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MINISTRY OF HEALTH - ETHIOPIA
የዜጎች ጤና ለሃገር ብልጽግና!
HEALTHIER CITIZENS FOR PROSPEROUS NATION!

Vaccine And Cold Chain Management Participant Training Manual

July, 2023

Forward

Even though there are multiple interventions underway in the area of Immunization, and supply chain interventions can significantly improve immunization coverage. There is significant gap in the Vaccine Supply Chain and cold chain management.

Lack of accountability for vaccines stock monitoring, absence of sensitive vaccine wastage monitoring indicator, lack of clear vaccine distribution plans, lack of budget specifically allocated for vaccine transportation at all levels and lack of taking actions based on temperature monitoring indicators/ devices are some of the challenges in the vaccine management system in the country. With pressures such as multi-skilled health staff, high staff turnover rates, and the introduction of new vaccines and technologies, like COVID-19 vaccines, the need for training for the better vaccine management practices has become a priority.

Accordingly, the Supply chain Practitioners who handle and involve in the Vaccine Supply Chain and cold chain management should be knowledgeable on vaccine supply chain & cold chain management system. They need to be acquainted with the necessary skills on forecasting and supply planning processes of vaccine and cold chain management, stock management systems for vaccine and supplies, vaccine distribution systems and vaccine wastage monitoring,

Therefore, it has been found necessary to enrich and advance the existing document as standardized training materials to enhance the capacity of Supply chain Practitioners to realize the proper vaccine supply chain & Cold Chain Management practices and related activities. It is the Ministry's belief that this professionals, and other health facility staffs engaged in the management of vaccine & cold chain management will benefit from this manual.

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Approval Statement of the Ministry

The Federal Ministry of health of Ethiopia has been working towards standardization and institutionalization of In-Service Trainings (IST) 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 Vaccine Supply Chain and Cold Chain Management IST training package has been reviewed based on the standardization checklist and approved by the ministry.

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Acknowledgment

Ministry of Health- PMED would like to express its gratitude and appreciation to all participants and their respective organizations for their unreserved commitment and support in the development of the training manual on Vaccine Supply Chain and Cold Chain Management-For Supply Chain Practitioners. PMED recognizes and values the technical expertise and experiences expressed in the document and it is hoped that this training material will contribute towards the effective utilization and management of vaccine & cold chain management.

Our heartfelt appreciation is extended to each of the members of the TWGs whose role was immense from inception to the preparation, coordination, and finalization of this training manual. We would like to thank USAID Global Health Supply Chain program- Procurement and Supply Management (GHSC-PSM) project, UNICEF, Clinton health access initiative and international rescue committee for their financial and technical support for the successful development of the training Manual.

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List of acronyms and abbreviation

AD	Auto-Disable Syringes
BCG	Bacille-Calmette-Guérin vaccine
CCM	Cold Chain Monitor Card
CTC	Controlled temperature chain
COVID-19	Coronavirus disease 2019
DPT-HepB-Hib	Diphtheria, tetanus, pertussis, Hepatitis B and Hemophilus influenzae type b
FEFO	First-Expiry-First-Out
EPI	Expanded program on Immunization
EUL	Emergency Use Listing
FIC	Fully immunized child
FIFO	First in First Out
FMOH	Federal Ministry of Health
HPV	Human Papilloma Vaccine
IPV	Inactivated Polio Vaccine
IU	International unit
LCD	Liquid-crystal display
MDVP	Multi-Dose Vial Policy
NIDs	National Immunization Days
OPRTT	Outbreak preparedness and Response Team
OPV	Oral Polio Vaccine
EPSS	Ethiopian Pharmaceutical supply Agency
PCV	Pneumococcal Conjugated Vaccine
PCM	Phase Change Materials
RTMD	Remote Temperature Monitoring Devices
TB	Tuberculosis
Td	Tetanus Diphtheria Vaccine
TT	Tetanus toxoid
ULC	Ultra Low temperature cold chain
UNICEF	United Nations Children's fund
VVM	Vaccine Vial Monitors
VMA	Vaccine Management Assessments
VWR	Vaccine wastage Rate
WHO	World Health Organization
WMF	Wastage multiplication factor

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Introduction to the manual

Immunization is the most cost-effective intervention in public health, and it is one of the indicators of development in most developing countries. The Expanded Program on Immunization (EPI) started in Ethiopia in 1980 with the aim of reducing mortality and morbidity of children and mothers from vaccine preventable diseases.

Vaccine management is the main component in all immunization efforts including accelerated disease control activities as well as improving coverage and introduction of new vaccines. Standard Cold chain management practices during entire supply chain operations help to ensure the appropriate temperature-controlled environment for vaccines and other temperature-controlled products, which will ultimately optimize the cold chain system performance that ensure life- saving vaccines reach every child and ensure adequate, sustainable vaccine storage for current and planned vaccines, with low maintenance requirements and reduced running costs.

There are many challenges in the vaccines supply chain management system. The high level of vaccine wastage exacerbated by absence of sensitive vaccine wastage monitoring indicator, poor utilization of available equipment and failure to observe important policies such as Vaccine Vial Monitors (VVM), and/or Multi-Dose Vial Policy (MDVP) have highlighted the need for improvement of the human resources capacity for better vaccine management and improve immunization practices. Adverse events due to inappropriate vaccine distribution practices are, partly, also believed to impact negatively on vaccine management.

Lack of accountability for vaccines stock monitoring, lack of clear vaccine distribution plans, lack of budget specifically allocated for vaccine transportation at all levels and lack of taking actions based on temperature monitoring indicators/ devices are some of the challenges in the vaccine management system in the country. These gaps are further exacerbated by such pressures as poorly skilled health staff, high staff turnover rates, and the introduction of new vaccines and technologies, like COVID-19 vaccines.

Cognizant to the gaps in vaccine supply chain & cold chain management, MoH-PMD LEO, EPSS in collaboration with GHSC-PSM, developed this training manual to develop the required competencies for Supply Chain practitioners at different supply chain levels; EPSS, RHBs, Health Facilities, Woreda Health Offices and Zonal Health Departments.

Core competency

After completing this course, the participants will have the following core competencies:

- Describe the basic concepts of vaccine and vaccine preventable diseases
- Quantify of vaccine and related supplies
- Manage stocks for vaccines and related supplies
- Manage the distribution of vaccine and related supplies
- Implement interventions to minimize vaccine wastage
- Apply standard cold chain management
- Monitor optimal temperatures for vaccines
- Monitor and evaluate vaccine and cold chain management performance

Course Syllabus

Course description: This five days course is designed to equip with the basic knowledge, skill and attitude required to manage vaccine and cold chain management for supply chain practitioners at MOH, EPSS, Regional, Zonal, Woreda and Health facilities. The course starts with basic concepts of vaccine and vaccine preventable diseases, followed by descriptions of the forecasting and supply planning processes of vaccine and cold chain management, stock management systems for vaccine and supplies, vaccine distribution systems and vaccine wastage monitoring, cold chain management and temperature monitoring in vaccine and cold chain management system. Finally, the course addresses strategies to measure performances for vaccine and cold chain management system.

Course goal:

The goal of this course is to improve participants competency on vaccine and cold chain management system.

Participant learning objectives:

At the end of this course, participants will be able to:

- Describe the basics of vaccine and vaccine preventable diseases
- Demonstrate quantification of vaccine and related supplies
- Explain stock management of vaccine and related supplies
- Describe vaccine and related supplies distribution
- Describe vaccine wastage management
- Describe cold chain management
- Demonstrate vaccine temperature monitoring
- Describe monitoring and evaluation for vaccine and cold chain management

Training Methods:

- Interactive lectures
- Group discussion
- Individual reflection
- Demonstration
- Field visit

Training material and Equipment

- Facilitator's guide
- Participant manual
- Power point presentation
- Temperature monitoring devices
- Cold chain equipment
- LCD projectors
- White board and marker
- Flip chart and marker
- Computer
- Video demonstration - cold chain management
- Formats(VRF, leger book, Temperature recording form, …)
- Inspection and performance checklist

Participant Selection Criteria

Participants for this course will be supply chain practitioners at MOH, EPSS, Regional, Zonal, Woreda, Health facilities and partners involved in Vaccine and cold chain management.

Facilitator/Trainer Selection

- Be a member(s) of the training material developer team or
- Have training of trainers (TOT) level on vaccine and cold management, or
- Have basic vaccine and cold management chain trainings plus facilitation skill and
- Two years of experience in vaccines and cold chain management

Certification Criteria

- Certificates will be provided to basic training trainees who score 70% and above on summative assessment and attend 100% of the course.
- For TOT trainees, certificate shall be provided to those who score 80% and above on summative and formative assessments and attend 100% of the course.
- In addition to summative the assessment, TOT participants will be will be evaluated against selected set of facilitator/trainer roles,

Continuing Educational Unit(CEUs)

- 15 CEUs

Methods of evaluation

Trainees/participant Evaluation

Formative

- Direct observation with feedbacks
- Group activities and presentations
- Pre-test
- Group exercises
- Demonstration using checklists

Summative

For Basic Training

- Post test

For TOT training

- Teach back session– 40%
- Post Test - 60%

Course Evaluation

- Daily Evaluation
- End of training evaluation
- Participant oral feedback
- Practice evaluation

Course duration:

- Five days

Suggested Class Size

- Suggested training class size shall be 30 participants for basic and TOT 25 per training venue.
- At least three trainers each staying for the whole duration of the training are needed for each training session.

Suggested Class Compassion:

- Trainer to participant ratio will be 1:6

Training Venue

- Accredited /CPD centers with attachment center.

Course schedule:

Day One	
08:30 - 08:45	Registration
08:45 - 08:50	Welcome
08:50 - 10:00	Introduction, Objective of the training, expectation and schedule of the course
10:00 - 10:40	Pre-course evaluation
10:40 - 11:00	Team/Coffee break
11:00 - 12:30	Chapter One: Basics of vaccine and vaccine preventable diseases
12:30 - 2:00	Lunch break
2:00 - 3:40	Chapter One: Basics of vaccine and vaccine preventable diseases
3:40 - 4:00	Team/Coffee break
4:00 – 4:20	Chapter One: Basics of vaccine and vaccine preventable diseases
4:20 - 5:30	Chapter Two: Quantification of Vaccines and Related Supplies
Day Two	
08:30 - 08:45	Recap of day 1
08:45 - 10:40	Chapter two: Quantification of Vaccines and Related Supplies
10:40 - 11:00	Tea/ coffee break
11:00 - 12:30	Chapter two: Quantification of Vaccines and Related Supplies
12:30 - 2:00	Lunch break
2:00 – 3:05	Chapter two: Quantification of Vaccines and Related Supplies
3:05 - 3:40	Chapter three: Stock management of vaccine and related supplies
3:40 - 4:00	Team/Coffee break
4:00 - 5:30	Chapter three: Stock management of vaccine and related supplies
Day Three	
08:30 – 08:45	Recap of day 2
08: 45 – 9:30	Chapter three: Stock management of vaccine and related supplies

09:30 – 10:40	Chapter Four: Vaccine distribution systems
10:40 - 11:00	Tea/ coffee break
11:00 - 12:30	Chapter Four: Vaccine distribution systems
2:00 - 3:40	Chapter Five: Vaccine wastage management
3:40 – 4:00	Team/Coffee break
4:00 - 10:45	Chapter Five: Vaccine wastage management
10:45 – 5:30	Chapter Six: Cold chain equipment management system
Day Four	
08:30 - 08:45	Recap of day 3
08:45 - 10:30	Chapter Six: Cold chain equipment management system
10:30 - 10:45	Tea/ coffee break
10:45 - 12:30	Chapter Six: Cold chain equipment management system
12:30 - 2:00	Lunch break
2:00 - 3:30	Chapter Six: Cold chain equipment management system
3:30 - 3:45	Team/Coffee break
4:45 - 5:30	Chapter Seven: vaccine temperature monitoring
Day Five	
08:30 - 08:45	Recap of day 4
08:45 - 10:30	Chapter Seven: vaccine temperature monitoring
10:30 - 10:45	Tea/ coffee break
10:45 – 12:30	Chapter Seven: vaccine temperature monitoring
12:30 - 2:00	Lunch break
2:00 - 3:30	Chapter Seven: vaccine temperature monitoring
3:30 - 3:40	Chapter Eight: Monitoring and evaluation for vaccine and cold chain management
3:40 - 4:00	Team/Coffee break
4:00 - 5:00	Chapter Eight: Monitoring and evaluation for vaccine and cold chain management
5:00 5:30	Post-test and closing remark

Chapter 1

Basics of Vaccine and Vaccine Preventable Diseases

Allocated Time: 190 minutes

Chapter Description:

This chapter describes vaccines preventable diseases, characteristics, types and doses of vaccines, vaccination schedule, storage conditions and route of administration for each vaccine.

Chapter Objective:

At the end of this chapter participants will be able to describes basics of vaccines and vaccine preventable diseases.

Enabling Objectives: -

By the end of this chapter participants will be able to: -

- Describe vaccines, their characteristics and vaccines preventable diseases (VPD)
- Identify the type of vaccine needed for each vaccine preventable disease.
- Explain the vaccine schedule for the routine EPI program and outbreaks.
- Explain vaccine supply chain management.

Chapter outline:

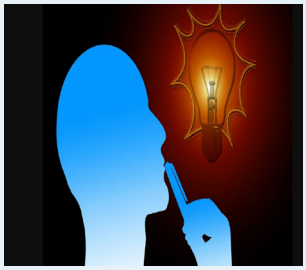
1.1. Introduction to vaccines

1.2. Types of vaccines and characteristics

1.3. Introduction to vaccine Supply Chain Management

1.4. Summary

1.1. Introduction

Activity 1.1. Individual – Reflection	
Instruction: What is vaccine, immunity (active/passive), immunization and vaccination, and vaccine preventable diseases? Minute: 20 minutes	

1.1.1. What is a vaccine?

The word "vaccine" originates from the Latin Variolae vaccinae (cowpox), which Edward Jenner demonstrated in 1798 could prevent smallpox in humans. Today the term 'vaccine' applies to all biological preparations, produced from living organisms, that enhance immunity against disease and either prevent (prophylactic vaccines) or, in some cases, treat disease (therapeutic vaccines). Vaccines are administered in liquid form, either by injection, by oral, or by intranasal routes. In Ethiopia, vaccines are mainly administered through oral, intradermal and subcutaneous routes.

Vaccines are composed of either the entire disease-causing microorganism or some of its components. They may be constructed in several ways.

- From living organisms that have been weakened, usually from cultivation under sub-optimal conditions (also called attenuation), or from genetic modification, which has the effect of reducing their ability to cause disease.
- From whole organisms that have been inactivated by chemicals, thermal or other means.
- From components of the disease-causing organism, such as specific proteins and polysaccharides, or nucleic acids.
- From inactivated toxins of toxin-producing bacteria.
- From the linkage (conjugation) of polysaccharides to proteins (this increases the effectiveness of polysaccharide vaccines in young children).

1.1.2. Common terminologies

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

Active immunity: is provided by a person's own immune system. This type of immunity can come from exposure to a disease or from vaccination.

Passive immunity: results when antibodies are transferred from one person or animal to another. The most common form of passive

immunity occurs when a fetus receives antibodies from his or her mother across the placenta during pregnancy.

Immunity is also classified as innate and adaptive immunity. Innate immunity is an immediate response to any infection, whereas adaptive immunity is a specific response to an infection, which involves cellular response (T-cells) and the antibody response (B cells). Innate immune response is immediately, while cellular and antibody response usually occurs after 6 to 8 days.

Immunization: is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease. A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.

Vaccination: is the administration (injection and Po) of a killed or weakened organism that produces immunity in the body against that organism.

1.1.3. Vaccine preventable diseases

Based on the global burden of vaccine-preventable infectious diseases (VPD) reports, vaccine preventable diseases are among a leading cause of morbidity and mortality worldwide. According to 2018 report on the global burden of VPD, seven hundred thousand under 5 children died of vaccine-preventable diseases from 5.3 million under five deaths, of which 99% of the children who died had lived in low- and middle-income countries.

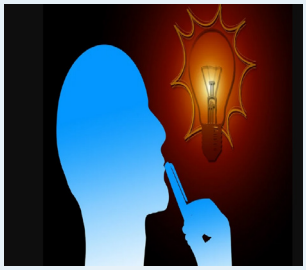
Table 1-1 Common vaccine preventable diseases with their characteristics

Target disease	Causative agent	Mode of transmission	Sign and symptom	Major complications	Treatment	Prevention
Diphtheria	Corynebacterium Diphtheria	Respiratory Droplets	Sore throat, tonsils, Fever	Respiratory Obstruction, Heart failure	Diphtheria Antitoxin and Antibiotics	Vaccination,(Diphtheria containing vaccine like Penta, Td)
Pertussis	Bordetella Pertussis	Respiratory Droplets	Fever, Cough, Vomiting, Apnea	Pneumonia and Convulsion	Antibiotics	Vaccination (Pertussis containing vaccines such as Penta vaccine)
Tetanus	Clostridium Tetany	Through wound or Cut	Fever, Neck stiffness and Muscle spasm	Respiratory failure, death	Antitoxin/ immunoglobulin, antibiotics	Vaccination (Tetanus containing vaccines Td, Penta vaccine)
Hemophilus Influenza type b	Hemophilus influenza type b	Respiratory Droplets	Fever, cough Neck stiffness	Neurological disability hearing loss, mental retardation	Antibiotics	Vaccination (Hemophilus influenza containing vaccines such as Penta vaccine)
Hepatitis B	Hepatitis B virus	Contact with infected blood & fluids, congenital (mother to newborn)	Fatigue Nausea, Jaundice, vomiting, abdominal pain	Fulminant hepatocellular carcinoma, cirrhosis,	Supportive, Antivirus drugs	Vaccination (Hepatitis B virus containing vaccine like Penta, and Hep B birth dose)
Tuberculosis	Mycobacterium tuberculosis	Respiratory droplets	Cough, fever, night sweating, weight loss, loss of appetite	TB meningitis, lung fibrosis	Anti TB	Vaccination (BCG), ventilation and nutrition
Pneumonia	Streptococcus pneumonia	Respiratory droplets	Cough, fever, shortness of breath	Empyema Meningitis, hearing loss, mental retardation	Antibiotics	Vaccination (PCV13)

Rotavirus gastroenteritis	Rotavirus	Fecal to oral route	Diarrhea, Vomiting	Dehydration, Shock	Fluid replacement (ORS) with zinc	Vaccination (Rota vaccine), Hygiene and sanitation
Poliomyelitis	Poliovirus types 1,2,3	Fecal to Oral	Fever, headache, sore throat	Muscle spasm, pain, Limb paralysis	Physiotherapy, use of brace	Vaccination, (OPV, IPV, nOPV)
Measles	Measles virus (paramyxovirus)	Respiratory droplets	Fever Coryza, skin rash, Conjunctivitis	Dehydration Pneumonia Otitis media Encephalitis	Antibiotics ORS Vitamin A	Vaccination (Measles Containing Vaccine)
Rubella, Congenital Rubella Syndrome	Rubella virus (Paramyxovirus)	Respiratory droplets	Fever, skin rash, Conjunctivitis, congenital cataract, loss of hearing	Encephalitis, hydrocephalus, Blindness	Supportive Antivirus, Vitamin A	Vaccination (Rubella containing vaccine)
Mumps	Mumps Virus (Paramyxovirus)	Respiratory droplets	Fever, neck swelling	encephalitis, deafness, orchitis, and pancreatitis	Supportive Antivirus, Vitamin A	Vaccination (Mumps containing vaccine)
Cervical cancer	Human papilloma Virus (HPV)	Sexual contacts	No symptom before cancer lesion	Cervical cancer, vaginal bleeding, pain	Surgery Chemotherapy, radiotherapy	Vaccination (HPV), Condom, early screening, and treatment
Meningitis	Neisseria meningitidis	Respiratory droplets	Headache, fever, vomiting convulsion, petechial rash	Pericarditis, Coma, Brain damage	Antibiotics	Vaccination, (Meningitis vaccine)

Yellow fever	Yellow fever Virus (Flavivirus)	Vector borne (Aedes mosquito)	Fever, muscle pain, vomiting	Liver, kidney failure, Coma.	Supportive	Vaccination (Yellow fever vaccine), Vector control
COVID 19	Sars Cov 2 or Corona Virus 2	Respiratory droplets	Cough, fever, body weakness, loss of taste and smell	Difficulty of breathing, organ failure, blood clot, pneumonia	Supportive, Anti-viral	vaccination(Covid 19 vaccine), Face mask, social distancing, hand washing,
Malaria	Plasmodium species (PF, PV, PM, PO)	Vector borne, (Anopheles)	Fever, Chills, headache, myalgia	Cerebral malaria, renal failure, shock, convulsion, anemia	Antimalaria	Vaccination (Malaria vaccine), environmental control, bed net, Indoor Residual Spray,
Cholera	Vibrio cholerae	Fecal to oral	Diarrhea and vomiting	Hypotension shock, muscle cramp	Rehydration, and antibiotics	Hygiene & sanitation, Vaccination (Oral cholera vaccine (OCV)
Ebola	Ebola virus (filovirida)	Direct contact with blood or other body fluids	Fever, fatigue, headache, muscle pain	Internal and external bleeding, rash, diarrhea	Rehydration, blood transfusion,	Vaccination (Ebola vaccine), avoid contact with blood and body fluids
Typhoid Fever	Bacteria, Salmonella Typhi	Fecal to oral	Fever, headache, vomiting,	Hemorrhage, intestinal perforation	Rehydration, antibiotics, antipyretics	Hygiene and sanitation, Vaccination (Typhoid vaccine),
Rabies	Rabies virus (Lyssaviruses)	Animal bite vial saliva	Tingling, burning pain	Hallucination, hydrophobia, aerophobia	Supportive	Vaccination (postexposure (PEP) prophylaxis rabies

1.2. Types of Vaccines and their Characteristics

Activity 1.2. Individual -Reflection	
Question: What types of vaccines do you know? What common characteristics do all vaccines share? Time 15min	

1.2.1. Types of vaccines

A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. There are several types of vaccines, including:

- Live attenuated
  - Are derived from disease-causing viruses or bacteria that have been weakened under laboratory conditions.
  - **Virus:** Oral Polio Vaccine (OPV), Measles, Yellow fever, rotarix,
  - **Bacteria:** BCG
- Inactivated:
  - Are produced by growing viruses or bacteria and then inactivating them with heat or chemicals. Inactivated vaccines may be whole-cell or fractional.
  - **Whole-Cell:** are made of an entire bacterial or viral cell.
    - Virus: Inactivated polio vaccine (IPV), COVID -19 Vaccines (Sinopharm, Sinovac)
    - Bacteria: Whole-cell pertussis, Oral Cholera Vaccine (ShancholTM, Euvichol®, and mORCVAXTM)
  - **Fractional:** composed of only part of a cell, are either protein- or polysaccharide-based.
    - **Protein-based**
      - Subunit: acellular pertussis
      - Toxoid: Tetanus, diphtheria
    - **Polysaccharide based:** vaccines are composed of long chains of sugar molecules taken from the surface capsule of the bacteria.
      - Pure: meningococcal
      - Conjugated (coupled with a protein):

- Hemophilus influenza type b (Hib), Pneumococcal conjugate vaccine ((PCV), Meningococcal conjugate vaccines (e.g., MenA)

- **Recombinant:**
  - oare produced by inserting genetic material from a disease-causing organism into a harmless cell, which replicates the proteins of the disease-causing organism.
  - **Recombinant:** Hepatitis b, HPV, Covid-19 vaccines (AstraZeneca, Janssen, Sputnik V (Gamaleya)
- **Nucleic Acid:**
  - It is a RNA or DNA vaccine which includes a target pathogen protein that promotes an immune response. When the nucleic acid is inserted into human cell, RNA or DNA is then converted to antigens.
  - **Nucleic Acid:** COVID -19 vaccines (Pfizer, Moderna)

1.2.2. Vaccines Characteristics

I. Vaccines used for routine immunization in Ethiopia

The vaccines listed under this sub-section are currently in use in Ethiopia.

A. Bacille Calmette-Guérin (BCG) vaccine

Ethiopia is among high burden countries having Tuberculosis disease globally. Thus, BCG vaccine is used to prevent childhood tuberculous meningitis and miliary disease. The BCG vaccine currently in use is formulated in 20 doses per vial.

Table 1- 2 Summary of BCG vaccines characteristics

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
Adverse 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

B. Penta valent vaccine (DTP-HepB-Hib)

Penta valent vaccine has five antigens (Diphtheria, Tetanus, Pertussis, Hemophiles Influenza type b and hepatitis B, formulated in single dose vial.

Table 1-3 Summary of Penta valent vaccine characteristics

Type of antigen in the Penta valent vaccine	Toxoid (**Diphtheria, Tetanus**), acellular (Pertussis), Conjugate polysaccharide (Hemophiles Influenza type b), Recombinant DNA (hepatitis B)
Number of doses	At least three primary doses
Schedule	6, 10, 14 weeks of age and ***During Catch up vaccination; it can be provided up to 24 months***
Booster	None
Contraindications	Anaphylactic reaction to previous dose or to any constituent
Adverse reactions	■ Mild local or systemic reactions are common after vaccination (Fever, injection site pain and swelling …) ■ For pertussis: Hypotonic-hypo responsive episodes in <1000-2000; febrile seizures <1 in 100; prolonged crying <1 in 100

	■ For Tetanus: Severe: rare anaphylaxis, brachial neuritis, GBS and Mild: injection site reactions and fever
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

C. Pneumococcal Conjugated vaccine (PCV)

Pneumococcal Conjugated vaccine protects against disease caused only by the pneumococcal serotypes causing pneumococcal pneumonia and meningitis. The PCV 13 vaccine currently formulated in one and four doses. Ethiopia is currently using PCV 13 vaccine.

Table 1-4 Summary of Pneumococcal conjugate vaccine characteristics

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 and ***During Catch up vaccination; it can be provided up to 24 months***
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

D. Rotavirus Vaccine

Rotavirus vaccination prevents rotavirus gastroenteritis and should be included as part of a comprehensive treatment and prevention strategy to control diarrhea. Ethiopia currently is using Rota Vaccine formulated in single dose vial (table 3).

Table 1-5 Summary of Rotavirus vaccines characteristics

Type of vaccine	Live attenuated
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

E. Measles vaccine

Measles vaccination resulted in a 73% drop in measles deaths. Vaccination with two dose measles vaccine per the schedule confers 95% immunity. All children should receive two doses of the vaccine at age 9 months and 15 months. Currently Measles vaccine is formulated in single, 5 doses and 10 doses vail; and 10 doses of vial is being used in Ethiopia.

Table 1-6 Summary of Measles-containing vaccines characteristics

Type of vaccine	Live attenuated
Number of doses	Two
Schedule	MCV 1: at 9 months of age. MCV 2: at 15 months of age Note: During catch up vaccination: two doses measles vaccine can be provided or vaccinate in 4 weeks interval time up to 59 months.
Booster	None
Contraindications	Known allergy to vaccine components (including neomycin and gelatin); 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
Note: Vit A supplementation highly recommended to be given during measles vaccination to develop high immunity for measles disease. (Refer further nutrition guide)	

F. Polio vaccines (OPV and IPV)

Polio vaccine is available in oral and injectable formulation. Oral polio vaccine (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). Polio viruses cause one in 200 infections leads to irreversible paralysis. Among those paralyzed, 5–10% die when their breathing muscles become immobilized. Polio vaccine significantly contributed for reduction wild poliovirus by 99% since 1988, from an estimated 350 000 cases then, to 6 reported cases in 20212. Currently there two types of polio vaccines 1) oral polio vaccine (OPV) 2) and In activated polio vaccine (IPV). OPV vaccines are formulated in oral drop form in 10 doses and 20 doses vial and IPV vaccine is formulated in injection form in 5 dose and 10 dose vials.

Table 1-7 Summary of polio vaccines characteristics

Characteristics	OPV	IPV
Type of vaccine	Live attenuated viral	Inactivated viral
Number of doses	4 (Four) doses	1 (one) doses, there is a plan of one addition dose at 9 month
Schedule	Birth, 6, 10, 14 weeks of age *During Catch up vaccination; it can be provided up to 59 months*	IPV 1 at 14 weeks *During Catch up vaccination; it can be provided up to 24 months*

Booster	None	None
Contraindications	Anaphylactic reaction to previous dose or to any constituent	Anaphylactic reaction to previous dose or to any constituent
Adverse reactions	Rare vaccine-associated paralytic polio (VAPP)	Serious: none known. Mild: injection site reactions
Special precautions	Postpone vaccination if the child has moderate to severe illness (with temperature =39 °C)	Postpone vaccination if the child has moderate to severe illness (with temperature =39 °C)
Dosage	Two drops into the mouth	0.5 ml
Route of administration	Oral only	Intramuscular: Right anterolateral (outer) mid-thigh in infants. There should be minimum of 2.5cm apart from PCV injections
Storage	Store between 2°C–8°C. OPV is very heat sensitive	Store between 2°C–8°C. IPV is freeze sensitive
Note: nOPV2 (noble oral polio vaccine type 2) are available for cVDPV2 outbreak response vaccination program.		

G. Tetanus diphtheria (Td) vaccine

Td vaccine can prevent tetanus and diphtheria. Td is provided for preschool children and older, adolescents, reproductive age mothers. Td vaccine contain both tetanus and diphtheria antigens. Td vaccine available in liquid formulation and 1, 10 and 20 dose presentations. Ethiopia uses 10 doses vial presentation.

Table 1-8 summary of Tetanus-diphtheria (Td) vaccine characteristics

Type of vaccine	Toxoid
Number of doses	5 (five), in practice only 2 doses of Td is being provided for pregnant women only.

Schedule and protection year	Td1	0 (as early as possible),	Elicits no protection
	Td2	4 weeks after Td1	3 years
	Td3	6 months after Td2 or subsequent pregnancy	5 years
	Td4	1 year after Td3 or subsequent pregnancy	10 years
	Td5	1 year after Td4 or subsequent pregnancy	All childbearing years
Booster	Td vaccine can be given as booster doses 18 months to 6 years of age (Two doses of Td at school age following Penta vaccination), thus prolonging the duration of protection from both diseases. However, Ethiopia is not yet started providing Td Booster doses.		
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	Intramuscular injection into the deltoid muscle		
Storage	Store between 2°C–8°C. Do not freeze		

H. Human papilloma virus vaccine (HPV vaccine)

Cervical cancer is the fourth most common type of cancer among women globally, with an estimated 604 000 new cases and 342 000 deaths in 2020. About 90% of the new cases and deaths worldwide in 2020 occurred in low- and middle-income countries. A large majority of cervical cancer (more than 95%) is due to the human papillomavirus (HPV). There are three types of HPV vaccine globally - Bi valent, quadrivalent and nano valent. Each vaccine addresses different serotypes of HPV. Ethiopia introduced quadrivalent HPV vaccine with formulation of single dose.

Table 1-9 Summary of HPV vaccines characteristics

Type of vaccine	Recombinant protein capsid, Quadrivalent
Type of vaccine	Recombinant protein capsid, liquid vaccine
Number of doses	One
Schedule	9 -14 years of age adolescent girls
Booster	None
Contraindications	Anaphylaxis or hypersensitivity
Adverse reactions	Severe: rare anaphylaxis Mild: injection site reactions; fever, dizziness, nausea
Special precautions	Postpone vaccination for pregnancy. Adolescents should be seated during injections and for 15 minutes afterwards since they sometimes faint
Dosage	0.5 ml
Route of administration	Intramuscular, Deltoid muscle of upper arm
Storage	Store between 2°C–8°C. Do not freeze

I. COVID-19 vaccines

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus. Most people infected with the virus will experience mild to moderate respiratory illness and recover without requiring special treatment. However, some will become seriously ill and require medical attention. Older people and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer are more likely to develop serious illness. There are different types of COVID 19 vaccines currently available worldwide such as Pfizer, Moderna, AstraZeneca, Janssen and Janssen, Sinopharm, Sinovac, Sputnik V, etc. Ethiopia has been using Pfizer, AstraZeneca, Janssen and Janssen, Sinopharm, Sinovac for COVID 19 pandemic response vaccination.

Table 1-10 Summary of COVID 19 vaccines characteristics

Characteristics	Pfizer tris formulation (gray cup)	Janssen and Janssen	Astra Zeneca	Sinopharm/ Sinovac
Type of vaccine	mRNA	Recombinant	Recombinant	Inactivated
Number of doses	2	1	2	2
Schedule	12 year and above, the 2nd dose after 3 to 4 weeks	18 year and above	18 year and above, the 2nd dose after 4 to 8 weeks	18 year and above, the 2nd dose after 3 to 4 weeks
Booster	6-month after 2nd dose	6-month after 1nd dose	6-month after 2nd dose	6-month after 2nd dose
Contraindications	Known allergy with previous doses	Known allergy with previous doses	Known allergy with previous doses	Known allergy with previous doses
Adverse reactions	Soreness, myalgia, headache, joint pain, injection site pain	Soreness, myalgia, headache, joint pain, injection site pain	Soreness, myalgia, headache, joint pain, injection site pain	Soreness, myalgia, headache, joint pain, injection site pain
Dosage	0.3 ml	0.5 ml	0.5 ml	0.5 ml
Route	Intramuscular, deltoid	Intramuscular, deltoid	Intramuscular, deltoid	Intramuscular, deltoid
Storage	When stored/ maintained at -80°C to -60°C can be used by the indicated expiration date on the vaccine vial. But if it is stored at 2°C to 8°C only used only 10 weeks.	2°C to 8°C	2°C to 8°C	2°C to 8°C
Note: Covid 19 administration, scheduling, storage, type, adverse reaction, contraindication might change overtime. Thus, we encourage vaccinators to use updated information.				

II.Emergency or outbreak response vaccines being provided in Ethiopia.

A. Yellow fever vaccine

Yellow fever is prevented by an extremely effective vaccine, which is safe and affordable for those aged 9 months or more living or travelling to high-risk areas. A single dose of yellow fever vaccine is sufficient to grant sustained immunity and life-long protection. A booster dose of the vaccine is not needed. The vaccine provides effective immunity within 10 days for 80-100% of people vaccinated. Currently Ethiopia is yellow fever vaccine for international travelers and yellow fever outbreak responses.

Table 1-11 Summary of yellow fever vaccine characteristics

Type of vaccine	Live-attenuated viral
Number of doses	One
Schedule	Age greater than 6 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
Note: the schedule for routine yellow fever vaccine not decided yet. It will be decided during routine introduction time.	

B. Oral Cholera vaccine

Cholera is an acute diarrheal disease that can kill within hours if left Untreated. Provision of safe water and sanitation is critical to prevent and control the transmission of cholera and other waterborne diseases. Severe cases will need rapid treatment with intravenous fluids and antibiotics. Oral cholera vaccine is tool used to prevent cholera diseases outbreaks in conjunction with improvements in water and sanitation in areas known to be high risk for cholera. Currently there are 3 WHO pre-qualified oral cholera vaccines Dukoral, Shanchol, and Euvichol. Ethiopia currently uses Euvichol-plus oral cholera vaccine for outbreak response and cholera high risk areas. It is not introduced as routine immunization program.

