

# Immunization in Practice Training Manual Participant Manual

July, 2015



Target diseases and vaccines 1 The cold chain and vaccine management 2 Communication for EPI 3 Micro planning for reaching every community 4 Immunization safety 5 Managing immunization session 6 Monitoring and surveillance 7

# **APPROVAL STATEMENT OF THE MINISTRY**

The Federal Ministry of health of Ethiopia has been working towards standardization and institutionalization of in-service (IST) trainings at national level. As part of this initiative the ministry developed a national in-service training directive and implementation guide for the health sector. The directive requires all in-service training materials fulfill the standards set in the implementation Guide to ensure the quality of in-service training materials. Accordingly, the ministry reviews and approves existing training materials based on the IST standardization checklist annexed on the IST implementation guide.

As part of the national IST quality control process, this Immunization in Practice IST package has been reviewed based on the standardization checklist and approved by the ministry in July 2015.

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#### Preface

The Ministry of Health recognizes the crucial role immunization contributes in reducing child morbidity and mortality and affirms its responsibility to ensure that every child is protected from vaccine preventable diseases. Expanded Program on Immunization (EPI), one of the most cost effective preventive health services, builds on the direction and planning of the Government's Health Sector Transformation Plan (HSTP) and other relevant documents.

Apart from other programmatic priorities, addressing the training gap of the EPI's front line work force in practical aspects of the program requires continuous interventions by ensuring adherence to standards and updating the training manuals, including this Immunization in Practice (IIP) manual.

In the performance improvement model, a well-conducted training provides critical support to health care workers who deliver services. When that role is carried out with commitment to meet service providers' needs, it helps close the gap between actual and ideal performance. The aim of this training course is to build participants' knowledge, skills, and attitudes, to enable improve performance on EPI coverage and the quality of immunization services. The concept of the Immunization in Practice (IIP) course is based on widely accepted immunization service provision activities and principles. Revision of this manual has been made following the introduction of new vaccines in the country as well as based on feedbacks collected after field tests of the previous training manual in different regions of the country.

The Ministry of Health appreciates the role of partner organizations and individuals for their technical contribution in the development of this 2015 edition of Immunization in Practice training manual. The Ministry would also like to express its appreciation for the unreserved efforts of the EPI case team, other Directorates at the MoH and other closely working partners for their inputs and constructive comments.

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# Acronyms

ACIONYINS	
AD	Auto-Disable syringe
AEFI	Adverse Event Following Immunizations
AFP	Acute Flaccid Paralysis.
AIDS	Acquired Immune-Deficiency Syndrome
BCG	Bacillus CalmetteGu'erin
CRS	Congenital Rubella Syndrome
DOTS	Directly Observed Treatment Short course
DT	Diphtheria-Tetanus toxoids
DTP	Diphtheria Tetanus Pertussis
DTP-HepB-Hib	Diphtheria Tetanus Pertussis -Hepatitis B Haemophilus influenza type b
EPI	Expanded Program on Immunization
GAVI	Global Alliance for Vaccine and Immunization
HEW	Health Extension Worker
HEP	Health Extension Program
HAD	Health Development Army
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
ILR	Ice-Lined Refrigerator
IPV	Inactivated Polio Virus vaccine
ITN	Insecticide Treated bed Net
MCV	Measles Containing Vaccine
MR/MMR	Measles, Rubella/ Measles Mumps Rubella vaccines
MNTE	Maternal and Neonatal Tetanus Elimination
NIDs	National Immunization Days
OPV	Oral Polio Vaccine
PAB	Protected At Birth
PATH	Project for Appropriate Technology for Health
PHCU	Primary Health Care Unit
SIAs	Supplemental immunization activities
ТВ	Tuberculosis
Td	Tetanus-diphtheria toxoid vaccine
ТТ	Tetanus toxoid vaccine
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VAD	Vitamin A deficiency
VAPP	Vaccine associated paralytic polio
VVM	Vaccine vial monitor
WHO	World Health Organization
YF	Yellow fever
-	

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# **Course Introduction**

**Rationale:** Immunization is the cheapest public health intervention available today in the world. However nearly 30 million of children born every year, most of them in developing countries, are not fully immunized. There is a disparity in the access of the lifesaving EPI vaccines to children in the world today. Reaching most children in developing counties still remains as a challenge. As a result of the traditional vaccines being underutilized and new vaccines introduced in these developing countries there are three million vaccine preventable child deaths each year in world today.

According to 2013 WHO and UNICEF estimates, 22% (4.3 million) unvaccinated children globally are located in four countries of the African region (Nigeria, Ethiopia, Democratic Republic of the Congo and South Africa).

In Ethiopia, vaccine preventable diseases are contributing substantially to under-five mortality. Measles is one of the leading causes of under-five mortality. However, recently there is substantial reduction in the number of measles caused under-five deaths in the country due to the catch up and follow up measles campaigns. Consequently, through EPI together with other primary health care interventions, the country has attained substantial reduction in morbidity and mortality due to vaccine preventable diseases and has been able to achieve the targets set for MDG4 three years before it is due.

In recent years, the EPI coverage is showing encouraging progress after many years of stagnation. The HEP is, therefore, a golden opportunity to increase the immunization coverage for the traditional, underutilized and new routine EPI vaccines.

However, there is a felt need for the IIP training to the health care workers as it is evident during supportive supervision, review meetings and different occasions for training need assessment. The frequent staff turnover and rotation calls for the periodic training using this updated training manual.

Capacity building on immunization for EPI managers and health workers is one of important and indispensable strategy for successful EPI service delivery. Health workers and Health Extension Workers are expected to handle immunization program in their areas and should be able to reach every child to get an opportunity for immunization services. This IIP manual is adapted from the immunization in practice (IIP, WHO 2014) to the Ethiopian situation. It will be of great use for health service providers as training manual and will be kept to be used as reference during day to day EPI operations as well.

**Course Description:** This is a five days course consisting of seven modules. Module 1 deals with target diseases for immunization program and the vaccines used to prevent them. Where combination vaccines are recommended, their details are presented in summary tables within the relevant sections. Module 2, deals with the cold chain system used for storing & distributing vaccines in good condition. Module 3 incorporates interpersonal communication skills for health workers and the general overview of building political commitment and community support for EPI. Module 4, micro-planning, discusses the process of micro planning to ensure immunization services reach every community. It starts with social maps at primary health care unit catchment area, which should be updated to include all population segments and

groups in the catchment area and to flag high-risk areas. Module 5, Insuring immunization safety, discusses practices that health workers should follow to ensure that they deliver immunization injections in the safest manner. Module 6, Managing immunization session, describes the tasks a health worker needs to perform to ensure the quality of an immunization session. It starts with the preparation required at the health facility and the immunization site before the infants arrive. Module 7, Monitoring and surveillance, explains how to collect and report data for monitoring of immunization services and surveillance of vaccine-preventable diseases and adverse events following immunization (AEFI). Tally sheets, registration books, immunization card, monitoring chart, reporting form, vaccine stock balance sheet utilization is dealt in detail.

**Course Goal**: To transfer the required knowledge, attitude and skills to participants to enable them provide quality immunization services.

**Course Objectives:** By the end of the training participants will be able to:

- Describe the 14 target vaccine-preventable diseases and Vitamin A deficiency
- Identify the vaccines used to prevent 14 target vaccine-preventable diseases
- Describe the elements of the cold chain and vaccine management
- Effectively communicate for quality EPI service provision
- Prepare micro-plans for community outreach services
- Explain the steps following safe procedures in administering immunization services
- Perform quality immunization session
- Monitor EPI activities.

**Methods and materials**: Orientation, presentation, group work and discussion, demonstration, exercise, home take assignment, practical session through health facility visit will be used throughout the training. Materials to be used for the training include, but not limited to, Pictorial aid (photo, video, posters or flip chart) of the specific modules, sample of vaccines (at different VVM stages) and syringes. Cold chain monitoring tools (thermometer and Fridge tags), cold boxes, vaccine carriers, foam pads, ice packs, refrigerators, burners, and wick, social map model, registration book, Vaccine stock balance sheet and other reporting formats.

**Target Audience:** The training takes five full days, number of participants are 30-35 per session, health workers (nurses, health officers, medical doctors) giving EPI service in their health facilities and Facilitator to participant ratio should not exceed 1:7.

**Instructor Qualifications:** Facilitators are health workers, who have taken the training of trainers course and have experience on immunization service provision.

**Core Competencies:** The participants are expected to conduct EPI sessions in their respective areas, support HEWs in outreach session, follow situation of the cold chain, assist the health center or health post in requesting vaccines, and prepare report, analyse it, use for local decisions and report to next higher level.

**Course Evaluation:** Participants will reflect on the course during their daily recap they evaluate the course daily using prepared evaluation format. Over all course evaluation will also be made by participants using prepared format and by the facilitators themselves to be included in their training report.

There is daily facilitator meeting during which they evaluate how participants follow the training and identify weak participants to provide additional support. Pre/post-test is given to see the knowledge and attitude; structured observations will be used to evaluate skill gained by participants. A minimum of 70% score is expected from participants in order to be certified. At the end of the training, facilitators decide who will be certified, using the daily follow up and post test results.

Post training follow ups after six to eight weeks should also be conducted and trainees are encouraged to participate in scheduled review meetings which can be done integrated with other programs.

# **Course Schedule**

#### **IIP Training for Health Workers: Schedule**

Venue:	Date:	
Day 1		
Time	Торіс	Responsible /time
08:30-9:00	Registration	Organizers
09:00-9:10	Objective of the training	Facilitator
09:10-9:20	Opening remark	RHB/ZHD/WoHO
09:20-9:30	Self-introduction of the participants and setting of norms	Participants
09:30-10:00	Pre-test	u
10:00-10:20	Tea break	Organizers
10:20-10:30	Group nomination (Group work and Daily reflection/recap)	Facilitator
Module 1	(Target diseases and vaccines) (8 hours)	
10:30: 10:45	Introduction of module	
10:45-11:30	Module reading and group work	
11:30-12:30	Plenary and group discussion	
12:30-13:30	Lunch	
13:30-14:45	Module reading and group work	
14:45-15:30	Plenary and group discussion	
15:30-15:45	Tea break	
15:45-16:30	Module reading and group work	
16:30:17:00	Plenary and group discussion	
17:00-17:15	Summary of module	
Module 2 (The cold chain and vaccine management)(8 hours)		
17:15-17:30	Introduction of module and assignment	
17:30-18:00	Demonstration of fridge tag (video)	

Day 2		
08:30-08:40	Day one recap	
08:40-9-25	Module reading	
9:25-10:30	Plenary and group discussion	

10:30-10:45	Tea break
10:45-11:30	Module reading cont'd
11:30-12:30	Plenary and group discussion
12:30-13:30	Lunch
13:30-14:10	Module reading cont'd
14:10-15:40	Plenary and group discussion
15:40-15:55	Tea break
15:55-16:10	Summary of module
Module 3(Communication) 4 hours	
16:10-16:25	Introduction of module
16:25-17:20	Module reading and group work
16:00-16:15	Tea break
16:15-17:00	Plenary and group discussion
17:00-18:00	Module reading and group work Summary of module
	Plenary and group discussion

Day 3		
Module 4 (Micro-planning for reaching every community) 7 hours		
08:30-08:40	Day two recap	
08:40-08:55	Introduction of module	
08:55-9:30	Module reading and group work	
9:30-10:15	Plenary and group discussion	
10:15-10:30	Tea break	
	Module 4 (Micro-planning for reaching every community)	
	7 hours	
10:30:11:15	Module reading and group work	
10:00-12:30	Plenary and group discussion	
12:30-13:30	Lunch	
13:30-14:15	Module reading and group work	
14:15-15:00	Plenary and group discussion	
15:00-15:45	Module reading and group work	
15:45-16:00	Tea break	
16:00-16:45	Plenary and group discussion	
16:45-17:00	Summary of module	
	Module 5 (Ensuring immunization safety) 3 hours	
17:00-17:15	Introduction of module	
17:15-18:00	Module reading and group work	

Day 4		
08:30-08:40	Day three recap	
08:40-09:00	Plenary and discussion	
09:00-9:45	Module reading and group work	
9:45-10:00	Tea break	

10:00-10:45	Plenary and discussion
10:45-11:00	Summary of module
	Module 6 (Managing Immunization session) 5 hours
11:00-11:15	Introduction of module
11:15-12:00	Module reading and group work
12:00-12:30	Plenary and discussion
12:00-12:30	Lunch
12:30-13:15	Module reading and group work
13:15-14:00	Plenary and discussion
14:00-14:15	Module reading and group work
14:15-15:00	Plenary and discussion
15:00-15:45	Module reading and group work
15:45-16:00	Tea break
16:00:16:15	Summary of module
Module 7 (Monit	toring and surveillance) 4 hours
16:15-16:30	Introduction of Module
16:30-17:15	Module reading and group work
17:15-18:00	Plenary and discussion

Day 5		
08:30-08:40	Recap day four	
08:40-09:25	Module reading and group work	
9:25-10:20	Plenary and discussion	
10:20-10:35	Tea break	
10:35-11:20	Module reading and group work	
11:20-12:00	Plenary and discussion	
12:00-12:30	Summary of module 7	
12:30-13:30	Lunch	
13:30-15:00	Practical session (field visit or in class demonstration of fridge	
	maintenance, review of completed registration books,	
	supervisory checklist)	
15:00-16:00	Plenary and group discussion on practical session	
16:00-16:15	Tea break	
16:15-15:40	Posttest	
15:40-16:10	Course evaluation	
16:10-17:00	General discussion and closing session	
17:00-17:30	Settle administrative issues	

NB: Modular reading and exercise should be guided as per the lesson plan

Individual exercises should be done by each participant and facilitator should make sure everyone understands the topic.

Practical session can be field visit if time and resource available otherwise it can be done in class by bringing required materials.

# Module 1: Target diseases and vaccines

#### About Module 1

This module describes about fourteen infectious diseases that cause suffering, disability and/or death for children and the vaccines that can prevent them. The diseases are: tuberculosis, diphtheria, pertussis, hepatitis, Haemophilus influenza infection type b related disease, Pneumococcal pneumonia, Rota virus diarrhea, tetanus, Human papilloma virus associated cervical cancer, rubella and congenital rubella syndrome, poliomyelitis, Measles, Meningitis and Yellow fever.

Vitamin A deficiency, and the use of Vitamin A to prevent it, is also covered in this module.

For each disease the following information is provided:

- What the disease is
- How it is spread
- The signs and symptoms
- The complications
- Treatment and prevention

For each vaccine the following information is provided:

- What it is
- How it is stored
- When it is administered
- The frequency and dosing of the antigen(s)
- Route of administration
- Site of administration

• Any adverse event following immunization related with the antigen and how it will be managed

A brief review of relative and absolute contraindications to immunization is also provided.

#### Learning Objectives

By the end of this session, participants will become familiar with 14 target vaccinepreventable diseases (plus Vitamin A deficiency - VAD) and the vaccines used to prevent them.

Participants will be able to:

• Explain key information of public health importance about the vaccine-preventable diseases

- Identify key information needed by health facility staff about vaccine use
- Identify relative and absolute contraindications to immunization
- Determine facility vaccine stock volume and select appropriate vaccine storage

#### 1. Diphtheria

1.1 What is diphtheria?

Diphtheria is caused by the bacterium Corynebacterium Diphtheria.

This bacterium produces toxin that can harm or destroy human body tissues and organs.

One type of diphtheria affects the throat and sometimes the tonsils. Another type, which is more common in the tropics, causes ulcers on the skin.

Diphtheria affects people of all ages, but most often it strikes unimmunized children. In temperate climates, diphtheria tends to occur during the colder

months. In 2008, an estimated 34 000 cases and 7686 deaths occurred worldwide due to diphtheria

#### 1.2 How is diphtheria spread?

Diphtheria is transmitted from person to person through close physical and respiratory contact.

1.3 What are the symptoms and signs of diphtheria?

When diphtheria affects the throat and tonsils, the early symptoms are sore throat, loss of appetite and slight fever.

Within two to three days, a bluish-white or grey membrane forms in the throat and on the tonsils. This membrane sticks to the soft palate of the throat and can bleed. If there is bleeding, the membrane may become greyish-green or black.

The patient may either recover at this point or develop severe weakness and die within six to 10 days.







Patients with severe diphtheria do not develop high fever but may develop swollen neck and obstructed airway.

1.4 What are the complications of diphtheria?

The most severe complication of diphtheria is respiratory obstruction followed by death.

During the early phase of the illness, or even weeks later, patients may develop abnormal heartbeats that can result in heart failure.

Some patients with diphtheria experience inflammation of the heart muscle and valves, and this may lead to chronic heart disease and heart failure.



1.5 What is the treatment for diphtheria?

Diphtheria antitoxin and antibiotics such as erythromycin or penicillin; isolation of patients to avoid exposing others to the disease. About two days after starting antibiotic treatment, patients are no longer infectious.

To confirm the diagnosis, health workers should obtain throat cultures from suspected cases. However, treatment should begin urgently without waiting for culture results.

Referral to better set up because neck swelling and heart problems may need intensive care

Generally treatment should follow the national IMNCI/ICCM guideline

1.6 How is diphtheria prevented?

The most effective way to prevent diphtheria is to maintain a high level of immunization in the community.

In Ethiopia, diphtheria vaccine is given in combination with DTP, hepatitis B (HepB) and Haemophilus influenza type b (Hib) vaccines in the form of pentavalent vaccine.

Pentavalent (DTP-HepB-Hib) vaccine reduces the number of injections needed for infant immunization.

Previous diphtheria infection does not provide lifelong protection.

1.7 What are diphtheria-containing vaccines?

There are different combinations of diphtheria-containing vaccines including:

Combination with tetanus toxoid (DT/dT);

Combination with tetanus and pertussis (DTP); and



The combination with tetanus, pertussis, hepatitis-B and Haemophilus influenza type b **known as pentavalent**.

#### Pentavalent combination is in use in Ethiopia

Pentavalent vaccines are supplied in single- and multi-dose presentations. They must be stored between +2 C and +8 C without being frozen. Pentavalent is freeze-sensitive.

Diphtheria-containing vaccines (Pentavalent in Ethiopia) are administered as 0.5 ml doses given intramuscularly in the left anterolateral (outer) thigh in infants.

1.8 How safe is diphtheria vaccine and what are the potential AEFI?

Diphtheria vaccine is one of the safest in use. Severe adverse events are rare and no anaphylaxis has been reported.

Mild events are more common – local injection site reaction (redness, swelling, tenderness) and rates vary widely depending on individual vaccine history.

1.9 When are diphtheria-containing vaccines administered?

The Ethiopia immunization schedule recommends three doses of diphtheria containing vaccine starting at 6 weeks, 10 weeks and 14 weeks; with minimum intervals of four weeks in between doses.

Three doses of diphtheria containing vaccines can produce 90% protection in children against diphtheria.

Booster doses are required later in life which is not currently provided in Ethiopia.

#### **Key Points About Diphtheria**

Diphtheria is spread from person to person in airborne droplets.

Symptoms of the disease include sore throat, loss of appetite and mild fever.

Patients with the disease can experience complications, such as abnormal heartbeat and inflammation of the heart muscle and valves, and this can lead to heart failure.

Children with diphtheria should be treated with diphtheria antitoxin and antibiotics.

The most effective way to prevent the disease is to maintain a high level of immunization within a community.

#### Table 1 Diphtheria-containing vaccine summary

Type of diphtheria vaccine	Toxoid	
Number of doses	At least three primary doses	
Schedule	6, 10, 14 weeks of age	
Booster	18 months to 6 years of age (not provided currently in Ethiopia)	
Contraindications	Anaphylactic reaction to previous dose or to any constituent	
Adverse reactions	Mild local or systemic reactions are common	
Special precautions	DTP containing vaccine not usually given over 6 years of age	
Dosage	0.5ml	
Injection site	Left outer mid-thigh in infants	
Route of administration	Intramuscular	
Storage	Store between 2°C–8°C. DTP-HepB-Hib vaccine should never be frozen	

# 2. Pertussis

#### 2.1 What is pertussis?

Pertussis, or whooping cough, is a disease of the respiratory tract caused by Bordetella pertussis bacteria that live in the mouth, nose and throats of human beings.

In 2008, 95% of pertussis cases that occurred worldwide were in developing countries and 195,000 deaths occurred.



**BordetellaPertussis** 

Because it is highly communicable and affects unimmunized infants in particular, pertussis remains a public health concern globally, including in countries where vaccination coverage is high.

#### 2.2 How is pertussis spread?

Pertussis spreads very easily from person to person in droplets produced by coughing or sneezing.

#### 10

Untreated patients may be infectious for up to three weeks after the typical cough starts.

In many countries, the disease occurs in regular epidemic cycles of three to five years.

2.3 What are the symptoms and signs of pertussis?

Incubation period: 7–10 days.

Illness begins with symptoms similar to a common cold about 10 days after infection.

After 1–2 weeks, coughing spells ending with whoop which is characterized by:

Severe cough sometimes followed by vomiting

May cause only apnea/cyanosis in young infants

May cause persistent cough in adolescents/adults

Illness may last several months

When whooping becomes frequent, children may turn blue because they do not get enough oxygen during a long burst of coughing. Vomiting and exhaustion often follow the coughing attacks, which are particularly frequent at night.

2.4 What are the complications of pertussis?

Pneumonia is the main complication of pertussis – it has been found to occur in about 6% of cases in industrialized countries.

The risk of pneumonia in infants under six months of age can be up to four times higher than that in older children.

Children may experience complications, such as convulsions and seizures, due to fever or reduced oxygen supply to the brain during bursts of coughing.

2.5 What is the treatment for pertussis?

Treatment with an antibiotic, usually erythromycin, may reduce the severity of the illness.

Because the medication kills bacteria in the nose and throat, antibiotics also reduce the ability of infected people to spread pertussis to others.

Generally management should follow the national IMNCI /ICCM protocol.

2.6 How is pertussis prevented?



Prevention involves immunization with pertussis vaccine, which is available in pentavalent combination form. (Refer to section 1.7 for pentavalent vaccines.)

2.7 What are pertussis-containing vaccines?

Pertussis vaccine is most often given in DTP or pentavalent combination form.

Pertussis-containing vaccines must be stored between +2 °C and +8°C without being frozen.

Pertussis-containing vaccines are administered as 0.5 ml doses given IM in the anterolateral (outer) thigh in infants

2.8 How safe is pertussis vaccine and what are the potential AEFIs?

Adverse events specifically noted with pertussis vaccine include prolonged crying and febrile seizures in less than one in 100 doses and hypotonic-hypo responsive episode in less than one in 1000–2000 doses.

2.9 When are pertussis-containing vaccines administered?

The national EPI implementation guideline of Ethiopia recommends three doses of pertussis vaccine at 6, 10 and 14 weeks of age with four weeks interval in between doses.

#### Key points about pertussis and pertussis containing vaccines

Pertussis, or whooping cough, is a disease of the respiratory tract.

Pertussis is a bacterial infection spread from person to person by sneezing and coughing.

Infants and young children are most likely to be infected, to have serious complications, and to die from the disease.

The most effective way to prevent pertussis is to immunize all infants with pertussiscontaining vaccine.

#### Table 2. Pertussis-containing vaccine summary

Type of vaccine	Killed whole cell or acellular (without intact cells). In Ethiopia killed
	type is in use

Number of doses	At least three primary doses		
Schedule	6, 10, 14 weeks of age		
Booster	none		
Contraindications	s Anaphylactic reaction to previous dose or to any constituent		
Adverse reactions	Adverse events include: Hypotonic-hypo responsive episodes in <1000-2000; febrile seizures <1 in 100; prolonged crying <1 in 100		
Special precautions	none		
Dosage	0.5ml		
Injection site	Left outer mid-thigh in infants		
Route of administration	Intramuscular		
Storage	Store between 2°C–8°C. DTP-HepB-Hib vaccine should never be frozen		

#### 3. Tetanus

3.1 What is tetanus?

Tetanus is caused by the bacterium Clostridium tetani, which is present in soil everywhere.

A person gets infected when a bacteria enters the body through wound or cut. A toxin released by the bacterium causes severe, painful muscle spasms that can lead to death.

Tetanus in newborns, or neonatal tetanus, is a serious problem particularly in areas where home deliveries without sterile procedures and cord treatment with dung and other application is exercised.

Globally, the number of deaths has decreased with widespread vaccination. In the 1980s, about 800,000 neonatal tetanus deaths were estimated per year, but in 2008, this number was estimated to be down to 59,000.

#### 3.2 How is tetanus spread?

Tetanus is not transmitted from person to person. In people of all ages, the bacterium can enter a wound or cut from items such as dirty nails, knives, tools, wood splinters, dirty tools used during childbirth, or from animal bites.



The bacteria grow well in deep puncture wounds, burns and crush injuries. In newborn babies, infection can occur when delivery occurs on dirty mats or floors; a dirty tool is used to cut the umbilical cord, dirty material is used to dress the cord or when the hands of the person delivering the baby are not clean.

Infants and children may also contract tetanus when dirty tools are used for circumcision, scarification and skin piercing and when dirt, charcoal or other unclean substances are rubbed into a wound.

3.3 What are the symptoms and signs of tetanus?

The incubation period is usually three to 21 days, but can be as much as several months depending on the wound. The risk of death from the disease increases as the incubation period decreases.

In children and adults, muscular stiffness in the jaw (trismus or lockjaw) is a common first sign of tetanus.



This is followed by stiffness in the neck, abdomen and/or back, difficulty swallowing, muscle spasms, sweating and fever.

Newborn babies with tetanus are normal at birth but stop feeding at three to 28 days of age. They then become stiff and severe muscle spasms occur.

3.4 What are the complications of tetanus?

When muscles used in breathing are affected, respiratory failure and death can occur.

Neonates and elderly patients are at highest risk. Pneumonia is also common.

Fractures of the spine or other bones may occur as a result of muscle spasms and convulsions.

Long-term neurologic impairment has been described in survivors of neonatal tetanus.

3.5 What is the treatment for tetanus?

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

Anti-tetanus immunoglobulin, antibiotics, wound care and supportive measures are needed.

3.6 How is tetanus prevented?

Prevention is using Tetanus toxoid-containing (TT or Td) vaccines.

Infants and school children may receive combination vaccines, such as pentavalent (DTP-HepB-Hib) or Td. Adult women of child bearing age may receive TT.

Td vaccine is given for school age children for both boys and girls

Neonatal tetanus can be prevented by immunizing women of reproductive age with tetanus toxoid, either during or before pregnancy. Clean delivery procedures are needed even when the mother has been immunized. Clean umbilical cord care for the newborn is equally important.

People who recover from tetanus do not have natural immunity and can be infected again. Repeat vaccinations are recommended.

3.7 What is needed for global tetanus disease elimination?

WHO, the United Nations Children's Fund (UNICEF) and United Nations Population Fund (UNFPA) have set 2015 as the target date for worldwide elimination of neonatal tetanus, which means less than one case per 1000 live births per year in every district. Because the tetanus bacterium survives in the environment, eradication of tetanus is not feasible and high levels of immunization must be maintained even after elimination. **Elimination is defined as one NNT case/1000LB at district level/ Year** 

The strategies to achieve the maternal and neonatal tetanus (MNT) elimination goal are:

improved vaccination of pregnant women with TT-containing vaccines,

vaccination of all women of reproductive age in high-risk areas,

promotion of clean delivery and cord care practices, and

improved surveillance and reporting of neonatal tetanus cases

After MNT elimination, countries must maintain strategies to sustain elimination through:

maintaining high coverage of pregnant women with tetanus toxoid-containing vaccines,

conduct yearly vaccination campaigns to reach all women of child bearing age in high-risk areas,

promoting school-based booster doses with Td,

promoting clean delivery and cord care practices, and

maintaining high quality surveillance of NNT cases: which is the detection, reporting and investigation of all suspected cases

#### NNT Surveillance Case Definition

**Suspected case:** "Any neonatal death between 3 and 28 days of age in which the cause of death is unknown;" Or " Any neonate reported as having suffered from neonatal tetanus between 3 and 28 days and the case is not investigated. "

**Confirmed case:** "Any neonate with a normal ability to suck or cry during the first two days of life, and between 3 and 28 days of age cannot suck or cry normally, and becomes stiff or has convulsions or both. "

In Ethiopia Tetanus toxoid vaccine is available as TT, which protects only against tetanus and neonatal tetanus. It is also available in pentavalent and Td combinations.

TT vaccine is supplied as a liquid in multi-dose vials.

Tetanus toxoid-containing vaccines must be stored between +2 C and +8 C without being frozen. They are freeze-sensitive.

Tetanus toxoid-containing vaccines are administered as 0.5 ml doses given IM in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of older children and adults.

3.9 How safe is tetanus toxoid vaccine and what are the potential AEFIs?

Tetanus toxoid causes very few serious events but quite frequent mild events.

Serious events include anaphylaxis, brachial neuritis and Guillain-Barre syndrome. Mild events include injection site pain, redness and/or swelling, and these are more common after later doses than earlier ones, and may affect between 50% -85% of people who receive TT booster doses.

Fever may develop in 10% of those vaccinated.

3.10 When are tetanus toxoid-containing vaccines given?

The national Immunization schedule recommends five doses of TT for women of childbearing age.

Infants receive three doses in the form of pentavalent combination and two booster doses are given for school age boys and girls.

#### Key points about tetanus

Tetanus is caused by a bacterium found in the environment.

Infection occurs during unclean delivery of babies, when contaminated objects are used to cut the umbilical cord, or whenever tetanus bacteria enter a wound or cut.

Neonatal tetanus remains a serious problem in countries with poor immunization coverage and unsafe childbirth practices.

Most newborns who contract tetanus will die.

The best way to prevent NNT is to immunize pregnant women in all areas (and all women of reproductive age in high-risk areas) and to ensure clean delivery and cord care practices.

#### Table 3. Tetanus-toxoid vaccine summary

Type of vaccine Toxoid

Number of doses	5 (five)
Schedule	For infants and children: three doses with pentavalent 1, 2 and 3 and two doses at school age. (See table below for women schedule)
Booster	Two doses of Td at school age following infant immunization
Contraindications	Known hypersensitivity or anaphylaxis to a previous dose
Adverse reactions	Severe: rare anaphylaxis, brachial neuritis, GBS Mild: injection site reactions and fever
Special precautions	None
Dosage	0.5 ml
Injection Site	Left anterolateral mid outer thigh ( pentavalent combination for infants); outer deltoid (TT/Td combination for school children and women of child bearing age)
Route of administration	Intramuscular
Storage	Store between 2°C–8°C. Do not freeze

Table 4. Tetanus toxoid immunization schedule for routine immunization of pregnant women

Visit	Interval	Duration of protection
1	0 (as early as possible)	NIL
2	4 weeks after TT1	3 years
3	6 months after TT2 or subsequent pregnancy	5 years
4	1 year after TT3 or subsequent pregnancy	10 years
5	1 year after TT3 or subsequent pregnancy	All child bearing years

Table 5. School based booster dose Td/TT schedule for boys and girls in primary school

level of enrolment	Year one	Year two	Year three and then after
Grade 1	1st dose	1st dose	1st dose
Grade 2	1st dose	2nd dose	2nd dose
Grade 3	1st dose	2nd dose	
Grade 4	1st dose	2nd dose	
Grade 5		2nd dose	

# 4. Haemophilus influenza type b

4.1 What is Haemophilus influenza type b?

Haemophilus influenza is a bacterium found commonly in the nose and throats of children.

There are six types that have an outer capsule and of these, type b is the largest public health concern.

Haemophilus influenza type b, or Hib, causes 90% of all serious Haemophilus influenza infections.



Hib is estimated to have caused 203,000 deaths in children under five years of age (in HIV-ve patients) in 2008. Serious Hib disease mainly affects children unde**Htinfluenza bacteria** years of age in developing countries.

4.2. How Hib spreads?

Person to person in respiratory droplets released when sneezing and coughing

Children may carry Hib in their noses and throats without showing any symptoms or signs of illness (known as healthy carriers) but they can still infect others.

4.3 What are the symptoms and signs of Hib disease?

The serious diseases caused most frequently by Hib are pneumonia and meningitis.

Children with pneumonia can have fever, chills, cough, rapid breathing and chest wall retractions.

Children with meningitis can have fever, headache, sensitivity to light, bulged fontanels (infants) neck stiffness and sometimes confusion or altered consciousness.

Hib can cause other diseases by infecting different parts of the body.

4.4 What are the complications of Hib disease?

Children who survive Hib meningitis may develop permanent neurological disability including brain damage, hearing loss and mental retardation, in up to 40% of cases.

4.5 What is the treatment for Hib disease?

Hib disease can be treated with antibiotics, such as ampicillin, cotrimoxazole, cephalosporin and chloramphenicol. Treatment should follow the national ICCM/IMNCI Guideline

4.6 How is Hib disease prevented?

The most effective way to prevent Hib is to maintain a high level of immunization in the community.

In Ethiopia, Hib vaccine is given in combination form with DTP, hepatitis B (HepB) and (Hib) in the form of pentavalent vaccine.

Pentavalent (DTP-HepB-Hib) vaccine reduces the number of injections needed for infant immunization.

4.7 What is needed for global Hib disease control?

Hib disease is included in the 2013 integrated Global Action Plan for Pneumonia and Diarrhea, which outlines a Prevent, Protect and Treat framework.

4.8 What are Hib-containing vaccines?

Hib-containing vaccines prevent pneumonia, meningitis, epiglottitis, septicemia and other Hib disease. They do not protect against other types of Haemophilus influenza or other bacteria that cause similar diseases.

In Ethiopia Hib containing vaccine is available in the form of Pentavalent

4.9 How safe is Hib vaccine and what are the potential AEFI?

Hib vaccine is one of the safest vaccines in current use. There are no known serious AEFIs to date. Mild events include injection site pain, redness or swelling in 10% of recipients & fever in 2%.

4.10 When is Hib-containing vaccine administered?

The national immunization schedule recommends administration of Hib containing vaccine at 6, 10 and 14 weeks of age as pentavalent combination.

#### Key points about Hib disease

Hib disease primarily affects children under two years of age in developing countries.

Healthy carriers as well as sick patients can spread Hib.

Hib disease can affect different parts of the body. The most frequently seen serious diseases are pneumonia and meningitis.

Hib conjugate vaccine protects only against the type b strain. The type b strain is found in 90% of serious Haemophilus influenza cases.

Hib vaccination should be given in infancy as part of a comprehensive package to reduce childhood pneumonia.

Type of vaccine	Conjugate (capsular polysaccharide bound to a carrier protein)	
Number of doses	At least three primary doses	
Schedule	6, 10, 14 weeks of age	
Booster	18 months to 6 years of age (not provided currently in Ethiopia)	
Contraindications	Anaphylactic reaction to previous dose or to any constituent	
Adverse reactions	Severe: none reported to date	
	Mild: injection site reactions, fever	
Special precautions	None	
Dosage	0.5ml	
Injection site	Left outer mid-thigh in infants	
Route of administration	Intramuscular	
Storage	Store between 2°C–8°C. DTP-HepB-Hib vaccine should never be frozen	

#### Table 6. Hib-containing vaccines summary

#### **5. Hepatitis B**

5.1 What is hepatitis B?

**Hepatitis B virus** 

Hepatitis B is caused by a virus that infects the liver.

Among adults who get hepatitis B, 90% recover completely.

Among infants infected during birth or before one year of age, 90%



develop chronic disease.

Current global estimates indicate that 240 million people have chronic hepatitis B infection and that it was the cause of 600,000 deaths in 2002.

5.2 How is hepatitis B spread?

The hepatitis B virus is spread by contact with infected blood and other body fluids in various situations:

From mother to child during birth;

During social interaction between children with cuts, scrapes, bites, and/or scratches;

From person to person during sexual intercourse; and

Through unsafe injections and/or transfusions, or needle stick accidents with infected blood.

Overall, hepatitis B is 50 to 100 times more infectious than HIV.

5.3 What are the symptoms and signs of hepatitis B?

Hepatitis B presents often with asymptomatic infection.

Symptoms of acute hepatitis B infection includes: fatigue, nausea, vomiting, abdominal pain and jaundice (yellowing of the skin and eyes).

Chronic hepatitis B patients have signs related to liver failure (such as swelling of the abdomen, abnormal bleeding and changing mental status) as the disease progresses.

Hepatitis B causes 60% to 80% of liver cancer deaths

5.4 What are the complications of hepatitis B?

A small proportion of acute infections can be severe (fulminant hepatitis) and lead to death. Other serious complications that occur in people with chronic infection include cirrhosis and liver cancer.

5.5 What is the treatment for hepatitis B?

There is no specific treatment for acute hepatitis B. All symptomatic infection should be referred to a hospital

5.6 How is hepatitis B prevented?

Hepatitis B can be prevented by immunization. In Ethiopia Hepatitis B vaccine is available in pentavalent combination form (DTP-HepB-Hib) which is given at 6, 10 and 14 weeks.

Monovalent Hepatitis B vaccines (currently available only in few private facilities) can be given at birth and also for pregnant mothers and adults at high risk of infection.

If birth dose is given, HepB vaccine should be administered to infants in the form of pentavalent vaccine at 6,10 and 14 weeks. Monovalent Hepatitis B vaccine is included in the comprehensive national hepatitis control strategy and the vaccine is expected to be integrated in the child immunization program.

People who recover completely from acute hepatitis B are protected from becoming infected again throughout their lives.

5.7 What are hepatitis B-containing vaccines?

Hepatitis B (HepB)-containing vaccines are available in combination (pentavalent DTP-HepB-Hib) formulations.

Stand-alone HepB vaccine is a liquid supplied in single- or multi-dose vials,

HepB-containing vaccines must be stored between +2 C and +8°C. They are freezesensitive. If freezing is suspected, the "shake test" should be performed.

HepB-containing vaccines are administered as 0.5 ml doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle of adults (pregnant women and high risk populations).

If HepB vaccine vials stand for a long time, the vaccine may separate from the liquid. When separated, the vaccine looks like fine sand at the bottom of the vial. Shake the vial to mix it before using.

5.8 How safe is HepB vaccine and what are the potential AEFI?

HepB vaccine has an excellent safety profile.

Severe AEFIs including anaphylaxis occur in about one per million vaccine doses administered.

Mild events include injection site pain in 3-29%, redness or swelling in about 3% of those vaccinated; headache in about 3%; and fever in 1-6%.

5.9 When are HepB-containing vaccines administered?

The national Immunization schedule recommends vaccination with HepB containing vaccine as pentavalent combination at 6, 10, 14 weeks of age.

Only stand-alone HepB vaccine can be used for the birth dose to prevent mother to child transmission, preferably within the first 24 hours. Birth dose can be given during the time of BCG vaccination.

Pentavalent vaccines are recommended for subsequent doses given at 6, 10 and 14 weeks of age. There should be a minimum of four weeks interval in between doses.

HepB vaccine may also be used for older age groups at risk of infection, including patients who require frequent transfusions, dialysis patients, injecting drug users,

household members and sexual contacts of known chronic hepatitis B patients, and health care workers.

## Key points about hepatitis B

Global estimates indicate that 600 000 people died in 2002 due to hepatitis B infection.

90% of infants infected develop chronic disease while 90% of healthy adults infected recover completely.

The hepatitis B virus is spread through contact with blood or other body fluids from an infected person. It is 50 to100 times more infectious than HIV.

Chronic hepatitis B infection leads to cirrhosis, liver cancer, liver failure and death.

Type of vaccine	Recombinant DNA or plasma-derived	
Number of doses	3 or 4 (including birth dose)	
Schedule	as soon as possible after birth (<24h): (Stand-alone HepB)	
	at 6, 10, 14 weeks of age respectively (Pentavalent combination for all infants)	
Booster	None	
Contraindications	Anaphylactic reaction to previous dose or to any constituent	
Adverse reactions	Severe: Rare Anaphylaxis Mild: injection site reactions, headache, fever	
Special precautions	Use only stand-alone HepB vaccine for the birth dose. (do not use pentavalent vaccine to provide a birth dose of hepatitis B vaccine)	
Dosage	0.5ml	
Injection site	Left outer mid-thigh in infants (Pentavalent) Deltoid muscle of upper arm in older children and adults (Monovalent)	

#### **Table 7**: HepB-containing vaccines summary

Route	of
administration	Intramuscular
Storage	Store between 2°C–8°C. Never freeze HepB containing vaccines.

## 6. Tuberculosis

6.1 What is tuberculosis?

TB is caused by the bacterium Mycobacterium tuberculosis, which usually attacks the lungs, but can also affect other parts of the body, including the bones, joints and brain.

Not everyone who is infected with TB bacteria develops the disease. People who are infected may not feel ill and may have no symptoms.

The infection can last for a lifetime, but the infected person may never develop the disease itself. People who are infected and who do not develop the disease do not spread the infection to others.



Mycobacterium tuberculosis

Although the TB death rate has decreased by 41% between 1990 and 2011, an estimated 970 000 people died from TB in 2011.

6.2 How is TB spread?

TB is spread from one person to another through the air, often when an infected person coughs or sneezes.

TB spreads rapidly, especially in areas where people are living in crowded conditions, have poor access to health care, and/or are malnourished.

A person can contract bovine tuberculosis, another variety of TB, by consuming raw milk from infected cattle.

People of all ages can develop TB, but the risk is highest in children younger than three years of age and in older people. People with TB infection who have weakened immune systems (for example, people with HIV/AIDS) are more likely to develop the disease.

6.3 What are the symptoms and signs of TB?

The period from infection to development of the first symptoms is usually four to 12 weeks, but the infection may persist for months or even years before the disease develop.

A person with the disease can infect others for several weeks after he or she begins treatment.

The symptoms of TB include general weakness, weight loss, fever and night sweats. In pulmonary TB, the symptoms include persistent cough, coughing up of blood and chest pain.

In young children, however, the only sign of pulmonary TB may be stunted growth or failure to thrive. Other symptoms and signs depend on the part of the body that is affected. For example, in tuberculosis of the bones and joints, there may be swelling, pain and crippling effects on the hips, knees or spine.

#### 6.4 What are the complications of TB?

TB can present in many ways and may be very difficult to diagnose. Untreated pulmonary TB results in severe complications such as military TB and TB meningitis and can lead to debility and death. This may be more rapid in people infected with HIV/AIDS.

#### 6.5 What is the treatment for TB?

People with TB must complete a course of therapy, which usually includes taking two or more anti-tuberculosis drugs for at least six months.

This therapy is called Directly Observed Treatment Short course (DOTS). Unfortunately, some people fail to take the medication as prescribed or do not complete the course of therapy. Some may be given ineffective treatment. This can lead to multidrug-resistant TB that is even more difficult to treat and more dangerous if spread to other people.

When people who have developed TB fail to complete standard treatment regimens or are given the wrong treatment regimen, they may remain infectious.

#### 6.6 How is TB prevented?

Vaccination before 12 months of age with BCG can protect against TB meningitis and other severe forms of TB in children of less than five years of age.

#### 6.7 What is BCG vaccine?

Bacillus Calmette–Guérin commonly referred to as Bacille de Calmette et Guérin or BCG) is a vaccine against tuberculosis. It is prepared from a strain of the attenuated (virulence-reduced) live bovine tuberculosis bacillus, Mycobacterium bovis, that has lost its virulence in humans. The BCG vaccine can be anywhere from 0 to 80% effective in preventing tuberculosis. BCG vaccine is supplied in freeze-dried powder (also called lyophilized) form. It must be reconstituted with a diluent before use.

#### 6.8 How safe is BCG vaccine and what are the potential AEFIs?

Severe adverse events following BCG immunization include generalized infection in about one per 230,000–640,000 doses of vaccine given, primarily in HIV-infected persons or those with severe immune deficiencies. Infants with severe HIV/AIDS manifestations or other cause of immune deficiency is a contraindication for BCG.

Other severe events include: swelling and abscesses (in about one per 1000–10,000 doses); Swollen glands (in the armpit or near the elbow) and/or abscesses sometimes occur because an unsterile needle or syringe was used, too much vaccine was injected or, most commonly, the vaccine was injected incorrectly under the skin instead of into the top layer.

A mild reaction at the site of injection occurs in almost all children. When BCG vaccine is injected, a small raised lump usually appears at the injection site and then disappears within 30 minutes. After about two weeks, a red sore (about the size of the end of an unsharpened pencil) forms.

This sore usually lasts for another two weeks and then heals, leaving a small scar about 5 mm across – the scar is a sign that the child has been effectively immunized.

#### 6.9 When is BCG vaccine administered?

It should be given routinely at, or as soon as possible after, birth to all infants except those known to have AIDS or severe immune deficiency.

In areas where TB is highly endemic but services are limited, BCG should be given at birth to all infants regardless of HIV exposure. BCG vaccine is not recommended after 12 months of age because the protection provided is less certain.

### Key points about TB

TB usually affects the lungs but can affect other parts of the body, including the bones, joints and brain.

TB is spread through air droplets.

The symptoms of TB disease include general weakness, weight loss, fever and night sweats.

People who develop TB disease must complete a course of drug therapy to cure & avoid spreading to others.

The recommended method of TB prevention for children is BCG vaccine given at, or as soon as possible after, birth and before 12 months of age.

