to continue giving BCG incorrectly.

How to give a subcutaneous injection

In Ghana measles-rubella and yellow fever vaccines are given subcutaneously. The injection is given into the layer below the skin on the upper arm. Yellow fever vaccine is given on the right upper arm from 9 months of the child's age. Measles-rubella vaccine is given on the left upper arm: the first dose is given from 9 months of age and a second dose from 18 months.

Positioning: This depends on the child's age, number of vaccines to be given and convenience of the vaccinator.

- Sit the child on the mothers lap. The mother holds firm and tucks away the arm that will not receive the vaccine
- Mother's arm go round the child to support the head with the hand supporting the shoulder
- Mother's other arm holds the child's legs with the hand holding the child's hand

Administration:

- Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards
- Quickly push the needle into pinched-up skin; the needle should point towards the shoulder at an angle of 45 degrees
- Depress the plunger smoothly, taking care not to move the needle under the skin
- Pull the needle out quickly and smoothly at the same angle as it went in

How to give intramuscular (IM) injection

The muscle on the **upper outer part** of the thigh is large and safe for intramuscular injections. If you inject into the buttocks, you may cause paralysis. In children aged less than 15 months the deltoid muscle of the upper arm is not safe to use since it is not developed enough to absorb the vaccine and the radial nerve is close to the surface.

The following vaccines should be given intramuscularly: DPT-HepB+Hib (Pentavalent vaccine), Pneumococcal conjugate vaccine (PCV), Meningococcal A conjugate vaccine (Men A) and Tetanus-diphtheria toxoid (Td). Pentavalent vaccine is given on the upper outer part of the left thigh and the PCV vaccine on the upper outer right thigh. MenA is giving on the right upper arm at 18 months. Td is given to women on the upper arm.

Administration:

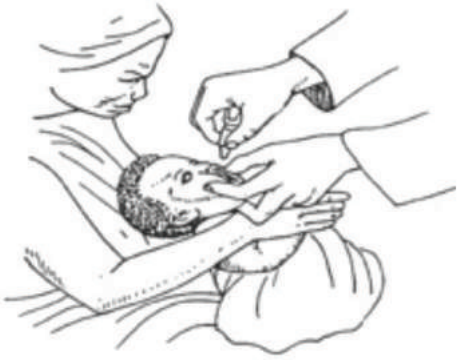
- Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards.

- Gently stretch and support the skin on the upper, outer thigh with the other hand and quickly push the needle at an angle of 90 degrees down through the skin into the muscle.
- Depress the plunger smoothly, taking care not to move the needle under the skin
- Pull the needle out quickly and smoothly at the same angle as it went in
- The caregiver may hold a clean swab gently over the site if it is bleeding. Do not rub or massage the area
- Calm the child

How to give oral vaccines

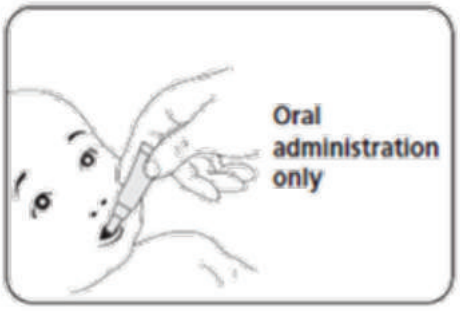
Rotavirus and oral polio vaccines are administered orally. The following step are necessary when administering oral vaccines

1. Oral Polio Vaccination



- Let the mother hold the child firmly
- Open the child's month by squeezing the cheeks gently between your figures
- With the dropper inserted on the vial, administer 2 drops of the vaccine unto the child's tongue

2. Rotavirus (Rotarix) vaccination



- The child should be seated in a reclining position.
- Administer the entire contents of the vial towards the check by a gentle squeezing several times.
- Repeat the dose if the child spits out the vaccine.

6.2 Recording immunisation data

Accurate and reliable records are vital for the individual child and also to track the immunisation status of communities through monthly and annual reporting. During a session, tally sheets, CWC registers and Maternal and Child Health Books have to be completed. Total number of children vaccinated should be recorded in the tally book for respective vaccines and age categories after the session.

Tallying and completing the Maternal and Child Health Book

1. Ensure that tallying is done during the immunisation session as the child receives the vaccine(s).
2. Tallying should be done at the appropriate column on the tally book
3. Write the date for each vaccine administered in its corresponding section on the Maternal and Child Health Book.
4. Write the next immunisation due date in the booklet and ensure that the caregiver understands when and where to return for the next dose(s) of vaccine(s).
5. Return the booklet to the caregiver
6. Explain to the caregiver that the Maternal and Child Health Book must be kept in good condition since it is an important document for future health care visits.
7. Remind the caregiver that the booklet should be taken along any time she is visiting a health facility

Do not miss any opportunity to immunise. Health workers should be in the habit of asking for and reviewing child health record booklets for each child at each visit regardless of the reason for coming.

Prepare a summary of the session

- Calculate total numbers of vaccines given, supplies used and stock remaining for inclusion in monthly vaccine and immunisation report
- Use the immunisation register to make a list of children who were due for vaccines but did not attend the session. The list should be used for defaulter tracking and for programme monitoring activities
- Inform community volunteers (members) who help with defaulter tracking of the children on the list; ask them to mobilize the defaulters for the next immunisation session.

6.3 Closing the session

Materials must be stored safely or disposed of after immunisation sessions. Equipment and sites must be cleaned and maintained for their next use. Discard or store opened vials depending on vaccine type based on open multi-dose vial policy.

After outreach sessions, the following steps are required for vaccines and supplies.

- Check the ice packs to make sure that the ice has not melted.
- Check each vial for VVM changes. Discard all vaccines in VVM stages 3 or 4
- Place unopened vaccines and labeled opened vials with date for which the multi-dose vial policy is applicable inside the carrier.
- Put empty vials and opened vials of reconstituted vaccines in a separate container for transport to a disposal site.
- Return vaccines in VVM stages 1 or 2 to the “use first” box in the refrigerator
- Put the ice packs from the carrier into the freezer
- Wipe the carrier with a damp cloth and check it for cracks: leave open to dry
- Place CWC registers, unused AD syringes and Maternal and Child Health Books in their designated storage areas
- Safety boxes containing used needles and syringes must be transported for incineration
- Clean and return tables, chairs and other equipment to their owners
- Leave the site clean and tidy
- Thank the local people who have helped to organize the session and remind them of the date of the next session

6.3 Using the immunisation session checklist

Before the immunization session

DID YOU:

Y N CHECK if sufficient quantities of vaccines and diluents are available for the session?

CHECK vitals for the following and take appropriate action:
- Y N Expiry dates?
- Y N Open vital dates?
- Y N VVM status?
- Y N Freezing status?

Y N PLACE vitals in the appropriate place in the immunization area?

ENSURE sufficient supplies are available for the session including:
- Y N Auto-disable (AD) syringes?
- Y N Reconstitution syringes?
- Y N Safety box?
- Y N AEFI kit?
- Y N Immunization tally sheets?
- Y N Blank immunization cards?

For selected clients attending the immunization session

DID YOU:

Y N GREET the client and caregiver

Y N REVIEW the client's immunization card?

Y N DETERMINE eligible vaccinations based on the national schedule, client's age and possible contraindications?

Y N RECONSTITUTE each vaccine with its matched diluent (for lyophilized vaccines)?

Y N FILL syringes just before administration using aseptic technique?

Y N ADMINISTER each vaccine according to recommended technique and correct injection site?

Y N IMMEDIATELY DISPOSE needles/AD syringes in safety boxes after each injection

Y N RECORD all vaccinations in register, tally sheet and immunization card?

Y N COMMUNICATE key messages, including potential AEFIs and date of next visit?

After the immunization session

DID YOU:

Y N CORRECTLY ASSESS if open vials can be used in the next session in accordance with national multi-dose vial policy

Y N DISCARD open vials that should not be used?

Y N RECORD date of opening on vials that can be used and PLACE them in the 'use first' box in the refrigerator?

Y N RETURN unopened vials to the refrigerator?

Y N COMPLETE session summary report?

Y N LIST the names of children who missed vaccination and require follow up?

Y N HANDLE full safety boxes correctly?

Y N TAKE appropriate action to ensure suffiicient vaccine stock for the next session?

Y N INFORM COMMUNITY of date and time of next session?

CHAPTER SEVEN

Monitoring of the Immunisation System

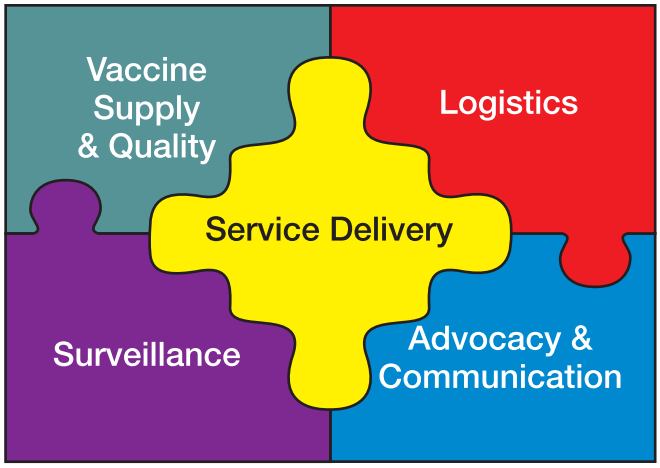
Monitoring is a key component of the immunization system. It helps measure the performance of all components of the immunisation system, by a combination of passive data collection (monthly reports) and active data collection eg. during supervisory visits. This chapter describes monitoring of the immunization system and how managers can use the data they collect to identify problems and take corrective action. The purpose is to improve the quality and success of the immunisation programme.

7.1 What is monitoring and why is it important

Monitoring is the systematic and continuous process of examining data, procedures and practices. It is used to measure progress, identify problems, develop solutions, and guide policies and interventions. Monitoring is an important tool for immunisation service providers and managers at all levels. It can help improve the quality of the immunisation programme by ensuring:

- All children and pregnant women are vaccinated
- Vaccines and injection safety equipment are delivered in the right time and in the correct quantities
- Staff are well trained and adequately supervised
- Information on disease incidence and adverse events following immunisation are collected and analysed
- The community has confidence in the vaccines delivered and the immunisation services they receive

7.2 Which aspects of the immunisation programme should be monitored?



For the purpose of monitoring the immunisation programme, it is useful to refer to five components of the immunisation system operations. Each component can be broken down into smaller parts that are easier to evaluate.

The component 'vaccine supply and quality' consists of forecasting vaccine needs, procurement of vaccines, monitoring of vaccine use and safety procedures. There is the need to look at each of these smaller parts in order to monitor overall 'vaccine supply and quality' component of the immunisation system.

How is the immunisation system monitored

The immunisation system is monitored using indicators. An indicator is a statement that describes the quality to be achieve. Developing good quality indicators is important in monitoring progress.

Key point: Indicators set the standard that you are aiming for in your immunisation programme. Monitoring is the continuous and regular measurement of progress towards these indicators.

Table 7-1 shows example of key indicators and their measuring parameters by system component.
Table 7-1: Indicators by system component

Components	Measuring Parameter	Indicators
Service delivery	Access	Coverage of Penta 1 and planned sessions
	Coverage	Coverage with: BCG, Penta3, OPV3, MR1, MR2, Men A, YF, Rota 2, PCV3, Td2+
	Equity	Proportion of organizational unit with Penta3 coverage of 80% and above
	Utilisation	DOR: Penta1/Penta3 , Penta1/MR1 and MR1/MR2
Logistics and cold chain	Availability and Functionality	Availability of equipment and transport, vaccine storage, distribution and supervision
Vaccine supply and quality	Forecasting and ordering	Vaccine stock out
Surveillance and Monitoring	Effectiveness of reporting	Timeliness and completeness
	Disease/Event incidence	Diseased incidence, AFP rate, AEFI
Advocacy and Communication	Community engagement	Existence of active community health committees, Number of community engagements
Human and institutional resources	Supervision	Supervisory visits
	Capacity building	Adequacy, training
Management	Ability to plan and implement	Existence of microplans of each district; Reports on implementation of the plans

7.3 Data Collection at the facility level

The following tools are used for routine recording of immunisation-related activities at the service-delivery level;

1. Tally sheet
2. Child health register (CWC register)
3. Maternal and Maternal and Child Health Book
4. Vaccine ledger
5. Temperature monitoring chart
6. Monthly vaccination reporting form

7.3.1 Tally sheet

Tally sheets are the forms that health workers use to document an immunisation session. They should be used for all sessions whether fixed or outreach. A new tally sheet should be used for each session. The tally sheet records data on vaccinations, vitamin A and long-lasting insecticide treated nets (LLINs) actually given by making a tally after an child or mother receives the dose or service. There is also a section on the tally sheet that records data on logistics used at the vaccination session and a section used to summarize the records on services provided for the session.