Table 1-12 Summary of Euvichol-plus oral cholera vaccine (OCV) characteristics

Type of vaccine	Inactivated, liquid formulation
Number of doses	2 (Two)
Schedule	Age greater than 1 year, the 2nd dose is given after 2 weeks of interval
Booster	None
Contraindications	Known hypersensitivity with previous dose
Adverse reactions	Abdominal pain, diarrhea
Dosage	1.5 mL
Route of administration	Oral
Storage	Store between 2°C–8°C. Do not freeze

C. Meningococcal vaccines

There are two Meningococcal vaccine Polysaccharide and Conjugate, these two vaccines prevent Neisseria meningitis. Ethiopia is in the African meningitis belt countries and vaccinated conjugate meningococcal vaccines (Men A) all aged one to 29 years between 2013 to 2015.

Table 1-13 Summary of Meningococcal polysaccharide and conjugate vaccines characteristics

Characteristics	Meningococcal conjugate (Men A)	Meningococcal polysaccharide (Men A)
Type of vaccine	Purified bacterial capsular polysaccharide bound to protein; monovalent, quadrivalent	Purified bacterial capsular polysaccharide; bivalent, trivalent or quadrivalent
Number of doses	One	One
Schedule	Monovalent: Single dose for all between 1 and 29 years of age through SIA; Single dose at the age of nine months through routine.	Two years of age and older
Booster	None	One dose after 3-5 years if still at risk
Contraindications	Anaphylaxis or hypersensitivity after a previous dose	Anaphylaxis or hypersensitivity after a previous dose
Adverse reactions	Severe: rare anaphylaxis Mild: injection site reaction, fever	Severe: rare anaphylaxis; Mild: injection site reaction, fever
Special precautions	See schedules above for age restrictions	Children under 2 years of age are not protected by the vaccine
Dosage	0.5ml	0.5ml
Injection site	upper arm	upper arm
Injection type	Intramuscular	Subcutaneous
Storage	Between +2 °C and +8 °C, do not freeze	Between +2 °C and +8 °C, do not freeze
Note: Men A vaccine not yet included in the routine immunization program.		

D. Rabies vaccine

Dogs are the main source of human rabies deaths, contributing up to 99% of all rabies transmissions to humans. Rabies can be prevented through vaccination of dogs and prevention of dog bites. After a potential exposure of people to a rabid animal, they can seek post-exposure prophylaxis (PEP), which consists of immediate, thorough wound washing with soap and water for 15 minutes, a series of rabies vaccinations and, if indicated, administration of rabies immunoglobulin or monoclonal antibodies, which can be lifesaving.

Table 1-14 Summary of rabies vaccines characteristics

Type of vaccine	Imovax, Rabavert, HDVC (Human Deploid Cell Vaccine), PCEC (Purified Check Embryo Cell Vaccine)
Number of doses	4, before signs and symptoms develop
Schedule	3, 7, days after the first
Booster	None
Contraindications	None
Adverse reactions	Soreness, redness, headache
Special precautions	For higher additional rabies immunoglobulin

E. Novel oral polio vaccine (nOPV2)

The novel oral polio vaccine (nOPV2) is granted for emergency use authorization (EUA) to be used for the cVDP. nOPV2 is a genetically modified version of the attenuated Sabin vaccine and it is supplied under a WHO Emergency Use Listing (EUL) – it must be approved by each country regulatory authority. It is a modified version of mOPV2, designed to be more genetically stable and avoid mutations and regaining of neurovirulence (vaccine derived poliomyelitis; VDP). Supply will be in 50 doses per vial (10 vial packs) with Volume per dose = 0.55cm³ (same as mOPV2) or 27.5 cm3 per vial. Expected wastage factor for 50 dose vials = 1.25 (wastage rate = 20%) – To be adjusted after initial use period. nOPV2 is not affected by freezing and thawing cycles or events and currently, nOPV2 shelf life is 12 months at -20°C and 3 months at +2°C and +8°C; this is subject to change as additional data is submitted and reviewed in line with EUL recommendations.

Type of Vaccine	nOPV2
Doses per vial	50
Vial size	5ml
Passive cold chain equipment	Stand cold carriers
Temperature monitoring in the field	VVM only
Containment	Required
Reverse Logistics	Required for all vials (usable& unusable) after each round
Disposal of empty vials	National or Regional (as perthe national guideline)
Disposal of unopened vials	
Verification Collection of vials	Yes, by supervisors
Validation of Collection	OPRTT (Outbreak preparedness and response Task Team) will decide

III. Vaccines not introduced in Ethiopia and those in pipeline

A. Hepatitis B birth dose

Hepatitis B virus is most transmitted from mother to child during delivery, as well as through contact with blood or other body fluids during sex with an infected partner, unsafe injections or exposures to sharp instruments. In 2019, hepatitis B resulted in an estimated 820,000 deaths, mostly from cirrhosis and hepatocellular carcinoma. Hepatitis B virus infection during delivery time is much more likely to persist as chronic HBV infection leading to cirrhosis and hepatocellular carcinoma resulting to premature death.

Hepatitis B birth dose vaccine prevents transmission of the virus from mother to child during birth and delivery. Pentavalent vaccine contains Hepatitis B antigen, but it doesn't prevent mother to child transmission (due to the fact that pentavalent vaccination is provided at 6, 10 and 14 weeks after birth), but it prevents Hepatitis infection during childhood period and beyond.

Table 1-15 Summary of Hepatitis B- Birth dose vaccine characteristics

Type of vaccine	Recombinant DNA or plasma-derived
Number of doses	1 (one) dose
Schedule	Highly recommended Immediately after birth within 24 hrs. It can be given after and until 2 weeks, but the effectiveness will be lower.
Booster	None
Contraindications	Anaphylactic reaction to previous dose or to any constituent
Adverse reactions	Mild: soreness at the injection site, irritability, and fever
Special precautions	Use only stand-alone Hep B birth dose vaccine for the birth dose.
Dosage	0.5ml
Injection site	Intramuscular injection anterolateral aspect of the thigh.
Storage	Store between 2°C–8°C.
Note: A child should get vaccinated with Hepatitis B vaccine containing Penta vaccine for full protection at later age, making the total dose to be 4 to be fully vaccinated	

B. Malaria Vaccine

Malaria affects 68% of the population in Ethiopia, estimated 10 million clinical cases/year. The main parasites are PF-60% and PV 40%. Malaria vaccine, RTSS works by targeting a portion of the circumsporozoite protein on the surface of the malaria parasite. The idea is that a vaccinated individual will generate antibodies and kill off the parasite before it can enter red blood cells. Studies shows Malaria Vaccine resulted in reduction in severity of the disease, and 21% reduction in hospitalization and up to 39 % prevention. Malaria vaccine should be implemented in combination with other prevention methods.

Table 1-16 Summary of malaria vaccines characteristics

Type of vaccine	RTS,S/S/A so1
Number of doses	4 doses
Schedule	Not yet decided
Booster	Not yet decided
Contraindications	Hypersensitivity to previous dose, or hepatitis B vaccine
Adverse reactions	Swelling, pain on injection site and fever
Special precautions	Do not freeze, store in temperature 2- 8 0 c

C. Typhoid vaccine

Typhoid fever is a life-threatening infection caused by the bacterium Salmonella Typhi. Two vaccines have been used for many years to prevent typhoid. The conjugate typhoid vaccine was available and can provide longer protection time.

Table 1-17Summary of Typhoid vaccines characteristics

Type of vaccine	Conjugated Vi polysaccharide, non vi polysaccharide vaccine, live attenuated oral 2yua
Number of doses	Single, 0.5 ml SC or IM
Schedule	Not yet decided
Booster	Not yet decided
Contraindications	Does not produce immune response in < 2 years old children
Adverse reactions	Common tenderness, redness
Special precautions	not recommended for use during pregnancy
Route administration	Intramuscular, deltoid
Storage	

D. Rubella vaccine

Rubella and congenital rubella Syndrome (CRS) are infections caused by a virus. Rubella is normally a mild childhood disease, but women who infected with rubella in early 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. Rubella containing vaccine reduces the burden of Rubella and congenital rubella Syndrome (CRS) globally. Rubella vaccine is available in form combination as measles and rubella (MR) or measles, mumps, and rubella (MMR) or measles mumps rubella and varicella (MMRV)

Table 1-18 Summary of Rubella-containing vaccines

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)
Adverse reactions	Common: injection site reactions, fever, rash, irritability, lymphadenopathy (swollen lymph glands), myalgia (muscle aches) and paranesthesia's (tingling sensations)
Special	None
Precautions	
Dosage	0.5 ml
Route	Subcutaneous, left upper arm
Storage	Store between 2°C–8°C. keep all Rubella vaccines away from sunlight

E. Mumps vaccine

Mumps disease can cause complications, such as permanent deafness in children, and occasionally, encephalitis, which could rarely result in death. Mumps containing vaccine reduces the burden of mumps disease globally. Mumps vaccine is available in form combination form as measles, mumps, and rubella (MMR) or measles mumps rubella and varicella (MMRV)

Table 1-19 Summary of mumps-containing vaccines

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, myalgia (muscle aches) and tingling sensations
Special	None
Precautions	
Dosage	0.5 ml
Route	Subcutaneous, left upper arm
Storage	Store between 2°C–8°C. keep all Rubella vaccines away from sunlight

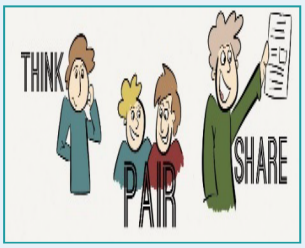
F. Ebola Vaccine

Ebola virus disease has case fatality rate is around 50%. Early supportive care with rehydration, symptomatic treatment improves survival. Ebola Vaccine to help control the spread of Ebola outbreaks.

Table 1-20 Summary of Ebola vaccines characteristics

Type of vaccine	Recombinant, live attenuated
Number of doses	2, 8 weeks apart
Schedule	For older than 18 years old
Contraindications	Pregnant and lactating
Adverse reactions	Joint pain or swelling, arthritis
Special precautions	After vaccination, people should be observed for at least 15 minutes
Route of administration	Intramuscular, deltoid muscle
Storage	When stored/maintained at -80°C to -60°C can be used by the indicated expiration date on the vaccine vial. But if it is stored at 2°C to 8°C only used only for 14 days.

1.3. Introduction to vaccine Supply Chain Management

Activity 1.3: Think Pair Share	
Instruction: Be in pair and discuss about the basic vaccines supply chain management and functions implemented in vaccines supply chains? **Time: 15 min**	

The Vaccines supply chain systems encompasses all the people, activities, infrastructure, resources and planning necessary to ensure that vaccines stay safe and effective and reach the clients who need them. Strong supply chains are a prerequisite to improving immunization coverage and equity, and they contribute to reduced child mortality.

Successful vaccine supply chain management is built on functional, end-to-end supply chain and logistics systems. These systems enable effective planning, quantification/forecasting, vaccine storage, distribution, handling, dispose, and management, ensure rigorous temperature control in the cold chain; and leverage logistics management information systems to promote resilient and efficient system performance. The goal is to ensure the uninterrupted availability of quality vaccines from manufacturer to service-delivery levels, so that opportunities to vaccinate are not missed because vaccines are unavailable.

Strengthening supply chains to ensure that high-quality vaccines are always available in the right quantity and form at the right time, in the right place and stored and distributed under the right conditions. A strong supply chain system is critical for the vaccine management. Building strong Vaccines SC systems and infrastructure help to safely manage and dispose of vaccine waste and helps to reduce their environmental footprint.

1.4. Chapter Summary

Exercise

Workings individually, identify vaccine characteristics and indicate in which form the antigen is presented in the following vaccines:

Vaccines	Preventable disease	Vaccine characteristics	Formulation/ Presentation	Dose	Handling procedures
BCG					
Measles					
OPV					
IPV					
DPT-HepB+Hib (Pentavalent vaccine or Penta)					
Td					
PCV					
Rotavirus					
Yellow fever					
Measles					
HPV					
OCV					
COVID -19 (Pfizer)					

Summary Points

Vaccine preventable diseases (VPDs) are infectious diseases caused by viruses or bacteria that can be prevented with vaccines. The most common vaccines are Vaccines, BCG, Measles, OPV, IPV, DPT-HepB+Hib(Pentavalent vaccine or Penta), Td, PCV, Rotavirus, Yellow, fever, HPV, OCV and COVID -19 (Pfizer)

Vaccines are composed of either the entire disease-causing microorganism or some of its components.

- From living organisms that have been weakened, usually from cultivation under sub-optimal conditions (also called attenuation), or from genetic modification, which has the effect of reducing their ability to cause disease.
- From whole organisms that have been inactivated by chemicals, thermal or other means.
- From components of the disease-causing organism, such as specific proteins and polysaccharides, or nucleic acids.
- From inactivated toxins of toxin-producing bacteria.
- From the linkage (conjugation) of polysaccharides to proteins (this increases the effectiveness of polysaccharide vaccines in young children).

Chapter 2

Quantification of Vaccines and Related Supplies

Chapter Allocated Time: 300 minutes.

Chapter description: -

This chapter describes quantification methods, factor affecting forecast accuracy and forecast for outbreak responses of vaccines and related supplies at different level.

Chapter Objective:

At the end of this chapter, participants will be able to describe quantification process of vaccine and related supplies.

Enabling Objectives

By the end of this chapter, participants will be able to:

- Describe different quantification methods
- Determine factors affecting accuracy of vaccine and related supplies forecast.
- Estimate of vaccines and related supplies
- Describe factor that affect vaccines and related supplies forecasting for outbreak responses.

Chapter outline

2.1 Introduction

2.2 Factors determining accuracy of vaccine and related supplies forecast.

2.3 Forecasting or estimate of vaccine and related supplies

2.4 Factors to consider during forecasting of vaccines and related supplies required for outbreak or pandemic responses.

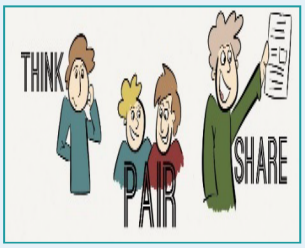
2.5 Summary

2.1. Introduction

Activity 2.1. Think/Pair/share

Instruction: Be in pair and share your reflection on the following words? 10 minutes

- Forecasting
- Supply Planning
- Quantification



In general terms, Quantification is used to determine how much of a vaccines or products is required for a specific health service. Forecasting is the process of estimating the quantities and costs of the products or vaccines required for a health program (or service) and Supply Planning is the process of determining how much should be procured and when the products should be delivered to ensure an uninterrupted supply for the program. –. It takes into account the expected demand for commodities, unit costs, existing stocks, stock already on order, expiries, freight, logistics and other costs, lead times, buffer stocks available funds, human resource capacity, storage space capacity, and capacity to deliver services. Using this information, the total commodity requirements and costs are calculated and compared with the available financial resources to determine the final quantities to procure.

It is very essential to have adequate stock of vaccines and its consumables at every level of the supply chain. If it is in less quantity the immunization program may suffer and in the case of excess quantity, wastages and the chances of vaccines to loss their potency increase. The quantity of the vaccines should be calculated for the period and a designated quantity (25%) should be added to keep as buffer stock.

Thus, accurately estimating stockholding (vaccine and supplies) is essential to the success of the EPI program and can be done by using the estimate of: -

- The target population,
- Coverage
- Number of doses per person
- Wastage rate (open and close vials) that include both supply chain and vaccine administration related wastages
- The consumption method based on historical vaccine usage (the necessary adjustment for stock out and other data quality related issues should be considered while applying this method)

2.2. Factors determining accuracy of vaccine and supplies forecast

Routine immunization program policy and vaccine supply chain system should be considered during forecasting exercise. Policy and program guidelines determine the target population, coverage, number of doses per target, wastage rate, supplies interval, maximum and minimum, and safety stock at all level of the system.

Factors determining accuracy of vaccine and supplies forecast

1. Vaccine type, formulation, and presentation
2. Vaccine storage requirement
3. Cold Chain storage Capacity
4. Immunization strategies
5. Vaccine stock on hand
6. Supply interval
7. Vaccine utilization and wastage rate

2.2.1. Vaccine type, formulation, and presentation

In Ethiopia, there are more than 12 antigens provided thorough routine EPI. In forecasting exercise identifying a type and presentation of vaccine that will be used in routine immunization program is a critical step and determine the result of consecutives activities. The presentations and formulations of vaccines selected in this step have great effect in terms of: -

- Storage capacity
- Cost of vaccines
- Distribution
- Utilization and wastage, and Administration procedures at the end users.

The presentation indicates the number of doses per vial/ampoules (single dose or multi dose). The formulations of vaccines are in liquid (solution and suspension), freeze dried, with preservatives and without preservatives.

2.2.2. Vaccine Storage Requirement

The presentation and formulation of vaccines determines the storage requirement, maximum stock level at primary and sub national level, type of cold chain equipment used during storage and transportation at all levels of the vaccine supply chain system. In Ethiopia there are vaccine which required two different temperature range storage requirements at central and EPSS hub level. A negative storage temperature is required (-25 0C to -150C) to store OPV vaccines, and currently ultra-cold chain (-80°C to -60 °C in freezer) is required for some of the COVID 19 vaccine such as Pfizer. A positive temperature required (2 °C to 80C) for the rest of the vaccines at all supply chain level. BCG and measles can be stored at (-25 0C to -150C) at central and ESPS hub level if there is adequate negative storage capacity. The maximum recommended storage period at Central and EPSS hub level is six and four months respectively. All vaccines and diluents in woreda and health facilities should be store in a temperature range of 2 0Cto 80C for a maximum of one month period.

2.2.3. Cold Chain Capacity

Cold chain is the backbone of a vaccine supply chain system. The cold chain capacity at all levels should be evaluated yearly for basic replacement and expansion plan in line with the demand of the immunization program. During forecasting exercise cold chain storage capacity should be considered to minimize vaccine wastage rate due to overstocking of vaccines.

2.2.4. Immunization strategies

In Ethiopia there are three types of immunization strategies to deliver the immunization service. These are static, outreach and mobile. The utilization of vaccines and supplies varies depending on the immunization strategies. Ethiopia adopts the WHO recommendation on the use of multi dose vial policy for opened vials. Currently, MDVP is applicable for bOPV, IPV, PCV and Td vaccines. All opened vial vaccines, which does not fulfill the WHO MDVP should be discarded at the end of the immunization session or after six hours which ever come first.

2.2.5. Vaccine stock on hand

It is the quantities of usable stock available in the system. It does not include damaged, expired, and VVM stage at discard point. The amount of stock on hand should be calculated before ordering new stock to avoid having too much vaccine delivered with no place to store it or storing vaccine for too long at the most peripheral level where the cold chain is weakest.

2.2.6. Supply Interval

It is the period during which vaccine store and frequency of delivering vaccines at each level. The supply periods determined based on transport availability, cold chain storage capacity, stock management system and continuity of energy supply and level of the supply chain. In Ethiopia the supply period at:

- EPSS hub level - Three months
- Woreda stores and health facilities - One month

2.2.7. 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 wastage is the number of vaccines that have not been administered during vaccine deployment in an immunization program.

2.2.8. Reserve requirements

Reserve stock is the additional amount of vaccine needed in case of an emergency, such as a sudden increase in demand, higher than expected wastage, or delays in re-supply. Most programs maintain a reserve stock of 25% over the amount they expect to use during the supply period, but experience should dictate this proportion.

2.3. Forecasting vaccine and related supplies

Forecasting is the process of estimating vaccines, and related supplies (diluents, syringes, safety box, Personal protective equipment (PPE) etc.) required for a target population in a specific period. The quantity of the vaccines should be calculated for the period and a designated (25%) quantity should be added to keep as buffer stock.

WHO and UNICEF recommends that vaccines shall be ordered with the necessary safe injection equipment. This module refers to diluents, droppers, auto-disable (AD) syringes, mixing syringes and safety boxes as safe-injection equipment and incorporates the principle of bundling that is vaccines and safe-injection equipment are always available together, corresponding the vaccine quantities, at each level of the supply chain. In the Context of COVID 19 pandemic, essential PPEs (personal protective equipment) shall be in place to prevent the transmission of COVID 19.

Whether the source of vaccine is local or international, managers must determine the target population, assess the probable impact of different delivery strategies on vaccine needs, set supply intervals, review data on vaccine utilization and wastage, and calculate reserve requirements.

There are three methods of Vaccines and related supplies forecasting: -

- Target population
- Consumption and
- Size of immunization sessions

Target population method is suitable for higher levels (National, Regional and Zonal) while number and type of sessions planned is more suitable for planning at lower levels such as the district and health-facility level.

a) Target population method

The accurate estimate of the target population is very essential for the target population forecasting method. Sources of information on population size include census data, birth registrations, and head counts at the local level.

Formula to be used in target population forecasting method

Annual Need of Vaccines in dose= Annual target population* Annual coverage plan* number of doses per individual target* wastage factor

Note: *This formula assumes that 25% buffer stock is available at any time. It has to be considered during new vaccine introduction or 25% buffer stock is not available during the planning session.*

Monthly Requirement: To calculate Monthly vaccine requirement divide the annual requirement by 12.

Wastage factor: The wastage factor is the factor (number) that you multiply your estimated vaccine needs by, in order to allow for some doses being wasted. The wastage factor is derived from the vaccine wastage rate (VWR) using the following formula.

$$\text{Wastage Factor} = \frac{100}{100 - \text{Wastage Rate}}$$

Vaccine utilization and wastage is another factor in forecasting vaccine needs. Vaccine utilization is the proportion of vaccine that is supplied and administered.

$$\textit{Vaccine usage Rate} = \frac{\textit{Doses Administered (used)} \times 100}{\textit{(BB+QR)-EB}}$$

Note: BB-Beginning Balance, QR–Quantity Received, EB-Ending Balance

Vaccine wastage is the proportion of vaccine that is wasted, calculated as a rate as shown in the box below:

Vaccine wastage rate = 100 - Vaccine Usage rate

Some wastage is predictable and acceptable. For example, most health workers do not get all of the doses out of a multi-dose vial, and managers should plan accordingly. However, wastage rates higher than expected can be an indicator of operational problems in a health facility.

High wastage can also indicate problems in cold chain or vaccine stock management if vaccine must be discarded because of breaks in the cold chain or expiration of vaccines. At the same time, high wastage may be an unavoidable consequence of policies to provide services to sparsely settled populations. Managers need to interpret findings of excessive wastage carefully before taking actions that result in lower immunization coverage.

Table 2-1 WHO indicative Wastage rate and Wastage factor commonly used for forecasting

S.N	Vaccine and Supplies	Wastage Rate	Wastage Factor
1	BCG	50%	2
2	Measles	35%	1.54
3	Td, OPV, IPV, PCV	10%	1.11
4	Pentavalent, Rotarix, HPV, HepB	5%	1.05
5	AD Mixing syringes	5%	1.05
6	Safety Box	5%	1.05

Activity 2.2: Group exercise

Instruction:

- Be in group of 5-6 people
- Discuss the below question in your group and report the work in the plenary (share group response to the larger groups using flipchart)

The time is August 2022, and the forecast for 2023 is being prepared for EPSS hub "X". The total population served under its catchment is 2,800,000 and under one children proportion estimated to be 3.2% of the total population. Expected coverage of PCV for next year is 90% and estimated PCV wastage was 10%. The hub is collecting vaccine from EPSS center in quarterly basis. Because of hub "X" located in the remote part of the region the time it takes to collect and come back from EPSS center is one week so calculate the following:

1. Total number of PCV doses needed per supply period
2. AD syringe and safety box needed for the supply period
3. Maximum, minimum and critical stock

Time- 25 Minutes

Estimating AD syringes mixing syringes and Safety box requirement

Formula to calculate AD and mixing syringes

AD Syringe required = Required number of doses*Wastage factor (1.05)

Note:

- *IPV, Pentavalent, Pcv-13, Measles, Hep BD, HPV, Td, Janssen, and Sinopharm use **0.5ml** AD Syringe*
- *BCG-uses **0.05ml** AD Syringe and Pfizer Vaccine uses **0.3ml** AD Syringe*

Reconstituting syringe

Mixing syringes required = Number of vials of vaccines required X Waste Factor (1.05)

Note:

- Currently, vaccines that require mixing syringes for reconstitution in Ethiopia are BCG and measles vaccines. The number of vials will be calculated by dividing total doses by doses per vial of specific vaccine.
- The wastage rate for AD syringe and the vaccine may not be similar (for instance in case of BCG, the vaccine wastage rate is 50% whereas the wastage rate for its AD syringe is 5%. Therefore, forecasting has to take in to account, this scenario during the forecasting Exercise.

Estimating required number of safety boxes

Safety boxes required = (Total AD syringes + Reconstituting syringes)/100

b. Consumption methods

This method is based on the consumption of vaccines during the previous reporting period (usually the previous year). Each parameter relative to previous consumption can be affected by many factors, especially program performance during the supply period. Estimating needs based on previous consumption, therefore may not be as reliable as the method based on target population. Consider the following parameters when estimating vaccine and safe-injection equipment needs based on previous consumption:

- Initial stock at the beginning of the given period (B)
- Stock received during the period (R) and
- Stock at the end of the period (E)
- Number of damaged unopened vaccines vials (destroyed, frozen or affected by high temperature or expired during the same period) (L)

Vaccine needs = (B+R)-(E+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. There is no single method for forecasting, mix of different methods can be used at time.

How to calculate the wastage multiplication factor (WMF)?

The vaccine wastage factor indicates how much additional vaccine should be ordered to compensate the given wastage rate. The vaccine wastage rate can vary greatly according to several characteristics of the program like session sizes, session plans, vial presentation, formulation, and supply management. In vaccine forecasting the vaccine wastage factor is used to calculate the demand for the specific supply period. The following formula shows the relationship between the VWR and the WMF.

$$\text{Wastage Factor} = \frac{100}{100\text{-Wastage Rate}}$$

- Where: - "100" is the total number (100%) of vaccine doses supplied
- "Wasted rate" – is the number of doses (in %) wasted

Example:

The wastage factor of 35% vaccine wastage rate will be Wastage factor = 100 = 100 =1.54
(100-35) 65

That means, for every dose of this particular antigen administered, managers should anticipate 1.54 doses to compensate for the 35% wastage. The most common wastage factors are given in table 1 for quick reference guide wastage rates and their corresponding wastage multiplication factors (WMFs).

Table 2-2 Common wastage rate versus wastage multiplication factor

Wastage Rate	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%
WMF	1.05	1.11	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2

C. Immunization sessions methods

Vaccine need based on size of immunization sessions:

= 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.

Note: For all methods, the accuracy of forecasted quantity of vaccine and supplies depends on the quality of the data used for forecasting and the knowledge of the health care worker doing the calculations

2.4. Forecasting vaccines and related supplies for outbreak responses

Substandard or low immunization coverage for continues period cumulate susceptible cohort for vaccines preventable diseases outbreaks. Measles and Meningitis outbreaks and polio virus circulations are few among vaccines preventable diseases. Required quantity of vaccines and other supplies may increase under special conditions like outbreaks, conflicts, and internal displacement, substandard or low immunization coverage (high number of unimmunized and under immunized children) etc. where separate planning is essential.

In such instance factors required for vaccines forecast are similar with routine vaccines except changes in

- Target population, age, etc.
  - e.g. Measles – consider <1 Yr. for route and under <5 or <15 Years for outbreaks
- wastage rate and
- Supply lead time.
- Additional, assessing the cold storage capacity, distribution plan including transport should be considered.

2.4.1. Vaccine Stock levels

Minimum stock level

The minimum stock represents the minimum number of doses of vaccine that should be in the storage point on the arrival of the next supply consignment. The level of minimum stock is generally fixed at 25% of the total estimate of vaccines need for a given supply period.

> **Formula:** Minimum stock (Smini) = Quantity for the supply period (Q period) x 25%

Example: If the number of doses required for a given period is 10,000 and percentage of desired minimum stock is 25%, then Minimum stock (**Smini**)= ????

Formula: Minimum stock (**Smini**) = Quantity for the supply period (Q period) x 25%

Minimum stock (doses) = 10,000 x 0.25 = **2,500 doses**

Maximum stock level

It implies the large amount of stock that should have usually expressed in terms of numbers of weeks/months/quarters of supply. 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 wastage of vaccines to expiry before use.

Quantity for supply period is the amount of vaccine required for one supply period. It is calculated by dividing the annual forecasted quantity to 12 month and multiplied by supply period in month.

> **Formula:** Maximum Stock (S_{maxi}) = Supply period stock (Q_{period}) + Minimum stock (S_{mini})

Example: If the number of doses required for a given period is 10,000 doses, then

- Minimum stock (doses) = 2,500
- Maximum stock (doses) = 10, 000 +2,500 = 12,500

Calculation sequence:

Maximum Stock = Number of doses required for a given period + Minimum stock

= 10,000 + 2,500 =12,500

Re-Order Point (Critical Stock)

This is also known as the re-order level. It implies the least amount that you should have in your stock or the stock level at which reorder should be initiated. It is usually expressed as the numbers of weeks/months/quarters of supply. It is an amount of stock, which is used in the time between placing and receiving the order plus the buffer (safety) stock. The critical stock is the least amount below which stock should never drop without having placed an order. In another word, the critical stock is the stock needed worth to cover the lead time plus the minimum stock

Formula: Critical Stock = Supply period stock (Qperiod) x Leadtime / Psupply) + S_{mini}

Example

Number of doses required for a period of 12 weeks = 10,000

- Delivery time (in weeks) = 2

- Minimum stock (in doses) = 2,500

- Critical stock (in doses) 10,000 x 2/12 +2,500 = 4,167

Lead time: is time between ordering of new stock and receipt/ available for use. The lead time varies, depending on reliability of transport, and sometimes the weather. For instances if pentavalent monthly requirement of a Health Center is 280 doses, the buffer stock will be 25% of 280 i.e., 70 doses. If the lead time is one week, then the re-order (critical) stock will be buffer stock plus requirement for lead time, one week which will be 280/4 (70 doses) i.e., the critical stock will be 70 doses (safety stock) + 70 doses (stock worth to cover the lead time) =140 doses.

The maximum stock level will be: the minimum stock + the stock required between the orders (for three-week stock) i.e., 210 doses. Therefore, the maximum stock level will be 140+210=350 doses. If the stock falls below the re-order level inform the higher-level vaccine store to replenishment and place an order to avoid any shortage or stock out.

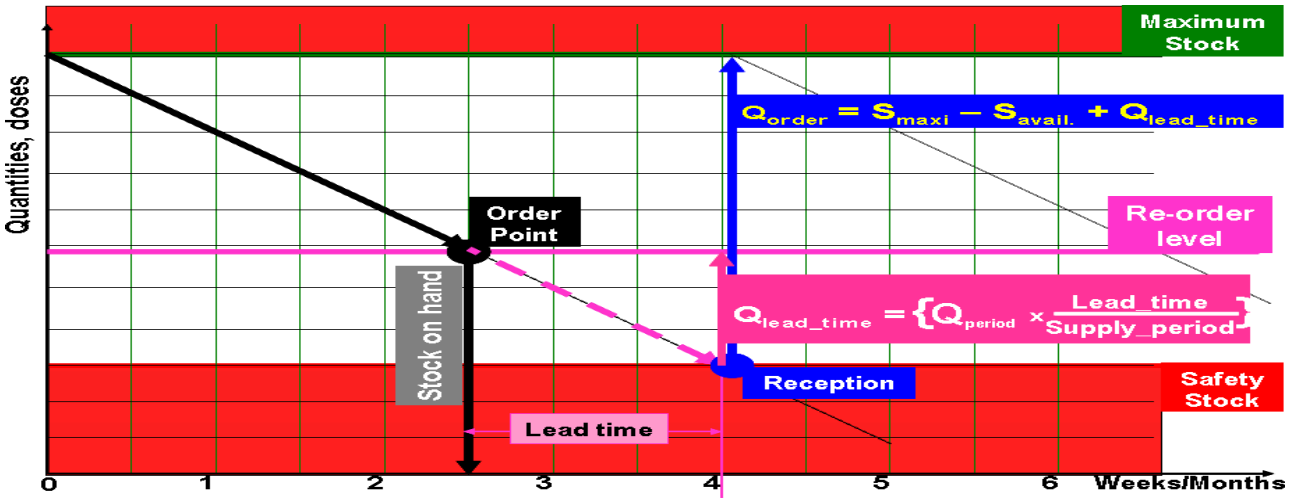


Figure 2-1 Different stock levels

Activity 2.3: Group discussion

Instruction:

- Be in group of 5-6 people
- Discuss the below question in your group and report the work in the plenary (share group response to the larger groups using flipchart)

Time- 15 Minutes

Table 2-3 Adama city, Geda XXY health center data (Ideal data for exercise purpose)

Vaccine	Target population	No of doses	Coverage	Wastage factor	Stock on hand (doses)	Minimum stock	Supply period	Presentation/ dose per vial
BCG	5,330	1	100%	2	1000	25%	One month	20
IPV	5,000	1	100%	1.11	500	25%	One month	10
PCV	5,000	3	100%	1.05	300	25%	One month	4
Measles	5,000	2	100%	1.54	700	25%	One month	10
Penta	5,000	3	100%	1.05	500	25%	One month	1
Rota	5,000	2	100%	1.05	0	25%	One month	1
bOPV	5,000	4	100%	1.11	1000	25%	One month	10
Td	5,330	3	100%	1.11	700	25%	One month	10

Taking into account the parameters given in the above table, calculate the vaccine needs as follows and present it for the large group

- Quantity that you intend to use for supply period
- Minimum stock
- Maximum stock

2.5. Chapter Summary:

- Quantification refers to process of estimating the quantities and costs of the products required for a defined health service and period,
- Quantification has preparation, forecasting and supply planning steps
- Well performed quantification exercises have so many benefits; on the other hand, bad practices of quantifications have negative consequences to the management of vaccines and related supplies
- Substandard and low immunization coverage for continues period cumulate susceptible cohort for vaccines preventable diseases outbreaks

Chapter 3

Stock management of vaccine and related supplies

Allocated Time: 3:00 hours

Chapter Description:

This chapter describes effective stock management, physical inventory, factors affecting vaccine stock levels and the management of damaged and expired vaccines and supplies.

Chapter Objective:

At the end of this chapter, participants will be able to describe Stock management of vaccines and related supplies.

Enabling Objectives: -

At the end of this chapter participants will be able to: -

- Describe effective stock management
- Identify and manage factors affecting vaccine stock level
- Explain planning and regular stock monitoring (physical inventory) ,
- Identify damaged and expired vaccines and supplies

Chapter outline:

3.1. Introduction to vaccine stock management

Activity 3.1. individual -Reflection	
Question: What are the benefits of regular vaccine stock monitoring? Time: 5 min	

A good stock recording system is a valuable tool in the management of vaccines, their storage, movement, and use. The availability of reliable and quality stock data is vital in availing lifesaving vaccines and for informed decision-making process at all levels of the supply chain system.