#### Table 8. BCG vaccines summary

Type of vaccine Live bacterial

Number of doses	One
Schedule	At or as soon as after birth
Booster	None
Contraindications	Known Symptomatic HIV infection or other immune deficiency
reactions	Severe: disseminated disease or infections such as osteomyelitis; abscess, lymphadenitis Mild: injection site reactions
Special precautions	Correct intradermal administration is essential
Dosage	0.05 ml; a specific syringe and needle are used for BCG
Injection Site	Right outer deltoid
Route of administration	Intradermal
Storage	Store between 2°C–8°C. Do not freeze

# 7. Pneumococcal disease

7.1 What is pneumococcal disease?

Pneumococcus

Pneumococcal disease is caused by infection with a bacterium called Streptococcus pneumoniae (also known as the pneumococcus) which affects different parts of the body.

The pneumococcus is a common cause of serious diseases, such as pneumonia, meningitis and septicemia (bloodstream infection) and milder ones, such as otitis media (middle ear infection) and sinusitis.

In 2008, an estimated 476,000 children under five years of age died from pneumococcal disease. Children less than two years of age are most at risk, especially in developing countries where death rates may rise to 20% for septicaemia and 50% for meningitis.

For infants, risk factors for pneumococcal disease include lack of breastfeeding and exposure to indoor smoke. HIV infection, sickle cell disease, asplenia (lack of a functioning spleen) chronic kidney disease and previous influenza virus infection are risk factors for all ages.

7.2 How is pneumococcal disease spread?

Pneumococcal disease is spread from person to person by coughing, sneezing or close contact.



Pneumococcus is transmitted by direct contact with respiratory secretions from patients and from people who have pneumococcus in their noses and/or throats (healthy carriers). In some groups, up to 70% may be healthy carriers.

7.3 What are the symptoms and signs of pneumococcal disease?

Because the pneumococcus can affect many parts of the body, symptoms and signs vary, depending on the site of infection.

Fever and shaking or chills can occur with all types of pneumococcal disease. Children with pneumonia can present with cough, fast breathing and chest wall retractions; older patients may complain of shortness of breath and pain when breathing in and on coughing.

Patients with meningitis can present with headache, sensitivity to light, neck stiffness, convulsions and sometimes confusion or altered consciousness.

Those with otitis or sinusitis may have pain, tenderness and/or discharge from the affected area.

7.4 What are the complications of pneumococcal disease?

Pneumonia can be complicated by septicemia (bloodstream infection) and/or empyema (pus in the pleural space, which is the space between the lung and the membrane covering it) and/or lung abscesses.

Meningitis survivors may suffer complications, including hearing loss, mental retardation, motor abnormalities and seizures.

7.5 What is the treatment for pneumococcal disease?

Pneumococcal disease can be treated with antibiotics, such as a penicillin or cephalosporin. Some of the commonly used antibiotics are no longer effective in some areas since the pneumococcus is developing resistance.

Generally all pneumococcal diseases should be managed according to the ICCM/IMNCI protocol.

7.6 How is pneumococcal disease prevented?

Pneumococcal disease can be prevented by vaccination using pneumococcal vaccines.

Improved living conditions (e.g. reduced crowding and indoor air pollutants) and nutrition can reduce the risk of pneumococcal disease and death. This is enhanced by provision of vaccines for prevention.

7.7 What is needed for global pneumococcal disease control?

The 2013 integrated Global Action Plan for Pneumonia and Diarrhea outlines a Prevent, Protect and Treat framework.
7.8 What is pneumococcal conjugate vaccine?

Pneumococcal vaccines have been developed based on the serotypes frequently found in severe pneumococcal disease patients.

There are two categories of pneumococcal vaccines: Pneumococcal polysaccharide vaccines and Pneumococcal conjugate vaccines (PCV). PCV-10 is used in the EPI schedule in Ethiopia.

Each pneumococcal vaccine protects against disease caused by the pneumococcal serotypes that it contains; it is unlikely to protect against serotypes that it does not contain.

It does not protect against other bacteria that cause the same types of infections (pneumonia, meningitis, etc.) as the pneumococcus, a fact that should be emphasized in health education.

Available pneumococcal conjugate vaccines include PCV 10 and PCV 13. The number indicates how many pneumococcal serotypes the vaccine contains (for example, PCV10 protects against 10 serotypes of pneumococcus). Both vaccines are freeze sensitive

PCV is administered by IM injection in the right anterolateral thigh with a dose of 0.5 ml.

7.9 How safe is pneumococcal conjugate vaccine and what are the potential AEFIs?

Pneumococcal conjugate vaccine is safe and well tolerated in all target groups.

No severe adverse events have been proven with use of these vaccines to date. Mild events include soreness at the injection site in about 10% of those vaccinated; fever in less than 1%.

7.10 When is pneumococcal conjugate vaccine administered?

The national immunization schedule recommends giving PCV at 6, 10 and 14 weeks of age with minimum interval of 4 weeks in between doses.

Key points about pneumococcal disease

Pneumococcal disease is a leading cause of death in children under five years of age, especially in developing countries.

The pneumococcus can cause infections in different parts of the body; the most common severe diseases are pneumonia, meningitis and septicemia.

Healthy carriers as well as patients can spread pneumococcus.

Pneumococcal vaccination should be given as part of a comprehensive package to protect, prevent and treat and to reduce mortality and morbidity from childhood pneumonia.

Each pneumococcal vaccine protects against disease caused only by the pneumococcal serotypes that it contains. It does not protect against other bacteria that cause the same types of infections (pneumonia, meningitis etc.).

Type of vaccine	Conjugate (pneumococcal polysaccharide bound to a carrier protein; does not contain any live bacteria)		
Number of doses	3 (three)		
Schedule	6, 10, 14 weeks of age		
Booster	none		
Contraindications	Anaphylactic reaction to previous dose or to any constituent		
Adverse reactions	Severe: none known Mild: injection site reactions and fever		
Special precautions	Postpone vaccination if the child has moderate to severe illness (with temperature =39 °C)		
Dosage	0.5ml		
Injection site	Right mid anterolateral (outer) thigh in infants and children		
Rout of administration	Intramuscular		
Storage	Store between 2°C–8°C. Do not freeze		

**Table 9**. Pneumococcal conjugate vaccine summary

### 8. Rotavirus gastroenteritis

8.1 What is rotavirus gastroenteritis?

**Rota virus** 

Rotavirus gastroenteritis is a highly infectious diarrheal disease caused by strains of rotavirus infecting the small intestine.

Rotavirus gastroenteritis is the leading cause of severe diarrhea in infants and young children worldwide. It occurs everywhere, including in countries where sanitation standards and access to safe water are good.

In 2008, an estimated 453,000 children died from rotavirus gastroenteritis. Deaths occur mainly in infants of between three and twelve months of age when they develop severe gastroenteritis following their first infection and are very vulnerable to the effects of dehydration.

Diarrheal diseases are among the top leading cause of under five deaths in Ethiopia accounting for 20% of under-five mortality. WHO estimates that 28,218 under five deaths due to rotavirus infection occurred in Ethiopia in 2008.

8.2 How is rotavirus spread?

Rotavirus spreads by the faecal-to-oral route. Large quantities of virus can be shed in the faeces of an infected child. Shedding can occur from two days before to 10 days after onset of symptoms.

Rotavirus is stable in the environment and can spread via contaminated food, water and objects.

8.3 What are the symptoms and signs of Rotavirus gastroenteritis?

Rotavirus gastroenteritis can range from mild loose stools to severe watery diarrhea and vomiting leading to dehydration.

Symptoms usually begin one to three days after infection. Fever and vomiting can occur before diarrhea. The diarrhea lasts for three to seven days on average.

8.4 What are the complications of rotavirus gastroenteritis?

Rota virus gastroenteritis can be complicated with severe dehydration which can lead to complications such as shock, kidney and liver failure, and death

8.5 What is the treatment for rotavirus gastroenteritis?

There is no specific antiviral treatment for rotavirus gastroenteritis.

As with other causes of diarrhea, key supportive measures are fluid replacement with oral rehydration solution (ORS) and treatment with zinc supplementation.

Severe dehydration may require intravenous infusion in addition to ORS for urgent replacement of fluid and electrolytes.

Diarrhea management should follow the national ICCM/IMNCI protocol

8.6 How is rotavirus gastroenteritis prevented?

Over the past 20 years, global deaths due to diarrhea from other causes have decreased significantly due to improved nutrition, hygiene and sanitation and the availability of ORS and zinc.

Improvements in sanitation and access to safe water are less effective for reducing Rota virus infections and vaccination has become important for prevention of severe rotavirus disease in particular.

The first infection will give some, but not complete immunity. The severity of infection tends to become less with each repeat infection.

8.7 What is needed for global rotavirus gastroenteritis control?

The 2013 integrated Global Action Plan for Pneumonia and Diarrhea outlines a Prevent, Protect and Treat framework.

8.8 What is Rotavirus vaccine?

There are two types of rotavirus vaccines that contain one or more live attenuated virus strains given orally to protect against rotavirus gastroenteritis. They do not protect against other causes of diarrhea, a fact that is important to emphasize in health education.

In Ethiopia (Rotarix<sup>®</sup>), also known as Rota virus vaccine1 or monovalent Rota virus which contains one strain, is available in the routine program.

Rota virus vaccine1 is available in liquid form in an oral applicator or a squeezable tube must be stored between +2°C and +8 °C without being frozen.

8.9 How safe are rotavirus vaccines and what are the potential AEFIs?

Apart from a low risk of intussusception (about one to two per 100,000 infants vaccinated), the current rotavirus vaccines are considered safe and well tolerated.

Both Rotarix<sup>®</sup> and Rotateq<sup>®</sup> vaccines are approved for administration with other vaccines in infant immunization programs.

Mild adverse reactions included irritability, runny nose, ear infection, vomiting and diarrhea (in 5% or more of children vaccinated).

Rotavirus vaccines are generally not recommended for infants with a history of intussusception.

8.10 When is rotavirus vaccine administered?

RV1 (monovalent RV, Rotarix<sup>®</sup>) is given on a two-dose schedule given at 6 and 10 weeks of age.

WHO recommendations encourage early vaccination (first dose of RV to be given as soon as possible after six weeks of age), but allows infants to receive rotavirus vaccine together with pentavalent (DTP-HepB-Hib) regardless of the time of vaccination.



The duration of protection of Rotarix<sup>®</sup> is not yet known, but boosters are also not recommended.

### Key points about rotavirus gastroenteritis

Rotavirus is a common cause of gastroenteritis in infants and young children.

The disease spreads by the faecal-to-oral route and the virus is stable in the environment.

Severe disease can lead to rapid dehydration resulting in shock and death if fluids are not replaced quickly by ORS and, if needed, intravenous infusion.

Vaccination is the best prevention for rotavirus gastroenteritis since safe water and sanitation measures are less effective in preventing rotavirus infections than in preventing other causes of diarrhea.

Rotavirus vaccination prevents only rotavirus gastroenteritis and should be included as part of a comprehensive treatment and prevention strategy to control diarrhea.

Type of vaccine	Live attenuated viral
Number of doses	2 (two)
Schedule	At 6 and 10 weeks of age
Booster	Not recommended at this time
Contraindications	Severe allergic reaction to previous dose; severe immunodeficiency (but not HIV infection)
Adverse reactions	Serious: intussusception Mild: irritability; nasopharyngitis; otitis media; diarrhea; vomiting
Special precautions	Should be postponed for acute gastroenteritis, fever with moderate to severe illness Not routinely recommended for history of intussusception or intestinal malformations possibly predisposing to intussusception
Dosage	1.5 ml
Route of administration	Oral only
Storage	Store between 2°C–8°C. Do not freeze

### Table 10. Rotavirus vaccines summary

### 9. Poliomyelitis

### 9.1 What is poliomyelitis?

Poliomyelitis, or polio, is a highly infectious disease caused by poliovirus types 1, 2 or 3. These are also called wild polioviruses (WPVs) since they are the naturally occurring types that circulate and infect people.

Polio mainly affects children of less than five years of age. One in 200 infections causes irreversible paralysis when the virus attacks the spinal cord nerve cells that control the muscles.

Due to the Global Polio Eradication Initiative launched in 1988, the number of reported cases has been reduced from about 350,000 in that year to 223 in 2012 and 403 in 2013. Of the 125 countries endemic for WPVs in 1988, only three remained to be endemic in 2013.

### 9.2 How is polio spread?

Poliovirus spreads by faecal-to-oral and oral-to-oral routes. In areas with poor sanitation, it is thought to more commonly enter the body through the mouth when people eat food or drink water that is contaminated with faeces.

In areas with high standards of sanitation, oral-to-oral spread may be more common. In most settings, mixed patterns of spread are likely to occur.

The majority of infected people does not show symptoms but can still spread the disease. Children with symptoms are most likely to shed poliovirus and spread it to others from 10 days before to 10 days after the onset of symptoms.

9.3 What are the symptoms and signs of polio?

Polioviruses usually multiply in the intestine over seven to 10 days (incubation period). After this, approximately 25% of those infected develop a minor illness, usually with fever, headache and sore throat.

When paralysis occurs, it usually begins during the first week of illness, with severe muscle pain and spasms principally affecting the legs. Paralysis can affect any of the limb muscles.

Breathing becomes difficult when specific chest muscles are affected.

9.4 What are the complications of paralytic polio?

Death may occur if the respiratory muscles of the chest are affected.

Limb paralysis that does not improve with physiotherapy can remain, causing crippling disability.

9.5 What is the treatment for polio?

There are no specific anti-viral drugs for polio.

Treatment consists of supportive, symptomatic care. A ventilator can help patients who have difficulty breathing. Orthopedic treatment, regular physiotherapy and the use of braces can help reduce the long-term crippling effects.

9.6 How is polio prevented?

Polio can be prevented through immunization with oral polio vaccine (OPV) and inactivated polio vaccine (IPV).

All children worldwide should be fully vaccinated with an IPV-containing schedule since OPV-only is no longer recommended.

9.7 What is needed for global polio eradication

Global Polio Eradication is defined as complete interruption of both wild and vaccine derived poliovirus transmission in the world. Global Polio Eradication Strategies include:

High routine immunization coverage: Achieve and maintain the highest coverage levels possible through administration of OPV in the routine immunization program.

Supplementary doses of polio vaccine to rapidly decrease the intensity of poliovirus transmission: Achieve the highest coverage through SIAs as NIDs or SNIDs.

Doses of OPV administered during NIDs/SNIDs are considered extra doses which supplement and do not replace the doses received during routine immunization services.

During NIDs/SNIDs, there are no contraindications to vaccinating a child withOPV (e.g. newborn, immunization status – recent dose of OPV, illness)

Surveillance for acute flaccid paralysis: strengthen the sensitivity of surveillance to detect and investigate all cases of AFP in children aged <15 years.

Targeted "mop –up" campaigns once wild polio virus transmission is limited to a specific focal area

# Acute Flaccid Paralysis Surveillance Case Definition

"Any child under 15 years of age with weakness or floppiness of one or more limbs or any person of any age in whom a clinician suspects polio."

9.8 What is polio vaccine?

There are two types of polio vaccines: OPV and IPV

OPV is a live attenuated virus vaccine that contains types 1, 2 and 3 individually or in combination (types 1, 2 and 3, or 1 and 3).

It is supplied in multi-dose vials. It is very heat-sensitive and must be kept frozen during long-term storage. After thawing, it can be kept at a temperature of between +2 °C and +8 °C for a maximum of six months or can be refrozen.

IPV is an inactivated Polio virus vaccine available as a stand-alone product or in combination with diphtheria, tetanus, pertussis, hepatitis B and/or Hib. It is stable outside the cold chain but should be stored between +2°C and +8°C.

It must not be frozen. It is supplied in one-, five- or ten-dose vials.

OPV is given orally and IPV is injected intramuscularly as a 0.5 ml dose.

9.9 How safe is polio vaccine and what are the potential AEFIs?

A) OPV safety: OPV is generally safe. The most serious adverse event it causes is vaccineassociated paralytic polio (VAPP), which is estimated to occur in 2 to 4 per one million children per year (in a birth cohort).

VAPP can also occur in unimmunized contacts of vaccinated children in cases where the vaccine-derived virus spreads. Vaccine-derived polioviruses are considered rare serious adverse events associated with OPV.

B) IPV safety: 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 in less than 1% of those vaccinated, swelling in 3–11% and soreness in 14–29%.

9.10 When is polio vaccine administered?

<u>OPV schedule:</u> In polio-endemic countries and in countries at high risk for importation and spread, an OPV birth dose (a zero dose, OPV0) followed by a primary series of three OPV dosed and at least one IPV dose is recommended.

OPV0 should be given to improve response to the primary series. After OPV0, the three OPV doses are given at 6, 10 and 14 weeks of age with a minimum interval of four weeks between the doses.

B) <u>IPV schedule</u>: the IPV dose should be given at 14 weeks and can be given at the same time as an OPV dose.

For infants starting the routine immunization schedule late (after three months of age), the IPV dose should be given at the first immunization contact.

The national immunization schedule of Ethiopia recommends four doses of OPV at birth, 6,10 and 14 weeks of age and one dose of IPV given at the age of 14 weeks

Both OPV and IPV may be given with other infant vaccines in the national schedule. A child may receive additional OPV doses in polio campaigns even if primary doses have been given.

### Rationale for IPV introduction

In May 2012 the World Health Assembly of WHO declared poliovirus eradication to be a global public health emergency. Under this plan to achieve a polio-free world, they recommend that the use of OPV must eventually be stopped worldwide. OPV will be withdrawn in 2 phases beginning with type 2 OPV. Type 2 OPV has the two risks: VAPP and cVDPV – and is no longer needed for eradication – hence the type 2 containing OPV will be eventually withdrawn from use globally.

WHO's Strategic Advisory Group of Experts (SAGE) recommends that all countries introduce at least one dose of IPV into their routine immunization schedule by the end of 2015, before type 2 OPV is withdrawn. The rationale for this includes contribute to the final phase of polio eradication; to reduce risks associated with type 2 OPV withdrawal; and maintain immunity against polio type 2 during the global withdrawal

### Key points about polio and polio vaccines

Polio is caused by wild type polioviruses 1, 2 and 3 and is easily spread by the faecal-tooral and oral-to-oral routes.

The majority of individuals infected does not have symptoms but can still spread the disease.

Less than 1% of infections result in paralytic poliomyelitis, but when paralysis occurs, it can lead to death or lifetime disability.

Vaccination with a combination schedule of OPV and IPV or an IPV -only schedule is recommended for children worldwide.

### Table 11. OPV summary

Type of vaccine	Live attenuated viral	
Number of doses	4 (Four)	
Schedule	Birth, 6, 10, 14 weeks of age	
Booster	none	
Contraindications	Anaphylactic reaction to previous dose or to any constituent	
Adverse reactions	Rare vaccine-associated paralytic polio (VAPP)	
Special precautions	Postpone vaccination if the child has moderate to severe	

	illness (with temperature =39 °C)
Dosage	Two drops into the mouth
Route administration	of Oral only
Storage	Store between 2°C–8°C. OPV is very heat sensitive

### Table 12. IPV summary

Type of vaccine	Inactivated viral	
Number of doses	1 (one)	
Schedule	Single dose at the age of 14 weeks	
Booster	none	
Contraindications	Anaphylactic reaction to previous dose or to any constituent	
Adverse reactions	Serious: none known; - Mild: injection site reactions	
Special precautions	Postpone vaccination if the child has moderate to severe illness (with temperature =39 °C)	
Dosage	0.5 ml	
Injection site	Right anterolateral (outer) mid-thigh in infants. There should be minimum of 2.5cm apart from PCV injections	
Route o administration	Intramuscular	
Storage	Store between 2°C–8°C. Do not freeze	

### 10. Measles

10.1 What is measles?

Measles is a highly infectious disease caused by a virus.

Measles is RNA virus and humans are the only reservoir. It multiplies in the respiratory tract.

Between the years 2000 and 2010, the numbers of deaths worldwide decreased by 74% due to improved vaccine coverage.



However, in 2011, there were still an estimated 157,700 deaths among children under five years of age.

Because the disease is so infectious, it tends to occur as an epidemic with high death rates in such settings as refugee camps.

Severe measles is particularly likely to occur in poorly nourished children, especially those who do not receive sufficient vitamin A, who live in crowded conditions, and whose immune systems have been weakened by HIV/AIDS or other diseases.

10.2 How is measles spread?

Measles is transmitted via respiratory secretion or aerosols.

The virus spread through contact with nose and throat secretions of infected people and in airborne droplets released when an infected person sneezes or coughs.

People with measles can infect others for several days before and after they develop symptoms.

The disease spreads easily in places where infants and children gather, such as health centers/hospitals and schools.

10.3 What are the symptoms and signs of measles?

Incubation period: 14 days (range, 7 – 18 days)

Prodrome: begins 10 – 14 days after exposure

High fever, cough, coryza, conjunctivitis

Period of greatest infectiousness (virus shedding)

Rash begins: 2 – 4 days after prodrome starts

Complications: occur mostly in 2nd and 3rd weeks

Any disease or death not clearly due to another cause (e.g., trauma) during the 30 days following rash onset

Case Fatality Ratio (CFR) 0.1 – 10 %

Fatality can raise up to 30% in humanitarian emergencies





#### 10.4 What are the complications of measles?

Unimmunized children under five years of age and, especially, infants are at the highest risk of contracting measles and suffering from its complications, which can include death.

Infected infants may suffer from dehydration due to severe diarrhoea.

Children may also develop malnutrition, inflammation of the middle ear, pneumonia and encephalitis (brain infection).

Measles is a major cause of blindness among children in Africa and other areas of the world where it is endemic.

# Severe Measles Complications



lote descuarr

Corneal scarring causing blindness Vitamin A Deficiency

Encephalitis Older children, adults ~ 0.1% of cases Chronic disability

Pneumonia &

diarrhea



Diamhea common in developing countries Pneumonia ~ 5-10% of cases, usually bacterial, major cause of death

Pneumonia is the most common cause of death associated with measles. The pneumonia may be caused by the measles virus itself or by a secondary bacterial infection.

10.5 What is the treatment for measles?

There is no specific antiviral treatment for measles.

Antibiotics should be prescribed only for bacterial ear infections and pneumonia. General nutrition support and treatment of dehydration with oral rehydration solution are important, so children with measles should be encouraged to eat and drink.

All children in developing countries diagnosed with measles should receive two doses of vitamin A supplement given 24 hours apart to help prevent eye damage and

blindness. Vitamin A supplementation should not wait until laboratory confirmation of suspected cases.

Vitamin A supplementation reduces the number of deaths from measles by 50% Vitamin A administration and dose should follow the national ICCM/IMNCI treatment protocol.

10.6 How is measles prevented?

Measles is prevented by immunization with measles-containing vaccine (MCV).

Because vaccination with measles at nine month confers only 85% immunity, high coverage with a two-dose schedule is needed to prevent measles epidemics.

Children who have recovered from measles are immune for the rest of their lives.

10.7 What is needed for global measles control?

The Global Measles and Rubella Strategic Plan (2012–2020) focus on five core components:

Achieving and maintaining high levels of population immunity by providing high vaccination coverage with two doses of measles-containing vaccine;

Achieve high coverage of first dose measles vaccination provided through routine immunization visits;

Provide a second opportunity for measles vaccination through campaign or routine strategies

monitoring disease and evaluating programmatic efforts to ensure progress;

Improve surveillance (case-based) for measles disease and monitor measles vaccine coverage (data management and epidemiological analysis)

developing and maintaining outbreak response and case management capacities;

Improve case management, including vitamin A supplementation and treatment of complications

communicating to build public confidence and demand for immunization; and

Performing research and development to support cost-effective operations and to improve vaccination and diagnostic tools.

# **Measles Surveillance Case Definition**

**Suspected measles case:** "Any person with Fever AND rash AND at least one of the "3 Cs" – cough, conjunctivitis or coryza;" or "Measles suspected by a clinician"

**Confirmed measles case: "** Lab confirmed: measles IgM positive or epidemiologically linked: when a case is linked, in time and place, to laboratory confirmed cases"

10.8 What are measles-containing vaccines?

Measles-containing vaccines include measles only (M) or a combination of measles with rubella (MR), mumps (MM, MMR) and varicella (MMRV) vaccines.

MCVs can be used interchangeably in immunization programs.

M, MR and MMR are supplied as freeze-dried powders (also called lyophilized) with diluents in separate vials. They must be reconstituted before use with only the diluent supplied

Measles-containing vaccines must be stored between +2 °C and +8 °C and protected from sunlight since they are sensitive to both heat and light.

MCVs are administered by subcutaneous injection.

In countries where vitamin A deficiency is common, vitamin A supplements are often given at the same time as the vaccine.

10.9 How safe is measles vaccine and what are the potential AEFIs?

All MCVs approved for immunization programs are safe and effective and severe events are rare.

Severe events include:

Anaphylaxis in 1-3.5 per one million doses administered,

Severe allergic reaction in one per 100 000 doses, and thrombocytopenia (decreased platelet count) in one per 30 000 doses.

Encephalitis (brain infection) has been reported rarely but there is no definite proof that the vaccine was the cause.

Mild events are not uncommon and these include:

local injection site pain and tenderness,

Fever (in 5–15%) and

rash (in about 5%) and can occur five to 12 days after vaccination.

If MR and/or MMR are used, the rubella vaccine component may cause a temporary form of arthritis one to three weeks after vaccination in up to one in four post pubertal females. This is very rare in young children.

10.10 When are measles-containing vaccines administered?

All children should receive two doses of MCV.

The first measles dose is given at 9 months of age or as soon as possible even after 12 months of age. In Ethiopia second dose of measles is given in the form of follow up campaign conducted at interval of 2-3 years. The target age group for specific campaign may be extended up to 14 years according to the cumulative age group at risk of measles infection.

In high-transmission areas, infants of six to nine months who have not received MCV and who are admitted to an inpatient ward should be immunized against measles. This is a supplemental dose that should be followed by MCV1 and MCV2 on the usual schedule.

If there is no card/record and the infant's caregivers do not know whether the infant has received measles vaccine, the infant should receive a dose of vaccine.

Other high-risk infants who may need a supplemental dose at or after six months of age (before receiving MCV1) include those who are HIV-infected (but are not advanced or in the AIDS category), malnourished, living in closed communities such as refugee camps and those in the presence of an outbreak.

### Key points about measles and measles containing vaccines

Measles is a highly infectious viral disease that is spread from person to person through sneezing, coughing and close personal contact.

The first sign of infection is a high fever lasting one to seven days. A generalized rash develops seven to 18 days after exposure to the virus.

Pneumonia is the most common cause of death associated with measles.

Severe complications can be avoided through proper case management, including vitamin A supplementation.

Measles can be prevented by immunization. All children should receive two doses of the vaccine.

# Table 13. Measles-containing vaccines summary (MCV = M, or MR)

Type of vaccine	Live attenuated viral		
Number of doses	two		
Schedule	MCV 1: at nine months of age; MCV 2: at least 1 month after MCV 1 if MCV 2 is provided through RI		
Booster	None		
	Known allergy to vaccine components (including neomycin and gelatin), ns pregnancy; severe congenital or acquired immune disorders, including advanced HIV infection/AIDS		
Adverse reactions	Serious (rare): thrombocytopenia (decreased platelets), anaphylaxis, encephalitis Mild (more common): fever, rash 5-12 days following administration		
Special precautions	None		
Dosage	0.5ml		
Injection site	Left upper arm		
Injection type	Subcutaneous		
Storage	Between +2 °C and +8 °C ; Keep all MCVs away from sunlight		

# 11. Rubella and congenital rubella syndrome

11.1 What are rubella and congenital rubella syndrome (CRS)?

Rubella is an infection caused by a virus and is usually mild in children and adults. CRS is a group of birth defects that occur when the rubella virus infects a fetus. A woman infected with the rubella virus early in pregnancy has a 90% chance of passing the virus on to her fetus and this can lead to death of the fetus or to CRS.

The most common birth defect is deafness, but CRS can also cause defects in the eyes, heart and brain. An estimated 112 000 children are born every year with CRS.

#### 11.2 How is rubella virus spread?

Rubella is spread in airborne droplets released when infected people sneeze or cough. The virus spreads throughout the body and, in a pregnant woman, to the fetus, about five to seven days after infection.

Infected individuals are most likely to spread virus on days one to five of the rubella rash (see below), but they can spread it from seven days before to about 14 days after the rash appears. Infants with CRS can transmit the virus for a year or more.

11.3 What are the symptoms and signs of rubella and CRS?

Incubation period: 7 to 14 days

Initial symptoms include: mild fever, conjunctivitis (more often in adults) and swollen neck lymph nodes may occur

Rash occurs five to 10 days after initial symptom.

The rash most often begins on the face and spreads towards the feet. It is an erythematous maculopapular rash, which means it is red and raised but usually fainter than a measles rash.

The rash typically lasts for one to three days. Studies have shown that 20–50% of rubella infections occur without a rash.

Up to 70% of adult women may have joint pain and stiffness.

Children with CRS usually show birth defects, such as cataracts and loss of hearing in infancy, but some do not show signs for two to four years. Mental retardation can occur.

11.4 What are the complications of rubella?

Complications of rubella tend to occur more often in adults than in children.

Encephalitis occurs in about one in 6000 cases and is most common in adult women.

Problems with bleeding occur in about one in 3000 cases, usually among children.

Guillain-Barre syndrome has been reported rarely.

11.5 What is the treatment for rubella and CRS?

There is no specific antiviral medication for rubella or for CRS. Supportive measures to improve symptoms should be taken.

11.6 How are rubella and CRS prevented?

Rubella and CRS are prevented with safe, effective rubella vaccines.

For infant immunization, rubella vaccine is usually given in combination with measles vaccine (MR).

In some countries, mostly in the industrialized world, rubella has been nearly eliminated through childhood immunization programs.

In areas where Rubella vaccine is included in the EPI schedule of infants, it is important to ensure that coverage in infants is sustained at over 80% to avoid shifting rubella transmission to older age groups. For prevention of CRS, women of childbearing age are the primary target group for rubella immunization.

11.7 What is needed for global rubella and CRS disease control?

Although the global burden of rubella and CRS has decreased over time due to vaccination, the remaining burden can be readily addressed along with measles control efforts using combination vaccines (MR, MMR).

Rubella and CRS are therefore part of the Global Measles and Rubella Strategic Plan. Because situations and approaches vary greatly, countries must decide on their use of rubella-containing vaccines based on the disease burden and its public health priority.

11.8 What are rubella-containing vaccines?

MR and MMR are supplied as freeze-dried powders (also called lyophilized). They must be reconstituted before use.

Rubella-containing vaccines must be stored between +2 °C and +8 °C. They are sensitive to heat but not damaged by freezing.

Rubella-containing vaccines are administered by subcutaneous injection as 0.5 ml doses.

11.9 How safe is rubella-containing vaccines and what are the potential AEFIs?

Adverse events following immunization with rubella-containing vaccines are mild in children. Rubella vaccine may cause a temporary form of arthritis one to three weeks after vaccination in up to one in four post pubertal females.

This is very rare in young children. Long-term joint disease has not been associated with rubella-containing vaccines after review of data from large studies.

11.10 When is rubella-containing vaccine administered?

Rubella-containing vaccine should be given at nine to 12 months of age. It can be introduced into childhood immunization programs with the two-dose schedule for measles-containing vaccines.

### Key points about rubella and CRS

Rubella and CRS are infections caused by a virus.

Rubella is normally a mild childhood disease, but women who contract rubella early in pregnancy can pass the virus on to their fetuses and this can lead to fetal death or CRS.

The rash associated with rubella infection may not occur in 20–50% of cases.

CRS includes birth defects of the ears, eyes, heart and brain.

### Table 14. Rubella-containing vaccines summary

Type of vaccine	Live attenuated viral		
Number of doses	2 (two)		
Schedule	The same as measles vaccine		
Booster	Not recommended at this time		
Contraindications	Known allergy to vaccine components (including neomycin and gelatin); pregnancy; severe congenital or acquired immune disorders, including advanced HIV infection/AIDS		
Adverse reactions	Common: injection site reactions, fever, rash, irritability, lymphadenopathy (swollen lymph glands), myalgia (muscle aches) and paraesthesias (tingling sensations); In susceptible adult women: arthralgia (joint pain) in 25%, arthritis (joint inflammation) in 12%.		
Special	None		

precautions	
Dosage	0.5 ml
Route	Subcutaneous
Storage	Store between 2°C–8°C. keep all Rubella vaccines away from sunlight

# **12**. Human papillomavirus infection and cervical cancer

### 12.1 What is human papillomavirus?

Human papillomavirus (HPV) is a common sexually transmitted virus that causes genital warts and various cancers.

There are more than 100 types of HPV. Some types cause only genital warts, but at least 13 different types cause cancer.

While HPV does cause cancer of the anus, external genitalia and oral cavity in both sexes, it is of particular concern in women since it is now known to be the cause of 99% of cervical cancers.

Cervical cancer is the leading cause of cancer death in adult women in the developing world and the second most common cancer among women worldwide. In

Ethiopia Cervical cancer is also the leading cause of death next to breast cancer a Human papilloma virus women. Annually 7,706 new cervical cancer cases are diagnosed among women aged 45-54 years. Studies also demonstrated that in Ethiopia serotype 16 is the most prevalent serotypes followed by 18. Other important serotypes in Ethiopia include types 35, 38.

12.2 How is HPV spread?

HPV transmits from person to person

HPV spreads easily by skin-to-skin contact. Almost all sexually active individuals become Infected with it at some point, usually early in their sexual lives.

12.3 What are the symptoms and signs of cervical cancer?

Most HPV infections do not cause symptoms or disease and usually clear within a few months.

About 90% of infections clear within two years, but some infections continue. Infection that continues can progress to cervical cancer with specific types of HPV (particularly types 16 and 18).

This progression takes 20 years on average and tends to cause symptoms only after the cancer has reached an advanced stage.





Symptoms and signs of cervical cancer include abnormal vaginal bleeding (after sexual intercourse and/or between menstrual periods); pelvic, back and/or leg pain, vaginal discharge, fatigue and weight loss.

Anemia, renal failure and fistulae can also occur in advanced stages of cervical cancer.

12.4 What is the treatment for cervical cancer?

If cervical cancer is caught early by screening methods such as the Papanicolau smear (Pap smear), HPV-DNA tests and/or visual inspection with acetic acid, then it can be removed and cured effectively with localized treatment (e.g. cryotherapy).

Treatment of advanced cancer is complicated and usually involves combinations of surgery, radiotherapy and chemotherapy.

12.5 What can be done to prevent and control cervical cancer?

Comprehensive cervical cancer prevention and control consists of:

**Primary prevention** by vaccination against HPV infection for girls nine to 13 years of age and, for both girls and boys, health education warning against tobacco use, sexuality education and promotion of condom use, and male circumcision;

**Secondary prevention** in women aged 30-49 years with a screen and treat approach, since vaccination does not protect against all cancer-causing HPV types; and

Tertiary prevention by treatment of invasive cancer at any age.

Currently available HPV vaccines can prevent infection with the two HPV types, 16 and 18, which are known to cause 70% of cervical cancers. This is important particularly in countries that lack resources for effective screening programs.

Screening by Pap smear, HPV-DNA or visual inspection with acetic acid is recommended for women between 30 and 49 years of age even after vaccination, since cervical cancer related to other HPV types may still occur.

Condom use can also reduce the risk of infection with HPV. For an HIV-positive woman, screening should start when the HIV diagnosis is confirmed, regardless of her age.

### 12.6 What is HPV vaccine?

Two HPV vaccines are currently available worldwide: a bivalent vaccine, Cervarix <sup>®</sup>, which protects against HPV types 16 and 18, and a quadrivalent vaccine, Gardasil <sup>®</sup>, which protects against four HPV types (6 and 11 (which cause genital warts), and 16 and 18).

Both are available in single-use vials or prefilled syringes. The bivalent HPV vaccine (Cervarix <sup>®</sup>) also comes in two-dose vials.

These vaccines do not require reconstitution. They must be stored between +2  $^{\circ}C$  and +8 $^{\circ}C$ .



Both vaccines are administered intramuscularly in two or three separate 0.5 ml doses.

12.7 How safe is HPV vaccine and what are the potential AEFI?

Both HPV vaccines are well tolerated and have good safety profiles.

Serious events include only rare anaphylaxis.

Mild events include local injection site reactions such as pain and swelling. These have been reported 10–20% more frequently in vaccinated groups when compared to unvaccinated groups.

Other mild events reported following HPV vaccination include fever, dizziness and nausea. Adolescents are known to sometimes faint after any injection and should be seated during vaccination and for at least 15 minutes afterwards.

12.8 When is HPV vaccine administered?

HPV vaccination is recommended for girls 9-13 years. Both vaccines require two doses given over at least a six-month period. If the interval between the two doses is less than five months, a third dose should be given at least six months after the first dose.

HPV vaccines can be delivered through a healthcare facility-based strategy, or a school- and/or other community-based outreach service. If a girl gets pregnant before she has been fully immunized, the remaining dose(s) should be postponed since it is not licensed for use in pregnancy.

Key points about HPV and cervical cancer

Cervical cancer is the leading cause of cancer death among women in developing countries.

Almost all cervical cancers are caused by HPV, a sexually transmitted virus. Two types of HPV (types 16 and 18) cause 70% of cervical cancer cases.

Cervical cancer develops many years after initial HPV infection and does not usually show symptoms and signs until it is late stage and difficult to treat.

HPV vaccination, condom use, prevention of tobacco use, and cervical cancer screening later in life are all needed to prevent cervical cancer.

Screening to detect early changes that lead to cancer is needed for all women aged 30-49 years, including those who were vaccinated because the vaccine does not protect against all HPV types that cause cervical cancer.

Two HPV vaccines, a bivalent and a quadrivalent, are currently available.

### Table 15: Summary of HPV vaccines for girls aged between 9 -13 years

	Bivalent (HPV types 16 and	Quadrivalent (HPV types 6, 11, 16
	18;	and 18; Merck Gardasil <sup>®</sup> )
	GSK Cervari x <sup>®</sup> )	
Type of vaccine	Recombinant protein capsid,	Recombinant protein capsid, liquid
Type of vaccine	liquid vaccine	vaccine
Number of doses	three	three
Schedule	At first contact (0 month),6	At first contact (0 month),6

	months after	months after
Booster	None	None
Contraindications	Anaphylaxis or hypersensitivity after a previous dose	
Adverse reactions	Severe: rare anaphylaxis Mild: injection site reactions; fever, dizziness, nausea	
	Postpone vaccination for pregnancy	
Special precautions	Adolescents should be seated during injections and for 15	
Dosage	0.5 ml	
Route of administration	Deltoid muscle of upper arm	
Injection type	Intramuscular	
Storage	Store between 2°C–8°C. Do not freeze	

# **13. Meningococcal Meningitis**

13.1 What is meningococcal disease?

Meningococcal meningitis is an infection of the meninges (membranes covering the brain and spinal cord) caused by the bacterium Neisseria meningitides (also known as the meningococcus).

Each Neisseria meningitides bacterium has a capsule and, depending on the type of this capsule, it is put in a serogroup.

Neisseria meningitides serogroups A, B, C, X, W135 and Y cause most cases of meningococcal meningitis. It occurs globally, but in the sub-Saharan Africa meningitis belt which extends from Senegal in the West up to Ethiopia in the East, epidemics occur every two to three years.

Since the 1980s, the intervals between major epidemics of meningococcal meningitis have become shorter and more irregular. In 2009, 14 African reported 88,199 suspected cases and 5352 associated deaths.

In Ethiopia, in 1981 there were 50,000 cases and nearly a thousand deaths and in 1989 there were 46,000 cases and 1,700 deaths due to meningococcal meningitis. Major epidemics usually occur every 8 to 12 years and the last report was in 2001 when 6,964 cases had been reported with 330 deaths.



Nisseria meningitides

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The meningococcus bacterium can also cause septicemia (bloodstream infection), which is less common but more severe and often fatal.

### 13.2 How is meningococcal disease spread?

The meningococcus is spread from person to person via airborne droplets emitted from the nose and throat of infected people.

Meningococcal disease is most common in young children, but older children and young adults living in crowded conditions can also be at high risk.

### 13.3 What are the symptoms and signs of meningococcal disease?

Meningococcal meningitis is marked by the sudden onset of intense headache, fever, nausea, vomiting, sensitivity to light and stiff neck.

Other signs include lethargy, delirium, coma and convulsions. Infants may not have sudden-onset illness and a stiff neck; they may only appear to be slow, inactive, irritable or feeding poorly and may be vomiting.



A petechial rash (petechiae are small spots of bleeding into the skin) is the key sign of meningococcal septicemia, which can be followed by rapid shock and death.

13.4 What are the complications of meningococcal disease?

Death occurs in almost all untreated cases. Even with early treatment, up to 10% of patients die.

About 10–20% of meningococcal meningitis survivors suffer from complications, such as mental retardation, deafness, paralysis and seizures.

13.5 What is the treatment for meningococcal disease?

Antibiotics such as ceftriaxone, chloramphenicol and penicillin G are effective.

Each case should be considered as a medical emergency and referred to a hospital to reduce the risk of death from rapidly progressing disease.

13.6 How is meningococcal meningitis prevented?



Several vaccines are available to protect against meningococcal serogroups A, C, W135 and Y.

In Ethiopia sero type A is the predominant sero group associated with outbreak followed by sero type C. MenAfrivac vaccine was introduced in 2013 in the form of campaign for individuals 1-29 years and it is expected to be introduced in to the routine immunization program.

No vaccine protects against serogroup X at this time. Vaccine choice for outbreak response and routine service depends on the identified meningococcal serogroups.

### 13.7 What is needed for meningococcal disease control?

Epidemic control relies on good surveillance with early detection and treatment of cases as well as immunization.

A mass immunization campaign that reaches at least 80% of the entire population with vaccine against serogroups A and C can prevent an epidemic in areas where these serogroups are the cause of outbreaks.

### 13.8 What is meningococcal vaccine?

There are two categories of meningococcal vaccine :polysaccharide vaccines with specific capsule serogroup antigens and polysaccharide-protein conjugate vaccines, which have serogroup antigens bound to a protein that helps increase the immune system response to the vaccine.

Conjugate vaccines result in better protection in infants and longer lasting effect in all (this is similar for pneumococcal conjugate vaccines).

Meningococcal vaccine category	Sero groups and other antigens	How vaccine is supplied
Polysaccharide	bivalent A, C trivalent A, C, W135 quadrivalent A, C, W135, Y	Freeze-dried powder requiring Reconstitution; Single or multi dose
Conjugate	monovalent A or C quadrivalent A, C, W135, Y	Freeze-dried powder requiring Reconstitution;

### Table 16. Meningococcal vaccines

ſ	combination C, Hib	Single or multi dose

Meningococcal vaccines should be stored between +2 °C and +8 °C. Polysaccharide vaccines are generally given as a 0.5 ml dose subcutaneously. Conjugate vaccines are administered as a 0.5 ml dose intramuscularly.

13.9 How safe are meningococcal vaccines and what are the potential AEFIs?

Severe adverse events with polysaccharide vaccines include rare anaphylaxis (one per one million doses of vaccine administered) and infrequent neurologic reactions, such as seizures.

Mild events include local injection site reactions in up to 56% & fever in less than 5% (common in infants).

MenAfrivac, like other conjugate vaccines have excellent safety profiles. No severe adverse events have been associated with them. Mild events include local injection site reactions, and fever and irritability in children.

13.10 When are meningococcal vaccines administered?

They can be given in routine sessions and supplementary activities, including mass campaigns during outbreaks. In countries with low case rates (less than two cases/100 000 population/year), vaccination should be given in high-risk groups, such as children and young adults living in closed communities (e.g. boarding schools, military camps and similar situations). Immune deficient (including HIV) patients, laboratory workers and travelers should also be immunized.

Conjugate vaccines are preferred (over polysaccharide vaccines) due to the increased immune system response. They also have a potential herd effect, which means that immunizing a proportion of the community may lead to less disease in the unimmunized as well.

In the African meningitis belt countries including Ethiopia, conjugate vaccines can be given to all aged one to 29 years. MenAfrivac can be given through routine immunization at the age of nine months. Polysaccharide vaccines may be used to control outbreaks in areas with limited resources. They are administered for those aged two years and older, and a booster may be given three to five years later if there is continued high risk.

### Key points about meningococcal disease and meningococcal vaccines

Meningococcal disease is caused by a bacterium, Neisseria meningitides, and most commonly affects young children.

The bacteria spread by contact with respiratory droplets from the nose & throat of the infected person.

Meningococcal meningitis typically presents with sudden-onset intense headache, fever, nausea, vomiting, light sensitivity and stiff neck. Infants may only be slow, irritable and feeding poorly.

A petechial rash is the key sign of meningococcal septicemia.

Meningococcal disease can be rapidly fatal and should always be treated as a medical emergency. Conjugate vaccine is the preferred choice.