The tally sheet is structured according to the vaccination schedule currently in use in the country as well as any new vaccine(s) to be introduced, target age to be vaccinated and other interventions that are provided together with immunisation.

The current tally sheet used in Ghana is shown in Figure 7-1 and Figure 7-2

Figure 7-1: EPI Tally sheet Side A: Children Immunisations

GHANA EPI TALLY SHEET (SIDE A): CHILDREN IMMUNIZATIONS

DATE: .... ./...../..... REGION: ..... DISTRICT: ..... HEALTH FACILITY: ..... OUTREACH (Village/Town): .....

ANTIGENS/ ITEMS	0-11 MONTHS	TOTAL	12-23 MONTHS	TOTAL	24 MONTHS & ABOVE	TOTAL	TOTAL CHN VACCINATED
BCG	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
CPV 0	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
CPV 2	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
CPV 3	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
IPV	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Rotavirus 1	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Rotavirus 2	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
DPT-HepB-Hib1	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
DPT-HepB-Hib2	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
DPT-HepB-Hib3	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Pneumococcal 1	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Pneumococcal 2	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Pneumococcal 3	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Measles-Rubella 1	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000		00000 00000 00000 00000		
Measles-Rubella 2			00000 00000 00000 00000		00000 00000 00000 00000		
Long Lasting Insecticial Net			00000 00000 00000 00000		00000 00000 00000 00000		
Yellow Fever	00000 00000 00000 00000 00000		00000 00000		00000 00000		
Meningococcal A Conjugate (Men A)			00000 00000 00000 00000		00000 00000 00000 00000		
Fully Immunized	00000 00000 00000 00000 00000		00000 00000		00000 00000		
Vitamin A (starting from 6 months)	00000 00000 00000 00000 00000		00000 00000		00000 00000		

Figure 7-2: EPI Tally sheet Side A: Children Immunisations

GHANA EPI TALLY SHEET (SIDE B): Td Among Women in their Fertility Age (WIFA)

Td Dose given to pregnant women 15-49 years				More than 5 Td doses - Fully Protected (f)	Long lasting Insecticidal net (h)	Td Dose given to non-pregnant women 15-49 years						Others (p)
Td 1 (a)	Td 2 (b)	Td 3 (c) Td 4 (d)	Td 5 (e)			Td 1 (i)	Td 2 (j)	Td 3 (k)	Td 4 (l)	Td 5 (m)	More than 5 Td doses (n)	
00000 00000	00000 00000	00000 00000	00000	00000	00000	00000 00000	00000	00000	00000	00000	00000	00000
00000 00000	00000 00000	00000 00000	00000	00000	00000	00000 00000	00000	00000	00000	00000	00000	00000
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00000 00000	00000 00000	00000 00000	00000	00000	00000	00000 00000	00000	00000	00000	00000	00000	00000
Total =	Total =	Total =	Total =	Total =	Total =	Total =	Total =	Total =	Total =	Total =	Total =	Total =

Summary of Td Immunizations and LLINs Issued

Status	Number
Td 2+ Among pregnant Women = (b+c+d+e+f)	
Td 2+ Among non-pregnant Women = (i+j+k+l+m+n)	
Td Vaccination to other persons (p)	
Long Lasting Insecticidal Nets Given = (h)	

Summary of Vaccines and other logistics

Antigens / Items	1 dose	2 doses	5 doses	10 doses	20 doses	Total doses
BCG						
OPV						
IPV						
Rotavirus						
DPT-HepB-Hib						
Pneumococcal						
Measles-Rubella						
Measles						
Men A						
Yellow Fever						
Td						
Vitamin A						

Total Children Vaccinated / Served

Antigen/Items	0-11 months	12-23 months	24 months and above	Total Vaccinated
BCG				
OPV 0				
OPV 2				
OPV 3				
IPV				
Rotavirus 1				
Rotavirus 2				
DPT-HepB-Hib 1				
DPT-HepB-Hib 2				
DPT-HepB-Hib 3				
Pneumococcal 1				
Pneumococcal 2				
Pneumococcal 3				
Measles-Rubella				
Yellow Fever				
LLIN				
Measles				
Men A				
Fully Immunized				
Vitamin A				

To use the tally sheet, the vaccinator should tally against the antigen or service provided to the child or mother and in the appropriate age category. At the end of each immunisation session, add up the number of tallies. This gives the total number of persons given specific vaccine and the dose in its series or given other services. Keep the tally sheet for the supervisor to review. Table 7-2 below describes some common errors in tallying.

Table 7-2: Common mistakes in tallying

Mistake in Tallying	Possible Result	Correct Practice
Tallying before the vaccine is administered	The child or pregnant woman may not receive the vaccine	Give the dose first and then tally using the tally sheet
Tallying at the end of a session according to number of doses contained in used vial	'Wasted' doses may be added to the total	Tally only those doses actually given.
Tallying all vaccines under one age group (including those outside the target group)	Will result in inaccurate coverage data	Separate tally for under one and over one year of age, and pregnant women
Totals and summaries of vaccinations and vaccines used not done	Inaccurate coverage and vaccine utilisation data	Make daily totals of children vaccinated and vaccines used

7.3.2 Child health register (CWC register)

The Child health register is used to record the immunisations received by each child. It is a book that stays in the health facility. Its main purpose is to keep track of the immunisation services provided to each child over time. It lists each child on a separate line and is important for several reasons:

- It is the health facility's primary source of information on a child's immunisation status and needed vaccinations. This information is particularly helpful if a child presents at a facility for a follow-up visit without a Maternal and Child Health Book.
- It helps identify children who miss scheduled vaccinations and who need to be added to the defaulter tracking list
- It is a source of information for data verification and preparation of reports

The Child health register can also be used as a birth register. As soon as a child is born in the community, the name can be entered in the register even before receiving any vaccinations. This will help to follow up new children along with older ones on the defaulter tracking list.

Figure 7-3: Child health register

GHANA HEALTH SERVICE CHILD WELFARE CLINIC REGISTER 0-11 MONTHS

											IMMUNIZATION																								
Serial No.	Child Registration No.	Child's Name	Date of Birth	Date First Seen	Sex	Birth Weight	Birth Registration No.	Sickling Status	Mother's Name	Telephone No./ Traceable Address	HEP B	BCG	POLIO				ROTA VIRUS		PENTA			PNEUMOCOCCAL			MEASLES1		YELLOW FEVER	OTHERS	VITA @ 6mths	REMARKS
													0	1	2	3	1	2	1	2	3	1	2	3						

The minimum information in a register usually includes the following information;

- unique identification number
- registration date (usually the date of the first visit)
- name of child
- child's birth date
- child's sex
- name, address and phone/mobile number of caregiver(s)
- dates and doses of vaccinations and vitamin A supplementation given

How to complete the Child Health Register (CWC register)

Children should be registered as soon as they arrive at the health facility,outreach site or at birth if delivered at the facility.

- At registration fill in all information except the space provided for vaccinations.
- Use a unique identification number on the register for each child and write the same number in the Maternal and Child Health Book. A unique identification number is easier to locate in the register if the Maternal and Child Health Book is available during follow-up appointments.
- Do not create a new entry in the register each time the caregiver brings the child for immunisation.
- Ask the caregiver for the Maternal and Child Health Book and look for a corresponding entry in the register. If the Maternal and Child Health Book is not available, ask the caregiver for the child's name, age and the month and/or other details of the first immunisation, then locate their line in the register.
- Vaccinations should be indicated by the date the dose was administered only after the child has been vaccinated.
- For every new child (never immunised), create a new entry in the register and a new Maternal and Child Health Book. For a child who has come to the health facility for the first time but has received immunisations in another facility, create a new entry in the register: ask for the Maternal and Child Health Book and write immunisations that the child has already received in the register.
- If there is no Maternal and Child Health Book, review the vaccines the child should have received (by age/status according to the national immunisation schedule) with the caregiver and record the ones the caregiver can recall that the child has already received. If the caregiver is not able to recall vaccines given, the immunisation schedule should be started again.

7.3.3 Maternal and child health book

Maternal and child health (MCH) book is a document that contains the antenatal records of mothers as well as the immunisation and other child health records of the child. The book is important for several reasons;

- Determines whether the child was protected from tetanus at birth
- Reminds the caregiver when to return to the clinic
- Records batch number of vaccines to support investigations in case an AEFI occurs
- Assists the MCH staff to ascertain the immunisation status of the child
- Allows continuity of service when the child moves to another area.
- During coverage surveys, the card is used to verify immunisation status of the child

Each child should be provided with an MCH book before delivery. The book is first issued to the mother at her first visit to the health facility during pregnancy. It then becomes the property of the child after delivery. Caregivers should be reminded to keep the Maternal and Child Health Book in a safe place and carry it for all immunisation and other health care visits.

How to complete the Immunisation section of the MCH book

Complete the book by writing down the date on which each vaccine, vitamin A or long-lasting Insecticide net (LLIN) is provided. Record the batch number for vaccines and diluents (where applicable). Write the next appointment date in the book and tell the caregiver when to return for the next vaccination. Explain to the care taker which disease each vaccine protects against.

Table 7-3: Immunisation records in the MCH book

Age Period	Vaccine	Date Given	Batch No.	Place Given	Date of Next Visit
At Birth	BCG		V: D:		
	Polio - 0				
	Hepatitis B				
6 Weeks	Polio - 1				
	DPT-HepB-Hib				
	Pneumococcal				
	Rotavirus				
10 Weeks	Polio				
	DPT-HepB-Hib				
	Pneumococcal				
	Rotavirus				
14 Weeks	Polio				
	DPT-HepB-Hib				
	Pneumococcal				
	IPV				
9 Months	Measles-Rubella		V: D:		
	Yellow Fever		V: D:		
18 Months	Measles-Rubella		V: D:		
	Men A		V: D:		
	LLIN				

7.3.4 Vaccine ledger

Wherever vaccines are stored, a system of stock management must be in place to record the movement of vaccines and safe injection equipment in and out of the storage facility, including those received, dispatched and used. This will help ensure that:

- vaccines and safe injection equipment are used before their expiry dates
- the vaccine vial monitor (VVM) status is recorded at receipt and issue of vaccines and
- there are no stock outs and over stocking.

Table 7-4 shows some common practices on the field and the possible negative consequences;
Table 7-4: Common problems with stock records

Common Practice	Possible Results	Correct Practice
No stock record	Can lead to over-stocking, shortage of storage space, or stock outs	Use stock records
Stock records not updated	Can lead to overstocking, shortage of storage space, or stock-outs.	Update stock record for every transaction.
Incomplete data - expiry date, VVM status and batch number missing	Expired vaccines in stock or vaccines with VVM status at discard point might be in stock.	Complete all fields of record and discard expired vaccines.

It is important to distinguish between different batches of vaccine because they may have different expiry dates and should be used accordingly. Additionally, in the event that a certain vaccine is recalled, it is important to easily identify the vaccine batch. Figure 7-4 shows a copy of the vaccine ledger;

Figure 7-4: EPI vaccine ledger

MINISTRY OF HEALTH / GHANA HEALTH SERVICE

EXPANDED PROGRAMME ON IMMUNIZATION

VACCINE LEDGER

ANTIGEN	
VIAL SIZE	

STOCK LEVELS		
MAXIMUM	MINIMUM	RE-ORDER

Date	Received from OR Issued to	VACCINES										DILUENTS					
		Batch/ Lot. No.	Expiry date	Manufacturer / country of origin	Quantity received	Quantity vissued	VVM status on arrival	Losses: VVM change / missing / broken vials	Balance	Batch/ Lot. No.	Expiry date	Quantity received	Quantity issued	Losses: Missing / broken vials	Balance

7.3.5 Temperature monitoring

The temperature of every refrigerator and freezer that stores vaccines should be monitored twice a day (including weekends and holidays) and recorded on a temperature monitoring chart. This information is not difficult to collect and can provide valuable information about the quality of vaccines, the training needs of health workers, and the availability of equipment (including thermometers) at the health-facility level. Table 7-5 shows a sample temperature monitoring chart.