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

Practical methods and format are described below: consider that vaccine and supplies will be received on a regular basis and issued to the 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, when that there is a serious adverse event, it will be useful to know the exact description of the vaccine (manufacturer, batch number etc.) to track the affected vaccine in the supply chain

Vaccines and supplies stock monitoring is an integral part of the overall EPI management system and should take place regularly. Monitoring vaccines stock:

- Ensures the availability of adequate quantities and assured quality of vaccines and supplies.
- Ensures appropriate use of vaccines at service delivery.
- Enables the timely detection of management problems so that corrective action can be taken.
- Guides the supply planning process

The responsible staff must be satisfied that the following control tools for the use of vaccines are correctly implemented.

- The use of VVM (Vaccine Vial Monitor) and other temperature monitoring devices
- The application of opened vaccine vial policy
- Correct diluents bundle
- Monitoring the use and wastage of vaccines

3.2. Effective stock management

The control of vaccines stocks is one of the main tasks of vaccine management. It consists of receiving and accepting vaccines, ensuring the required storing conditions and controlling the distribution of vaccines through the different structures (National cold store to immunization sessions) in order to ensure the quality of vaccines for immunization programs.

3.2.1. International vaccine shipment arrival

During transport and transit, the integrity of vaccines must be ensured through a reliable cold chain. Recipient agencies and governments should only accept vaccines if shipment procedures and quality assurance during the shipment have been guaranteed and followed. It is the responsibility of the trained transistors to clear shipments through customs authorities upon arrival and prompt transfer to central vaccine stores.

Vaccine Arrival Report(VAR) is a register for recording the conditions of vaccines upon delivery and possible anomalies in the shipment. It is the responsibility of the program manager and warehouse manager to ensure that all sections of the VAR are completed and returned to the procuring agent or UNICEF country office within 72 hours. The VAR completed only at national level and it is a basic and important document for claims in cases of litigation.

3.2.2. Vaccine Arrival

Responsible staff should understand the importance of accurate record-keeping and should receive training in the use of the stock management system, whether paper-or computer-based.

As a minimum, the following information should be recorded and checked against the arrival:

- **Vaccines:** quantity (in doses), type, manufacturer, vial size, batch or lot number(s), expiry date for each batch or lot, VVM status (1,2), cold chain monitoring (CCM) card status (A,B,C,D) and freeze indicator status etc.
- **Diluents:** quantity (in doses), type of diluents (e.g. Measles 10 dose), manufacturer, batch or lot number(s), expiry date for each batch or lot.
- **Droppers**: quantity, type of dropper (e.g. OPV20dose), manufacturer, manufacturing batch or lot number(s).
- **Other consumables:** quantity, type, manufacturer and (where relevant) expiry date. Other consumables include AD syringes, mixing syringes, safety boxes, etc.
- Enter delivery information of each vaccine and diluents in the stock record system as soon as received.

It is advisable to have separate books, ledger sections, or stock cards for each type of vaccine and diluents. Where books are used, label each book or ledger section clearly with the vaccine and diluents type. Label it clearly– e.g. diluents for 10 dose measles vaccine manufactured by XYZ Inc'.

Where stock cards are used, open a new card for each new item and record only one vaccine batch or lot on each card. Again, label each card clearly. Where a computer-based stock control system is used, either a separate file for each vaccine and diluents type or keep separate sheets for each vaccine and diluents type in the same file.

In Ethiopian context there is a computer-based health commodity management information system (HCMIS) at national and sub-national level. EPSS central and its hubs used health commodities management information system to monitor stock and manage transactions. At Woreda Health office and health facility level there is an effort to deploy, a mobile based application to manage inventory and transactions. This application also generates monthly vaccine request.

3.2.3. Issue vaccines, diluents, and supplies in FEFO order

Responsible staffs should know and take into account the expiry date, VVM stages, and first-expiry, first-out'(FEFO) stock management system during dispatch of vaccines and other consumables. They should also understand that freeze-dried vaccines must always be issued with the correct diluents in matching quantities.

- **Expiry date:** All stocks must be distributed well before their expiry date is reached in order to allow sufficient time for them to pass through the distribution system and to reach the end user. During the period that vaccines remain in storage, regularly check the expiry dates of the stock to ensure that older batches are distributed before more recent arrivals.

- **FEFO principle:** Newly arrived stocks will generally have a longer period before expiry than those which have been in storage for some time irrespective to VVM stage. Thus, older stocks and VVM stage 2 should normally be distributed first so as to ensure proper rotation of supplies, and to ensure that no batch or lot remains too long in storage. All vaccines and diluents must be systematically arranged in the store so as to facilitate a first-expiry, first-out'(FEFO) stock management system.

- **VVM stage:** In addition, regularly check the integrity of the stocks by reviewing the status of the VVMs for each vial. If the VVM shows any significant color change during the period that the vaccines have remained in storage, this indicates a weakness in the cold chain system. Repair or maintenance of the cold chain equipment may be needed. If any freeze indicators have burst/ an alarm triggered this shows a serious failure of temperature control and vaccine may as well have been damaged.

- **Heat-exposed vaccines** may have to be issued ahead of its FEFO sequence, and in such cases, the reason for doing so should be recorded. However issuing vaccine in this way should be done with care because it may cause displaced batch to reach its expiry date before it can be used.

- **Matching Freeze-dried vaccines with diluents (Quantity, manufacturer):** Incorrect issuing of diluents is a commonly observed system failure. Consignments of freeze-dried vaccine should always be dispatched with the correct quantity and manufacturer of diluents for reconstituting the vaccine. Diluents must always be used with the vaccine for which they are manufactured. Diluents are not all the same, and they must NEVER be interchanged. Careful stock control and accurate records are vital to ensure that the correct diluents is always kept and distributed with each vaccine type and batch.

3.2.4. Stock keeping records

Responsible staff should know how to inspect vaccine before dispatch, how to record the transaction in the stock record system and to complete the delivery section of arrival form. Record the details of each consignment leaving the store in the appropriate ledger

book, stock card or bin card and calculate the balance or the remaining balance in stock. Alternatively record the information on the computerized stock recording system, which will automatically recalculate the balance stock. Do this at the time of distribution and ensure that all detail correctly recorded.

For vaccines, diluents, injection devices and droppers: quantity distributed (in doses); destination for the consignment (i.e., name of intermediate store); balance stock (in doses) of that batch or lot number after subtracting the amount distributed.

All details of the items being distributed should then be written on the delivery/arrival form (vouchers) which will accompany the consignment to its destination. The receiving store will then know exactly what items are being delivered, and they can then enter the correct details on their own stock record system. The details on the delivery/arrival form(vouchers) should include:

For vaccines, diluents, and droppers: Type of vaccine or diluents; quantity distributed (in doses); vaccine/diluents manufacturer; manufacturing batch or lot number(s); expiry date(s) for each batch or lot, and status of the VVMs and CCMs (if used) as the vaccine leaves the store.

For injection devices: Type of product; quantity distributed; product manufacturer; manufacturing batch or lot number(s) (where relevant),and expiry date(s)for each batch or lot(where relevant).

See annex 2 for recording ledger book

NOTE:

- Record any change in VVM status in the stock record system and transfer this information accurately to the vaccine delivery/arrival form.
- Stock records, requisition form, delivery note/arrival form like voucher should be kept appropriately for atleast 3years and archive following the organizations procedures.

3.3. Factors affecting vaccine stock levels.

Activity 3.2. Individual -Reflection	
Instruction: list factors affecting vaccine stock level. Time;15 min	

Poor forecasting and stock management usually cause delay in ordering and receiving supplies. Likewise, diseases outbreak and cold chain failure also affect the stock level. The program managers and responsible staff members should give due attention; forecasting appropriate quantity of vaccines and supplies, ensure the quality of stock records and use the information for action.

3.4. Physical inventory

Activity 3.3: Group discussion	
Instruction: ■ Form a group 5 participant per each group ■ Discuss the below question in your group and present to the larger groups by using flipchart Discussion Question: 1. List and discuss the types of physical inventory? 2. Steps in conducting a physical inventory? Time: 3 min for reading and discussion 7 min for presentation Total time: 10 minutes	

Physical inventory: The process of counting by hand the number of each type of product (vaccines, diluents, syringes, etc.) in warehouse at a given time.

- It helps/ensure that the stock on hand balance recorded on stock keeping records match the quantities of products actually in warehouse.
- The counting must include all stocks of every vaccine, diluents or dropper and injection devices.
- The counting should also match diluents and droppers to the correct vaccines quantity and manufacturer.

There are two types of physical inventory

3.4.1. Complete physical inventory:

- All products are counted at the same time.
- Should take place once a year
- More frequent inventory quarterly or monthly is recommended for large warehouses. This may require closing business/storage facility for a day or longer

3.4.2. Cyclic or random physical inventory

- Selected products are counted and checked against the stock keeping records on a rotation or regular basis throughout the year
- Complete physical inventory is easier to conduct regularly at facilities that manage smaller quantities of products(vaccines, diluents, syringes etc.)
- Cyclic or random physical inventory is more appropriate for facilities managing larger quantities of products (vaccines, diluents, syringes etc.)

Steps in conducting a physical inventory

- detail plan with schedule
- arranging required staffs
- organize the cold and dry store
- Count all the products (vaccines, diluents, syringes etc.)
- Update the stock keeping records
- Act based on the results of the inventory.
- discuss the findings of the inventory with the facility staff members
- Prepare detailed report of the inventory findings

Note: The recommended Physical Inventory is

- At Central EPSS should conduct inventory quarterly while EPSS hubs and health facilities have to conduct quarterly and monthly respectively.
- At all levels–conduct a physical inventory and update the stock recording formats whenever you prepare VRF for resupply.

3.5. Managing expired and damaged stock

Activity 3.2. individual -Reflection	
Question: How do you handle damaged and expired vaccines and supplies at your facility? Time;15 min	

Responsible staff should know the correct procedures for storing, writing off and safely disposing of expired or damaged stock.

Expired vials, heat damaged vials (vials with VVMs at discard or beyond the discard point) and frozen vaccines (vaccines that failed shake test) should not be kept in the cold store, refrigerator, or freezer, as they may be confused with good quality vaccines. If unusable vaccines must be kept for a period before disposal, for example, until accounting or auditing procedures have been completed, such vials should be kept outside the cold chain, separated from all usable stocks, and clearly labeled *"Damaged/expired vaccine – do not use"* to avoid mistaken use.

Similarly, only vaccine stocks which are fit for use should be included in stock records. Damaged or expired vaccines should not appear in the available stock balance. If such vaccines do need to be kept until accounting or auditing procedures have been completed, details should be recorded on a separate page or card, pending disposal.

Once disposal has been authorized, damaged items should be disposed of safely by incineration or other nationally approved means. It is advised to keep a record of discarded vaccines at least for three years.

CASE STUDY 3.1

Complete vaccine ledger based on the following data found at Woreda "X" cold store. On 20/03/2013 E.C -XI Woreda received the following vaccines from -ZII EPSS hub:

Table 3-1 Case study managing expired and damaged stock

Antigen	Formulation/ Presentation	Dose	VVM status	Expiry date	Batch #
BCG	20	2,000	1st	Nov.2023	004N0128
DPT-HepB-Hib	1	1,800	2nd	March.2023	044N0130
Measles	10	1,800	1st	Aug.2023	004N0141
PCV13	4	1,800	2nd	June.2023	004G0128
OPV	10	1,800	1st	June.2023	054N0133
Td	10	2,000	1st	July.2023	064L0145

On previous day the Woreda cold store manager physically checked the refrigerator and there are only 52 doses of PCV vaccine with 1st stage VVM status, 004G0111 batch number & Sept. 2023 expiry date. On the next day KIIHC received 200 doses of Td of Batch # 064L0145 with the 1st VVM status and July2023 expiry date. After 2 days KIIHC issued 20 doses of Td of Batch # 064L0145 to LII health post with the 1st VVM status and July2023 expiry date. On the same day afternoon, LIIHP after vaccinating 8 girls returned 10 doses of Td of Batch # 064L0145 to KIIhealth Centre with the 2nd VVM status and July.2023 expiry date. All the transactions are for routine EPI purpose.

3.6. Summary

- A good stock recording system is a valuable tool in the management of vaccines, their storage, movement and use.
- The availability of reliable and quality stock data is vital in availing lifesaving vaccines and for informed decision-making process at all level of the supply chain system,
- poor forecasting, stock management, diseases outbreak and cold chain failure are factors affects vaccine and supply stock levels
- in vaccine stock management complete and random/cyclic physical inventory should conducted to ensure that the stock on hand balance recorded on stock keeping records match the quantities of products actually in warehouse and
- finally, expired vials, heat damaged vials (vials with VVMs at discard or beyond the discard point) and frozen vaccines (vaccines that failed shake test) should not be kept in the cold store, refrigerator, or freezer, as they may be confused with good quality vaccines.

Chapter 4

Vaccine storage and distribution systems

Allocated Time: 2:30 hours

Chapter Description:

This chapter describes characteristics of a good storage and distribution practice, planning for vaccine distribution, packing and loading of vaccine bundles, monitoring temperature during vaccine transportation, and vaccine arrival checks and reporting procedures.

Chapter Objective:

At the end of this chapter, participants will be able to describe the concept of good storage and distribution practice.

Enabling Objectives:-

By the end of this chapter participants will be able to:-

- Describe vaccine distribution systems.
- Describe characteristics of good storage and distribution practice
- Demonstrate distribution planning.
- Monitor temperature during vaccine transportation.
- Identify vaccine arrival checks and reporting procedures.

Chapter outline:

4.1. Introduction to vaccine distribution systems

4.2. Characteristics of a good storage and distribution practice.

4.3. Vaccine distribution planning.

4.4. Monitoring temperature exposure during vaccine transportation.

4.5. Vaccine arrival checks and reporting procedures.

4.6. Summary

4.1. Introduction to vaccine storage and distribution systems

Activity 4.1. individual -Reflection

Question: What does it mean by vaccine distribution system?

Time 5 min

Vaccine distribution systems need to be efficient so that vaccines are always available in the facilities where they are needed. Correct stock levels with minimum and maximum levels indicated, proper vaccine request and reviewing practice, good receiving and distribution processes are all essential components of the supply chain. In addition, good inventory management procedures must be implemented. Sometimes vaccine might be returned to store from the lower level of the supply chain system due to different reasons and hence reverse logistics system should be in place with standard procedure and protocols.

4.2. Characteristics of a good storage and distribution practice

Activity 4.2: Group discussion

Instruction:

- Be in group of 5-6 people
- Discuss the below question in your group and share your idea for the rest of the groups.

Discussion Point:

List and discuss characteristics of a good storage and distribution practice.

Time: 10 min for reading and discussion 15 min for presentation

Total time: 25 minutes

A well-run vaccine storage and distribution system should:

- Maintain a uninterrupted supply of vaccine and related supplies and waste management supplies
- Keep vaccine and related supplies and waste management supplies in good condition
- Rationalize the storage locations of vaccine and related supplies
- Ensure timely vaccine distribution as per VRF
- Ensure bundling of vaccine is practiced at all level
- Use available transport as efficiently as possible.
- Use temperature monitoring tool during transportation
- Minimize vaccine wastage due to spoilage and expiry
- Maintain accurate and up to date inventory records using stock monitoring tool

A good distribution system should be cost-effective. This requires systematic cost-effectiveness analysis and operational planning. Once the system is in place, regular performance monitoring is needed to ensure its functionality and flexibility.

In designing or redesigning a vaccine distribution system it is necessary to:

- Determine how and to what extent it is to be integrated into the national drug distribution system;
- Design the distribution channel and route map
- Determine the number of storage levels in the system;
- Determine the level of the vaccine supply system at which ordering decisions are to be made;
- Fix resupply intervals or the frequency of placing orders;
- Select a method of distributing vaccines to service points;
- Develop a set of feasible and economic delivery routes and work out a practical delivery schedule
- Estimate operating costs and assess the cost-effectiveness of contracting out for storage and transport at one or more levels
- Determine the key indicators to be used for monitoring performance.
- Evaluate distribution plan against the actual performance
- Ensure systematic temperature monitoring or journey profiling has been regularly carried out
- Ensure driver/cold room manager, warehouse operatives and the delivery person has adequate knowledge on how to load refrigerated vehicle
- Ensure a written transport contingency plan is available.

Table 4-1 Recommended stock level of vaccines and supplies at each level

Level	Recommended Reorder Period	Maximum Months of Stock	Minimum Months of Stock
Central	3 months	6 month	1 month
EPSS Hub	3 months	4 month	1 months
Woreda	1 month	5 weeks	1 weeks
Health Facility	1 month	5 weeks	1 weeks

"Pull" and "Push" Systems of distribution.

"Pull and Push" system describes vaccine needs based on where the forecast is initiated. In a -Pull systemll, staff members at the service delivery level estimate their needs. Health facility and district estimates are consolidated and procurement proceeds at the central level. Vaccine is then distributed according to these local requests. In a push system, national-level staff estimate health facility needs based on census data, population projections, and/or usage history. This system seems to work best in countries where district and health facility staff have limited forecasting skills or in situations when vaccine must be ordered and distributed quickly, such as an unanticipated influx of refugees and in the case of pandemics.

4.3. Vaccine Distribution Planning

Before starting vaccines and other EPI supplies distribution and/or collection planning is very important. The vaccine distribution plan must be agreed upon among the issuing and receiving stores. The same copy of distribution plan should be available at both stores. The plan should include a timetable or schedule of the distribution. In addition, it should consider:

- Number of sites and the route
- Mode of transportation and available transportation capacity,
- Required and available storage capacity,
- Human resource required and
- List and volume of items to be bundled (vaccine, diluents, AD syringes, mixing syringes, dropper, M&E tools, etc.)

4.3.1. Ordering vaccines

To avoid vaccine stock out and over stock, every order of vaccines and other supplies should consider the following:

- Ensure that there are adequate cold chain storage facilities (with adequate capacity and at appropriate temperature).

- Ensure that vaccines received are in conformity with standards of the national regulatory authority, or by WHO and UNICEF.
- Ensure that stocks of supplies (e.g. diluents, syringes and safety boxes, etc.) are available and sufficient.
- Ensure that bundling strategy is adopted and followed as per global guidance or recommendations.

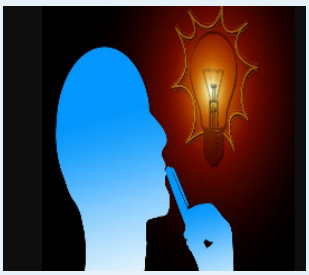
4.3.2. Bundling

The term "bundling" refers to arranging items in collection. Vaccine bundle comprises the following items:

- Good quality vaccines5, adequate diluents and droppers.
- AD syringes and mixing syringes
- Safety boxes.
- Printed materials, if any.

The implication of bundling is that all the items required for the immunization service are planned, distributed and delivered to service sites all together. Bundling has no physical connotation and does not imply that the items must be packaged together.

Activity 4.1. Self-Reflection



Assuming the stocks available are considered at the time of placing the order, answer the following questions.

a. Calculate the quantity to be ordered
b. Calculate the number of vials to be ordered per antigen
c. What do you comment regarding the stock level of this health facility? (Stock out, below stock, between minimum and maximum stock, overstock)
d. Submit your request using vaccine requisition form to the respective higher level

Time 15 min

Table 4-2 Bundling Exercise of the following data refer to X health center

Vaccine	Target Population	No of Doses	Coverage	Wastage factor	Stock on hand	Minimum stock	Supply period	Presentation/no of dose per vial
BCG	5,330	1	100%	2	1000	25%	One month	20
IPV	5,000	1	100%	1.11	500	25%	One month	10
PCV	5,000	3	100%	1.11	300	25%	One month	4
Measles	5,000	2	100%	1.54	700	25%	One month	10
Penta	5,000	3	100%	1.05	500	25%	One month	1
Rota	5,000	2	100%	1.05	0	25%	One month	1
bOPV	5,000	4	100%	1.11	1000	25%	One month	10
Td	5,330	3	100%	1.11	200	25%	One month	10

4.3.3. Processing Requisitions

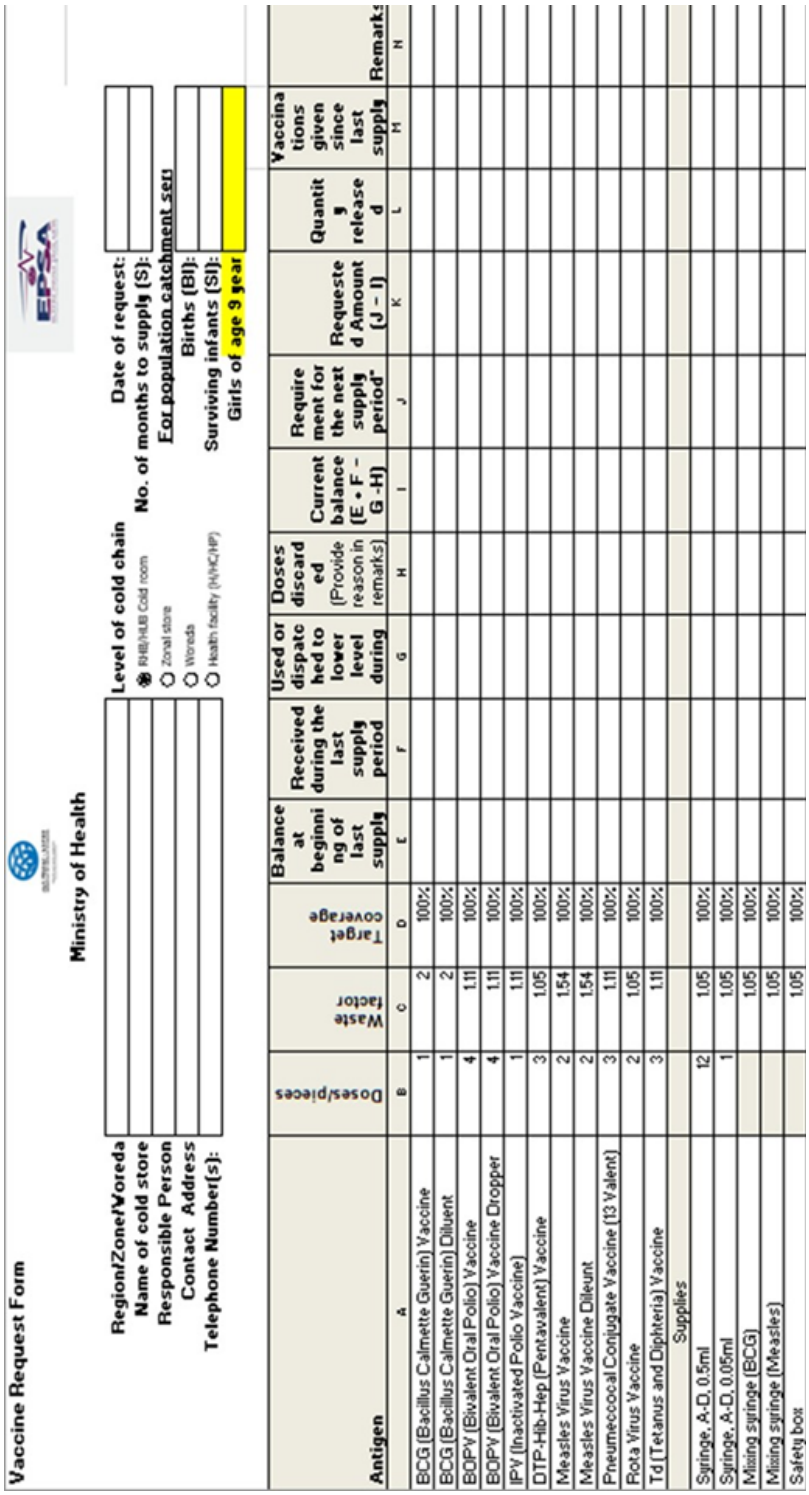
Stringent inventory management system of vaccine and supplies, based on the acceptable review period is very important to avoid stock out and over stock. Vaccines and supplies stored at different level of the immunization supply chain system are limited to serve a specific period because of the limitation in the storage capacity. and supplies, At all levels of the supply chain system, 25% of safety stock should be held to prevent stock out of vaccines and supplies for unforeseen events.

As per the recommended resupply schedule, health facilities and districts place order monthly to EPSS Hubs whereas Hubs place order every quarter to EPSS central. Logistics staff should know how to process requisitions received from the intermediate stores. The responsible health worker must place order of vaccine based on the stock at hand and forecasted vaccine plan. All requisitions should be checked against the agreed distribution plan and any deviation from the expected requisition quantities should be communicated.

4.3.4. Vaccine Requisition Form

Vaccine Requisition Form (VRF) is used to place monthly or quarterly order of vaccines and supplies to the next level of the supply chain system. EPSS hubs place vaccine and supplies request to EPSS central stores in quarterly basis; and Woreda and health facilities request their monthly demand using VRF from EPSS hubs. The vaccine requisition form should be submitted to next level of the supply chain regularly before the end of the period, considering the lead time, to avoid

stock out. (See figure 4 below for the standard vaccine requisition form). Regional health bureau or Zonal health departments monitor and evaluate VRF quality and reporting rate, consumption rate, stock levels, vaccine storage conditions, etc. and provide feedback to the respective health facilities and Woredas. The central EPSS should conduct similar VRF analysis for all respective hubs and provide feedback for improvement.



Vaccine Request Form

Ministry of Health

Region/Zone/Woreda
Name of cold store
Responsible Person
Contact Address
Telephone Number(s):

Level of cold chain
(•) RHB/HUB Cold room
( ) Zonal store
( ) Woreda
( ) Health facility (HVHC/HP)

No. of months to supply (S):
For population catchment serv
Births (BI):
Surviving infants (SI):
Girls of age 9 year

Date of request:

Antigen	Doses/pieces	Wastage factor	Target coverage	Balance at beginning of last supply	Received during the last supply period	Used or dispatched to lower level during	Doses discarded (Provide reason in remarks)	Current balance (E + F - G -H)	Requirement for the next supply period*	Requested Amount (J – I)	Quantity released	Vaccinations given since last supply	Remarks
A	B	C	D	E	F	G	H	I	J	K	L	M	N
BCG (Bacillus Calmette Guerin) Vaccine	1	2	100%										
BCG (Bacillus Calmette Guerin) Diluent	1	2	100%										
BOPV (Bivalent Oral Polio) Vaccine	4	1.11	100%										
BOPV (Bivalent Oral Polio) Vaccine Dropper	4	1.11	100%										
IPV (Inactivated Polio Vaccine)	1	1.11	100%										
DTP-Hib-Hep (Pentavalent) Vaccine	3	1.05	100%										
Measles Virus Vaccine	2	1.54	100%										
Measles Virus Vaccine Diluent	2	1.54	100%										
Pneumococcal Conjugate Vaccine (13 Valent)	3	1.11	100%										
Rota Virus Vaccine	2	1.05	100%										
Td (Tetanus and Diphteria) Vaccine	3	1.11	100%										
Supplies													
Syringe, A-D, 0.5ml	12	1.05	100%										
Syringe, A-D, 0.05ml	1	1.05	100%										
Mising syringe (BCG)		1.05	100%										
Mising syringe (Measles)		1.05	100%										
Safety box		1.05	100%										

Figure 4-1: Standard Vaccine Requisition Forms

Establish a Pre-delivery or Pre-collection notification system

Whenever vaccines are to be delivered, responsible staff at the receiving store should be notified in advance when the shipment is due to arrive. There should be an effective procedure in place for the pre-arrival notification which includes telephone, e- mail, text message, social media platforms or fax. Such notification system is important to ensure that:

- The receiving store is ready for receiving the shipment. This might be done by re-organizing existing stock to free space in cold rooms and freezers.
- The authorized staff member for receiving the vaccines is on site at the time of arrival to check the vaccine quality, receive and sign.

4.3.5. Planning and preparing for icepack /cool water pack

It is important to plan and prepare ice packs sufficient time before needed, depending on the requirements. Large number of icepacks preparation is needed during campaigns. Salt should never be added to the water, as it lowers the temperature to sub-zero level, which is not recommended. For health facility, using cool water pack is recommended.

At Health facility level:

- Calculate the requirement of the cool water packs for immunization sessions. Check your micro-plan and identify the maximum numbers of sessions in a week and numbers of vaccine carriers required in that week.
- Prepare adequate ice packs for cold box lining for the time of emergency. The total icepack requirement will be the sum of the above two.

At National, Sub national and Woreda level:

- Calculate the requirement of the icepack or cool water packs based on vaccine distribution and/ collection program. It is also important to consider campaigns.
- Based on the level of vaccine distribution, and volume of the vaccine add adequate ice packs or cool water for the time of emergency. The total icepack requirement will be the sum of the above two.
- Stack 20-25 (depending upon the ambient temperature) unfrozen ice packs and allow freezing for 24 hrs in the large compartment of Deep Freezer.
- The next batch of 20-25 unfrozen packs are to be kept on the top of the frozen ice packs.
- The frozen ice packs should be stored only up to half the height of the large compartment. The small compartment in the DF can also be used to store ice packs.
- Continue the procedure till you get required numbers of ice packs.

4.3.6. Conditioning icepacks/making chilled water pack

When icepacks are removed from a freezer at (say) - 25°C they need to be kept at room temperature for long enough to allow the temperature of the ice at the core of the icepack to rise to 0°C. This process is called "conditioning". it is advisable that an icepack is adequately "conditioned" as soon as beads of water cover its surface. When icepacks are laid out on a table they create their own microclimate. This extends the conditioning process. The following procedure is recommended:

- Lay out icepacks, preferably in single rows but never in more than two rows.
- Leave a 5cm space all round each icepack.
- Wait until there is a small amount of liquid water inside the icepacks. This will take up to one hour at +20°C ambient temperature and rather less at higher temperatures. Shake one of the icepacks every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.
- Check if an icepack has been conditioned by shaking it and listening for sound.

Figure 4-2: Ice/water pack conditioning

Making cool water pack

To make cool water pack, cool the water packs (regular, unfrozen ice packs) in a +2° to +8°C cold room or refrigerator for at least 12 hours. Cool water can be made in a vaccine cold room or refrigerator (but avoid contact between the water packs and the vaccines). Use cool water packs by loading into cold boxes and vaccine carriers just as you would load ice packs. Cool water packs do not need conditioning.

When the intermediate store or the health facility collects vaccine, the store supplying the vaccine provides froze ice packs and/or cool water packs. The collecting store brings its own cold boxes /vaccine carrier and returns a set of melted ice packs for the next collection.

When the intermediate store or health facility receives vaccine, the store supplying the vaccine provides both the cold boxes/vaccine carrier and the frozen ice packs. The receiving store must return the empty cold boxes / vaccine carrier and the melted ice packs when vaccine is received and store appropriately until the next delivery is made.

Remember:

- Load cool water packs into cold boxes and vaccine carriers just as you would load frozen ice packs.
- Do not condition cool water packs for loading vaccines

Packing area:

The vaccine packing area should be directly connected to the vaccine store and the vehicle loading area. Ensure that the space is large enough to process the maximum anticipated daily throughput of vaccine and diluents, and to accommodate the maximum number of personnel employed to pack vaccine for dispatch. Provide curtains or blinds as necessary to avoid direct sunlight. Ensure that

the packing area can be kept cool (15° to 25° C) when vaccine packing is taking place. The packing area should be laid out to encourage a logical flow of work. Vaccines should be moved as little as possible to minimize the risk of breakage. There should be a sink in the packing area for handwashing and provision for hygienic hand-drying.

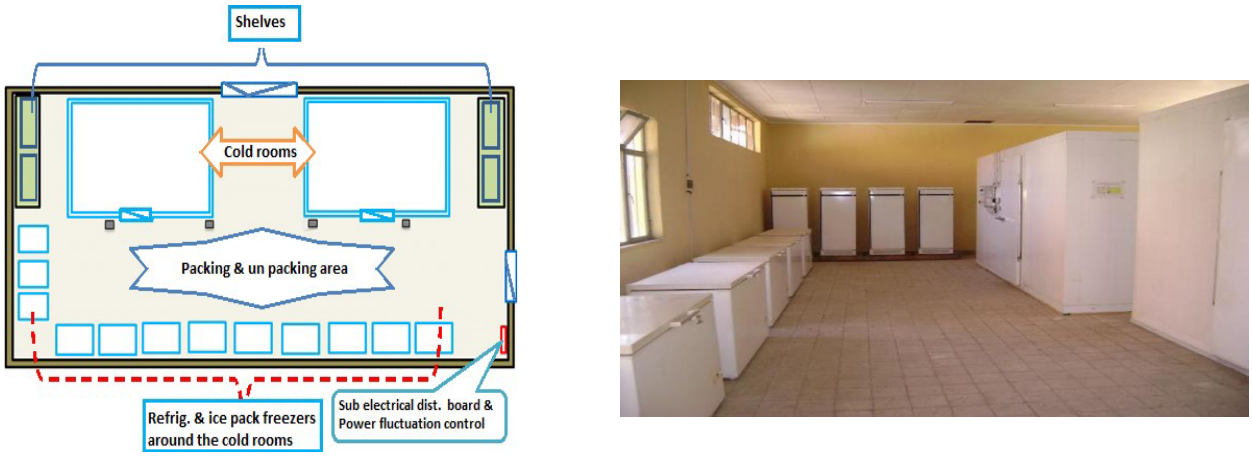


Figure 4-3: Example of Packing Layout of cold room

Packing vaccine and diluents for transport, using cold boxes and vaccine carriers

If vaccines are not correctly handled, they can be damaged by exposure to excessive heat or cold. Evidence from many countries has shown that transport between vaccine stores and outreach sites are the most vulnerable stages in the supply chain. The most common cause of exposure to freezing temperatures is the failure to correctly condition ice packs prior to transport. Deep-frozen ice packs can reach temperatures as low as negative 20°C. The practice of immediately placing unconditioned ice packs in well-insulated cold boxes places freeze-sensitive vaccines at the greatest risk. From national to sub-national level OPV must ALWAYS be transported using fully frozen ice packs and for district and health facility level use conditioned ice packs. BCG, Measles, PCV, Rota, IPV MR and MMR vaccine can be transported safely in cold boxes using cool water packs.

How to pack cold boxes?

- Place conditioned ice packs/cool water pack side by side against the inside walls and floor of the cold box as per the diagram given on the lid of the cold box.
- Make sure that the cold box is cool to prevent early melting
- Stack vaccine and diluents in the box.
- Place conditioned ice packs/cool water pack over the top of the vaccine and diluents.
- Place the plastic sheet to cover the ice packs kept on top to ensure full hold over time.
- Secure the lid tightly.
- Do not open the lid unless required.

How to Pack a Vaccine Carrier?

- Confirm that there are no cracks in the walls of the vaccine carrier.
- Make sure that the vaccine carrier is cool to prevent early melting
- Take out the required number of ice packs from the deep freezer and wipe them dry. Keep them out side for conditioning before placing into carrier.
- Place four numbers conditioned ice packs in the carrier and wait for few minutes for temperature to fall to less than 8 degree Celsius in the carrier. Never use only two conditioned ice pack/ cool water pack for vaccine carrier.
- Place foam pad at the top of ice packs.
- Ensure that some ice is present in the ice packs while conducting immunization sessions.
- Secure the lid tightly
- Collect vaccines in the carrier on the session day (Vaccine carriers may not store vaccines effectively beyond 12 hrs).
- If more than one vaccine carrier is being carried, keep the whole range of the vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

Cautions!