MenAfrivac was introduced in Ethiopia in 2013 in the form campaign and will be integrated in the routine immunization program

Type of vaccine	Purified bacterial capsular polysaccharide; bivalent, trivalent or quadrivalent					
Number of doses	one					
Schedule	Two years of age and older					
Booster	One dose after 3-5 years if still at risk					
Contraindications	Anaphylaxis or hypersensitivity after a previous dose					
Adverse reactions	ions Severe: rare anaphylaxis; Mild: injection site reaction, fever					
Special precautions	Children under 2 years of age are not protected by the vaccine					
Dosage	0.5ml					
Injection site	upper arm					
Injection type	Subcutaneous					
Storage	Between +2 °C and +8 °C					

**Table 17.** Meningococcal polysaccharide vaccines summary

Table 18. Meningococcal A conjugate vaccine summary

Type of vaccine	Purified bacterial capsular polysaccharide bound to protein; monovalent, quadrivalent.								
Number of doses	one								
	Monovalent: Single dose for all between 1 and 29 years of age through SIA; Single dose at the age of nine months through routine.								
Booster	none								
Contraindications	Anaphylaxis or hypersensitivity after a previous dose								
Auverse	Severe: rare anaphylaxis Mild: injection site reaction, fever								
Special precautions	See schedules above for age restrictions								
Dosage	0.5ml								
Injection site	upper arm								
Injection type	Intramuscular								
Storage	Between +2 °C and +8 °C , Do not freeze								

### 14. Yellow fever

14.1 What is yellow fever?

Yellow fever (YF) is a mosquito-borne viral disease of humans and other primates that is currently endemic (occurring regularly) in 44 tropical zone African and South American countries.

WHO estimates for the early 1990s indicated that 30 000 deaths were expected each year due to YF, with the majority occurring in sub-Saharan Africa.

There were reports of yellow fever outbreak in Ethiopia at different time affecting areas in Southern region of the country that are bordering Kenya.

Yellow fever virus

14.2 How is yellow fever spread?

YF is spread by several species of Haemagogus and Aedes mosquitoes.



In forest areas and humid regions of Africa, people become infected by the bites of mosquitoes that have previously fed on infected nonhuman primates.

During large epidemics in crowded urban areas, mosquitoes can spread the disease from person to person.

### 14.3 What are the symptoms and signs of yellow fever?

Infection with YF virus can cause no symptoms or signs in some cases. In other cases, signs usually appear three to six days after the infected mosquito bite and include fever, muscle pain, shivering, loss of appetite, nausea and vomiting, congestion of the conjunctivae and face and a relatively slow heart rate during fever.

Approximately 15% of infections are associated with more severe symptoms, such as jaundice (yellowing of the conjunctivae and skin), bleeding and liver and kidney failure that can lead to death. Severe YF can be confused with malaria, leptospirosis, viral hepatitis, and other types of hemorrhagic fevers and poisoning.

### 14.4 What are the complications of yellow fever?

About 20–50% of patients who develop liver and kidney failure die, usually seven to10 days after the onset of the disease. Survivors may experience prolonged weakness and fatigue, but the liver and kidneys usually heal completely.

### 14.5 What is the treatment for yellow fever?

There is no WHO recommendation for antiviral medication in YF treatment. Supportive measures to improve symptoms should be taken. Severe cases usually require hospital care. Paracetamol is issued in mild cases that can be managed at home. Aspirin and similar medications should be avoided since they may cause bleeding, particularly in the stomach and intestines.

Yellow fever is best managed in hospitals.

### 14.6 How is yellow fever prevented?

YF is prevented by immunization, which is recommended to protect people living in endemic and epidemic disease areas and travellers visiting these areas and to prevent international spread by infected travellers.

Large-scale YF vaccination has been very effective in endemic areas, but major outbreaks have occurred where coverage has decreased after discontinuation of immunization campaigns.

Measures to control mosquito populations in urban areas have also been part of prevention strategies.

### 14.7 What is yellow fever vaccine?

Live attenuated vaccines for preventing YF are currently in use. They are supplied in freeze-dried (also called lyophilized) form and must be reconstituted with the diluent supplied by the manufacturer before use:

YF vaccine must be stored between +2 °C and +8 °C. It is not damaged if accidentally frozen. It is administered as a single 0.5 ml dose either subcutaneously in the upper arm or intramuscularly in the anterolateral thigh.

14.8 How safe is yellow fever vaccine and what are the potential AEFI?

Serious adverse events after YF vaccination include:

Immediate severe hypersensitivity reactions or anaphylaxis (five to 20 cases per one million doses)

YF vaccine-associated neurologic disease (inflammation of different parts of the nervous system, including the brain) and

Viscerotropic disease (affecting internal organs) have been reported; overall rates are low but older patients (over 60 years) receiving primary YF vaccine doses seem to be at higher risk

Historically, up to four cases of encephalitis (brain infection/inflammation) per 100,000 doses were reported in infants aged less than six months and for whom the vaccine is not routinely recommended.

Mild events include headache, muscle pain and/or mild fever in less than 5% of those receiving YF vaccine.

14.9 When is yellow fever vaccine administered?

A single dose of YF vaccine is sufficient for life-long protection and, in endemic countries, should be integrated into routine immunization programs, with children aged nine to 12 months receiving the vaccine at the same time as measles-containing vaccine.

Preventive mass immunization campaigns are recommended in endemic countries where YF vaccine coverage is low. It should be provided to everyone aged nine months or more in areas with reported cases.

Unvaccinated travellers aged nine months or more going to and from high-risk areas should receive YF vaccine unless otherwise contraindicated.

YF vaccine is contraindicated in children aged under six months and not recommended for children aged six to eight months, except during epidemics. It is contraindicated in anyone with allergies to egg antigens and in HIV-infected individuals with CD4 T-cell values of < 200 per mm  $^3$ .

### Key points about yellow fever

Yellow fever is viral disease spread by infected mosquitoes primarily in tropical zones of Africa and South America.

YF symptoms and signs can range from none to liver and kidney failure that leads to death; they can be easily confused with other diseases.

No specific antiviral treatment is recommended at this time.

YF vaccine is effective as a single dose and, if not contraindicated, should be given to all people aged nine months or more living in or travelling to high-risk areas.

### Table 19. Yellow fever vaccine summary

Type of vaccine	Live-attenuated viral					
Number of doses	of doses One					
	In endemic areas: 9-12 months of age with MCV1					
Schedule	In areas with reported cases: all persons aged >9 months					
	For travelers to high-risk areas: all persons aged >9 months					
Booster	None					
Contraindications	Age <6 months; age 6 –8 months except during epidemics; Known allergy to egg antigens or to a previous dose; Symptomatic HIV infection (AIDS stage)					
Adverse reactions	Severe: anaphylaxis; YF vaccine-associated neurologic disease and viscerotropic disease; encephalitis in infants aged <6 months Mild: headache, muscle pain, fever					
Special precautions	Risk-benefit assessment before administering to pregnant women or people aged >60 years					

Dosage	0.5 ml
Injection Site	Outer upper left arm or shoulder (for subcutaneous)
Injection type	Subcutaneous or intramuscular
Storage	Store between 2°C–8°C. Do not freeze

### **15. Opportunities for integration of services**

Immunization programs provide an opportunity to deliver other essential health services such as vitamin A supplementation, de-worming, malaria prevention with insecticide-treated nets and Integrated Management of Childhood Illness. These additional services are part of EPI Plus programs. Vitamin A deficiency is discussed further here.

### **15.1 Vitamin A deficiency**

Any immunization contact is an opportunity to screen infants and young children for eligibility to receive vitamin A, particularly if vaccinations have been delayed and the child is six months or older.

15.2 What is vitamin A?

Vitamin A is a substance that is required by the human body. It strengthens resistance to infection, increases a child's chances of surviving an infection, promotes growth and protects the cornea (the transparent part of the eye).

Lack of vitamin A, or vitamin A deficiency, can result in poor vision in dim light.

The human body cannot make vitamin A. So all the vitamin A it needs must come from food intake. Vitamin A is present in the following foods:

Breast milk; liver, eggs, meat, fish with liver; milk, cheese and other dairy products;

Yellow and orange fruits, such as mangoes and papayas;

Yellow and orange vegetables, such as pumpkins and carrots;

Dark green, leafy vegetables;

Red palm oil.

Vitamin A can be added to such foods as sugar, vegetable oil and wheat flour during processing. This is called food fortification.

15.3 When does vitamin A deficiency occur?

Vitamin A deficiency occurs when a person does not eat enough food containing vitamin A or when the body uses it up too fast. This often happens during illness,

during pregnancy and lactation, and when children's growth is most rapid – from six months to five years of age.

15.4 What are symptoms and signs of vitamin A deficiency?

Vitamin A deficiency (VAD) reduces resistance to infections, leading to more severe and prolonged illnesses and increasing the risk of death. It can cause eye damage, such as corneal lesions and, when severe, can cause blindness. Generally, the first clinical sign of vitamin A deficiency is night blindness (impaired vision in dim light).

Because vitamin A deficiency reduces the body's resistance to infection, it is a threat even before any direct signs become apparent. Vitamin A deficiency can also cause anaemia.

Children suffering from vitamin A deficiency are more likely to get infections, such as measles, as well as diarrhea and fevers. These infections are more likely to be severe, sometimes resulting in death.

### 15.5 What is vitamin A supplementation?

When diets do not contain food with enough vitamin A, it is possible to increase vitamin A levels in the body by periodically taking a concentrated dose in the form of a capsule. This is called supplementation.

When given to children, vitamin A capsules are cut open and the drops of liquid inside are squeezed into the mouth.

Vitamin A supplementation can be combined with immunization services for children when health officials know or suspect that vitamin A deficiency is present in an area or among a certain population.

In addition, vitamin A supplements are also given for treatment of measles and xerophthalmia (dryness of the eyes that can lead to corneal damage and blindness).

15.6. Are there any side effects of vitamin A supplements?

Usually, there are no side effects. On rare occasions, a child may experience headache, loss of appetite or vomiting. These symptoms pass in time, and no treatment is necessary. Parents should be advised that this is normal.

15.7 What are the opportunities to link vitamin A and routine immunization?

### Table 20: Linking vitamin A supplementation with routine immunization

Target for vitamin A	Immunization contact	Vitamin A dose
Infants 6-11 months	Measles/Yellow fever	100 000 IU

	Polio NID/SNID	
Children 12 months and older	Other EPI campaigns	200 000 IU
Children 12-59 months	Other EPI campaigns; Delayed primary immunization	200 000 IU

The optimal interval between doses of vitamin A is four to six months. The minimum recommended safe interval between doses is one month. The interval between doses can be reduced to treat clinical vitamin A deficiency and measles cases. Follow national guidelines for the appropriate measles treatment schedule.

# **16. The integrated Global Action Plan for Pneumonia and Diarrhea**

Immunization is one component of comprehensive plans for disease control and services should be managed as part of an integrated whole rather than working in isolation from other health activities. The following brief summary of GAPPD is included here to emphasize the complementarity of services that may be integrated with immunization.

As shown in Figure 1 below, GAPPD emphasizes a Protect, Prevent and Treat framework to achieve pneumonia and diarrhoea control: protecting children by establishing and promoting good health practices; preventing children from becoming ill from pneumonia and diarrhoea by ensuring universal coverage of immunization, HIV prevention and healthy environments; and treating children who are ill from pneumonia and diarrhoea with appropriate treatment.

Protection measures include:

- Exclusive breastfeeding for the first six months of life;
- Adequate complementary feeding;

- Vitamin A supplementation.

Prevention measures include:

- Vaccines (measles, pertussis, H. influenza type b, pneumococcus and rotavirus);
- Hand washing with soap;
- Safe drinking water and sanitation;
- Reduced indoor air pollution;
- HIV prevention;
- Cotrimoxazole prophylaxis for HIV -infected children as indicated.

Treatment measures include:

- Improved care seeking and referral;
- Case management at health facility and community level;
- Supplies (ORS, zinc, antibiotics and oxygen);
- Continued feeding (including breastfeeding)

GAPPD goals are to reduce deaths and diseases as well as stunting in children by 2025. Achieving these goals will require reaching the following coverage targets by the end of 2025:

90% full-dose coverage of each relevant vaccine (with 80% coverage in every district);

- 90% access to appropriate pneumonia and diarrhoea case management (with 80% coverage in every district);
- At least 50% coverage of exclusive breastfeeding during the first six months of life;
- Virtual elimination of pediatric HIV.

The following targets will then need to be achieved by the end of 2030:

- Universal access to clean drinking water in health care facilities and homes;
- Universal access to adequate sanitation in health care facilities by 2030 and in homes by 2040;
- Universal access to hand washing facilities (water and soap) in health care facilities and homes;
- Universal access to clean and safe energy technologies in health care facilities and homes.

### GAPPD Protect, Prevent and Treat framework

Complementarity of Pneumonia and diarrhea interventions



### Table 21: Summary of target diseases and vaccine schedules in the national EPI program

BCG	Tuberculosis	One	At birth or soon after	0.05 ml; ID	Right upper arm (deltoid)	Symptomatic HIV infection or other immune deficiencies	Correct intradermal administration is essential ;a specific syringe and needle are used for BCG
Polio	Poliomyelitis	3-4	At birth, 6,10 &	Two drops	Oral	Anaphylactic reaction to	None
			14 weeks			previous dose or to any constituent	
-------------------------	---	------------------------------	---	----------------	--	--	--
IPV	Poliomyelitis	one dose with penta	At 14 weeks with penta	0.5 ml IM	l; Right (outer) mid-thigh	Anaphylactic reaction to previous dose or to any constituent	Postpone vaccination if the child has moderate to severe illness (temperature>39°C)
DTP- HepB-Hib	Diphteria, Tetanus, Pertussis. H. influenza pneumonia & meningitis, Hepatitis B	3 doses	6,10 & 14 weeks (birth dose Hep B if available )	0.5 m IM	Il Left (outer) mid-thigh (two cm away from IPV injection)	Anaphylactic reaction to previous dose or to any constituent	Use only stand-alone HepB vaccine for the birth dose (Do not use pentavalent combination for birth dose Hep B)
PCV 10	Pneumonia and others caused by Streptpneumon iae	three doses	6,10 & 14 weeks	0.5 m IM	l Right (outer) mid-thigh	Anaphylactic reaction to previous dose or to any constituent	Postpone vaccination if the child has moderate to severe illness (temperature>39°C)
Rotarix®	Rota virus gastroenteritis	Two doses	6 weeks and 10 weeks	1.5ml; Oral	Oral only	Severe allergic reaction to previous dose; severe immunodeficie ncy (but not HIV infection)	Should be postponed for acute gastroenteritis, fever with moderate to severe illness. Not routinely recommended for history of intussusception or intestinal malformations possibly predisposing to intussusception.
Measles	Measles	Two doses	9 months	0.5 ml	l, Left upper arm	Known allergy to vaccine; pregnancy; severe congenital or acquired immune disorders, including advanced HIV infection/AIDS	None
Rubella	Rubella	Two doses	9 or 12 months of age with MCV	0.5 m SC	l, Left upper arm	Same as measles	None
MenA (conjugate )	Meningitis (Sero Type A)	One dose	1-29 years and single dose at 9 months	0.5 m IM	l, Upper arm	Anaphylactic reaction to previous dose or to any constituent	None
HPV	Cervical cancer (type 16 & 18)	Three doses	0 month, 1 month and 6 month	0.5 m IM	l, Left upper arm (deltoid)	Anaphylactic reaction to previous dose or to any	Postpone vaccination for pregnancy; Adolescents should be seated during injections

constituent	and for 15
	minutes afterwards since they sometimes faint

### Exercises

### 1. Describe each vaccine preventable diseases in terms of the followings

Target	Causativ	Mode	of	Sign and	Major	Treatme	Prevention
diseas	e agent	transmiss	io	sympto	complicatio	nt	(comprehensiv
е		n		m	ns		e)

2. Summarize in a table site and the recommended age for vaccination, dose, route of administration, and number of doses for all the EPI vaccines (schedule for children and women of child bearing age).

- 3. In Woreda X, a keen medical officer named Abebe is managing a successful immunization program. One day, he visits a district hospital and is shocked to find 19 children with measles, some of them severely ill. He asks the hospital staff for information on the immunization histories of the children.
  - 15 had not received measles vaccine.
  - 4 of these 15 had never been to a health center or health facility
  - 11 of these 15 had gone to a health center for measles immunization but had not received it because the health workers would not immunize children with colds or diarrhea
  - 4 children had received measles vaccine immunization in the same health center and had been in the right age for this.

a) Which of these measles cases could have been prevented? How?

b) What should the medical officer do to reduce the number of measles cases in the region?

4. Write severe adverse reactions following measles, pertussis, OPV, IPV and BCG vaccines?

5. Describe the control, elimination and eradication strategies of the following vaccine preventable target diseases

- A. Maternal and neonatal tetanus elimination strategies
- B. Hepatitis control strategies

- C. Polio eradication strategies including rationale for IPV introduction
- D. Measles control/elimination strategies
- E. Cervical cancer control strategies

6. Define EPI plus and give example of interventions that can be included in EPI plus Program?

# Module 2: The cold chain and vaccine management

About this module

This module provides guidance for workers at health facility level. It covers the use of cold-chain equipment, temperature-monitoring devices and the basic preventive maintenance of cold-chain equipment.

The vaccine stock management and vaccine wastage, practices that health workers should follow during storage, transportation and vaccination sessions of vaccines are also discussed.

The contents of the module are,

The basic concept of the cold chain

Health facility cold chain equipment

Arranging vaccines inside cold chain equipment

Temperature monitoring devices

Monitoring cold chain temperatures

Basic maintenance of cold chain equipment

Vaccine stock management at health facility level

Learning Objective:

By the end of this session, participants will become familiar with elements of the cold chain and vaccine management.

Participants will be able to:

Identify cold-chain equipment for health facility, temperature-monitoring devices,

Monitor temperature and respond to temperature violation

Implement basic preventive maintenance of cold-chain equipment, and

Practice on proper vaccine stock management and vaccine wastage monitoring.

# **1.** The cold chain

### 1.1 About the cold chain

The system used for storing & distributing vaccines in good condition is called the cold chain. It is sometimes referred to as the vaccine supply chain, or the immunization supply chain. The cold chain 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. Figure 1 illustrates the complete cold chain. The bottom row of arrows shows the flow of vaccines down to the health facilities; the top row of arrows shows where data are collected, recorded, checked and analysed, and how reporting information flows back up the chain. This ensures that cold chain performance is properly monitored and that the necessary information is gathered for vaccine forecasting.

### ANNUAL STATISTICS BESTIMATES ANALYSIS ANALYSIS ANALYSIS ANALYSIS CENTRAL STORE DAILY RECORD CENTRAL STORE ANALYSIS ANALY

### Figure 1:The vaccine cold chain and information flow

Vaccines are temperature sensitive products. Some vaccines are sensitive to freezing temperature. Therefore they must be kept at the correct temperature from the time they are manufactured until they are used. The system used for keeping and distributing vaccines in good condition is called the cold chain. The cold chain consists of a series of storage and transport links, all designed to keep vaccines within an acceptable range until

In order to maintain a reliable vaccine cold chain at the peripheral level, the following key procedures must be observed:

- Store vaccines and diluents within the required temperature range at all sites
- Pack and transport vaccines to and from outreach sites according to recommended procedures
- Keep vaccines and diluents within recommended cold chain conditions during immunization sessions.
- 1.1.1 Temperature requirements for vaccines

Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and others to light. Vaccine potency, meaning its ability to adequately protect the vaccinated client, can diminish when the vaccine is exposed to inappropriate temperatures. Once lost, vaccine potency cannot be regained. To maintain quality, vaccines must be protected from temperature extremes. Vaccine quality is maintained using a cold chain that meets specific temperature requirements. Figure 2 shows recommended vaccine storage temperatures at each level of the cold chain. It is essential that all those who handle vaccines and diluents know the temperature sensitivities and the recommended storage temperatures for all the vaccines in the national schedule.

### Figure 2:Recommended vaccine storage temperatures

	National (up to 6 months)	Sub-national (up to 3 months)	District (up to 1 month)	Service (up to 1 month)	
+8°C +2°C	Liquid Lyophil	Liquid Lyophil	Liquid Lyophil All OPVs	Liquid All OPVs	
-15°C -25°C	All OPVs Lyophil	Acceptable All OPVs Lyophil			

### Note:

Diluents should never be frozen.

If diluents are packaged with vaccine, the product should be stored at +2°C to +8°C.

 $Bundled \ lyophilised - liquid \ combination \ vaccines \ should \ never \ be \ frozen \ and \ should \ be \ stored \ at \ +2^{\circ}C \ to \ +8^{\circ}C.$ 

### NB: All vaccines must be stored and transported at $+2^{\circ}c$ to $+8^{\circ}C$

# Freezing

Some vaccines are also sensitive to freezing. Freezing destroys the potency of freeze sensitive vaccines. Therefore these vaccines should not be frozen. The sensitivity of vaccines to freezing is illustrated in Table 22 below.

### Heat Sensitivity of vaccines

All vaccines are sensitive to heat to some extent, but some are more sensitive than others. The commonly used EPI vaccines may be ranked according to their heat sensitivity as follows (Table 23)

### Table 22: Vaccine freeze sensitivity

Freeze sensitivity Vaccine Cautions	
-------------------------------------	--

Most sensitive	Hepatitis B	
		Never expose these
	DTP	vaccines to zero or sub-zero temperatures.
	Hepatitis AHuman papillomavirus (HPV)	
	Meningitis C (polysaccharide-protein conjugate)	Avoid the use of ice for transport.
_	conjugate)	Liquid Rota vaccine should not be frozen keep it from +2oC - +8oC all the time.
	TT, DT, Td	the time.
	Inactivated poliovirus (IPV)	
Least sensitive	Hib (liquid)	
	Rota vaccine (liquid)	
		These vaccines are not damaged by
	Meningitis A (polysaccharide-protein conjugate) Yellow fever	freezing.
Vaccines not damaged by	Bacillus Calmette-Guérin	
freezing	Hib (freeze dried)	
	Measles	
	Measles, mumps, rubella	
	Oral poliovirus	
	Rabies	
	Rubella	

# Table 23: Vaccine heat sensitivity

Heat sensitivity	Vaccine	Remarks
Most sensitive	Oral poliovirus (OPV)	
	Inactivated poliovirus (IPV)	
	Measles, Mumps, rubella (MMR)	

	DTP	Use vaccine vial monitors to
	DTP-Hep B-Hib ( pentavalent)	monitor heat exposure.
	Hib (liquid)	
	Measles	
	Rotavirus (liquid )	
	Rubella	
	Yellow fever	
		All freeze-dried vaccines
	Bacillus Calmette-Guérin (BCG)	become much more heat
	Human papillomavirus (HPV)	sensitive after they are reconstituted.
	TT, DT, Td	
	Hepatitis A	
	Hepatitis B	Note: Bolded vaccines are
	Hib (freeze dried)	freeze dried vaccines
	Meningitis A (polysaccharide-protein conjugate)	
	Meningitis C (polysaccharide-protein conjugate)	
	Pneumococcal (polysaccharide- protein conjugate) (PCV)	
	Rabies	
Least sensitive		

**Note:** - The heat stability information shown for freeze-dried vaccines applies only to *unopened* vials; most freeze-dried vaccines rapidly lose potency after reconstitution. In addition, *opened* vials of vaccines that do not contain a preservative are at risk of contamination; to keep this risk to a minimum, opened vials must be kept cool.

### Light sensitivity of vaccines

Some vaccines are very sensitive to light and will lose potency when exposed to it. Such vaccines should always be protected against sunlight or any strong artificial light, and exposure should be minimized. Vaccines that are as sensitive to light as they are to heat include BCG, measles, measles-rubella, measles-mumps-rubella and rubella. These

vaccines are often supplied in dark glass vials that give them some protection from light damage, but they should be kept in their secondary packaging for as long as possible to protect them during storage and transportation.

1.1.2 The cold chain at health facility level

At the health facility level (usually health centres and health posts), health workers can adequately protect vaccines by doing the following:

Keep vaccines in appropriate vaccine refrigeration equipment

Use a temperature-monitoring device all time to ensure temperatures remain between +2  $^{\circ}C$  and +8  $^{\circ}C$ 

Transport vaccines to immunization sessions in a vaccine carrier, correctly packed, using coolant-packs that have been properly prepared, to maintain temperature between +2 °C and +8 °C.

During immunization sessions, fit a foam pad at the top of the vaccine carrier.

At the health facility, one trained person must have overall responsibility for managing the vaccine cold chain. A second person can fill in when the primary person is absent. Their responsibilities should include:

Checking and recording vaccine temperatures twice daily; typically in the morning and at the end of the session or day

Properly storing vaccines, diluents and water-packs

Handling preventative maintenance of the cold chain equipment.

All health workers in a facility should know how to monitor the cold chain and what to do if temperatures are out of range, as described in section 1.5.2 of this module.

# 1.2. Health facility cold chain equipment

Different levels within the national cold chain system require different types of equipment for transporting and storing vaccines and diluents within the recommended temperature range.

**Primary level (national):**Depending on the capacity required, the primary level generally uses cold or freezer rooms, freezers, refrigerators, cold boxes and, in some cases, refrigerated trucks for transportation.

**Intermediate level (Region Zone or Woreda):** Depending on the capacity required, intermediate level generally uses cold and freezer rooms and/or freezers, refrigerators and cold boxes and, in some cases, refrigerated trucks for transportation.

**Health facility level:** Depending on the capacity required, health facilities generally need refrigerators (in certain instances with water-pack freezing/cooling compartments), cold boxes and vaccine carriers.

To ensure optimal performance, cold chain equipment used for immunization programmes at any level must comply with relevant technical specifications, as defined

under WHO prequalification standards or as determined by national regulatory authorities. This module focuses on cold chain equipment needed at peripheral-level health facilities.

### 1.2.1 Refrigerators

Health facility refrigerators may be powered by electricity, solar energy or kerosene. A health facility refrigerator should be chosen based on the most reliable power supply available and the combined capacity needed for vaccine and water-pack storage. Table 24 briefly describes the different refrigerator categories.

Categories of vaccine refrigerators	Description
Electric (alsoreferred to as	Ice-lined refrigerators are the preferred option where there is at least eight hours per day of reliable mains electricity. Even with periodic breaks in electricity, the inner lining of the unit
compression units)	can preserve the +2°C to +8°C holdover time <sup>1</sup> . A few models are available that can operate effectively on as little as four hours of electricity per day.lce-lined refrigerators can expose vaccines to freezing temperatures if vaccines are not loaded properly.
Solar energy	Solar refrigerators are more expensive to buy and install than
(also referred to as photovoltaic units)	electric refrigerators, but they have no running costs, apart from cleaning and preventative maintenance. The two types are: a) solar-battery units connected to a battery bank, which is charged by the solar panels and b) solar direct-drive units that are powered directly by the solar panels.
Kerosene) (also	Kerosene refrigerators can expose vaccines to freezing
referred to as	temperatures. Keeping vaccines in the $+2^{\circ}C$ to $+8^{\circ}C$ range is
absorption units <b>)</b>	particularly difficult with kerosene refrigerators.

**Table 24:** Different refrigerator categories

**Note:** - Domestic refrigerators do not have good temperature control and they cannot keep vaccines cool during electricity cuts of more than one or two hours. These units are not specifically built or designed to store vaccines. For this reason, domestic refrigerators are **not** recommended by WHO for vaccine storage.

<sup>&</sup>lt;sup>1</sup>Holdover time: The time in hours during which all points in the vaccine compartment of a vaccine refrigerator remain below +10°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected.



# Figure 3: Three commonly used refrigerator types



**Note:** - Since 2009, all WHO prequalified ice-lined, solar battery and solar direct-drive refrigerators have been fitted with thermostats that **cannot be adjusted by the user**. Provided power cuts are not excessive, the temperature in these refrigerators should always remain between +2°C and +8°C. If there is a recurring problem with the temperature control in these models, you must notify your supervisor and call the refrigerator technician<sup>1</sup>.

For all older ice-lined and solar equipment, refrigerators, and kerosene refrigerators, proceed as follows:

When the refrigerator is first installed, set the thermostat so that the refrigerator compartment stays between +2°C and +5°C during the coldest part of the day (typically the morning). It is essential to avoid freezing temperatures and the freezing risk is greatest when the ambient room temperature is low.

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.

*Do* **not** adjust the thermostat if the temperature occasionally rises a degree or so above +8°C after a power cut, or in very hot weather.

A health facility refrigerator must never be packed solid – always leave plenty of space around the vaccines and diluents to allow air to circulate freely, and to make vaccine handling easier. Typically, a health facility refrigerator should be chosen so that it is able to hold:

At least one month's supply of vaccines and diluents in the refrigerator compartment

<sup>&</sup>lt;sup>1</sup>These newer refrigerators all carry a round red and blue sticker; the top red semi-circle shows the maximum allowableoperating temperature and the bottom blue semi-circle shows the minimum operating temperature.

A one- or two-week reserve stock of vaccines and diluents (usually an additional 25–50% of the one-month supply)

A minimum of four water-packs in the freezer/cooling compartment. (Note: For technical reasons, some solar direct-drive refrigerators cannot freeze ice-packs.)

### 1.2.2 Cold boxes

A cold box is an insulated container that can be lined with water-packs to keep vaccines and diluents in the required temperature range during transport or short-term storage – see Figure 2.4. Depending on the model, cold boxes can be used to store vaccines for periods of up to two days or more when there is no power (electricity, kerosene, solar energies are not available), when the health facility refrigerator is out of order, or when a passive container is needed while the refrigerator is being defrosted. Once packed, cold boxes should not be opened until the vaccine is needed.

The "cold life" of a cold box is the maximum length of time that a closed cold box can maintain temperatures below +10°C when it is lined with frozen ice-packs. Current prequalified cold box models have a maximum cold life of two to seven days when tested at a constant +43°C.

The "cool life" of a cold box is the maximum length of time the closed cold box can maintain temperatures below +20°C if lined with cool water-packs that have been stored in a refrigerator. Current prequalified cold box models have a maximum cool life of 12 hours to two days when tested at a constant +43°C.



### Figure 4:Vaccine cold box

A cold box to be used at health facility level should be chosen based on the following factors:

the vaccine and diluent storage capacity needed for the supply period

the cold or cool life required, which depends on the maximum time vaccines will be stored in the box (including transport time)

the type and number of water-packs designed to be compatible with the size of the cold box.

Different models of cold boxes have different vaccine storage capacities and need different numbers and sizes of water-packs. It is important to use the correct number and size of water-packs, exactly as specified by the container manufacturer, otherwise cold life or cool life will be affected.

Cold boxes can be used to carry monthly vaccine supplies from district stores to the health facility and also from the health facility to outreach sessions if a vaccine carrier is too small (see section 2.2.3 below). In general, a cold box in a health facility should be large enough to transport at least one month's supply of vaccines.

### 1.2.3 Vaccine carriers

Vaccine carriers are smaller than cold boxes and easier to carry. Current prequalified vaccine carriers have a cold life with frozen icepacks of between 18 and 50 hours at +43°C and a cool life with cool water-packs of between three and 18 hours.

Vaccine carriers are generally used for the following purposes:

to transport vaccines and diluents to outreach sites and store them during health facility immunization sessions



Vaccine carrier

to store vaccines temporarily when the health facility refrigerator is out of order or is being defrosted

to transport vaccine supplies from the district store to health centres or from health centres to health posts.

Vaccine carriers used at the health facility should be chosen based on the following factors:

the type and quantity of vaccines and diluents to be transported

the cold or cool life needed for the longest planned journeys

the transport method used (for example, the requirements for a vaccine carrier that will be carried for short distances on foot are not the same as those for one that will be transported for long distances on the back of a motorcycle).

1.2.4 Water-packs

Water-packs are flat, leak-proof plastic containers that can be filled with tap water. They are used to line the inside of the cold box or vaccine carrier. Water-packs are used to keep vaccines at the required temperature range inside cold boxes and vaccine carriers. In order to protect the vaccines it is important to use the correct number and size of water-packs and to follow the instructions printed inside the lid of the container. To ensure optimal performance, WHO recommends the use of pre-qualified water-packs.

Health facilities must have a minimum of two complete sets of water-packs for each of its cold boxes and vaccine carriers so that one set can be frozen or cooled in the freezer/refrigerator while the other set is being used in the cold box or vaccine carrier.

The appropriate temperature of the water-pack will depend on the type(s) of vaccines being transported, the ambient temperatures to which the cold box or vaccine carrier will be exposed, and the duration of transport.

Water Pack

Water-packs can be used in any of the following ways:

Frozen ice-packs - taken directly from a freezer at temperatures between -10°C and -25 °C

Conditioned ice packs containing a mixture of water and ice at an initial temperature of about 0°C

Cool water-packs-containing liquid water at an initial temperature of +5 °C or less

**<u>NB</u>**: The appropriate water-pack strategy to use at health facility level, for transport or outreach operations, will be guided by national policy and practice.

If cool water-packs are used for outreach operations, there **must** be additional provision at the outreach session to keep both reconstituted lyophilized vaccines – and unpreserved multi-dose vaccines that have been opened – cool at between +2°C and +8°C. Exposure of reconstituted unpreserved vaccines and liquid vaccines that do not contain preservative to temperatures above +8°C during immunization sessions can result in an increased risk of microbial growth in opened vials of vaccine. In practice, this means that one or more frozen or conditioned ice-packs must also be available at the session.

Note that taking frozen, conditioned or cool water-packs out of the vaccine carrier will shorten their cold/cool life. Therefore, water-packs should not be removed during

immunization sessions to hold opened vials. Opened vials should be placed in the foam pad that is provided with the vaccine carrier.

WHO strongly discourages the use of wet ice in plastic water bags as this may expose the vaccines to freezing temperatures.

### 1.2.5 Foam pads

A foam padis a piece of soft sponge-like material that fits precisely on top of the water packs inside a vaccine carrier while still permitting the lid of the vaccine carrier to fully close.

The foam pad is provided by the manufacturer of the vaccine carrier. The foam pad usually has slits in which vaccine vials can be inserted snugly and protected.

The foam pad should be used during an immunization 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 immunization 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 conserve the inner temperature.

Health workers should use the foam pad supplied with the carrier and try to keep it clean and free from dirt or dust. If the original foam pad procured with the vaccine carrier is not available for use during the immunization session, it is advisable to prepare the foam pad using the locally available sponge with acceptable thickness not less than 4 cm.

# 1.3 Arranging vaccines inside cold chain equipment

Vaccines must be arranged inside cold chain equipment in a manner that helps ensure that they remain in good condition with minimum risk of exposure to damaging temperatures. This section describes how to arrange vaccines inside vaccine refrigerators, cold boxes and vaccine carriers.

### 1.3.1 General rules for using vaccine refrigerators

Health facility refrigerators are used to store vaccines and diluents. Several types of refrigerator are available and the arrangement of items inside them varies according to the type.

The following general rules (Dos and Don'ts) apply to all health facility refrigerators.

### DO's - arrange the vaccines in the health facility refrigerator like this:

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- Store vaccines and diluents in a refrigerator that is reserved for this purpose only.
- Always arrange vaccines and diluents so that air can circulate freely; this also makes it easier to handle the vaccines.
- If vaccines or diluents are supplied in their original cartons, arrange the boxes so that there is at least a two-centimetre space between stacks. Mark the cartons clearly and make sure the markings are visible when the door or lid is opened.
- If vaccines or diluents are supplied as individual containers (vials, ampoules or tubes), use a plastic tray, plastic box or other arrangement to store the vaccines in an orderly fashion. Figure 2.8 show a good arrangement using local-made stacking boxes.
- If diluent is packaged with the vaccine, store the complete packaged product in the refrigerator. If diluents are supplied separately from the vaccine, store them in the refrigerator if there is adequate space. If there is no adequate space, move the diluents to the refrigerator at least 24 hours before they are needed so they are cooled.
- Place vaccines with VVMs that show the most heat exposure (darker squares) in a separate container in the refrigerator, clearly marked "Heat-exposed vials – Use first". If there are other vaccines of the same type in the refrigerator, the vaccines with the darkest squares should be always used first even if the expiry date is later than the vaccines with the lighter squares.
- If an opened multi-dose vial will be used for the next session, the vials must be placed in a separate container in the refrigerator, which is clearly marked "Opened vials – Use first." A summary of the WHO Multi-dose Vial Policy is outlined in the box below.

# DON'T arrange the vaccines in the health facility refrigerator like this:

- Never store non-vaccine products in vaccine refrigerators.
- 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. Do not keep vaccines with VVMs that have reached, or are beyond their discard point. Do not return reconstituted vials and open liquid vaccines without preservative to the refrigerator. Discard all these items immediately according to your national guidelines. Refer any questions to your supervisor.
- Discard reconstituted vaccines after six hours of opening or at the end of an immunization session whichever comes first.

### Summary of WHO Multi-dose Vial Policy (MDVP), 2014

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

1. The vaccine is currently prequalified by WHO.

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

If ALL of the criteria cited above are present, the vaccine vial may be kept and used for up to 28 days after opening, or until all the doses are administered.

1.3.2 Specific rules for using front-opening refrigerators

Different types of front-opening vaccine refrigerators are used for storing vaccines. Figure 5 show how a kerosene vaccine refrigerator or an electric front-opening refrigerator should be organized.

# Figure 5.Vaccine and diluent arrangement in a front-opening kerosene vaccine refrigerator



The following rules apply for front-opening refrigerators:

Never put vaccines or diluents in the door shelves.

The temperature is too warm for vaccine storage and vaccines are exposed to room temperature each time the door is opened.

Never put freeze-sensitive vaccines in contact with, or close to, the evaporator plate in the refrigerator.

Put water-packs or plastic bottles full of coloured water in the space below the bottom shelf. This helps to stabilize the temperature if there is a power cut. Do not use the water-packs in vaccine carriers. Never drink the water.

Put measles, MR, MMR, BCG, OPV, yellow fever, meningococcal A conjugate and/or any other vaccines not damaged by freezing on the top shelf.

Put DTP, DT, Td, TT, HepB, DTP-HepB, DTP-HepB-Hib, Hib, HPV, rotavirus and/or any other freeze-sensitive vaccines on the middle or lower shelves.

Store the diluents next to the freeze-dried vaccine with which they are supplied, on the appropriate shelf; if there is not enough space on the shelf; put the diluents on the bottom shelf, clearly labelled so they can be easily identified to their matching vaccine.

Figure 6 shows the recommended arrangement for an upright ice-lined refrigerator. In these models there is very little variation in the temperature inside the refrigerator compartment, so vaccines and diluents can be placed safely on any of the shelves. However, in humid climates, there is a risk of condensation. Cartons and vials should be stored in plastic boxes with tightly fitting lids to reduce the risk of moisture damage. Neverstore vaccines below the bottom shelf – this area may be wet because it collects and drains the condensation from the roof and walls of the compartment.

Figure 6.Vaccine and diluent arrangement in a front-opening water-lined refrigerator



1.3.3 Specific rules for using top-opening refrigerators without baskets

Table 25 briefly describes the two types of top-opening vaccine refrigerators used for storing vaccine. Some top opening refrigerators are supplied without baskets.

Types of top- opening vaccine refrigerators	Description
Type 1	Kerosene refrigerators. These have a small compartment for freezing ice-packs.
Type 2	Solar direct-drive models with a lining containing a phase-change material (PCM) to protect the vaccine overnight and during cloudy periods. The PCM 'freezes' at around +5°C so vaccine can be in contact with the lining without risk of damage. Current models do not have a freezer compartment.

Table 25: Types of top-opening vaccine re	efrigerators
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Figure 7.Vaccine and diluent arrangement in a top-opening refrigerator without baskets



The following rules apply to these two types of refrigerator:

Never put freeze-sensitive vaccines in the bottom of kerosene refrigerators or next to the freezer compartment. There is a risk of freezing in these areas.

Put measles, MR, MMR, BCG, OPV, yellow fever and/or any other vaccines not damaged by freezing in the bottom of the compartment.

Put diluents, DTP, DT, Td, TT, HepB, DTP-HepB, DTP-HepB-Hib, Hib, meningococcal, HPV, rotavirus and/or any other freeze-sensitive vaccines in the upper part of the compartment and well away from the freezing compartment in gas and kerosene models.

Store the diluents close to the freeze-dried vaccine with which they were supplied; if this is not possible; make sure the diluents are clearly labelled so they can be easily identified to their matching vaccine.

1.3.4 Specific rules for using top-opening refrigerators with baskets

Many top-opening ice-lined refrigerators are supplied with baskets for storing vaccines. There are also a few top-opening solar-battery models; typically, these models do not have an ice lining, but they generally have baskets.

The following rules apply to these refrigerators:

Always store vaccines and diluents in the baskets provided. Never store them outside the baskets.

If there is an internal lid on the freezer compartment and/or the refrigerator compartment, always replace it before you close the main lid.

Some solar direct-drive refrigerators have an ice-bank at one end. Never remove ice-packs from this area.

Some solar direct-drive refrigerators have a separate ice-pack freezing compartment. Make sure you follow the manufacturer's instruction on the use of this feature – instructions vary.



### Figure 8.Vaccine and diluent arrangement in a top-opening refrigerator with baskets

Use the bottom baskets to store measles, MR, MMR, BCG, OPV, yellow fever, and/or any other vaccines not damaged by freezing.

Use the top baskets to store products for immediate use and to store diluents, DTP, DT, Td, TT, HepB, DTP-HepB, DTP-HepB-Hib, Hib, HPV, rotavirus and/or any other freezesensitive vaccines. Never put freeze-sensitive vaccines in the bottom baskets. In some models there is a risk of freezing in these areas.

Store the diluents close to the freeze-dried vaccine with which they were supplied; if this is not possible; make sure the diluents are clearly labelled so they can be easily identified to their matching vaccine.

1.3.5 Preparing ice-packs and cool water-packs

If the vaccine refrigerator has a freezer compartment, this can be used to freeze and store ice-packs. If cool water-packs are used, these must be prepared and stored in a separate refrigerator.

Every health facility should have at least two sets of water-packs that correspond in size and number to its stock of cold boxes and vaccine carriers.

### Filling and checking water-packs

New water-packs are supplied empty and must be filled before use. All water-packs should be checked for leaks. Proceed as follows:

*New empty water-packs*: Fill each pack with clean water, up to the fill line. Do not over-fill; leave a little air space at the top. Fix the cap on tightly.

**Used water-packs**: It is not necessary to empty and refill water-packs unless they have leaked. If there is a leak, top up the water and make sure the cap is fixed securely.

**Before use**: Hold each pack upside down and squeeze it to make sure it does not leak. If the pack has been damaged, discard it.

### Freezing ice-packs

Depending on a range of factors, it can take 24 hours or more to fully freeze a batch of ice-packs.

Most mains electric ice-lined refrigerators have a separate freezing compartment; these models can freeze up to six large or 12 small water packs every 24 hours. Small kerosene models may be able to freeze only one or two packs per day.

Some recent solar direct-drive refrigerators can also freeze ice-packs. However their freezing capacity depends on the amount of sunshine available, and in cloudy weather it may not be possible to freeze any ice-packs. The ice-packs will always melt slightly overnight when there is no power and you should expect to find some liquid water in the packs at the beginning of the day, but this is normal.

Older solar direct-drive models do not have an ice-pack freezing compartment. The latest models do. Instead of an ice lining, the Vest frost, Solar Chill and Haier solar direct-drive models have a bank of standard water-packs in a compartment that looks like a freezer compartment. These water-packs must **never be removed** for use in vaccine carriers.

Always follow the manufacturer's instructions and neveroverload the freezing compartment. Put packs in the freezer, arranged upright or on their sides so that the surface is touching the evaporator plate. If there is a door or lid to the compartment, make sure it is properly closed.

The more packs placed in the freezing compartment, the longer they will take to freeze. If too may water packs are placed in the unit, they may not freeze at all. Keep extra, unfrozen water packs that do not fit into the freezer in the bottom part of the main refrigerator compartment to keep this section cold in case of a power failure. When these water packs are placed in the freezer, they will freeze relatively quickly because they are already cold. Neverstore frozen water-packs in the refrigerator compartment; this will lower the temperature and increase the risk of freezing vaccines.

### Conditioning frozen ice-packs

Frozen ice-packs, taken directly from the freezer, are **not** suitable for immediate use. If they are not correctly conditioned it is very likely that freeze-sensitive vaccines will be frozen and destroyed. *Wrapping vaccines in newspaper or other materials does not protect against freezing.* 

Except where cool water-packs are used, WHO recommends the use of "conditioned" ice-packs for transporting vaccines in cold boxes and vaccine carriers. An ice-pack is correctly conditioned when it has melted enough to allow the ice to move inside the pack. Use the following procedure.

Remove the required number of frozen water-packs from the freezer compartment. The number and type of pack required is shown on the inside of the lid of the cold box or vaccine carrier.

Lay the frozen ice-packs on a work surface in a single layer leaving gaps of about 5cm between packs.