Table 7-5: Temperature monitoring chart

DAY	AM	PM	▲	ALARM/OK	DURATION	INITIALS	▼	ALARM/OK	DURATION	INITIALS
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
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30										
31										

7.3.6 Monthly vaccination report

Daily vaccinations must be summarized into a monthly vaccination report. The report must then be entered into the EPI section of the District Health Information Management System (DHIMS) platform. The hard copy report, which is dated and endorsed, must then be filled at the health facility as it is the only source document for reported data. DHIMS will automatically aggregate health facility reports into a sub-district report and subsequently aggregate sub-district reports into a district report etc.

Health workers should ensure that reports are:

Complete: The completeness of reporting for each particular period is calculated on the basis of total number of reports expected (denominator) and number of reports received (numerator) and is expressed as a percentage. If reports are not complete for a district, the cumulative immunisation coverage figure will drop and not reflect the true situation. In addition, all sections of the monthly vaccination report should be completed without blank spaces.

Timely. Monthly vaccination reports completed, entered into DHIMS and analysed on time help ensure prompt and effective response. There may be situations where data for a particular period and/or facility is late. The best way to manage a late report is to submit an addendum to the monthly report. Late incoming data should not be rejected or ignored; they must be used to update the existing data set at all levels.

Accurate. All monthly vaccination reports should contain data that correspond to the actual figures from the health facilities and that are doubly-checked for correct calculations and totals.

District, regional and national levels should keep track of the completeness and timeliness of reporting as well as missing or late reports. Timeliness and completeness of reporting should be used as an indicator for measuring the performance of health facilities.

With the advent of the web-based District Health Information Management System (DHIMS), data entry is done at the lowest level (either sub-district or health facility depending on the availability of computer with access to internet and trained personnel). All higher levels can access a facility specific data or an aggregated data for any level depending on the type of user. Table 7-6 and Table 7-7 show a sample of the monthly reporting form.

Table 7-6: Monthly vaccination report: Front page

MONTHLY VACCINATION REPORT

A. Region: _____ B: District: _____ C: Name of Reporting Facility: _____

D. Month: _____ E. Sub-District: _____ F. Year: _____

1. Demographic data	Annual	Monthly
1.1 Total Population		
1.2 Infants 0-11 months		
1.3 Children 12-23 months		
1.4 Expected Pregnancy		

2. Vaccination sessions	Planned	Conducted
2.1 No. of fixed vaccination sessions		
2.2 No. of outreach vaccination sessions		
2.3 No. of school vaccination sessions		

3. Vaccination coverage rates	BCG	Penta1	Penta3	PCV3	IPV	MR1	MR2
3.1 Monthly coverage (%)							
3.2 Cumulative coverage (%)							
3.3 Dropout rate (%)			Cum (Penta1 - Penta3) * 100 / Penta1				Cum (BCG - MR1) * 100 / BCG

4. Monthly vaccinations given by Age				
Vaccine / Commodities	Number Given (by age group)			
	0-11 months	12-23 months	>=24 months	Total vaccinated
BCG				
Hep B				
OPV0				
OPV-1				
OPV-2				
OPV-3				
IPV				
Rotavirus - 1				
Rotavirus - 2				
Penta-1				
Penta-2				
Penta-3				
PCV-1				
PCV-2				
PCV-3				
MR1				
MR2				
YF				
Men A				
Fully Immunized				
LLIN - Children				
	Pregnant Women	Non-Pregnant		Others
Td-1				
Td-2				
Td-3				
Td-4				
Td-5				
Td-5+ (Not vaccinated)				
LLIN - Pregnant Women				

5. HPV Vaccination at 9 years			
Dose	In-school	Out-of-school	Total vaccinated
HPV 1			
HPV2			

6. Vitamin A Supplementation			
	6-11 months	12-59 months	Post-partum
Vitamin A			

7. A.E.F.I.		
	Non-serious	Serious
No. of cases reported		

8. Waste management	
8.1 No. of safety boxes used	
8.2 No. of safety boxes disposed	

9. Cold chain temperatures at Health Facilities	
9.1 Maximum temperature recorded	
9.2 Minimum temperature recorded	
9.3 Number of days with high temperature alarms	
9.4 Number of days with low temperature alarms	
9.5 Number of refrigerators available	
9.6 Number of functional refrigerators	

10. IE & C	Planned	Conducted
10.1 No. of IEC sessions		
10.2 No. of participants		
10.3 No. of hom visit sessions		

Table 7-7: Monthly vaccination report: Back page

11. Status & utilisation of vaccine stocks and other commodities								
	Quantity (doses)							
	Beginning	Received	Total doses opened for vaccination	VVM Status Change (3 or 4)	Expired	Other losses	Stock at end	No. of days of stockouts
BCG								
Hep B								
OPV								
IPV								
Rotavirus								
Penta								
PCV								
Measles-Rubella								
Measles								
YF								
Men A								
Td								
HPV								
RTS,S								
LLIN								
Vitamin A (100,000 IU) - Blue								
Vitamin A (200,000 IU) - Red								
Auto Disable Syringe (0.05ml)								
Auto Disable Syringe (0.5ml)								
Dilution syringe (2ml)								
Dilution syringe (5ml)								
Safety boxes								
Child Health Records								

12. Remarks

COMPILED BY: **Name:** _____ APPROVED BY: **Name:** _____

Designation: _____ **Designation:** _____

Date: _____ **Date:** _____

Contact Number: _____ **Contact Number:** _____

7.4 Storage of immunisation data

For purposes of verification, data must be stored at all levels either electronically or hard. At the health facility, tally sheets, registers and reports should be stored for at least three years. Stored records are useful for immunisation programme reviews.

The following records should be stored at each health facility for at least three years; immunisation registers, tally sheets, monthly reports, Immunisation monitoring charts, case/outbreak reports, supervisory visit reports, vaccine ledger and cold chain maintenance records.

7.5 Data Analysis and Display

At every level, staff should use the data they have collected to monitor immunisation performance for their catchment area. This will allow them to examine priority locations that may have performed poorly in the past, or areas that have experienced an unexpected change in the quality of performance.

In this section, you will be shown the most common tools to help staff analyze and display data, and identify problem areas. A number of methods are described, including coverage, dropout rates, completeness, timeliness of reports etc.

7.5.1 Coverage

This is a measure of the extent to which the services being rendered are reaching the intended targets. Immunisation coverage is the proportion of vaccinated individuals among the target population. It is one of the most important indicators of a successful immunisation programme. Coverage is calculated by dividing the number of individuals vaccinated with a particular antigen (numerator) by the number of individuals targeted for vaccination with the antigen (denominator) within the same period. This proportion is then multiplied by 100 to get percentage coverage.

Coverage formula:

$$\frac{\text{(Number of persons vaccinated)}}{\text{(Number of persons targeted for vaccination)}} \times 100$$

The following coverage rates are routinely calculated

- Coverage for each vaccine dose
- Coverage for fully immunised child by age one and age two
- Td2+ coverage

Example: During the previous year, Mpasatia Health Centre of Atwima Mponua District administered 102 doses of Penta-3 and 73 doses of first dose of measles-rubella vaccine to children less than one year of age.

If the number of doses of Penta-3 immunisations given over the past year is 102 and the target population of children below one year of age in Mpasatia Health Centre is 150, then the coverage for Penta-3 will be 68%.

$$\text{Penta-3 coverage} = \frac{102}{150} \times 100 = 68\%$$

The measles rubella 1 immunisation coverage is calculated in a similar way.

$$\text{Measles coverage} = \frac{73}{150} \times 100 = 49\%$$

A fully vaccinated child by age one (1) is a child who has received BCG, three doses each of pentavalent, pneumococcal and polio vaccines (excluding polio vaccine given at birth), two doses of rotavirus and a dose each of measles-rubella and yellow fever vaccines before he/she is one (1) year old.

A fully vaccinated child by age two (2) is a child who has received BCG, three doses each of pentavalent, pneumococcal and polio vaccines (excluding polio vaccine given at birth), two doses of rotavirus and a dose each of measles-rubella and yellow fever vaccines as well as a second dose of measles-rubella and meningitis A vaccinations from 18 months.

7.5.2 Completeness

Completeness of reporting is defined in two different ways depending on the level and function of the reporting unit. At the health facility level, completeness means all required fields in a report have been filled. How well this is done determines the quality of data being reported. At the sub-district, district, regional and national levels, completeness of reporting for a particular period is defined as the number of reports received out of the total expected reports (proportion of reports received). This is calculated by dividing the total number of reports received from the reporting units (numerator) by the total number of reporting units (denominator). The result is then multiplied by 100 to make it a percentage.

$$\text{Completeness formula: } \frac{\text{Total reports received}}{\text{Total expected reports}} \times 100$$

Health workers should ensure that all monthly reports are sent to the district including late reports. Non-reporting of late data affects the overall district coverage and, subsequently, the national immunisation coverage.

7.5.3 Timeliness

Timeliness of reporting is defined as the proportion of reports that are received on time. It is the number of reports received on time divided (numerator) by the total number of reports expected for the period (denominator)

$$\text{Timeliness formula: } \frac{\text{Total reports received on time}}{\text{Total reports expected}} \times 100$$

Data collected from the tally sheets need to be summarized at the health facility level onto the monthly vaccination report. This report must be entered into DHIMS latest by 5th of the ensuing month.

7.6 Immunisation monitor charts

Immunisation monitor chart is a simple and effective tool for visually monitoring the progress towards immunisation coverage targets across the catchment area of a health facility, sub-district, district, region and the national level. The following information is presented on a graph.

- The number of vaccines administered on a month-by-month basis compared with the number of children who should receive them (the target population).
- If the coverage rates of two vaccines are plotted on the same graph, then it is possible to monitor the drop-out rate/gap between the two vaccines i.e. the number of children that started receiving immunisations compared to the number of children that received all doses of the vaccine

Each level, from health facility to the national level, should display a current coverage/drop-out monitoring chart. It is important that immunization staff are familiar with producing these charts. Figure 7-5 shows a blank immunisation monitor chart for Penta.

Figure 7-5: Immunisation monitor chart for Penta

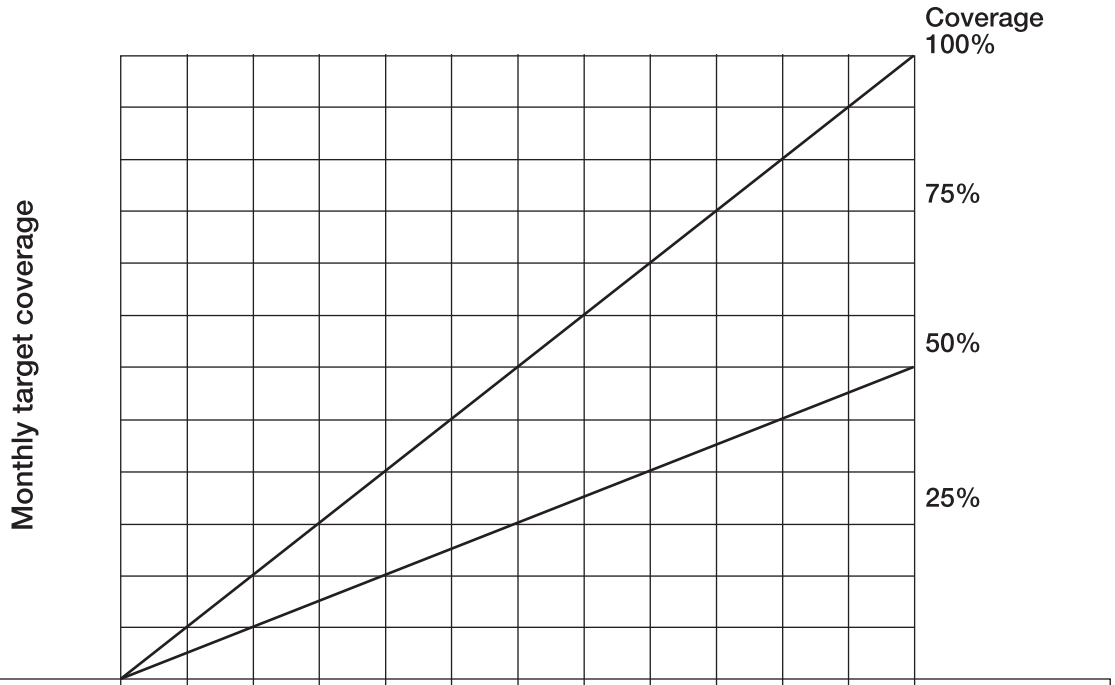
IMMUNIZATION MONITOR CHART

Penta

Health Facility: _____ Annual target population (0 - 11 months): _____

Minimum coverage target for the year with Penta 1: _____

Year: _____ Minimum coverage target for the year with Penta 3: _____



Vaccine	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
A **Penta 1** DPT-HepB-Hib 1													Total Immunized this month
													Cumulative for the month
B **Penta 1** DPT-HepB-Hib 2													Total Immunized this month
													Cumulative for the month
C **Penta 1** DPT-HepB-Hib 3													Total Immunized this month
													Cumulative for the month

DROP-OUT RATE = (use cumulative) $\frac{(A-C) * 100}{A}$												
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	

Please note: The calculation of the drop-out rate is only rational if all doses of the same vaccine Penta 1, Penta 2, and Penta 3 are recorded.