- Do not drop or sit on the vaccine carrier.
- Do not leave the vaccine carrier in sunlight. Keep it in shade.
- Do not leave the lid open once packed.

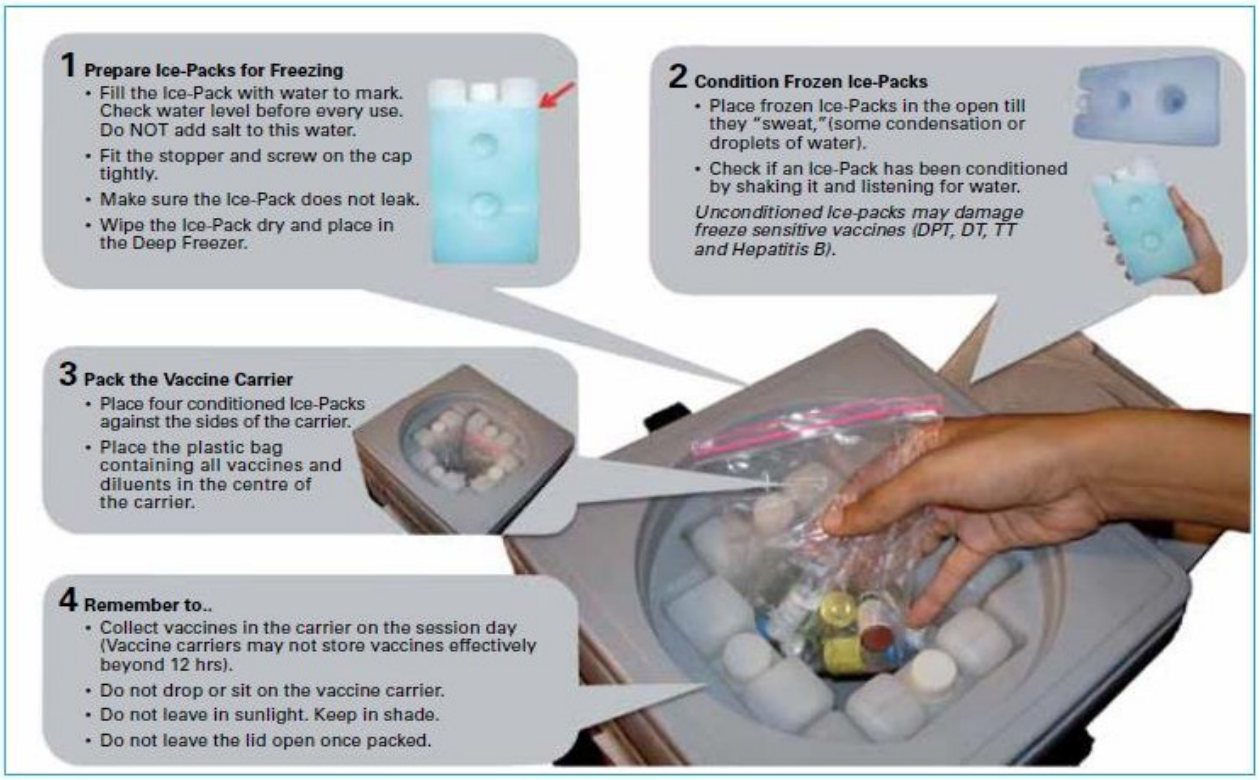


Figure 44: Packing vaccine carrier

Packing and loading of vaccine and diluents on refrigerated truck

- Pack the vaccine and diluent cartons in the shipping containers or cartons with the vial caps upside.
- Use newspaper or other materials for loose packing to ensure that the load do not shift during transport.
- Place a packing list in the container/carton.
- Place a freeze indicator into at least one container/carton per destination.
- Label the container/carton with the name of destination.
- If there is a lid: Close the lid or seal the carton with packing tape.
- Keep the shipping containers/cartons in a cold room (+2°C to +8°C) until the vehicle is ready to load.
- The refrigerated vehicle should be pre-cooled before loading.

4.3.7. Loading refrigerated vehicles

Refrigerated vehicles require specialized facilities and training if they are to be used safely and effectively for the transport of vaccines. In particular, responsible personnel must ensure that drivers know how to ensure their vehicle is road worthy, how to operate the vehicle and its cooling unit and how to safeguard the vaccine throughout the journey. Details of all journeys must be recorded by the driver in the vehicle logbook/route report.

Preparation

- Estimate the number of reusable shipping containers or disposable cartons which will be required for each delivery.
- If the vehicle is delivering to more than one store, plan load layouts so that loading takes place on a first- out-last-in basis.
- Schedule deliveries to arrive at designated times during working hours and notify receiving stores of the intended times of arrival.
- Thoroughly clean the interior of the refrigerated compartment before loading.
- Clean reusable shipping containers before each delivery.
- Keep cleaning records for vehicles and reusable shipping containers to demonstrate compliance.

Note: Air must be able to circulate underneath the load. Refrigerated vehicles can be supplied with a corrugated 'or inverted T floor' to allow for floor level air circulation. However, if the refrigerated compartment has a smooth floor, it is essential to place plastic pallets on the floor before loading the vaccine containers.

Pre-cool the refrigerated Compartment

Before loading the vaccine, the refrigerated compartment should be the pre-cooled.

To pre-cool:

- Park the vehicle in the shade.
- Close the doors and pre-cool the refrigerated compartment to +2°C to +8°C before loading vaccine.
- If the vehicles is fitted with continuous temperature monitoring, switch on the on-board continuous temperature monitoring equipment. Record the time of activation on the Trip Record Form.
- If data logger is used, securely attach an activated temperature data logger device in the refrigerated compartment. Record the time of activation on the Trip record.

Figure 4-5: Loading refrigerated truck

Loading

- During the loading operation, keep the loading door open for the minimum time possible. Ideally, the door opening should be fitted with a strip curtain to reduce loss of cold air.
- Load the vehicle so that shipping containers can be unpacked at the receiving stores on a first-out-last-in basis. This means that the containers which are to be delivered to the first store on the delivery round should be packed last, containers for the second store next to last, and so forth.
- Stack containers so as to encourage the even flow of cool air through the load. See below Figure for guidance principles.
- Stack the containers so as to ensure even weight distribution.
- Restrain the load securely with straps or netting. DO NOT cover the load with tarpaulin or other impermeable material – this will restrict air flow.
- Lock the doors to the refrigerated compartment.
- Record the time when loading is complete on the Trip Record Form.
- Brief the driver on the route, planned delivery times, details of special or urgent deliveries, mobile phone numbers and any areas of concern on the route.

Refrigeration unit

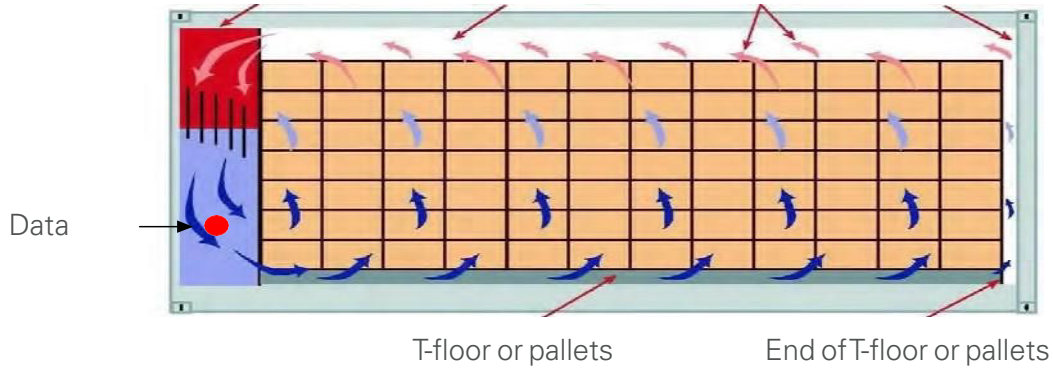


Figure 46: Air flow in cold room

Unloading

- Park the vehicle in the shade, as close as possible to the unloading bay.
- Continue to run the refrigeration unit throughout the unloading operation.
- During the unloading operation, keep the cooling compartment door open for the minimum time possible.
- Take the shipping containers into the cold storage immediately. Check and unpack the containers as rapidly as possible and place the vaccines in the appropriate cold storage. If a cold room is available, unpack and check the shipment in the cold room.
- Stack empty shipping containers in the refrigerated compartment. Restrain the containers securely. Ensure that exposed areas of T-floor or pallets are covered with cardboard to maintain even air flow through the remaining load.
- Record the time of arrival and departure on the Trip Record Form. Notify the supplying store by telephone once the delivery has been completed and report any problems.
- Lock the doors of the refrigerated compartment.
- Check the condition of the vehicle and refrigeration unit before departure.

Overnight stops for refrigerated truck

- Drivers should always park in a secure compound, in the shade.
- Ensure that the refrigerated compartment and driver's cab are kept locked.
- Ensure that one person always remains with the vehicle.
- Continue to run the refrigeration unit throughout the night stop.
- Monitor the temperature of the refrigerated compartment at least once an hour using the in-cab thermometer. Record the temperature on the Trip Record Form.
- Take appropriate action if the temperature goes outside +2°C to +8°C and respond to any emergencies during vaccine transport operations.

- Record the time of arrival and departure at the overnight stop on the Trip Record. Notify the supplying store by telephone when you depart in the morning.

4.3.8. Arrival checks and reporting procedures

- Check and record the quantity.
- Check the status of the freeze indicator(s) as soon as the vaccine arrives in the store. If the indicator has triggered, carry out the shake test (as described in section 4.9)
- Inspect a sample vial for every vaccine and every batch in the shipment; check the VVM status. Record, discard, and report to the next level if there is any VVM change.
- Complete the temperature monitoring section of the requisition and issue voucher form. The quantity and condition of vaccines received and the freeze indicator and VVM status must be checked and recorded.
- Complete IGRV at EPSS hub level.
- Receiving stores should send the completed returning voucher (Model 22) to the issuing store.
- Return devices to the issuing store along with the vehicle. Store freeze indicators at room temperature. Receiving stores which collect vaccine from issuing store should return the devices at the time when the next shipment is collected.

Note: SMS and satellite tracking systems are available for refrigerated vehicles, which allow for centralized monitoring. System-specific procedures need to be written for this type of equipment.

Activity 4.4. Think/Pair/share	
Instruction: First think alone and pair up with the person sitting next to you to discuss the following questions and share your thoughts to the larger group. Question: What is the purpose of "shake test"? Time: 10 min	

4.3.9. The "Shake test"

Purpose of the shake test:

The **shake test** is designed to determine whether adsorbed vaccines (DPT-HepB-Hib, PCV or Td have been frozen. When frozen, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes which gradually settle to the bottom after the vial during shaking. Sedimentation occurs faster in a frozen than unfrozen vaccine vial from the same manufacturer. It must be noted that individual batches of vaccine may behave differently. Therefore, 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 lot.

Test procedure:

- **Prepare a frozen control sample:** Take a vial of vaccine of the same type and batch number as the vaccine you want to test. Freeze the vial until the contents are solid (at least for 10 hrs), and then let it thaw. This vial is the control sample therefore clearly mark the vial as "control".
- **Choose a test sample:** Take a vial of vaccine from the batch that you suspect has been frozen. This is the test sample.
- **Shake the control and test samples:** Hold the control and the test sample together in one hand and shake vigorously for 10-15 seconds.
- **Allow to rest:** Leave both vials to rest on a flat surface.
- **Compare the vials:** View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample is probably potent and may be used. If the sedimentation rate is similar and the test sample contains flakes, the vial under test has probably been damaged by freezing and should not be used. Note that some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

Subsequent action: If the test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately. Standard Operating Procedures should then be followed to ensure that all damaged vaccine is identified and none of the damaged vaccine is distributed or used. In addition, the cause of the CCE failure has to be identified and measures has to be taken accordingly.

Figure 47: Shake test

4.4. Summary Question and answer quiz

Questions	Answer
How do you avoid freezing during transportation?	
Which temperature indicator status should be mentioned on a dispatch form?	
15minutes of keeping the frozen icepacks in the room temperature is enough for conditioning. True or false?	
List at least two vital information that need to be entered in a dispatch form?	
What temperature monitoring device should be included in transportation of all freeze sensitive vaccines?	
Give one characteristic of a good storage and distribution system?	
What are two unsatisfactory delivery conditions?	
What should you do when you see this freeze indicator when you receive a delivery from a primary store or for lower temperature alarm during temperature recording?	
What do you do when you receive lesser quantity of vaccines than it is indicated in the dispatch form?	
Shake test is conducted with a suspected vial and a never frozen sample. True or false?	
What should you do first if a recipient facility orders a higher quantity than it is expected.	
Direct sunlight should be excluded from the packing room and ideally there should be no fluorescent lighting. True or False?	
Give two reasons for short shipments from a primary store to an intermediate	
When you receive a delivery of vaccine that is heat damaged, where do you register this wastage?	
Which vaccine should be transported with frozen ice packs?	

4.5. Summary

- Vaccine distribution systems need to be efficient so that vaccines are always available in the facilities where they are needed.
- Before starting vaccines and other EPI supplies distribution and/or collection planning is very important.
- Temperature monitoring is important to eliminate vaccine losses due to freezing and/or excessive heat exposure.
- The shake test is designed to determine whether adsorbed vaccine have been affected by freeing.

Chapter 5

Vaccine wastage management

Chapter Allocated Time: 3:00 hours

Chapter Description:

This chapter describes vaccine wastage, calculation of vaccine wastage, different types of vaccine wastage and different methods used in vaccine wastage management.

Chapter Objective:

At the end of this chapter, participants will be able to describe vaccine wastage and the different methods used in vaccine wastage management.

Enabling Objectives: -

At the end of this chapter participants will be able to: -

- Describe vaccine wastage
- Explain types of vaccine wastage
- Calculate vaccine wastage
- Identify methods used to minimize vaccine wastage

Chapter outline:

5.1. Introduction to vaccine wastage

5.2. Types of vaccine wastage

5.3. Vaccine wastage calculation

5.4. Interventions used in vaccine wastage management

5.5. summary

5.1. Introduction

Activity 5.1. Individual -Reflection	
Question: What does it mean by vaccine wastage and vaccine wastage management? Time; 5 min	

The World Health Organization reports over 50% vaccine wastage around the world. Despite the availability of many tools to reduce vaccine wastage, countries still score high wastage rates. Increasing EPI vaccine costs during the last couple of years in combination with tightening vaccine security, as well as the introduction of new and under-used vaccines through the Global Alliance for Vaccines and Immunizations (GAVI), are motivating countries to take a more serious look at vaccine wastage. GAVI has also requested countries to bring down vaccine wastage rates: —The country would aim for maximum wastage rates of 25% set for the first year with a plan to gradually reduce it to 15% by the third year. For vaccine in single or two-dose vials the maximum wastage allowance is 5%. No maximum limits have been set for yellow fever vaccine in multi-dose vials.

Vaccine wastage is expected in all programs; the question is whether any of the wastage is preventable and how to prevent it. Wastage in unopened vials is usually due to cold chain and stock management problems and can be minimized.

Wastage in opened vials cannot be eliminated, but can be reduced with introduction of the multi-dose vial policy, effective use of vaccine vial monitors (VVM) and improved immunization strategies and practices and revising immunization policy including refining the wastage rate and introducing smaller number of doses per vial.

Vaccine wastage is an important factor in calculating vaccine needs. If incorrect figures are used, the country may face serious vaccine shortages or be unable to consume received quantities leading to increased wastage through expiry. Therefore, it is crucial that all immunization points using the vaccine and stores handling the vaccines must monitor its use on a continuous basis. This monitoring would provide good guidance to program to introduce actions whenever necessary

5.2. Types of Vaccine wastage

Activity 5.2: Group discussion

Instruction:

- Be in group of 5 participant
- Discuss the below question in your group and report the work in the plenary (share group response to the larger groups using flipchart)

Discussion Question:

classify the following vaccine loss in Wasted and Sacrificed doses:

- Doses of Measles administered to children aged 4 years
- Doses of frozen DPT-HepB-Hib vials
- Doses in expired vials
- Doses of Td administered to the informal sector
- OPV vials with VVM reached discard point
- Measles vaccine from a 10-dose vial used only for two children

Time :10minutes

Common Agenda

- More advocacy efforts are required to mainstream nutrition across sectors. This is because the commitment of different sector offices is not to the level that enables them to be actively engaged in nutrition activities. Advocacy should also be pinned towards bringing about structural change within all the ministries to incorporate nutrition in the federal ministries, regional bureaus and woreda offices.
- Jobs need to be created with defined roles and responsibilities within each sectoral office. Nutrition graduates are big assets and could be provided with short-term training to allow them to implement the Food and Nutrition strategy.

No matter how successful a program is, some vaccine wastage can be expected. Many factors influence vaccine wastage. Improved vaccine management practices are the key to addressing vaccine wastage. Vaccine wastage is best classified as occurring in either unopened or opened vials. Wastage in unopened vials results from incorrect/inappropriate vaccine storage and transportation practices and mainly occurs at or between primary and intermediate vaccine storage facilities. Wastage at the service level occurs because of a combination of many factors and mainly involves opened vials.

All immunization points monitor their performance by monitoring immunization coverage. The monitoring of vaccine wastage rates on a regular basis by all immunization points brings additional value to this quality performance indicator. The analysis of immunization coverage and vaccine wastage rates over a period of time allows health workers and immunization managers to identify areas that need improvement. The evaluation of wastage in isolation, without any consideration of coverage, makes it impossible to conclude whether it should be considered high or acceptable.

The management of a vaccine store is best evaluated through the monitoring of proportional vaccine wastage in unopened vials. The global criteria for effective vaccine management laid down in the WHO-UNICEF Cold Store Certification Initiative require cold stores not to discard more than 1 % of vaccines that are handled.

If the reasons for vaccine wastage are not known the problem cannot be addressed, because measures may not be appropriate and may result in compromising immunization coverage.

One way of classifying vaccine wastage is to distinguish the reasons for it as either system- related or program-related. However, this is confusing since some wastage in unopened vials cannot be considered as system wastage. For example, vials taken for an outreach session, even if not used, do not usually return to the cold chain if VVMs are not attached. This wastage occurs because of program implications but involves unopened vials.

Table 5-1 Types of vaccine wastage

Vaccine wastage in unopened vials	Vaccine wastage in opened vials
■ Expiry ■ VVM indication ■ Heat exposure ■ Freezing ■ Breakage ■ Missing inventory ■ Theft ■ Discarding unused vials returned from an outreach session if VVM is	■ In addition to the types of unopened vial wastage listed in the previous column: ■ Discarding remaining doses at end of session ■ Not being able to draw the number of doses indicated on the label of a vial ■ Poor reconstitution practices ■ Submergence of opened vials in water ■ Suspected contamination ■ Patient reaction requiring more than one dose

Expired vials, heat-damaged vials, frozen vials or vials with VVMs beyond the discard point should not be kept in a cold room, refrigerator or freezer, as they may be confused with those containing vaccine of good quality. If unusable vaccines have to be kept for a period before disposal, e.g. until accounting or auditing procedures have been completed, they should be kept outside the cold chain, separated from all usable stocks and clearly labeled Damaged/ expired vaccine – do not use in order to avoid mistaken use. Similarly, only vaccine stocks that are fit for use should be included in stock records. Damaged or expired vaccines should not appear in available stock balances. If such vaccines have to be kept until accounting or auditing procedures have been completed, details should be recorded on a separate page or card pending disposal.

Since damaged vaccine cannot be used the stock records should be adjusted and the loss should be recorded on a Loss and adjustment report.

Once disposal has been authorized, damaged items should be disposed of safely by incineration or other nationally approved means. Vaccination points may be required to return all damaged vaccine vials.

5.3. Vaccine wastage calculation

Activity 5.3: Group discussion

Instruction:

- Be in group of 5-6 people
- Discuss the below question in your group and report the work in the plenary (share group response to the larger groups using flipchart) Cheleleka Health Centre received 2000 doses of OPV vaccine in 20-dose vials in January. Monthly reporting indicated that 1300 children were immunized. There was a start balance of 300 doses on 1 January and by 31 January the stock level was 600 doses calculate the wastage and usage rate?

Time :15 Minutes

Since wastage is defined as loss by use, decay, erosion or leakage or through wastefulness, it is wise to begin a discussion of wastage by considering vaccine usage. Usage is firmly established and generally acceptable practice or procedure. Since vaccines are designed to be administered to prevent certain diseases, vaccine usage can be defined as the proportion of vaccine issued which is administered.

$$\text{Vaccine Usage Rate} = \frac{\text{Number of doses administrated}}{\text{Number of doses issued}} \times 100$$

$$\text{Vaccine Wastage Rate} = 100 - \text{Vaccine Usage Rate}$$

Vaccine wastage is the opposite of vaccine usage and is given by:

Vaccine wastage calculation at storage level

The best vaccine wastage indicator for vaccine stores is the proportional vaccine wastage in unopened vials. This can easily be calculated as follows.

$$\text{Proportional vaccine wastage rate in unopened vials} = \frac{\text{Number of doses discarded}}{\text{Start balance + number of doses received}} \times 100$$

The number of doses discarded includes all discards of unopened vials because of expiry, VVM indication, heat exposure, breakage, freezing, missing inventory and theft. This rate, which is specific for vaccine stores, should not be used for comparison with the vaccine wastage rate explained above. It gives the management performance levels of vaccine stores, since these only handle unopened vaccine vials. Because this category of wastage can be minimized the question arises as to what the acceptable level for such failures is. Vaccines delivered during the calculation period should not be subtracted from the denominator because, if any quantities of vaccine are damaged during transportation, this wastage is recorded in the sender's vaccine store account.

5.3.1. Vaccine wastage calculations at service level

All immunization points monitor their coverage rates monthly. Similarly, vaccine usage and wastage should be monitored monthly at all service points. This has to be a self-audit and should be used as a managerial tool as well as for producing new forms and/or tables to submit to higher levels.

The formula given at the beginning of this section can be detailed as follows.

$$\text{Vaccine Usage (rate)} = \frac{\text{Number of doses administrated}}{\{\text{Number of doses usable at beginning of period}\} + \{\text{Number of doses received during period}\} - \{\text{Number of usable doses in stock at end of period}\}} \times 100$$

It is always recommended that calculations are based on numbers of doses rather than on numbers of vials. If numbers of vials are used the calculations are complicated because of variation in the number of doses in a vial.

the vaccine wastage rate includes wastage in both unopened and opened vials. Since discards and losses of unopened vials should always be recorded, a detailed analysis of vaccine wastage is also possible at all service levels. Details of vaccine wastage give program managers an improved understanding of problems, which can then be addressed. The vital matter is that of reducing vaccine wastage. In order to make a plan for inclusion in the inception reports, as required by GAVI, the sources of wastage have to be revealed. If the reasons for wastage are unknown, plans are bound to be unrealistic and may have a negative impact on immunization coverage.

Note: Vaccine wastage must be calculated at all levels on a routine and regular basis.

Although direct calculation is possible, it is always recommended that usage rates be used as a start point in calculating wastage.

5.4. Interventions used in minimizing vaccine wastage

Activity 5.3: Group discussion

Instruction:

- Be in group of 5-6 people
- Discuss the below question in your group and report the work in the plenary (share group response to the larger groups using flipchart)

Discussion Question:

1. What are the interventions used in reducing vaccine wastage management?

Time: 10 min for reading and discussion 15 min for presentation
Total time: 25 minutes

Improving the use of vaccine supplies and avoiding unnecessary wastage often depends upon better management at all levels. The key concepts and activities associated with tackling vaccine wastage are indicated below.

5.4.1. Monitoring vaccine wastage regularly

All immunization points should monitor their vaccine usage and wastage on a monthly basis. This has to be done as a self-audit and not for the sake of submitting data to higher levels.

- Vaccine stores should monitor their wastage rates on a monthly basis.
- All immunization services should establish a sound vaccine wastage monitoring system.
    - Sentinel reporting should be considered in preference to the compilation of data from all parts of the country concerned.
- The minimum data that have to be collected at the service level are:
    - start balance.
    - doses received.
    - doses discarded unopened.
    - doses opened for use;
    - number of children immunized.

The vaccine wastage rate at the service level should be monitored against the immunization coverage for the same period. Any changes in the trends of wastage rate and immunization coverage should be carefully analyzed

Optimizing vaccine presentation to reduction of wastage rate

The use of smaller vaccine presentations results in less vaccine wastage. However, changing the vial size to reduce vaccine wastage should be carefully studied, since there may be negative inputs regarding vaccine storage volume, transportation cost and operations.

5.4.2. Vaccine vial monitors (VVM)

The effective use of VVM is not only ensures that vaccine administered has not been damaged by heat but also reduces vaccine wastage. VVM use also facilitates immunization outreach and increases access and, consequently, immunization coverage. Vaccine itself exhibits no visible change with heat exposure. Before the development of the VVM, health workers had no means of identifying whether vaccine had suffered damage from heat exposure at any point during transport and/or storage. The VVM can change this situation. Its gradual and irreversible color change makes it possible to assess cumulative heat exposure and the remaining shelf life of vaccines, even with vials which have been out of the cold chain or stored in a malfunctioning refrigerator.

VVMs give a visual measure of the heat exposure of each vial. This enables the health worker to:

- Use vaccine selectively so that, for instance, vials with minimal heat exposure can be selected for use in outreach sessions or mobile services.
- Estimate the remaining shelf-life of vaccines and rotate inventories, so that the vials with the greatest heat exposure can be selected for use before the others.

- Identify cold chain problems or confirm problems suggested by VVMs or refrigerator thermometers
- Reduce wastage by selecting the vials on which the VVMs are nearest to the endpoint and in which the vaccine is still usable. If health workers are thoroughly trained in the use of VVMs the EEFO policy for vaccine handling can be modified. In larger stores, however, where vaccines are kept in their cartons and the VVMs are not visible, the EEFO policy may still be the most appropriate management option.

Table 5-2 Summary of how vaccine vial monitor (VVM) works

Questions	Response
What is a vaccine Vial Monitor (VVM)?	A vaccine vial monitor (VVM) is a label containing a heat-sensitive Material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly. The VVM indicates the accumulated heat to which the vaccine has been subjected.
Does a VVM measure vaccine potency?	**No.** The VVM does not directly measure vaccine potency, but it gives information about the main factor that affects potency: heat exposure over a period of time. The VVM does not register information about freezing factor that may contribute to vaccine degradation.
How does a VVM work?	The **inner square** of the VVM is made of heat-sensitive material that is light in color initially and **becomes darker** when exposed to heat. The inner square is initially lighter in color than the outer circle. It remains so until the temperature and/or the duration of heat reaches a level that is likely to degrade the vaccine beyond the acceptable limit. At the discard point the inner square is the same color as the outer circle. This indicates that the vial has been exposed to an unacceptable level of heat and that the vaccine may have degraded beyond the acceptable limit. The inner square continues to darken as heat exposure continues, until it is much darker than the outer circle. If the inner square becomes as dark as or darker than the outer circle the vial must be discarded.

Does a VVM immediately change color when exposed to temperatures above 8°C?	No. The VVM reflects the heat stability of the vaccine to which it is attached. It does not undergo an immediate color change in response to brief exposure to moderate heat. Vaccines have a level of heat stability that enables them to withstand temperatures above 8 °C, outside the cold chain, for a limited time. The rate at which a VVM changes color reflects the ability of the vaccine in question to withstand heat. The gradual change of VVM depends on the room temperature and varies greatly with the place, season, time of day and type of vaccine.
What testing and quality control procedures are used to ensure that a VVM performs correctly?	Each batch of VVMs is tested twice with a color reflectance densitometer in order to ensure that the VVM changes color correctly in response to heat exposure. The first test is conducted at the factory before shipment and the second by the vaccine manufacturer before dispatch. Before WHO approved the use of VVMs, all aspects of this technology were subjected to extensive independent laboratory testing and field trials.
If the VVM has not reached the discard point, can a vaccine still be used if it has passed its expiry date?	No! A vaccine must never be used if it has passed its expiry date. The expiry date is calculated on the assumption that the vaccine is stored within an appropriate range of temperatures (2-8°C) throughout the cold chain. Even under correct storage conditions, however, vaccines undergo gradual degradation because of such factors as aging and exposure to light. Once a vaccine has passed its expiry date it cannot be expected to stimulate sufficient immunity.
If a vial carries a VVM, does it need to be kept in the cold chain?	Yes, most of the time, depending on the vaccine and the temperature. All vaccines are sensitive to heat and if kept refrigerated they remain potent for longer than would otherwise be the case. The VVM does not change a vaccine's heat stability. It simply gives a visible indication of the extent to which the vaccine's resistance to heat has been used up, i.e. when heat exposure has exceeded the limit for the vaccine in question. Each vaccine has a certain level of resistance to small amounts of heat. OPV has the lowest resistance. Careful cold chain handling preserves a vaccine's ability to withstand any accidental or unavoidable heat exposure. Some vaccines, especially hepatitis B and TD can be taken out of the cold chain if the VVM is properly used to monitor heat exposure. These circumstances should be carefully planned and monitored.

Should vaccines with VVMs showing some heat exposure but not yet at the discard point be handled differently to other vaccines?	Yes. These vaccines must be distributed first. The VVM enables the storekeeper to pick out the batches that have been most exposed rather than adopting the earliest-expiry-first-out (FEFO) approach.
COVID-19 vaccine without VVM	Most of the vaccines used for emergency response for COVID-19 pandemic have no VVM. Hence, stringent temperature monitoring mechanism should be in place using available temperature monitoring devices.

5.4.3. Multi dose vial policy (MDVP)

As the cost of vaccines rises, the need to minimize wastage through the reuse of certain vaccine vials opened in previous sessions rather than discard all opened or partly used vials becomes more important. WHO has introduced policy guidelines to assist managers in decisions on which vaccines to reuse, and which should be discarded. Careful consideration needs to be given to individual needs of countries as well as storage and vaccine practices and the strength of the cold chain before this new policy is adopted and implemented.

The multi dose vial policy (MDVP) previously called"open vial policy" was first introduced in 1995 and revised in 2000 and 2014 based on scientific data collected on the safety and potency of vaccines recommended for use in immunization services by the WHO . The revised policy applies only to OPV, DTP, Td, hepatitis B, IPV and liquid formulations of Hib vaccines that meet WHO requirements for potency and temperature stability; are packaged according to ISO standard 8362.

Note: In Ethiopia MDVP applies only to Td, OPV, IPV, PCV13

Liquid injectable vaccines such as DTP, Td and hepatitis B contain preservatives that prevent growth of bacterial contamination. Should contamination take place within the vial, the action of these preservatives prevents any increase in bacterial growth over time and actually decreases the level of contamination.

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.

- The vaccine is currently prequalified by WHO.
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
- The expiry date of the vaccine has not passed.
- The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures.

Furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing. 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.

Implementation of MDVP requires a series of operational issues such as proper training of personnel, availability of AD syringes to ensure aseptic technique, training and use VVMs to monitor heat exposure, and re-evaluation of vaccine wastage rates for vaccine forecast. The implementation of MDVP results in dramatic decreases in the wastage of liquid vaccines, because multi-dose vials of vaccine from which one or more doses have been removed during an immunization session may be used in subsequent sessions for up to four weeks. It is estimated that after adopting the MDVP new wastage rates would be approximately 15-20%. Most freeze-dried (lyophilized vaccines) do not contain preservatives and consequently must not be kept more than the manufacturer's recommended limit and never longer than six hours after they are reconstituted. So, the revised MDVP does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, Pfizer vaccine and some formulations of Hib vaccines should be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

Note: FEFO handling is safer than FIFO handling.

5.4.4. Prevent freezing

The freezing of vaccines is one of the major reasons for wastage. Freezing occurs at all levels of the cold chain. Practices that avoid the risk of freezing must be followed and promoted. The causes and how to prevent freezing were repeatedly mentioned in different part of the manual. The most important are appropriate packing of vaccines and proper cold chain temperature monitoring.

5.4.5. Vaccine wastage and Immunization coverage

Do not compromise immunization coverage:

Whatever measures are taken to reduce vaccine wastage, they should not compromise immunization coverage. If a selected approach to reducing vaccine wastage results in reducing immunization coverage, other approaches should be considered.

Table 5-3 The relationships between immunization coverage and vaccine wastage

Immunization coverage	Vaccine wastage	Where to focus
Same	Same	Types of vaccine wastage should be analyzed in order to determine whether new tools could be introduced to reduce wastage.

Same	Increasing	Focus on the storage and transportation of vaccines, because increasing wastage while coverage remains the same indicates wastage in unopened vials. If the increase is too high, vaccine forecasts should be reviewed so as to understand whether too much vaccine is being ordered.
Same	Decreasing	Validation of the data is the first step. Since wastage is decreasing, special attention should be given to determining how to increase immunization coverage.
Decreasing	Increasing	Vaccine damage occurs in unopened vials. Consequently, losses occur where the system cannot replace the vaccines and therefore planned immunizations cannot be achieved. The problem is likely to be found at the storage level and/or during vaccine transportation (either freezing or heat damage). The first step in analyzing the data should be to rule out expiry discards.
Decreasing	Decreasing	The possibility has to be considered that measures used to reduce wastage contribute to decreased immunization coverage. Likely reasons are a reduced number of immunization sessions and a refusal to give immunization where this would require multidose vials to be opened, in order to prevent high wastage.
Increasing	Increasing	This circumstance may arise because of increased outreach activity. The implementation of the multi-dose vial policy (MDVP), effective VVM use and the organization of sessions during outreach activities should be examined in order to determine whether vaccine wastage can be reduced.

5.5. SUMMARY

- Vaccine wastage is defined as vaccine loss by use, expiry, damage and due to other cause
- Vaccine wastage generally classified as either unopened or opened vials.
- Wastage in unopened vials results from incorrect/inappropriate vaccine storage and transportation practices and mainly occurs at or between primary and intermediate vaccine storage facilities.
- Wastage at the service level occurs because of a combination of many factors and mainly involves opened vials
- Vaccine wastage can be minimized by Monitoring vaccine wastage regularly, Adopt global policies, Vaccine vial monitors (VVM) and Multi dose vial policy (MDVP)

Chapter 6

Cold chain equipment management system

Allocated time: 8 Hrs.

Chapter Description:

This chapter describes cold chain systems, and their types, safe handlings, maintenance procedures, vaccine storage capacity calculations and temperature monitoring devices in the vaccine cold chain management system.

Chapter Objective:

At the end of this chapter, participants will be able to describe the cold chain equipment management system.