Wait until **all** packs are properly conditioned – there must be liquid water inside every pack and the ice-cores should move inside the packs when shaken. This will take at least 30–45 minutes in hot weather and much longer in cool conditions – from 90 to 120 minutes at +20°C. (Figure 9)



Figure 9: Checking that an ice-pack is properly conditioned

Listen for the sound of the ice core moving

### Preparing cool water-packs

Where cool water-packs are used for vaccine transport, the health facility must be equipped with a separate refrigerator for preparing these packs. This refrigerator must not be used for storing vaccines and the thermostat should be set as low as possible to ensure the water-packs are cooled to +5°C or below.

**Note**: If a cool water-pack strategy has been adopted for outreach operations, one or more frozen ice-packs must be brought to the session to ensure that opened multi-dose vaccine vials are kept at recommended temperatures. It is particularly important that vaccines that do not contain preservative – whether lyophilised or liquid – are kept at temperatures between +2°C and +8°C during the session

1.3.6 Packing vaccines in cold boxes and vaccine carriers

It is very important to pack cold boxes and vaccine carriers correctly. Proceed as follows.

Arrange the conditioned ice-packs or cool water-packs in the cold boxes and/or vaccine carriers exactly as shown on the manufacturer's instructions on the inside of the lid.

Put the vaccines and diluents in a plastic bag in the middle of the cold box or carrier to protect them from damage due to condensation.

If conditioned ice-packs are used, put an electronic freeze indicator with the vaccines.

For vaccine carriers, place the foam pad in the top of the container.

Close the cold box or vaccine carrier lid tightly.

### Figure 10: Arranging a vaccine carrier



# 1.4. Temperature monitoring devices

It is essential to monitor and record the temperature of vaccines throughout the supply chain. This is the only way to prove that vaccines have been kept at the right temperature during storage and transport. Temperature monitoring also shows up any problems with equipment and procedures. More detailed information is given in the WHO Vaccine Management Handbook<sup>1</sup>

This section only describes the type of temperature-monitoring equipment that is used in health facilities; these facilities are generally equipped with one or two vaccine refrigerators, cold boxes and vaccine carriers.

### 1.4.1 Monitoring heat exposure using Vaccine Vial Monitors

Vaccine vial monitors (VVMs)are the only temperature-monitoring devices that routinely accompany the vaccine throughout the entire supply chain. A VVM is a chemical indicator label attached to the vaccine container (vial, ampoule or dropper) by the vaccine manufacturer. As the container moves through the supply chain, the VVM records its cumulative heat exposure through a gradual change in colour (see Figure below). If the colour of the inner square is the same colour or darker than the outer circle, the vaccine has been exposed to too much heat and should be discarded.

### Figure 11.VVM showing colour change sequence and interpretation



<sup>&</sup>lt;sup>1</sup>WHO Vaccine Management Handbook Module VMH-E2-01.1. *How to monitor temperatures in the vaccine supply chain.* 



There are currently four types of VVM, chosen to match the heat sensitivity of the vaccine. These four types are: VVM2, VVM7, VVM14 and VVM30. The VVM number is the time in days that it takes for the inner square to reach the colour indicating a discard point if the vial is exposed to a constant temperature of  $37^{\circ}$ C.

The main purpose of VVMs is to ensure that heat-damaged vaccines are not administered. The VVM status is also used to decide which vaccines can safely be kept after a cold chain break occurs; this minimizes unnecessary vaccine wastage. In addition, VVM status helps the user decide which vaccine should be used first; a batch of vaccine showing significant heat exposure should be distributed and used before a batch that shows lower heat exposure, even if its expiry date is longer.

VVM status should always be checked and recorded manually on the arrival voucher when it first reaches the health facility. The vaccinator must also check the VVM before the vaccine is opened, to see whether the vaccine has been damaged by heat. Only use the vial if the expiry date has not passed, and if the inner square of the VVM is lighter in colour than the outside circle. VVMs **do not** measure exposure to freezing

temperatures. If the vaccine is freeze-sensitive and freezing is suspected, then the Shake Test must be conducted.



Figure 12. Location of VVMs on ampoules and vials

There are two different locations for VVMand each is associated with specific guidance for handling opened multi-dose vials of vaccine:

WHO-prequalified vaccines, where the VVM, if attached, is on the label of the vaccine. The vaccine vial, once opened, can be kept for subsequent immunization sessions up to 28 days, regardless of the formulation of the product (liquid or freeze-dried). WHO-prequalified vaccines where the VVM is attached in a location other than on the label (e.g., cap or neck of ampoule). In this instance, the vaccine vial, once opened, must be discarded at the end of the immunization session or within six hours of opening, whichever comes first. This is regardless of the formulation of the product (liquid or freeze-dried). This would apply, for example, to a reconstituted product of which the vaccine vial cap, which has a VVM attached, has been discarded after opening.

### 1.4.2 Temperature-monitoring devices

### 30-day electronic temperature loggers (30 DTR)

These devices are placed with the vaccine load in a vaccine refrigerator. They record the refrigerator temperature at no more than 10-minute intervals and show the temperature history for any day in the last 30 days. They also record and display a 30-day history of any heat and freeze alarms that have occurred. Alarms are triggered if the temperature of the refrigerator drops to -0.5°C or below for 60 minutes or if it exceeds +8°C for a continuous period of 10 hours. As long as the temperature has remained within the recommended range, the device displays 'OK' or a tick symbol. Several types of 30 DTR are prequalified by WHO and the figure below shows two examples. On newer models, data can also be downloaded via a connection to a computer. 30 DTRs should **not**be used in vaccine freezers. Current models have built-in batteries with a battery alarm feature; the device must be discarded and replaced when the battery expires, which is typically every two or three years.



### Figure 13:30-day electronic temperature loggers

FridgeTag2<sup>™</sup> with USB

LogTag<sup>®</sup> temperature recorder

30 DTRs should be placed in an accessible position where they can be read easily and are unlikely to be damaged. This will vary depending on the type of refrigerator. Try to observe the following rules.

If the refrigerator is used to store vaccines that are **not**freeze-sensitive, place the device on top of the load, in the warmest part of the refrigerator.

If the refrigerator is used to store anyfreeze-sensitive vaccines, preferably the device should be placed in the coldest part of the refrigerator that is being used to store these vaccines. This will be the bottom of a basket in chest refrigerators or nearest to the evaporator plate in front-opening models and absorption units.

### Electronic freeze indicators

Theseare small digital devices that are placed with freeze-sensitive vaccines during transport or storage. The devices have a visual indicator that shows whether the vaccine has been exposed to freezing temperatures. Once the alarm indicator is triggered, the device is no longer usable and should be discarded. Otherwise the device can be used until the built-in battery expires.

### Figure 14. Electronic freeze indicators



FreezeAlert™

Q-Tag<sup>®</sup> Quad

Note that electronic freeze indicators are **not** needed in refrigerators where a 30 DTR is used.

# Integrated digital thermometers

Current prequalified vaccine refrigerators and freezers are equipped with devices like the one shown in the figure below. An internal temperature sensor monitors the storage compartment and an instantaneous temperature reading is displayed on the unit's control panel. Solar Direct-Drive (SDD) refrigerators typically have a device powered by an integrated photovoltaic cell; these do not work at night or in dim light and may have to be activated by shining a torch onto the display.



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### Figure 15. Integrated digital thermometer

**Stem thermometers:** These devicesonly provide an instantaneous temperature reading. For this reason, WHO no longer recommends them as the main monitoring device in vaccine refrigerators. However, they remain an essential back-up device because they do not require a battery or other power source. WHO no longer recommendsbi-metallic dial thermometers for any purpose because they lose their calibration overtime, especially if they are dropped. **Figure 16.Stem Thermometer** 

1.4.3 Recommended equipment

Table 26 Temperature-monitoring options in health facilities for storage and transportation of vaccines in order of preference.

	Vaccine refrigerator	Cold boxes and vaccine carriers
Best practice	30-day temperature logger	Conditioned ice-packs
	Integrated digital thermometer	Freeze indicator, VVMs
	Stem thermometer for back-up	Cool water-packs
	VVMs	Stem thermometer, VVMs
Minimum requirement	Integrated digital thermometer	VVM
	Stem thermometer for back-up	
	Electronic freeze indicator	
	VVMs	

Vaccine Vial Monitors

VVMs provide a key indicator during storage and transport because they show whether the individual vaccine container has been exposed to excessive heat. Remember: VVMs **do not** measure exposure to freezing temperatures, only to heat.

### Refrigerators

Wherever possible, health facility refrigerators should be equipped with a 30-day temperature logger and facility staff should be trained in their use. These devices provide a complete history of the refrigerator temperature. Thermometers cannot do this; they only indicate the temperature at the time when a reading is taken. An electronic freeze indicator and a stem thermometer is the next best choice. The freeze indicator shows whether freeze-sensitive vaccines have been exposed to sub-zero temperatures, the most common cause of damaged vaccine. However, a freeze indicator cannot be used again once it has been triggered; it must be replaced immediately with a new one. The worst choice is a stem thermometer on its own. As noted above, a thermometer only indicates the temperature at the time a reading is taken, which is no more than 14 times per week. A 30-day temperature logger takes at least a thousand readings a week.

### Cold boxes and vaccine carriers

If conditioned ice-packs are being used to transport freeze-sensitive vaccines, an electronic freeze indicator should be included with the load; the indicator shows if the vaccines have been exposed to freezing temperatures. Freeze indicators are not needed if cool water-packs are used because there is no freezing risk. If warm water-packs are used to protect freeze-sensitive vaccines in very cold climates it is also good practice to use freeze indicators, since the temperature of the load may drop below zero on a long journey.

# 1.5. Monitoring cold chain temperatures

The data gathered from temperature-monitoring devices must be recorded and analysed on a regular basis to demonstrate that vaccines are being stored and transported at the correct temperatures. This section reviews temperature monitoring of vaccine refrigerators, cold boxes and vaccine carriers at the health facility level.

### 1.5.1 Monitoring vaccine refrigerator temperature

A standard manual temperature-recording pad/chart should be available for each and every vaccine refrigerator. Readings should be taken twice a day seven days per week, including weekends and holidays. Daily readings should be taken from the **same** temperature-monitoring device each time. The health worker should read the 30 DTR and write the data on the chart. If there is no 30 DTR, you should check the integrated dial thermometer or, where necessary, the stem thermometer. Recording temperatures in this way provides evidence that the refrigerator is being monitored and that regular readings are being taken. This can help identify performance trends, sometimes even before automatic alarms are generated.

Manual readings should be recorded on a temperature monitoring pad/chart using the following procedure:

Check the refrigerator temperature first thing in the morning and at the end of the day.

Record the temperature by date and time on the temperature chart (an example specifically designed for 30 DTRs is shown in Figure 17). When a chart is completed, replace it with a new one. Keep completed charts together in a file for future reference. (Note: action should be taken when the temperature goes out of range; see section 1.5.2 of this module.)

### Figure 17:Vaccine refrigerator temperature monitoring chart

For refrigerator without Fridge tag

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# Fridge-tag<sup>®</sup> 2 Temperature Recording Shee

1.5.2 Taking action when a vaccine refrigerator's temperature is out of range

If the temperature is below  $+2^{\circ}$ C, which is too low, the following actions should be taken:

For the temperature between 0.5-2°C the health worker should closely follow up.

For temperature below  $0.5^{\circ}$ C and if the refrigerator is working on electricity- turn the thermostat knob so the arrow points to a lower number. For kerosene refrigerators decrease the size of the flame.

This will make the refrigerator warmer.

Check whether the door of the freezer closes properly. The seal may be damaged. If broken, a technician should be called to make repairs.

If the temperature has fallen below 0°C for any length of time, protect the vaccine from freezing by moving to the safe storage (apply the contingency plan) then check freeze-sensitive vaccines to see if they have been damaged by freezing using the Shake Test.

Remember: slight heat exposure is less damaging to most liquid vaccines and diluents than freezing exposure.

If the temperature is above +8°C, which is too high, a report should be made to the supervisor. The following corrective action should be taken:

Make sure that the refrigerator is working. If it is not working, check whether the power supply (electricity, kerosene or solar) is adequate.

Check whether the door of the refrigerator or the freezing compartment closes properly; if the seal is broken, the temperature will fluctuate. Call a technician to make repairs.

Check whether frost is preventing cold air in the freezing compartment from entering the refrigerator compartment. Defrost if necessary.

If the power supply, door seal and frost levels are all in working order:

If the temperature is between 8-10°C you should follow up closely.

For refrigerator working on electricity and if the temperature goes above 10°C turn the thermostat knob so that the arrow points to a higher number. This will make the refrigerator cooler. For kerosene if the temperature goes above 10oC increase the flame size.

If the temperature cannot be maintained between +2°C and +8°C, store vaccines in other cold chain equipment that can maintain this temperature range until the refrigerator is repaired.

Remember: to avoid freezing vaccines, do not adjust the thermostat to a cooler (higher number) setting after a power cut or when vaccines arrive.

1.5.3 Maintaining the correct temperature in cold boxes and vaccine carriers

To maintain the correct temperature in cold boxes and vaccine carriers, proceed as follows.

Place the correct number and type of properly conditioned ice-packs or cool waterpacks in the cold box or vaccine carrier.

If you are using conditioned ice-packs you should preferably put an electronic freeze indicator in each cold box or vaccine carrier containing freeze-sensitive vaccines.

Keep the cold box or vaccine carrier in the shade.

Keep the lid tightly closed.
Use the foam pad to hold opened vials at the top of the vaccine carrier during an immunization session; keep the hard carrier lid closed whenever possible.

During the immunization session, vaccines must be kept at the recommended temperatures after opening. In particular, it is important to keep opened multi-dose vaccine vials that do not contain preservative – whether lyophilised (BCG, Measles) or liquid (PCV-10) – cooled at temperatures between +2°C and +8°C.

At the end of the immunization session, health workers should follow national policy in handling remaining vials. In general, this means:

Discarding all opened vials of vaccines that do not contain preservative; this includes all reconstituted vaccines and some liquid multi-dose vaccines (e.g. PCV 10).

Checking the VVMs of all unopened vials and returning the unopened vials with VVMs that are not past the discard point to a working refrigerator or appropriate cold box as soon as possible.

Where multi-dose vial policy is applied, checking the VVMs of all opened vials that contain preservative and returning those with VVMs that are not past the discard point to a working refrigerator or appropriate cold box as soon as possible. Use these vaccines first for the next immunization session.

1.5.4 The Shake Test

What is the Shake Test?

The Shake Test is used to check whether freeze-sensitive vaccines have been damaged by exposure to temperatures below 0°C. After it has thawed, a vial of vaccine that has been frozen no longer has the appearance of a cloudy liquid, but tends to form flakes that settle at the bottom of the vial.

The Shake Test requires two vials of the same vaccine from the same manufacture and with the same batch number. One of these is a vial that you suspect has been frozen and the other is a vial that you have deliberately frozen solid overnight. Allow the frozen test vial to melt completely, shake the two vials in the same hand, place them side-by-side and watch the contents settle. If the suspect vial settles at the same speed as the frozen vial you know that it has been frozen. If it settles more slowly, it has **not** been frozen and can be used.

When is the Shake Test needed?

If a freeze indicator is activated, or temperature recordings show negative temperatures, freeze-sensitive vaccines may have been damaged. If this occurs, carry out the Shake Test on a sample of the freeze-sensitive vaccines and notify your supervisor.

How is the Shake Test done?

The Shake Test protocol is shown below.

## NOTES:

1) **This protocol must not be altered**. There is only one correct way to conduct a Shake Test.

2) The test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.

Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer.

Clearly mark the vial as "FROZEN."

Freeze the vial in a freezer or the freezing compartment of a refrigerator until the contents are completely solid.

Let it thaw. Do **NOT** heat it!

Take your "TEST" vial from the batch that you suspect has been frozen.

Hold the "FROZEN" vial and the "TEST" vial together in one hand.

Shake both vials vigorously for 10–15 seconds.

Place both vials on a flat surface side-by-side and start continuous observation of the vials until the test is finished.

(NOTE: If the vials have large labels that conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.)

Use an adequate source of light to compare the sedimentation rates between vials.

IF,

The TEST vial sediments slower	Sedimentation is similar in both vials
than the FROZEN vial, <b>THEN,</b>	OR The TEST vial sediments faster than the FROZEN vial THEN,
11. Use the vaccine batch.	Vaccine damaged: Notify your supervisor. Set aside all affected vaccine in a container marked "DAMAGED VACCINE FOR DISPOSAL– DO NOT USE"
	Discard all affected vaccine once you have received permission to do so.



flame for a kerosene refrigerator.

Leave the door open and wait for the ice to melt. Never try to remove the ice with a knife or ice pick; this can permanently damage the refrigerator. A pan of boiling water can be placed inside and the door closed.

may NOT be used.

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Clean the inside of the refrigerator and door seal with a clean damp cloth.

Re-start the refrigerator. Do not adjust the thermostat.

When the temperature in the main section falls to +8°C or lower (but not less than +2°C), arrange the vaccines, diluents and water packs in their appropriate places.



Solar panels need to be cleaned and checked and the batteries of solar-battery refrigerators must be inspected and maintained. Tasks can be divided into daily, periodic and annual system:

## Daily

Check the status of the control panel display. Take appropriate action as described in the instruction manual if status is not normal.

For battery systems only: Check the indicator lights on the battery charge regulator every day. Do not freeze water-packs if the low battery warning light is on. Move vaccine to a safe location if the load-disconnect warning light or alarm sounder is activated.

## Periodically

Clean dust or snow off the solar array. The frequency with which this needs to be done will vary. **In very dusty areas, clean the array weekly**. Remove any snow accumulation as soon as possible.

Do not attempt to carry out this task unless you have the correct access and safety equipment and have received training in safe working at height. Make sure you have somebody to help you and to hold the ladder.

Never stand on corrugated roof sheets or tiles – use a properly designed roof ladder.

Clean the array in the early morning or evening when the sun is weak.

Use a soft cloth dampened with water. Wipe gently, starting at the top and working downwards.

Do not lean or stand on the array panels because you may damage them. Report any damage to wiring or hardware to your supervisor.

#### Once a year

Make sure the solar panels are not shaded by trees, plants, new buildings or overhead cables between 9.00 am and 3.00 pm. If there is shading from vegetation, arrange for the vegetation to be cut back. If there is shading from newly constructed buildings or new overhead cables, contact your supervisor. The solar array may have to be moved or increased in capacity.

Check the electric cables between the solar array, the charge regulator, the batteries and the refrigerator. Inspect grounding/lightning protection. If you see any damage, contact your supervisor.

Solar battery and solar direct-drive refrigerators should be defrosted only on a sunny day; they should **never** be defrosted in cloudy or rainy weather. A solar direct-drive refrigerator should generally be defrosted in the early morning. It will have partly

defrosted overnight so this will speed up the process. Defrosting in the early morning will also allow the refrigerator to make best use of the day's supply of solar power.

## 1.6.3 Maintaining kerosene refrigerators

## Daily

Fill the tank with clean kerosene. Always fill the tank before it is completely empty. Always keep enough spare kerosene to ensure you never run out. Never use any other fuel (e.g. diesel or gasoline).

Check the flame height and colour is correct for the type of burner fitted. If the flame smokes, turn it down a bit. If it still smokes, clean or trim the wick, burner, flue and baffle as shown in the instruction manual. Always clean the flue if the flame has been smoking.

## Weekly

Clean the burner, flue and baffle as shown in the instruction manual.

Trim the wick as shown in the instruction manual. Use a wick trimmer if possible.

Check that you have enough kerosene for at least another week. If not, replenish the supply immediately.

## Periodic tasks

Check the fuel tank to see if there is sediment at the bottom. If there is, blow out the burner and remove the tank. Remove the burner from the tank. Empty out the dirty kerosene. Flush the tank with a little clean kerosene. Wipe the outside of the tank with a clean cloth dipped in kerosene. Replace the burner and refill the tank.

Replace the wick when you cannot turn it up any more to trim it. Use the correct type of wick and follow the instruction manual. Always keep two spare wicks in a safe place.

1.6.4 Managing vaccine refrigerator breakdowns

If a vaccine refrigerator stops working, first protect the vaccines and then check the cause of the problem.

## Protecting the vaccines

Move the vaccines to other cold chain equipment until the refrigerator is repaired. For a problem that can be solved quickly, a cold box or vaccine carrier lined with conditioned ice-packs can be used for temporary storage. For a problem that might take longer to solve, another refrigerator is needed. Always keep a freezer indicator with the freeze-sensitive vaccines.

## Restoring the refrigerator to working order

Check the electricity, gas, kerosene or solar power supply and make arrangements to deal with any interruptions.

If a lack of electricity, gas, kerosene or solar power is not the problem, contact your supervisor and ask for a repair service visit. Do not attempt to repair the refrigerator yourself unless the problem is a simple one that you have been trained to deal with.

Record the breakdown on the daily temperature-monitoring chart.

1.6.5 Maintaining cold boxes and vaccine carriers

Vaccine carriers and cold boxes must be dried well after use, with their lids propped open. If they are left wet with their lids closed, they will become mouldy. Mould and damp can affect the seal of the cold boxes and vaccine carriers and may contaminate the vaccines. If possible, store cold boxes and vaccine carriers with the lids open.

Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers.

# 2. Vaccine management

## **2.1.** Stock management at health facility level

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

Two simple and practical methods that are used at health facility level are briefly described below. These methods take into account that different batches of vaccine and supplies will be received on a regular basis and dispatched to the network of health facilities, or issued to health workers for immunization sessions.

It is important to distinguish between different batches of vaccine because they may have different expiry dates and should be used accordingly. Also, in the rare situation that there is a serious adverse event, it will be useful to know the exact description of the vaccine (manufacturer, batch number<sup>1</sup>, etc.)

# Method 1: Using EPI vaccines and injection materials stock recording book for stock management each year (See Figure 19 below).

For each supply of vaccine, diluents and other supplies received or issued, all details including batch number, date of expiry, VVM status, quantity etc. presentation, minimum - maximum stock levels, discarded. Quantities of other supplies should be recorded in the same way.

<sup>&</sup>lt;sup>1</sup> Batch number, also called Lot number or serial number

After each receipt or issue, the balance in stock should be calculated and recorded. The balance recorded should be physically checked and verified at periodic intervals (e.g. once every month).

**Note:-**All types of vaccines, diluents, AD-syringes, mixing syringes, droppers, and other consumables like safety box has to be recorded.

During the period that vaccines remain in storage, regularly check the **expiry dates** of the stock to ensure no older batches are present which should have been distributed before more recent arrivals.

Only vaccine stocks which are fit for use should be included in stock records. Any expired vials, heat damaged vials or vials with VVMs beyond the discard point should **not** appear in the available stock balance.

**Physical Inventory:** A regular physical check is the only way to ensure that stock records and running balances are accurate and complete. Count all stocks of every vaccine, diluent or dropper in storage, and compare the totals to those shown as the running balance in the stock records. The count should also match diluents and droppers to the correct vaccine batches. Physical stock checks should be completed each time a monthly or before ordering the next request.

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#### Figure 19: EPI vaccines and injection materials stock recording book.

#### Method 2: Using stock cards (see figure below).

Prepare a card for each vaccine and label columns. A separate card is used to record the details of each type of vaccine or AD syringes (including a different card for different vial sizes) or diluents or other supplies/equipment.

Between each bunch of stock cards (for each type of vaccine or other equipment) a separator should be placed which is slightly bigger than the stock cards and indicates the vaccine or other material whose stock cards are immediately behind it.

For each supply received or issued, all details including batch number, date of expiry, VVM status, quantity etc. should be noted.

After each receipt or issue, the balance in stock should be calculated and recorded. The balance recorded should be physically checked and verified at periodic intervals (e.g. once every quarter).

Figure 20: Simple box to keep stock cards



# **2.2.** Ordering vaccines

Every order for vaccines and supplies should take into account the following considerations:

- Avoid stock shortages especially when mass immunization campaigns are planned
- Avoid stock excesses making excessive orders or exceeding recommended storage periods
- Avoid situations where vaccines expire during their storage period
- Ensure that there is adequate cold chain storage facilities (both in capacity and temperature)
- Ensure that the other necessary inputs for the storage (e.g. diluents, syringes and needles, safety boxes or wick and paraffin for fridges, etc.) are ordered at the same time as the vaccines.
- Follow up on the WHO and UNICEF recommendation on "bundling" the supplies. The term bundling defines the concept of a bundle, which comprises the following items: Good quality vaccines and adequate diluents, A-D syringes, Safety boxes, etc.

For appropriate stock management and well-timed ordering of vaccines and other EPI supplies, stock levels determination is imperative. The three stock levels that have to be followed for meticulous stock management and ordering of vaccines are discussed below. Please note that the vaccine and other immunization forecasting will be discussed in Module 4, planning session.

**Safety Stock:**-Represents the minimum number of vaccine doses that should be in the store on the arrival of the next supply consignment. The level of minimum stock is generally fixed at 25% of the total estimate of vaccines and supplies needs for a given supply period.

**Maximum stock level**: It implies the largest amount of stock that should be in the store during the supply period. It is the minimum stock plus the amount of stock used between orders. The maximum level is set to guard against the excess stock, which results in loosing vaccines to expiration before use.

Furthermore it important to estimate the required vaccine storage capacity needed during the supply period.

**Minimum Stock (Time to Order):-** This is also known as the reorder level or critical stock. It implies the least amount that should have in your stock or the level which, when reached, initiates a re-order. It is an amount of stock, which is used in the time between placing and receiving the order plus the buffer stock. It is the minimum stock level below which stock should never drop without having placed an order.



**Figure 21:** Movements and relation between minimum (re-order level), maximum and safety stocks<sup>1</sup>

**Example:** If the number of doses of Rotarix vaccine required for a month (for the supply period) is 10,000, then calculate the safety stock and maximum stock for rotarix vaccine.

<sup>&</sup>lt;sup>1</sup> WHO vaccine management guideline. WHO\_IVB\_06.12 (page 7)

a) Safety stock for Rotarix (in doses)= 10,000 doses x 25%= 2500 doses

b) Maximum stock for Rotarix (in doses) = 10,000 + (10,000 x 25%) = 12,500 doses

#### **Requisition Format**

Health facility have to use standard vaccine and supply requisition format during each and every ordering of vaccine and check the types and quantity of every arrival against the requested one. Like other documents of EPI program, copy of completed request format has to be documented and stored for at least three years. (See the vaccine requisition format below).

Vaccine Request Form							$\bigstar$			
						7	l Ministry of H	ealth		-
Region/Zone/Woreda						Level of cold ch				e of reque
Name of cold store						RHB/HUB C			No. of months t	
Responsible Person Contact Address			_			<ul> <li>Zonal store</li> <li>Woreda</li> </ul>			For population	Births (E
Contact Address Telephone Number(s):						<ul> <li>Woreda</li> <li>Health facili</li> </ul>	њу (H/HC/HP)		Survivin	Births (E g infants (S
									Surviving	g Illianus (.
Antigen	Doses	Waste factor	Target coverage	Balance at beginning of last supply period	Received during the last supply period	Used or dispatched to lower level during last supply period	Doses discarded (Provide reason in remarks)	Current balance (E + F – G-H)	Requirement for the next supply period*	Requesto Amoun (J – I)
A	В	С	D	E	F	G	Н	I	J	К
BCG + diluent	1	2								
OPV + droppers	3	1.11						-	-	-
DPT-Hib-Hep (Pentavalent)	3	1.05	_					-	-	-
Measles + diluent	1	1.33	ļ							-
Pneumoccoal vaccine (PCV10)	3	1.11						-	-	-
Rotavirus vaccine	2	1.11	<b> </b>					-	-	-
Syringe, A-D, 0.5ml	9	1.11	<b> </b>					-	-	-
Syringe, A-D, 0.05ml	1	1.11	<u> </u>					-	-	-
Mixing syringe (BCG)			ļ					-	-	-
Mixing syringe (measles)			L					-	-	-
Safety box			1						_	-

n.b. all figures are indicated as doses, pieces; supply requirement includes requirement for number of months indicated at target coverage PLUS

Equipment monitoring	N	o. of u	nits	No. Temperatu	ure excursions	Remarks		
Type of fridge	F	NF	FT*	< 0°C	> 8°C			
Cold rooms								
Refrigerators						]		
Freezers								
*Functional (F); Non-functional	(NF);	Fridge	s tag (I	T) in use				

Figure 22: Vaccines and EPI supplies recording and reporting flow at health facility level.



#### 2.2.1. Vaccine wastage

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

#### 2.2.2. Unavoidable vaccine wastage factors

The most important unavoidable wastage factors involve:

The use of reconstituted vaccines that have to be discarded at the end of the session.

Other vaccines used in situations under which conditions for the multi-dose vial policy cannot be met example PCV-10.

#### 2.2.3. Avoidable vaccine wastage factors

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

Poor stock management resulting in over-supply and vaccines reaching expiry before use

Cold chain failure that exposes vaccines to unacceptably high or low extremes of temperature.

Incorrect dosage, e.g. the administration of three drops of OPV instead of two, or the injection of 0.6 ml of vaccine instead of 0.5 ml.

Failure to comply with the multi-dose vial policy.

Vials lost, broken or stolen.

2.2.4. Reducing vaccine wastage

In many countries where outreach is needed to reach all infants, vaccine wastage rates will need to remain at relatively high levels, especially for freeze-dried vaccines, in order to maintain and increase immunization coverage.

However, at all levels measures to control and reduce avoidable vaccine wastage are very important. These include:

At health facility level and above, regular reporting on stock levels, improved estimation of requirements and effective stock management.

Improving district and health facility levels planning, with special regard to reliability of services.

Planning sessions efficiently to balance session size and convenient opportunities.

Using the multi-dose vial policy when appropriate.

Establishing systems to monitor and regularly report vaccine wastage at all levels.

The corrective measures, however, should not be introduced at the expense of coverage.

2.2.5. Vaccine wastage calculations at health facility level

Vaccine wastage rate = 100 - vaccine usage rate

	N	um	ber of doses admin	istere	d	- 100
Vaccine usage (rate)	Number of usable doses at	+	Number of doses received during	}	Number of usable doses in stock at	x 100
	↓ beginning of ↓ period		period J		end of period	

Note- Number of doses administered is the same as the number of children / women administered.

## Examples of Wastage rate calculation

## Example of unavoidable wastage at outreach session

The examples depicted in Table 27 below show the expected level of wastage when a single outreach session of 35 injections is conducted. Note that the wastage for freezedried vaccines is very high.

## Table 27: Example of unavoidable wastage at outreach session

Vaccine	Vial size	Vials used	Doses used (administered)	Number of children immunized	Formula	Wastage rate
DTP- HepB- Hib	1 dose	20	20X1=20 doses	19	= <u>(20X1)-19)</u> (20X1)	1/20 = 5%
Measles	10 doses	1	1X10=10 doses	5	=((10X1)-5)/10X1	5/10 = 50%
BCG	20 doses	1	1X20= 20 doses	5	=((20X1)- 5)/(20X1)	15/20 = 5%
OPV	10 doses	2	2x10=20 doses	15	=((10X2)- 15)/(10X2)	5/20 = 25%
TT	10 doses	1	1X10=10 doses	10	0	0%
PCV	2 doses	8	8X2=16 doses	15	=((2X8)-15)/(2X8)	1/16=6.3%
Rotarix	1 dose	20	20X1=20 doses	19	=((1X20)- 19)/(1x20)	=1/20=5%

Wastage for other vaccines can be greatly reduced by using the multi-dose vial policy provided the cold chain is maintained throughout, from point of use back to the health centre refrigerator. However careful management of stocks, the session plan and work plan can help reduce wastage.

#### Remember:

The goal is to immunize the maximum number of infants and women. Reducing wastage should not be allowed to compromise this goal.

The opportunity to immunize may be more valuable than a dose of vaccine.

#### Example:

#### The example below explains how to calculate vaccine usage and wastage step by step:

Health facility -X received 200 doses of DTP-HepB-Hib vaccine in a 1 dose vials in January. During monthly reporting, 130 children were found to be recorded as immunized. They had 30 doses as a start balance on 1 January and by 31 January their stock level was 60 doses.

_	30 doses     200 doses received       start balance     during January																		
	130 children immunized during JanuaryEnd balance 60 doses usable by 31 JanuaryWasted amount 40 doses																		
							(E	Each	bloc	ck re	pres	ents	10 (	dose	s)				

## Step 1: Calculate the number of doses used during the month

In the beginning of the month the facility had 30 doses and had received 200 doses during the month. This makes a total of 230 doses available for use. End balance showed 60 doses at the end of the month. Subtracting the end balance from available doses gives us the number of doses used during the month, which 230 minus 60 is 170 doses.

#### Step 2: Calculate your vaccine usage during the month

Divide number of children immunized with number of doses used during the month, which is 130 divided by 170= 0.764. Multiply this with 100, which gives you 76.4%. We can round this up as 76%.

#### Step 3: Calculate your vaccine wastage

As indicated in the above formula 100 minus vaccine usage (100 minus 76) = 24% vaccine wastage.

For further details on vaccine wastage and calculations please refer to "Monitoring vaccine wastage at country level: Guidelines for programme managers. WHO/V&B/03.18"

## **Exercises**

List down all temperature monitoring devices and describe the use of each device.

Using the completed refrigerator temperature chart below discuss the following questions in group.

Read the fridge tag temperature reading (Morning, Evening, Maximum, and minimum on third, sixth, ninth days of the month).

Identify the high alarms and when they occurred?

Identify the low from the charts and when they occurred?

List the action that the responsible health worker has to take for both low and high alarms observed.

Which vaccines would be affected most with high and low alarms? What procedures should be conducted to identify vaccines affected by temperature excursions? Explain your answers to the group.

Re	zion:						Zon	e							w	ored	1				Fa	icility	' nam	e:							
Ref	rigerator mode	d:							_				tor No									Fr	idge-1	Гаg II	num	ber: _					
R	ecord the refr	igera	tor te	mper	ature	twice	per o	day. T	empe	ratur	e sho	uld st	ay be	twee	n 2 -	8°C t	o pro	tect	vacci	nes.	N	fonth				Yea	r				
	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	3
Today	Morning Temp. AM (°C)	2	3.4	4.2	3.4	3.4	5	4.5	15.4	14.6	5	6	2	4	1	7															
Tot	Evening Temp. PM (°C)	3.2	3.4	4.5	6.4	2	9	4	19.4	18.5	6.6	6.3	3.2	4.2	6.1	8															
	▲Maximum temp (°C)	5.3	4	4.5	8.5	9	9	13	20	19	7	8	5	5	7	9															
	Alarm (Y/N)	N	N	N	N	N	N	Y	Y	Y	N	N	N	N	N	N															
Previous day	▲Duration (HH:MM)	0.0	0.0	0.0	1.35	5.4	1.05	11.21	24	12.34	0.0	0.0	0.0	0.0	0.0	2															
Previo	▼Minimum temp (°C)	-1.2	-1.9	-1.1	2.5	2	3.4	4	14.6	14.5	5	4.5	1.5	3.3	-0.5	6.5															
	▼Alarm (Y/N)	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N															
	▼Duration (HH:MM)	2.13	1.12	0.25	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0															
							I	Date o	f alaı	m an	d cori	rectiv	e Me	easur	es ta	ken f	or Te	mpe	ratur	e Exc	ursio	ns									
Da	ate of alarm	▼							Actio	ns take	en (co	de)*										Impa	ict of e	excur	sions	on va	ccines				
_																															_
																															_
	(Indicat	e tvn	e of a	n ala	rm by	~	(tick	) und	ler	<b>A</b> 0	r <b>v</b>	for	hiah	and	low	, ter	nner	atu	re re	esne	ctive	-lv f	or si	necit	ic da	ate d	of ala	arm	)		
	se the followi																														
U	1. Vaccine				ons to			i chec		<b>m</b> :			3.	Froze	n va	cine	disca	rded			4. Sł	nake	test o	ond	ucted	1					
	5. Refriger	ator	maint	taine	d	6.	Repo	orted	to hi	gher l	evel		7.1	Thern	nosta	nt adj	usteo	ł.			8. o	ther	meas	ure	(spe	cify)					

In Awash health center, Abebe, the person in charge of the cold chain management found that the refrigerator was not working and the  $T^0$  of the refrigerator was raised up to 20°C on Monday. He did not see the refrigerator during the weekend. If you are the EPI expert of the district, what are the actions you would like to take step by step? Explain your answer based on the following questions.

What would you do with the vaccines?

What would you do to prevent the occurrence of such problems in future?

Considering the assignment of a person to check the refrigerator during the weekends what are the emergency plan you would consider?

What was your past experience in the twice daily records of the temperature in your area?

Managing a cold chain problem: You are in charge of a HC with 5 health posts:

HP A is situated 20 km from the district health centre and has a population of 10,000; during the rainy season the centre is inaccessible and does not have a refrigerator. Your request for refrigerators has not been granted by higher officials.

HP B is 5 km along the main road and has a population of 6,000. It has its own refrigerator but no cold chain technician to make repairs. The health extension worker - in-charge of the health post informed you by telephone that the vaccine refrigerator is broken.

HP C is 10 km from the district health centre and has a population of 5,000. It has a refrigerator. During recent supervision visit to centre C, you established that there is only one health extension worker at the post and that the HEW does not have any tools for cold chain monitoring.

What measures are you going to put in place to ensure that immunization is not interrupted in any of the posts?

Which cold chain option, in your opinion, would be most suitable for these situations?

On Friday, Ahmed decides to defrost his refrigerator because a lot of ice has collected around the freezer compartment. He puts TT and penta vaccines from the refrigerator into a vaccine carrier lining with cool water packs, and Polio and measles vaccines into another vaccine carrier lining with ice packs. There was no enough room in the carriers for everything, so he puts the diluents on the window ledge out of the way. After defrosting and cleaning he turns ON the refrigerator. On the next day the temperature of the refrigerator was stable at 5°C and he returns back all vaccines into the refrigerator. On the following Monday, immunization day at the clinic, many children come in for measles immunization. Ahmed takes the measles vaccines out of the refrigerators and the measles diluents from the window ledge to reconstitute the vaccine.

Is measles reconstituting practice of Ahmed correct? Explain your answer based on the given scenario.

Complete vaccine ledger book based on the following data found at health center "X" cold store. On 20/03/2013 "X" the health center received the following vaccines from "Z" woreda:

Antigen	Formulation	dose	VVM status	Expiry date	Batch#	Remarks
BCG	20	2000	1st	Nov. 2014	004N0128	
DPT-HepB-Hib	1	1800	2nd	March. 2014	044N0130	
Measles	10	1800	1st	Aug .2014	004N0141	
PCV	2	1800	3rd	June. 2014	004G0128	
OPV	10	1800	1st	June .2012	054N0133	
TT	10	2000	1st	July. 2014	064L0145	

On previous day the health center EPI officer cold store manager physically checked the refrigerator and there is only 50 doses of PCV vaccine with 1st stage VVM status, 004G0111 batch number and Sept. 2014 expiry date. On the next day "K" HC received 200 doses of TT of Batch # 064L0145.

# Module 3: EPI Communication

## About this module

This module incorporates interpersonal communication skills for health workers and the general overview of building political commitment and community support for EPI. Thus at the end of this course the trainee will be expected:

- To conduct effective Interpersonal Communication skills with client during immunization session.
- To identify essential messages for caretakers and explains how to effectively communicate these messages—both as a means to provide valuable information that can be used to address parent's concerns about immunization.
- To identify communication gaps in EPI and give timely corrective responses
- To plan, implement and monitor activities to build political commitment and support of community and leaders by using different communication strategies in EPI.

By the end of this session, participants will be able to:

- Identify what concerns of mothers/ caretakers may have about immunization
- Describe what the concerns of mothers/ caretakers have about immunization
- Recognize factors that can influence mother's/ caretakers' attitude to bring their children for immunization
- Explain the most important characteristics of effective communication for immunization
- List the key messages caretakers need to know about immunization
- Describe community & health worker attitudes which impact immunization coverage.
- Use/employ structures and systems to increase demand for and use of immunization services.

## **1. EPI Communication Overview**

## 1.1 What is Communication?

In most cases, the term "communication" is described as - a process of transmitting and receiving idea, information and experience on a particular topic between two or more people that share the same code (verbal and non-verbal) aimed at reaching a mutual understanding.

## 1.2 Behaviour Change Communication

## Behaviour Change Communication (BCC) is:

An interactive process that includes health workers, communities and caretakers

Integrated into an overall immunization program

A process of developing tailored messages and approaches using a variety of communication channels

Promoting positive behaviours by families, health workers, and communities and encourages sustainable behaviour change

## 1.3 The Role of BCC

Behaviour Change Communication plays an important role in immunization programs. By improving health worker communication with caretakers and communities and focusing on messages that address parents' concerns about immunization BCC helps to reduce the number of "left-outs" (unreached) and drop-outs by raising community support and demand for services. BCC helps to:

Achieve higher coverage rates for all antigens and reductions in missed opportunities, unreached children, and drop-out rates by mobilizing communities to support and plan immunization services;

Improve quality of services to meet demand, improve interaction between health workers and communities, and improve safety of injections and safe handling of vaccines; and

Prevent or dispel misinformation, doubts and rumours related to immunization through the use of multiple channels, information sources, and media that influence the population and public opinion.

#### 1.4 Desired immunization-related behaviours

Immunization services are less likely to be used by people who are:

- Uninformed
- Dissatisfied
- Too busy
- Misinformed
- Distant

This module describes how to take a comprehensive approach to behaviour change in order to improve the delivery of immunization services and encourage their appropriate use.

Achievement of immunization goals is affected by the behaviour of many groups, including: community and religious leaders, health care providers, managers and supervisors, caretakers and their families. The focus of this chapter is on health care providers, caretakers, community leaders, and community-based health workers (HDA/WDA etc.). Some of the desired behaviours for different groups that affect immunization services are listed as follows.

## Desired Immunization-Related Behaviours

## Mothers and Other Primary Caretakers

• Bring children to immunization service delivery points at the ages recommended in the national schedule.

• Bring each child's health or vaccination card to each health visit.

• Seek tetanus toxoid immunizations for yourself and bring your health card. (This is applicable to mothers and other women of childbearing age (15-49 years)

## Fathers

• Bring children to immunization service delivery points yourself, or encourage their mother to do so.

• Provide mothers with money for transport or other expenses related to immunizing children.

## Health Workers

• Perform immunization tasks correctly, including those that ensure safe injections.

• Give mothers and other care takers essential information and treat them respectfully.

• Work with communities to schedule and organize services to make them convenient for parents.

• Praise families whose children are fully immunized by one year of age.

## **Community Leaders**

- Describe the benefits and safety of vaccinations to others in the community.
- Remind families when children need to receive the next dose(s) of vaccine.

• Encourage families to complete each child's basic immunizations in his or her first year of life.

- Inform families about outreach services, supplemental immunization activities, and new vaccines and improvements in the immunization program.
- Assist health facility staff in planning and monitoring services.
- Provide logistical support, e.g., by transporting vaccines, supplies, and staff.

Political and Public Health Leaders

- Allocate sufficient financial and human resources for immunization services.
- Show personal support for immunization services.

Source: WHO, UNICEF, and USAID 2002

**Results of Behavioural Determinant Survey** 

#### Distribution of individual behavioral stages of caretakers for immunization service utilization in Ethiopia,2012



**Figure 1:** Distribution of individual behavioural stages of care takers for immunization services

## Taking immunization program as an example:

**Stage 1**: target audience should understand what immunization program means (knowledge); recalling immunization message such as type of antigens, targeted age and schedule, place of service provided.

**Stage 2**: audience shows a favourable response to immunization message (Approval); responds favourably to immunization messages; the person discusses immunization message with people who are close to the individual such as friends, family, spouse, etc.

**Stage 3**: person intends to consult a health care provider (intention) about the immunization schedule; recognize benefits in relation to need; intend to vaccinate the child sometime in future.

**Stage 4**: individual chooses an immunization place and starts vaccination (practice) and plan to (complete) and continues to utilize it;

**Stage 5**: individual reaches at stage where s/he advocates immunization practice to others and shares experiences and benefits (advocacy); supports the program in the community.

#### 1.5 Communication in EPI Context?

Communication is one of the major components of EPI program. Communication in EPI encompasses the major communication strategies, namely Advocacy, Social Mobilization and Program Communication. Each of communication strategies of EPI has its own objectives, target group with different activities (See the details below, under communication responses).

Effective EPI communication contributes to:

Disseminate Immunization messages, facilitating discussion and supporting action in the community

Improve relations among health facilities, communities, stakeholders and partners

Identify and develop strategies to trace and track immunization defaulters

Improve interpersonal communication skills of health workers to disseminate appropriate information, hold session and provide counselling services for caretakers

Support communities to identify and report suspected diseases under surveillance (polio, measles and NNT and others)

## 2. Communication Gaps and Responses in EPI

2.1 Communication gaps

Different surveys and monitoring reports indicate a number of communication gaps in Ethiopia's Immunization program, among which the following are the major ones:

- Poor interpersonal communication between health service provider and caretakers (57.6%)

-Poor utilization of traditional, clan, religious and Kebele leaders for EPI communication intervention

- Shortage of locally tuned EPI IEC Materials

- Less knowledge of communities on adverse events following immunization

-Less use of mixed communication approaches (Channels) for routine immunization.