A drop-out rate of more than 10% is an indication for immediate action - Please check on how tallying is done in the tally book at immunization centres, staff attitidue towards clients and educate the public

How to complete an immunisation monitoring chart

Calculate the annual target population who should receive immunisation services

Annual target population = total population × % of children in population

Aim to vaccinate every child in the catchment area, including those who are hard to reach. The proportion of children under 1 year in Ghana is 4%. Multiplying the total population by 4% (the proportion of under 1 children) give you the target population.

Data for peripheral health facility calculations are often difficult to find and more accurate targets can be set by:

- immunisation staff and district supervisors, who may need to discuss and agree on target population adjustments based on local knowledge and past experience;
- drawing the past year's results on the current year's chart in order to follow progress from year to year.

The monthly target population is the annual target population of children divided by 12.

Monthly target = annual target population/12

Example: If the total population is 3900, then the annual target population of children is;

Annual target: $\frac{4}{100} \times 3900 =$ **156**;

Monthly target: $\frac{156}{12} =$ **13**

Plotting the chart

- Write the name of the facility and year
- Fill in the annual under one population of the catchment area
- Complete the minimum coverage target for the year
- Divide the under one annual target by 12
- Label the left side of the chart with the monthly target numbers.
- Enter the months on the horizontal axis
- Draw a diagonal line from zero to the top right-hand corner to show the ideal rate of progress from month to month using the cumulative monthly target numbers.
- Locate the space for the month being recorded in the row of boxes underneath the graph and enter the monthly total of vaccine given.
- Plot the graph using cumulative immunisation data
- Calculate the cumulative total for the current month as shown:
- Current cumulative total = current month's total doses + sum of doses provided in previous month's
- Note that cumulative means the total number of doses of vaccines given in the current month plus the monthly totals for previous month in the current calendar year; for example, the cumulative number of penta3 doses given by the end of March is the total number of doses given in January plus the total number given in February plus the total number given in March.
- Make a dot on the graph corresponding to the cumulative total of the month being recorded; the dot should line up with the correct monthly number on the left side of the chart.
- Connect the new dot to the previous month's dot with a straight line.
- Repeat every month until the end of the year.
- Plot other immunisations given on the same chart, as needed.

- Calculate the total number of dropouts between the first and last dose of the same vaccine series.
- Number of dropouts = (cumulative total for the first dose) – (cumulative total for the last dose of the vaccine series)
- Dropout rate (%) = (number of dropouts/cumulative total for the first dose) × 100
- The dropout rate can be seen easily in the doses administered chart: it is the gap between the lines for the first and last dose of a vaccine.
- Example calculation: If all 156 children in the annual target population received penta1, but only 100 finished all three doses during the year, then:
- Number of dropouts = (156) – (100) = 56
- Dropout rate = [56/156] × 100 = 35.9%

How to analyse the immunisation monitor chart

To determine whether you are on track with your vaccination, compare the chart line (cumulative total line) with the target line: If it is above or on the coverage target line, good progress is being made. If it is below but still close to the target line, moderate progress is being made. If it is far below the coverage target line, a serious problem exists.

Estimate the coverage rate: You will get an approximate coverage of where you are in relation to your annual target. Each interval on the right hand side of the chart represents 7.5 percentage points. Look at the first point plotted, and compare with the 25%, 50% and 75% indicated lines to get an indication as to where you are. If you for example are close to the 25% line, you will not achieve a target of 50% by the end of the year if you do not re-strategize in order to increase performance.

You can also compare this month's number of immunisation with last month's: Were there any changes? Have the numbers increased or decreased? What are the reasons? And what can you do next month?

Is there a problem with dropouts or left outs in your clinic? Look at the chart if the distance between BCG and Penta3/OPV3 or measles-rubella 1 is wide. If there is more than a 10% difference, there is a problem with dropouts. For example, there is a big problem with dropouts if 65 children have been vaccinated with BCG and only 30 of these children received Penta3.

7.7 Analysis of Vaccination Coverage data

Full analysis requires data to be compiled by area. Table 7 8, Figure 7 6 and Table 7 9 suggest how to compile and analyze vaccination coverage data. The first part of the process shown below focuses on prioritizing areas by the number of unimmunised children during microplanning. The additional calculations given and Figure 7 6 are included here to help define problems that cause children to remain unimmunised. Defining problems in detail helps identify potential solutions.

How to compile the analysis table

- List each geographic area or community served in Column a.
- List the target population for children less than one year of age in Column b.
- Enter the number of doses of each vaccine type administered to the target group during the preceding 12-month period in Columns c, d and e.
- Calculate immunisation coverage as follows: Immunisation coverage is the total number of children who have received a dose of a selected vaccine in the preceding 12 months divided by the annual target population.

Table 7-8: Sample format for compilation and analysis of health facility data

Community name	Compilation of immunization coverage data for the previous 12							Analysis of problem						Prioritize - highest number of penta3 unimmunized children is #1, and so on
	Annual target population	Doses of vaccine administered			Immunization coverage (%)			Unimmunized (number)		Dropout rates (%)		Identified problems		
	Children ≤ 1 year of age	penta1	penta3	MCV1	penta1 (c/b)*100	penta3 (d/b)*100	MCV1 (e/b)*100	penta3 (b-d)	MCV1 (b-j)	penta1 - penta3 (c-d)/c*100	penta1 - MCV1 (c-e)/c*100	Access (good, poor)	Utilization (good, poor)	

Immunisation coverage (%) = (number of children who have received a dose of the selected vaccine during the last 12 months/annual target population) × 100

Example
Immunisation coverage (%) in Column g = (children who received Penta-3 in the last 12 months in Column d/annual target population in Column b) ×100 = (100/156) × 100 = 64.1%

Calculate the number of children unimmunised
Unimmunised number = (annual target population) – (number of children vaccinated)

Example
Unimmunised for Penta-3 in Column i = annual target population in Column b – number of children given Penta-3 in Column d = (156) – (85) = 71

Calculate the dropout rate
The dropout measures utilization/continuity of service

Example
Dropout rate:
= ((doses of pentavalent1 in column c) – (doses of pentavalent3 in column d))/(doses of pentavalent1 in column c) × 100 = (105) – (85)/105 × 100 = 19%

Identify and categorize problems for each area
In Column m, enter the quality of access (good = coverage of 90% or better; poor = coverage less than 90%) based on Penta-1 coverage in Column f. Note that the 90% cut-off is suggested here as a general indicator and districts/sub-districts may use different cut-offs to define good and poor coverage based on local targets/performance.

In Column n, enter the quality of utilization (good = dropout rate less than 10%; poor = dropout rate 10% or more) based on the Penta-1/Penta-3 dropout rate given in Column k.

In Column o, use your data to prioritize communities for problem solving. Rank the community that has the most unimmunised children (not necessarily the lowest coverage) as the highest priority (#1).

Figure 7-6: Access and utilization problem analysis flowchart

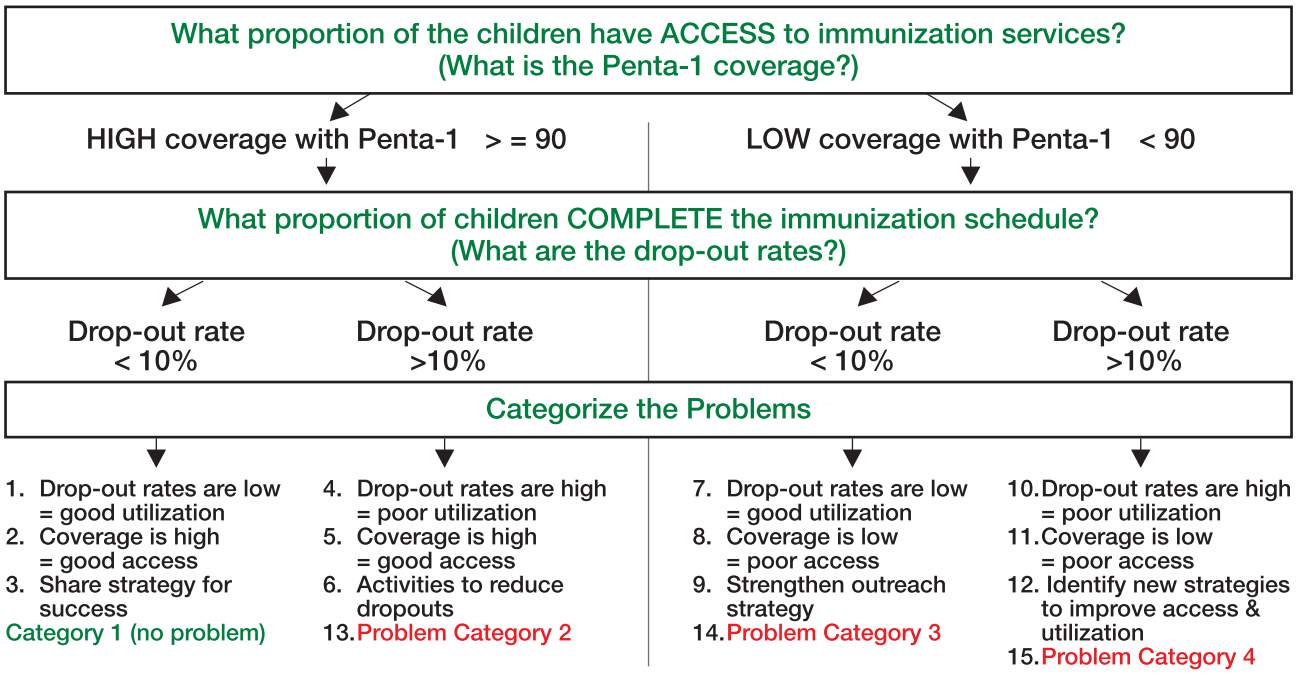


Table 7-9: Prioritizing districts according to total unimmunised children

District Name	Population	Population under 1 year	Measles coverage under 1	Unimmunised children	Priority
A	100 000	4 000	50%	2 000	2
B	75 000	3 000	60%	1 200	4
C	120 000	4 800	70%	1 440	3
D	10 000	400	20%	320	5
E	250 000	10 000	75%	2 500	1

Improvement of services

Problems can be broadly associated with access and utilization and the categories in Figure 7 6 indicate the different combinations of the two issues. Problems may be related to one or more communities or areas or may apply to the entire district. Access problems result in children missing immunisation sessions and may be due to:

- sessions not being held as planned
- session site and times being inconvenient or not advertised
- Geographical, cultural, financial, racial, gender or other barriers preventing access to and use of immunisation services.

Utilization problems result in children not coming back to complete the full series of immunisations and may be caused by:

- caregivers' lack of information about the complete immunisation schedule
- caregivers not informed when to come back
- missed opportunities for vaccination
- vaccinations not being given as expected; for example supply shortages, delayed doses due to incorrect assessment of contraindications
- poor relationship between health workers and the community
- adverse events following immunisation.

The microplanning process includes identifying possible solutions. Discussion should occur at community and health facility level, and also at district or higher levels as needed. Solutions should be prioritized for implementation. At any level, changes are likely to be more feasible when implemented with available resources. Supervisory visits from higher levels can also be helpful in identifying problems and solutions.