Enabling Objectives:

By the end of this chapter participants will be able to:-

- Identify different types of cold chain system and the refrigeration technologies
- Explain safe handling of cold chain equipment
- Demonstrate preventive maintenance procedures of cold chain equipment
- Calculate vaccine storage capacity
- Identify temperature monitoring devices for vaccine storage and transportations

Chapter outline:

6.1. Introduction to cold chain system

Activity 6.1 Individual reflection	
Activity 6.1 Individual reflection Activity 6.1 Individual reflection Activity 6.1 Individual reflection	

Cold chain is a system of different elements, i.e. human, material and financial resources, and certain norms and standards that ensure the high-quality of vaccines. Cold chain consists of different levels called links, which deal with vaccine orders and supplies, their transportation, storage and distribution from factory to the point of administration to the target population

A cold chain system is a temperature-controlled supply chain that involves the storage, transportation, and distribution of vaccines. Vaccines are those that are sensitive to temperature and must be kept within a specific range in order to maintain their quality and safety. The cold chain system is essential for ensuring the safe and effective delivery of vaccines. If the temperature of vaccines falls outside of the recommended range, they can lose their potency. This can have serious consequences, such as the spread of disease or the loss of life. The cold chain system is made up of a variety of components, including:

- Refrigerated storage facilities
- Refrigerated transportation vehicles
- Cold boxes and other packaging
- Monitoring and tracking systems
- Trained personnel

Here are some of the challenges that the cold chain system faces:

- Climate change: Climate change is causing more extreme weather events, which can disrupt the cold chain. For example, heat waves can cause the temperature of refrigerated storage facilities to rise, and flooding can damage refrigerated transportation vehicles.
- Power outages: Power outages can also disrupt the cold chain. If refrigeration units lose power, vaccines can quickly lose the potency.
- Inadequate infrastructure: In some parts of the world, the infrastructure for the cold chain is not well-developed. This can make it difficult to transport and store perishable goods at the correct temperature.
- Human error: Human error can also lead to problems with the cold chain. For example, if a cold box is not properly closed, vaccine potency lose.

As depicted in the following picture the factors affecting the functionality, efficiency, and effectiveness of different components of immunization supply chain systems are multiple and interlinked though their importance varies based on the level of vaccine distribution. In developing countries like Ethiopia, in addition to the factors related with policies and availability of appropriate technologies, the performance of immunization supply chain system is further affected by the limited number of trained human resources and the strength of the existing general health system.

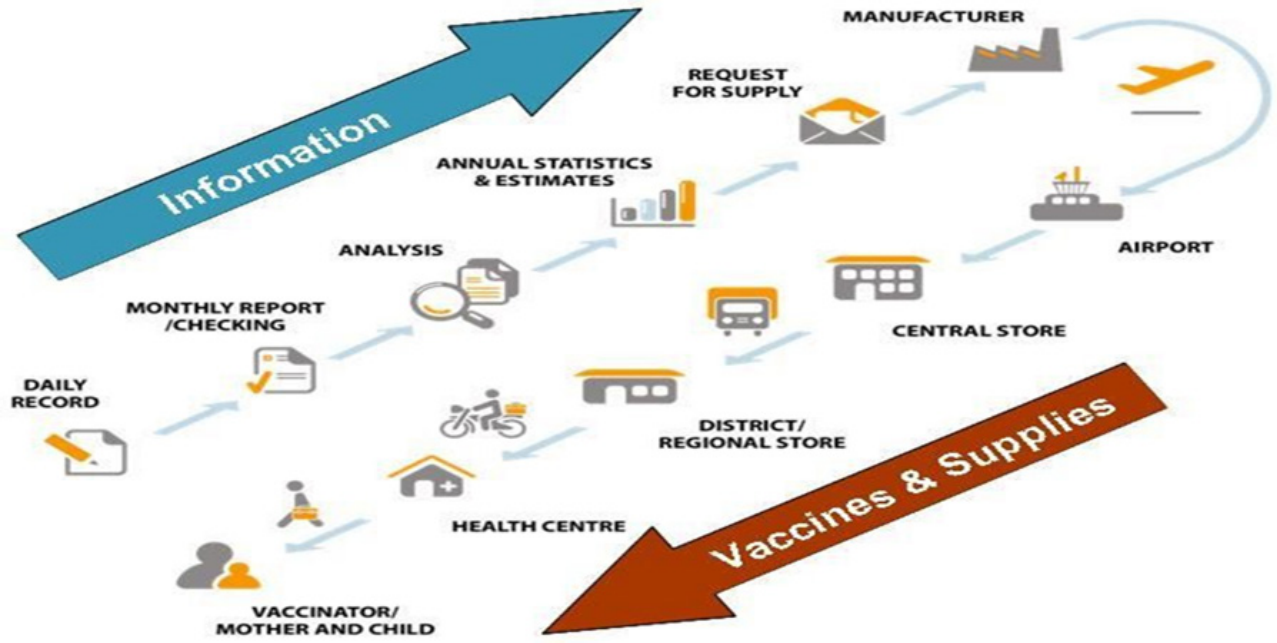


Figure 6-1 The cold chain system

Note: 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 analyzed, 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.

The equipment for storage of vaccines must have recommended temperature conditions for vaccine storage round the year. There is different equipment of different capacity for storage of vaccines at different levels. Some of the equipment are dependent on electric, solar energy, or kerosene supply to maintain the recommended temperature, while others can maintain the desired temperature range even in the absence of power supply for a specific time period.

Newer optimal technology, such as solar direct drive refrigerators show promise in minimizing these costs and the Government of Ethiopia developed ambitious plan to equip all health facilities with optimal or extend cold chain equipment.

GAVI (Global Alliance for Vaccine and immunization) also has established the CCE optimization platform to support countries to improve their supply chains and contribute to efforts to strengthen the coverage and equity of immunization. The platform aims to:

- Accelerate the upgrading of existing equipment through the deployment of higher- performing, innovative devices to health facilities in GAVI-supported countries.
- Extend appropriate cold chain devices into health facilities which have no equipment, and potentially contribute to outreach activities being conducted from these and nearby facilities.
- Make supply chains more efficient and effective using equipment that is better adapted to needs; and

Strong and efficient supply chains – equipped with reliable cold chain equipment (CCE) are vital to helping countries increase immunization coverage and equity, reaching children with lifesaving vaccines and protecting them

against deadly diseases. To ensure that vaccines are widely available and remain safe, and effective throughout the entire supply chain, each country's immunization program needs access to high performing and well-maintained cold chain equipment. Such cold chain equipment, when available at the required cold chain points-in-country, will increase vaccine availability, potency, and safety. This will help to improve immunization coverage.

6.2. Cold Chain Equipment in Vaccine Management System and Refrigeration Technologies

Activity 6.2 Think/Pair/share

- List and explain main types of refrigeration technologies
- List cold chain equipment used in vaccine management system

Time: 15 min

6.2.1. Compression Refrigeration (Compression cycle appliances)

Compression refrigeration is the most common refrigerator found in the health sector for storage of vaccines that uses a compressor to circulate a refrigerant through a closed system. The refrigerant undergoes a series of phase changes, from a liquid to a gas and back again, as it absorbs and releases heat. The compressor is powered by electricity and the source of electricity could be either from the mains or, if it is solar unit, from solar energy. This system is the most efficient compared to absorption systems. Some of the compression type equipment are: Cold rooms, Freezers, Deep Freezers (MF 314, MF 214, MF 114, etc.), Ice pack freezers (TFW 800, etc.), ILR (TCW3000, MK 404, MK 304, MK204, TCW 4000, VLS 300, etc.). Some equipment can be used as freezers or refrigerator interchangeably (TCW 3000 AC) by switching to freezing or cold storage. Currently, there are a number of new optimal (non-freeze) cold chain equipment (ILR and Solar direct drive (SDD) refrigerators, such (VLS 400A Green Line, BFRV-55 SDD, TCW 15R SDD, etc.) developed

6.2.2. Cold Rooms and Freezer Rooms

These are used for bulk storage of vaccines at EPSS Center and EPSS Hubs stores. They maintain a temperature (+2oC to +8oC cold rooms) & (-25oC to -15oC freezer rooms).

They are available in different sizes. These are used for storage of large quantities of vaccines and used as national distribution point and stock reserve. They have two identical cooling units and standby generator sets with automatic or manual start and stop facilities. They are also provided with temperature These are used for bulk storage of vaccines at EPSS Center and EPSS Hubs stores.

Figure 6-2 Clod room/freezer room

6.2.3. Refrigerator Trucks

A refrigerator truck is a van or truck designed to carry temprature senentive health products. The transport of temperature sensitive products in refrigerator vehicles is a critical part of the cold chain, which is the system used to keep vaccines at a constant temperature to ensure their safety and effectiveness. Refrigerator vehicles are used to transport vaccines from manufacturers to distribution centers, and from distribution centers to vaccination clinics and other healthcare facilities.

Refrigerator vehicles must be equipped with a reliable refrigeration system that can maintain a constant temperature of 2°C to 8°C (36°F to 46°F). The vehicles must also be well-insulated to prevent heat from entering the cargo area.

The drivers of refrigerator vehicles and deliverables must be trained in the safe transport of vaccines. They must be aware of the importance of maintaining the cold chain, and they must take steps to prevent the vaccines from being exposed to heat.

To ensure the safe transport of vaccines in refrigerator vehicles:

- The vehicles should be regularly inspected to make sure that the refrigeration system is working properly
- The vehicles should be well-insulated to prevent heat from entering the cargo area
- The drivers should be trained in the safe transport of vaccines
- The vaccines should be properly packaged and labeled.
- The vaccines should be transported in a secure manner to prevent theft or tampering.
- The vaccines should be monitored during transport to ensure that the temperature remains within the safe range.
- Avoid overloading the vehicles.
- Do not store food, dry products and other items in the same vehicle as the vaccines
- Keep the vehicles clean and free of debris.
- Inspect the vehicles regularly for signs of damage
- If the vehicles are not going to be used for an extended period of time, empty them and turn off the refrigeration system.

Figure 6-3 Refrigerated truck for vaccines

6.2.4. Deep Freezers

Deep Freezers with top opening lids have been supplied under the immunization program. The cabinet temperature is maintained between -15oC to -25oC. This is used for storing of OPV and also for freezing ice packs. In case of power failure, it can maintain the cabinet temperature in the range of -15oC to -25oC for 18 & 26 hours at ambient temperatures of 42oC and 32oC respectively, if not opened. The deep freezers have vaccine storage capacity and ice pack freezing capacity. These are available in different sizes (large and small). Example: Deep Freezer: Model MF 314 - vaccine storage capacity 281 liters or 380 icepacks.

6.2.5. Ultra Low Temperature Freezers

An ultra-low temperature (ULT) freezer is a refrigerator that stores contents at between −40 to −86 °C. An ultralow temperature freezer is commonly referred to as a "minus 80 freezer" or a "negative 80 freezer", referring to the most common temperature standard. ULT freezers come in upright and chest freezer formats.

Ultra Low Temperature Freezers are designed specifically for laboratories to preserve biological samples. These ultra-low freezers provide stable temperatures from -40°C & -86°C. These Ultra-Low freezers are available in a variety of sizes to fit all of your research application low temp preservation needs. Some of the Covid-19 vaccines (Pfizer, etc.) which are approved for emergency use require low temperatures as (-80 °C/-60 °C) for storage and transportation and using available ULT insulated containers on the market recommended to use for Covid-19 vaccines.

Figure 64 Ultra Low Temperature Freezers

The UCC equipment encompasses active equipment (ULT freezers)that store vaccines at very low temperature (-80°C/-60 °C) and passive equipment (ULT insulated containers) that are used to store or distribute low temperature vaccines.

- **Active equipment (ULT freezers):** ULT freezers produce ultra-low temperatures to store ultra-low temperature vaccines, with a temperature requirement ranging from -80 °C to -60 °C, and to produce and store the PCM packs needed for keeping the vaccines in ULT while stored in passive equipment.
- **Passive equipment (ULT insulated containers):** There are two types of passive equipment recommended for transporting and storing ULT vaccines at facility level. When selecting which passive container to use, consider the storage temperature and duration of storage.

ULT freezers recommended for COVID-19 vaccines needs to fulfill the following:

- Temperature range: -86 °C to -60°C
- Used to store vaccine and PCM packs/dry ice
- Temperature display (actual and set point)
- High/low temperature alarms with remote monitoring
- Open-door and power-failure alarms

6.2.6. Ice Lined Refrigerator (ILR)

These types of refrigerators are top opening and they can hold the cold air inside better than a refrigerator with a front opening. Where there is no electric power for 24 hrs, it can keep vaccines safe for 8 hours. This type of refrigerators are available in different sizes such as ILR- Model MK 304 of vaccine storage capacity 105 liters or 26,000 to 30,000 doses of mixed antigen.

Inside the ILR there is a lining of water containers (ice packs or tubes) fitted all around the walls and held in place by frame and these water containers have to be filled with water for ILR that has ice packs inside before starting to use it. When the refrigerator is functioning the water in the containers freezes and if the electricity supply fails, then the ice lining maintains the inside temperature of the refrigerator at a safe level for vaccines. Therefore, the temperature is maintained in ILR for much longer duration than in deep freezers and ILRs can keep vaccines safe.

Remember

- Keep all vaccines in a basket.
- Leave space between the vaccine boxes.
- Place a fridge tag or thermometer in the basket in between the vaccines.
- Keep freeze sensitive and closer expiry vaccines at TOP of the basket.
- Keep heat sensitive and further expiry date vaccines in the bottom of the basket.

6.2.7. Solar Refrigerators (Solar-powered refrigerators)

A solar refrigerator operates on the same principle as normal compression refrigerators but incorporates low voltage (12 or 24V) DC compressors and motors, rather than mains voltage AC types. A photovoltaic refrigerator has higher levels of insulation around the storage compartments to maximize energy efficiency, a battery or number of batteries depending upon the size of panel for electricity storage, a battery charge regulator and a controller that converts the power from the battery to DC form required by the compressor motor. Most of the battery powered solar refrigerators are non-optimal and their replacement with optimal SDD refrigerators has started.

6.2.8. Solar Direct Drive Refrigerators

A solar direct drive (SDD) vaccine refrigerator is a type of refrigerator that is powered directly by solar energy. It does not require a battery or a generator, making it a reliable and cost-effective option for vaccine storage in areas where there is no reliable electricity.

SDD vaccine refrigerators work by using a solar panel to convert sunlight into electricity. This electricity is then used to power a compressor, which cools the refrigerator. The refrigerator is designed to maintain a constant temperature of 2°C to 8°C, which is the ideal temperature for storing vaccines.

SDD vaccine refrigerators are a good option for use in rural areas, remote communities, and other places where there is no reliable electricity. They are also a good option for use in emergency situations, such as natural disasters. There are currently four technologies existing: PCM (phase change material), Ice-lined (ILR), water- lined and ice bank.

As of August 2021, the following four BFRV-55, SDD HTC-60, TCW 3000 SDD and BLF100 DC (replaced with GVR 100 DC (Sure Chill)) solar direct drive refrigerators are available in the country and out of them BFRV-55, TCW 40 SDD, TCW 15R SDD, models are optimal (prevent freezing). In the near future, additional optimal SDD refrigerators are expected to be deployed in the country.

Here are some of the advantages of SDD vaccine refrigerators:

- They are powered by solar energy, so they are a reliable and sustainable option.
- They do not require a battery or a generator, which makes them more cost-effective than other types of vaccine refrigerators.
- They are designed to maintain a constant temperature, which is important for vaccine storage.
- They are relatively easy to install and maintain.

Here are some of the disadvantages of SDD vaccine refrigerators:

- They can be expensive to purchase.
- They may not be as efficient as other types of vaccine refrigerators in cold climates.
- They may not be able to maintain a constant temperature in hot climates.

Figure 6-5 Solar refrigerators

6.2.9. Absorption type refrigerators

An absorption refrigerator is a type of refrigerator that uses heat to operate. It does not use a compressor, but uses a chemical reaction to absorb and release heat. The heat source can be kerosene, electricity, or even solar energy. Absorption refrigerators have some advantages over other types of refrigerators, such as being relatively quiet, having no moving parts, being powered by a variety of heat sources, being efficient in low ambient temperatures, being used in remote areas where there is no electricity, and being less likely to break down. The disadvantages of absorption refrigeration are:- less efficient than compressor refrigerators, more expensive to purchase, can take longer to cool down, is environmentally unfriendly, has kerosene fire accidents, the cost of kerosene is high, and may require periodic maintenance.

Examples of some of the absorption type refrigerators in Ethiopia are:

- SIBIR – Sibir V170KE, Sibir V110 EK
- Dometics - RCW50KE,
- Zero Refrigerators – PR 245, PR265KE (*NB: currently not recommended to use due to heater problems and already obsolete.)

As all absorption refrigerators are non-optimal and the process of decommissioning and removing them from the system is under way, and WHO also not recommend to use in the health care sector, in the near future all absorption refrigerators will be replaced by optimal CCE.

Figure 6-6 Absorption refrigerator

6.2.10. Passive Cold Chain devices

Passive cold chain devices are used to transport and store a variety of temperature-sensitive products, such as vaccines, blood products, and other temperature sensitive products.

The choice of passive cold chain device depends on the specific application. The size and weight of the device, the length of time it needs to keep the contents cool, and the temperature range that needs to be maintained are all factors to consider.

Passive cold chain devices are a cost-effective way to transport and store temperature-sensitive products. They are also a reliable option in areas where there is no reliable electricity.

Here are some of the advantages of passive cold chain devices:

- They are relatively inexpensive.
- They are easy to use and maintain.
- They can be used in areas where there is no reliable electricity.
- They are environmentally friendly.

Here are some of the disadvantages of passive cold chain devices:

- They can only maintain a cold temperature for a limited time.
- They are not as reliable as active cold chain devices.
- They can be bulky and difficult to transport.

6.2.11. Cold Box

Cold boxes are big insulated boxes. These are of different sizes- 5, 7.2, 8, 20, 22 and 23.1 liters with a requisite number of ice packs. The 5 & 8 liters cold box can transport about 1,500 & 2,400 doses of mixed antigen vaccines respectively and 20-22 liters cold box has enough space to transport about 6,000 – 6,600 doses of mixed antigen vaccines respectively. Freeze free vaccine cold boxes which don't need cool water packs or condition Ice packs produced and available in the market.

Figure 6-6 Cold box

Uses of cold boxes

- Collect and transport large quantities of vaccines.
- Store vaccines for transfer up to five days, if necessary for outreach sessions (fast cold chain option) or when there is power cut. The hold over time is more than 90 hours for 5 Liter and six days for 20 Liter cold box at +43oC ambient temperature, if the cold box is not opened at all.
- Store vaccines in case of breakdown of refrigerators.

How to keep Cold Boxes in good condition when not in use

- Clean and dry after every use.
- Do not keep any load over the cold box.
- The lid of the box should be kept unlocked and opened in the store while the box is not in use. This will increase the life of the rubber seal
- Examine the inside and outside surface after every use for cracks.
- Check that the rubber seal around the lid is not broken; if broken, replace immediately.
- Knock and sunlight can cause cracks inside the wall and lid of the cold boxes.
- Lubricate hinges and locks routinely.

6.2.12. Vaccine Carriers

Vaccine carriers are used for carrying small quantities of vaccines (16-20 vials) to the sub-centers or session sites. The vaccine carriers are made of insulated material, the quality of which determines the cold life of the carrier. Four ice packs are laid in the vaccine carrier as per manufacturer's guidelines. The lid of the carrier should be closed tightly.

The vials of Td, Pentavalent, PCV13, Rota and IPV vaccines should not be placed in direct contact with the frozen ice packs; hence only conditioned/chilled water parks should be used. Different models of freeze free vaccine carriers which don't need cool water packs or condition ice packs produced and available in the market.

Figure 6-7 Freeze-Free Vaccine carrier

Uses of Vaccine Carrier

- To carry vaccine from health facilities to outreach sessions
- To carry vaccine from nearby cold store to health facilities

How to keep vaccine carrier in good condition when not in use

- Keep the vaccine carrier in good condition when not in use.
- Do not use any sharp tool to open the lid of the carrier.
- Clean and dry the inside after every use.
- Never use a vaccine carrier containing two ice packs. except vaccine carriers made for 2 water packs

6.2.13. Long Term Passive Vaccine Storage Device

The long term passive vaccine storage device is designed to keep vaccines at appropriate temperatures for a month or more with repeat vaccine retrievals and no need for electricity. The device combines the best attributes of vaccine cold boxes and stationary refrigerators currently used. Unlike other vaccine cold boxes that keep vaccines cold for one to five days, the device holds temperatures for over a month, and unlike refrigerators, it is transportable, low cost, low maintenance, and can be used anywhere. The frozen ice pack should be replenished at least three to five days from nearby health facilities.

The long term passive device technology uses super insulation techniques; its design is specific to vaccine storage and can maintain the necessary temperatures. Vaccines can then be retrieved without jeopardizing the remaining vials and the insulated container can remain in the field for repeated use. Due to their limited storage capacity, they are mostly used by small, off-grid facilities. Because they cannot freeze or chill coolant packs, they are not suitable for facilities that perform high levels of outreach unless paired with a separate freezer. The device is designed to be used for off grid health facilities with a small target population.

6.2.14. ULT insulated containers (Arktek)

The Arktek (YBC-5) is a super-insulated, double-walled large bottle-like container that uses multi-layer insulation technology and eight PCM packs (1 L each) to keep vaccines at ULTs (-80 °C to -60 °C) in remote storage and vaccination sites for up to 5 days and longer under hot zone conditions of 43°C without any powered refrigeration or extra coolant. It comes with a vial rack system and has a storage capacity of 7.9 L. Each unit is built to withstand a lot of use in the field; and each one is equipped with a built-in temperature data logger capable of monitoring and reporting ULTs. The special PCM used as coolant for the Arktek has to go through a process of conditioning to be able to maintain ULT

Arktek parts:

- Vaccine rack
- ULT PCM metal packs

Figure 6-8ULT insulated containers (Arktek)

6.2.15. Ice Packs and their use

Ice packs are a key component of the cold chain system. It is used for ice lining inside the cold box and vaccine carrier. The ice packs are frozen inside the freezer under the temperature range of -15oC to -25oC. The specifications of ice packs vary with the manufacturers and they come in different sizes:

- 0.4 liter to be used with vaccine carriers
- 0.6 liter to be used with cold boxes.

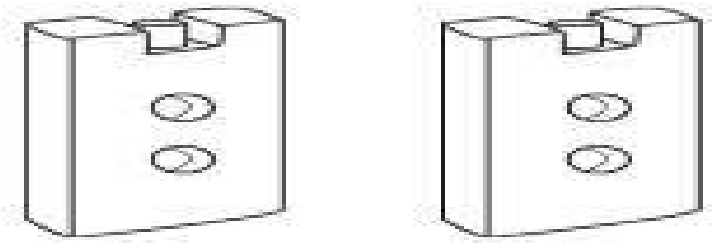


Figure 6-9Ice/Water packs

Normally, for an icepack to be completely frozen it needs to be 12 hours in a freezer or 24 hours in a freezing compartment of a refrigerator. Always have two sets of water packs for each cold box or vaccine carrier – one set to be chilled while the other is being used.

6.2.16. Special ULT phase change materials (PCMs)

Special PCMs are used for passive freezing when transporting and temporarily storing vaccines in ULT insulated containers. PCMs are known for their ability to store or release energy in transition between solid (frozen) and liquid (melted) states. During phase transition from solid to liquid, a PCM maintains a constant temperature until all the PCM has melted. Typically, the amount of energy required to melt a PCM is large. The combination of the high amount of energy required to melt (latent heat) with the (low) heat leak of the insulated container at a given ambient temperature determines the hold-over times. For ULT passive freezing, special PCM is used in

place of water. The suitable PCMs used in this application have melting point of -78 °C to -65 °C, which is within the required vaccine storage temperatures range of -80 °C to -60 °C. However, using PCM for freeze sensitive vaccines transportation is not recommended.

6.2.17. Foam pads

Foam pads is a piece of soft foam that fits on top of the ice-packs in a vaccine carrier; serves as a temporary lid to keep unopened vaccines and to hold, protect and keep cool opened vaccine vials

During an immunization session, vials are protected from heat for a longer period of time if they are inserted in a foam pad as illustrated in the Figure below.

Figure 6-10: Foam pad in use

6.3. Safe handling of cold chain equipment

Activity 6.3 Individual-Reflection

Instruction: Share your experience on safe handling of cold chain equipment.

Time 5 minutes

The term safety, as applied to any cold chain equipment, may have three different applications. It may apply to Safety of the operator, Safety of the equipment and Safety of the vaccine contents. The Cold chain operators work close to many potentially dangerous situations: liquids and gasses under pressure, electrical energy, heat, cold, chemicals and so on.

To receive vaccines requiring UCC there should be a plan and resources to ensure that the staff responsible for managing the UCC system are provided with necessary Personal Protective Equipment (PPE) and training. Some of the required PPEs are cryogenic/insulated gloves, eye shield/goggles, respirator mask, Shoes, Jackets, etc.

For the cold chain equipment to operate properly the following safety procedures must be followed.

- Always ensure that the area you are placing the device is free of paper or other flammable materials, and make sure there is enough space at least 10cm behind the device for air to circulate freely.
- Never block the interior or exterior ventilation openings of the devices.
- Don't use the cold chain outdoors or anywhere it is likely to come into contact with the elements.
- Don't place cold chain devices near heat emitting sources, radiators, or in direct sunlight, as this will result in it having to work harder to maintain the required internal temperature.
- Do not use a heater to defrost the inside of the refrigerator.
- Do not overload the refrigerator.
- Do not store food or other items in the refrigerator with the vaccines.
- If the refrigerator is not going to be used for an extended period of time, empty it and unplug it.

Climate Zone: is other area which is related to safely handling of refrigerators. Cold chain equipment are designed to effectively operate in a given ambient temperature range. If we operate this cold chain equipment in a place which is either above or below a given operating range stated by manufacturer then the cold chain equipment might not operate effectively. Manufacturers of cold chain equipment design cold chain equipment to operate in four different ranges of ambient temperature zones. These are;

- SN (Subnormal) 10 °C - 32 °C
- N (Normal) 16 °C - 32 °C
- ST (Subtropical) 18 °C - 38 °C
- (Tropical) 18 °C - 43 °C

6.3.1. Climatic factors (Temperature Zones)

All refrigerators and freezers are classified on the basis of their performance in specific temperature zones:

- Hot zone that ranges from 0°C to +43°C
- Temperate zone that ranges from 0°C to +32°C
- Cold zone that ranges from –5°C to +32°C

The temperature zones, for which the appliances were tested and approved, should be clearly marked on the appliance (see figure below).

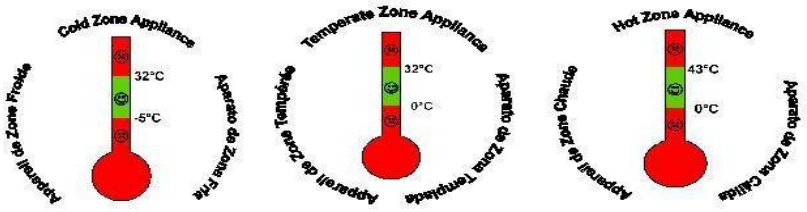


Figure 6-11 Temperature zones

The choice of temperature zones specific equipment can be based on one or a combination of the following considerations:

- A geographic distribution: use the equipment in geographic zones on the basis of the prevailing climate. The average temperature during the hottest/coldest months should be taken as criteria for the determination of the zones. Hot zone equipment can be used in temperate zones.
- A functional distribution: use temperate zone appliances in health facilities with sufficient ventilation or air conditioning, maintaining the temperature below +32°C and hot zone equipment at peripheral level where these conditions are not met and temperatures regularly exceed 32°C.

6.4. Preventive maintenance procedures

Activity 6.4: Group discussion

Instruction:

- What is maintenance?
- List preventive maintenance activities
- List basic personal protective equipment used during preventive maintenance.

Time: 45 min

The main objective of maintenance is to ensure that cold chain equipment and transport systems function well for the implementation of immunization activities. Maintenance can be categorized in two groups: preventive maintenance and corrective maintenance.

Corrective maintenance is unanticipated and should be minimal if preventive maintenance is effective.

6.4.1. Preventive maintenance:

Preventive maintenance is the servicing of equipment according to a predefined plan and schedule in compliance with established Standard Operation Procedures (SOP).

Servicing is done before equipment failure. Maintenance officer should perform two types of preventive work:

- **Preventive maintenance:** service task to replace consumable components (wick replacement, defrosting, cleaning the compartment and solar panels, topping up batteries, oil/air filter replacement, etc.) at predetermined criteria (age, working hours, transport mileage, etc.)
- **Conditional preventive maintenance:** service tasks from a checkup or periodic inspection (oil level alarm, subsequent temperature alarms, etc.)

Preventive maintenance for vaccine refrigerators is important to ensure that they are working properly and that vaccines are stored safely. Here are some of the things that should be done as part of preventive maintenance:

- Inspect the refrigerator regularly: Check the temperature inside the refrigerator at least once a day. The temperature should be maintained between 2°C and 8°C (36°F and 46°F). If the temperature goes outside of this range, the refrigerator should be repaired or replaced.
- Defrost the refrigerator regularly: If the refrigerator has a built-in defrost system, it should be run according to the manufacturer's instructions. If the refrigerator does not have a built-in defrost system, it should be defrosted manually every 2 to 3 months.
- Clean the refrigerator regularly: The refrigerator should be cleaned inside and out with a mild disinfectant solution. The door gaskets should be cleaned and inspected for tears or cracks.
- Check the door seals: The door seals should be checked to make sure they are tight and that they are not damaged. If the door seals are damaged, the refrigerator should be repaired or replaced.
- Check the temperature alarm system: The temperature alarm system should be checked to make sure it is working properly. The alarm should sound if the temperature inside the refrigerator goes outside of the safe range.
- Replace the filters: The filters in the refrigerator should be replaced according to the manufacturer's instructions.

Defrosting procedure

A refrigerator works well only if it is cleaned and defrosted regularly. Thick ice in the freezer compartment does **not** keep a refrigerator cool. Instead, thick ice makes the refrigerator work harder and uses more power or fuel. Defrost the refrigerator when ice becomes more than 0.5 cm thick or once a month, whichever comes first.

To defrost and clean a refrigerator: Remove vaccines from the inside of the refrigerator and store them in a functioning unit such as another vaccine refrigerator or an appropriately cooled insulated container.

- Take out all the vaccines, and diluents and transfer them to cold boxes as follows
  - OPV with fRemove vaccines from the inside of the refrigerator and store them in
  - a functioning unit such as another vaccine refrigerator or an
  - appropriately cooled insulated container.rozen ice packs for OPV
  - Other vaccines and diluents with conditioned/chilled water pack
  - Temperature monitoring device should be transferred to cold boxes together with vaccines
- Turn off the power supply to the refrigerator.
- Leave the door open and wait for the ice to melt. Do not try to remove the ice with a knife or ice pick, since doing so can permanently damage the refrigerator.
- Clean and dry the inside of the refrigerator and door seal with a cloth.
- Turn the refrigerator on again.

When the temperature in the main section falls to +8°C or lower, return the vaccines, diluents, and ice-packs to their appropriate places.

If the refrigerator requires frequent defrosting (more than once a month):

- Check if the door of the refrigerator is repeatedly opened (more than three times daily); or
- Check the door for proper closing, and lid properly fit or
- Check the functionality of the door (it may need cleaning or replacement)

If frequent frosting of your refrigerator continues, despite the above measures, contact cold chain equipment maintenance technician for further evaluation.

6.4.2. Maintaining cold boxes and vaccine carrier

Vaccine carriers and cold boxes must be well dried after their use. If they are left wet with their lids closed, they will mold. Mold may affect the seal of the cold box and vaccine carriers. Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. If this happens the vaccines inside will be exposed to heat.

If a cold box or vaccine carrier wall has a small crack you may be able to repair it with adhesive tape until you can get an undamaged one.

Activity: Video show in the classroom:

1. What Is Cold-Chain Equipment?
2. Types of Refrigerators Found in Health Facilities
3. Using Front-Opening Refrigerators
4. Using Top-Opening Refrigerators without basket and with basket

6.5. Vaccine storage capacity calculation

Activity 6.5: Group discussion

Instruction:

1. The importance of vaccine storage capacity calculation.
2. List methods of vaccine calculations.

Time: 25 min

The storage volume per dose of vaccine varies based on the type of vaccine, the number of doses per vial or ampoule, the physical size of the vial or ampoule and the bulkiness of the external packaging.

Two of the most reliable sources of information on vaccine volumes are:

- Guidelines on the international packaging and shipping of vaccines (WHO/V&B/01.05). Geneva: WHO; 2001.
- Vaccine volume calculator (WHO/V&B/01.27).

In countries where vaccines are purchased, figures should either be based on data obtained from all the manufacturers who regularly supply vaccines or from the latest version of the WHO vaccine volume calculator.

6.5.1. Estimating required net volume for vaccine storage

The vaccine storage volume is calculated by adding the maximum volume of the working stock to the volume occupied by the safety stock. A safety margin is then added to take account of stock peaks. Stock peaks occur when the volume of vaccine actually distributed in the period between any two supply intervals is less than the volume predicted to be distributed during this period. They can also arise if a vaccine delivery arrives earlier than anticipated. A realistic safety margin can be derived by analyzing stock records, which, for example, show past instances of overstocking and understocking caused by seasonal fluctuations in demand, campaigns, NVI and so forth. A short-cut method based on vaccine volume per fully immunized child (FIC), is usually used when introducing new vaccines. The vaccine volume per fully immunized child will be computed based on the number of doses per vial, number doses of each vaccine per schedule, packed volume of each vaccine and wastage factor of each vaccine. (See Table 6-3 below) of each vaccine and wastage factor of each vaccine. (See the Table 11 below)

Table 6-1 Calculation of vaccine storage volume per fully immunized child (including three doses of Td for women)

Calculation of vaccine storage volume per fully immunized child (including two doses of Td for women)							
Vaccines	**Number of doses per vial**	**No. of doses for immunization**	**Packed volume per dose (cm3)**	**Vaccine Wastage**		**Storage volume in cm3**	
				VWR (%)	**WF=100/ (100-VWR)**		
	A	B	C	D	E	F=B*C*E	G=F/1000
bOPV	10	4	1.76	10	1.11	7.8144	0.0078
Measles	10	2	2.11	35	1.54	6.4988	0.0065
Measles diluents*						1	0.0010

BCG	20	1	0.88	50	2	1.76	0.0018
BCG diluents *						0.6	0.0006
DTP-Hep B-Hib	1	3	14.06	5	1.05	44.289	0.0443
PCV13	4	3	3.6	10	1.11	11.988	0.0120
Rotarix	1	2	17.13	5	1.05	35.973	0.0360
IPV	5	1	4	10	1.11	4.44	0.0044
HPV	1	2	15	10	1.11	33.3	0.0333
Td	10	3	2.7	10	1.11	8.991	0.0090
HepB	1	1	14.1	10	1.11	15.651	0.0157
COVID-19	1	2	21.8	1	1.05	45.78	0.0458
Net storage volume per fully immunized child for health facility							0.2181
*For woreda cold stores Storage volume of Diluents will be deducted and net storage volume for FIC (lit)							0.2165
**For PSA hubs and above cold stores storage volume of Diluents and OPV will be deducted and net storage volume for FIC (lit)							0.2087

Note:

- √ IPV may have two preparations (number of doses per vial) 10 and 5 doses.
- √ COVID 19 Vaccines may have different formulations and preparation so the number of doses per vial also differs. Due to these it will bring FIC variations.