#### 2.2 Communication Responses

As indicated in the Communication gaps section above, the following are the major responses recommended to address the gaps and consequently improve EPI coverage

**Advocacy:** It is a strategy aimed at political leaders and other influential, partners and stakeholders at all levels to promote long term commitment, financial sustainability and appropriate resource allocation. Advocacy activities include well-designed meeting with stakeholders, allies and partners. Advocacy for routine immunization activity includes:

Social mapping and listing partners

Committee /team formation from partners and organizations

Conduct advocacy visit/meeting

Document and report partners contribution and resource allocation

Briefing routine immunization outputs and provide feedback to partners and all stakeholders.

**Social mobilization:**It is a process of gaining and sustaining the involvement of stakeholders (GOs, NGOs, etc.) In order to take action to attain common goal, EPI communication employs this strategy to ensure good participation and support of these stakeholders for the improvement of Immunization program. Social mobilization activities include:

Develop simple immunization message to mobilizers

Use health extension worker /health development armies as mobilizers in each Kebele for routine immunization activities

Provide orientation and immunization message to the health mobilizers.

Involve partners and volunteers for social mobilization

Establishing or revitalizing the social mobilization sub-committees at Woreda, health centre and community levels.

Organizing community meetings /community conversation sessions for the dissemination of information

Distributing health learning materials to communities

Disseminating immunization services information by utilizing inter personal, electronic, print media, drama, song and dance to care takers, families and communities

Utilizing school teachers, pupils, traditional leaders, religious leaders, political leaders, volunteer health workers and others to mobilize care takers to take children for the immunization sessions.

Countering misinformation regarding immunization

**Program communication:** It is a research-based consultative process of addressing knowledge, attitude and practices through identifying, analysing and segmenting audience and participating in programmes and by providing them with relevant information and motivation through well-defined strategies, using an appropriate mix of interpersonal, group and mass – media channels, including participatory method.

The following are the key program communication activities to be conducted to properly respond to some of the major gaps of EPI communication.

Develop communication activity plan

Conduct rapid Kebele focused assessment through group discussion

Define audiences (primary, secondary and tertiary) for communication

Identify audiences' potential capacity and problems

Identify appropriate and available channels

Map potential partners and stakeholders for the communication responses

Design communication approaches using interpersonal, HDA – one to five network, and public communication for mass events)

Implement activities

Follow up and monitor the implementation process

Develop monitoring and evaluation systems

Prepare and submit report

Table 28: Summary of EPI communication strategies	s, target, objective and activities
---	-------------------------------------

Communication strategies	Targets	Objectives	Activities
Advocacy	Administrators at all levels, sector organizations, partner organizations, religious and Clan/community leaders, School head, Women group leader, veterinary clinic head, Development army	To gain political will and commitment.	One to one meeting, Group Sensitization meeting Lobby with leaders.

	leader, etc		
	,		
Social mobilization	Kebele administration, religious institutions (mosques and churches), NGOs, Community members, traditional leaders, students and teachers, Development Agents	TobuildcommunityparticipationandsupportimproveToimproveimmunizationserviceutilizationimmunizationTobuildtrustTobuildtrustonimmunizationimmunizationservicesTomobilizeresourcesforimmunizationservices	Sensitization on Immunization Message dissemination, Conduct community dialogue Community mobilization for immunization session.
Program communication	Parents, Caretakers.	To improve their knowledge, attitude and practices on immunization To improve demand for Immunization services To complete the child full immunization schedule timely	ConductKebelefocused Focus GroupDiscussionthroughHDAFacilitateimmunizationmessagesdisseminationthroughdifferentchannelsConducteducationImmunizationConductinterpersonalcommunicationduringimmunization

#### Group Exercise 1

#### Case scenario 1: Case study

# Case study

**Kassim** has recently been appointed as a PHCU supervisor. During his first few months in the job, he visited every health facility. One health facility located in a remote area, has a large population but few clients. **Kassim** wants to know why.

First, he talked to the health facility catchment area community leaders. They told him that the health centre is too far away for most of the people and there is no transport to go to the health facility.

Then he went back to the health facility and discussed with **Fatuma**, the health extension worker. He greeted her and asked about her family and work. She was glad for getting the opportunity about her life and business.

While **Kassim**was at the health facility, he sat among mothers, and conversed with the mothers about their families, work, and health. He also asked them whether they had difficulty in getting to the health facility.

**Fatuma** was amazed at how relaxed and friendly the mothers were with **Kassim**, and she observed how he treated them. She usually feels too tired to bother with the details and just rushes the mothers through and sends them away.

She decided to try working in **Kassim's**way. Since that day onward, she started offering caretakers seats, asking them about their family, business and health, and whether the health facility is meeting to their health service demands or not.

The next time while Kassim visited the health facility he found many mothers. The atmosphere was warm and friendly. He observed that Fatuma spend some minutes talking with every mothers. No one had any complains about the health facility.

## Read case study, review and discuss on the following issues:

What is the actual problem of the community and the caretakers with the health facility

What did you learn from Kasim?

What was the weakness and strength of Fatuma?

What is the end status of the health facility?

#### Group Exercise 2

Provide piece of card to all participants while they are seating and tell them to make a small group (maximum three members in each group) with their nearby seat. Ask each small group to discuss and write 3 key messages (one key message on one card) that a mother needs to know to better understand immunizations and address any concerns she may have. **(5 minutes)** 

#### 3. Interpersonal Communication

## Overview

The goal of communication is to bring positive behaviour change for immunization. In EPI programme, this involves encouraging caretakers to bring their children for immunization based on standard schedule until they get fully immunized. This goal is effectively achieved by integrating interpersonal communication to the mother/care taker during immunization service and disseminating messages to the community by using different channels.

In human communication exchange there are levels of communication, including intrapersonal communication where a person processes the communication issue/message in its mind. On the second level, there is interpersonal communication, described as face-to-face communication. In the third level, we find group communication, where members exchange their views. This is followed by public communication. To entertain mass issues, mass media communication comes, where issues are addressed through radio and television and other media.



However the focus of this section is interpersonal communication. Interpersonal communication may occur between two people or in a group by which the people involved have eye-to-eye contact with each other. Interpersonal communication settings involve people relating in close proximity. The people, more importantly hear each other, observe and respond to each other's non-verbal reactions and exchange ideas, views and experiences deeply.



Figure 2: Parents' reasons for not fully completing immunization schedule

Source: Behavioral Determinant survey -Ethiopia – 2012

However, as indicated in the above figure, there is critical IPC problem in routine immunization vaccination program. Over seventy per cent of reasons for not fully immunize children is accounted for gap in Interpersonal communication.

#### Strengths of interpersonal communication

Interpersonal communication has much strength in supporting the behaviour change process, particularly in:

Explaining in detail, responding to questions and doubts, persuading and convincing target audiences about the value of the proposed behaviour.

Legitimizing programme ideas.

Building consensus, bringing about behaviour change and providing support for continuation of the new behaviour.

Addressing rumours and dealing with counter-rumours campaigns.

Responding to issues, problems and questions of a personal nature.

#### **Opportunities for interpersonal communication in EPI programmes**

Interpersonal communication occurs in almost all areas of the EPI programme, but it is particularly important:

During advocacy efforts in such as between health service providers and community leaders (Kebele administration, religious, clan, traditional leaders ---).

Between health workers providing immunization and caretakers

Between community mobilizers and caretakers.

3.1 Basic Interpersonal Communication Skills

Skills for engaging in effective IPC may be divided into three categories:

a) Skills for caring communication

b) Skills for problem-solving

c) Skills for counselling

## a) Skills for caring communication

This refers to skills needed to make the client feel welcome and appreciated. These include skills for:

Welcoming the client

Empathizing with the client

Praising and encouraging the client

**Welcoming skills** include the capacity to greet a client warmly, offer her/him a seat and carry out other preliminaries as the culture may demand. These preliminaries are important, especially at the health facility, and are helpful in establishing a relationship and making the client feel at home.

**Empathizing with the client:** Empathy refers to the ability to step into the shoes of the other person in order to see issues from his/her perspective. When you see issues from the other person's perspective, you are able to understand the other person better and show more sympathy towards his/her views.

**Praise and encouragement:** Caretakers need to be praised for the little they know and the efforts they make to keep immunization cards and bring in children for immunization. Praise and encouragement increase caretaker's deciding to continue the practice.

## b) Skills for problem-solving

Apart from making clients feel at home and appreciated, health workers carrying out interpersonal communication need to effectively use the skills of asking and listening.

Skills of asking

Skills of listening

The two skills will not only lead to understanding clients better, but they will also facilitate identification and solution of issues may hinder positive response to the recommended health behaviour.

**Asking:** Asking skills help individuals engage in a conversation to verify information, observations and impressions. Asking skills also help people to find out how much has been understood and appreciated or rejected during a conversation. By asking, the communicator gets to know the difficulties the target audiences may be having with the messages and the help that may be needed to act positively on them. To promote a smooth conversation, questions are asked in the following order:

Start with short, general, easy-to-answer questions such as: What is your name? What is the name of your child? What is the child's father name? Where do you live?

Follow with questions that need some explanations, such as: How is the child feeling today? Does the child eat well? Why have you not brought the child to the health facility for the last six month?

Then ask probing question if needed. These include questions such as: why do you say that sick children cannot be immunized?

End with checking questions: What do you think about the conversation we have just had? How does immunization help the child? When will your child need to come back for the next immunization?

When asking, encourage the other party to give more information. Avoid interruptions or premature judgements.

**Listening:** Listening is a crucial skill in a conversation. Practice active listening to encourage the person you are communicating with to volunteer for more information. In active listening, the people engaged in a conversation give gestures that show that they are listening and are following what is being said. These include hand or head movements and remarks such as "yes", "I am listening" and "good"

Figure 3: Sitting arrangement and position for effective listing during IPC



**Problem-solving skills:** Listening actively and attentively, encouraging dialogue, asking clients about their opinions, avoiding interruption, avoiding judgement, probing, paraphrasing.

## c) Skills for counselling

Counselling skills include the following:

Speaking simply and directly Explaining logically and systematically Exploring clients' beliefs Correcting misconceptions Using visual aids Motivating clients and discussing concrete behaviour change Summarizing key information Checking for understanding Giving clients a chance to ask questions Confirming follow-up steps

**Speaking simply and directly:** This skill is important for the health workers to explain things in a simple, clear and direct manner. Use familiar words and imagery. Ask checking questions and repeat the explanation if the other person has difficulties understanding.

**Explaining logically and systematically:** People understand things better when they are explained in a logical and systematic way. Illogical explanations confuse people and make understanding difficult.

**Exploring clients' beliefs:** Beliefs stand in the way of acceptance of a message and positive action. It is, therefore, important to understand what the client believes about the message. When his/her beliefs are known, they can then be discussed with a view to leading the client to a decision. The client's may be known through careful use of the skill of asking.

**Correcting misconceptions:** A client may refuse to bring his/her child for immunization because he/she believed that vaccines contain family planning substances. The health worker should establish such misconceptions and find a skilful way of correcting them. Good listening and asking skills should help the communicator to become aware of such misconceptions.

**Using visual aids:** Health workers should learn how to use teaching aids effectively in order to improve communication with clients.

*Motivating clients and discussing concrete behaviour change*: The ultimate purpose of communication for development is to bring about behaviour change. A caretaker will:

- (1) need to be convinced that immunization is good for his/her child
- (2) make a decision to take his/her child for immunization
- (3) taking the child for immunization consecutively.

During conversations, motivate caretakers to take a definite decision to take the child for the next immunization.

*Summarizing key information*: Summarizing skills help a person engaged in a conversation to find out if he/she understood what the other person said. Summarizing also helps people engaged in a conversation to check and confirm areas of agreement and disagreement.

**Checking for understanding:** It is important to check from time to time to find out if the person you are in a conversation with is understanding you or not. From time to time, ask questions such as: Do you understand what I am saying?

*Giving clients a chance to ask questions*: At appropriate moments in the conversation, give the client an opportunity to ask any questions he/she may have, so that, you can respond and help the client to understand better.

**Confirming follow-up steps:** State and explain the next steps, what needs to be done and when. It could be helpful to give the client a memory aid with simple and easy- to-understand instruction. Memory aid with figures and images could be developed for illiterate clients.

#### Key messages during IPC

Interpersonal communication is one of the critical activities of Immunization session. Providing key messages to the caretaker during health workers contact with caretaker coming to health facilities for vaccination of the child has many advantages.

The following are the five essential immunization messages the health worker expected to tell for the mothers/caretaker during IPC.

1. What disease do the vaccines prevent (which the child received today).

- 2. What side effects may occur and how can be managed.
- 3. Number of visits the child still needs in order to be fully immunized or protected.
- 4. Not to miss the next schedule, even if the child gets sick.
- 5. Date, time and place of next immunization.
- 6. Remind a mother to keep the card and bring it with her.

## 3.2. Communication materials Utilization

Utilization of communication materials: Communication materials are the major communication channels to disseminate important information to target audience and to help health workers remember key issues on certain health topics.

The preparation of Communication demands the knowledge, skills and time of different professionals and huge amount of money is spent for experts preparing the materials and the printing process. Consequently, they should be properly distributed to and used by the target community. The following are key points on the proper utilization of communication materials:

#### a) Poster:

Poster has key messages for the general public and sometimes it is prepared targeting specific groups like students, parents/caretaker.

Identify places where many people pass by or gather and post in visible area (like churches/mosques, Kebele offices). You can cluster your Kebele and give the responsibility to cluster leaders to post the posters.

Follow the availability of the posters without any destruction.

#### b) Brochure

It is communication materials which help to give detail messages to community or specific groups on Immunization.

Identify the target audiences for the brochures (families who can read or have a child who can read for them)

Proportionally allocate the brochures for each cluster and give responsibility for cluster leaders or HDA or distribute during home visit.

Check the availability of the brochures during your home visit.

## c) Banner

It is another communication material that can disseminate key messages to the community

It also give messages on specific activity like campaign, new vaccine introduction and others

Identify public gathering area to hang the banner in an area which is visible to those who pass by the area.

## c) Job Aid

These are communication materials prepared to help or aid health workers remember the basic issues on immunization

They can be posted on the wall in health facilities or placed on the table or appropriate place where that can be seen by the health workers

## **Group Exercise 3**

#### Demonstrate role play based on case scenario two and case scenario three

#### Case scenario 2: Role play 1

**W/roAlmaz** is a resident of village 1; three km far from the health facility. She is 21 years old, married and illiterate. Almaz went to the health facility seeking vaccination for her six weeks old baby girl. She met the health worker at the health facility for the first time.

Immunization Service provider (Boge):

Boge: What is the name and age of your baby girl?

Almaz: six weeks.

Boge: Have you come for vaccination of your baby before?

Almaz: No, this is my first visit.

Boge: Ok, as you can see, I have many clients, and please prepare your baby for the vaccination, while I get prepared.

Almaz: Ok

Boge: Please open your baby's mouth
Boge: Good, now hold your baby's thigh.

Almaz: OK

Boge: Hold tightly... What happen....nn to you (shouting at Almaz)

Almaz: Ok..OK... mean while the baby cried

Boge: You can go home

#### based on case scenario two;

Q.1: "How do you think the mother felt in the role play?"

Q.2: "What did you think about he health worker communicated to the mother?"

Q.3: "What did you think about **<u>what</u>** information the health worker gave the mother?" "Was it helpful?" "How would you do things differently?"

#### Case scenario 3: Role play 2

HW:	Baby Netsanet, please, come this way.
Almaz:	Yes Nurse (she stands up and moves towards the procedures table with her baby)
HW:	Please sit down. How are you and how is your baby today? May I see your card?
Almaz:	Fine sister! (Sits down and gets her baby ready for vaccination). I do not have a card. Today is my first day.password2
HW:	Don't worry. I will give you a card. (Health worker takes the card out and records all the necessary information and directs Wro. Almaz to get her child ready for vaccination).
	Wro. Almaz can I confirm that your child's name is Netsanet, and he is 4 weeks old.
Almaz:	Yes, Nurse. Thank you.
HW:	I am going to give your child a vaccine on his left upper arm and some drops into his month. The vaccine in the upper arm protects your child against tuberculosis, which give children a chronic cough. The drops prevent polio, that disease which can make children lame. The small injection does not cause much pain. It may give a small lump that will last only a few weeks. You should keep the injection site dry and do not dress it (HW gives the injection on the left upper arm of the child). The drops do not cause any problems.
Almaz:	Thank you Nurse. I am so happy you are not angry with me.
HW:	Wro. Almaz, why would be angry with you?

Almaz:	Ah! You know the other mothers told me that because I did not bring my child
	immediately after birth, the nurses were going to shout at me. Thank you very much.
HW:	Records the vaccine given and tells Wro. Almaz the date, place and time of the next vaccinations. The HW also explains that to be fully immunized the child needs to complete several visits before the child's first birthday. Your next visit will on this same
	day, Monday, in four weeks' time.
	Do you have any questions or anything, which you would like me to explain further?
Almaz:	Yes, Nurse. What should I do if I miss my child's immunization appointment?
HW:	Wro. Almaz, I know it is not always easy to keep all the appointments, but you should try as much as possible to keep the immunization appointments. Immunizations are very important for protecting your children against dangerous childhood diseases. But if you fail to keep an appointment, just come on the next immunization day even if the child is sick. We give immunizations every Monday in this clinic.
Almaz:	Thank you Nurse, (smiling). I will make sure I do not miss any immunization appointment.
HW:	Bye-bye Wro. Almaz, see you in 4 weeks' time.

#### **Discussion**

By referring <u>role play one</u> (Case scenario two) and <u>role play two</u> (Case scenario three) compare the behavior of the health worker in the two scenes.

- Q.1: What do you think about the way the health worker dealt with the mother?
- Q.2: What should the health worker have done under both circumstances?
- Q.3: How well did health worker understand the mother's situation and communicate?

## Remember always

- Act respectfully toward the mother/parent.
- Praise them for bringing their child to immunizations.
- Encourage them to continue to bring their child until fully vaccinated.
- Keep messages simple and clear.
- Have the caretaker repeat what you have said.

## Module 4: Micro planning for reaching every community

#### About this module

This module discusses the process of micro planning to ensure immunization services reach every community.

By the end of this session, participants will become familiar with:

- Developing social maps at primary health care unit catchment area, which should be updated to include all population centers and groups in the catchment area and to flag high-risk areas.
- Describing how to identify priority, high-risk health facilities and communities based on numbers of unimmunized children.
- How to clarify barriers to service access and utilization in priority communities and to make a work plan for solutions.
- Making a session plan and arranging follow up of defaulters.

#### LEARNING OBJECTIVES

At the end of the training session, participants should be able to:

- Map PHCU catchment area identifying high priority facilities and communities.
- Analyze the prevailing problems
- Select priority problems
- Determine strategies and activities for reaching every community
- Quantify resources required for immunization sessions

#### 1. Making or updating a map

Every primary health care unit (PHCU) should display a map that shows the current location and relative size of the population groups in their catchment areas. A catchment area for PHCU is a health center with satellite health posts. Specific facilities are made responsible for specific catchment areas and the population living in them.

PHCU and health facility maps should include all eligible population groups in their catchments; see Figure 1 below. A table listing these populations or communities should be displayed next to each map, see Tables 29 and 30. The maps should be updated regularly to include any changes in the catchment areas, including new administrative divisions (PHCU catchment area).

Priority, high-risk areas identified based on their high numbers of unimmunized children (see section 2 of this module) should be clearly marked.

All sources of updated maps should be used; polio eradication micro planning activities in particular may have current versions to offer. Community leaders and administrative officials should collaborate on creating and updating local maps, just as they should be involved in all micro planning steps.

#### 1.1 PHCU catchment area map

This map should display the important geographical features and population centers of the whole PHCU catchment area. It should also show the locations of the health center and the satellite health posts under PHCU supervision.

The PHCU map should include:

List of health posts with their catchment areas shown as boundaries and their distances to the health center and communities facilities marked;

List of communities such as urban communities, towns, villages, rural settlements, isolated households;

Rivers, mountains, valleys and other similar geographical features and landmarks;

Natural seasonal barriers, such as flood zones during the rainy season;

Roads and tracks

The table to be displayed next to the PHCU map should include:

List of health posts under the PHCU. Include also the HC if it has catchment area it is responsible for provision of immunization service

The total population and target population in the catchment area of each health facility;

Approximate distances and travel times to each health facilities;

Health facility contacts and any other information that may be useful in coordination and supervision efforts

Figure 1: Example PHCU catchment area sketch map



Health	Total	Population < 1	Distance between	Name of	Phone
Facility	population in	year of age in	the PHCU center	contact	number
Name	the HF	the HF	and HFs	person in	of
	catchment	catchment area	I	the HF	contact
	area		Km Hour		person
HP 1					
HP 2					
HP 3					
HP 4					
HP 5					
HC*					
Cluster					
total					

Table 29: PHCU catchment area-level list of peripheral HFs and their catchment area populations

1.2 Health facility/kebele map

Each health facility should make a simple map of its catchment area which is equivalent of kebele catchment map. The communities in the catchment area should be listed and the list updated regularly. Community boundaries should be confirmed with the help of community leaders.

The health facility catchment area map should be an operational diagram with details that can help with planning. Maps created for polio or other mass vaccination and health intervention campaigns may serve as examples.

The health facility/Kebele map should include:

Locations of every village /sub-kebele in the catchment area, including those that are not reached and/or are new;

Landmarks and significant buildings, for example, religious centers, markets, schools, bus stations;

Settlements of urban poor and migrants within towns and cities;

Settlements of migrants and/or displaced persons in rural areas

The table displayed next to the health facility map should include:

The total population and target populations in each community in the catchment area;

Approximate distances and travel times to each village/sub-kebele;

Community volunteer names and their mobile phone numbers

Figure 2:Example health facility/kebele map



Table 30 Health facility-level list of catchment area communities and populations

		Total Population < 1			
Community/vil lage name	Total population in the community (a)	year of age in the Village/sub- kebeles (b*)	Distance between HFs and Village/ sub-kebeles	Name of contact person in the community	Phone number of community focal person
Village 1					
Village 2					
Village 3					
Village n					
HC/HP Total					

\*b=a multiplied by surviving infant conversion factor

2. Identifying priority health posts and communities

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

At PHCU catchment area level, analysis of health post immunization data for the past year should identify those health post and communities in need of priority support.

At health post level, analysis of community immunization data for the past year should identify those in need of priority visits. Visits may be needed for evaluation of low coverage and the reasons behind it, (see section 3 of this module).

2.1 Analysis of PHCU catchment area immunization data

Table 31 shows a format for analysis of PHCU catchment area immunization data from the preceding 12 months.

The format identifies and prioritizes high-risk health posts where immunization performance is problematic. Health posts are ranked and prioritized primarily based on the number of penta-3 unimmunized infants in their catchment areas and RED/REC categorization is applied to further separate health posts with similar number of unimmunized number of children.

How to prioritize health post using PHCU catchment area immunization data

Use all available information to complete the analysis of immunization data; to best assemble all available information, the input of community and administrative leaders is needed.

Rank Health Posts by the number of unimmunized infants; the one with the highest number of unimmunized children is ranked first (1) and so on. The health post ranked 1 has the highest priority, and so on.

Consider prioritizing health post with inaccurate data; for example, a health facility that shows negative values for unimmunized children due to inaccurate population data or negative vaccine wastage rates may need to be given priority or high coverage.

Consider prioritizing health post with known management problems (supervision findings.

Table 31: PHCU catchment area immunization data analysis: example format (includedata from all health facilities in the PHCU catchment area over the past 12 months)

Health	Annual target	Doses of vaccine administered			Unimmu	nized	Prioritize HFs (highest # of penta		
facility	population <1				children		3 unimmunized as priority 1 and		
name	year of age		1	T			so on)		
		Penta 1	Penta 3	MCV 1	Penta 3	MCV 1			
HP 1									
HP 2									

HP n				
HC				
Cluster total				

2.2 Analysis of health facility/ Kebele data

Table 42 shows a format for analysis of health post data from the preceding 12 months. The format identifies priority communities by number of unimmunized children. Data to complete this table should be taken from monthly reports or be gathered from tally sheets, and registers/family folder.

How to prioritize communities using health post immunization data

Use all available information to complete the analysis of health post data; to best assemble all available information, the input of community and administrative leaders is needed.

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 unimmunized infants; the one with the highest number of unimmunized children is ranked first (1) and so on. The community ranked 1 has the highest priority, and so on.

Look for any monthly variation in immunizations given in a community when reviewing data from the preceding 12 months and note any seasonal changes in the last column (for example, decrease during rainy season).

Table 32 Health post data analysis: example format (include data from all communities in the catchment area over the past 12 months)

Name of	Target	Penta 1	Penta 3	Unimmunize	Priority:	Dista	No of	No of	Main
village/S	populati	doses	doses	d (missed	highest no	nce	outrea	outrea	community
ub-	on < 1	given	given	penta 3	of	from	ch	ch	characteristic
kebele	year of	during	during	doses)	unimmunize	HP	visits	visits	s: urban
	age	the year	the year	<i>.</i>	e (c)is 1, and	(Km)	planne	compl	poor, semi-
		(b)	(c)	(d=a-c)	so on		d	eted	urban, rural,
	(a)						during	during	migrant,
							year	year	ethnic
									minority, new
									settlements,
Village 1									
Village 2									
Village 3									

Total					

#### 3. Identifying barriers to access and utilization

To identify and understand the issues that become barriers to access and utilization, prioritized communities need visits from teams of PHCU catchment and catchment area staff. Community chiefs, leaders and volunteers must be engaged in the evaluation visit. Permission from community authorities is essential before conducting surveys, focus groups and similar exercises to identify barriers. Two basic evaluation exercises are included here: household survey and community discussion.

3.1 Household survey of immunization status

Table 33 shows a questionnaire format for evaluating the immunization status of children aged 12–23 months by household. In a small community, a sample of five partially immunized or unimmunized children may be sufficient, but in a larger community such as an urban slum, where there may be different subgroups of people, a sample of at least 10 may be needed.

Vaccine information given by households can be checked with the immunization register. The questionnaire can be modified to meet local evaluation needs. (See table 33 below: Household immunization status questionnaire assessing children aged 12 –23 months).

The household survey should be done by the PHCU and district staffs. After reviewing the immunization performance, the survey team chooses a village with high number of unimmunized children. Then from the center of the village, a starting house is randomly selected.

From the first house, move to the next houses until a total of five partially immunized or never immunized children are obtained.

#### How to complete the household questionnaire

#### See format below (Named as table 4.5)

Tally each household with eligible children visited;

Tally the total number of children aged 12–23 months in the household;

Tally the number of children with immunization cards

#### Under "Immunization status of child":

For each child ask whether vaccination card is available or not and tally immunization status as follows

For each child with an available card, tally whether s/he is fully, partially or never immunized under the column **"From card – tally"**;

If the card is not available but the caregiver gives the immunization history (in response to prompting questions), tally whether the child is fully/partially/never immunized under the column **"By recall – tally"** 

#### In the lower part of the form:

If a child is partially or never immunized, write the name of the child and ask the caregiver the question, "Why was the child not fully immunized?";

Mark the row with the choice that best matches the answer the caregiver gives

After noting the answer to the question about a child not being fully immunized, try to understand issues from the household's point of view. For example, when a caregiver says she is "too busy", you may need to find out whether she may be able to attend sessions at specific times, or whether there are additional problems such as cancelled sessions that discourage people from going to the next one.

Understanding the situation will help in adding appropriate solutions to the work plan.

NB: partially or never immunized children identified in this exercise should be added to defaulter tracking lists.

### Table 4.5 Household immunization status questionnaire assessing children aged 12-23 months

Date:			Community name:												
Distance from health centre (in kr	n):	Heal	th cer	tre n	ame:										
				Tal	ly										То
Number of visited households with children 12-23 months of age															
Total number of children 12-23															<u> </u>
months of age															
Number of children with immunization cards															
Immunization status of child	From card - tal	lly								3viiteca	lianal	v			то
Fully immunized for age		-													
Partially immunized															
Never Immunized															
For each child who is partially or r	ever immunized, ask only one question - 'W matches					ully in	nmuni	zed?'	Then	mark	an 'x' i	next to	the n	eason	that b
	₽ ≽														
	ja ja														
	Child's name of number														
	.pie														
	0														
	unaware of need for immunization														
	unaware of need to return for 2nd or 3rd dose														
	place &/or time of immunization unknown														
Lack of information	fear of adverse reactions														
	incorrect ideas about contraindications														
	other														
	postponed unitl another time														
Lack of motivation	no faith in immunization														
Lack of molivation	rumours														
	other														
	place of immunization too far														
	time of immunization inconvenient														
	vaccinator absent														
	vaccine not available														
Obstacles	caregiver too busy														
	family problem, including illness of caregiver														
	child ill - not taken for immunization														
	child ill - taken for immunization but not vaccinated														
	long waiting time														
	other														

3.2 Community discussion

Table 33 is a guide to community discussions on barriers. It aims to gather information on community perceptions and ideas for improvement and is meant to complement the household survey. It requires the involvement of caregivers, community health workers and community leaders.

Interviews may be done with individuals or groups separately or together as appropriate for the situation. The questions can be modified as needed and the exercise is intended to take about an hour. Responses will be applicable only to the community involved but are necessary for solving local issues.

#### Table 33: Community discussion guide

Community description	
Distance from health center - km and time	
Total population from health center data	
Total population from community leaders' information	
Results of household immunization status questionnaire*	
Number of children 12-23 months of age partially or never immunized	
Discussion with caregivers (done after completing the household questions:	survey) – suggested
Where do you get immunizations? (Outreach/HC fixed site/other)	
Where was your last child delivered?	
If at home, what was your main reason for not using a health facility?	
Where do you take sick children? (Traditional healer/HC/HP/private/other)	
How much does it cost to travel to the HC/PHCU catchment area?	
Do you have to pay any fees at the HC/PHCU catchment area facilities?	
When was the last outreach visit from the health facility to your community?	
What do you think the health facility can do to get children fully immunized?	
Discussion with community health worker(s) – suggested questions:	

What supplies of medicines do you have in the community? (ORS, antibiotics, paracetamol, antimalarials, etc.)	
In what health programs do you work? (ANC, nutrition, EPI, TB,	
malaria)	
Do you have mobile phone #s?	
Are you informed in advance of outreach sessions?	
If so, how?	
How are the communities you work with informed about an	
outreach session before and on the day of the session?	
When did you last receive any training?	
Do you do defaulter follow up for the immunization program?	
Discussion with community leader(s) – suggested questions:	
What do you see as the main health problems in your community?	
How can the health facility improve services for the community?	

## 4. Identifying solutions and preparing a work plan

Some people do not live within reach of health services, whether they are in permanent or mobile nomad/seasonal migrant communities. In many countries, geographical barriers are not the only, or even the primary, reason that limits access and utilization of immunization services. Access is also made difficult by inconvenient scheduling, lack of information and/or lack of opportunities. All these problems can be solved relatively simply by improving scheduling, raising awareness and/or expanding outreach.

This section is a guide to taking the information collected in Sections 1–3 above and planning solutions to overcome the barriers to access and utilization identified. Solutions should be added to a work plan to guide a practical approach, and a work plan should be developed for each priority community.

Annex 1 lists common problems and possible solutions. While not exhaustive, this may help to complete a work plan.

4.1 Outline solutions

Table 34 shows a format for outlining solutions at health facility, community and PHCU catchment area levels.

How to list identified solutions

Hold a brainstorming session with key people from the health facility, community and PHCU catchment area to gather ideas. Be sure to include a session on how higher

performing health facilities and communities have been able to solve their problems and achieve improvements (this will give evidenced-based ideas).

Get consensus on the main problems (not every problem) and list the priority ones. To address the problems, limit priority problems to about three. Working on a longer list of problems usually becomes too difficult for a practical approach.

Choose practical and feasible activities to solve the prioritized problems, since:

Health facilities problem-solving activities should be within existing capacity and resources;

community activities may be limited to the capacity of its volunteers since additional resources are often not available;

PHCU catchment area-level activities may provide support to the health facilities with extra technical or financial resources.

#### 4.2 Make a work plan to implement identified solutions

Table 35 shows a work plan format to follow planned health facilities and community activities over a six-month period.

#### How to complete the PHCU work plan

Complete one form for each Heath unit by responsible person involved in immunization; the same form can be used for both health center and health post staffs.

List the main health facility and community-level problem-solving activities from the exercise given in Section 4, compiled on the form shown in table 34. Activities should be defined as specific tasks for the person named on the form.

Make a schedule for completing the activities over the next six months (see table 35); the person named on the form should track their progress as the activities/tasks are completed each month.

Village one			
Solutions			
Health	facility	Community	PHCU activities
(HC/HP) activ	vities	activities	
	Solutions Health	Solutions	Solutions Health facility Community

#### Table 34 Identified solutions list – example format

the community			
Example: Poor community attendance at outreach sessions	Call the community chief or community worker by mobile phone in advance of the session to confirm time and place	Mobilize mothers and children by informing them in advance and encouraging attendance at session	Ensure costs of outreach sessions are budgeted (transport and per diem) according to HC session plan

#### Table 35 Work plan to achieve identified solutions-example format

Name of health facility staff or community worker											
Activities to be done by the health facility staff or community worker	Schedule by month										
Mobilize mothers and children by informing them in advance and encouraging attendance at sessions	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6					

#### 4.3. Making a session plan

A session plan lists all communities served by the health facilities and specifies how frequently each community will be reached based on such factors as distance, target population, workload and other relevant operational issues. This section provides an example format and gives a simple method for choosing session frequency, scheduling dates and organizing the supplies needed to complete a session plan that reaches every community in a health center catchment area. It is based on a maximum workload of about 30 injections per vaccinator per static session and 20 injections per vaccinator per outreach. It uses an immunization 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.

4.4. Immunization session plan

Table 36 shows an example immunization session plan format. It compiles a list of communities and the distances from the health center that is responsible for their immunization services. The type of session needed – fixed (at the health HC and HP) or outreach (at a site in the village) – for rural communities usually depends on the distance of the community from the health post or on the travel time needed if the terrain is difficult. Mobile session may be appropriate for communities living beyond the outreach areas.

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 infants expected at each session.

The number of infants an immunization program should expect to serve in a community depends on its total population.

Туре	Definition	Area served	Advantages	Disadvantages			
בואכת זונע	Delivery of vaccination services in a health post on a regular basis	distance which mothers can travel to reach service approx. five km	reliable regular service, minimum one staff, low cost, no transport problems	cannot reach much of the population in rural areas			

Table 36: Types of immunization session(s).

Туре	Definition	Area served	Advantages	Disadvantages
mmunization site(IS)?Out-Reach (OR)	Delivery of vaccination services in specific site away <u>from</u> a health post on a regular basis. sites are usually not fully equipped health facility staff carries the needed equipment to the ""outreach site"	Villages away from Health post but in the catchment area that Health extension worker can easily visit in a day. Can be established depending on geographic barriers	regular service can reach populations beyond the fixed range	needs good communication with communities higher costs (transport, more than one person per site
Mobile team In	Delivery of vaccination services in areas beyond the "immunization sites on less frequent basis. like quarterly In hard to reach and inaccessible locations or villages health extension worker carries all the needed equipment to the "mobile site"	area beyond immunization site area especially for difficult to reach areas/populations may be conducted over several days	can reach difficult to reach areas/populations, If transport adequate, can include other interventions e.g. Malaria help to improve coverage	high costs and time subject to availability of extra resources takes HEW time

4.5 How to choose session frequency based on average injection load

This method of planning session frequency is based on average injection load per session per kebele. The steps are as shown below:

#### Step 1: Determine annual target population

To determine the target beneficiaries, use the best estimate figures, stating source and year of the population figures. Each catchment area is expected to register and update the number of less than one year population every three months using existing community based structure.

The target for different antigen is calculated based on the proportion of target population for specific antigen in the region.

There are two types of annual target populations: one for children's vaccine and the other for tetanus toxoid vaccine for women.

The target group for BCG vaccine is total live births

The target group for other infant vaccines (Penta/PCV/OPV/Rota/Measles) is total surviving infants

The target group for vitamin A supplementation is children 6-59 months

The target group for TT vaccine are pregnant and non-pregnant women of child bearing age.

Due attention should be given for hard to reach area/difficult to reach population and high risk group of population (like refugees and underserved/minority).

Table 37: How to calculate target population for	or immunization services
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Antigen		Target population	Formula**
BCG		Total number of live birth	Total population multiplied by proportion of crude birth (Total popn* % of LB))
Penta ,	Polio,	Total number of	Total population multiplied by proportion of Surviving
Measles, P	CV, Rota	surviving infants	infants (Total popn* % SI)
	PW	Total possible no	Total population multiplied by proportion of possible
тт		of pregnancies	number of pregnancies in the region (Total popn* % PW)
	NPW	Total no of Non	Total population multiplied by proportion of possible
		PW in the child	number of Non- pregnancies in the region.(Total popn* %
		bearing age	NPW)
Vitamin A		Children age 6-59 months	Total population multiplied by proportion of children age 6- 59 months in the region.(Total popn* % children 6- 59 months)

\*\*Often population proportions are provided by central statistics authority or regional bureau

After the annual number of target population for vaccines and vitamin A determined, the monthly target can be obtained by dividing the annual target population by 12.

#### Class room exercises-1

If the total catchment population of the PHCU is 30,000 and crude birth rate of 3.7% and surviving infants of 3.2%, then calculate the number of eligible children for BCG and penta.

The target populations for tetanus toxoid (TT) vaccine can also be determined in the same way by multiplying total population by proportion of pregnant and non-pregnant women respectively.

#### Class room exercises- 2

If the total catchment population of the primary health care unit is 50,000 and pregnant women and non-pregnant women represent 3.7% and 19% of the population, then calculate the number of pregnant women and non-pregnant women eligible for tetanus toxoid vaccine.

#### Step 2: Determine number of injections needed per year

To determine the number of injections required per month, it is assumed that a child will need a total of eight injections to complete his immunization including: three for pentavalent, three for PCV, one for BCG, and one for measles. In addition, two TT injections are needed to immunize pregnant women. This makes a total of eight infant injections, plus two injections of TT for pregnant which makes up ten injections in all for full immunization of an infant and pregnant woman.

Since most areas of the country are fully covered with TT through campaign, it is difficult to estimate the number of injection needed for non-pregnant women. Hence injection for NPW TT doses is not included in the calculation.

Therefore, the total number of injection load will be calculated for each village by multiplying the number of target children in each village by 10.

Divide the total number of injection needed per year by 12 to get the number of injections needed per month

#### Step 3: Determine type of immunization strategy for each community

Based on the number of children to be immunized per month, settlement pattern of the communities in each village, decide the type of immunization strategy (Static, outreach (OR) or mobile) needed for each village and where each village receives the service.

#### Step 4: determine number of sessions based on average injection load per session

It is assumed that a static and an outreach sessions can serve on average 30 and 20 injections per session respectively.

Therefore, divide number of monthly injections by 30 for static and by 20 for outreach to determine the number of sessions required per month

### Steps to calculate number of sessions for communities in a kebele catchment based on injection load

Step 1: List the name of kebeles and communities/ villages and their respective target population for immunization services.

Step 2: Calculate the number of annual injection load per village/sub-kebele: surviving infant\* 10

Step 3: calculate the number of monthly injections needed: annual injection/12

**Step 4: Determine the strategy for each community/village** 

Step 5: determine number of sessions per month: divide number of monthly injections by 30 and 20 for static and outreach sessions respectively.

Step 6: Determine the number of sessions per month per kebele: sum up the number of

#### **Classwork activity 3**

Calculate the number of static sessions needed per month for a community with a total no. of surviving infants of 120.

#### **Class work activity 4**

Calculate the number of injection per month and decide the session frequency for a community where there are 25 births annually in a proportion of 1000 population.

Answer: There would be approximately 2 infant and 2 pregnant women for immunization every month. Therefore the number of injection would be:

2 infant for BCG and 2 infant for measles= 4 injection;

2 infant for pentavalent, & PCV 1, 2, 3= 12 injection;

2 PW each for TT1&TT2 = 4 injection;

A total of 20 injections required,

Therefore, one session is required every month.

Table 38: C	Calculating number of	f sessions based	on injection load
-------------	-----------------------	------------------	-------------------

Sub	Total	SIs	Sessio	Total #	# of	Number of	Actual
kebel	popn.		n type	of	injections/mon	session/mont	sessions
e				expecte	th	h (30 /20	planned
				d		injection per	per month
				injectio		session per	
				n		static and	
				(SI*10)		outreach)	
А	10,00	32	fixed	3200	267	9	HC fixed
	0	0					post(2
							days/wee
							k)
В	4000	12	OR				
		8					
С	5000	16	Fixed				
		0					
D	2500						
E	1500						
F	3500						
	3300						
G	25,00						
	0						

#### 4.6 Health post outreach session plan

Every health post should make, display and monitor an outreach schedule to show the date and place of each session, the means of transport and the person responsible for arranging it. It should also include a community contact person who will communicate session dates and other reminders to the wider community. An example format is

shown in Table 39; note that fixed sessions can be added to this if needed to keep all sessions in on one sheet (leave the transport column blank or write "fixed" here).

Outreach sessions are often planned for rural communities that are 5–15 km from the health center and for urban populations who use convenient locations such as markets, community centers and schools. Outreach sessions may also need to be planned to take place before and/or after seasonal rains or other factors that make populations hard to reach at certain times of the year. In some programs, communities living more than 10 km away from the health center may be served by mobile activities organized from PHCU catchment area level, as shown in Figure 4.3 below. Follow national and PHCU catchment area guidelines for micro planning.

Other activities, such as EPI Plus and maternal-child health interventions, may be integrated in immunization sessions. Follow national guidelines on including additional staff, logistics and financial resources as needed.

Comm	Sessi	dista	Trans	Perso	Comm	Dates	Мо	Μ	Μ	Μ	Μ	Μ	Μ	Μ	Μ	Μ	Μ	М
unity	on	nce	port	n	unity	schedu	nth							-				
name	frequ		need	respo	contac	led &	(m)	2	3	4	5	6	7	8	9	1	1	1
	ency		ed*	nsible	t name	done^	1									0	1	2
				for	and													
				transp	mob.													
				ort	no													
						Dates												
						schedu												
						led												
						dates												
						done												
						Dates												
						schedu												
						led												
						dates												
						done												
						Dates												
						schedu												
						led												
						dates												
						done												
		I				Dates												
						schedu												
*In the	*In the transport column, write 'overnight' if				led													

Table 39 Health post/center outreach session plan-example format

needed to complete sessions in the community. Leave the transport Sessions column blank or write 'fixed' in it if the	dates done
community is served by fixed sessions at the health centre.	Dates schedu led
<ul> <li>Write all dates each month (for example, 2 dates if biweekly sessions)</li> </ul>	dates done

Following the identification of problem/bottlenecks and addressing the problems with the proposed solutions, a health facility has to develop a detailed work plan using annex 3 as a template.

Figure 4.3 Illustration of fixed, outreach and mobile strategy service distance requirements (example from WHO AFRO)



# 5. Immunization session supplies: Estimating resource requirement

#### 5.1 Vaccine and other supply need

Without sufficient vaccines in the facilities, the needs of the immunization programme cannot be met, and children will not be fully protected against these diseases. The same problem will occur if there are stock-outs of vaccines in the facilities. Accurate estimates

for stockholding are thus essential to the success of the EPI programme. The availability of an adequate supply of vaccines, diluents and safe-injection equipment of assured quality is critical to every immunization service. Effective management and storage of supplies can help save on programme costs, prevent high wastage rates and stock-outs, and improve the safety of immunizations. It is essential that accurate forecasting occurs. There is a shrinking supply of the vaccines used in routine EPI and if we are to have sufficient supplies for the future needs of the children, we should become more vigilant in our forecasting and management of these vital items. It is very essential to have adequate stock of vaccines at every stage of cold chain. If it is in less quantity, the immunization programme may suffer and in the case of excess quantity, there are chances of losing their potency. The quantity of the vaccines should be calculated for the period and a designated quantity (25%) should be added to keep as buffer stock.

#### There are three methods;

- Target population,
- Previous consumption and
- Size of immunization sessions

#### a. Target population method

Target population method is suitable for higher level (National, Regional and Zonal, District), whereas number and type of sessions planned is more suitable for planning at lower levels such as the district and health-facility level. The accuracy with which the size of the target population is measured is an essential element in forecasting vaccine requirements, as well as in planning, implementing, monitoring, and evaluating program performance. In developing country immunization programs, the total number of children below one year of age and pregnant women (or women of child-bearing age) should be estimated for the catchment area of each health facility and, cumulatively, at the district, regional, and national levels. Sources of information on population size include census data, birth registrations, and head counts at the local level.

Annual need of vaccine in doses/AD syringes = (Annual target population X Annual coverage planned X Number of doses per child X Vaccine Wastage Multiplication Factor)+25% buffer stock Annual need of AD syringes = (Annual target population X Annual coverage planned X Number of doses per child X AD syringe Wastage Multiplication Factor)+25% buffer stock

For monthly vaccine requirement divide the annual requirement by 12. The wastage factor is derived from the vaccine wastage rate (VWR) using the following formula.