Table 7-10: Common problems associated with poor access and utilization, and possible solutions

	Examples of common problems	Examples of solutions: activities to be included in health facility work plans
Service delivery	Stock-outs of vaccine(s), AD syringes, diluents, safety boxes, Maternal and Child Health Books	• Request immediate supplies from appropriate level. • Review stock recording system • Review vaccine usage and wastage rates and take action
		Review method of estimating needs
Supply quality	Expired vaccine(s)	Review stock recording system
	VVMs show that vaccine has reached the discard point	Review method of estimating needs Review management of cold chain system
	Frozen DTP- and HepB-containing vaccines in refrigerator	Review management of cold chain system
Staffing quality	Some staff are not using correct protocols/procedures	Inform supervisor and select subjects for on-the-job training/ supportive supervision, for example: • using AD syringes • new vaccines • reading vaccine vial monitors • implementing multi-dose vial policy • interpersonal communication skills.
	Irregular supervisory visits	Include supervisory visit schedule in district workplans.
Staffing quantity	Vacant positions; general staff shortage	Inform supervisor
		Request temporary assignment from district level and consider volunteers for some duties. Schedule rotation of staff in the interim.
		Ensure staff are available for each session
Service quailty 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 the schedule to make sessions more convenient
		Check whether all planned sessions have been held. Aim to improve reliability by holding all planned sessions
		Screen all children for immunisation whenever they visit the health facility and give all of the vaccines they are eligible to receive
		Review use of true contraindications to ensure that children are not missed
		Consider conducting a missed opportunities study to understand the reasons for low utilization.
	Mothers lose or do not bring the Maternal and Child Health Books	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 if the vaccinations given are recorded in the register

	Examples of common problems	Examples of solutions: activities to be included in health facility work plans
	Parents fear adverse events	Inform parents about benefits of immunisation and reassure them about vaccine safety
	There are rumours that Injection practices are not 100% safe	Review safe injection practices: ensure AD syringes supply and use safety boxes and safe disposal practices
		Meet community to discuss rumours
		Review information on AEFI and how to report AEFI cases
		Arrange information brief sessions with community leaders, community influencers, media depending on level
	Unreliable information about catchment population	Request a list of all households, families and newborns from each community
		Map the catchment area to include all populations
		Compare population data from various sources including data from National Immunisation Days (NID) or polio activities
		(use the NID under 5 year population and divide by 5 to get target for children under one).
		Take the newborn register during house-to-house campaigns – register all newborns found and give them a Maternal and Child Health Book.
	Inaccurate coverage data	Check record keeping and reporting systems for completeness
		Review all tally sheets and reports– does the numerator include all areas?
		Organize and complete refresher training for staff.
	Some areas are distant and underserved	Discuss with supervisor and organize mobile team approach from district/region – minimum 4 sessions per year
		Discuss service with the communities and arrange adequate sessions, dates and times
	Transport not available for some outreach sessions	Identify sessions that were not held due to lack of transport.
		Look for alternative means of transport, such as public transport.
		Request a vehicle from the district/next higher level.
	Poor attendance at antenatal care (ANC) clinics and/or poor Td2+ coverage	Promote the value of antenatal care, including Td immunisation, during any contact with pregnant women.
		Inform the community about dates of ANC clinics. Find out if session timing or location is convenient. If so, make appropriate changes in next quarter's workplan.
		Use all opportunities to give Td immunisation including when mothers accompany children for childhood immunisations.

7.8 Good practice

Each immunising health facility should observe the following requirements:

- Calculate and display its catchment area population
- Calculate and display its target population (<1 year)
- Display a map for catchment population indicating hard to reach areas & special populations
- File and store used tally sheets and summary sheets by month and year for at least 3 years
- Send immunisation summary reports to the district by 5th of the ensuing month.
- Regularly update the district with late reports
- Have an up-to-date immunisation monitor chart displayed on the wall
- Have a mechanism in place to track defaulters
- Establish linkage with the community

CHAPTER EIGHT

Vaccine preventable diseases surveillance

Vaccine preventable disease surveillance is a key component of immunization system. The purpose of this chapter is to provide guidance to health workers at all levels about the importance of vaccine-preventable disease (VPD) surveillance. It also seeks to support the use of the generated VPD surveillance data and information for action in the immunisation program.

8.1 What is surveillance?

Surveillance is data collection for action. The mere collection and compilation of disease-related data without analysing them and taking appropriate action is not surveillance. 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 immunisation services.

8.2 Why is disease surveillance necessary?

Disease surveillance is needed to:

- predict or detect disease outbreaks with a view to investigation and containment
- identify high risk populations and areas requiring special attention
- monitor impact toward disease control eradication and elimination
- identify areas in which system performance is poor, so that corrective measures can be taken
- determine the burden of disease in a community
- monitor programme effectiveness by documenting short- and long-term effects of immunisation on disease burden and epidemiology
- identify circulating strains, including serotypes and genotypes

The type of surveillance for a specific vaccine-preventable disease depends on the attributes of the disease and the objectives of the disease control programme —control, elimination or eradication

Table 8-1: The purpose of surveillance of selected VPDs

Vaccine Preventable disease		Surveillance activity			
	Disease Control Objective	Find all cases or chains of transmission	Monitor trends, predict and detect outbreaks and identify at risk populations	Provide evidence of disease burden, epidemiology of disease and impact of immunisation	Identify circulating strains
Tuberculosis	Control		x		
Diphtheria	Control		x		
Pertussis	Control		x		
Neonatal Tetanus	Elimination	x	x		
Hepatitis B	Control		x	x	
Haemophilus Influenza b	Control			x	x
Poliomyelitis	Eradication	x			x
Measles	Elimination	x	x		x
Pneumoccal disease	Control			x	x
Rubella and Congenital Rubella	Elimination	x	x		
Rotavirus	Control			x	
Yellow Fever	Control		x		
Meningitis	Control		x		x

8.3 Definition of control, elimination and eradication

Control: The reduction of disease incidence, prevalence, morbidity or mortality to a level that is locally acceptable as a result of deliberate efforts. Continued intervention measures are required to maintain the reduction. Example: diphtheria and pertussis.

Elimination: Reduction to zero or a very low defined target rate new cases of a specified disease in a defined geographical area as a result of deliberate efforts. Continued intervention measures are required. Example: Neonatal tetanus

Eradication: Eradication is the reduction to zero of the worldwide incidence of infection caused by a specific agent, the complete interruption of transmission and the extinction of the causative agent so that it no longer exists in the environment. Intervention measures are no longer needed. Example: smallpox.

8.4 Types of surveillance

There are two main types of surveillance. These are:

8.4.1 Passive or routine surveillance:

In passive surveillance health workers collect and report information on diseases to designated centres. The process of voluntarily detecting and reporting information on diseases that bring patients to the health facility is known as passive surveillance

8.4.2 Active surveillance:

Regular collection of surveillance data on specific diseases through the review of medical records and registers during regular visits to reporting sites or through regular soliciting of information on diseases. This method is usually used when a disease is targeted for eradication or elimination, when every possible case must be found and investigated.

8.5 Core functions of VPD surveillance

Identify cases: Use standard case definitions to identify vaccine diseases

Report suspected cases to the next level: If this is an epidemic prone disease or a potential Public Health Emergency of International Concern (PHEIC) eg yellow fever, or a disease targeted for elimination or eradication e.g poliomyelitis, respond immediately by investigating the case and submit a detailed report with the support of the next level.

Analyze and interpret findings: Compile the data, and analyze by time, place and person (eg:for trends, location, persons affected etc). Compare information with previous periods and summarize the results.

Investigate and confirm suspected cases or outbreaks: Take action to ensure that the case or outbreak is confirmed including laboratory confirmation wherever it is feasible. Gather evidence about what may have caused the outbreak and use it to select appropriate control and prevention strategies.

Prepare. Take steps in advance of outbreaks so that teams may respond quickly and essential supplies and equipment are available for immediate action.

Respond: Coordinate and mobilize resources and personnel to implement the appropriate public health response.

Provide feedback: Encourage future cooperation by communicating with levels that provided data, reported cases or outbreaks about the investigation outcome and success of response efforts.

Evaluate and improve the system: Assess the effectiveness of the surveillance and response systems, in terms of timeliness, quality of information, preparedness, thresholds, case management and overall performance. Take action to correct problems and make improvements.

8.6 Standard case definitions for reporting suspected vaccine preventable diseases

Case definitions are important in the identification of cases. They assure coparabiity and consistency of VPD surveillance data and have impact on the sensitivity of the surveillance system.

Table 8-2 Case definitions for VPDs and AEFI

Disease / Event	Standard case definition for suspected cases
Acute viral hepatitis	Any person with onset of an acute illness with the following: (a) fever, jaundice, dark urine, anorexia, malaise, extreme fatigue, right upper quadrant abdominal pain and
Adverse events following immunisation (AEFI)	Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease
Congenital Rubella Syndrome	Infant 0-11 months with heart disease and/or suspicion of hearing impairment and/or mother with suspected/confirmed rubella in pregnancy and/or one or more of the following eye signs: white pupil (cataract), or larger eye ball (congenital glaucoma) or pigmentary retinopathy
Measles / Rubella	i. Any person with generalized maculo-papular rash and fever plus one of the following: cough or coryza (runny nose) or conjunctivitis (red eyes) ii. Any person in whom a clinician suspects measles
Meningitis	Any person with sudden onset of fever (>38,5°C rectal or ≥38.0°C axillary) and one of the following signs: neck stiffness, bulging fontanel, convulsions, altered consciousness or other meningeal signs
Neonatal tetanus	Any newborn with a normal ability to suck and cry during the first two days of life, and who, between the 3rd and 28th day of age, cannot suck normally, and becomes stiff or has convulsions or both
Poliomyelitis / Acute Flaccid Paralysis	Any child under 15 years of age with acute flaccid paralysis or any person with paralytic illness at any age in whom the clinician suspects poliomyelitis.
Pneumonia in Children under 5 years	A child presenting with cough or difficult breathing and: - 50 or more breaths per minute for infant age 2 months up to 1 year - 40 or more breaths per minute for young child 1 year up to 5 years.
Severe Pneumonia in Children under 5, continued	A child presenting with cough or difficult breathing and any general danger sign, or chest in-drawing or stridor in a calm child. General danger signs for children 2 months to 5 years are: unable to drink or breast feed, vomits everything, convulsions, lethargy, or unconsciousness
Tuberculosis	Any person with a cough of 2 weeks or more +B6
Yellow Fever	Any person with acute onset of fever, with jaundice appearing within 14 days of onset of the first symptoms

8.7 Performance indicators for surveillance quality of selected VPDs

Acute Flaccid Paralysis (AFP)/Poliomyelitis

- Rate of non-polio acute flaccid paralysis (AFP cases) >=2/100000 children under 15 per year
- Proportion of AFP cases with 2 adequate stools taken within 14 days of paralysis onset >=80%

Meningitis

- Percentage of all suspected cases for which CSF/blood was obtained for evaluation >= 90%

Measles/Rubella

- The proportion of districts reporting at least 1 case with blood specimen per year >= 80%
- Non-measles non rubella febrile rash illness cases >=2 per 100,000 population
- Incidence rate of confirmed measles cases < 1 per 1,000,000

Yellow fever

- Percentage of districts reporting and investigating at least one suspected yellow fever case per year >=80%

Neonatal tetanus

- Incidence of neonatal tetanus < 1 per 1000 live births in every district.

CHAPTER NINE

Partnering with communities

Introduction:
This Chapter focuses on partnering with communities in order to increase immunisation coverage. It outlines community engagement mechanisms such as community entry, microplanning, strategic communication tools such as building trust through community engagement, responding to Adverse Events Following Immunisations (AEFI) and addressing rumours and resistant groups.

9.1 Building Effective Community Participation

Building partnership with communities for immunisation and other child health interventions is critical in ensuring trust and ownership of these services. A community partner should include all individuals and groups who should be involved in the planning, providing and evaluating immunisation services. This includes not only individual community members and leaders, but also community-based social or professional groups and nongovernmental organizations (NGOs).

9.1.1 Benefits of partnering with communities

Increased immunisation coverage – community involvement can help immunisation programmes increase coverage and reduce dropout rates.

Greater equity for underserved populations – greater involvement of communities ensures that immunisation services gets to under or unimmunised groups.

Satisfaction for health workers and community members - Partnering can increase job satisfaction and enthusiasm for the health professional. Positive feedback from the community is a personal benefit to staff. Any feedback – even complaints that may come up when communities are asked for opinions – can be used to continuously improve services to the benefit of all.