6.5.2. Required Storage Volume Calculation

The total vaccine storage net volume is obtained by multiplying the volume per fully immunized child and the total number of expected children during the course of the year (this will depend on the objectives of immunization coverage).

> Required Vaccine Volume in liters = Net volume per fully immunized child (in lit.) x Number of under 11 months x Immunization coverage target

> Required Vaccine Volume in liters = Net volume per fully immunized child (in lit.) x Number of under 11 months x Immunization coverage target

The next step is to determine the necessary cold chain capacity to accommodate the vaccine volume we have just calculated. If cold chain equipment in use has known net storage capacity, the calculated required vaccine volume will be the final required cold storage capacity. However, if the net storage volume of available cold chain equipment is not known, we need to multiply the computed required vaccine volume by gross factor or equipment factor which is nearly 2.0 for refrigerators or freezers and this takes into consideration the need for air circulation between vaccine boxes. The result of this calculation gives an overall capacity needed for the cold chain.

> Required Gross Storage Capacity = Vaccines Storage Volume X Equipment Volume Factor

6.5.3. Selecting Cold Chain Equipment based on vaccine volume

Once the capacity needs for refrigeration have been determined, the officer in charge can select or request the right model of refrigerators appropriate for the supply chain level.(See annex 3 for Common (non-optima1) cold chain equipment in Ethiopia annex 4 for currently available optimal cold chain equipment.)

Examples:

Selecting cold chain equipment for health facilities

XI health center have a total population of 25,000, proportion of live birth is 3.5% and planned coverage is 100%. Recommend the type of required refrigerator for ~~—X—~~health center.

Total population = 25,000; Live births = 25,000*0.035 = 875 children

Net storage volume per fully immunized child (lit) at health facility level= 0.02181. Supply period for health facility = monthly

Required Storage Volume in liters per one month – (875* 0.02181)/12 = 15.9 lit

Note: In addition to monthly vaccine requirements, the calculation of required storage capacity should take into account the storage space needed for safety stock. Hence, the total required storage capacity for the above health center will be 15.9 lit + 15.9*25%= 19.88 lit.

Therefore, any cold chain equipment with net storage capacity greater than 19.88 lit can be used for this health facility.

Example-

Vest frost: VLS 024SDD,- 26 Dometic RCW 50 EK, Sibir 170 EK,

However, if we have cold chain equipment with unknown net storage capacity, we multiply the calculated required vaccine volume with equipment factor and then compare the final required capacity with the gross storage capacity of the available refrigerator.

Currently most of the WHO prequalified refrigerators listed in WHO PQS have their net storage capacity.

Selecting cold chain equipment for EPSS hub level

Recommend the type of cold chain equipment required for cold and freezing storage for PSA hubs with total population of 5,000,000, 3.5% proportion of live birth and planned coverage is 100%.

- Total population –5,000,000
- Live births – 5,000,000*0.035 = 175,000
- Net storage volume (cold) per fully immunized child (lit) for cold & freezing is 0.02087 and 0.0078 respectively.
- Supply period for EPSS hub – Quarterly
- Required cold Storage Volume in liters per supply period for Cold storage (+2oc to +8oc) - (175,000 * 0.2087)/4= 9,130.63lit and
- Freezing storage (175,000*0.0078)/4= 341.25 lit

Note: In addition to quarterly vaccine requirements, the calculation of required storage capacity takes into the storage space needed for safety stock. Hence, the total required cold storage capacity for the above zone will be,

- Cold storage (+2oc to +8oc) - 9,130.63+ 9,130.63*25%= 11,413.28 lit for one quarter
- Freezing storage - 341.25 + 341.25 *25% = 426.56 lit for one quarter

Based on the result, vaccine Cold store manager and/or EPI manager can select refrigerators and freezers the net cold storage volume which sum up to computed required cold and freezing storage capacity. (See Annex 3 and 4 for the list of CCE with their storage capacity).

If the EPSS hub selects TCW 4000 AC of 240 lit, a total of 31 Ice lined refrigerators are required to accommodate the total volume of vaccine needed for the supply period. For sub national level (EPSS hubs level) cold stores where multiple cold chain equipment is required it is advisable to select cold chain equipment with large net storage capacity. For this particular hub, it is logical to recommend a cold room with cold storage capacity of about 15 m3.8 For freezing storage two MF314 freezers (storage capacity 264 lit) can be used.

6.6. Temperature monitoring devices

Activity 6.6: Group discussion

Instruction:

1. What is temperature monitoring device (TMD)?
2. List different types of TMDs and their uses.
3. List TMDs for vaccine transportation

Time: 25 minutes

To ensure the stability, safety, and potency of vaccines, appropriate cold chain temperature control devices are vital throughout the vaccine cold chain system from manufacturer to the point of end-users, including outreach sites both during storage and transportation. Every refrigerator, freezer and cold store used for vaccine storage must be fitted with an independent temperature-monitoring device. Ideally, an automatic alarm system should be available to alert staff whenever the temperature of the vaccine is outside the safe limits.

There must be reliable procedures for protection against failure at all times of day and night. Temperatures must be checked and recorded by a responsible member of staff. There must be a contingency plan to safeguard the vaccine if there is a long power cut or if the refrigeration equipment fails.

The following section describes the temperature monitoring devices, and the temperature monitoring principle and procedures will be dealt with in Chapter 7.

Vaccine Vial Monitors (VVMs)

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 color (see Figure 4). If the color of the inner square is the same color or darker than the outer circle, the vaccine has been exposed to too much heat and should be discarded.

Note: VVMs do not measure exposure to freezing temperatures, only to heat.

The grossing factor for a cold room with 15 m3 storage capacity is estimated to be 3.3.

(WHO MLM training manual, Module 7: Cold chain management, 2013)

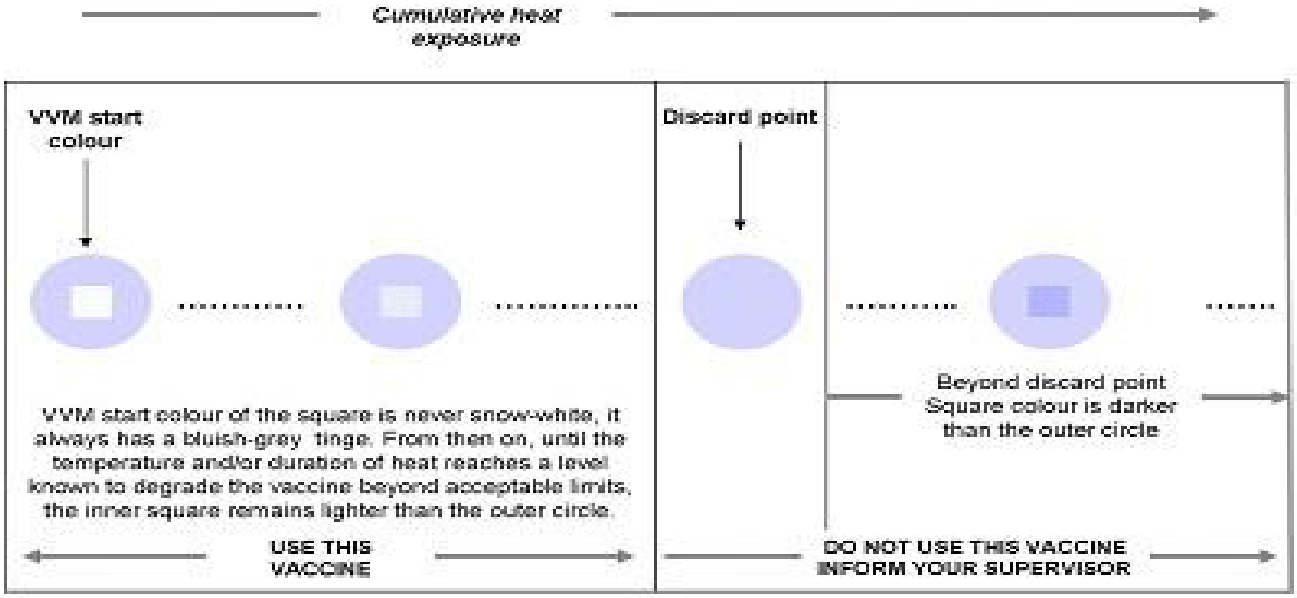


Figure 6-12 VVM stages

The table below describes VVM reaction rates by category of heat stability.

Table 6-2 VVM reaction rates by category of heat stability

Category: (Vaccines)	No. days to end point at +30°C	No. days to end point at +25°C	Time to end point at +5°C
VVM30: HIGH STABILITY	30	193	> 4 years
VVM14: MEDIUM STABILITY	14	90	> 3 years
VVM7: MODERATE STABILITY	7	45	> 2 years
VVM2: LEAST STABLE	2	NA*	225 days

*VVM (Arrhenius) reaction rates determined at two temperature points

The reactions of VVMs vary in accordance with the category of vaccine to which they are assigned. VVM2, which is assigned to OPV, the most heat-sensitive vaccine, reaches its end-point in 48 hours at 37 oC, whereas VVM30 on hepatitis B vaccine, one of the most heat-stable vaccines, takes 30 days to reach its end-point at this temperature. However, vaccines

made by different manufacturers may have different heat stability characteristics and may therefore be assigned to different categories by WHO. Manufacturer X's BCG might use a VVM30 while manufacturer Y's BCG needs a VVM14. However, as of 31 July 2021 some of the vaccines produced to prevent Covid-19 virus are produced without VVM and to control and monitor their potency and safety, it needs different mechanisms such as continuous temperature monitoring devices/data loggers.

6.6.1. Thermometers

Dial Thermometers

Dial thermometers have been provided to record the temperature in the refrigerators/ Freezers. It has a dial with a moving needle to show the temperature of the vaccine within the range of -50°C to +50°C. Bi-metallic dial thermometers are no longer recommended because they easily lose their calibration .

Alcohol Stem Thermometers

Alcoholic thermometers are much more sensitive and accurate than dial thermometers; they can record temperatures from -50°C to +50°C and can be used for refrigerators and deep freezers.

Currently, WHO advises not to use stem thermometer as the primary temperature monitoring device because they do not provide a continuous record of vaccine temperature exposure.

Figure 6-13: Dial thermometer and Stem thermometer

6.6.2. Freeze Indicator

It is also an electronic device to monitor vaccines exposed to less than 0°C. It contains an electronic temperature measuring circuit with associated LCD display. If the indicator is exposed to a temperature below - 0.5°C for more than 60 minutes the display will change from -good status into -alarm status. Freeze tag and Freeze watch are some of the examples of freeze indicators. For fridge tag with alarm (-×I) or activated freeze watch shake test is recommended.

Figure 6-14 : Freeze Indicator

Electronic temperature monitor Model Q-tag® CLm doc

Electronic temperature monitor Model Q-tag® CLm doc is one of the temperature monitoring devices used to monitor freezing of the temperature during vaccine shipment. Q-tag® CLm doc:

- Is an irreversible electronic temperature indicator that shows if a product, such as vaccine, has been exposed to temperatures beyond assigned alarm settings described above and used to monitor all kinds of shipments of vaccines and other perishable goods.
- It consists of an electronic temperature measuring circuit with associated LCD-display.
- As long as the temperature is within the allowed range, the OK- shown on the display. If the indicator is exposed to an out-of-range temperature the ALARM-sign (X) appears on the display. Furthermore, you have a USB interface and the device will create a PDF document with all relevant temperature data including temperature graph. No additional software needed.

6.6.3. Cold Chain Monitor Card (CCM)

A vaccine cold chain monitor is a card with an indicator strip that changes color when vaccines are exposed to temperatures that are too high. The vaccine cold chain card is used to estimate the length of time that vaccine has been exposed to high temperatures.

- Manufacturers pack these monitors with vaccines supplied by WHO and UNICEF.
- Usually the cold chain monitor is only used for large shipments of vaccines.

The same card should remain at all times with the same batch of vaccine. The change in color is cumulative and relates to heat exposure over the whole life of the shipment and not to a specific point in the cold chain.

Figure 6-15: Cold chain monitor carigure xx: Cold chain monitor card (CCM)

6.6.4. Fridge-Tag

Features of Fridge-Tag2

Electronic data loggers are also being introduced to monitor the temperature of the refrigerator. It is an electronic device placed with the vaccine which records the vaccine temperature for 30 days. It has an alarm system and as soon as the temperature of the equipment storing the vaccine crosses the safe range the alarm alerts the handlers. This device assists in temperature monitoring through following features:

It shows temperature of refrigerator in digital LCD screen at all the time

1. It indicates if there was any alarming situation during the pas 30 days. The devices shows X alarm on the LCD screen if there was any alarming situation in the past 30 days. The alarming situation is when the temperature goes above +8ºC over a consecutive period of ten hours or temperature drops down below - 0.5oc for a consecutive period of 60 minutes.
2. It shows the duration of temperature violation for every alarming situation that happened in the past 30 days on the LCD screen. To see the duration of temperature violation, device is equipped with a -ReadII button which guides the user through the history of past 30 days starting from -todayII till -30 days agoII.
3. It shows a OK sign if there has been no violation of temperature in pas 30 days
4. It has a shelf life of three years from the date of activation of the device. The device once activated, cannot be stopped throughout its operational life. Hence, it provides round the clock monitoring of refrigerators without any need of intervention of the user for three years of time.
5. It has been specifically designed to be used with refrigerators and cold rooms that are required to maintain the temperature between +2 ºC to +8 ºC

Figure 6-16 Frige tage

6.6.5. Remote Temperature Monitoring Device (RTMD)

As with all temperature monitoring solutions, the purpose of RTMD systems is to keep CCE in optimal working order, to ensure vaccines are stored safely and kept potent. Expected advantages of RTMD as compared to other temperature monitoring devices:

- Enable rapid response to temperature excursions through continuous surveillance of the equipment with immediate alarming triggering faster reaction by responsible person to prevent damage to the vaccines;
- Allow for systematic and routine review of CCE at a given level of the cold chain (through analysis of available data from the RTMD), and to increase accountability for corrective follow-up actions (e.g. maintenance and repairs of equipment);
- Collection of data enables high-level review to inform relevant decisions (e.g. procurement of equipment, maintenance planning).

Additional benefits of the Remote Temperature Monitoring Devices may include:

- Improved understanding of the CC data as main alarm triggers are exposed through RTM, helping to reduce/eliminate these common causes (door being open too often, inadequate cold storage loading, overloading, equipment or generator out of kerosene, mechanical failures of the equipment, bad state of the door seal, thermostat needing adjustments, solar panels not cleaned, solar battery needing replacement, etc.).
- EPI managers having direct access to the data are better aware of the cold chain issues it reveals.
- Increased procedural compliance by health workers due to increased transparency of temperature excursions.
- Reduced replacement costs due to improved maintenance of equipment.
- Reduced fuel and per diem costs for CC technicians, as diagnosis on equipment failure can be remote performed, so the technician only travels for serious issues that could not be resolved by staff on-site.
- Reduced closed-vial waste due to CC failure and possibly leading to stock out.

The ultimate goal is to design a structure that can record temperature, notify the relevant individuals and trigger follow up actions on critical issues to achieve increased equipment uptime (e.g. for refrigerators, within the temperature range recommended by WHO of 2oC - 8oC), increased transparency and vaccine management efficacy, to make sure that no child is inoculated with vaccines of substandard quality.

The preceding criteria will help EPI decision makers debate and discuss the appropriate TMD for a given level of the cold chain, and whether RTM is indicated. In the following sections, a step-by-step process is provided to walk through how to effectively implement that decision.

Based on the above objectives and benefits MOH/EPSS introduced RTMD (FridgeFone) from Beyond Wireless and currently most cold rooms in the country are equipped with remote temperature monitoring device (RTMD).

Figure 6-17 Fridge-Fone

6.6.6. Temperature monitoring devices for vaccine transportation

Poorly managed and monitored transport operations place vaccines at particular risk of damage from exposure to heat and freezing temperatures. If vaccines have VVMs, heat damage can be detected by monitoring VVM changes. However, if no temperature monitoring devices are used, it is impossible to detect freeze damage. Based on different vaccine transportation modality (refrigerated track or passive container), type of vaccine being transported (freeze sensitive or not), type of coolant pack used in the container. The currently recommended temperature monitoring devices for refrigerated trucks are discussed below.

Dashboard-mounted electronic temperature recorder with integrated printer for refrigerated trucks: Mobile programmable electronic temperature and event logger systems can be installed in refrigerated vehicles. These are equivalent to the event logger systems used for fixed storage locations and have similar functionality options, including multi-point temperature monitoring and a dashboard mounted display and alarm system.

The more sophisticated models can be integrated with Internet-or intranet-based vehicle tracking and remote monitoring, including SMS event alerts and local wireless area data retrieval.

Figure 6-18 Dashboard-mounted electronic temperature record

Other temperature monitoring options for refrigerated truck are;

a. **Data logger or electronic temperature recorder –** This is a user's programmable temperature logger that can be packed with the load and the temperature history can be downloaded at the end of the trip. This option can provide a continuous temperature and alarm record for traceability purposes but cannot alert the driver if a temperature excursion occurs

b. **Dashboard-mounted digital thermometer -** A dashboard-mounted digital thermometer does not provide a continuous temperature record for traceability purposes and the driver may not notice if a temperature excursion occurs. Moreover, the thermometer sensor only monitors temperatures at a single point in a compartment with a volume of many cubic meters. Traceability relies entirely on checking and recording the freeze indicator and VVM status at the point of delivery. Manually recording temperatures at regular intervals is a possibility; however, this can only be done in a safe and reliable manner if the driver is accompanied by a member of the EPI team.

Temperature monitoring devices for temperature study and cold room/ refrigerated truck mapping. To monitor the temperature monitoring system WHO recommends conducting temperature monitoring study every 3 years and temperature mapping for cold rooms on a regular basis. Therefore, data loggers like -Logtag TRIX-8II can be used to conduct mapping and study.

LogTag TRIXI8 Temperature Logger is a battery powered stand-alone measurement system for digital time- temperature monitoring. It incorporates a temperature sensor arranged in a recess in the case. This design protects the sensor from damage but still provides a fast reaction time.

Using the LogTag interface and LogTag free available companion software LogTag Analyzer, it is easily set up for recording conditions including delayed start, sampling interval, continuous or fixed number of readings and configuration of conditions to activate the ALERT indicator. Readings are downloaded using LogTag Analyzer which provides facilities for chart, zoom, and listing data statistics and allows exporting the data to other applications such as Excel. The data downloading requires an external USB based docking station (Logtag interface).

Figure 6-19 Log tag TRIX-8

6.7. Summary

- Cold chain equipment management system is essential for the safe and effective delivery of temperature-sensitive vaccines.
- There are different types of refrigeration technologies in cold chain equipment management. Its essential to select appropriate technology and types of equipment during storage and transportation of vaccines.
- To ensure the safety and quality of cold chain, it is important to handle the equipment carefully and follow all safety procedures.
- Preventive maintenance includes regular cleaning, defrosting, and inspection of equipment to identify and address potential problems before they cause a failure.
- Temperature monitoring devices for all types of cold chain equipment shall be placed within the equipment and regularly record the temperatures inside cold chain equipment. This data can be used to identify problems with equipment or to track the performance of the cold chain system over time

Chapter 7

Vaccine temperature monitoring

Allocated Time: 3 hours

Chapter Description:

This chapter describes vaccine temperature monitoring, sensitivity, storage, loading, reconstitution, contingency plan, and temperature mapping.

Chapter Objective:

At the end of this chapter, participants will be able to describe vaccine temperature monitoring and temperature mapping.

Enabling Objectives: -

By the end of this chapter participants will be able to: -

- Describe vaccine temperature monitoring.
- Explain vaccine sensitivity and storage conditions.
- Explain loading of vaccine, storage and handling diluents
- Demonstrate vaccine reconstitution.
- Prepare elements of a contingency plan
- Demonstrate temperature mapping for cold room/ freezer rooms

Chapter outline:

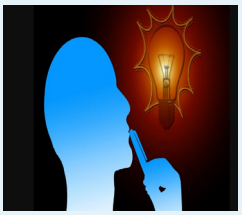
7.1. Introduction to vaccine temperature monitoring

Activity 7.1 Individual-Reflection

Instruction:

What does it mean by Vaccine Temperature Monitoring?

Time 5 minutes



Vaccines are sensitive to heat and freezing and 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 it reaches the user.

Reliable cold chain enables vaccines and diluents to be:

- Collected from the manufacturer or an airport as soon as they are available.
- Transported between 2°C and 8°C from the airport and from one store to another.
- Stored at the correct recommended temperature at all level vaccine stores and in health facilities.
- Transported between +2°C and +8°C to outreach sites and during mobile sessions.
- Kept between +2°C and +8°C range during immunization sessions; and
- Kept between +2°C and +8°C during return to health facilities from outreach sites.
- Kept between -80oc and -60oc in case of Pfizer, Moderna and other COVID-19 vaccine that require ultra-low temperature.

Equipment and facilities need to be monitored and maintained for reliable performance, and people responsible for these tasks should be aware of the important role they play in maintaining the health of our children. Because it is so important to ensure that quality vaccines are always available, one should be ready for the unexpected. Spare parts for the different types of equipment must be stocked, and maintenance plans implemented at all levels of the cold chain.

Managers can only assure reliability of the cold chain if they are actively involved in the supervision which covers performance assessment of both equipment and staff involved in vaccine management.

Two important terms used in the cold chain system are "alternative" and "contingency". An alternative cold chain refers to a duplicate system, which is in place to take over the functions of the original cold chain system in cases where the original system fails or cannot be used. On the other hand, a contingency plan for the cold chain refers to a plan of action that can be implemented immediately in the case of a failure of one or more of the functions/ components of the original cold chain.

7.2. Vaccine sensitivity and storage conditions

Activity 7.2: Group discussion	
Instruction: ■ List the most common vaccine used in Ethiopia ■ Explain the sensitivity with freeze and temperature ■ Arranged the loading with respective of sensitivity **Time: 25 minutes**	

7.2.1. Sensitivity to heat

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 sensitivity to heat as follows:

Table 7-1 Vaccine heat sensitivity

Heat sensitivity	Vaccines	Remarks
Most sensitive	Oral poliovirus (OPV) Inactivated poliovirus (IPV) Measles Mumps rubella (MMR)	√ Use vaccine vial monitors to monitor heat exposure.
	DTP DTP-Hep B-Hib (pentavalent) Hib (liquid) Measles Rotavirus (liquid) Rubella Yellow fever	√ All freeze-dried vaccines become much more heat sensitive after they are reconstituted.

Least sensitive	Bacillus Calmette-Guérin (BCG) Human papillomavirus (HPV) TT, DT, Td Hepatitis A Hepatitis B Hib (freeze dried) Meningitis A (polysaccharide-protein conjugate) Meningitis C (polysaccharide-protein conjugate) Pneumococcal (polysaccharide-protein conjugate) (PCV) Rabies	√ Note: Bolded vaccines are freeze dried vaccines

Note: all freeze-dried vaccines become much more heat-sensitive after they have been reconstituted, and it is then even more important that they are not exposed to heat. For details, see "section on proper diluent use for freeze-dried vaccines.

Video Show on VVM use:

How to read VVM? https://watch.immunizationacademy.com/en/videos/133

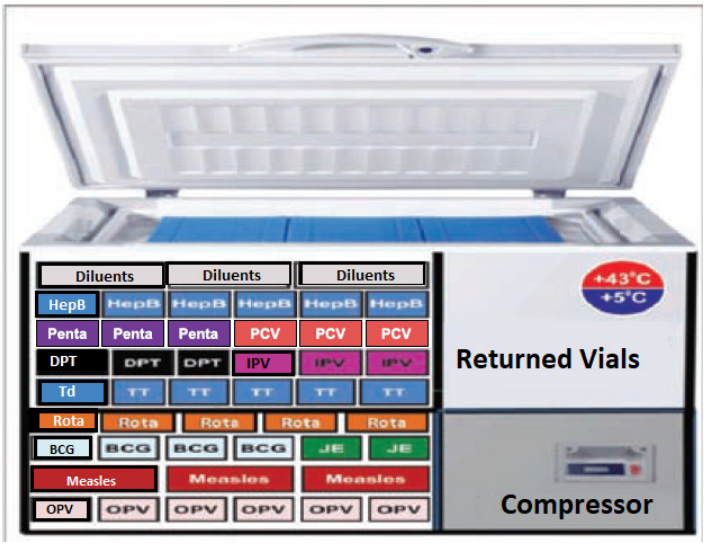


Figure 7-1 Sensitivity to heat

7.2.2. Sensitivity to cold (freezing)

Some vaccines are sensitive to being too cold. For these vaccines, freezing or exposure to temperatures below zero degrees centigrade (0oC) can also cause loss of potency, and the vaccine will become useless. For these vaccines, it is therefore essential to protect them not only from heat, but also from freezing. The vaccines sensitive to freezing (as well as to heat) are:

Table 7-2: Vaccine freeze sensitivity

Freeze sensitivity	Vaccine	Cautions
Most sensitive  Least sensitive	Hepatitis B DTP-HepB-Hib DTP Hepatitis A, Human papillomavirus (HPV) Meningitis C (polysaccharide-protein conjugate) Pneumococcal (polysaccharide-protein conjugate) TT, DT, Td Inactivated poliovirus (IPV) Hib (liquid) Rota vaccine (liquid)	Never expose these vaccines to zero or sub-zero temperatures. Use cool water pack/ conditioned ice pack. Avoid the use of ice for transport.
Vaccines not damaged by freezing	Rota vaccine (freeze dried) Meningitis A (polysaccharide-protein conjugate) Yellow fever Bacillus Calmette-Guérin Hib (freeze dried) Measles Measles, mumps, rubella Oral poliovirus Rubella [1]	These vaccines are not damaged by freezing.

1 Most the listed vaccine are not available in Ethiopia, explain the difference

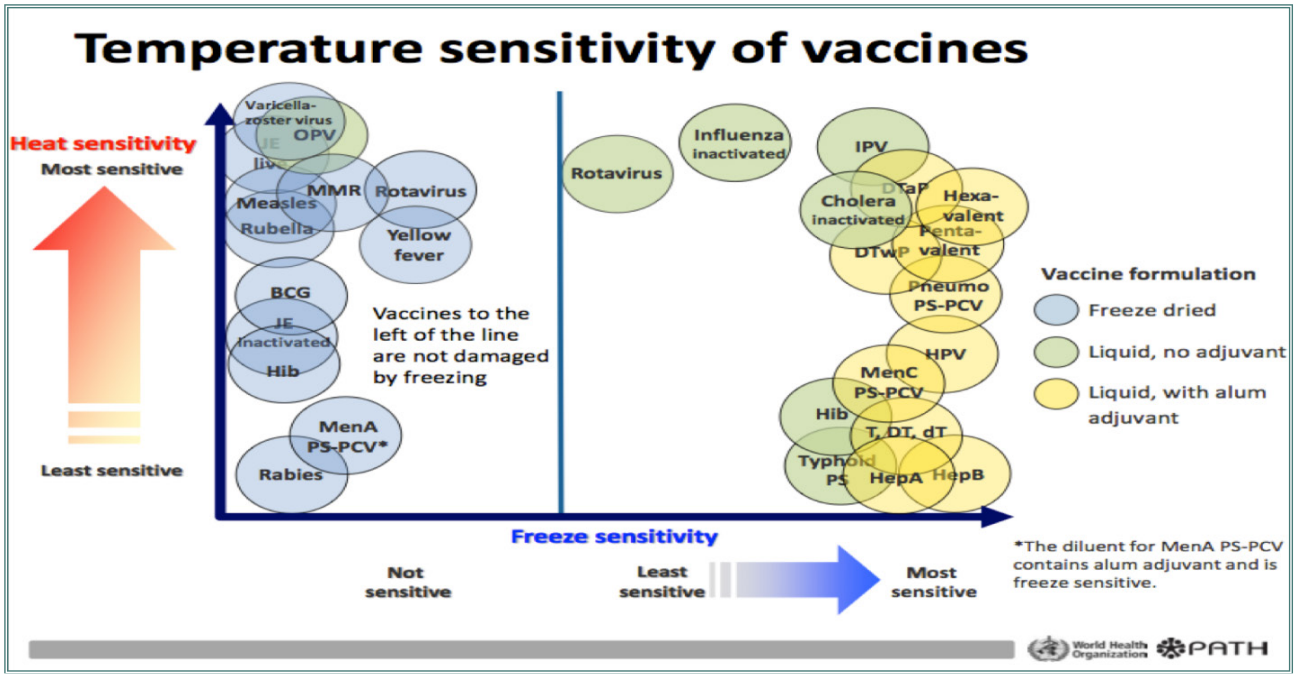


Figure 7-2 Temperature sensitivity of vaccines

7.2.3. Sensitivity to light

Some vaccines are very sensitive to strong light. For these vaccines, exposure to ultraviolet light will cause loss of potency, so they must always be protected from sunlight or fluorescent (neon) light. BCG, measles, MR, MMR and rubella vaccines are sensitive to light (as well as to heat). Normally, these vaccines are supplied in vials made from dark brown glass, which gives them some protection against light damage, but care must still be taken to keep them covered and protected from strong light at all times.

Remember, if a vaccine is damaged by heat and loses some of its potency, this loss can never be restored, and the damage is permanent. Each time heat damage occurs the loss of potency accumulates, and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless.

Even when stored at the correct temperature, vaccines do not retain their potency forever as all vaccines have an expiry date. The expiry date shown on each vaccine vial and on each packet assumes the vaccine has been properly stored and transported all the time, in accordance with the guidelines. If the vaccine is damaged by heat or other causes, its potency will be reduced even before the expiry date is reached.

Only vaccine stocks which are fit for use should be kept in the vaccine cold chain. Any expired vials, heat damaged vials or vials with VVMs beyond the discard point should not be kept in the cold store, refrigerator, or freezer, to avoid confusing with good quality vaccines. If unusable vaccines need to be kept for a period before disposal, for example, until accounting or auditing procedures have been completed, such vials should be kept outside the cold chain, separated from all usable stocks, and carefully labelled.

7.3. Loading of vaccine

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

7.3.1. Loading front-opening vaccine refrigerators

Front opening refrigerators have two compartments.

- A main compartment (the refrigerator) is for storing vaccines and diluents, in which the temperature should be kept between +2°C and +8°C. The thermostat or flame adjustment is used to adjust the temperature.
- A second compartment (the freezer):- is for freezing ice-packs and if the refrigerator is working properly, this section will be between -5°C and -15°C.

7.3.2. Load a vaccine front opening refrigerator as follows:

1. Freeze and store ice-packs in the freezer compartment. The frozen ice packs should only be used to transport OPV.
2. All the vaccines and diluents must be stored in the refrigerator compartment. If there is no enough space, diluents can be stored at ambient temperature. It is important, however, that diluents be chilled by putting them in the refrigerator at least for 24 hours before use.
3. Arrange the boxes of vaccine in stacks so air can move between them; keep boxes of freeze-sensitive vaccine away from the freezing compartment, refrigeration plates, side linings or bottom linings of refrigerators where freezing may occur.
4. At health facility level
   - 4.1. Keep opened vials of OPV, IPV/Td, and PCV13 vaccines in the "use first" box for first use during the next session.
   - 4.2. Keep vials with VVMs showing more heat exposure than others in the box labelled "use first." Use these vials first in the next session.
5. Keep vials only that are good for use in the refrigerator. Do not include the following vaccine in a refrigerator.

- Expired vaccines and diluents
- Reconstituted vials with doses remaining after an immunization session
- Vials with VVMs that have reached or are beyond their discard point.

6. Keep cool water packs filled with water on the bottom shelf of the refrigerator. They help to keep the temperature cool in case of a power cut.
7. Store vaccines and diluents in front opening refrigerators as follows:

- Keep Measles, BCG and OPV on the top shelf;
- Freeze sensitive vaccines like DTP-HepB-Hib , HPV, Td, PCV, Rota and IPV on the middle shelves; and
- Diluents next to the vaccine with which they were supplied.

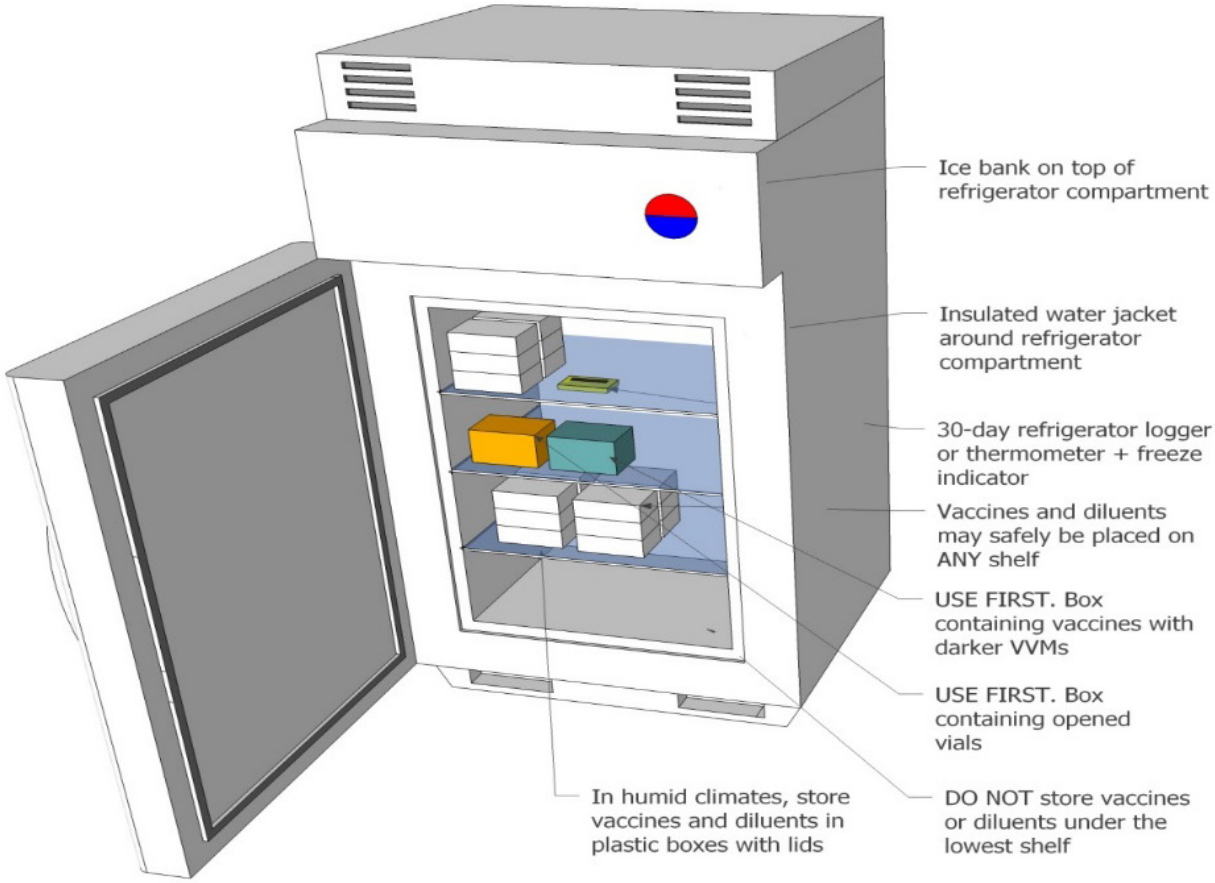


Figure 7-3: Loading vaccine in Front opening refrigerators

7.3.3. Loading Top opening refrigerators

Arranging vaccine in Top opening refrigerators follows the same principles as outlined above with the following exceptions:

1. All the vaccines should be stored in the basket provided with the refrigerator
2. Measles, BCG and OPV in the bottom only; and
3. Freeze-sensitive vaccines DTP-HepB-Hib, HPV, Td Rota PCV and IPV vaccines in the top only.