Wastage factor = 
$$\frac{100}{100-r}$$
 where r is the vaccine wastage rate

#### Vaccine utilization and wastage

Vaccine utilization and wastage is another factor in forecasting vaccine needs. Vaccine utilization is the proportion of vaccine that is supplied and administered.

Vaccine Usage Rate =  $\frac{Children vaccinated(dose used)}{(Begining balal the+Recieved during the months)-end balalnce}X100$ 

Vaccine wastage is the proportion of vaccine that is supplied but not administered, calculated as a rate as shown in the box below:

Vaccine wastage rate (r) is calculated as: 100-vaccine usage rate

Vaccine	Target popu.	Target coverage	doses	Wastage Multiplying factor (WMF)	Annual need	Monthly need
BCG	3700	100%	1	2.0	7030	586
Pentavalent	3200	100%	3	1.05	9072	756
OPV	3200	100%	3	1.11		
Measles	3200	100%	1	1.33		
Rota	3200	100%	2	1.05		
PCV	3200	100%	3	1.11		
TT(PW)	3700	100%	2	1.11		
TT(NPW)	19000	100%	2	1.11		

Table 40: Calculating vaccine requirement of primary health care unit with 100,000 populations.

#### Estimating AD syringes and mixing syringes requirement

Formula to calculate AD and mixing syringes

ADsyringes required= target population\* target coverage\* No of doses\* Wastage factor

**Table 41:** Example how to calculate AD syringes requirement for a PHCU with population of 100,000 (consider % LB 3.7% and % SI 3.2%)

vaccine	Target pop	Target Cov	Doses	WF	Annual need	Monthly need
BCG	3700	100%	1	1.11	3902	325
Penta valet						
Measles						
PCV						
TT(PW)						

#### Special issue of AD syringes supply

The supply of AD syringes must match the supply of vaccine available at every session. AD syringes are usually ordered with 10% wastage factor. This wastage factor takes in to account normal handling but it is very important to ensure that the AD syringes supply intended for immunization is not used for other purpose.

#### **Reconstituting syringe**

Mixing syringes required for BCG= Number of BCG in Vials X Waste Factor (1.11)

**Example 1:** As calculated in Table 5, the annual forecasted doses of BCG doses for the given woreda were 10067. If we consider procurement of 20 dose vials of BCG then the number of mixing required will be calculated as follows:

• 1<sup>st</sup> convert the BCG doses into vials of 20 doses. The number of vials can be calculated by dividing the number of BCG doses by 20.

Number of BCG vials of 20 doses =  $\underline{\text{Number of doses}}_{20}$  = (10067/20) = 503 <u>vials</u>

• 2<sup>nd</sup> The number of mixing syringes required is then calculated by multiplying the number of vials by wastage factor. The wastage factor commonly used for mixing syringe is 1.11.

Therefore the number mixing syringes for BCG will be:  $503 \times 1.11 = 559$  BCG mixing syringes.

Similarly, the mixing syringes for measles can be calculated in the same way the only difference is that vials of 10 doses will be used instead of 20.

Example 2: The annual measles vaccine doses forecasted for the same woreda were 6630.

Thus the number of 10 dose measles vials will be:

No of 10 dose measles vials = (6630/10) = 663 vials; therefore the number mixing syringes for measles will be:  $663 \times 1.11 = \overline{736}$ 

#### Calculating required number of safety boxes

Safety boxes required= (total AD syringes + Reconstituting syringes)/100.

#### Class room Exercises-5

Calculate needed vaccines, AD and mixing syringes and safety boxes for PHCU with 50,000 population. Assume % of LB 3.7% and % SI 3.2%

#### b. Previous consumption methods

Each parameter relative to previous consumption can be affected by many factors, especially program performance, during the supply period in question. Estimating needs based on previous consumption may, therefore, not be as reliable as the method based on target population Consider the following measurements when estimating vaccine and safe-injection equipment needs based on previous consumption:

- ✓ Initial stock at the beginning of the given period (I);
- ✓ Stock received during the period (R) and
- ✓ Stock at the end of the period (F)
- Number of unopened vaccines vials lost (destroyed, frozen or affected by high temperature or expired during the same period) (L)

```
Vaccine needs = (I+R) – (F+L)
```

Whichever method is used, the accuracy will depend on the quality of the data used and the knowledge of the person doing the calculations.

c. Immunization sessions methods

Vaccine needs = number of immunization posts x number of weeks of operation in the year x number of immunization sessions per week x average number of vials opened per session x number of doses per vial

## 5.2 Health facility monthly stock report

Monthly stock reports are needed to ensure adequate supplies and avoid stock-outs. Table 50 shows an example format for a health centre stock report, giving an estimated monthly consumption requirement based on expected immunization service activities. Stock report data may be added to the monthly summary report.

Table 42 Health facility monthly stock report-example format

Monthly stock report						
Health center name	Date report completed					
Stock month and year	Stock month and year			<b>/</b> :		
	Monthly consumptio n	Opening stock	Order received	Closing stock	Order for next month	
RV single dose						
OPV- 10 dose vial + dropper						
PCV two-dose vial						
Penta single-dose vial						
BCG 20-dose vial + diluent						
Measles 10 dose vial + diluent						
AD syringe (0.5 ml)						
BCG AD syringe-0.05 ml						
RUP reconstitution Syringe-5 ml + needle						
RUP reconstitution Syringe-2 ml + needle						
Safety box						
Other						

NB: Refer Annex 2: Health facility microplanning summary form

#### Exercises

#### Exercise One: How to prepare outreach session plan

Dejena health post serves a total population of 40,000 with one static and 40 outreach sites. The community lives in five kebeles (kebele A = 10,000 population in three Gotts, kebele B = 6,000 population in two Gotts, kebele C 20,000 all within 5kms of the Health facility, kebele D = 2,000 population in 4 Gotts this kebele is sparsely populated and kebele E = 2,000 population in 4 Gotts this village is hard to reach and totally inaccessible during the rainy season (June to August). See Fig 28. The people have misconceptions on disease causation and lack knowledge on the benefits of immunization.

Fig 28:Kebeles in Dejena health post catchment population



In the previous year the DPT1, DPT3 and measles administrative coverage was 46%, 20% and 12% respectively and there was measles outbreak in village E, 57 cases and two deaths.

- 1. What are the problems in the population served by Dejena HC
- 2. Write the actions you would take step by step to solve the problems in the EPI program of the health facility.
- 3. Prepare a session plan for the health facility (assume 30 injections per session and take SI=3.2%)<sup>1</sup>
- 4. Draw the map of the health facility catchments area and put the corresponding population size to each village in the map and mark the immunization sites (use the alphabets M, F and O for mobile, fixed and outreach sites respectively)
- 5. What communication activities and strategies would you plan?
- 6. What monitoring tools and indictors would you include in your plan to track the implementation of your plan and measure your achievements? Plan to monitor communication activities, Coverage and Utilization

#### **Exercise Two:**

Balchikebele has three villages and a population of 10, 000 people it has also a total birth of 3,700 and surviving infants of 3,200 children. Assume that pregnant women and non-pregnant women represent 3.7% & 19% of the kebele's population respectively. Assume the kebele will be covered with outreach session.

#### A) Calculate the target population and no. of sessions

- What is the number of children eligible for BCG
- What is the number of children eligible for DPT-HepB-Hib /OPV1, DPT-HepB-Hib3/OPV3 and Measles
- What will be the total number of sessions required per month?
- In what condition would you consider mobile teams?

#### B) Vaccine forecast

<sup>&</sup>lt;sup>1</sup> SI = surviving infants= Total births – Infant deaths

Assume you have planned to cover 90% of all births with BCG, 90% of the surviving infants with DPT-HepB-Hib1, and 80% of the surviving infants with DPT-HepB-Hib3 and Measles, 30% of Pregnant & 20% of the Non pregnant women in BalchiKebele with TT. Assume also the Wastage factor for BCG, DPT-HepB-Hib, TT and Measles are 2, 1.05, 1.11, and 1.25 respectively.

- Calculate the annual number of BCG vials of 20 dose needed
- Calculate annual number of DPT-HepB-Hib doses needed
- Calculate the annual number of Measles doses needed
- Calculate the annual number of TT doses required
- C) AD SYRINGE, Reconstituting syringe and Safety box forecast.

Assume you have the above plan for next year and assume also the wastage rate/Wastage factor for AD Syringe, Reconstituting syringe and safety box are 10/1.11,10/1.111 and none respectively.

- Calculate the annual amount of BCG (.05ML) ADSYRINGES needed for one year
- Calculate the annual amount of 0.5ml (for measles, DPT-HepB-Hib and TT) AD Syringes needed for one year
- Calculate annual amount of BCG (2ML) reconstituting syringes required for one year
- Calculate the annual amount of 5ml reconstituting syringes required for one yea

**Annex 1.** Framework for Identifying Problems, Causes and Possible Solutions for Low Coverage

Categories of	Problems	Root Causes of problems	SOLUTIONS with existing resources	SOL
	. Shortage of HWs	. High turnover, inappropriate assignment	. Regular supportive supervision & review meeting	/ . Hir
	. Shortage of/ trained/ staff	. Absence of regular training, lack of budget	. In-service training	. Bu
Staffing/Training	. high staff turn over	. Lack of motivation, lack of upgrading	. Improve personnel management	. Im
	. Shortage of Motor bike/Car	. No regular supply & lack of regula maintenance	r . Frequent maintenance	. Su
	shortage of budget	. Poor flow of budget from Higher level		. Re
Logistics	. Shortage of vaccine	. High Vaccine Wastage, Inavailabilty from ZHD	.Regula monitoring	
	. Shortage of spare parts	. No regular supply & poor distribution system from Region		. Re
	. Shortage refrigerators	. No regular supply		. Re
	. Shortage Of megaphone	. No regular supply		. Re
	. lack of tally sheets	.No regular supply	. Print at local level	
	. Lack of frridge maintenance	. Lack of skill	. Coonduct cold chain maintenance training	
Service Delivery	. Interruption of outreach services	. Lack of vaccine, lack of HWs, & Soc. Mob.	. Regular supervision and review meeting	
Quantity	. Few attendants	. Lack of linkage with community	. Strengthen linkage with leaders & CHAs	
	. Geographical difficulties		. Use mobile type strategy	
v	. Absence of defaulter tracing	. Lack of attention & communication with	. Regular supervision & review meeting	
	. Mothers loose cards	. Lack of IPC skill	. Train staff on IPC	
Quality	. Poor waste disposal	. No regular supervision	. Regular supervision & discussion with HWs	

<sup>1</sup> Wastage factor =  $\frac{100}{100}$ 

100 – wastage rate

	. Lack of activity schedule	. Lack of skill, Shortage of HWs	. Supportive supervision & training	. As
Management/	lack of HWs motivation	. Law payment		. Inc
Planning	. Inadequate resource mgt. & missuse	. Lack of skill & accountability	. Regular supportive supervision	
	. Total population exaggeration \eligible			
	overestimation	. Lack of appropriate data	. House to house registration for time being	
	lack of microplanning	. Lack of attention at various level		. Atl
Data collection/	. Delay in report	. Lack of attention & poor communication means	. Regular supportive supervision	
Reporting	. Shortage materials	. Shortage of budget	. Allocate budget at woreda level	. Su
			. Frequent supportive supervision & feed	ł
	. DPT3 > DPT1	. Fualse report	back	
Monitoring and	. In adequate supervision	. Lack of attention	. Regular monitoring	
Supervision		. Shortage of transportation	. Integrate with other activities/sectors	

#### Annex 2. Health facility micro - Planning Summary Form

Woreda:

 Region:
 \_\_\_\_\_Zone:

 \_\_\_\_\_Date:
 \_\_\_\_\_\_

Kebele	Vacine	(in dose)	&Vit.A (ir	n capsule) N	Veeded	Vit.A Tin*	AD syrir	nge for	Reconstituti	ing syringes				
											Safety box	Budget n	needed fo	or the yea
	BCG	Meas.	DPT- HepB- Hib	OPV	π		BCG	Others	BCG M.Syringes	Measles M.syringes	Safe	Allowance	Supervisio n	Training
Kebele 1	515	319	1076	1076	2464	1	400	3804	29	33	45	420	240	825
Kebele 2	543	323	962	962	2832	1	422	4100	30	38	48	0	240	825
Kebele 3	527	438	1094	1094	2158	1	409	3640	29	49	43	394.8	240	825
Kebele 4	537	339	992	992	2226	1	417	3520	30	38	42	789.6	240	825
Kebele 5	463	277	945	945	2968	0	359	4159	26	31	48	1410	240	825
Kebele 6	547	346	999	999	2206	1	424	3512	30	38	42	0	240	825
Kebele 7	483	385	992	992	2450	1	375	3784	27	43	44	0	240	825
Kebele 8	536	480	1116	1116	3095	1	416	4637	30	53	54	1410	240	825
Kebele 9	608	384	1009	1009	2427	1	472	3777	34	43	45	394.8	240	825
Kebele 10	572	340	1006	1006	2052	1	444	3359	32	38	41	420	240	825
Kebele 11	526	331	1002	1002	2711	1	408	4007	29	37	47	420	240	825
Kebele 12	549	344	969	969	2187	1	426	3461	30	38	42	0	240	825
Kebele 13	464	286	948	948	1811	1	360	3013	26	32	36	394.8	240	825
Kebele 14	480	302	985	985	2126	1	373	3379	27	34	40	789.6	240	825
Kebele 15	468	289	957	957	2145	1	364	3359	26	32	40	1410	240	825
Total	10068	6630	19248	19248	46266	12	7815	71401	559	736	845	9488	4800	16500

Annex 3. Work Plan for HFs

No	ACTIVITIES	WHERE?	WHO IS	WHEN (Dates)
		(Location)	RESPONSIBLE?	

				Jan	Feb	Mar	Apri	May	Jun	july	Aug	Sep	Oct
1	Kebele A	Outreach site	HC staff	×	x	x	x	x	x	x	x	x	x
2	Kebele B	Outreach site	HC staff	х	-	х		х		х		х	
3	Refresher training of HF staff	нс	HC head		-	х			x				×
4	Supervision of HPs	HPs	нс	x	x	x	x	х	x	x	x	x	×
5	Review meeting with HC and HP staff	нс	HF staff	×	×	x	x	х	x	х	x	×	х
6	Supply collection & distribution		1	х	х	х	х	х	х	х	х	х	х
7	Submission of monthly report		нс		-	х			x			х	
8	Collection of vaccine and injection materials		нс	×	x	x	x	x	x	x	x	x	x
L	Name of the Coordinator:	·					Signati	uro:			4	-L	

Name of the Coordinator: \_\_\_\_

Signature: \_\_\_\_\_

## Module 5: Immunization Safety

#### About this module

This module describes what a health worker should follow to ensure that they deliver immunization injections in the safest manner such as:

- How to ensure immunization safety /safe injections
- Safe injections equipment and techniques
- Prevent needle stick injury and infection
- Using safety box
- Disposal of used syringes and needles
- Adverse events following immunization /AEFI/

#### Learning objectives

By the end of this session, participants will be able to:

- Ensure safe injection and their disposal
- Practice steps of using AD syringe
- Give right vaccine safely

## 1. Using safe injection equipment and techniques

#### **1.1 Types of injection equipment**

Table 43 Types of equipment used to administer injectable vaccines

Equipment	Remarks
Auto-disable(AD) syringes	Equipment of choice
Prefilled AD injection devices	Available for some antigen only
Hypodermic syringes with reuse prevention feature (RUP) and needles	For mixing purpose only
Single used syringes and needles	Not recommended

## WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services

"The auto-disable syringe, which is now widely available at low cost presents the lowest risk of person-to-person transmission of blood borne pathogens (such as HepB or HIV) because it cannot be reused. The auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns."

#### Auto-disable (AD) syringes for immunization

AD syringes are recommended for all types of immunization sessions not just because they can only be used once and can reduce disease transmission from contaminated equipment, but also because they are disposable and save time previously spent on sterilization.

AD syringes for fixed-dose immunization have the following main features: a self-locking mechanism that allows only one use; this is called a reuse prevention feature (RUP);

- a fixed needle (usually 23G x 25 mm, but various sizes are manufactured); and
- a specific scale mark showing only the quantity to be administered.

Each AD syringe is sterilized and sealed in plastic or paper blisters by the manufacturer. All AD syringes have plastic caps to keep the needle sterile; some also have caps on the plungers. They are supplied in three volumes: 0.5 ml for most vaccines and 0.05 for BCG.

AD syringes have different types of locking mechanisms that are triggered at different times. Some syringes lock their plunger at the start of the injection while others do so at the end. AD syringes that lock at the start are preferred since they completely prevent reuse. Some AD syringes are retractable, meaning that the needle can be pulled in the barrel. This mechanism adds stick injury protection (SIP) to reduce the risk of needle-stick injuries.

#### General steps for using AD syringes

Each type of AD syringe requires a specific technique for its use. But for all types, the plunger can go back and forth only once. Health workers should not move the plunger

unnecessarily and should not inject air into a vaccine vial when using an AD syringe, as this might disable it.

General steps to follow when using AD syringes are below. Note that they should be adapted depending on manufacturer's instructions for the type of syringe being used.

- 1. Remove the syringe from its plastic wrapping (peel the package open from the syringe plunger end), or detach the plastic caps.
- 2. Take off the needle cap without touching the needle.
- 3. Insert the needle in the vaccine vial its tip should be in the lowest part or bottom of the vial.
- 4. Pull the plunger back to fill the syringe just past the 0.5 ml or 0.05 ml mark.
- 5. Remove the needle from the vial. To remove air bubbles, hold the syringe upright and tap the barrel. Then carefully push the plunger to the volume mark. For the last dose of a multi-dose vial, keep the needle tip in the fluid at all times, making sure to empty the full contents of the vial.
- 6. Proceed with the injection at the appropriate site (see Module 6 Managing an immunization session for details on injection technique).
- 7. Push the plunger forward and inject the vaccine. At the beginning or just at the end of the injection, the plunger will automatically lock so the syringe cannot be reused.
- 8. Do not recap the needle after use.
- 9. Dispose of the needle and syringe in a safety box, which is a leak-proof, puncture-resistant container for sharps waste.

#### Hypodermic syringes with reuse prevention features (RUP)

RUP syringes are disposable syringes with self-locking mechanisms that allow only one use. They are the recommended choice for reconstituting vaccines, just as AD syringes are recommended for administering vaccines.

General steps for using RUP syringes for reconstituting vaccines

Just as with AD syringes, each type of RUP syringe requires a specific technique for its use. But for all types, the plunger can go back and forth only once and so, health workers should take care not to move it unnecessarily.

General steps to follow when using RUP syringes are given below. Note that they should be adapted depending on manufacturer's instructions for the type of syringe being used.

- 1. Remove the RUP syringe from its wrapping (peel the package open from the syringe plunger end) or detach the plastic caps.
- 2. If there is a detachable needle, fit it onto the hub of the syringe and take off the cap without touching the needle.
- 3. Insert the needle in the diluent vial and move the tip of the needle to the lowest part or bottom of the vial.
- 4. Pull the plunger back to fill the syringe, making sure to empty the full contents of the vial.
- 5. Remove the needle and syringe from the vial. If needed, remove air in the syringe by holding it upright and pushing the plunger slowly until the air goes out.

- 6. Insert the needle and syringe into the vaccine vial.
- 7. Push the plunger in completely to ensure that all the diluent goes into the vaccine vial.
- 8. Remove the needle and syringe from the vial and ensure that the syringe is locked.
- 9. Dispose of the needle and syringe directly in a safety box.
- 10. Shake the vial to mix the diluent with the vaccine (see Module 6 Managing an immunization session for details on reconstitution technique).

#### Prefilled AD injection devices

Prefilled AD injection devices are single-dose packets of vaccine with a needle attached (see Figure 51). This type of injection device can also be used only once. Some prefilled devices are equipped with a vaccine vial monitor. In addition to having the same advantages as AD syringes, they:

- are easy to use since no vaccine reconstitution is required
- prevent vaccine contamination
- make administering an accurate dose easy
- deliver vaccine and syringe in the same set (separate orders are not needed)
- reduce waste that can occur with multi-dose vials.

Prefilled hepatitis B vaccine and tetanus toxoid vaccine AD injection devices are currently available. Prefilled hepatitis B AD devices are used primarily to provide home vaccination to newborns. Prefilled tetanus toxoid AD devices are used for home vaccination of women during mass campaigns.

#### General steps for using prefilled AD injection devices

Every prefilled AD injection device is sterilized and sealed in its own foil package by the manufacturer. The vaccine is contained in a sealed syringe or bubble-like reservoir that prevents it from coming in contact with the needle until its administration. Using it requires the steps below.

- 1. Prepare or activate the prefilled bubble-like injection device by pushing the needle shield (or cap) into the port as shown in Figure 29. This opens the fluid path between the needle and the reservoir that contains the vaccine.
- 2. Remove the needle shield.
- 3. Insert the needle into the injection site (see Module 6: Managing an immunization session, section 4 for details on injection technique).
- 4. Deliver the dose by squeezing the reservoir until it is empty.
- 5. Dispose of the used AD device directly in a safety box.

Figure 1: Activation and use of prefilled bubble-like auto-disable device



Disposable single-use syringes and needles that could potentially be reused because they do not have RUP devices are not recommended for immunization programmes. Reuse of syringes and needles carries a high risk of transmitting infections. This risk prompted the 1999 WHO, UNICEF and UNFPA joint policy statement.

While RUP reconstitution injection devices are the equipment of choice for mixing vaccine with diluent, they may not always be available. If RUP devices are not available and disposable syringes and needles are used to reconstitute vaccine, they must never be reused for reconstitution or injection.

## 2. Giving the right vaccine safely

Proper vaccine storage and handling as well as clinical assessment and administration at immunization sessions are essential. Module 2: The cold chain and vaccine management discusses how to handle vaccines to ensure that they are safe and effective at the time of use. Module 6: Managing an immunization session contains details on assessing which vaccines are needed for each child and the techniques for their reconstitution and administration. Table 44 introduces some examples of incorrect immunization practices, and adverse events following immunization are discussed further in Module 6 and Module 7: Monitoring and surveillance.

**Table 44** Examples of incorrect immunization practices and possible adverse events

 following immunization

Incorrect practice	Possible adverse event following
	immunization
Non sterile injection due to	Infections such as local abscess at
• Reuse of disposable syringe or	injection site, sepsis, toxic shock
needles	syndrome, or death, transmission of

Improperly sterilized syringe or needle	blood borne infections such as hepatitis and HIV
Contaminated vaccine or diluent	
Reconstitution error due to	local abscess at injection site
<ul> <li>Inadequate mixing of vaccine</li> </ul>	vaccine ineffective
Reconstitution with incorrect	Negative effect of drug(for example
diluent	Insulin, Oxytocin, muscle relaxant) Death
<ul> <li>Drug substituted for vaccine or diluent</li> </ul>	
<ul> <li>Inappropriate reuse of reconstituted</li> </ul>	
vaccine in subsequent session	
Injection at incorrect site suc as	Local reaction or abscess
<ul> <li>BCG given subcutaneously</li> </ul>	Local reaction or abscess
<ul> <li>DTP/DT/dT/TT too superficial</li> </ul>	Sciatic nerve damage
Injection in to buttock	
Vaccine transportation/ storage incorrect	Local reaction
such as	Vaccine ineffective
VVM change color	
Clumping of adsorbed vaccine	
Contraindication ignored	Avoid sever reaction
Strictly speaking , ineffective vaccine is	
considered to be an effect, not adverse	
event	

#### 2.1 Simple ways to improve injection safety

The following is a summary of points to improve injection safety:

- Prepare injections in a clean, designated area that is free from blood and body fluid contamination.
- Prepare each dose immediately before its administration do not prepare several syringes in advance.
- Never leave the needle in the top of the vaccine vial.
- Follow product-specific recommendations for storage, handling and use of vaccines.
- Follow safe procedures to reconstitute vaccines.
  - The correct diluent must be used for reconstituting freeze-dried vaccines.
  - Use only the diluent supplied by the manufacturer for each vaccine check the labels.
  - Diluents must be cooled before reconstitution.
- Dispose of used AD and RUP needles and syringes in a safety box.
- Follow national multi-dose vial policy for opened vials.
- Use a new AD needle and syringe for every child.
  - Inspect the packaging very carefully.
  - Discard the needle and syringe if the package has been punctured, torn or damaged in any way.
  - Do not touch any part of the needle.
• Discard a needle that has touched any non-sterile surface.

• Position the child carefully to minimize risk of movement and injury. See figure 2 below

Figure 2. Diagrams on Unsafe immunization practices



# 3. Preventing needle-stick injuries

Needles can be dangerous. They can injure health workers and, if contaminated with hepatitis B, hepatitis C, HIV or other infections, they can transmit diseases.

Needle-stick injuries can happen at any time, particularly during and immediately after an injection. This risk is increased when:

- Health workers recap needles or walk around carrying used needles
- Children are not positioned properly during injections
- Unsafe disposal practices leave people and/or animals exposed to used needles and syringes.

This section describes steps to prevent needle-stick injuries by addressing potential risks from handling equipment, workspace arrangement, positioning of children and waste disposal.

3.1 Minimizing the need to handle needles and syringes

In general, the more injection equipment is handled, the greater the risk of needle-stick injuries. Reduce risk due to handling of equipment through the following steps.

Place a safety box close to the person giving vaccinations so used needles and syringes can be disposed of immediately, easily and without walking to find a sharps container.

- Avoid recapping the needle. If recapping is absolutely necessary for example, if the injection is delayed because the child is too agitated use the one-hand technique of placing the cap on a table or tray and reinserting the needle by sliding it inside without using the other hand.
- Do not remove the used needle from the syringe with your hands.
- Do not carry used syringes and needles around the work site for any reason.
- When ready to administer, draw the vaccine into the syringe, give the injection and dispose of the syringe in the safety box without putting it down between steps.
- Close the safety box securely when it is three quarters full.
- Do not manually sort needles and syringes.

# 4. Handling syringes and needles safely

Any part of the syringe that is touched becomes contaminated. Although the barrel and plunger of a syringe have to be touched to prepare and give an injection (see Figure 3), care should be taken to avoid touching parts that come into contact with the vaccine or the child (see Figure 4).

#### Figure 3: Parts of a syringe and needle that may be touched



Do not touch:

- The shaft of the needle
- The bevel of the needle
- The adapter of the needle
- The adapter of the syringe
- The plunger seal of the syringe.

Figure 4: Parts of a syringe and needle that must not be touched



# 5. Setting up the immunization work area to minimize risk of injury

To minimize risk of needle-stick injury, staff should arrange their workspace following general rules.

- The vaccinator (person giving doses of vaccine) should be between the child and all needles and sharp objects.
- The vaccinator should be able to see the opening of the safety box when discarding needles.
- The safety box may be on a table or the floor depending on whether the vaccinator is standing or sitting. He or she should be able to reach it easily and without much change in position.
- The vaccinator should be able to dispose of used needles and syringes directly in the safety box without putting them down on other surfaces.
- The vaccinator should have only one child with caregiver(s) at a time in her/his workspace.
- Each vaccinator should have a separate safety box, especially at busy sites.
- The vaccine carrier should be in the shade.
- Tally sheets should be within easy reach.

See Module 6 – Managing an immunization session for more details and illustrations.

# 6. Positioning children correctly for injections

Unexpected motion at the time of injection can lead to needle-stick injuries. This may occur more often with children who are not positioned properly before injections are given. See figure 5 below for more elaboration

Figure 5: An example of correct positions for child receiving injection at the thigh



Health workers cannot hold the child because they need both hands for the injection.

Always tell the mother when you are about to give the injection.

# 7. Practicing safe disposal of all medical sharps waste

Used sharps must be placed in a safety box and then disposed of properly. Follow the procedures for safe disposal outlined in the next section of this module.

7.1 Disposing of used syringes and needles

Why is it important to handle sharps waste properly?

Sharps waste can cause serious health and environmental problems. Unsafe disposal can spread some of the very same diseases immunization programmes are working to prevent.

#### Dangers to health

Leaving used syringes and needles in the open or on the ground puts the community at risk. Most frequently, children are the unfortunate victims of needle-stick injuries from haphazard disposal of needles.

#### Dangers to the environment

Inappropriate treatment of waste leads to environmental pollution. Open burning and low-temperature incinerators release toxins into the air; they should be used only as temporary emergency solutions when no other options are available. Throwing used needles and syringes into bodies of water can contaminate the natural environment and injure wildlife.

#### 7.2 Safety boxes

All used disposable injection equipment should be disposed of in a safety box immediately (see Figures 6 and 7). Safety boxes are waterproof, tamper-proof containers that needles cannot pierce. If a safety box is not available, locally available materials can be used to create a functional and safe sharps container (see below).

Figure 6: Safety box when a safety box is not in use, close the opening on the top.



#### How to assemble a safety box

Safety boxes require proper assembly before use, as shown in Figure 7. Many come with picture instructions printed on the side.

Figure 7. Safety box assembly and use



#### What to do if safety boxes are not available

If safety boxes are not available, strong cardboard boxes, metal cans or thick plastic containers may be used to collect needles and syringes and transport them to a site where they can be properly treated (buried, incinerated or autoclaved and shredded). Containers should be sealed when they are three quarters full. They should not be reused once filled – emptying sharps containers for reuse increases the risk of accidental needle-stick injuries and infections.

How to create a good sharps container if a safety box is not available

Find a strong cardboard box (a local shop may have some). Ideally, the walls of the box should be strong enough to keep needles from piercing through and causing needle-stick injuries.

If needed, place one box inside another to create a stronger container that can prevent needles piercing through.

Close the box securely on the top and bottom – seal it with strong adhesive tape or similar material.

Cut a small hole in the top – it should be just big enough for a needle and syringe to enter (maximum 38 mm).

When the box is three quarters full, seal the opening.

Dispose of the box properly (see next sections of this module).

Figure 8: Homemade safety box.



How to help ensure safe handling of safety boxes

Never squeeze, sit or stand on safety boxes. Do not handle or shake the safety box more than necessary.

Take extra care when carrying safety boxes to disposal sites. Hold the box by the handle on top (or at the top above the level of the needles and syringes if there is no handle).

Keep safety boxes in dry places that are out of children's and others people's reach.

Train staff on safe handling; do not ask untrained staff to handle safety boxes.

7.2.1. Using safety boxes

All injection equipment should be destroyed by proper waste disposal methods. Collecting sharps waste in safety boxes or similar containers both decreases risk of injury during handling and helps ensure proper disposal.

Safety boxes should be placed within reach of the staff administering injections so that needles and syringes can be disposed of immediately. If needle removers or needle cutters are available, used needles and syringes should be separated immediately after each injection. After removing the needle with one of these devices, the syringe should go in the safety box. Needles remain in a separate safe container, which, when almost full, should be closed and disposed off properly (see section 8 for disposal methods).

Safety boxes should be closed when they are three quarters full. Used needles and syringes should never be transferred from safety boxes to other containers. A five-litre safety box can hold about 100 syringes and needles.

For best use of safety boxes, you should never dispose the following items in them:

Empty or discarded vials

Cotton pads

Dressing materials

Intravenous bags or tubes

Latex gloves

Any plastic materials or waste products.

Once three quarters full, safety boxes should be closed, treated and destroyed appropriately, preferably quickly at a nearby site to minimize handling.

Used needles and syringes must never be dumped in open areas where people might step on them or children might find them (inside safety boxes or loose). They should never be disposed of along with general non-sharps types of waste.

# 8. Disposing of filled safety boxes

Methods commonly used to destroy or dispose of filled safety boxes are described below. Any selected method of waste disposal must comply with national and subnational environmental and health regulations.

#### Incineration

Incineration can completely destroy needles and syringes. Fires burning at temperatures higher than 800 °C will kill microorganisms and reduce the volume of waste to a minimum. Properly functioning incinerators ensure the most complete destruction of needles and syringes. High temperature, dual-combustion incinerators with air filters produce less air pollution than incinerators burning at lower temperatures (see Figure

9). Some hospitals have on-site incinerators. Others transport the waste to cement factories to dispose of it in high-temperature kilns.

The compound in which incineration takes place must be secure. Staff members conducting the incineration should wear safety glasses, heavy gloves and any other personal protective equipment required by local and national guidelines.



Figure 9: Common types of incinerators (This is not an exhaustive illustration.)

Steam treatment (autoclaving)

Autoclaving, if available, is an alternative that avoids pollution associated with incineration (see Figure 10). Waste treatment autoclaves can range in size from about 20 L to over 20 000 L.

The operation of autoclaves requires the proper combination of temperature/pressure and exposure time to achieve disinfection. A minimum recommended temperatureexposure time criterion of 121 °C for 30 minutes is suggested for sharps waste. Since the autoclave does not eliminate the physical hazard from sharps, a post-treatment shredder that is designed to minimize handling is also recommended.

Figure 10. Simplified schematic of a vacuum autoclave



Source: WHO (in press) Safe management of wastes from health care activities. Second edition. Geneva: World Health Organization.

#### Encapsulation

A safety pit is an option for the disposal of used needles and syringes that are loose. A safety pit is usually two meters deep and one meter in diameter so that it can be lined with a locally made concrete pipe. The pit should have a concrete lid with a capped metal pipe set in it. Used needles and syringes are dropped through the metal pipe and into the pit (see Figure 11). Cement is poured into the pit to seal the opening when it is full.

#### Figure 11. Safety pit



#### Burial in a disposal pit

Used injection equipment may be buried in a disposal pit. The site should be chosen carefully – there should be enough space for a pit large and deep enough for bulky boxes to be buried with minimum risk of contaminated sharps being released into the surroundings and doing harm.

If a disposal pit is to be used, several steps must be followed.

- Choose a site where people will not dig or build latrines in the future.
- Choose a qualified staff person to supervise the burn using appropriate equipment.
- Fence off and clear the area.
- Dig a pit at least two meters deep. Make sure that buried materials will not escape from the pit, for example, during the rainy season.
- When ready to bury them, take filled safety boxes to the pit site and place them in it. Do not open or empty the boxes.
- After placing the boxes in the pit, immediately cover them with at least 30 cm of soil. If possible, cover the site with concrete when the pit is full. Only qualified staff should perform this task.

The two options below are to be considered as last resort options since they are not in keeping with WHO policy for the treatment of waste.

#### Burning in a metal drum

This option should only be considered as a last resort, short term emergency response since low-temperature burning produces toxic emissions and is a public health and environmental hazard.

If contaminated sharps must be destroyed by burning in a metal drum or container (see Figure 12), several steps must be followed.

- Choose a site in an unused area that is as far from buildings as possible. The area should be fenced and cleared.
- Choose a qualified staff person to supervise the burn using appropriate equipment.
- Place four bricks on the ground in a square pattern.
- Put a metal screen or grate on top of the bricks.
- Remove both ends of a 210-litre steel drum. This will allow air to flow through the drum and the contents to burn better. If a metal drum is not available, build a cylinder from sheet metal, bricks or clay. A chimney may be added to the removable top of the drum or container.
- Place the drum on top of a metal screen or grate.
- Put filled safety boxes in the metal drum. Mix paper, leaves or other flammable material in among the safety boxes to help them burn.
- Sprinkle a small amount of kerosene, if available, on the boxes and other material in the drum.
- Place a fine metal screen over the top of the drum to reduce flying ashes.
- Put wood, paper or other flammable material under the drum and ignite the material.
- Warn people to stay away to avoid smoke, fumes and ash from the fire.
- Allow the fire to burn until all of the safety boxes have been destroyed.
- Once the fire is out, allow the residue at the bottom of the drum to cool and carefully collect it. Bury it in an unused location. Cover it with at least 30 cm of soil. If possible, seal the residue pit with cement once it is full. Only qualified staff should perform this task.



Figure 12: Metal drum

Burning in an open pit

This option should also only be considered as a last resort since it produces toxic emissions and is a public health and environmental hazard. It is always preferable to collect safety boxes for later disposal at a more appropriate treatment site.

If burning waste in the open as shown in Figure 13 is the only option, several steps must be followed.

- Choose a site in an unused area that is as far from buildings as possible. The area should be fenced and cleared.
- Choose a qualified staff person to supervise the burn using appropriate equipment.
- Dig a pit at least one metre deep, but not so deep that it will be difficult to start the fire. Staff should not have to enter the pit to start the fire.
- Place filled safety boxes in the pit. Mix paper, leaves or other flammable materials with the boxes to help them burn.
- Sprinkle a small amount of kerosene on the boxes, if available, and ignite the fire.
- Warn people to stay away to avoid smoke, fumes and ash from the fire.
- Let the fire burn until all boxes are destroyed and then follow the instructions for burying residue stated above.

Only qualified staff should perform this task.

#### Figure 13: Open burning in a pit



IMPORTANT: The remains of safety boxes, including needles, should be buried after burning, whether a metal drum or an open pit was used. The remains should be buried deep in a pit, controlled landfill or similar location where people cannot access them.

# 9. Adverse Events Following Immunization

AEFIs need to be reported individually and tallied for the monthly summary report. The WHO definitions of AEFI and AEFI categories are given in the below. With investigation, an AEFI should fall into one of the five categories.

Investigation is usually carried out based on an initial health facility report of a suspected AEFI (discussed further below).

9.1 WHO definition of AEFI and AEFI categories

AEFI is defined as "any untoward medical occurrence, which follows immunization 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.

AEFIs are grouped into five categories:

**1. Vaccine product-related reaction**: An AEFI that is caused or precipitated by a vaccine due to one or more of the properties of the vaccine product itself.

Example: Extensive limb swelling following Pentavalent vaccination.

**2. Vaccine quality defect-related reaction**: An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.

Example: Failure by the manufacturer to completely inactivate a batch of inactivated polio vaccine leads to cases of paralytic polio.

**3. Immunization error-related reaction**: An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.

Example: Transmission of infection by contaminated multi-dose vial.

**4. Immunization anxiety-related reaction**: An AEFI arising from anxiety about the immunization.

Example: Vasovagal syncope (fainting) in an adolescent during/following vaccination.

**5. Coincidental event:** An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

Example: A fever occurs at the time of the vaccination (temporal association) but is in fact caused by malaria. Coincidental events reflect the natural occurrence of health problems in the community with common problems being frequently reported.

#### **Exercises:**

Exercise 1: (Plenary session)

Demonstration of use of A-D syringes

Discussion on possible difficulties in handling the material

#### Exercise 2:

Demonstration of the safety box

Discussion on possible injuries while disposing of used syringes and needles.

#### Exercise 3:

Demonstration of correct and incorrect practices of injection safety at health facility level followed by a discussion

#### Exercise 4:

Consider local conditions, availability of incinerators and number of used syringes and needles in your districts. Choose the proper disposal systems at peripheral and district levels according to their advantages and disadvantages.

When finished, share your findings with the facilitator.

**Exercise 5:** Give two reasons why must you discard reconstituted and opened PCV vaccines after six hours or at the end of the immunization session

Exercise 6:

#### Case Study # 1

#### The recapping quandary:

Your clinic has a special container for disposing of needles and syringes. The container is located in the vaccination room, since that is where most injections are given. Occasionally, patients need to be given injections in the treatment room, which is down the hall from the vaccination room. When this occurs, the nurse recaps the hypodermic needles, carry them down the hall to the vaccination room, and deposit them in the sharps disposal container.

#### Questions for review:

What should be done differently to reduce the risk of infections at your clinic?

# Module 6: Managing an immunization session

#### Total time allocated: 5 hours

#### About this module

This module describes the tasks a health worker needs to perform to ensure the quality of an immunization session.

Learning objectives

By the end of this session, participants will be able to:

- Get all preparation required at the health facility and the immunization site before the children arrive.
- Discuss the communication needed throughout each encounter with caregivers during the session.
- Proceed with screening of children before vaccination,
- Apply the correct technique for administering vaccines and instructions for closing sessions and recording data.
- Use the reminder chart/key information throughout the child encounter during the immunization session

This module touches on topics that are covered in more detail in other modules and references are specified in the text. It focuses mainly on child immunization, but the principles may be applied to older age groups.

# **1. Preparing for the session**

Preparation for sessions should be part of micro planning. This begins well before the day of the session and should continue throughout the session to include feedback for improving the planning of the next sessions.

The main objectives are:

- a) To inform the community in advance: the community should be aware of the session and those who are due for immunization should know about the location and time; and
- b) To set up the site for safe immunization: staff should organize adequate quantities of vaccines, safe injection materials, safe disposal containers and recording tools as well as an adequate cold chain for conserving vaccines.

The order of the steps may vary by site; for example, for outreach sessions, vaccines have to be packed for transport at the health facility before the workplace is prepared at the remote site. Community focal person should set up as much of the outreach site as possible before the vaccinators arrive.

#### 1.1 Plan the immunization session

Each health facility should have a session plan showing where and when immunizations will be given. This session plan should be developed with and communicated to the community as part of micro-planning. Immunization sessions may be held daily, weekly, every two weeks, monthly or quarterly at fixed, outreach or mobile sites. The frequency of the sessions depends on the size of the community being served and the workload for staff, as described in Module 4 (Micro-planning for reaching every community).

For outreach, health facility staff should get to know people in the community and learn who can help with arranging the session, including choosing a suitable time (for example, religious days, market days etc...) and tracking children who are due and overdue for immunization. A place where it is agreed by the community known and accessible by the community should be selected with the community to conduct immunization session.

#### 1.2 Prepare the workplace

The final arrangement of space for an immunization session will depend on whether it is being held in a fixed health facility or outreach site, and whether other services are being provided (for example, nutrition screening, antenatal care and/or health education). Figure 41 shows an example of the basic requirements for a fixed or outreach site.

The ideal site will be:

- easily accessible and identified with a sign stating "Immunization Site";
- located in the same place each time;
- in a clean area, out of the sun, rain and dust;

- near a sheltered/shaded area where those needing vaccination can wait;
- large enough to provide space to have separate stations for registration and assessment, immunization and record keeping and screening/education on other health issues;
- Quiet enough for health workers to be able to explain what they are doing and to give advice.

Whenever possible, the immunization site itself should be separated from other activities so that crying children do not cause distress to those waiting. Ideally, the whole circuit should have a separate entrance and exit, and be well marked with signs, ropes and other visual aids through which community members or health workers may guide those attending.

In practice, workplace situations are often less than ideal. Large numbers of people crowding the area may cause safety issues, as well as confusion and stress, not just for the health worker, but also for everyone concerned. Careful preparation and a positive, welcoming manner help ensure a successful immunization session.

**Figure 1:**Immunization session: example outreach immunization site arrangement in the open air



#### 1.3 Prepare supplementary materials and equipment

A basic list of supplementary items includes:

- Adverse Events Following Immunization (AEFI) kit; example Adrenalin
- water container, basin, soap, towel for hand washing and drying;
- metal file to open ampoules, if needed;
- immunization register;

- Immunization diploma;
- Family health card
- new immunization/child health cards;
- scissor
- safety box
- vaccine carrier with foam pad
- weight scale and MUAC tape
- thermometer
- immunization tally sheets;
- cotton wool;
- container for rubbish that does not go into a safety box;
- paper, pencils and pens;
- table(s);
- stool(s)/chair(s);

#### Figure 2 Immunization station: example arrangement



#### 1.4. Prepare required vaccines and safe injection supplies

For sessions at the health facility, required vaccines should be taken from the fridge beforehand to reduce the number of times the fridge is opened.

For outreach, enough vaccine has to be taken to meet demand since the refrigerator will, of course, not be nearby during the session. Extra vaccine should be added to meet unexpectedly high demand at the session. For example, an extra 10% can be added to the estimated need. Ideally, the quantity of each type of vaccine should be calculated from a list of children who are due and overdue. When such lists are not available, the quantity can be estimated based on previous session demand, especially if this is stable. Verify that vaccines are safe to use

Before opening the refrigerator, estimate the number of each vaccine needed for the session as noted above.

When opening the fridge, first check the temperature and the freeze indicator. If there has been freeze exposure, as fridge tags, check the alarm and duration do a shake test on the freeze-sensitive vaccines.

Select vaccines from the refrigerator in the order given below.

1. Opened vials kept in the so-called "use first box" in the fridge

2. Unopened vaccine vials that have been returned from outreach sessions or have been outside of the refrigerator and returned (usually also in the "use first box").

3. Vaccine vials with VVMs that have started to change to a darker color (stage 2).

In general, vaccines should be organized in the refrigerator by expiry date, with those with the closest expiry date kept in front and used first.

When selecting vials from the refrigerator, check each vaccine and diluent vial/ampoule and remember to:

- Use only vials/ampoules in good condition; discard vials/ampoules that are damaged and/or have no label;
- Discard any vials/ampoules that have passed their expiry date;
- Discard any vials/ampoules with VVMs past the discard point;
- Do not use any vials/ampoules with fluid that has changed color or contains particles: seek the advice of your supervisor if any are found.

Figure 3 How to read a vaccine vial monitor



Include an adequate number of auto-disable syringes and safety boxes

Take one AD syringe for each dose of injectable vaccine and add 10% buffer stock. Note that separate calculations for two types of syringes, AD and BCG AD, are needed in most programs.