Building a sense of joint responsibility for child health can provide many psychological and practical benefits on the community members involved. People change from being passive recipients of services to partners who have a role to play in health service achievements. Community members have the opportunity to gain knowledge and understanding of immunisation, diseases and public health skills in collecting and analysing information, educating and counselling fellow community members, and facilitating discussions during community meetings.

Community engagement also addresses issues such as the inability to pay transportation and/or other costs and when children should be taken for vaccination as well as addressing issues of disrespectful treatment from health workers during service contacts. This builds the confidence of the community on how they can contribute to improving services and how they can effectively support programmes.

9.2 Get Started: Learn about the community

Understanding the community and its needs is essential for increasing immunisation coverage. Effective partnering depends on clear and open communication between health staff and communities. As part of the initial engagement, and at least once a year , health centre staff should consult with community leaders and members in open meetings. This will increase opportunities for gathering valuable community feedback on services, assessing current collaboration, exploring and planning new ways to partner with the community, preventing misunderstandings and/or rumous, and effectively addressing challenges to the programme, including rumours.

When community partners feel respected and listened to, they develop a growing sense of trust and ownership, and are more likely to increase their appropriate utilization of services.

9.3 Gather information about this community

Different information gathering methods will give different data that can be compared to form a more complete picture of the community. Start with any past studies and social data (eg. Previous NID, coverage surveys etc.) that may apply to the local context. Conduct focus group discussions and try to speak to people directly rather than having others speak on their behalf. For example, learn about mothers' current perceptions and experiences with immunisation directly from mothers themselves rather than from community leaders.

9.4 Identify Who to talk to

In planning information gathering, first consider who to talk to. Be sure to include people from different areas or groups in the catchment and include those that have persistently low coverage and/or high dropout rates (for example, people in remote communities or in dense urban areas); are particularly difficult to reach (for example, nomads, migrant families, homeless families, street children, urban slum dwellers); are more likely to avoid some or all vaccinations (for example, highly educated people, religious or traditional sects, ethnic minorities, persons without proper official documentation).

It is often useful to plan separate meetings with caregivers whose children are fully immunised and those whose children are under- or unimmunised to try to understand the factors affecting each group.

9.5 Micro planning at Community Level

Community participation in immunisation service planning is important for promoting a sense of ownership and accountability. Involve community partners in regularly scheduled programme microplanning and evaluations. Hold quarterly update and feedback meetings in larger communities and annual meetings in smaller communities. These provide opportunities to learn about current community perceptions of services, to inform community leaders about the programme and to plan activities that build community engagement while addressing relevant needs and concerns.

9.5.1 Invite participation for microplanning

Explain the purpose and importance of microplanning to community partners and invite representative caregivers, leaders, NGOs etc. For better microplanning, health workers should consult with communities on the location, schedule and services offered in fixed and outreach sites. Communities should be encouraged to give input on the following:

- *Should outreach sites be moved (day, site) to reach more children?*
- *Are special sessions (evenings/weekends) needed if caregivers are unable to attend during routine vaccination times?*
- *Do any seasonal changes (heavy rains/mud, harmattan) need to be kept in mind for scheduling?*
- *Can convenient gathering points and times (such as market days, festivals and large gatherings) be used to maximize attendance at immunisation sessions?*

Microplanning should include budgeted activities to promote partnering. For example, information exchange with communities, mobilizing families for immunisation, obtaining community feedback on immunisation services, providing non-financial incentives for community volunteers to assist in service provision and monitoring. Micro-plans may integrate other high-priority services with immunisation according to national guidelines and/or community needs such as growth monitoring, vitamin A supplementation, deworming ITN distribution etc.

9.5.2 Planning and Implementing Services with the Community:

It is important to maintain a permanent dialogue and partnership with community leaders and caregivers in order to increase and sustain their support and participation in the immunisation program and to enhance their understanding of the importance and timely completion of the vaccination schedule.

Share your achievements with the community: inform people on how many children you have immunised each month and the number of cases of target diseases that have decreased compared to the previous years.

Communicate programme needs: tracking of pregnant women and newborns, support for ensuring outreach and reducing drop-outs, etc. Children do not get vaccinated if caregivers do not know the value of vaccines, when children need to be immunised, where vaccines are available and the appropriate series of vaccines to be followed, or the schedule for immunisation. Health workers and Community Health Educators are encouraged to learn what community leaders and caregivers know and feel about the services.

The type of information that is communicated and the channels used will vary depending on the audience, the purpose and resources available (e.g., informational, managerial, awareness building, educational), the level of knowledge, attitudes and practices, the level of resistance to the adoption of the new behaviour.

Define respective responsibilities

Work with each community to agree on its responsibilities for managing outreach sessions. Community responsibilities may include mobilizing those on the due list and setting up the immunisation site before the session; providing health education and assisting patient flow during the session. Community responsibilities should also be discussed during microplanning sessions and changes made as needed based on feedback.

Many NGOs can provide essential support for mobilizing and informing communities, session logistics and defaulter tracking. Community NGOs often provide services to marginalized and hard-to-reach populations and so can help ensure participation in immunisation and other health care services. NGOs can also advocate for recognizing vaccination as a child right and for programme financing at different government levels.

9.6 Communication Essentials for immunisation

In effective immunisation programmes, caregivers have a basic understanding of the purpose of immunisation, its importance and where and when it is available. They should also have basic information on possible adverse events and how to handle them. This understanding can be built through education at health facilities and in communities. Information can also be passed on via radio, print and other mass media. Although caregivers do not need to become immunisation experts to have their children vaccinated, they should have the opportunity to learn more about immunisation, vaccine-preventable diseases and any related concerns.

Some communication strategies that can be used are:

9.6.1 Advocacy

It aims to shape public opinion and influence decision-makers at various levels to develop and implement good immunisation policies, including allocating sufficient resources. It can be done at all levels using multiple channels – Interpersonal, Print as well as Mass media.

9.6.2 Social and community mobilization

This creates partnerships that support immunisation efforts and stimulate engagement, dialogue and commitment for immunisation. These groups can include private companies and commercial enterprises, government sectors, NGOs and civic groups.

9.6.3 Behavior Change Communication

Behaviour Change Communication (BCC) enhances immunisation knowledge and positively influence attitudes and practices of individuals and groups towards immunisation. This can be aimed at parents as well as health workers and other critical groups. Behaviour change communication uses a mix of different channels: mass media (e.g. TV, radio), small media (e.g. factsheets, durbars, and street plays) and interpersonal communication channels (e.g. health workers, religious leaders, respected community members).

The communication strategy mix varies according to the situation and context. What is important and common in all communication strategies is the need for the communicators – the health workers and those who support immunisation programmes - to establish trust and credibility among parents and the communities we serve. It is important to note that trust cannot be forced, it has to be earned.

9.7 Communicating during Routine Immunisation

At the vaccination center:

- Warmly welcome caregivers to the vaccination site
- Thank the caretaker in a friendly manner for coming for vaccination and for her/his patience if s/he had to wait.
- Write the date of the current vaccination(s) being given on the Maternal/Maternal and Child Health Book (immunisation or weighing card) and explain to the caretaker in simple terms and the local language the disease(s) against which the vaccination protects.
- Inform caregiver about the possible minor reaction after the vaccination and explain how to handle them.
- If the vaccine received is one in a series (e.g. DPT-HepB-Hib 2, OPV 2; or Pneumo 2, Rota 2), the health worker explains to the caretaker the need for the child to complete the series to be fully protected against the disease(s). The health worker uses the vaccination chart on Maternal/Child Health Reciord Booklet as an instructional guide, and congratulates the caretaker if the child has completed the series.
- The health worker writes the date for the next vaccination in the booklet and tells the caretaker.
- The health worker explains to the caretaker that if s/he and/or the child cannot come on the return date, they can obtain the next vaccination at another location or another date close to the due date.
- The health worker reminds the caretaker that s/he should bring the Maternal and Child Health Book to the location where the child receives the next vaccination.
- The health worker congratulates the caretaker if the child is fully vaccinated.
- Implement schemes to honour families whose children are fully immunised by age two years.
- The health worker asks the caretaker if s/he has any questions and politely answers all questions.
- The health worker asks the caretaker if she has received her five doses of tetanus toxoid (TT) vaccination and explains the importance of protecting the mother and her future children against tetanus.
- If vitamin A is being given, the health worker explains to the caretaker that it is important to bring the child back in six months (and give the date) for subsequent vitamin A supplementation to help protect her child from infections.
- Good relationships, politeness, gentleness and RESPECT go a long way towards meeting our goals for saving children's lives.

9.8 Behavior needed to achieve immunisation objectives

A programme can be seriously damaged by the poor interaction between staff and clients. In some cases, staffs have been observed to be rude. Even when correct information was provided, the manner in which it was delivered was not conducive to parents' returning to complete immunisation for their children. This kind of situation is obviously undesirable but the reasons for such behaviour may be complex, not always directly within the control of the health worker, and require considerable effort to correct.

The effectiveness of information provided to the public depends on the quantity of information provided, the clarity of the information and the source of the information. Information needs to be presented in a form that is readily understood by the lay public. It must be relevant and accurate regarding the disease and its potential risks with and without vaccine, the effectiveness and any contraindications or associated risks of the vaccine, and the procedures required for successful completion of the immunisation programme.

9.9 Communication on Adverse Event Following Immunisation

Building and maintaining public trust in immunisation is not a one-time effort but a continuous well planned endeavour. Any vaccine related rumor or misinformation or poorly managed AEFI, whether true or perceived, can have a long-term impact on any immunisation efforts. A proactive approach to communication makes it possible to mitigate potential negative impact of rumors and misinformation on immunisation. There is therefore a need to listen to what the public is saying and try to understand their concerns and the underlying reasons. This includes understanding the local perception of the disease, perception of injections and perception of the vaccine. Remember people are entitled to information that affects their lives.

9.9.1 Developing a crisis communication plan for AEFIs

A crisis situation caused by an AEFI can often be avoided by good preparation, training of staff as well as partners and having a communication plan. A communication plan supporting immunisation programmes is the basic tool for minimizing the possible negative repercussions of an AEFI (and other causes for public concerns around vaccine related issues). In order to have a sustainable impact on behaviours of individuals and among groups on a large scale, communication efforts need to be strategic, participatory, evidence-based, results-oriented and well-funded. In addition, strategic communication plans have to be closely coordinated with immunisation services and based on a well-developed surveillance system.

Every immunisation team needs to be prepared with a communication plan. A communication plan allows us to be proactive as well as reactive if an AEFI occurs. Preparing such a plan involves:

- Developing strategic links with local journalists and a variety channels (TV, radio, newspaper) and identify key persons who will speak to the media
- Researching on the level of knowledge, attitudes and practices among community members towards immunisation activities
- Training staff, especially health workers and vaccinators, on how to communicate vaccine related issues in case an AEFI occurs or any other questions
- Ensuring everybody involved knows what the action plan is and what their individual roles are.

If an AEFI occurs, get information out as quickly as possible. The public needs to know that you share their concerns, that the situation is being investigated and that you will keep them informed.

Make sure that all health workers are giving out the same message. But tailor explicit communication messages to the specific situation. It is useful to differentiate between the general public and the medical community and their respective information needs. **Avoid technical/academic terms and long words or sentences when explaining issues.**

The media is the gateway to public opinion. Keep the media and the public informed. Identify and meet the needs of the media. Trust-based relationship with the media is the basis for all effective communication; it can result in messaging that informs, directs, and calms the public with regard to the response. IT IS IMPORTANT THAT ONLY A DESIGNATED PERSON (preferably the Senior-most or other delegated authority) DEALS WITH THE MEDIA AT ALL TIMES.

9.10 Addressing Resistance, Obstacles and Rumours

It is critical that immunisation service staff analyse the reason for less-than-satisfactory coverage – to determine who and where low-coverage groups are and the relative importance of possible causes for poor results such as limited access to services, health system problems, including rumours, inconsiderate treatment of clients; and lack of demand or acceptance of immunisation.

Who starts rumours?

A rumour is an unsubstantiated opinion, allegation, belief, claims and it spreads from person to person quickly and easily since they are easy to tell and usually believable. People who may have contradicting vested interests: they could be the health workers themselves, traditional healers, medical practitioners, the press, politicians/political groups, anti-vaccine lobbyists, religious/cultural objectors. Examples of rumours: “Polio vaccine is a contraceptive to control a population to limit a certain ethnic group”; “OPV is contaminated by the AIDS virus or mad-cow disease”; “The vaccine has expired” etc.