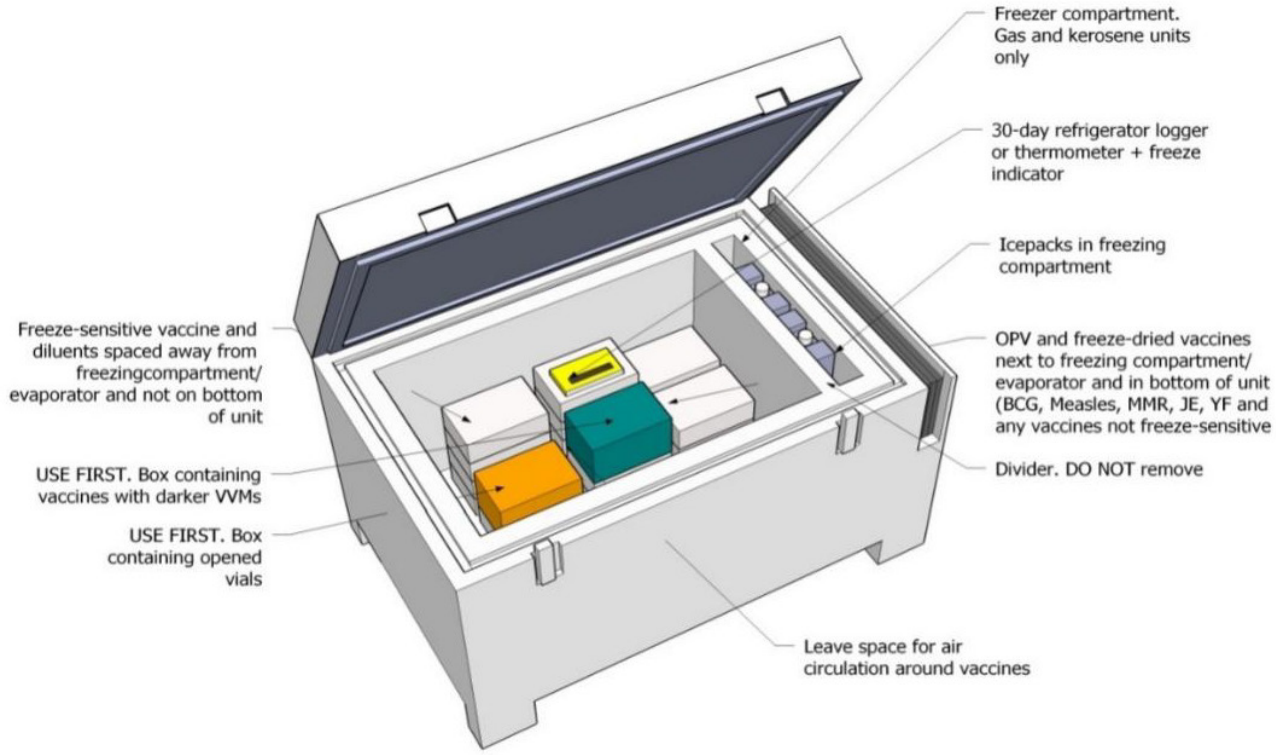


Figure 7-4 Loading front opening refrigerators

7.3.4. Loading vaccine in cold room

1. Before loading ensure that the internal temperature is in safe range (+2°C and +8°C for cold room and -25°C and -15°C for freezer room)
2. Use shelves with tertiary package (do not store vaccine with primary package, because it occupies more space and also temperature may not stable)
3. Load vaccine by type of antigen, expiry date and VVM status
4. Keep freeze-sensitive vaccines away from evaporator
5. During loading or unloading, cold room doors should be closed, the curtains should be properly used and the engine/ power should not be off.
6. There should be free space between boxes for air circulation
7. There should be adequate space in the cold room for walking and accessing vaccines comfortably.
8. At the end, do not forget to turn off the light.

7.4. Storage and handling of diluents

Activity 1.3. Think/Pair/share	
Instruction: First think alone and pair up with the person sitting next to you to discuss the following questions and share your thoughts to the larger group. **Question:** How should diluents be stored, handled and reconstituted? Time: 10 min	

7.4.1. Proper Handling and use of Diluents:

Diluents for vaccines are less sensitive to storage temperatures than the vaccines but may be kept in the cold chain between +2oC to +8oC if space permits. When vaccines are reconstituted, the diluent should be at same temperature as the vaccine, so sufficient diluent for daily needs should be kept in the cold chain at the point of vaccine use (health Centre or vaccination post). At other levels of the cold chain (central, /EPSS hub or district stores) it is not necessary to keep any diluent in the cold chain unless it is planned to use it for reconstituting vaccine within the next 24 hours. However, diluent vials should not be frozen to avoid risk of cracking the glass and contamination the contents. Thus, diluents should be kept outside of freezer and avoid direct contact with any frozen surface.

Freeze-dried vaccines and their diluents should always be distributed together in matching quantities. The vaccines must be always kept in the cold chain between +2oC and +8oC, or optionally, at –15oC to –25oC for OPV and freeze-dried vaccines. For each distribution link, the cold chain will normally comprise cold boxes or vaccine carriers with ice packs. The correct types and quantity of diluents from the same manufacturer must accompany vaccines in the distribution practice. This is essential to ensure that the health worker always has equal numbers of vaccine and diluent vials for reconstituting them. Diluents may appear to be simple water, but in fact usually contain a variety of salts, chemicals and additives required to stabilize a specific vaccine after reconstitution.

Diluent composition

Because of the variety of diluents available, a vaccinator must be meticulous in verifying that each vaccine is reconstituted ONLY with its assigned diluent in order to ensure that the vaccine is effective. Diluents are formulated specifically for their corresponding vaccine and may contain any or all of the following:

- stabilizers that affect heat sensitivity,
- preservatives to maintain the integrity of the vaccine during storage and distribution;
- bactericides to maintain the sterility of the reconstituted vaccine:
- chemicals to assist in dissolving the vaccine into a liquid;
- buffers to ensure the correct pH balance (level of acidity or alkalinty);
- adjuvants to enhance immune response; and
- a separate and different vaccine.

Each vaccine requires a specific diluent and, therefore, diluents cannot be used interchangeable. Therefore, diluent made for measles vaccine, for example, must not be used for reconstituting BCG, yellow fever or any other type of vaccine. Likewise, diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting the same type of vaccine produced by another manufacturer. This means that diluent for measles vaccine made by company 'X' cannot be used for reconstituting measles vaccine made by company 'Z'.

Vaccine reconstitution

Vaccines are produced in two different forms: as a liquid, which is ready to administer, or as a freeze-dried powder that must be mixed with a liquid in a process known as 'reconstitution' before it can be used. Reconstitution of freeze-dried vaccine must be carried out using a sterile syringe and needle for each vial of diluent. The process of reconstitution requires careful attention and use of the correct diluent for each type and batch of vaccine to ensure adequate potency, safety and sterility of the resulting mixture.

Discard all reconstituted freeze-dried vaccines and opened COVID-19 vaccines at the end of the session, or within 6 hours, whichever comes first.

7.4.2. Recording of diluents:

When packaged separately from their corresponding vaccine, diluents should be treated as individual products in a stock ledger. Therefore separate stock cards should

be prepared for each diluent and should also indicate which vaccine should be reconstituted with it. In the case of computerized stock management programs, the diluent item should be linked to the appropriate vaccine item for additional stock control and to reduce possible errors in distribution and usage for reconstitution

7.5. Elements of a contingency plan

All staff responsible for vaccine management should know when and how to respond in the event of an emergency related to a cold chain equipment breakdown, a major power supply failure, a transport emergency or any other situation that puts vaccine at risk. Managers and storekeepers should develop facility- and equipment-specific contingency plans that clearly describe the steps and actions to be taken in response to common emergencies. Contingency plans should be in the form of a written checklist, easily accessible to all relevant staff.

Ensure that all staff knows how to follow safe storage rules in case of an emergency:

- Freeze-sensitive vaccines. Maintain vaccines at +2°C to +8°C.
- Freeze-dried vaccines packed with diluent. Maintain vaccines & diluent at +2°C to +8°C.
- Freeze-dried vaccines packed without diluent. Maintain vaccines at +2°C to +8°C and Store diluents at room temperature as normal.
- COVID-19 vaccines that require ultra-low temperature (Pfizer, Moderna &..) store between -80oc to -60oc

The most common emergencies in a cold chain are:

- Failure of refrigerators, freezers or cold rooms
- Discontinuation of electric power
- Shortages of fuel, vaccines, syringes or needles
- Freezing of freeze-sensitive liquid vaccines
- Turn of VVM spot color of vaccines
- Breakdown of vaccine delivery vehicle
- Sudden or unplanned supply of large quantities of vaccine
- Absence of members of staff due to illness or other reasons
- Destruction of the vaccine store due to manmade or natural disasters/accident

Action to be taken when a vaccine refrigerator is not working:

If a vaccine refrigerator stops working, first protect the vaccines and then repair the refrigerator.

Protecting the vaccines

Move the vaccines to another place until the refrigerator is repaired. If you think that the problem will last only a short time, you may use a cold box or vaccine carrier lined with chilled/conditioned ice packs for temporary storage. For a longer duration, use another refrigerator. Always keep the thermometer / Fridge tag with the vaccines and continue to monitor the temperature.

Restoring the refrigerator to working order

Check the power or fuel supply. If there is no power, make other arrangements until power is restored. If there is no fuel, get more fuel as soon as possible.

If lack of power or fuel is not the problem, repair the refrigerator or report to your repair technician or supervisor.

Never use dry ice. Dry ice may lower the temperature of a cold room to below 0°C. In addition, when it evaporates it gives off carbon dioxide gas which may build up in the cold room and could suffocate anybody who enters the room.

Prepare and maintain at least two contingency plans based upon these options.

- Forecasting of emergency situation with "The three A's" questions:-
  - Is there Another solution?
  - Is it Adequate for the situation?
  - Is the solution Affordable/ Accessible?
- Whatever plans you choose, make sure they are discussed and agreed beforehand with your staff, and with all the other parties involved.
- Confirm the plan in writing. Keep a copy in the vaccine store. Make sure your staff know where it is.
- Check alternative stores to ensure that they are in good condition, have adequate space and are capable of maintaining vaccine at the correct temperature.
- Do not wait until an emergency occurs. Study the plans before they are needed.
- Prepare a list of emergency contact names, addresses and telephone numbers and post a copy of the list in the vaccine store. Keep the list up to date.
- Make sure that emergency contacts can be made both inside and outside normal working hours.
- Clearly describe initial and follow-up actions that can be implemented both inside and outside working hours.
- Review the plan at least once a year to ensure that it is still valid.
- Document the emergency event, complete the appropriate reports and inform the supervisor who will decide what follow up action is to be taken (depends on volume of vaccine).

Remember!

Cold chain problems must be solved quickly. Otherwise, there will be:

- Destruction of vaccines
- Loss of huge amount of money
- Service interruption
- Negative effect on the health seeking behavior of the community.
- Endanger the life of those in need of vaccines (children/target population)

Table 7-3 Sample emergency plan for vaccine store (to be posted on the wall)

Based on the situation in your health institution prepare a plan for safely storing vaccines during equipment breakdown or long electricity failure

(Prepared on :_____)

Name of health institution: _____

When to act:

- Breakdown of refrigerators, freezers or cold rooms
- Discontinuation of electric power
- Shortages of fuel, vaccines, syringes or needles
- Freezing of freeze-sensitive liquid vaccines
- Turn of VVM spot color of vaccines
- Breakdown of vaccine delivery vehicle
- Sudden or unplanned supply of large quantities of vaccine
- Absence of members of staff due to illness or other reasons

Equipment	Action
ILR/Refrigerators	**1.** Shift the vaccines in cold boxes with conditioned Ice packs. **2.** Arrange shifting of vaccine to the nearby health facility and store in refrigerator (If cold chain capacity available), if not
Deep Freezers	**1.** Shift the Ice packs in to cold boxes, if extra cold box available, after shifting of vaccine from refrigerators.
Refrigerated trucks cooling unit	Identify nearby cold store and **2.** Arrange shifting of vaccine to the nearby cold stores (If cold chain capacity available and adequate), and
Cold rooms	**1.** Shift the vaccines in refrigerated truck (If adequate). **2.** Arrange shifting of vaccine to the nearby cold stores (If cold chain capacity available), if not **3.** Contact higher level, for arranging the cold chain space and arrange shifting.

In case of ILR/DF under break down for long period, immediately inform to:

Organization	Name	Designation	Phone no.
1.			
2.			
3.			
4.			

7.6. Temperature monitoring at storage

To ensure safety, and potency of vaccines, proper temperature control using appropriate temperature monitoring technologies (devices) are imperative throughout the vaccine cold chain system from manufacturer to the point of end-users, including outreach sites both during storage and transportation.

7.6.1. Recommended storage temperatures for vaccines

The recommended conditions for storing EPI vaccines are shown in below Figure. This diagram indicates the maximum times and temperatures in each case.

Table 7-4 HO recommended vaccine storage conditions

<table>
<tr><th colspan="5">WHO recommended vaccine storage conditions</th></tr>
<tr><th rowspan="2">Vaccines</th><th rowspan="2">Primary</th><th colspan="2">Intermediate</th><th rowspan="2">Health center</th><th rowspan="2">Health post</th></tr>
<tr><th>Hub</th><th>District</th></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td rowspan="20" colspan="3"></td></tr>
<tr><td>BCG</td><td colspan="2" rowspan="6">WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2°C to +8°C.</td></tr>
<tr><td>MMR</td></tr>
<tr><td>Measles</td></tr>
<tr><td>MR</td></tr>
<tr><td>YF</td></tr>
<tr><td>Hib freeze-dried</td></tr>
<tr><td>HepB</td><td colspan="2" rowspan="14">+2°C to +8°C</td></tr>
<tr><td>DT</td></tr>
<tr><td>DTP</td></tr>
<tr><td>DTP-HepB</td></tr>
<tr><td>PCV13</td></tr>
<tr><td>IPV</td></tr>
<tr><td>Rotarix</td></tr>
<tr><td>HPV</td></tr>
<tr><td>Hib liquid</td></tr>
<tr><td>Td</td></tr>
<tr><td>COVID-19 vaccines</td></tr>
<tr><td colspan="6">Note: Diluent vials shold NEVER be frozen. If the manufacturer supplies a freeze-dried vaccine packed with its diluent, ALWAYS store the product at between +2°C and +8°C. If space permits, diluents supplied separately from vaccine may safely be stored in the cold chain between +2°C and +8°C or at list for 24 hrs at HFs before the session.</td></tr>
</table>

At the higher levels of the cold chain, i.e., at central and EPSS hubs level, OPV must be kept frozen between minimum -15°C to -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at –15°C to –25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain, these vaccines should be stored between +2°C and +8°C. All other EPI vaccines should be stored at between +2°C and +8°C at all levels of the cold chain.

COVID-19 vaccine are stored with recommended temperature range given by manufacturer, some of the vaccine need ultra-low temperature (Pfizer/Moderna…) and most other COVDI-19 vaccine are expected to be stored between 2°C - 8 °C at all level.

Note: COVID-19 vaccines that require ultra-low temperature (Pfizer & Moderna….) are expected to be stored from -80oc to -60oc at vaccine storage level.

7.7. Temperature mapping for cold room/ freezer rooms

Temperature mapping is the process of recording and mapping temperatures within a three-dimensional space, such as cold- and freezer-rooms, dry storage areas, refrigerated trucks refrigerators and freezers. Temperatures will not be the same everywhere within the storage area. Even in a small refrigerator or in a well-designed cold or freezer room, and particularly in a large warehouse, temperatures can vary by as much as 10°C from one location to another within the same space. Temperatures in the corners will most likely be different from those measured in the center and close to cooling units. In dry stores, the temperatures close to the ceiling tend to be higher than those close to the floor.

The Temperature mapping process

Temperature mapping consists of several key steps:

1. Deciding when to perform temperature mapping.
2. Placing an appropriate number of sensors in different areas, particularly areas that might go above or below specified safe temperature ranges. Generally, 20 sensors are used to map the temperature in a medium-sized cold storage unit, with an additional sensor to measure the ambient temperature. Temperatures are recorded at a specified regular interval, continuously, for a period of at least 48 hrs.

1. Reading and transferring recoded temperatures (minimum, maximum, mean and mean kinetic5) to a three-dimensional sketch of the storage vessel (cold- and freezer-rooms, dry storage areas and equipment, such as refrigerators and freezers) to be temperature mapped.
2. Identifying areas where vaccines and thermo-sensitive pharmaceutical products should not be stored.
3. Taking action to reduce the exposure of vaccines and pharmaceuticals to incorrect temperatures.

Note: Temperature mapping is recommended to be conducted bi-annually.

7.7.1. Monitoring temperature exposure during vaccine transport

The aim of vaccine distribution management is to ensure that vaccines are transported within the correct temperature range to minimize vaccine losses due to freezing and/or excessive heat exposure. Records must be kept to ensure that this guide is being achieved.

- Where freeze-sensitive vaccine is transported in cold boxes or vaccine carriers, at least one freeze indicator must accompany every delivery.
- Freeze indicators are not required in cold boxes, packed with fully frozen or conditioned icepacks, when these are used to transport OPV and lyophilized vaccines that are not damaged by freezing.
- Refrigerated vehicles, used for transporting vaccine, must be equipped with cab-mounted continuous temperature recording equipment and alarm systems. In addition, at least one freeze indicator device must also accompany every shipment.
- The freeze indicator device(s) should be placed with the most freeze-sensitive vaccine in the shipment at the time when the vaccine is packed in the issuing store.

The status of the freeze indicator(s) and of the Vaccine Vial Monitors (VVMs) must be checked at the time of arrival in the receiving store and details must be recorded on the Requisition and Issue Voucher form. Where refrigerated vehicles are used, temperature alarm events must be reported to the receiving store(s) so that additional checks of the vaccines can be carried out.

Freeze indicators should be placed with the most freeze-sensitive vaccine in each shipment. Typically, this will be either the HepB or the pentavalent DTP-HepB-Hib or DTP-HepB+Hib vaccine. Freeze indicators DO NOT need to be placed in cold boxes which only contain BCG, OPV, Measles, MR or MMR because these vaccines are not damaged by freezing.

7.7.2. Monitoring temperatures in refrigerated vehicles

- ***Vehicle without electronic temperature recorder:*** The driver or delivery person must keep a Trip Record Form. Read the temperature of the refrigerated compartment once an hour from the dashboard-mounted thermometer and mark it on the Trip Record Form when the vehicle is stopped. During the course of each trip, respond immediately and appropriately to all high and low alarm events. Notify the receiving store(s) if such an event occurs so that vaccine can be double-checked for exposure to freezing or excessive heat during the arrival inspection.
- ***Vehicle equipped with data logger or electronic temperature recorder:*** Complete the Trip Record Form. At the end of each trip, download and print out the temperature trace and attach it to the Trip Record Form.
- ***Vehicle with electronic temperature recorder and integrated printer:*** If the vehicle has an electronic temperature recorder with an on-board temperature trace printer of the type shown below, provide the receiving store(s) with a copy of the trace so that this can be attached to the Requisition and Issue voucher.

7.7.3. Review temperature records for each trip

- At the end of each trip complete the log book/route report.
- Download and print out the data from the on-board temperature recorder or temperature data logger and check the temperature record. Complete the Trip Record Form.
- Investigate unexplained excursions outside the +2°C to +8°C range. Instruct the maintenance contractor or maintenance engineer to investigate and carry out necessary adjustments and/or repairs.
- File the temperature record and the completed Trip Record Form and keep the records for a minimum of "three years".

Inspect temperature records at least twice every 24 hours, 7 days per week.

To ensure good storage and distribution practices, effective and well-managed temperature monitoring and record-keeping procedures are crucial. These procedures help to ensure that:

- Vaccine quality is maintained throughout the vaccine supply chain;
- Vaccine is not wasted due to exposure to heat or freezing temperatures at fixed storage locations or during transport;
- Cold chain equipment performs according to recommended standards; and
- When problems arise, they are rapidly detected and corrective action is taken.

The temperatures to which vaccines are exposed must be monitored, recorded, reviewed and reported throughout the vaccine supply chain, from the manufacturer's point of origin to the point of vaccination. This provides documented evidence of the temperatures to which products have been exposed during storage and transport; it also provides a means of detecting cold chain equipment failures and other operational problems so that they can be rectified.

Responsible personnel need to know the correct storage conditions for all vaccines in their country's schedule. They must also know how to do the following:

- Use the appropriate temperature monitoring devices,
- Consistently and correctly record temperature reading,
- Recognize and respond to temperature excursions
- Conduct monthly temperature review and
- Take corrective action when problems occur.

To achieve these outcomes, countries should develop suitable policies and standard operating procedures (SOPs) and provide adequate training, tools, supervision and resources to ensure that these policies and procedures are properly implemented.

7.7.4. Temperature Recording:

Responsible staff should know how to complete a temperature inspection record sheet. Regardless of the temperature monitoring device used, temperatures in

fixed storage locations should continue to be recorded manually twice a day, seven days a week including weekends and holidays. Recording temperatures twice daily manually ensures that there is a staff member tasked with monitoring cold chain equipment performance and who can act to resolve issues quickly.

Many countries use graphical charts for temperature recording. These are acceptable provided the identity of the person recording the temperature is noted and provided there is a space on the chart for recording notes. It is essential that this process is not purely mechanical. Staff must be made responsible for their actions, and trained to react effectively to problems as soon as they arise.

7.7.5. Managing and using temperature records:

Accurate and comprehensive temperature records are a key component of good storage and distribution practices. However, records alone are of no value unless they are actively used for management and quality assurance purposes. Active use of records shows whether vaccines are systematically being exposed to damaging temperatures and enables equipment performance problems to be identified and addressed.

Once collected, the data must be stored in a systematic manner so that they can easily be accessed. Paper-based temperature charts and chart recorder disks should be filed in date order and by appliance. Electronic records should be similarly filed either on a computer supplemented by regular backups or on a secure server.

Temperature data should be included in the existing monthly reporting procedure. At each supply chain level, supervisors should aggregate and analyze these data and generate a report that includes KPIs on supply chain and equipment performance; these KPIs can be used to guide decision-making. When a problem is identified, there must be specific and appropriate action to maintain or repair the equipment.

Table 16: Temperature monitoring checklist

Cold rooms and vaccine refrigerators:
Temperature between +2° C and +8°C. Situation normal, no action necessary.
Temperature at or below 0°C. VACCINE AT RISK. Take immediate action to correct the low temperature and ensure that the problem does not arise again. Inspect the freeze-sensitive vaccines and/or carry out a shake test to establish if any has been frozen. Frozen vaccine must either be destroyed or tested to establish whether it is still potent. Make a report.
Temperature between +8°C and +10°C. No further action is necessary if there has been a temporary power failure. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if the temperature is not within the normal range at the time of the next inspection.

Temperature above +10°C. VACCINE AT RISK. Take immediate action to implement the agreed contingency plan and make a report.
Freezer rooms and chest freezers:
Temperature between -25°C and -15°C. Situation normal, no action necessary.
Temperature below -25°C. Adjust thermostat. Check that the temperature is within the normal range at the time of the next inspection.
Temperature above -15°C. No further action is necessary if there has been a temporary power failure. A temporary rise to +10°C is permissible following an extended power cut. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if conditions are not normal at the time of the next inspection.
Temperature above +10°C. VACCINE AT RISK. Take immediate action to implement the agreed contingency plan and make a report.
Note: For COVID-19 vaccine requiring ultra-low temp, take immediate action for above -60oc and below -80oc.

7.7.6. Responding to temperature alarms

A temperature alarm is a serious event that requires prompt and adequate response by the person in charge of the vaccine cold stores. Staff in charge of vaccine management should be ready for this scenario, ideally with a written contingency plan. There are four key action steps that you should be taken when a temperature alarm is noticed:

1. **Safeguard the vaccines:** Remove the vaccines from the unsafe storage condition to prevent further exposure to damaging temperature.

2. **Separate the damaged vaccines from the usable ones**

   - Check VVM of all vaccine vials
   - Conduct shake test for freeze sensitive vaccines exposed to freezing
   - Discard
     - Vaccines with VVM at or beyond discarding point
     - Vials that failed shake test
     - Frozen vials of freeze sensitive vaccines

3. **Fix the underlying problem:** understand and address the root cause of the temperature problem.

4. **Document and inform relevant people:** get other people, notably the higher level, informed and involved. Those people ought to support in safeguarding the vaccines as well as fixing the problems.

Fridge-tag recording sheet

Region:	Zone:	Woreda:
Facility name:		Month/Year: /
Refrigerator model:	Refrigerator No.:	Fridge-tag ID number:

Record the refrigerator temperature twice per day. Temperature should stay between 2-8°C to protect vaccines

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	30
Morning Temp. AM (°C)																														
Evening Temp. PM (°C)																														
▲Maximum temp (°C)																														
▲Duration (HH:MM)																														
▲Alarm (Y/N)																														
▼Minimum temp (°C)																														
▼Duration (HH:MM)																														
▼Alarm (Y/N)																														

Date of alarm and corrective Measures taken for Temperature Excursions

Date of alarm	▲	▼	Impact of ecursions on vaccines and actions taken

(Indicate type of an alarm by ✓(tick) under ▲ or ▼for high and low temperature respectively for specific date of alarm).

Important Notes For Health workers

- ✓ To ensure that the refrigerator temperature stays between +2 - +8°c record the refrigerator temperature twice a day.
- ✓ The maximum and minimum temperature of the day has to be recorded in the morning of the next day.
- ✓ The health worker has to check any alarm for the day beforing leaving the facility.
- ✓ When a temperature alarm occurs, it is a serious concern for the vaccine and fridge. Take and document actions until resolved

Code for Actions to taken During Alarm

1. Vaccine transferred
2. VVM checked
3. Frozen vaccine discarded
4. shake test conducted
5. Reported to higher level
6. Refrigerator maintained
7. Thermostat adjusted
8. other measure (specify)

In addition to recording the code for taken action, outcome of shake test and VVM checking has to be recorded.

Figure 7-5 Fridge tag temperature recording tag

7.7.7. Maintaining cold boxes and vaccine carrier

Vaccine carriers and cold boxes must be well dried after their use. If they are left wet with their lids closed, they will mold. Mold may affect the seal of the cold box and vaccine carriers. Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. If this happens the vaccines inside will be exposed to heat.

If a cold box or vaccine carrier wall has a small crack, you may be able to repair it with adhesive tape until you can get an undamaged one.

Group work

Time allowed:

5 minutes

Instruction:

Using the temperature sheet below (figure 2.25), do the following activities in group of 5 participants and present your discussion result to a larger group.

Activities:

1. Read the fridge tag temperature reading (morning, evening, maximum, and minimum on third, sixth, ninth days of the month).
2. Identify the high temperature alarms and when they occured? Identify the low temperature alarms from the chart and when they occurred?
3. List the action that the responsible health worker must take for both low and high alarms observed.
4. 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.

Sample of used Fridge tag Temperature recording sheet for exercise XXX

Fridge-Tag@ 2 Temperature Recording Sheet

Region: _____ **Zone** _____ **Woreda** _____ **Facility name:** _____

Refrigerator model: _____ _____ **Refrigerator No** _____ **Fridge-Tag ID number:** _____

Record the refrigerator temperature twice per day. Temperature should stay between 2 - 8°C to protect vaccines. **Month** _____ _____ **Year** _____

	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	30
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															
	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															
Previous day	▲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															
	▲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															
	▼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															

Date of alarm and corrective Measures taken for Temperature Excursions

Date of alarm	▼	▲	Actions taken (code)*	Impact of excursions on vaccines

(Indicate type of an alarm by ✓(tick) under ▲ or ▼ for high and low temperature respectively for specific date of alarm)

*** Use the following code for actions to be taken during alarm:**

1. Vaccine transferred
2. VVM checked
3. Frozen vaccine discarded
4. Shake test conducted
5. Refrigerator maintained
6. Reported to higher level
7. Thermostat adjusted
8. other measure (specify)

In addition to recording the code for taken action, outcome of shake test and VVM checking has to be recorded.

Case Scenarios 1:

In awash health center, Abebe, the person in charge of the cold chain management found that the refrigerator was not working and the temperature of the refrigerator was raised to 20°C on Monday morning. What are the actions you would like to take step by step? Explain your answer based on the following questions.

1.1 What would you do with the vaccines?

1.2 What would you do to prevent the occurrence of such problems in future?

Case scenario 2:

On Friday, Ahmed decided to defrost his refrigerator because a lot of ice had collected around the freezer compartment. He put Td and pentavalent vaccines into a vaccine carrier lining with cool water packs, and Polio and measles vaccines into another vaccine carrier lining with ice packs. There was not enough space in the carriers for everything, so he put the diluents on the window ledge. 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 returned all vaccines into the refrigerator. On the following Monday, immunization day at the clinic, many children came 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.

Question: Is measles reconstituting practice of Ahmed correct? Explain your answer based on the given scenario.

Exercise 7.1 Case study

7.8. Summary:

- Vaccines, diluents, and cool water packs should be kept in a refrigerator that is used only to store them. The current EPI standard equipment do not have door shelves. If the refrigerator is not an EPI standard and has a door shelf, do not put vaccines on the door shelves. The temperature is too warm to store vaccines, and when the door is opened shelves are instantly exposed to room temperature.
- Do not keep the following vaccines in the refrigerator/cold room
  - Vaccines and diluents which are expired
  - Vaccines with VVMs that reached or are beyond their discard point, vaccine which are reconstituted for more than six hours. Discard them immediately according to your national guidelines.
- Food and drinks should not be stored in a vaccine refrigerator/cold room
- Do not open the refrigerator/cold room door frequently since this raises the temperature inside the refrigerator.
- All EPI standard refrigerators/cold room has door lock, always lock the door of the refrigerator to avoid unnecessary opening of the door by other non-authorised personnel.
- If, however, you are in an area with only one refrigerator and you need to store other heat-sensitive supplies such as drugs, ointments, serum, and samples, is sure to label them clearly and keep them separate from vaccines and diluents.

Chapter 8

Monitoring and Evaluation in Vaccine Supply Chain Management

Allocated Time: 2 Hrs

Chapter Description:

The chapter outlines the significance of monitoring and evaluation (M&E) processes, highlights indicator identification, and introduces the concept of continuous monitoring, evaluation, and supportive supervision in the context of vaccine supply and cold chain management to drive informed decision-making and program enhancement.

Chapter Objective:

By the end of this chapter, participants will be able to explain how to monitor and evaluate vaccines supply and cold chain management activities.

Enabling Objectives: -

By the end of this chapter participants will be able to: -

- Describe basic concepts of vaccine supply chain management monitoring and evaluation.
- Describe common monitoring processes in vaccine supply and cold chain management.
- Identify Key performance indicators (KPI) which can measure vaccine supply and cold chain management activities.

Chapter outline:

8.1. Introduction to Monitoring & Evaluation of vaccine & cold chain supply management

8.2. Monitoring processes in the vaccine & cold chain supply management

8.3 Summary

8.1. Introduction to Monitoring & Evaluation of vaccine & cold chain supply management

Activity 8.1 : Think/Pair/share

Instruction:

1. What is the difference between monitoring and evaluation?
2. Why do we measure performance of vaccine supply and cold chain activities?**Question:** How should diluents be stored, handled and reconstituted?

Time allowed: 10 min.

Monitoring: is a systematic and continuous process of examining data, procedures, and practices to identify problems, develop solutions and guide interventions. Monitoring is conducted on a regular basis (daily, weekly, monthly, and quarterly). It is linked to the implementation of program activities. The information collected is used to direct program activities on a continuous basis.

Monitoring can help improve the quality of the immunization supply chain by ensuring that vaccines and safe injection equipment are delivered in correct quantities and on time. Also, the vaccines storage and transportation are in the optimum temperature recommended to keep the vaccines safe, effective, and potent.

Evaluation: is a periodic assessment of overall program status: performance, effectiveness, and efficiency. It is linked to policies, program processes, systems under which the program operates, strategic choices, outcomes, and impact.

Indicator: is a variable that is used to measure progress towards the achievement of targets and objectives. It is used to compare performance in terms of efficiency, effectiveness, and results. It is also used to measure the impact of interventions.

The main objectives of result-oriented monitoring and evaluation are to:

- Enhance organizational development learning.
- Ensure informed decision-making.
- Support substantive accountability.

Build capacity in monitoring and evaluation.

8.2. Common Monitoring Practices in Vaccine and cold chain Management

8.2.1. Effective vaccine management (EVM)

Effective Vaccine Management (EVM), launched by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in 2010, is a quality improvement process for immunization supply chain systems to compare their effectiveness against best-practice benchmarks. It is both a consultation and a survey tool, designed to identify the strengths and weaknesses of immunization programs. By periodically repeating the process, program managers can measure their program's health, chart a course for improvement and measure progress against their improvement plans.

EVM is a tool and process that assesses each component of the immunization supply chain, such as the people and management, infrastructure and equipment, or policies and procedures, looking for strengths and weaknesses. This allows countries to develop plans and allocate resources to implement improvements where they are needed most.

EVM is a quality management tool that is designed to help countries to develop strength-in-depth by building a culture of quality based on a structured approach to supply chain management, monitoring and evaluation.

The EVM process is about embedding good storage and distribution practices. The package has been designed to be used both as an assessment tool for the systematic analysis of strengths and weaknesses across the supply chain and as a supervisory aid to monitor and support the long-term progress of individual facilities.

EVM follows the well-established principles of quality management used throughout the industrialized world – for example the ISO 9000 series of quality standards.

EVM assists immunization programs by:

- Building in-country immunization supply chain management capacity
- Supporting implementation of best practices
- Attracting funding for improvement

EVM 2 – is an improved tool builds upon the original EVM assessment tool (EVM1) by providing countries with an agile and sustainable solution for engaging in a process of continuous improvement that allows users to better identify the root cause of the challenges, plan for improvements, implement the changes and then continuously monitor to make sure they are on the right track.

EVM 2 offers new tools to support implementation:

- Ease of use- Designed for easy, quick, and accurate use of devices by staff at all levels.
- Redesigned questionnaire- Yields better insights into supply chain inputs, outputs, and performance for improvement plan development.
- Targeted assessments- Multiple targeting options are available to customize an assessment to suit a country's needs.
- Saves crucial time and money- Reduces need for external support, enables targeted assessments and improvements, and builds national talent and capacity.