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 water packs and vaccine carriers

Do not use frozen water packs for vials that will be out of the cold chain for a limited time at fixed or outreach immunization sessions as the risk of freezing is greater than the risk of damage from heat for vials kept in a vaccine carrier for less than a day.

Chilled water packs are recommended to avoid freezing vaccines.

Keep open vials inserted in the foam pad of the vaccine carrier during immunization sessions. Do not keep opened vials on ice.

# 2. Communicating with caregivers

Communication involves giving information verbally (including the tone of voice) and nonverbally (body language). It is an essential part of vaccinator technique needed from start to finish of the interaction with each child and caregiver. Communication during the immunization encounter is also important for giving health education; studies show that health workers are the primary source of such information for caregivers.

This section describes how to prepare for the communication needed to accompany the more technical activities described in module 3. It suggests how to make good communication part of vaccinator technique and gives a general sequence to match activities during the immunization encounter. Actual content of communication ultimately 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 immunization.

#### 2.1 Communication use

Communication that welcomes, calms and reassures anxious children and adults makes vaccination easier and more pleasant. While immunization sessions can be very busy, taking time to give at least the minimum key information at each encounter improves results for all.

Asking about families and showing interest and concern will, over time, build trust and respect between health workers and communities. It may also bring to light health problems in the community that need to be reported and addressed.

Most communication is nonverbal. It is conveyed in many ways: posture, facial expression, gestures, eye contact and attitude, for example. Welcoming families to an immunization session with a smile and a calm manner will reassure the anxious,

whereas arriving late can communicate a lack of respect. Being bad-tempered, criticizing caregivers, using words that are unfamiliar to the community and hurrying will increase anxiety and reduce the likelihood that people will return willingly for the next sessions.

# 2.2 Communication tips

Show concern and empathy with the community and, even more importantly, with each individual, treating them with respect and courtesy. Vaccinators have an important role in protecting communities from vaccine preventable diseases, not only by administering the vaccines, but also by creating trust so that children and adults are willing to attend immunization sessions.

- Working with different cultures often presents challenges and individual differences occur within any culture. For an individual health worker, it may help if s/he:
- Understands her/his own attitude to immunization;
- Maintains confidence in her/his ability to talk about the vaccines and the diseases they prevent;
- Develops skills for giving one or more injections quickly, safely and with little discomfort;
- Has a genuine interest in each individual;
- Listens without judgment; immunization may challenge people's views of health and well-being;
- looks beyond what is being said; the health worker should observe body language and ask questions to check understanding of what is being said and felt;
- Checks that the caregiver understands the information given, which should be accompanied by giving written and other reminders as appropriate for the situation;
- Remains patient and kind
- 2.3 Communicating accurate information

The essential elements of every encounter are highlighted below:

- Advice on what is given
- Alert on side effects and how to respond
- Arrange for when to return

Some caregivers will want detailed information while others will be happy to trust that they are receiving appropriate care, and lengthy explanations may cause them anxiety. Use words that are readily understood rather than technical terms. The following issues may need to be covered, depending on individual needs and understanding:

• Vaccine-preventable disease;

- Vaccines and their schedules, including the number of doses, their timing, the importance of completing the series and due date(s) for the next dose(s);
- Route of vaccine administration: oral or injectable;
- Potential adverse events and what to do if they occur;
- Explanation and reassurance in response to inaccurate information (for example, contraceptive effect of vaccines);
- Vitamin A, if needed and when;
- Importance of immunization cards and documents and what is written on them;
- Immunization session locations and times, especially for the next visit

#### 2.4 communicating potential adverse events

The following points are important when talking about the potential adverse events of any vaccine.

Reassure the caregiver that reactions, such as fever, pain or swelling at the injection site, and changes, such as the child being irritable or off color, are common and indicate a good response to the vaccine.

Instruct the caregiver to give extra fluids in the form of breast milk or clean water.

Instruct the caregiver that paracetamol may be given and specify the appropriate dose and timing for the individual infant.

Remind the caregiver to give extra hugs and attention, but to avoid pressure to the injection site(s).

Explain that placing a clean, cold, damp cloth can help to ease pain if there is a local injection site reaction.

Tell the caregiver to bring the infant to the health facility 1 if the infant's condition worsens or the reaction continues for more than a day or two, since the infant may develop an illness, unrelated to immunization, that needs treatment.

**After BCG vaccine:** Explain to the caregiver that the flat-topped swelling on the infant's arm is normal and indicates that the vaccine is working. Ask the caregiver to return with the infant if s/he develops such signs as abscesses or enlarged glands.

**After measles vaccine**: Explain to the caregiver that a rash or fever may develop after 6–12 days. Other people will not catch the rash and it will go away on its own. The caregiver should give the infant extra fluids and keep them cool. See Module 1 (Target diseases and vaccines) for more details on vaccines and potential adverse events.

#### 2.5 communicating other measures to help keep children safe and healthy

Additional specific information to convey depends on the major concerns for children in a community. In general, hand washing, exclusive breastfeeding for the first six months of life and appropriate complementary feeding after the first six months should be promoted. It is also important to explain to caregivers that even if their child receives rotavirus and pneumococcal vaccines, the child may still

develop diarrhea or pneumonia from other causes, and they should be aware of treatment methods and danger signs.

Communication during each encounter/contact with the care giver At the start Greet the caregiver in a friendly manner. Thank her or him for coming for vaccination and for her/his patience if s/he had to wait.

Ask the caregiver if s/he has any questions or concerns and answer them politely.

During assessment write the date of the vaccination(s) being given on the immunization card and explain the disease(s) against which the vaccination(s) protect(s) in simple terms (in the local language). If there is a poster or chart, use it to help your explanation.

Mention possible adverse events and explain how to handle them.

Explain the need for the child to return for each contact in the immunization schedule to be fully protected. Use the immunization card as an instructional guide, and congratulate the caretaker if the child has completed a series.

Write the date for the next vaccination on the immunization card and tell the caregiver. If appropriate, associate the date with a well-known occurrence, such as a holiday or seasonal event, that will help her/him remember to bring the child back.

Ask the caregiver to repeat the date to be sure it is understood.

Explain to the caregiver that if the child cannot come on the return date, s/he can obtain the next vaccination at another location or another date close to the due date.

Remind the caregiver to bring the immunization card when s/he brings the child back for the next vaccination. Proceed with vaccination, including explanation of positioning, as described in Section 4 of this module.

After vaccination, remind the caregiver when to return with the infant.

In the event of any out-of-stocks of vaccine at the time of the session, inform the caregiver where and when to return for the next doses.

Remind the caregiver about other services given during immunization sessions, as per national policy; for example, vitamin A supplementation, and deworming or tetanus toxoid for women.

If immunization campaigns are planned in the coming months, inform the caregiver about the date of the campaign, what vaccination is being given, and where the vaccination site will be.

Offer relevant print information to caregivers who are literate.

Ask the caregiver if s/he has any questions or concerns and answer them politely.

# **3**. Assessing infants for vaccination

Before administering a vaccine to an infant, it is important to check which vaccines are due.

#### 3.1 Assess eligibility for immunization

Whenever an infant visits the health facility, s/he should be screened for immunization and given all the vaccines needed. If there is no immunization session that day, the earliest possible appointment should be made and explained to the caregiver. The steps below should be followed at any health care visit as well as at any immunization session.

1. Verify the infant's age on the immunization card if the infant does not have an immunization card, ask the caregiver for the infant's age. If the caregiver does not know the infant's age, estimate it by asking if the infant was born during/around a notable community event, for example during a certain season or celebration. A local events calendar can help with this.

2. Verify which vaccines the infant has received by reviewing the immunization card If the infant does not have an immunization card but has come to the health facility before, check the register and fill out a new card. If the infant is new to the health facility, ask the caregiver questions to prompt recall of each vaccine the infant should have received and fill out a new card.

3. Verify all vaccines the infant needs at this session to allow efficient preparation follow the national schedule (See Module 1, Target diseases and vaccines) for WHO recommendations on each vaccine) remembering these general points:

- If the infant is eligible for more than one type of vaccine, it is safe to give the different vaccines at different injection sites during the same session.
- Never give more than one dose of the same vaccine at one time.
- If the vaccine is overdue, do not restart the schedule. Simply provide the next needed dose in the series.
- If there is a delay in starting the immunization schedule, give the vaccine(s) and an appointment for the next dose at the interval recommended in the national schedule.

#### **3.2.** Assess possible contraindications

For the first dose of a vaccine, assess the general status of the child to rule out signs of serious illness. For a subsequent dose in a vaccine series, ask the caregiver whether any adverse events, including anaphylaxis, occurred following the previous dose(s).

All infants should be immunized except in these situations:

Do not give a vaccine if the infant has had anaphylaxis (a serious allergic reaction) or other severe reaction to a previous dose of the vaccine or a vaccine component.

Refer to Table 54 for guidance on vaccinating HIV-infected children

Do not give a vaccine if the caregiver objects to immunization for a sick infant after explanation that mild illness is not a contraindication. Ask the caregiver to come back when the infant is well.

Vaccine	Asymptomatic	HIV	Symptomatic	HIV
	infection/HIV+		infection/AIDS	
RV	Vaccinate		Vaccinate	
OPV	Vaccinate		Vaccinate	
BCG	Vaccinate		Do not vaccinate	
Pneumococcal	Vaccinate		Vaccinate	
DTP containing	Vaccinate		Vaccinate	
HepB containing	Vaccinate		Vaccinate	
Hib containing	Vaccinate		Vaccinate	
Measles/Rubella	ella Vaccinate <b>Do not vaccinate</b>			
containing				
Yellow Fever	Vaccinate		Do not vaccinate*	
Tetanus Toxoid	Vaccinate		Vaccinate	
Meningococcal	Vaccinate		Vaccinate	
Influenza inactivated Vaccinate		Vaccinate		

#### Table 45: Recommendations for immunization of HIV-infected children

\*Pending further study

#### Immunizing sick infants

Many health workers do not like vaccinating an infant who is ill. Infants can have many illnesses, but delaying immunization puts them at risk of vaccine-preventable diseases when they could receive the protection safely.

For infants with a minor illness and/or fever below 38.5°C (axillary), vaccinate as usual. This includes respiratory tract infections, diarrhea and similar mild infections without significant fever.

For very ill infants who need to go to hospital, or infants who have a very high fever, vaccinate if possible. A senior health worker may have to decide in each case, but infants do need protection from diseases that could be transmissible in hospital (measles, for example).

For malnourished infants, vaccinate as usual. Malnourished infants do develop immunity after vaccination, and when they do not receive vaccines, they are more likely than well-nourished children to die from vaccine-preventable diseases.

Other conditions when infants should be immunized. The following are not contraindications and infants with these conditions or circumstances should be immunized:

- Allergies or asthma, with the exception of a known allergy to a specific component of the vaccine as mentioned;
- Ongoing treatment with antibiotics;
- Family history of adverse events following immunization;
- Prematurity or low birth weight;
- History of jaundice at birth;
- Ongoing breastfeeding;
- Recent or upcoming surgery;
- Chronic non-communicable diseases of the heart, lung, kidney or liver;
- Stable neurological conditions, such as cerebral palsy or Downs syndrome;
- Family history of convulsions, seizures or fits

# 4. Giving vaccinations

Immunization is a routine procedure for health workers, but can be frightening for children and adults attending the session. There are many things a health worker can do to make an immunization experience a safe and positive one. This section focuses on techniques for injection preparation, comfortable and safe positioning of children, and safe disposal of materials.

4.1 Preparing to vaccinate

Injectable vaccines can be ready to use or can require reconstitution (mixing) with diluent. Oral vaccines may require manipulation of the packaging to enable administration. With the increasing range of products and presentations available, the aim of this section is to cover general principles that can be adapted to specific vaccines in each program.

Firstly, use aseptic technique to prepare vaccines:

Start with hand washing; 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 talk to the caregiver while preparing injections as showing interest in them is reassuring.

4.2 Reconstituting vaccines

Common vaccines that need to be mixed with diluent before use include BCG, yellow fever, measles, MR and MMR. The correct diluent must be used.

Points to remember about diluents

Always use diluent from the same manufacturer as the vaccine.

Diluent is not interchangeable, different vaccines have different diluents. Administering a vaccine with the wrong diluent has led to serious adverse events, including death.

Diluent should be cooled (kept at least for 24 hours before use) before being mixed with the vaccine.

Vaccines should be reconstituted with diluent immediately before use.

Unused reconstituted vaccine must be handled according to national multi-dose vial policy; WHO policy is outlined in Module 2 (The cold chain).

Steps for Reconstitution

1. Double check VVM status before the vaccine can be used

2. Double check each vial/ampoule to make sure it is not past its expiry date and read the label carefully.

3. Open the vial. For a metal cap, use a file to lift the pre-cut center and bend it back; for a plastic cap, flip it off with your thumb or slowly twist it depending on the specific instructions for the type of vial.

4. 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. If you injure yourself, discard the ampoule since the contents may have been contaminated. Cover the wound before opening a new ampoule.

5. Draw the entire diluent out with a new disposable reconstitution needle and syringe.

6. Insert the needle of the reconstitution syringe into the vaccine vial and empty all the diluent; depress the plunger slowly to avoid frothing inside the vaccine vial.

7. Draw the fluid slowly and gently in and out of the vial several times to mix the diluent and vaccine or gently swirl the vial to mix the diluent and vaccine; take care not to touch the rubber membrane or opening.

8. Remove the reconstitution needle and syringe and discard them in the safety box.

9. Put the reconstituted vaccine vial in the foam pad of your vaccine carrier.

4.3 Making vaccination easier and more comfortable

The way a health worker interacts with children and their caregivers has a huge impact and they will respond positively to a friendly, welcoming attitude.

Recent recommendations for new vaccines and catch-up dose schedules often mean giving two (or more) injections to an infant during the same session. Giving multiple injections at the same time is, of course, more difficult, but it is a skill that must be

learnt. With practice, giving injections quickly and safely with little distress to the infant and caregiver will become routine. Even the most experienced vaccinator should take time to review their injection technique and seek out refresher materials that might improve their skills. Vaccinators should also share their knowledge and learn from each other.

# 4.4 Good general techniques

#### Welcome the family:

Put them at ease by smiling and maintaining a kind, reassuring manner. Ask if they have any questions or concerns and take time to answer them. Complete the assessment. If more than one injection is needed, explain this and confirm that the caregiver agrees that it is better to vaccinate according to the schedule than to miss the opportunity.

# Be prepared:

After assessing the infant, prepare the necessary vaccines and place them close at hand in the order of administration. The order in which vaccines should be given will depend on national guidelines

#### Take time to position the infant with the caregiver:

Explain what will happen. This will help plan movements. Always have the infant's whole limb(s) for injection bare before starting. The vaccinator needs to move from one site to another, with minimum delay.

#### Follow a preset sequence for administering the vaccines based on national guidelines:

Countries often choose one site for each vaccine Using the same site for each infant can help during follow up (for example, PCV should always be given in the left anterior thigh and pentavalent always in the right anterior thigh). This can help, if the card is lost and recall questions need to be asked, or if any adverse events occur. The order in which vaccines are given to each infant can help make administering them easier; in general, the suggestion is to give oral vaccines first, while the infant is still calm, and then follow with the injectable ones. The choice of whether to give a new vaccine first or last usually depends on local factors. Table 46 shows a suggested order based on the current WHO schedule. Remember that spending a little time, particularly on welcoming and positioning, will help the procedure go more smoothly and efficiently.

S/No	Route	Vaccine
1	Oral	Oral Polio Vaccine
2	Oral	Rotavirus vaccine
3	Injectable/ID	BCG

**Table 46**: Example sequence for giving infant vaccines based on current WHO schedule

4	Injectable/IM	Pentavalent
5	Injectable/IM	Pneumococcal
6	Injectable/IM	IPV
7	Injectable/SC	Measles- and rubella-containing
8	Injectable/SC	Yellow Fever
9	Injectable/IM	Meningococcal

#### 4.5 Giving the right vaccine safely

#### **Reconstituting vaccines**

Reconstituting vaccines means mixing a powdered form of a vaccine with a fluid called a diluent so that the vaccine can be injected.

The table below lists the vaccines that need to be mixed with diluent before use.

#### Table 47: Vaccines that require reconstitution

Vaccines that need to be reconstituted	Powder		Diluent
BCG	freeze-dried	Vial	liquid provided with vaccine
Measles	freeze-dried	Vial	liquid provided with vaccine

Follow the steps indicated below to mix most powder vaccines with a fluid so that the vaccine can be used.

#### Remember:

Diluent are not interchangeable, different vaccines have different diluents; mixing and administering the wrong diluent has led to serious adverse events including death.

Always use diluent from the same manufacturer as the vaccine.

Diluents should be cooled before being mixed with the vaccine

Do not reconstitute vaccines until you are ready to immunize.

You must discard reconstituted vaccine after six hours or at the end of the immunization session, whichever comes first.

#### **Reconstituting BCG and Measles**

#### Step 1: Wash your hands

Wash your hands with clean water and soap before reconstituting vaccines.

#### Step 2: Inspect the vaccine vial or ampoule

Most vaccines come in vials, except for BCG vaccine which comes in ampoules. A vial is a glass bottle with a rubber stopper held in place by a metal or plastic cap.

Check the vaccine vial monitor (if there is any) to ensure that the vaccine has not passed the discard point.

Read the expiry date on the label to make sure that you can still use the vaccine. If the date has passed, discard the vaccine.

#### Step 3: Flick the vial or ampoule

Make sure that all of the vaccine powder is at the bottom of the vial. Flick or tap the vial with your finger.

#### Step 4: Open the vaccine vial or ampoule

The centre of the metal cap is pre-cut so that it can easily be removed. Lift the centre of the metal cap and bend it back, using a metal file.

Some vials have coloured plastic caps instead of metal caps. Flip off the plastic cap with your thumb.

#### Step 5: Inspect the diluent ampoule or vial

The diluent for reconstituting vaccines is usually held in ampoules, which are glass or plastic bottles that you open by breaking off their pointed tops. Make sure the ampoule is not cracked.

#### Step 6: Read the label on the diluent ampoule or vial

Make sure that you are using the diluent the manufacturer sent with the vaccine and the expiry date has not passed.

Use only the ampoule or vial sent by the manufacturer for the specific powder vaccine. Do not use sterile water or saline provided for other purposes as a diluent. Each vaccine has its own diluent and must not be reconstituted with anything else.

#### Step 7: Open the glass ampoule

Hold the ampoule between your thumb and middle finger.

Use your index finger to support the top.

Take the metal file that is packed with the ampoules and scratch hard around the neck of the ampoule you wish to open.

Hold the top of the ampoule in a piece of clean cloth and gently break off the top. It breaks where you made the scratch.

In case of injury while breaking the ampoule, discard the ampoule as the content may have been contaminated. Cover the wound/cut before opening a new ampoule.

# Step 8: Draw diluent into a mixing syringe



"Scratching and breaking" the neck of the vial

# Use a new disposable mixing syringe (5 ml) and a mixing needle (76 mm, 18 gauge) to reconstitute each supply. Put the needle in the open top of the ampoule. Pull back the plunger to draw all the diluent from the ampoule into the syringe. Do not reuse disposable mixing syringes.

# Step 9: Reconstitute the vaccine

Insert the mixing syringe that is filled with diluent into the Inserting diluent into a vaccine vial vaccine vial or ampoule.

Hold the plunger end of the mixing syringe between your index and middle fingers and push the plunger in with your thumb. This empties the diluent into the vaccine vial or ampoule.

To mix the diluent and vaccine, draw them up slowly into the syringe and inject them slowly back into the vial or ampoule. Repeat several times.

Put the mixing syringe and needle in a safety box after use.

#### Step 10: Handling reconstituted vaccines



Put the reconstituted vaccine on the foam pad of your vaccine carrier.

Please refer to table 48 below for more elaboration on administering vaccine for infants

Name of vaccine	BCG	DPT-HepB – Hib	Measles
Where given	Outer upper right arm or shoulder	Outer mid-thigh in infants/outer upper arm if older	Outer mid-thigh/upper depending on the age
How given	Intra-dermal injection	Intramuscular injection	Subcutaneous injection
Dose	0.05 ml	0.5 ml	0.5 ml
Needle size	10mm, 26 gauge	25mm, 23 gauge	25mm, 23 gauge
Туре	Powder + Diluent	Ready-to-use	Powder + Diluent
Appearance	White, cloudy liquid with sediment that suspends when shaken (see shake test Module 3)	White, cloudy liquid with sediment that suspends when shaken (see shake test Module 3)	Clear, slightly yellow liquid
- Cert			

How to give an injection using AD syringes

Wash skin that looks dirty with water. It is not necessary to swab clean skin.

Hold syringe barrel between thumb, index and middle fingers. Do not touch the needle. The plunger can go back and forth only once, so health workers should not draw up air to inject into the vial as this will disable the syringe.

Insert needle with a smooth action.

It is not necessary to aspirate first.

Use thumb to push the plunger without moving the syringe around.

Pull needle out quickly and smoothly (less painful than doing it slowly).

Ask the parent to press the site gently with a clean swab for a few seconds (to stop bleeding and relieve pain).

Do not rub the area where the injection was given.

#### Figure 4: Different needle positions



BCG vaccine: intradermal (ID) injection in arm

The injection is given into the skin in the **right upper arm**. The dose of BCG is very small (0.05 ml). To measure and inject such a small dose accurately you must use a special small syringe and needle.

BCG is the only childhood vaccine that is injected into the layers of skin for slow absorption (intradermally). To give an intradermal injection correctly you must use a short, very fine needle (10 mm, 26 gauge). Position infant sideways on mother's lap and remove clothing from the arm and shoulder.

The mother should hold the infant close to her body, supporting his or her head and holding the arms close to the body.

Hold the syringe in your right hand with the bevel of the needle facing upwards.

Stretch the skin out flat with your left thumb and forefinger.

Lay the syringe and needle almost flat along the infant's skin.

Insert the tip of the needle just under the surface but in the thickness of the skin — just past the bevel (the hole in the end of the needle).



Keep the needle FLAT along the skin, so that it goes into the top layer of the skin only. Keep the bevel of the needle facing up.

Do not push too far and do not point down or the needle will go under the skin. Then it will be subcutaneous instead of an intradermal injection.

To hold the needle in position, put your left thumb on the lower end of the syringe near the needle, but do not touch the needle.

Hold the plunger end of the syringe between the index and middle fingers of your right hand. Press the plunger in with your right thumb.

Inject 0.05 ml of vaccine and remove the needle.

**Note.** When an intradermal injection is given correctly the plunger is hard to push. If the vaccine goes in easily you may be injecting too deeply. **Stop** injecting immediately, correct the position of the needle, and give the remainder of the dose, but no more.

If the whole dose has already gone under the skin, count the infant as having received a dose of vaccine. **Do not** repeat the dose. Ask the parent to return with the child if he or she shows any side-effects, such as abscesses or enlarged glands.

If you have injected BCG correctly, a flat-topped swelling appears on the skin. The swelling may look pale with very small pits, like an orange peel. If the technique is incorrect, the vaccine will go in easily and no swelling will be visible.

DPT-HepB- Hib vaccine: intramuscular (IM) injection in thigh

Position the infant sideways on the mother's lap with the infant's whole leg bare.

The parent should hold the infant's legs.

Gently stretch the skin flat between your thumb and forefinger.

Insert the needle at a 90° angle.

Quickly push the entire needle straight down through the skin and into the muscle. Inject slowly to reduce pain.



Diagram showing how to locate the site to give IM injection to infants



#### Intramuscular injections for older children and adults

For vaccinating older children, adolescents and adults, the deltoid muscle of the upper arm may be used. In infants and young children under 15 months of age the deltoid muscle does not provide a safe intramuscular (IM) site due to the superficiality of the radial nerve and the deltoid muscle being insufficiently developed to absorb medication adequately.



#### Measles vaccine, subcutaneous (SC) injection

Position infant sideways on mother's lap with the whole arm bare.

The parent should hold the infant's legs.

Reach your fingers around and pinch up the skin.

Quickly push the needle into the pinched up skin — the needle should point towards the shoulder.

To control the needle, support the end of the syringe with your thumb and forefinger but **do not** touch the needle.

**OPV** administration

Ask the parent to hold the infant with the head supported and tilted slightly back.

The chin and cheeks should be dry: OPV is less likely to spill out.

Open the infant's mouth gently, either with your thumb on the chin (for small infants) or by squeezing the infant's cheeks gently between your fingers.

Let 2 drops of vaccine fall from the dropper onto the tongue. Do not let the dropper touch the infant.

TT vaccine (for women): intramuscular (IM) injection in the left arm

Ask the woman to sit down.

Tell her to drop her shoulder and place her left hand behind her back or resting on the hip. This relaxes the muscle in the arm and makes the injection nearly painless.

Put your finger and thumb on the OUTER part of the upper arm.

Use your left hand to squeeze up the muscle of the arm.

Quickly push the needle straight down through the skin between your fingers. Go deep into the muscle.

Press the plunger with your thumb to inject the vaccine.







Pull out the needle quickly and smoothly and ask the woman to press the site gently with a cotton pad in case of bleeding

Vitamin A supplementation

Check the expiry date on the label. If the expiry date has been reached, discard the bottle.

Open the bottle and write the current date on the label so that you will know when to stop using it. Opened bottles of vitamin A capsules are good for one year.

Open a capsule by cutting the tip or nipple off with a clean pair of scissors or a clean nail clipper.

Squeeze the capsule firmly so that the drops fall into the mouth of the client. For a young child, you may need to pinch his or her cheeks gently to open the mouth.

4.6 Give the correct amount of vitamin A supplement: too much can cause harmful side-effects.

If you are giving vitamin A to children ages 6 through 11 months and you have only 200 000 IU dose capsules, you need to know the number of drops in this size of capsule in order to be able to give a half dose (100 000 IU). To do that:

**Step 1**: Open one 200 000 IU capsule, and squeeze out the contents while counting the number of drops that are contained in it.

**Step 2**: Divide the total number of drops by two — this is the number of drops equal to a half-dose or 100 000 IU. It is safe to assume that all capsules in a batch contain the same number of drops.

Completing the tally sheet and infant's immunization card

Recording the vaccines and vitamin A supplement given on the tally sheet

Soon after you finish immunizing the infant and woman, record a mark for each vaccine and vitamin A supplement given on the tally sheet (more information in Module 7).

Completing the infant immunization card

Complete the immunization card by writing down the date for each vaccine administered or vitamin A supplement given and return the card to the parent. If there is no special place on the card for recording vitamin A supplementation, write "Vit. A" and the date in the margin or any blank space on the card.

Immunization cards should be kept by the parents and not by the health staff.

Mark the next immunization date on the card after every dose, and tell the parent when and where to return for the next dose of vaccine.

Tell the parent that the card must be kept in good condition. Explain that it is an important document because it keeps track of her infant's health and immunization status and will help health workers understand how to treat her infant in the future.
Tell the parent that the card should be brought along every time the infant comes to the health centre, whether or not the infant is coming in for services or not.

Ask to see immunization cards for both mothers and infants every time they come to your health centre. Assess whether they are eligible for any vaccine or vitamin A supplementation. Do not miss an opportunity to immunize.

#### 5. Recording data

Accurate and reliable records are vital, not only for the individual child but also to track the immunization status of communities through monthly and annual reporting (see Module 7, Monitoring and surveillance) for details).

During a session, individual immunization cards and health centre records – such as registers, reminder cards and tally sheets – have to be completed. Tally sheets need to be totaled after the session and these totals need to be added to program monitoring data.

#### 5.1 Complete the infant immunization and reminder cards

Follow these steps to complete infant immunization and reminder cards:

1. Write the date for each vaccine administered in its corresponding section on the card.

2. Mark the next immunization due date on the card if another dose is needed, and ensure that the caregiver understands when and where to return for the next dose(s) of vaccine(s).

3. If new vaccines are not included on immunization registers and/or cards, ask your supervisor for instructions about how to record them on all reporting tools.

4. Use the immunization card to update the reminder card/due list kept in the health facility as shown in Module 7(Monitoring and surveillance).

5. Return the immunization card to the caregiver.

6. Explain to the caregiver that the immunization card must be kept in good condition since it is an important document for future health care visits.

7. Remind the caregiver that the card should be taken to all of the child's health care visits for review.

Do not miss any opportunity to immunize; health workers should be in the habit of asking for and reviewing immunization cards for each child at each visit regardless of the reason for coming.

#### 6. Closing the session

#### 6.1. Material collection

Materials must be stored safely or disposed of after immunization sessions. Equipment and sites must be cleaned and maintained for their next use.

Discard or store opened vials depending on vaccine type Refer to national policy on open multi-dose vials and act accordingly; WHO multi-dose vial policy is included in Module 2 (The cold chain).

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

1. Pack the vaccine carrier. Check the water packs to make sure that the ice has not melted. If conditioned water packs have completely melted and/or the thermometer in the vaccine carrier shows a temperature above +8 °C, all vaccines inside the vaccine carrier should be discarded unless they have VVMs that show they are still safe to use, so check each vial.

Place unopened vaccines and opened vials 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.

2. Return vaccines to the refrigerator. Return vaccines with acceptable VVMs to the use first box in the refrigerator. If the conditioned water packs in the vaccine carrier have melted during the trip back to the health centre, discard the vaccine vials unless the VVMs indicate that they are safe to use. Put the water packs from the carrier into the freezer and record the temperature of the refrigerator.

3. Clean the vaccine carrier. Wipe the carrier with a damp cloth and check it for cracks. Repair any cracks with adhesive tape and leave the carrier open to dry.

4. Return other supplies. For example, place immunization registers, unused AD syringes and immunization cards in their designated storage areas.

5. Dispose of used vaccine vials and injection equipment safely. Safety boxes containing used needles and syringes must be disposed of properly, see Module 3 (Ensuring safe injections).

6. Leave the site clean and tidy.

Specifically after using an outreach site:

Do not leave anything behind that might be a health threat to the community.

Clean and return tables, chairs and other equipment to their owners.

Thank the local people who have helped to organize the session and remind them of the date of the next session.

6.2 Prepare a summary of the session

Calculate total numbers of vaccines given, supplies used and stock remaining for inclusion in monthly report data, as described in Module 7 (Monitoring and surveillance).

6.3 Prepare a defaulter tracking list

At the end of each session, use the immunization register and/or reminder cards to make a list of children who were due for vaccines but did not attend the session. The format for the list is shown in Module 7. The list should be used for defaulter tracking and for program monitoring

activities (as described in Module 7). Inform community members who help with defaulter tracking of the infants on the list; ask them to mobilize the defaulters for the next immunization session.

#### 7. Using the immunization session checklist

Figure 5 shows a checklist that can help ensure safety before, during and after immunization. This checklist is a reminder of key points in preparation, vaccination and closure of sessions that are described above, and is meant to reinforce positive actions.

Health workers should be familiar with national immunization schedules, vaccine administration, waste disposal, data collection and other details of standard operating procedure from relevant national program documents and be able to quickly recognize and complete the checklist items. A printed copy of this checklist can be posted on a wall in the immunization area for easy viewing throughout sessions.

#### Figure 5: Immunization session checklists



# **Exercises**

#### Exercise -1

Discuss in group in plenary the importance of immunization card

Why immunization card is important?

How do you explain its importance to mothers/care takers?

What immunization, if any, each of the following clients is due to receive?

A new born

A ten months child who has had BCG, OPV3, DPT-HepB-Hib3

An eight months old child who has had BCG, OPV3, DPT-HepB-Hib3

A six weeks old child who has had BCG and OPV-0

A five weeks child who has never been immunized

A 20 years old woman who has never received TT immunization

A four weeks old child who had received BCG at birth but has no scar

What immunization can you give on the same day to an 11 months old child who has never been immunized?

#### Exercise - 2

#### The date stamp

Fozia and Belay, the two health extension workers run outreach sessions once a week in a crowded market neighbourhood to the village health post. Belay registered clients, weighing the children and decides which vaccine or vaccines a client should take. He then writes the date in the corresponding space or spaces on each client's immunization card.

Fozia examines the card and gives the vaccine or vaccines indicated by the date recoded in the immunization card.

One day, three children with measles came to the health post for treatment. Belay examines their immunization cards and finds that they all have record for measles immunization. He asked the parents whether their children have taken measles vaccine on the date indicated in the immunization card. One of the mothers says she left the outreach site without her child getting the injection, because, she was late for cooking lunch for her family. The second child received Penta 3 in the same day and his mother says that she did not know whether the child needed another vaccine. The third child mother could not remember what was happening.

Find out why these three children missed the vaccination.

Identify possible ways to prevent such events

#### Exercise -3

#### The sick child

Anneny's was brought by her grandmother to the neighbouring health facility when she was six weeks old and she received OPV1, DPT-HepB-Hib1 vaccines. Three days later, Anneny became very sick and lost her consciousness. After a brief hospitalization, she recovered fully.

Subsequently, when Anneny was 11 month old, her mother brought her to health centre to be treated for a cold.

What would you do if you were a health worker in this health centre?

Exercise -4 Balguda is 6 months old. He has a common cold, anemia and is underweight.

Immunization history: BCG, OPV 0, OPV 1, OPV 2, DPT1-HepB1-Hib1 and DPT2-HepB2-Hib2,PCV 1,PCV2,Rota 1, Rota 2 given 6 weeks ago.

- a. What immunizations, if any, does Balguda need today?-
- b. When should he return for his next immunization?

**Exercise 5.**Sara is 3 months old. She has diarrhea with no dehydration Immunization history: BCG, OPV 0, OPV 1, OPV 2, DPT1-HepB1-Hib1 and DPT2 –HepB2-Hib2,PCV1,PCV2,Rota 1,Rota 2 given 5 weeks ago

- a. What immunizations, if any, does Sara need today?
- b. What immunization will she receive at her next visit?

c. After the next visit when should Sara return for next immunization?

**Exercise 6**. Halima is 20 years old and 20 weeks pregnant: Immunization history: TT 1 taken 2 years ago.

- a. What immunizations, if any, does Halima need today?
- b. When should she return for her next immunization?
- c. What immunization will she receive at her next visit?

# Module 7: Monitoring and surveillance

### About this module

This module describes how to collect and report data, and how to monitor PHCU performance using their own data. It also shows how PHCU can improve the performance of their service by identifying and solving problems, and incorporating the solutions as activities in their work plan.

This module covers the following topics.

- Basic monitoring tools: Immunization registers, immunization card, tally sheet, and system for tracking defaulter
- How to construct and use EPI monitoring chart, temperature monitoring tools (like the Fridge tags) and logs
- How to monitor performance and manage identified problems
- Factors for low immunization coverage and strategies to improve immunization coverage
- Calculation of vaccine usage rate and vaccine wastage rate
- Surveillance of VPD (Vaccine Preventable Diseases)

#### Learning Objectives:

By the end of this session, participants will be able to:

- Use and analyze immunization cumulative coverage monitoring charts and use of data for decision making
- Explain the importance of using data to monitor immunization performance based on the administrative data (HMIS)
- Use monitoring tools and forms for EPI and surveillance
- Identify action needed to improve immunization service

# **1**. Tools for monitoring

Every health facility needs a system of recording data for monitoring immunization services. Systematically and regularly recording the vaccinations given at each session and monitoring performance ensures that services meet coverage targets , identifies defaulters and helps to actively follow up all those who need to complete their vaccinations.

The tools required for effective monitoring include:

- 1. the immunization register;
- 2. the immunization card;
- 3. the tally sheet;
- 4. monitoring chart
- 5. the defaulter tracking list and tickler box
- 6. family folder

1.1 The immunization register

The immunization register is used to record the immunizations received by each child. It is a book or a form that stays in the health facility. Its main purpose is to keep track of the immunization services provided to each infant over time. It lists each infant on a separate line and is important for several reasons. It is the health facility's primary source of information on a child's immunization status and

needed vaccinations. This information is particularly helpful if an infant attends for a follow-up visit without her/his immunization card.

It helps identify infants who miss scheduled vaccinations and who need to be added to the defaulter tracking list.

It is a source of data for monthly and other reports.

Health facilities may keep separate registers for each community that they serve; they may also use specific registers for outreach activities and/or children who present from outside their catchment area.

#### What information should be included in the immunization register?

The revised immunization and growth monitoring register contains the following information shown in table 49.

The immunization register can also be used as a birth register. As soon as an infant is born in the community, her/his name can be entered in the register. If the infant is not yet given a name, name of the mother should be recorded in the registration book. This will help to follow up new infants along with older ones on the defaulter tracking list.

**Table 49**: Instructions for infant immunization and growth monitoring registration at all facilities(Location information to be completed at front of register)

		Address			Date	e imm	unizat	ion			Polic	D		Rota			
													٨d	R1	R2		
														-			

Region	Write the region where the facility is located
Woreda / Sub-City	Write the Woreda/sub-city where the facility is located.
Kebele	If Health Post, write the name of the kebele where the Health Post is located.
Name of Facility	Write the name of the health facility where the EPI and GM services are provided.

Register begin date	Enter the date of the first entry in the register, written as (EC) Day / Month / Year (DD/MM/YY)
Register end date	Enter the date of the last entry in the register, written as (EC) Day / Month / Year (DD/MM/YY)

Datum	Comments					
Identification: Personal informati	ion					
Serial Number	Sequential serial number in registration book; to be entered on client's registration card for later identification in register					
Medical Record Number (MRN)	Unique individual identifier used on medical information folder, fills only at HC and hospital.					
Name of infant	Write the name of the infant					
Date of birth*	Infant's date of birth, written as (EC) Day / Month / Year (DD/MM/YY)					
Sex	Child's sex: <i>M</i> =Male; <i>F</i> =Female					
Name of mother	Write the name of the mother					
Mother's Medical Record Number (MRN)	Unique individual identifier used on mother's medical information folder, fills only at HC and hospital.					
Identification: Address						
Woreda	Write the Woreda					
Kebele	Write the kebele					
Ketene / Gott	Write the Gott or ketene or village name					
House No.	Write the house number					
Immunization services: Registrati	ion					
Registration date	Date infant registered in this registration book, written as (EC) Day / Month / Year (DD/MM/YY)					
Immunization services: Antigens	Received					
BCG	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)					
OPV0	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)					
	Identification: Personal information         Serial Number         Medical Record Number (MRN)         Name of infant         Date of birth*         Sex         Name of mother         Mother's Medical Record         Number (MRN)         Identification: Address         Woreda         Kebele         Ketene / Gott         House No.         Immunization services: Registration         BCG					

SN	Datum	Comments
15	OPV1	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
16	OPV2	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
17	OPV3	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
18	IPV	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
18	DPT-HepB-Hib1	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
19	DPT-HepB-Hib2	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
20	DPT-HepB-Hib3	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
21	PCV1	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
22	PCV2	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
23	PCV3	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
24	Rota 1	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
25	Rota2	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
26	Measles	Date antigen received, written as (EC) Day / Month / Year (DD/MM/YY)
27	Fully immunized by first birthday	Tick if child completes full series of immunizations by first birthday
	Neonatal tetanus protection	
28	Mother received 2 doses of TT in last pregnancy	Tick if mother received 2 doses of TT in last pregnancy (Quality check for PAB in column 25: either column 23 or 24, but nor both, should be ticked if PAB (column 25) is ticked.)
29	Mother received a total of 3 or more doses of TT	Tick if mother received a total of 3 or more doses of TT (See note on column 23 for purpose of this column.)

SN	Datum	Comments						
30	Protected from neonatal tetanus at birth (PAB)	Tick if newborn protected against neonatal tetanus at infant birth**						
	Associated Services							
31	Date growth monitored	Date growth monitored, written as (EC) Day / Month / Year (DD/MM/YY)						
32	Weight in kilograms	Weight in kilograms						
33	z-score of WFA	Z-score of the weight-for-age						
34	Vitamin A received	Date Vitamin A received, written as (EC) Day / Month / Year (DD/MM/YY)						
35	Remarks	Moved / died / other comments						

\* If date of birth is not known, the health worker should estimate it based on age in months and date of registration as follows.

Step 1: Ask the mother/care taker age of the infant in months (m0)

Step 2: subtract the number of months (m0) from the month of registration (m1)

Step 3: Add the date of registration (d1) to the calculated month (m2)

Example: the date of birth a 4 months old infant who was registered for vaccination on Mesmerism 16/2007 EFY can be estimated as follows:

Age in months= 4

Subtract 4 months (m0) from Mesmerism which will be May 2006

Add 16 days on May, and then the date of birth is 16 May 2006EFY

\* \*The EPI program defines the Protection at birth (PAB) indicator as follows:

#### a) Computation of PAB

The TT2+ indicator works well when coverage with TT is relatively low. However, as TT coverage increases, fewer women will need to receive TT (they are already protected) so the numerator will go down, but the denominator (births) will not. This will lead to an incorrect estimate of program performance. One way to avoid this problem is by using the protection at birth indicator. This indicator measures the percentage of infants who were protected from NT at birth by the immunization of their mothers with TT before the birth.

Percentage of protection at birth = <u>No. of infants whose mothers had protective doses of TT X 100</u>

Total live births

b) How to measure protection at birth (PAB)

The best way to measure this indicator is during the first visit of the infant for its DPT1 dose. Ask the mother accompanying the infant if she has a TT record card. If she has not, ask if she can remember receiving doses of TT during pregnancy. You can consider that the infant was protected from NT at its birth (PAB) if the mother has received protective doses:

Ideally, PAB questions should take into account all doses received as well as intervals between these doses based on the table below.

#### Table 50

Dose	Interval	Duration of protection			
One dose	Any child bearing age women with no evidence of primary immunization	None			
Two doses	One month after the first	3 year			
Three doses	6 months after the second	5 years			
Four doses	One year after third	10 years			
Five doses	One year after fourth	For the whole child age			

Where this is not feasible: two doses of TT during the recent pregnancy with the second dose given at least two weeks before delivery or at least three or more doses of TT in the past.

#### How to complete an immunization register

Infants should be registered as soon as they arrive at the health facility or outreach site. Fill in all information except the space provided for vaccinations. Vaccinations should be marked only after being administered.

Use a unique identification number on the register for each infant and write the same number on the immunization card. A unique identification number is easier to locate in the register if the immunization card is available during follow-up appointments.

Do not create a new entry in the register each time the mother brings the infant for immunization. Ask the caregiver for the immunization card and look for a corresponding entry in the register.

If the immunization card is not available, ask the caregiver for the child's name, age and the month and/or other details of the first immunization, then locate her/his line in the register.

For every new infant (never immunized), create a new entry in the register and a new immunization card. For an infant who has come to the health *facility for the first time but has received immunizations in another facility, create a new entry in the register, ask for the immunization card and write immunizations that the infant has already received in the register.* 

If there is no documented evidence if vaccination for eligible child, the immunization schedule should be started again.

#### Key points

Fill in all information on the register line for each infant.

Mark vaccinations in the register only after they are given to the infant.

When an infant returns for a follow up visit, find the register line for the infant using the immunization card (or the infant's name and age and/or month of first vaccination if the card is not available).

#### 1.2 The immunization card

The infant immunization card is used to record the immunizations a child has received. It may be a separate document or part of a general infant or mother/child health record, such as a Road to Health Card or Child Health Booklet, and is important for several reasons:

it serves to remind caregivers to return to the clinic for the next dose(s) of vaccine(s);

it helps the health worker determine an infant's immunization status;

it is useful when health workers conduct coverage surveys

it serves as a document of vaccination for school entry

it has key messages on child and maternal health care

Serves as a document for international travel

Serves for growth monitoring follow up

Serves as the only document of vaccination when parents move.

#### Key points

Remember that the immunization card may be the only record of immunization status available for health workers if registers are not well maintained or if families move from one health facility to another.

Each infant should have a card with vaccinations marked correctly.

Review Module 5 for the process of filling and explaining the card to caregivers during the immunization encounter.

#### What information is commonly included on an immunization card?

An immunization card usually includes the following information:

unique identification number (which is the same number written in the immunization

register as shown in Figure 2 and 3 below;

infant' s name;

infant' s birth date;

infant' s sex;

name and address of caregiver(s), including mobile/phone number if available; date, dose and lot number of each vaccine given; date and dose of vitamin A supplementation given, if applicable; PAB status (infant protection at birth from neonatal tetanus); date, dose and lot number of each TT vaccine given to the mother due date for next immunization(s); National immunization schedule;

Growth monitoring chart.

The infant's caregiver should be reminded to keep the immunization card in a safe place and to take it to all immunization and other health care visits.



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# Figure 3: Immunization Card for Women

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How to use an immunization card

Complete the card by writing down the date for each vaccine administered or vitamin A supplement given. Include doses of TT given to the mother if she is eligible and the card has space to enter it (there may be a separate women's immunization card).

Mark the next appointment date on the card and tell the caregiver when and where to return for the next vaccination.

#### **Key points**

Remember to mark the next appointment date on the immunization card. Make sure that the appointment corresponds to a planned immunization session.

Inform the caregiver of the next appointment verbally as well as in writing on the card.

Always return the immunization card to the caregiver. Remind the caregiver to keep the immunization card in a safe place and to take it to all health care and immunization visits.

#### 1.3 The tally sheet

Tally sheets are forms that are marked every time a health worker administers a dose of vaccine. They are used to monitor performance and complete monthly reporting.