What fuels rumours?

Inadequate/inaccurate knowledge, mistrust of the government, past untoward or negative experiences with/poor treatment by health workers, ulterior motives (greed), desire for publicity, coincidental events.

Proactive activities to prevent and limit rumours

- Use local NGOs, religious organizations or community groups that have the respect of these groups/ individuals as mobilizes and educators.
- Involve communities through leaders in planning, implementing and evaluating health activities.
- Approach communities promptly; ensure frequent contact.
- Present health issues as national issues.
- Discuss immunisation activities with public and private practitioners in advance to obtain support.

Make communication and social mobilization a continuous activity: Design strategies that establish continuity between NIDs and routine immunisation

Responding to Rumors

Analyse the situation: Move quickly to respond to rumours, but first clarify the extent of the rumour or misinformation (type of messages, circulating, source, persons or organizations spreading the rumour); determine the motivation behind the rumour (lack of information, questioning of authority, religious opposition…).

Turn the rumour around: Go to the source. Ask the source what the concern is, acknowledge shortcomings if necessary and offer the source the chance to be part of the solution.

Advocate: Target key opinion leaders for meetings (politicians, traditional/religious leaders, community leaders, health workers); launch a corrective campaign at the highest level, e.g. the Minister of Health, Governors, district administrators, etc.; meet with local leaders at sites where the individuals/groups are comfortable and can feel at ease to ask questions and have peers present.

Strengthen alliances: Involve all immunisation partners through social mobilization committees, ICCs, etc.; alert and collaborate with relevant ministries and NGOs; encourage onward briefings (cascade effect).

Conduct training: Train volunteers and health workers to handle rumours; disseminate tailored information on common misconceptions and guidelines on response; promote positive key messages.

Mobilize communities: Empower local people to address and take responsibility for the issue; "demystify" polio eradication, taking the initiative to the community durbars, schools, community seminars, discussion groups, etc.

Recruit assistance from the health community: Establish linkages and good interpersonal relationships with and seek collaboration from doctors in the public and private sectors, nurses and vaccinators, community volunteers, other members of partner organizations, e.g. Rotarians, Red Cross etc.

Use mass media: Involve all appropriate media, e.g. TV, radio, newspapers, street theatre (national and local stations/editions); seek out media that have been misinforming the public; call on previously established relationships with the media; delegate spokesperson to handle the media questions; display confidence, e.g. photograph and publicize iconic figures giving vaccination e.g. the First Lady or another prominent personality with good charismatic appeal giving vaccination such as OPV to her/his own baby or to a baby in the presence of its mother; interview pop idols/sports persons explaining the truth; print resources where appropriate, e.g. questions and answers on common misconceptions, positive messages etc.

The media form an established and powerful communications network that can disseminate outbreak information quickly.

Good media communication aids by:
- building, maintaining or restoring trust;
- improving knowledge and understanding;
- guiding and encouraging appropriate attitudes, decisions, actions and behaviours; and
- Encouraging collaboration and cooperation.

Good communication can rally support, calm a nervous public, provide much needed information, encourage cooperative behaviour and help save lives. Poor communication can fan emotions, disrupt economies and undermine confidence.

9.11 Increasing Demand for Immunisation

At the community level, several actors can play critical roles to increase demand for immunisation. The list below are not exhaustive and can be adopted to suit the local situation:

9.11.1 Engage traditional and religious leaders

Traditional and religious community leaders can promote immunisation and provide practical information such as session locations and schedules. Provide written information on immunisation and other health topics for these leaders to read during community announcements and after religious services. In places where there is resistance to vaccination based on traditional or religious beliefs, it is essential to engage these leaders since their cooperation is usually needed to help improve acceptance of services.

9.11.2 Engage schools and other potential collaborators

The school system and teachers should be engaged to teach children about immunisation for several reasons:
- older, school-age children are the target for some vaccines (for example, MenA, Measles-Rubella and Human Papilloma Virus vaccines)
- students who are well-informed about immunisation are more likely to have their own children immunised when they become parents

- well-oriented, older students can check the Maternal and Child Health Books of younger children in their own and neighbouring families and urge the caregivers to take their children for any missing vaccinations.

Parent–teacher association (PTA) meetings or similar occasions can provide opportunities for health staff and community educators to remind parents about the importance of immunisation and to relay practical information. Where active, PTAs may help track and follow up children who have missed vaccinations or those who have dropped out of school, but may need follow-up.

In Ghana, children are given MenA and the second dose of Measles-Rubella vaccines from eighteen (18) months, when most children may be in pre- schools. This requires good coordination between education and health officials for the delivery of both information and vaccination. Education officials and teachers may also serve as volunteers during national or subnational vaccination days or campaigns.

9.11.3 Engage the media

Health staff (often from district level) can actively engage with local mass media (radio, television, mobile phone companies) to inform people about the availability and impact of immunisation services. Media can be responsible, proactive partners for health services. Health staff and community members can discuss immunisation in the local media; for example, community leaders can promote immunisation and parents can share experiences with vaccine-preventable diseases in unimmunised children during radio interview shows.

It is important to note that the media is usually most effective as a secondary channel of information to build on information provided through personal communication with trusted individuals, as described above. Ideally, mass media messages should be tested and validated using appropriate research methods before being spread widely.

9.12 Key Messages on immunisation

Besides basic information on the purpose and benefits of immunisation, the vaccines and diseases, and the days, times and places where vaccination is offered, communities should understand the following points.

- Immunisation saves the lives of millions of children every year by preventing serious illnesses.
- Every child has a right to be immunised and it is the duty and responsibility of parents to take their children for immunisation.
- Immunisation is free and available at health facilities and outreach sites (specify all relevant sites, including NGOs, if applicable).
- Immunisation is an easier step than treatment of any vaccine-preventable disease.
- Immunisation helps caregivers since they do not have to take time off work to care for a child sick with a preventable disease.
- Vaccines are safe and effective and have been tested and approved by regulatory authorities, ministries of health, WHO and the United Nations Children's Fund.
- It is safe to vaccinate a child who has a mild illness, a disability or malnutrition.
- Caregivers should take the Maternal and Child Health Book every time they take their children to a health facility or outreach site. A child's immunisation status should be reviewed every time they have a health care visit for any reason.

10 Reference

1. Heyman, D. L., Ed. (2008). Control of Communicable Diseases Manual. Washington DC, American Public Health Association.

2. World Health Organization (2016). Expanded Programme on Immunisation (EPI) and Integrated management of Childhood Illness (IMCI) in the African Region: Pocket Guide for Good Practice. Brazzaville, Republic of Congo, World Health Organization.

3. World Health Organization (2015). Immunisation in Practice: A Practical Guide for Health Staff – 2015 update. Geneva, Switzerland, World Health Organization.

ANNEX 1: Selected childhood vaccines, associated severe reactions, onset interval, and rates

Vaccine	Reaction	Onset interval	Rate per million doses given
BCG	Suppurative (BCG) adenitis BCG osteitis Fatal Dissemination of BCG infection	2-6 months up to many yrs. 1-12 months	100-1000 Very rare 0.2-1.6
HepB	Anaphylaxis (Severe hypersensitivity)	0-1 hour	1-2
Measles/ MR/ MMR	Febrile seizures Thrombocytopenia (low platelets) Anaphylaxis (Severe hypersensitivity)	6-12 days 15-35 days 0-1 hour	330 30 10
OPV	Vaccine Associated Paralytic Poliomyelitis (VAPP)**	4-30 days	2-4
TT	Brachial neuritis Anaphylaxis (Severe hypersensitivity) Sterile abscess	2-28 days 0-1 hour 1-6 weeks	5-10 1-6 6-10
DPT	Persistent (Prolonged: >3h.) inconsolable crying; and seizures*** Hypotonic hypo-responsive episode (HHE) Anaphylaxis (Severe hypersensitivity)	0-24 hours 0-24 hours 0-1 hour	<10 000 <1000-2000 1-6
YF	Anaphylaxis (Severe hypersensitivity) Acute Neurotropic Disease (YEL-AND) Acute Viscerotropic Disease (YEL-AVD)	0-1 hour Up to 30 days Up to 10 days	5-20 Very rare 10-400
Hib	None known	-	-
PCV-13	None known	-	-
Rotavirus	None reported to WHO	-	-

*Reactions (except anaphylaxis) do not occur in those already immune
**Risk of VAPP is higher for first dose and for adults and immunocompromised
***Seizures are mostly febrile and less common in children <4months
Adapted from: WHO Vaccine Safety Basics: Leaning Manual 2013 and Vaccine Safety Basics: e-learning course: Available on http://vacine-safety-training.org/vaccine-reactions.html. Assessed 17 January 2017

ANNEX 2: AEFI Investigations and causality assessment

AEFI Investigations

Some AEFI reports will need further investigation. The purpose is to confirm the diagnosis (or propose other diagnoses), or determine the outcome of the adverse event. There may also be the need to identify specifications of implicated vaccine(s) used to immunise client(s), examine operational aspects of the programme which may have led to immunisation errors, justify the search for other AEFI cases/ clustering or to compare background risk of adverse event (occurring in unimmunised people) to the reported rate in the vaccinated population.

However, not all AEFI reports will need investigation. Reported events requiring investigation are:

- Serious events;
- Rumors;
- AEFI Clusters: i.e. two or more adverse events occurring in time and/or space/place
- AEFIs that may have been caused by immunisation error
- Events causing significant parental or community concern
- Significant events of unexplained cause occurring within 30 days after a vaccination,
- Signals and events associated with newly introduced vaccines

Investigations should be systematically conducted using guidelines and appropriate tools. This requires team approach (See National Guidelines on AEFI).

Causality assessment of AEFI

Causality assessment (CA) is when there is a determination of a causal association between an AEFI and the vaccine(s) received. During CA, there is a systematic review of data about an AEFI case (mostly, serious AEFIs or AEFI clusters). CA is ONLY done at the Central level by a group of experts with diverse biomedical and psycho-social background (the National Expert Committee) based at the FDA.
CA helps to determine:

- If an AEFI is attributable to the vaccine or the vaccination programme;
- What steps should be taken to address the event if needed.

CA outcomes help raise awareness of vaccine associated risks among HCWs. This, combined with knowledge of benefits of immunisation, forms the basis of vaccine information for care-givers and/or vaccine recipients. The quality of a causality assessment depends on:

- Quality of AEFI case report,
- Effectiveness of AEFI reporting system,
- Quality of the causality review process.

Therefore, accurate and timely data collection is an important first step in early detection of potential negative consequences of vaccination to prevent harm. It is also an essential step in preventing/ managing rumours. HCWs and managers should be on top of issues to assure public confidence in the vaccination.

ANNEX 3: Emergency Procedures in case of Anaphylaxis

Anaphylaxis is a rare but severe reaction, which may occur after any injection including vaccination. Characteristically, the patient collapses with signs of shock, wheezing, and difficulty in breathing. There may also be swelling of the face. Once recognized,

1. Immediately lay the patient down on left lateral (semi-flat) position, preferably with the legs raised and call for assistance.
2. Set up an intra-venous line
3. Check breathing and pulse or heart beat
4. If the patient is not breathing, clear the airway and ventilate (mouth to mouth or with an Ambu-Bag). Give Oxygen at 4-6 litres per min if available
5. If there's no heartbeat, do Cardio-Pulmonary Resuscitation (CPR)
6. Give Adrenaline – 1:1000 concentration
   a. Children up to 3 years: 0.1ml subcutaneously at once
   b. Children 4 to 5 years: 0.2ml subcutaneously at once
7. Give Hydrocortisone slowly intravenously
   a. Children Under 1 yr. – 100mg
   b. Children 1-3 yrs. - 200mg
   c. >3 yrs. - 300mg
8. Check blood pressure – if systolic is less than 80 mm Hg
9. Give adrenaline 1: 10 000 (i.e. 1 ampoule diluted with normal saline to make 10 ml) at a dose of 0.1 ml/kg of the child's body weight – slowly intravenously, or via endo-tracheal tube. This can be repeated every 10-20 minutes if necessary until the situation stabilizes. Monitor the heart rate so that it does not exceed 160 per minute.
10. Give 0.9 % Saline or Ringer's Lactate at 20mls per kg of the child's body weight fast. Repeat if necessary – if the peripheral pulse is weak or absent
11. Arrange evacuation by ambulance to a well-equipped facility if necessary
12. Explain and reassure the parents and the community

For management of all other AEFIs, **refer Guidelines for surveillance of adverse events following immunisation in Ghana, April 2013.**

ANNEX 4: AEFI Reporting Form

Reporting → Sub-District: District: Region:

AEFI Reporting ID Number

Region Code ☐☐☐ District Code ☐☐☐ Year ☐☐ Serial Number ☐☐☐

Vaccination Card/Booklet ☐ Yes ☐ No

If no, state other source of information:

A. PATIENT DETAILS

*Name:

Sex: ☐ M ☐ F

Mother's Name (if child):

Contact Phone No:

Vaccination centre:

Community:

*Date of birth (DD/MM/YYYY): _ _ _ _/_ _ _ _/_ _ _ _ _ _ _

OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age Group: ☐ < 1 Year ☐ 1 to 5 Years ☐ > 5 Years

*Address (landmarks and other contact information):

*B. DESCRIPTION OF AEFI

☐ 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 AEFI started (DD/MM/YYYY): _ _ _ _/_ _ _ _/_ _ _ _ _

Time AEFI started ☐☐ Hr ☐☐ Min

AEFI (Signs and symptoms- please give a summary of the case, including any prior disease(s)/condition and patient's medicines before vaccination)

Indicate treatment given for the AEFI:

*C. OUTCOME OF AEFI

***Serious:** ☐ Yes ☐ No; → If Yes ☐ Death ☐ Life threatening ☐ Disability ☐ Hospitalization ☐ Congenital anomaly

☐ Other important medical event (Specify_____)

***Outcome:** ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown ☐ Died

If died, date of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Autopsy done: ☐ Yes ☐ No ☐ Unknown

D. DETAILS OF ALL VACCINE(S) ADMINISTERED												
VACCINES(S)							DILUENT (if applicable)					
*Name	*Date and time of Vaccination		*Route (if injection indicate L/R site)	*Lot / Batch No.	Manufacturer	Expiry Date	Manufacturer	*Lot / Batch No.	Expiry Date	*Date and time of reconstitution		
	Date	Time								Date	Time	

E. REPORTER DETAILS

*Name: Profession / Designation: Tel No.:

Name of Institution: Today's Date: _ _ _ /_ _ _ /_ _ _ _ _ Signature:

For District Level Office

Date Report Received: __ __ / __ __ / __ __ __ __	**Checked by:**	**Designation:**
Investigation needed ☐ **Y** ☐ **F**	**If yes, date started:** __ __ / __ __ / __ __ __ __	

For National / Central Level Office

Date Report Received: __ __ / __ __ / __ __ __ __	**Checked by:**	**Designation:**
Comments (include results of Causality Assessment):		

ANNEX 5: AEFI Investigation Form

AEFI INVESTIGATION FORM

MINISTRY OF HEALTH-GHANA HEALTH SERVICE / FOOD AND DRUGS AUTHORITY

(Only for Serious Adverse Event Following Immunization – Death / Disability / Hospitalization / Cluster)

Section A **Basic details**

Region **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
(use a separate form for each case in a cluster)

Sex: ☐ M ☐ F

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 / Unknown	
Adverse event after previous vaccination(s)	Yes / No / Unknown	
History of allergy to vaccine, drug or food	Yes / No / Unknown	
Pre-existing illness (30 days) / congenital disorder	Yes / No / Unknown	
History of hospitalization in last 30 days, with cause	Yes / No / Unknown	
Patient currently on concomitant medication? (If yes, name the drug, indication, doses & treatment dates)	Yes / No / Unknown	
Family history of any disease (relevant to AEFI) or allergy	Yes / No / Unknown	

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 multi-dose 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 / Unknown
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 / Unknown
b. If no, number of vials used in the cluster (enter details separately)	

GHANA HEALTH SERVICE
EXPANDED PROGRAMME ON IMMUNIZATION (EPI)
COLD CHAIN EQUIPMENT MAINTENANCE FORM
(COMBINED SERVICE REQUISITION AND REPORTING FORM)

A. BACKGROUND INFORMATION

REGION: **DISTRICT:** **SUB-DISTRICT:**

1	HEALTH FACILITY		
2	TYPE OF EQUIPMENT		
3	MODEL		SERIAL NO:
4	ENERGY SOURCE		
5	YEAR OF INSTALLATION		
6	PLANNED PREVENTIVE MAINTENANCE SCHEDULE:	[√] YES [ ] NO	DATE OF MOST RECENT SERVICING:

B. PROBLEM DESCRIPTION

1	WHAT IS THE PROBLEM?		
2	DATE PROBLEM OCCURRED		
3	IMMEDIATE ACTION(S) TAKEN		
4	DATE THE NEXT LEVEL WAS INFORMED	DATE:	
		PERSON INFORMED:	
5	DATE HIGHER LEVEL RESPONDED	DATE:	
		PERSON TAKING ACTION:	

C. MAINTENANCE/REPAIR DETAILS (To be completed by maintenance Team)

1	ON SITE REPAIRS:	DATE:	
2	EXTERNAL REPAIRS:	DATE TAKEN AWAY:	DATE RETURNED:
3	REPAIR DESCRIPTION: (To be filled by the Engineer/Technician)		
4	ANY FURTHER ACTION RECOMMENDED BY THE MAINTENANCE TEAM		
5	FACILITY OFFICER'S COMMENT ON THE WORK DONE		

NAME:

(MAINTENANCE TEAM LEADER)

SIGN:

DATE:

NAME:

(OFFICER I/C OF FACILITY)

RANK:

SIGN:

DATE:

GHANA HEALTH SERVICE
EXPANDED PROGRAMME ON IMMUNIZATION
EPI SUPERVISORY CHECKLIST

Region:……. District……. Subdistrict…….

Facility…….. Date…… Total Population:……

Total population < 1 yr

Number of CHNs:…… Number of TOs/FTs:……

No	Question	Response		Comments
		Yes	No	
Program Management				
1.	Is EPI Plan available in this facility?			
2.	Does plan cover key EPI operations?			
3.	Is there a map of the district/subdistrict/ Region			
4.	Does the map indicate communities, health facilities, HTRA, static points, outreach points?			
5.	How many of the planned outreaches were implemented in the past one month	(…….. out of ……..)		
6.	Has there been a supervisory visit in the past three months? (Check feedback report)			
7.	Have the recommendations been implemented?			
Quality of Cold Chain and vaccine management				
8.	Is there a temperature monitoring chart for each refrigerator?			
9.	Is the temperature monitored and recorded on the chart for each fridge morning and evening each day?			
10.	Is the thermometer in the fridge working properly? (Take it out of the fridge and watch the temperature change)			Fridge tag?
11.	Are vaccines being stored at the appropriate temperature? (+2 to +8°C) (Check temperature charted for the past 3 months)			
12.	Are expired vaccines being kept in the fridge?			
13.	Are minimum and maximum stock levels being observed? Use Penta as proxy			
14.	Did the facility experience stock-out of any vaccine in the past 3 months (Review ledger and indicate the vaccine(s))			
15.	Is the vaccine ledger appropriately updated?			

No	Question	Response		Comments
		Yes	No	
16.	Does the physical stock of vaccines match with the ledger records? (use Penta , Measles-Rubella and Men A as proxies)			
17.	Are vaccines stored systematically in batches?			
18.	Are vaccines issued according to FEFO (First to Expire, First Out)?			
19.	Are vaccines appropriately arranged in cold room / refrigerators)?			
20.	Is there any unauthorized substance(s) stored in the refrigerator(s)?			
21.	Is the cold room and/ or refrigerator tidy?			
22.	Is there a contingency plan in the event of power outage?			
Performance Monitoring, Data Quality and evidence of Data use (Skip if not applicable)				
23.	Are there immunization monitoring charts for; • Penta • PCV/Rota • BCG/Measles-Rubella			
24.	Are immunization monitor charts drawn correctly?			
25.	Are the monitor charts up-to-date?			
26.	Does the facility have the Child Health Record books ?			
27.	Is there a gap between the following in the tally book / Monthly report in the past 3 months • Penta 1 and OPV1 (How wide) • Penta 1 and Rota 1 (How wide) • Measles-Rubella 2 and Men A (How wide			
28.	What is/are the reason(s) for the disparity (if any)			
29.	Is there a gap between the following in the tally book / Monthly report in the past 3 months • Penta 2 and Rota 2 (How wide) • Penta 3 and OPV 3 (How wide)			
30.	What is/are the reason(s) for the disparity (if any)			
31.	Are areas of low access (Penta 1 coverage less than 90%) identified? If yes check for evidence for actions taken?			
32.	Is there monitoring of drop-out rate? If yes, is drop-out rate correctly calculated?			
33.	Does the facility have utilization problem (drop-out rate more than 10%)? If yes, indicate actions taken.			
34.	Is there negative drop-out rate? (If yes probe for reasons)			

No	Question	Response		Comments
		Yes	No	
35.	Is vaccine preventable diseases (VPDs) incidence monitored? Check for evidence including spot maps			
36.	Is EPI data in DHIMS complete for all facilities? (If applicable)			
37.	Is EPI data in DHIMS complete for all antigens? (If applicable)			
38.	Is there variation between reported and verified Penta 3 immunizations? Check monthly form against records in DHIMS or tally sheet			
39.	Is there a file for each subdistrict/CHPS zone/facility?			
40.	If files are available, are number of reports up to date?			
41.	Is there a table that monitors completeness and timeliness of reports?			
42.	Does the facility monitor vaccine wastage?			
Capacity Building (Verify documents)				
43.	Are copies of EPI field guide available?			
44.	Are fact sheets for VPDs available?			
45.	Has there been any training programme on EPI in the last six months?			
46.	Has there been program review meeting at this level in the last three months?			
Logistics Management				
47.	Are there tally cards for all logistics?			
48.	Has there been any shortage of safety boxes in the last three months?			
49.	Are monthly vaccination report forms available? check for either e- or hard copy			
50.	Are there a spare thermometers?			
51.	Is there a cold chain inventory?			
52.	Is the cold chain inventory up-to-date?			
53.	How many refrigerators are available at this level (Comment on excess/deficit)			
54.	How many freezers are available at this level (Comment on excess/deficit)			
55.	Does the district/sub-district/CHPS/facility have motorbike(s)?			
Waste Management				
56.	Is there an incinerator? If yes skip to 59			
57.	If there is no incinerator, is there a pit for burning?			

No	Question	Response		Comments
		Yes	No	
58.	If there is no pit, how are injection wastes disposed of?			
59.	Inspect the site for disposing sharps and comment.			
Advocacy and Communication				
60.	Has there been a formal community engagement within the last quarter (eg durbars, engagement of chiefs etc)			
61.	Are there posters or flipcharts on immunization? Indicate types			
62.	Has there been any home visits/defaulter tracing in the last month (Check home visit book / defaulter tracing book) for facilities			
63.	Has there been any health education on immunization in the past month? Look for evidence			
At the facility level:				
64.	Is tally book available?			
65.	Are entries done correctly? (count tallies against total)			
66.	Are records on vaccination entered in tally book appropriately?			
67.	Are vaccines used recorded in tally book?			
AEFI Monitoring				
68.	Does the facility have updated AEFI reporting forms?			
69.	Does the facility have updated AEFI investigation forms?			
70.	Does the facility have AEFI Guideline and/or Job Aids?			
71.	Does the facility monitor AEFI? Indicate number of reports.			
72.	Do AEFI Reports at the facility match with those reported in DHIMS or to the National level (check line listed AEFI Reports sent to National)?			
VPD surveillance				
73.	Are weekly reports up to date?			
74.	Are there case definitions for AFP, NNT, YF, and measles? check			
75.	Are there separate files for Polio Eradication activities and individual VPDs under surveillance (Include comments in report)?			
76.	Is there a spot map or a chart showing VPDs in the area covered?			
77.	Second Year of Life (2YL) Interventions			
Second Year of Life (2YL) Interventions				
78.	Have the staff been trained or orientated on the algorithm?			
79.	Can staff demonstrate understanding of the algorithm?			
80.	If no, discuss the algorithm with staff			
81.	Are there communication materials on 2YL?			

Please give details of any other findings as appropriate: include best practices, weaknesses and agreed areas for improvement

Practices that need improvement (one to three)

What the providers will do

What the supervisors will do to support the provider

What others need to do: write who will do what

Supervisors: …… Sign: …… Date: ……..…..

…… …… ……..…..