A new tally sheet should be used for each session, and tally sheets should be kept for at least three years.

#### What information is commonly included on a tally sheet?

Tally sheets record vaccinations actually given by marking them after an infant receives a dose. The dose is recorded in the immunization register, family folder and on the immunization card and the caregiver is informed of which vaccinations were given.

#### How to use a tally sheet

Mark the tally sheet next to the dose received (there are various ways of making tally marks, for example: |||| ). Tally sheets with preprinted symbols that can be marked through may help to ensure more accurate counting of totals for reports .

If preprinted sheets are not used, all vaccinators in a health facility should use the same type of tally marks to make it easier to count the totals.

After vaccinating an infant (who is by definition less than one year of age), place the mark in the column headed "Age <1 year". After vaccinating an older child, place the mark under "Age >1 year".

If a dose of vitamin A is given, mark it on the tally sheet.

Use tally sheet for each session and At the end of each reporting month , add up the number of marks recorded during the sessions. This gives the total number of immunizations given in the month with each antigen and each dose in its series.

Keep the tally sheet for the supervisor to review. Table 51 describes some common errors in tallying.

The specific format of the tally sheet depends on the vaccines that are included in the national immunization schedule. HPV and other vaccines given to older age groups may be recorded on separate tally sheets.

#### Table 51: Common mistakes in tallying

Mistake in tallying	Possible problem that may occur	Correct practice
Tallying before the vaccination is given	The child may not receive the vaccination	Give the dose first then mark it on the tally sheet
Tallying at the end of a session according to number of doses contained in the used vials	Wasted doses may be counted	Tally each dose given (as above)
Tallying all vaccines under one age group (to include those outside the targeted age)	Will result in inaccurate coverage data	Separate tally for under 1 and over 1 year old

#### Table 52: Immunization tally sheet for all vaccines

#### **EPI Immunization Tally**

Woreda:\_\_\_\_\_\_ Facility:\_\_\_\_\_\_

Type of session: 2 static 2 outreach

Year:\_\_\_\_\_ Month:\_\_\_\_\_

	doses given								
	tally	count	tally	count					
Children immunizations									
ANTIGEN	Under 1 year		One year and older						
1. BCG									
2.1. Pentavalent 1									

2.2. Pentavalent 2						
2.3. Pentavalent 3						
3. 1 OPV 0						
3.2 OPV 1						
3.3 OPV 2						
3.4 OPV 3						
IPV						
4.1 PCV1						
4.2. PCV2						
4.3 PCV3						
5.1 Rota 1						
5.2 Rota 2						
6. Measles						
7. Fully immunized						
8. Protected at Birth from						
Neonatal Tetanus (PAB)						
Women of reproductive age						
9.TT						
all doses (TT1-TT5)						
pregnant and non-pregnant						

tally the dose immediately after giving it

equals 5

equals 8

# 2. The defaulter tracking system

The term "defaulter" refers to individuals who miss scheduled vaccinations for any reason, including health facility problems, such as cancelled sessions or vaccine stock outs. Defaulters need to be followed up and mobilized to attend the earliest available session, since the goal is to complete any missed vaccinations.

#### Finding defaulters and vaccinating them using reminder cards (tickler card)

Reminder cards are copies of infants' immunization cards that can be filed in a box by the month when the next vaccination is due (see Figure 47). For example, when an infant receives pentavalent1 in January, mark it on the reminder card and place the card behind the February divider, since this is when pentavalent2 is due.

In February, if the infant receives pentavalent2, update the reminder card and place it in the March section when pentavalent3 is due. If the infant does not come for pentavalent2 in February, or does come but does not get vaccinated (due to stock-outs or other reasons), the card will remain in February. At the end of each month, review all the reminder cards remaining and add the names of the infants who have missed vaccinations to the defaulter tracking list.



Reminder cards are copies of infants' immunization cards that can be filed in a box by the month when the next vaccination is due (see Figure 5). For example, when an infant receives pentavalent1 in January, mark it on the reminder card and place the card behind the February divider, since this is when pentavalent2 is due.

In February, if the infant receives pentavalent2, update the reminder card and place it in the March section when pentavalent3 is due. If the infant does not come for pentavalent2 in February, or does come but does not get vaccinated (due to stock-outs or other reasons), the card will remain in February. At the end of each month, review all the reminder cards remaining and add the names of the infants who have missed vaccinations to the defaulter tracking list.

#### Preparing Defaulter tracking list

# Defaulters can be listed by reviewing different immunization records. Two suggested methods are:

A tracking list, such as the one shown in Table 53, should be filled in after each immunization session or at least monthly as described below. It should be given to the person(s) tasked with finding defaulters.

#### **Table 53** Defaulter tracking list examples

Date:\_\_\_\_\_

Health cent		Ca						
S/No	Infant's name	Care name	giver's	Caregivers information	contact	Age months	in	Vaccinations needed
1								
2								
3								
4								
5								
6								
7								

#### Listing defaulters from the immunization register

At the end of each month, review the immunization register to identify infants who may have failed to receive vaccinations when due. For example, in March check to see that any infant who received a pentavalent1 dose in February returned for pentavalent2 (in March) when it was due.

Add the names of any infants who missed vaccinations to the defaulter tracking list. Names should be listed for tracking and follow up as soon as possible after a missed appointment.

#### How to use the defaulter tracking list

The defaulter tracking list will be effective only if every infant receives vaccinations that are overdue. Listing defaulters regularly every month makes it easier to find them and follow them up. To follow up defaulters, caregivers may be contacted directly (for example by phone or text messaging) or with the help of other community members.

#### **3. Reporting EPI**

EPI activities should be reported on a monthly basis to the next higher levels. Copies of reports with dates and signatures are sent to the next central level and the originals stored at the health facility. Health workers should ensure that reports are:

- Complete: All sections of the summary reports should be filled in and no parts left blank. All reports due from different services and/or outreach sites should be received and their data included in the summary report.
- Timely: All summary reports should be submitted to the next level before the assigned deadline. Summary reports completed and submitted on time help to ensure prompt and effective disease control response.

- Accurate: All summary reports should contain figures that correspond to the actual figures from the health facilities and that are double -checked for correct calculations and totals.
- PHCU, District, zones, regions and national levels should keep track of the completeness and timeliness of reporting by more peripheral levels and remind them of missing or late reports. Timeliness and completeness of reporting should be used as an indicator for measuring the performance of health facilities. Each PHCU should conduct EPI specific data quality assessment on a monthly basis before reporting to the next higher level.

Figure 6: Example of monthly summary report form at health facility level

ZONE	_	WOREDA									MONTH				
		YEAR													
	Vaccir	nation		IATION AND VITAMIN A GIVEN TO											
Health Unit	Site			UNDER	DER ONE YEAR CHILDREN										
	Static	Out	BCG	Measles	HepB-Hib			POLIO				Fully		Vitamin	
	Reach			1	2	3	0	1	2	3	Vaccinated PA	AB			
											_				
											_				
											_				
Total															
Other age groups (12-24 months)															
Grand Total															

		VACCINATION AND VITA	AMIN A
No	Health Unit	GIVEN TO WOMEN	
		NON PREGNANT	PREGNANT

1								Vitamin							Vitamin
		TT1	TT2	TT3	TT4	TT5	TT2+	А	TT1	TT2	TT3	TT4	TT5	TT2+	A*
	Total														

Though vaccine preventable modifiable diseases are reported to PHEM suing a prepared reporting format is customary to include this table on VPD in the EPI reporting

Compiled V	Compiled Vaccine Preventable Disease Report														
Target	Total	Age			Sex	(	Vaccination								
disease		<1	1-4 Year	>5	Μ	F	Dos	es				Vaccination	Number		
		year		year								status	of		
							0	1	2	3	3+	unknown	deaths		
Polio/AFP															
NNT															
Measles															
Diphtheria															
Pertussis															
Other VPD															

Figure 7: Monthly summary report example, page 2

Stock Report			
ITEM	Start Balance	Received Balance	End Balance
Penta			
PCV			
OPV			
Rota			
Measles			
BCG			
ТТ			
IPV			
Other			
AD Syringe Other			
AD syringe BCG			
Myxing syringe			

AEFI reporting report (rep	ort serious AEFIs								
immediately to your supervisor for further									
investigation)									
Type of Event	No of cases								
Serious events (A)									
Non-serious events (B)									
Total (A+B)									
Additional comments if any									

Safety box			
Vaccination card			
Notable Activities	During the	Reporting P	eriod
(Supervisory \	/isits, tr	ainings, s	social
mobilization activ	itiues)		

Date of report \_\_\_\_\_

Name of reporter

Designation\_\_\_\_\_

Signature\_\_\_\_\_

# 4. Archiving data and reports

For purposes of verification and retrieval, data must be stored at each different level. Data can be stored in hard copy or electronically. At the health facility, tally sheets, registers and reports should be stored for a specific period (on average three years). Where higher administrative levels use computers, back-ups (hard copies and/or electronic copies) must be kept to avoid data loss in the case of system failure. Stored records are also useful for supervisory visits and immunization service reviews.

#### Types of data to store

The following types of data should be stored at each health facility for a period of three years or as long as required by national policy.

- ✓ Immunization registers
- ✓ Tally sheets
- ✓ Defaulter tracking lists
- ✓ Monthly reports
- ✓ Target population data files (information used in Micro planning see Module 4)
- ✓ Immunization monitoring charts (see next section)
- ✓ Case/outbreak charts and reports
- ✓ Supervisory visit reports
- ✓ Stock cards
- ✓ Cold chain maintenance records

# 5. Analysis of monitoring data

Data collected and summarized in reports are useful only when analyzed and interpreted regularly and used to improve service delivery. This section describes the initial analysis of monitoring data that begins at health facility level.

#### 5.1 Vaccination coverage charts

Creating a chart showing doses administered and dropout rates is a simple, effective way to monitor immunization service progress. This type of chart tracks monthly progress towards immunization service goals. The number of doses administered can be compared to the number of infants eligible to receive them,

and target population dropout rates can be calculated. The dropout rate compares the number of infants who completed the immunization schedule for a selected vaccine to the total number who failed to finish the course.

Every health facility should display a current monitoring chart on a wall where all staff can see it. Charts can be produced at every level of the health system by combining data manually or electronically. Figure 8 shows a completed monitoring chart.

#### How to make a monitoring chart showing doses administered and dropouts

Vaccine doses administered and dropout rates can be charted using the following steps

#### Calculate the annual and monthly target population who should receive immunization services

Aim to vaccinate every infant in the catchment area, including those who are hard to reach. Use existing population data for infants obtained from national statistics offices, ministry of health planning sections or community censuses. If data are not available, estimate the number of infants by multiplying the total population by 3% (or the percentage of infants in the population suggested by national/central authorities, if applicable). Always use the most precise percentage available; a measured, specific percentage for calculating the number of infants is preferred.

Data for peripheral health facility calculations are often difficult to find and more accurate targets can be set by: a) immunization staff and district supervisors, who may need to discuss and agree on target population adjustments based on local knowledge and past experience; and b) 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 number of infants calculated above divided by

12.

Example calculation: If the total population is 3900, then the annual target population of infants is 3900 x 3/100 = 117; and the monthly target is 117/12 = 10.

#### Label the chart and draw the ideal monthly target line

Complete the information on the top of the chart by adding the area and year.

Label the left (and/or right) side of the chart with the monthly target numbers.

Label the boxes at the bottom with the selected vaccine.

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.

#### Plot immunization data on the chart

Locate the space for the month being recorded in the row of boxes underneath the graph and enter the monthly total of vaccine given. Calculate the cumulative total for the current month as shown:

Note that cumulative means the total number of doses of vaccines given in the current month plus the monthly totals for 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.

#### Enter the current cumulative total on the right side of the month being recorded

Make a dot on the graph corresponding to the cumulative total recorded on the right side 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 immunizations 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)

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 117 infants in the annual target population received penta1, but only 100 finished all three doses during the year, then Number of dropouts = (117) - (100) = 17

Dropout rate = [17/117] x 100 = 14.5%



# 6. Analysis of immunization data to categorize the problem and prioritize intervention

Full analysis requires data to be compiled by area (Woreda, kebele, sub Kebele).

#### How to complete the compilation and analysis table

- 1. List each geographic area or community served in Column a.
- 2. List the target population numbers for infants less than one year of age in Column b.

- 3. 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. The vaccines used for analysis will vary by program.
- 4. Calculate immunization coverage as follows:

Immunization coverage is the total number of infants who have received all required doses of a selected vaccine in the preceding 12 months divided by the annual target population.

Example: Calculate annual Penta 3 coverage; given that Number of <1 year in the year is 117; number of infants received Penta 3 in 12 months is 100

Penta 3 coverage = (100)/(117) x 100=85%

5. Calculate the number of unimmunized.

Unimmunized number = (annual target population) – (doses of vaccine administered)

Example calculation for the table in Figure 51: unimmunized pentavalent3 in Column I = annual target population in Column b – doses of pentavalent3 administered in Column d = (117) - (85) = 32

6. Calculate the dropout rate.

Example calculation for the table in Figure 51: dropout rate pentavalent1- pentavalent3 = column k = (doses of pentavalent1 in column c) – (doses of pentavalent3 in column d)/(doses of pentavalent1 in column c) x 100 =  $(105) - (85)/105 \times 100 = 19\%$ 

7. Identify and categorize problems for each area.

In Column m, enter the quality of access (good = coverage 90% or better; poor = coverage less than 90%) based on pentavalent1 coverage in Column f.

Note that the 80/90% cut-off is suggested here as a general indicator and regions with low baseline coverage may use 80% cut-offs to define good and poor coverage.

In Column n, enter the quality of utilization (good = dropout rate less than 5%; poor = dropout rate 5% or more) based on the pentavalent1–Pentavalent 3 dropout rate given in Column k.

Note that regions with high base line dropout rate can use the 10% cut-off. Negative dropouts should be considered as poor quality of utilization.

In Column o, use your data to prioritize communities for problem solving. Rank the community that has the most unimmunized infants (not necessarily the lowest coverage) as the highest priority (#1) Figure 9 illustrates this principle.

Table 54 Sample format for compilation and analysis of health facility data (Compilation of immunization coverage data for a given period Analysis of problem)

#### Table 54 coverage data

	Compila	tion of imm	unization co	overage dat	ta for the p	revious 12 r	months	Analysis of problem						Prioritize - highest number of	
Community name	Annual target population	Doses of vaccine administered			Immuni	Immunization coverage (%)			Unimmunised (number)		rates (%)	Identified problems		penta3 unimmunized children is	
	children <u>≤</u> 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)	Utilisation (good, poor)	#1, and so on	
а	b	c	d	e	f	g	h	i	j	k	1	m	n	0	



Figure 9. Access and utilization problem analysis flowchart and graph

 Table 55: Prioritizing PHCUs according to total unimmunized infants (completed example using measles vaccine coverage)

District	Population	Population	Measles Coverage	Unimmunized	Priority
Name		under 1 year	under 1 year	infants	
А	100,000	4,000	50%	2,000	2
В	75,000	3,000	60%	1,200	4
С	120,000	4,800	70%	1,400	3
D	10,000	400	20%	320	5
E	250,000	10,000	75%	2500	1

# 7. Improvement of services

Problems can be broadly associated with access and utilization and the categories in Figure 9 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 infants missing immunization sessions and may be due to:

- Sessions not being held as planned;
- Session site and times being inconvenient or not known;
- Cultural, financial, or other barriers preventing access to and use of immunization services
- Geographic access problem

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

- Poor IPC skill of service provider; caregivers' lack of information about the complete immunization schedule;
- missed opportunities for vaccination such as not checking immunization status during visit to Under 5 OPD, false contraindications ,lack of daily service
- other problems leading to caregivers not returning due to vaccinations not being given as expected, for example supply shortages, delayed doses due to incorrect assessment of contraindications or other problems in the relationship between health workers and the community.

The Micro planning process includes identifying possible solutions as described in Module 4.Discussion should occur at community and health facility level, and also at PHCU or higher levels as needed. Solutions should be prioritized for implementation. Those that affect district level should generally come before those that affect more local levels. At any level, changes are likely to be more feasible when implemented with available resources.

Supervisory visits from more central levels can also be helpful in identifying problems and solutions. Annex 2 shows an example checklist for such visits.

#### 8. Vaccine usage and wastage patterns

The usage and wastage of vaccine will vary greatly from one session to another. It is useful to monitor these patterns regularly at all immunization points to improve supply and avoid stock-outs. Stock cards provide the data for this part of the summary report.

The number of vaccine vials in stock at the start of the month (Start balance), the number received during the month (Received) and the number of vials in stock at the end of the month (End balance) should be entered into the corresponding boxes in the form.

Vaccine stock data should be recorded and reported regularly, since this information may be needed at the Woreda level. The stock monitoring book (vaccine and EPI supply recording book) can be used in vaccine usage and wastage calculations, as shown below. Note that the formula shown uses the number of doses. The stock monitoring book may track only the number of vials. In this case, the number of doses can be calculated by multiplying the number of vials by the number of doses per vial.

Vaccine usage rate (%) =

# infants immunized during the period

((# usable doses + # doses received) at the beginning of the period))-(# usable doses in stock at the end of the period)) / 100

Vaccine wastage rate (%) = 100 - (vaccine usage rate)

#### Specific problems encountered during the reporting period

A narrative description of any problems, such as stock-outs, transportation problems, cold chain failure, etc., should be added as needed to prompt review and improvement of service-related issues.

# 9. Vaccine Preventable Diseases Surveillance and Tools for Surveillance

Definition of surveillance: Disease surveillance is the systematic collection; coalition, 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 the diseases.

Disease surveillance is used to:

Predict or detect disease outbreaks with a view to investigation and control.

Identify high-risk populations and areas requiring special attention.

Monitor impact and progress towards disease eradication, elimination and control.

Identify areas in which system performance is poor, so that corrective measures can be taken.

Determine the frequency and magnitude of a health problem in the community.

Monitor Program effectiveness by documenting short- and long-term effects of immunization on disease burden and epidemiology; and

Identify circulating strains including serotypes, genotypes and subtypes.

There are different types of surveillance and the type of surveillance for a specific vaccinepreventable disease depends on the attributes of the disease and the objectives of the disease control Program —controls elimination or eradication.

Passive surveillance: regularly reporting of disease data by all institutions that see patients (or test specimens) and is part of a reporting network. It relies on the cooperation of health-care providers; laboratories, hospitals, health facilities and private practitioners; that report the occurrence of a vaccine-preventable disease to a higher administrative level.

Sentinel surveillance: this approach is used when high-quality data are needed about a particular disease that cannot be obtained through a passive system. Selected reporting units, with a high probability of seeing cases of the disease in question, good laboratory facilities and experienced well-qualified staff, identify and notify on certain diseases. It involves only a limited network of carefully selected reporting sites.

Active surveillance involves visiting health facilities, talking to health-care providers and reviewing medical records to identify suspected cases of disease under surveillance.

Active surveillance is more difficult to set up and expensive to carryout and does not replace passive surveillance but rather complements it.

The term 'active search' is used to describe searches for cases in a community.

#### **Surveillance function**

There are core and supporting functions of a surveillance system

The core functions: are detecting cases based on the case definition, recording it on the recording form, reporting the cases to those concerned in investigating cases and confirming the diagnosis, analyzing the data to describe and characterize the problem, and thereby provide feedback and feed-forward

The support functions of a surveillance system are: preparing a guideline ,standard formats for the reporting, training health workers on what and how to report, providing logistic support and communication means, allocating the necessary resources for doing the monitoring and evaluating surveillance system using the prepared monitoring and evaluation indicators

#### Diseases target for surveillance in Ethiopia.

Nationally there are 23 modifiable diseases including important VPDs, these diseases are divided in to immediately and weekly reportable diseases are identified for reporting by the PHEM program., all of them are weekly reportable but 13 of them are also immediately reportable. Case based forms are available for immediately reportable diseases integrating all of them. There is also weekly reporting format for all of the 23 prepared by PHEM.

**Zero reporting:** If there are no cases of a disease during the reporting period, the number zero should be reported in the summary. This is called zero reporting and is important, since it shows an absence of cases presenting to the health facility rather than a forgotten point in data collection

#### Table 56: Diseases under surveillance

Weekly Reportable Diseases
All the diseases mentioned in immediately
reportable diseases and the following
1. Dysentery
2. Malaria
3. Meningitis
4. Relapsing Fever
5. Typhoid Fever
6. Typhus
7. Malnutrition

The main tools used for surveillance in health facilities are:

the vaccine-preventable diseases or integrated communicable diseases tally sheet;

the disease-specific case investigation report form;

weekly PHEM reporting form

the line list;

The AEFI report form.

#### 9.1. The vaccine-preventable disease tally sheet

Vaccine-preventable disease cases should be tallied when they are seen at a health facility or outreach site. The total number for each type of disease should be added for reporting to central levels. This is often done monthly in a summary form.

#### What information is commonly included in a vaccine-preventable disease tally sheet?

The vaccine-preventable diseases included in the tally should match the list of diseases that must be reported to national or central authorities. A case definition for each disease on the list should be obtained from national or central level to help make the reporting more accurate. Age, sex and vaccination status of the patient are usually required. Health center consultation registers should be adapted as needed to allow space for this and/or other information required by national authorities.

9.2 The line list

During specific disease outbreaks, suspected cases may need to be listed individually, with details of the history including immunization status and management of each patient.

#### How to use a line list

After determining that a case meets the standard case definition of a reportable disease, start with the case identification number and fill in all the items across the line for that case. The format of the line list may vary by disease and disease control activity requirements, but the column headings should be a guide to filling it in correctly.

#### Table 57: Health center level measles line list example

Health Facility: XY Health Center\_

Woreda/Zone: BL/GE

Month: February-March

Year: \_\_\_\_

Region:

ID No	Kebele / Town	Nam e	SEX	Age( montl Year	Year + hs) mont hs	Date of onset of rash	No. of valid measles doses (0,1,2,99)	Lab .Sp Blood taken Yes/N o	ecimen Results Pos /Neg	Outcome 1=Alive 2= Dead 9=Unknow n	Commen ts
1			м	13	2	2/20/20 12	0	Yes	Pos	1	
2			F	25	0	2/20/20 12	0	Yes	Pos	1	
3			F	19	6	1/12/20 12	0	Yes	Pos	1	
4			F	15	0	1/13/20 12	0	No		1	
5			м	6	4	1/13/20 12	0	Yes	Pos	1	
6			м	1	8	2/15/20 12	0	Yes	Neg	1	
7			м	6	5	2/15/20 12	0	No		1	
8			м	6	9	2/15/20 12	0	No		1	

(Use this form if there are more than 5 cases of suspected measles cases seen in a health facility in a village in 1 Week. This indicates that an Outbreak may be occurring. Include the first 5 cases on this form)

# **10.** Analysis of surveillance data

Just as monitoring data are useful only when they are regularly analyzed by person time and place for the purpose of improving service delivery, disease surveillance and AEFI data collected and summarized in reports are useful only if regularly analyzed and interpreted to guide disease control activities. In fact, surveillance data may need more immediate reporting and analysis. Initial analysis of surveillance data that begins at health facility level is described here.

#### 10.1 Vaccine-preventable disease case number charts

The objective of surveillance is to report vaccine-preventable diseases according to national protocol; reports may be required immediately weekly or as needed for outbreak response;

Surveillance information , In addition to predicting or detecting outbreaks, identifying high-risk populations or areas and monitoring the impact of immunization services, surveillance data can highlight system weaknesses, determine disease burden in a community and document circulating strains of pathogens.

Case numbers can be presented in graphs for display in the health facility. Trends in disease occurrence (usually incidence) are easy to visualize and compare to immunization data in this format. Keeping updated graphs will allow comparisons between seasons and years and alert to any increases in the number of cases or other relevant trends.

#### How to make a surveillance chart showing the number of cases per month



#### Figure 10:Number of measles cases reported per month

#### 10.2 Analysis of vaccine-preventable disease data

Surveillance data can be used to show trends of an outbreaks, as in the example above. analysis of the cases may include a breakdown of cases by area or by age and sex to better identify those at high risk and to define a targeted response. This type of analysis is often conducted at district or more central levels, but can begin with individual health facility data.

Cases can be marked on the district and health center catchment area maps prepared for Micro planning, as described in Module 4.



Figure 11: Example of a catchment area map showing origins/places of residence of measles
Each 'x' represents one case

Table 58 shows the age and sex distribution of cases during an outbreak in a certain area. This is useful for evaluating an unidentified disease or an unusual pattern of a familiar disease, for example, measles cases occurring in older age groups.

Age	0-5m	6-11m	1-4 yr	5-9 yr	10-4yr	15-4yr	yr	65+ yr	Total
Male	1	1	0	0	5	26	15	3	51
Female	2	2	0	0	6	35	15	5	65
Total	3	3	0	0	11	61	30	8	116

Table 58: Age and sex distribution of cases in a disease outbreak

Case data can be compared with immunization data to illustrate disease patterns or evaluate the impact of control activities. This is usually done over a longer time frame and from district or higher levels using population-level measures, such as incidence.

Accurately reported peripheral health facility-level data is needed throughout. Figure 12 compares measles case numbers (charted as incidence per 100 000 people) after immunization services were improved in a district and high coverage was maintained.


Figure 12: Comparison of measles incidence and vaccine coverage over time (district-level data)

Different surveillance related reporting and investigation formats are annexed at the end of this module (Annex 1-6)

## 11. Adverse Event Following Immunization (AEFI)

All vaccines used in national immunization Programs are generally safe and effective if used correctly. In practice, however, no vaccine is completely risk-free and adverse events can occasionally occur after immunization.

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with usage of the vaccine. Adverse events can range from minor side-effects to more severe reactions. AEFIs are grouped into five categories as described in immunization safety module.

Immediate investigation of a severe adverse event attributed to a vaccine, but not causally related to it, is critical in order to:

- respond to a community's concern about vaccine safety; and
- Maintain public confidence in immunization.

Part of the work of health professionals and regulatory authorities thus is to:

- Anticipate and evaluate AEFIs.
- Facilitate investigation and response to serious AEFIs; and
- Analyze the data if there is real increase in adverse events,

## 12. AEFI surveillance (Vaccine pharmaco-vigilance)

Vaccine pharmaco-vigilance is defined as the science and activities relating to the; detection, assessment, understanding and communication of adverse events following immunization and to the prevention of untoward effects of the vaccine or immunization. Like drug pharmaco-vigilance, vaccine pharmaco-vigilance aims to detect adverse events early to initiate accurate risk assessment

and prepare as appropriate response (risk-management) to the problem. This ensures minimizing negative effects to individuals and lessen the potential negative impact on immunization Programs.

12.1 Objective of AEFI surveillance

Identify problems with vaccine lots that lead to vaccine reactions caused by the inherent properties of vaccines.

Detect, correct and prevent immunization Programs.

Prevent false blame arising from coincidental adverse events following immunization.

Maintain confidence in immunization by properly responding to parent/community concerns, and increasing awareness about vaccine risks.

Generate new hypotheses about vaccine reactions that are specific to the population of specific areas; and

Estimate rates of occurrence of AEFIs in a given population compared with others and research situation thereof.

12.2. The components of AEFI surveillance:

Detection and reporting; Parents; health workers at immunization facilities and staff and emergency staff are most likely to recognize or detect AEFIs when they first occur. Health workers have the responsibility to detect AEFIs; report and treat or refer patients for treatment when necessary. *All vaccination staff must be able to diagnose adverse events.* Detection requires effective training to ensure accurate diagnosis of AEFIs based on clear case definitions and guidelines.

To ensure that reporting of adverse events is effective, Immunization Program managers must decide:

What should be reported? Who should make the AEFI report and to whom? How should reporting be done?

What is the route of reporting? When should AEFIs be reported? How do we improve/encourage reporting?

Any AEFI that is of concern to parents or to health care worker should be reported.

Table 59. AEFI Reporting form

Demographic detail

Name		_ sex	Date of birth//
Region	zone	wereda	l
kebele tell	gott/ketena	a	
Health facility	Name	of health work	er reported

Vaccine(s) given*	Route	Site	Dose 1 <sup>st</sup> 2 <sup>nd</sup> etc.	Lot number	Manufacturer	Expiry date

Date and time suspected vaccine given	Date and time AEFI started	Onset interval from administration	Date and time AEFI reported
// hh –- mm	// hh mm		// hh mm

Tick box(es) and describe event:	Symptom and sign :
□Seizure	
Danaphylaxis	
Toxic shock syndrome	
□ Abscess: sterile □ bacterial □	
□ Lymphadenitis: > 1.5 cm □ or draining sinus □	
$\Box$ Severe local reaction: > 3 days $\Box$ beyond nearest joint $\Box$	
or hospitalized 🗆	
□ Vaccine reaction on list (state):	
Other AEFI(state):	

Hospitalized	Yes / No date and time admitted	I							
*Outcome:									
Recovering,	Recovered, Recovered with sequel, Not	Recovered Unknown							
Died if died, date of death (DD/MM/YYYY): / / Autopsy done: Yes /No Unknown									
Past medic (e.g. other		ilar reaction or other allergies)	and any other relevant information						
	Reporter's Name:	Institution / Designation,	Department & address:						

Telephone & e-mail:

Woreda/Zonal level office to complete

Date report received:	Checked by:
Investigation needed:	If yes, date started
Investigator	AEFI investigation ID
Causality assessment:	Certainty:

Figure 13. General guides for AEFI reporting from health facility level

		Serious AEFIs.
		Signals and events associated with a newly introduced vaccine.
In particular, health workers should <u>report</u> :	$\mid$	AEFIs that may have been caused by an immunization error.
		Significant events of unexplained cause occurring within 30 days after a vaccination.
	$\mid$	Events causing significant parental or community concern.
		Swelling, redness, soreness at the injection site IF it lasts for more than 3 days or swelling extends beyond nearest joint.

12.3. What information is commonly included in an AEFI report?

An AEFI report usually contains the following information at a minimum:

AEFI reporting identification number;

patient's address (of her/his caregiver for children) and mobile/phone number if available;

reporter's address and mobile/phone number, if different from those of the patient or caregiver;

patient's date of birth;

patient's sex;

date and time of onset of AEFI;

description of the event and the outcome from the patient or reporter;

details of all vaccines given and diluents used, including generic and brand name, batch number and time of vaccination.

Serious AEFIs

Signals and events associated with a newly introduced vaccine; AEFIs that may have been caused by an immunization error; significant events of unexplained cause occurring within 30 days after a vaccination;

Events causing significant parental or community concern; swelling, redness, sore at the injection site if it lasts for longer than 3 days or swelling extends beyond nearest joint.

Investigation: Some AEFI reports will need further investigation. The purpose being to:

Confirm or propose alternative diagnosis and determine the outcome of the adverse event.

Identify specifications of implicated vaccine used.

Examine operational aspects of the immunization Program, in case they have errors

Detect additional cases AEFI cases/clustering; and

Compare background risk of adverse event (occurring in unimmunized people) to the reported rate in the vaccinated population.

## 12.4 Analysis of AEFI data

Health facility-level AEFI reporting can be compiled at district and more central levels for analysis by specific vaccine, for comparison with expected rates of adverse events in vaccinated and unvaccinated individuals, and to facilitate investigation and response to serious AEFIs.

Analysis of multiple AEFI reports can help health authorities clarify whether observed reaction rates are higher than expected and, if so, are more likely to be related to the vaccine than to coincidence. Comparisons of reaction rates are made with published studies if possible. But studies are often not ideal for comparisons. Data from AEFI reporting are important on vaccines being used in immunization programme.

## 12.5 Weekly summary reports

AEFI surveillance data collected with the tools need to be consolidated into a summary form, either manually or electronically, for transmission from the health facility to the Woreda level. Woreda compile data for use by and transmission to the next level, and eventually to central level.

**12.6 Causality assessment of AEFIs:** is the systematic review of data about an AEFI cases to determine the likelihood of a causal association between the event and the vaccine(s) given. It requires a team of investigators, including an immunologist or other experts, depending on the nature of the adverse event. Causality assessment helps determine; if an AEFI is attributable to vaccines or the vaccination Program, what steps – if any, need to be taken to address events. The later must be done by an independent body organized by the National Regulatory Authority and not connected with the immunization Program owners.

## 13. Exercises

## Exercise 1

A health centre serving a population of 10,000 with surviving infants of 3.6% has one static and three outreach EPI sites. The numbers of children vaccinated for measles in one month were 18 under one year (0-11 months old) and two 12-23 month old children. During the same month the health centre has received 10 vials of 10-dose measles vaccine from the district health office and another 5 of the same dose vials carried forward from the previous month. At the end of the same month it was find out that five vials were used for vaccinating children, three vials reported to be discarded because the ice melted during the outreach session, five vials were available at the end of the month in the refrigerator and nothing was known what happened to the remaining two vials.

- 1. List problems you noted in the above health centre
- 2. What is the measles coverage for under one- year children for the given month?
  - a. Is the coverage below 80%? If so list possible reasons
  - b. What actions would you take to improve the measles coverage?

## 3. What is the measles vaccine wastage?

- a. Calculate the vaccine wastage rate
- b. And what are the types of vaccine wastage?
- 4. What are the causes of the vaccine wastage?

## 5. What can the health centre do to decrease its vaccine wastage rate?

## **Exercise 2: Monitoring EPI performance.**

Health post serves a total population of 10, 000, where surviving infants constitute 3.6%. The number of under-one year children vaccinated monthly for DPT-HepB+Hib1, DPT-HepB+Hib3 and measles for the 2001-year is the table below.

Month	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
DPT-HepB+Hib1	20	45	10	30	28	25	30	27	33	36	30	10
DPT-HepB+Hib3	30	36	42	24	18	12	15	30	27	12	9	6
Measles	10	12	6	12	3	15	18	9	21	6	0	0

## Exercise 2-Q

A) Construct an EPI monitoring chart and plot the cumulative DPT-HepB+Hib1, DPT-HepB+Hib3 and measles graph

B) In the monitoring chart indicate the number of monthly and cumulative dropouts.

C) What were the DPT-HepB+Hib1, DPT-HepB+Hib3 and measles coverage for Balchi Health post for the year 1997?

What conditions would account for the above result?

## Exercise 3: Case based surveillance

Define the community and clinical case definitions for Measles, AFP and NNT

Describe all the steps you would take when you find a suspected case of measles an AFP

Define AEFI

Explain which AEFIs are immediately reportable and describe the steps you take when a severe AEFI is detected.

## **Exercise 4: Monitoring Indicators**

Assume you are assigned to a district with poor performance in the EPI program. What tools would you use to assess the;

Immunization service delivery operation

Communication for immunization operations

Vaccine quality and forecast operations

# Annexes

# Annex 1: Case based reporting format (CRF)

# **Case based Reporting Format (CRF)**

					Reporting WoredaZone   REGION:								
Disease type (put tick mark ✓ )	Anth	rax	Cholera	Me	asles	Meningitis		eonatal He etanus		lemorrhagic Fever		llow ver	Others/Specify
Name of Patient	t:	-	•										
Date of Birth (D	OOB):		/ /	(Day	/Month	/Year)		Age	(If DO	B unknown):	Ve	ear	Month (if <12)
Sex:		W	rite M for M	lale	F for F	emale						cui	Monut (II <12)
Patient's Addre	ess:	Ket	oele:					House	numb	er:			
Woreda:					Zone	:		Regio	n:				
Locating			ation when							Current locat	ion		
Information			ptom started		nationt	is neonate or	child	1 please	write	full name of m	other	r and fathe	er of the patient
Date seen at He	alth	11 4	pheable of			Ith Facility n			write	Date			
Facility:	unn		/ /		oreda/2		oum	cu	/	/	01 0	ibeti	/ /
Number of vaco	cine/TT	f dose	es received:							ļ.			e e e e e e e e e e e e e e e e e e e
Ī					For cases of NNT* , Measles, Yellow Fever, and Meningitis (For NNT, Measles,								
					Yellow Fever – refer immunization card & for Meningitis - ask history) *For NNT cases please complete the additional case investigation form								
Date of last vac	cinatio	n:			/	/							
				(N	NT, M	easles, Yellov	ow Fever and Meningitis only)						
						2= NO							
In/Out Patient 1=Inpatient					2=outpatient								
Treatment given 1=YES (specify)					pecify)	2= NO							
Outcome of the report	patien	t at tl	he time of	1=	Alive				2=De	ad		3=Unknov	wn

#### Fill only if specimen is collected and sent to Lab

Date of specimen collection:	/	/	Ι	Date of specim	/ /	
Type of specimen: (put tick mark ✓ )	Stool	Blood	Serum	CSF	Throat swab	Other/specify

Date form sent to Woreda: / / (Day/Month/Year - EC)

Name and signature of the person completing the form\_\_\_\_\_ Tel \_\_\_\_\_

For official Use only

ID Number	Date form received at National/Regional level:/ (Day/Month/Year - EC)						
Final Classification of case	1=Confirmed	2=Probable	3=Discarded	3=Discarded 4=Suspect			
Final Classification for Measles	1= Laboratory Confirmed	2= Confirmed by Epidemiological linkage	3=Clinical Compatible	4=D	iscard	5=Suspect	

Name and signature of the official	Date (EC)
------------------------------------	-----------

Name and signature of the official	Date (EC)	
and signature of the official	Date (20)	

## Annex 2: Detailed case investigation form

Modified IDS Case-based Reporting Format–NNT (additional information)\_

#### Official Use only Epid Number: \_\_\_\_\_-\_\_\_-

#### MOTHER'S VACCINATION HISTORY

Please use the following key, 1=Yes, 2=No, 9=Unknown\*, where applicable.

Query	Response
Mother vaccinated with TT?	
Have card?	
Number of doses:	
Vaccination status of mother prior to delivery? **	
Did the mother die?	



\*\*1= up-to-date, 2= not up-to-date, 9= unknown

#### **BIRTH OF INFANT**

#### Please use the following key, 1=Yes, 2=No, 9=Unknown\*, where applicable.

Query	Response	Query	Response
Mother received antenatal care?		Location of birth: ***	
How many prenatal visits?		If birth in institution, name of institution:	
Attended by a trained TBA/midwife?		Cut cord with a sterile blade?	
If attended by a trained TBA/midwife, give name		Cord treated with anything?	
Attended by doctor/nurse?		Describe treatment of cord: Where?	

\*\*\* 1=Hospital, 2=Health centre, 3=Home, trained attendant, 4=Home, untrained attendant, 5=Home, no attendant, 9=Unknown

#### **BABY'S INITIAL CLINICAL HISTORY**

Onset of symptoms: \_\_\_\_/\_\_\_/\_

#### Please use the following key, 1=Yes, 2=No, 9=Unknown;

Query	Response	Query	Response
Was baby normal at birth?		Did it have Spasms or Convulsions?	
Normal cry and suck during first 2 days?		Did it have Complications?	
Arched back?		Did the baby die?	
Stopped sucking after 2 days?		Age at death: in days	
Stiffness?		Age of onset in days:	
Tremors?			

Query	1=Y, 2=N, 9=U
Seen in OPD?	
Admitted?	

Date of admission \_\_\_\_\_/ \_\_\_\_/

Medical record number:

Name of health facility: \_\_\_\_\_

Health Facility Address:

RESPONSE

Please use the following key, 1=Y, 2=N, 9=U, where applicable.

Mother given protective dose of TT within 3 months of report?	
Supplemental immunization within same locality as the case?	
Date of response://	

Details of response: \_\_\_\_\_

INVESTIGATOR			
Name:		Title:	
Unit:	Address:		
Phone:			

# **Annex 3: Line Listing form Use during Outbreaks**

Health Facility:	Date received at Woreda/zone:
Woreda/zone/Region:	Disease/Condition:

Serial number	(O) Out/ /(I) In-Patient	Name	Kebele/ PA's Town, House No.	Sex	Age **	Date seen at health facility	Date of onset of	Blank variable	Blank variable	Blank variable	Specimen taken (Yes/No) If yes, date collected	Outc Lab results ome (A) Live (D)	Com men ts	
1														
2														
3														
4														
5														
6														

# **Annex 4: Weekly Report Form for Health Extension Workers**

Health Post		Woreda	
name		Woreua	
Kebele		Zone	
Start of week from (day) (month) (	,	<pre>&gt; Sunday///</pre>	

## 1. Record below the total number of cases for each disease/condition for the current week.

Indicator		Total Cases
Total Malaria (confirmed by RDT + clinically diagno		
Total malaria suspected fever cases examined by R		
Number of fever cases positive for malaria	P. falciparum	
parasites (by RDT)	P. vivax	
Meningitis (suspected)		
Bloody Diarrhoea		
Acute febrile illness (other than malaria and menin		
Severe Acute Malnutrition (MUAC < 11cm and/or	Bilateral Oedema in under 5 years children	
(new cases only))		

*RDT* = *Rapid Diagnostic Test; MUAC* = *mid upper arm circumference* 

## 2. Summary for Immediately Reportable Diseases/Conditions:

DISEASE	С	D	DISEASE	С	D	DISEASE	С	D
AFP/Polio			Fever + Rash			Haemorrhagic Diseases		
Anthrax			Neonatal Tetanus			Guinea worm		
Acute Watery Diarrhoea			Influenza Like Illnesses			Other (specify):		
Rabies			Other (specify):			Other (specify):		

C = case; D = death

Look at the trends, abnormal increase in cases, improving trends? Actions taken and Recommendations:

Date sent by Health Post: _	
Sent by:	
Tele:	

Date received at Woreda:	
Received by:	
Tel:	

# Annex 5: Weekly Disease Report Form for Outpatient and Inpatient Cases and Deaths

Health facility name and		10/2	oreda				
type			breda				
Zone		Re	gion				
Start of week from Monday		to	Sunday	/	/	-	
(day) (month) (Year in Eth	liopian Calendar)	(day) (month)  (	Year in EC)				

## 1. Record below the total number of cases and deaths for each disease/condition for the current week.

Indicator	Out - Patient In		In - Patient	n - Patient	
mulator		Cases	Cases	Deaths	
Total Malaria (confirmed and clinical)					
Total malaria suspected fever cases examined by RDT or Microscopy					
Number cases positive for malaria parasites (either by	P. falciparum				
RDT or Microscopy)	P. vivax				
Meningitis					
Dysentery					
Typhoid fever					
Relapsing fever					
Epidemic Typhus					
Severe Acute Malnutrition /MUAC < 11cm and/or Bilateral Oedema in under 5 years children (new cases only)					

*RDT* = *Rapid Diagnostic Test; MUAC* = *mid upper arm circumference* 

### 2. Report timeliness and completeness (to be filled only by Woreda Health Office and Zone/Regional Health Bureaus)

	Government		NGO		
Indicator	H. Post	Н.	Hospital	Health	Others
		Centre		Facility	
Number of sites that are supposed to					
report weekly					
Number of sites that reported on time					

# 3. Summary for Immediately Reportable Case-based Disease / Conditions: (Total cases and deaths reported on case-based forms or line lists during the reporting week)

DISEASE	С	D	DISEASE	С	D	DISEASE	С	D
AFP/Polio			Measles			SARS		
Anthrax			Neonatal Tetanus			Small pox		
Cholera			Pandemic Influenza			Viral haemorrhagic fever		
Dracunculiasis (Guinea worm)			Rabies			Yellow fever		
Other (specify):			Other (specify):			Other (specify):		

C = case; D = death; SARS = severe acute respiratory syndrome NOTE: Official counts of immediately notified cases come only from case forms or line lists.

Look at the trends, abnormal increase in cases, deaths, or case fatality ratios? Improving trends? Actions taken and Recommendations:

Date sent by HF/Woreda/Zone/Region:	Date received at Woreda/Zone/Region:
Sent by:	Received by:
Tele:	Tel:
E-mail:	E-mail:

# Annex 6. Immunization service supervisory visit checklist

Question	Yes/No	Problem observed and/or comments	Corrective action on-site	Corrective action longer term
Is the session organized efficiently?				
Are immunization cards in use for every infant and pregnant woman?				
Is the register used for recording information on each child/mother/pregnant woman?				
Are caregivers advised on when to return?				
Does the health facility have a monitoring chart displayed?				
Does the health facility have a map of the catchment area displayed?				
Does the health facility have a workplan for the quarter?				
Are planned sessions monitored for completeness/timeliness?				
Is there a system for tracking defaulters?				
Does the health facility display a spot map of measles cases?				
Is a temperature monitoring chart in use?				
Are the vaccines stacked properly inside the refrigerator?				
Are there any expired vaccines inside the refrigerator?				
Are there any vaccines with VVM reaching the discard point?				
Do the health workers know how to read and interpret the VVM? (Ask them to describe VVM changes and what they mean)				
Do the health workers know when and how to perform the shake test? (Ask them to demonstrate how to do it)				
Is there an adequate supply of AD syringes for the planned sessions?				
Are AD syringes used for every immunization?				
Is the injection technique appropriate?				
Is each used AD syringe and needle disposed of in a safety box?				
Are immunization posters displayed on the health facility wall(s)?				
Is there a schedule of community meetings?				
Are community volunteer(s) involved with immunization services?				
Is there a stock register?				
Does the stock register show adequate vaccines and supplies?				