8.2.2. Cold Chain Equipment Inventory (CCEI)

In Ethiopia, the Ministry of Health has recently developed a window based cold chain equipment database to record essential data concerning available cold chain equipment, and the process of developing web based CCEI database has started.

The inventory helps to improve planning for cold chain, updates the information CCE status, identify available storage capacity and gaps for short term and future requirement.

There are at least three ways to carry out continuous cold chain equipment inventory. These are:

- During regular visits by cold chain technicians to the health facility
- Inventory by the EPI or logistics manager using inventory form.
- Collect information during distribution of vaccines to the health facilities.

Census Method: is counting each CCE by visiting all health facilities in the country using standard data collection tools. It is conducted every three to five years at the national level because it is resource intensive.

Besides the simple physical count, inventory acts as a management tool for the immunization program. The collected data must be of good quality to serve this purpose. The cold chain equipment inventory should contain at least the following data: Equipment location (health posts, health centre, hospital, district health office, zone health office, regional health bureau/EPSS hubs or central EPSS).

Major data to be collected for CCE inventory includes:

- Type, make, model and serial number of equipment.
- Age or year of installation
- Functional status of equipment (working well, need to be repaired, obsolete, etc.)
- Source of energy (Solar, Electric etc)
- Capacity (storage volume, freezing capacity)

In addition, the following should also be obtained:

- Origin or supplier of equipment
- Other technical characteristics (e.g., power consumption, voltage, etc.).
- Available spare parts

Note: The cold chain equipment inventory data should be updated regularly to:

- monitor the functionality status,
- forecast maintenance need and spare parts,
- plan for replacement & standardization
- increase efficiency by minimizing avoidable vaccine wastage

It is suggested to update the inventory according to time intervals by using cold chain equipment database or standard forms. The collected data must be documented, analyzed, and used for action at all levels.

8.2.3. Closed Vial Wastage Rate:

This indicator refers to percentage of the total number of closed vial vaccine doses managed by a store or health facility during a particular

period that are spoiled because of expiry, heat exposure, freezing, breakage, loss of the accompanying diluent or discard of unopened vials at the end of an outreach session. The indicator is used to measure potential avoidable waste during transportation and storage. Wastage is related to the performance of vaccine ordering, distribution, and store management. It can indicate excessive ordering practices that are not well-aligned to actual consumption rates, vaccine exposure to heat or freezing temperatures, breakage and mishandling of inventory.

Note: Wastage at the point of administration, because of incomplete use of the contents of a multi-dose vial, is referred to as open vial wastage and is not included in closed vial wastage.

Closed vial wastage should include vials wasted due to:

- Expiry: which may indicate ordering practices that are not aligned to actual consumption rates, failure to respect first expiry first out (FEFO) policies, a supply design that moves too slowly (i.e., it takes too long for a vaccine to go through the chain to the point of administration) or poor organization in a vaccine store such that an older lot or batch can be overlooked.
- VVM status 3 or 4: (at or beyond the discard point) before the vaccine's expiry date has been reached, which may indicate poor cold chain quality or breaches in the cold chain.
- Freezing: which is an indication of poorly functioning cold chain equipment or poor adherence to standard operating procedures during storage or transportation?
- Breakage: either of the vials or accompanying diluent.

Inclusion of reason codes in reporting of closed vial wastage allows additional precision and more thorough investigation of root causes.

Calculation:

$$\textit{Closed vial wastage} = \frac{\text{number of doses discarded during reporting period}}{\text{doses under management during the same period}} \times 100$$

Doses under management are defined as the opening balance plus all doses that were received during the period. Issued doses should not be subtracted.

The following are potential corrective actions from this KPI:

- Perform root cause analysis to identify the reasons for closed vial wastage and identify areas for improvement based on the reason for wastage
- Implement improvement activities
- Develop or review relevant standard operating procedures for store and stock management.

8.2.4. Forecasted Demand Ratio:

Refers to ratio of actual consumption of a given vaccine product during a particular period compared to the consumption forecasted for the same period. Consumption includes administered and wasted doses. The indicator is used to validate and improve forecasting practices and assumptions (e.g., target population, coverage, wastage) to increase forecasting accuracy.

Calculation

$$\text{Forecasted Demand Ratio} = \frac{\textit{Doses Consumed Per Product in a period}}{\textit{Doses Forecasted Per product for the same period}}$$

It is important that the doses consumed and the doses forecasted apply to the same period. The longer the period, the more accurate the forecasted demand ratio. A rolling year, half year or quarter is recommended, but the length of the period might depend on the reliable data available and the staff's ability to calculate indicator performance for a long period.

Interpreting the ratio:

- Forecasted demand ratio below 1: actual consumption (through administration and wastage) was less than the forecasted consumption for a given period.
- Forecasted demand ratio above 1: actual consumption (through administration and wastage) was more than the forecasted consumption for a given period.
- A forecasted demand ratio close to 1: implies that the forecasted consumption matched well with actual vaccine consumption.

$$\text{Average forecasted demand ratio} = \frac{\sum \textit{ Health Facility Forecasted Demand Ratios}}{\textit{Total \# of Health Facilities}}$$

The indicator can also be expressed as the percentage of facilities with a forecasted demand ratio meeting certain criteria (for example, within the range of 0.7 to 1.3).

The following are potential corrective actions from this KPI:

- Perform root cause analysis to identify the reasons for closed vial wastage and identify areas for improvement based on the reason for wastage.
- Verify the actual usage with health facilities
- Review the forecasting methodology and perform a root cause analysis to identify reasons for forecasted demand ratios beyond the established tolerance level (e.g., stock-out can lead to a forecasted demand ratio < 1).
- Root causes could be: inaccurate assumptions (target population, coverage and wastage), inaccurate on-time and in-full deliveries, higher wastage than expected.
- Revise ordering policies and practices when the forecasted demand ratio is consistently outside of the tolerance level or there is a large imbalance
- Revise minimum and maximum stock levels when forecasted demand ratio is consistently too high or too low

8.2.5. Full Stock Availability:

Refers to percentage of storage points with full availability of all or a selected set of tracer vaccines and immunization supplies over a resupply period. Full availability is defined as no stock-out in the store or health facility at any point during the time. The indicator Measures the availability of immunization products. Availability of vaccines and immunization supplies is important to reach immunization program targets.

Full stock availability = Resupply Periods without stock-out of any (tracer) vaccine or immunization supplies.

- At sub-national and national level, the indicator is aggregated as % of health facilities or % of districts with full stock availability. The calculation for a sub-national region is % health facilities with full stock availability = (# health facilities with full availability of all (tracer) immunization products)/(total number of health facilities in sub-national region) x 100
- Alternatively, for the national level, the aggregation can be based on the percentages of health facilities in a district exceeding a set threshold.
- Districts with full availability of all (tracer) immunization products in more than x% of health facilities = (# districts with more than x% health facilities with full availability of all (tracer) immunization products in the last resupply period)/ total # districts) x 100

The percentage of health facilities in the above calculation is set to reflect the expected standards. When reporting the value of the indicator, the threshold value must be included.

The following are potential corrective actions from this KPI:

- Verify that equipment is not functioning
- Verify the full availability of products in the past resupply period
- Perform root cause analysis to identify the reason for low stock availability, including inventory management, reorder policies (push or pull), distribution plans, national stock availability and distribution performance
- Review emergency resupply policies if there is a historical pattern of low stock availability
- Review of supply pipelines and planned orders for stores

8.2.6. Functional Status of Cold Chain Equipment:

Cold chain equipment functioning compares the proportion of cold chain equipment (CCE) operable for storing vaccines with the overall number of commissioned CCE devices in a particular area. CCE is defined as all refrigerators, freezers, passive storage devices, and walk-in cold rooms and freezer rooms designated for storing vaccines. CCE functioning can be measured at a point in time or over a particular period.

The indicator measures operational cold chain equipment to identify where maintenance is needed for maintaining vaccine quality. Used for operational purposes, such as updating the maintenance plan, and for strategic purposes, such as to plan for replacement.

Over time, the trend in the proportion of functional equipment can be used to measure performance of in-house or contracted maintenance and repair services. If the proportion of functional equipment is disaggregated by reason for the non-function or by equipment type, the indicator can also be used to assess the performance of particular types or models of CCE in the field.

Note that the functional status of CCE does not include a provision regarding the temperature maintained by the equipment; other indicators (such as Temperature Alarm Rate) must be used to fully understand the cold chain management system.

Calculation

$$\% \text{ CCE functioning} = \frac{\textit{\# functioning CCE devices}}{\textit{Total \# CCE devices designated for use in reporting facilities}} \text{ X } 100$$

The indicator can be calculated either at a point in time or over a period of time. When calculated over a period of time, % CCE functioning needs to take into account how long the non-functional periods were:

$$\% \text{ CCE functioning} = \frac{\textit{Number of functional CCE unit-days}}{\textit{Total number of CCE unit-days in a given reporting period}} \text{ X } 100$$

where CCE unit-days are the total number of days in the reporting period multiplied by the number of CCE devices.

Both the numerator and the denominator should be collected from the same geographic area, and decommissioned equipment should not be counted in either the numerator or denominator. Functionality of CCE is broadly meant to mean that the device is operable at a particular point in time for storing vaccines.

Disaggregation of both the numerator and denominator by location and by type, manufacturer, model, energy source, PQS (performance, quality and safety) code or year of installation can add value in investigating root causes of CCE failures, in targeting maintenance and replacement, and in performance monitoring of equipment and of maintenance systems.

The following are potential corrective actions from this KPI:

- Verify that equipment is not functioning
- Determine the root cause of equipment dysfunction; solicit repair or replacement of non-functional equipment
- Ensure that contingency plans are in place for all facilities, so that vaccines can be safely stored or transported elsewhere when one or more devices are non-functional
- Perform routine maintenance of all CCE to prevent future breakdown
- Use equipment status (including reasons) to inform future procurement decisions
- Reallocate functional CCE equitably, as appropriate
- The indicator can also be used in combination with other inputs, such as a cold chain inventory, to estimate the total volume of cold chain space available and is useful in assessing whether there is adequate functional cold chain capacity to meet needs for routine immunization, campaigns and new vaccine introductions

8.2.7. On-Time and In-Full Delivery:

This refers to the percentage of product deliveries delivered on-time and in-full (OTIF), with OTIF defined as:

On time: Order is delivered when expected (e.g., on a specific date or within a specified time range)

Order fulfilled: Store can fulfill the complete order (i.e., provide all products and quantities requested)

Accurate: The correct products are delivered in the correct quantities (i.e., delivered products and quantities match the delivery note)

This indicator is used to ensure the store has the ability to meet the needs of lower-level stores, as well as the timeliness and reliability of order deliveries. The indicator can be used to monitor incoming shipments and performance of in-country distribution by the national store or outsourced distributor. Including the indicator in a dashboard can facilitate store management improvements: increased reliability, consistency (client receives product needed each resupply period) and efficiency (reduction in emergency orders).

Note that OTIF delivery does not consider damage to products during distribution (e.g., broken vials, VVM stage 3 or 4). Other indicators (such as Closed Vial Wastage or Temperature Alarm Rate) should be used to identify such issues.

Calculation

$$\% \text{ of orders delivered on-time and in-full} = \frac{\textit{\# Order delivered OTIF}}{\textit{Total \# orders delivered}} \text{ X } 100$$

For stores that are not able to measure all three processes, an intermediate indicator (such as % of on-time deliveries) can be used.

The following are potential corrective actions from this KPI:

- Assess system or policy changes (e.g., outsourcing or changing distribution system)
- Improve forecasting and procurement procedures to ensure adequate stock at supplying stores
- If services are outsourced, review past performance with warehouse and distribution service providers and agree on improvement actions
- Improve or define standard operating procedures where needed
- Revise demand plan to ensure adequate stock at supplying store
- Adjust delivery schedule dates according to the actual capacity of the transportation services, if necessary
- Negotiate with procurement service agents and freight forwarders on in-bound shipments to the country
- Review and/or revise inventory policies including buffer stock and minimum and maximum levels for stores

8.2.8. Temperature Alarm Rate:

This indicator refers to the number of times the temperature inside cold chain equipment (CCE) exceeds or drops below a reference range. The indicator is applicable where vaccines are stored and during transportation. CCE is defined as all refrigerators, freezers, passive storage devices, walk-in cold rooms and freezer rooms and Ultra low temperature freezer (UCC) designated for storing vaccines.

The indicator requires continuous, or point-in-time temperature readings recorded over a time. Continuous temperature monitoring is highly preferred since it allows greater accuracy in detecting temperature fluctuations. For primary and sub-national stores, programmable electronic temperature and event logger systems are the best option. In smaller stores and health facilities, 30-day electronic temperature records with a stem thermometer as a backup are considered best practice.

A stem thermometer alone 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 per week.

The number of excursions, or alarms outside the designated temperature ranges, is needed. Alarm thresholds are set by WHO as follows:

- An excursion is defined as any event during which the temperature inside the cold chain equipment goes below 2° C or above 8° C.
- A high temperature alarm is defined as any event during which the temperature goes above 8° C for 10 continuous hours.
- A low temperature alarm is defined as any event during which the temperature goes below –0.5° C for one hour.

For locations measuring and recording temperatures manually twice daily, alarms may be difficult or impossible to record. Record any excursion outside the range of 2°C to 8°C for refrigerators and –15°C to –25°C for freezers. A point-in-time 'temperature in range' indicator may be used instead.

However, a point-in-time temperature reading within temperature range does not provide any indication about temperature excursions that may have occurred at other times throughout the day when the temperature was not being recorded (e.g., a cold exposure overnight, when ambient temperatures dropped). Note that WHO no longer recommends stem thermometers and point-in-time recording of temperature as the primary means to monitor temperature in cold chain equipment.

The Temperature Alarm Rate as an indicator is used as a proxy for measuring vaccine potency and safety. Exposure to temperatures outside this range indicates a risk of heat or freeze damage to sensitive vaccines.

Calculation

Temperature alarm rate = number of high and low temperature alarms per reporting period

- This indicator can also be calculated using the number of CCE devices with more than a set threshold of temperature alarms in a given period.
- It can be further broken down by reasons for alarms (if known) or into 'resolved' and 'unresolved' alarms. That is, an alarm due to a resolved power outage would not be treated the same as an alarm due to mechanical problems. The alarm rate can also be disaggregated by facility, by device or by device type (make, model, energy source, etc.) to monitor performance.

Potential corrective actions from this KPI include:

- Ensure that facilities follow standard operating procedures through supportive supervision. For instance, facility staff should remove vaccines from CCE not maintaining temperature within recommended ranges in accordance with contingency plans and should discard vaccines that have VVM stage 3 or 4 and vaccines that fail the shake test.
- Determine cause of equipment dysfunction; solicit repair or replacement of non-functional equipment
- Ensure that contingency plans are in place for all facilities
- Perform regular routine maintenance of all CCE to prevent future breakdown
- Train facility staff to improve inventory management practices
- Use temperature alarm profiles of various types and models of CCE to inform procurement
- Use temperature alarm profiles to plan for repair and replacement of CCE

8.2.9. Percentage of VRF reports Placed through Electronic Ordering System

Using the Vaccine Requisition Form (VRF) at the service delivery point and administrative level is one of the critical components of vaccine requisition procedures to conduct quality vaccine requisitions in standard ways.

During a specific timeframe, this indicator calculates the percentage of administrative level/health facilities that have the capability to submit their VRF reports using an electronic ordering system. The electronic system might be electronic LMIS or other electronic communication methods, depending on the system approved and utilized by the Ministry of Health.

Supervisors sometimes find it confusing to define what qualifies as an electronic ordering system. However, when using this indicator, any electronic system that the Ministry of health has approved to speed up the ordering process is generally seen as suitable for measurement.

Potential corrective actions from this KPI include:

- Ensure that facilities and woredas have better stock management of vaccines and immunization supplies to optimize vaccine availability.
- Monitoring vaccines and immunization regularly supplies data visibility of Health facilities.
- Optimize Immunization Supply chain Management at different levels of the health system.
- To ensure the availability of quality vaccines and immunization supplies for effective program delivery to achieve high immunization coverage.
- Reports from the electronic ordering system that record how and when orders were placed as a data source.
- The total number of orders expected to be placed via electronic system during a defined period should be used as a data requirement.

Percentage of facilities that submitted complete VRF reports on time.

It is expected that a standard vaccine leger book be available at each level of the immunization supply system and to report VRF on time to resupply from EPSS hubs by updating their vaccine stock status during receiving, issuing, and transferring.

This indicator measures the proportion of facilities that timely submit complete VRF reports according to an established schedule.. It assesses the percentage of facilities that have accomplished both completeness and timeliness in their submissions.

A deeper analysis of facilities by the number of complete reports submitted on time will help managers to plan supervision to improve the situation. This indicator is applied to a defined retroactive period, e.g. the past year or past reporting period.

This indicator assesses the way health facilities report on VRF. This indicator is employed over a specific past period, like the previous year or a recent reporting period.

Potential corrective actions from this KPI include:

- VRF reports need to encompass all essential information necessary for monitoring the performance of the supply chain system. This information includes starting inventory, requested quantities, received quantities, current stock, duration of stock-outs if applicable, prescribed minimum and maximum stock levels, losses due to various reasons, and the available cold chain capacity during the reporting period. Ideally, achieving 100% completeness is the target.
- However, a minimum acceptability level is set at 80% completeness: falling below this level comprises the dependability of the data.
- It is important that VRF reports be sent in a timely manner from all levels to higher supplying levels to facilitate real-time data analysis, reporting, re-supplying, and decision-making. This indicator is easy to measure, as the information is available.
- Disaggregation of this indicator allows calculation of the number of reports that are on time or complete. VRF reports can be disaggregated by timeliness, according to the established reporting schedule, and by completeness.
- Total number of health facilities under the supplying facility and number of VRF reports expected from each health facility should use as data requirements.

8.2.10. Vaccine Arrival Report (VAR)

Vaccine arrival and clearance through customs without exposure to extreme temperature is one of the criteria that must be regularly monitored as national level. The vaccine arrival report (VAR) provides a means of indicating inadequacies in the shipping process and problems relating to the condition of vaccines at the time of delivery.

The Vaccine Arrival Report (VAR) is a comprehensive record of cold-chain conditions during transport and required compliance with shipping instructions. Recipient governments (MOH/EPSS) and procurement agencies (UNICEF country offices, UNICEF Supply Division, PAHO Revolving Fund), are responsible for the report, and for taking appropriate action if problems are reported (e.g. follow-up with

the manufacturer, forwarding agent, WHO, etc.). This report is to be filled in by authorized staff, ratified by the Store Manager or the EPI Manager, and forwarded to the UNICEF Country Office within three working days (< 72 Hrs) of vaccine arrival. Use one report for each vaccine in the shipment.

Any defect in the process can lead to compensation claims and/or rejection of a shipment. Each individual situation will be investigated and dealt with by all involved parties. If the quantity of damaged vaccine is substantial it could affect immunization delivery. In such cases, emergency measures will have to be taken to obtain sufficient vaccine to maintain the programme's scheduled activities.

VAR format contains advance notice, flight arrival details, details of vaccine shipment, documents accompanying shipment, status of shipping indicators, general conditions of shipment, name, and signature.

Potential corrective actions from this KPI include:

- To measure time elapsed on vaccine clearance and compare against the standard (<72 hrs)
- To highlight impact of port clearance delay on quality of the vaccine and financial impact.

To understand major contributing factors on delay of vaccine clearance.Monitoring: is a systematic and continuous process of examining data, procedures, and practices to identify problems, develop solutions and guide interventions. Evaluation: is a periodic assessment of overall program status: performance, effectiveness, and efficiency.

Common Monitoring Practices in vaccine and cold chain management are cold chain equipment inventory, vaccine wastage study, temperature mapping, temperature monitoring study, and effective vaccine management.

Effective vaccine management (EVM) is a tool and process that assesses each component of the immunization supply chain, such as the people and management, infrastructure and equipment, or policies and procedures, looking for strengths and weaknesses.

The indicators for vaccine supply and cold chain are intended to be implemented at each level of the supply chain, so all managers can use them to manage the immunization supply chain. The indicators are selected, so they collectively provide an overview of the performance of the essential elements of the immunization supply chain.

The following key performance indicators (KPIs) are selected to measure performance of immunization supply and cold chain management:- closed vial wastage rate, forecasted demand ratio, full stock availability, functional status of cold chain equipment, on-time and in-full delivery, stock according to plan, temperature alarm rate, percentage of VRF reports placed through electronic ordering system, percentage of facilities that submitted complete VRF reports on time and vaccine arrival report . The Vaccine Arrival Report (VAR) is a comprehensive record of cold-chain conditions during transport and required compliance with shipping instructions.

Table 8.1 Summary of Selected Key Performance Indicators of Vaccine and Cold Chain Management

Indicator	Closed Vial Wastage	Forecasted Demand Ratio	Full Stock Availability	Functional Status of Cold Chain Equipment	Temperature Alarm Rate
Definition	Percentage of the total number of closed vial vaccine doses managed by a store or health facility during a particular period that are spoiled because of expiry, heat exposure, freezing, breakage, loss of the accompanying diluent or discard of unopened vials at the end of an outreach session.	Actual consumption of a given vaccine product during a particular period compared to the consumption forecasted for the same period. Consumption includes administered and wasted doses.	Percentage of storage points with full availability of all or a selected set of tracer vaccines and immunization supplies over a resupply period. Full availability is defined as no stock-out in the store or health facility at any point during the time.	The proportion of cold chain equipment (CCE) which are functional from the avaiable CCE devices in a particular facility	The number of times the temperature inside cold chain equipment (CCE) exceeds or drops below a reference range.
Formula	Closed vial wastage =(number of doses discarded during reporting period)/(doses managed during the same period)X100	Forecasted Demand Ratio = (Doses Consumed Per Product in a Period)/ (Doses Forecasted Per product for the same period)	Full stock availability = Resupply Periods without stock-out of any (tracer) vaccine or immunization supplies.	% CCE functioning = (# functioning CCE devices)/(Total # CCE devices designated for use in reporting facilities) x100	Temperature alarm rate = number of high and low temperature alarms per reporting period

Interpretation	The indicator is used to measure potential avoidable waste during transportation and storage. Wastage is related to the performance of vaccine ordering, distribution, and store management. It can indicate excessive ordering practices that are not well-aligned to actual consumption rates, vaccine exposure to heat or freezing temperatures, breakage and mishandling of inventory.	*Forecasted demand ratio below 1: actual consumption (through administration and wastage) was less than the forecasted consumption for a given period. *Forecasted demand ratio above 1: actual consumption (through administration and wastage) was more than the forecasted consumption for a given period. *A forecasted demand ratio close to 1: implies that the forecasted consumption matched well with actual vaccine consumption	The indicator measures the availability of immunization products. Availability of vaccines and immunization supplies is important to reach immunization program targets.	The indicator measures operational cold chain equipment to identify where maintenance is needed for maintaining vaccine quality. Used for operational purposes, such as updating the maintenance plan, and for strategic purposes, such as to plan for replacement.	The indicator requires continuous, or point-in-time temperature readings recorded over a time. Continuous temperature monitoring is highly preferred since it allows greater accuracy in detecting temperature fluctuations.
Level of use	All levels	National & Regional levels	All levels	All levels	All levels

Data Needed	■ Number of discarded (wasted) doses reported by vaccine and preferably by reason code;	■ Forecasted demand/ usage by product	■ Product stock-outs in stores and health facilities, OR	■ Primary reason for not functioning or not in use: needs spare parts/no finance/no fuel/ surplus/dead/ not applicable	■ Continuous or point-in-time temperature readings recorded over a time period
	■ Number of doses under management during a certain period defined as the starting balance plus all of the doses received during that period	■ Actual consumption by product (opening balance + receipts – closing balance of product)	■ Closing balances at the end of the resupply period in stores and health facilities	■ Number of CCE devices designated for storing vaccines in a particular geographical area	■ The number of excursions, or alarms outside the designated temperature ranges, is needed
				■ Functional status of each CCE: functioning/ awaiting repair/ unserviceable	
				■ Optional additional data: temperature of CCE	
Data Sources	■ Vaccine stock ledgers/ cards	■ Logistics management information system (LMIS)	■ Stock cards/ ledgers	■ Maintenance worksheet	

	■ Vaccine orders	■ Monthly immunization reports	■ Physical inventory/ physical stock counts	■ Cold chain equipment inventories by location; for example, WHO Excel-based tools such as Cold Chain Equipment Inventory (CCEI), Cold Chain Equipment Manager (CCEM)	
	■ Batch management to track vaccine vial monitor (VVM) status and expiry dates	■ Micro plans	■ Stock-out reports from health facilities	■ On-site assessment of equipment functioning	
	■ Logistics management information system (LMIS)	■ Stock ledgers/cards	■ Logistics management information system (LMIS)	■ CCE distribution plan	
	■ Wastage reporting tools				
Frequency	**Monthly**	**Quarterly**	**Quarterly**	**Annually**	**Monthly**

8.3. Summary

- Monitoring is routine collection and analysis of measurements or indicators to determine the ongoing progress toward objectives. It is an essential component of a plan.
- Evaluation is periodic comparison of objectives, with accomplishments, to determine how well the objectives were achieved.
- The overall purpose of monitoring and evaluation is the measurement and assessment of vaccine and cold chain management performance in order to effectively manage the outcomes.
- Effective Vaccine Management (EVM) is a quality management tool that is designed to help countries to develop strength-in-depth by building a culture of quality based on a structured approach to supply chain management, monitoring and evaluation.
- Supervision is a process that could assist staff to improve their performance through evaluation by peers, self-evaluation, and teamwork.
- To achieve better results supervision should be planned and carried out with regular intervals by a team of multi-disciplinary experts such as an EPI officer, logistics officer and any other relevant official.

References

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- WHO Immunization in Practice, Modules for health workers, 2013 Update
- Training for mid-level managers (MLM) - WHO/IVB/08.01; Module 1: Cold chain, vaccines and safe-injection equipment management.
- WHO Vaccine Management Handbook Modul http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index5.html
- Monitoring vaccine wastage rate at country level: Guide for program manager: (WHO/V&B/03.18) http://www.who.int/iris/handle/10665/68463
- WHO Policy Statement: Multi-dose Vial Policy (MDVP): Revised 2014; available at http://www.who.int/immunization/documents/en/
- FMOH Ethiopia; Immunization in practice, August 2014
- WHO. EVM website

ANNEX:

Annex I: Vaccine Request Format

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MINISTRY OF HEALTH-ETHIOPIA

Vaccine Request Form

Ministry o Health

Region/Zone/WoredaName of cold store Responsible PersonContact Address Telephone Number(s):

Level of cold chain
RHB/HUB
Cold room
Zonal store
Woreda Health fa cility (H/HC/HP)

Date of request:No. of months to supply (S):
For population catchment ser ed
Births (BI):Surviving infants (SI):Girls of age 9 year

Antigen	Doses/pieces	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*	Requested Amount (J – I)	Quantity released	Vaccinations given since last supply (all doses)	Remarks
A	B	C	D	E	F	G	H	I	J	K	L	M	N
BCG (Bacillus Calmette Guerin) Vaccine	1	2	100%										
BCG (Bacillus Calmette Guerin) Diluent	1	2	100%										
BOPV (Bivalent Oral Polio) Vaccine	4	1.11	100%										
BOPV (Bivalent Oral Polio) Vaccine Dropper	4	1.11	100%										
IPV (Inactivated Polio Vaccine)	1	1.11	100%										
DTP-Hib-Hep (Pentavalent) Vaccine	3	1.05	100%										
Measles Virus Vaccine	2	1.54	100%										
Measles Virus Vaccine Dileunt	2	1.54	100%										

Syringe, AUT (1 ml)
Syringe, AUT (0.05ml)
Mixing syringe (BCG)
Mixing syringe (Measles)
Safety box

N.B all figures are indicated as doses, pieces; requested amount includes requirement for number of months indicated at target coverage PLUS 25% buffer (min. stock), LESS current stock

Equipment monitoring	No. of units			No. Temperature excursions		Remarks
Type of fridge	F	NF	FT*	< 0˚C	> 8˚C	
Cold rooms						
Refrigerators						
Freezers						

**Functional (F); Non-functional (NF); Fridges tag (FT) in u se*

Requested by: _____

Approved by: _____

Annex 2: Vaccine and Other EPI Equipment Recording Sheet

Vaccine and other EPI Equipement Recording Sheet (Revised)

Vaccine BCG Syringes

Minimum stock (Doses)	Requirement for supply period (Doses)	Maximum stock (minimum + Requirement for supply period) (Doses)

Month: _____

Date	Received from/ Distributed to	Purpose of Collection/ Distribution (Routine EPI or SIA)	Movements (Doses)				Presentation (dose/vials)	Manufacturer	Status of VVM	Batch No	Expiry Date	Balance	Number of Children Vaccinated (Only for those who have vaccination sessions)	Remarks
			Received	Returned	Issued	Withdrawn (Discarded)								
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Carried over from previous period														

A = Date of received or issued or returned or discarded	I= Name of manufacturer
B = Name of organization received from or distributed to	J = Stage of VVM (1, 2, 3 or 4)
C = Reason for receive or distribution (Routine EPI of SIAs)	L= Expiry date of material
D = Amount received in dose or unit	K= Batch or Lot number of material vaccination session
E = Amount returned from session or other HFs in dose or unit	M =Balance at the beginning or at the end
F = Amount given to others or lower level or vaccination	N =Number children vaccinated with vaccine issued for
G = Discarded to Expiry, VVM, contamination, etc	O =Any points to be noted such as reasons for discard
H= Number of doses per vial or Number of AD/Mixing syringes	
NB. Put your minimum stock (25% of your supply period), Your supply period stock and maximum stock (Your supply period stock + minimum stock) S	

Annex 3: Common (non-optimal) cold chain equipment in Ethiopia

S. NO	Manufacturer	Model	Vaccinestorage capacity (Lit)	Remarks
1	Zero	PR 265 EK	37.5	Refrigerator
2	Solar	Sun Frost	38.7	Solar fridge
3	Dometi c	TCW 1152	169	Refrigerator
4	Dometi c	TCW 1990	37.5	Refrigerator
5	Dulas	VC-150 F	85	Solar fridge
6	Dulas	VC-65 F	37.5	Solar fridge
7	BP Solar	VR50F	17.5	Solar fridge
8	Vestfrost	MF 114	72	Freezer
9	Zero	PR 245 EK	18	Refrigerator
10	Vestfrost	MF 214	192	Freezer
11	Sibir	V240KE	55	Refrigerator
12	Vest frost	MK 404	135	Refrigerator
11	Vestfrost	MF 314	264	Freezer
12	Vestfrost	MK 204	75	Refrigerator
13	Vestfrost	MK 144	45	Refrigerator
14	Vestfrost	MK304	105	Refrigerator
15	Sibir	V 110 EK	17	Refrigerator
16	Dometi c	RCW 42 EK	18.2	Refrigerator
17	Sibir	V 170 EK	55	Refrigerator
18	Dometi c	RCW 50 EK	24	Refrigerator
19	Dometi c	TCW 3000	126.5	Refrigerator
20	SunDazer	BFRV 55	54.5	DD solar Fridge
21	True Energy	BLF 100 DC	99	DD solar fridge

Annex 4: Current Optimal (freeze free) cold chain equipment

No	Manufacturer	Model	Vaccine storage capacity
Ice-lined refrigerators			
1	Vestfrost	VLS 400A Green Line	145
2	Zero (Sure Chill)	ZLF150AC	128
3	Vestfrost	VLS 350A Green Line	127
4	Godrej (Sure Chill)	GVR100AC	99
5	Vestfrost	VLS 300A Green Line	98
6	Zero (Sure Chill)	ZLF100AC	93
7	Vestfrost	VLS 200A Green Line*	60
8	Godrej (Sure Chill)	GVR50AC	47
9	Zero (Sure Chill)	ZLF30AC	27
Dual-compartment ice-lined fridge-freezers			
10	B Medical	TCW 2000AC	60
Dual-compartment SDD freezers			
11	Dulas	VC150FF	102
12	Haier	HTCD-160	100
13	B Medical	TCW 2043SDD	70
14	B Medical	TCW 40SDD	36
Long-term passive devices			
15	Aucma	Arktek-YBC-5	5.4

No	Manufacturer	Model	Vaccine storage capacity
Solar Direct Drive refrigerators			
16	Vestfrost	VLS154 Green Line SDD	170
17	Dulas	VC200SDD	132
18	Dulas	VC110 SDD	110
19	Godrej (Sure Chill)	GVR100DC	99
20	Zero (Sure Chill)	ZLF100DC	93
21	Vestfrost	VLS094 Green Line SDD	92
22	B Medical	TCW 3043	89
23	Dulas	VC88 SDD	88
24	Vestfrost	VLS 054 Green Line SDD	56
25	SunDanzer	BFRV-55 SDD	55
26	Godrej (Sure Chill)	GVR50DC	47
27	SunDanzer	BFRV-15 SDD	15
28	Vestfrost	VLS 024	26
On-grid freezers			
	Manufacturer	**Model**	
1	Haier	HBD 286	
2	Vestfrost	MF 314	
3	B Medical	TFW 800	
4	Vestfrost	MF 214	
5	Haier	HBD 116	
6	Vestfrost	MF 114	
7	Aucma	DW-25W147	
8	Aucma	DW-25W300	

Annex 5: Supervision checklist

Self-assessment[15] checklist for Health facility and cold stores for vaccine management activities

Introduction to self-assessment checklist:

This self-assessment checklist is designed for health facilities and immunization cold stores to enhance regular analysis and use of routine data at point of generation for continuous service and program improvement. It facilitates assessment of their vaccine management, cold chain management and vaccine temperature monitoring activities on regular basis which can be weekly, monthly or quarterly basis. The assessment can be done by immunization officer or vaccine cold store manager together with his/her immediate supervisor or health facility head or peer groups. Following identification of strengths and weakness of the vaccine management performance of the vaccine management, the team will prepare improvement action plan for identified gaps. Completed checklist and prepare improvement plan will be documented in safe place for future references. The implementation status of the previous month action points will be revised during the next self-assessment period.

Instructions for health facility or cold stores self-assessment:

1. Conduct monthly peer assessment or with the health facility head
2. Calculate wastage rate of all antigens on monthly basis
3. Calculate the proportion of the temperature alarms on monthly basis.
4. Calculate the average monthly vaccine management score and evaluate the trend of the performance.
5. Discuss the implementation status of the previous month action points
6. Identify the gaps of the current assessment and outstanding problems
7. Discuss the solution of the problems

15 Self-assessment is literally defined as assessment or evaluation of oneself or one's actions and attitudes, in particular, of one's performance at a job or learning task considered in relation to an objective standard.

Effective Vaccine Management implementation in Ethiopia

Self-assessment checklist for Health facility and cold stores for vaccine management activities

Region_____ Zone_____ Woreda_____ Name of facility_____

S.NO	Temperature monitoring Self assessment Questions	Months of self Assessement						Remark
		Hamle	Nehase	Meskerem	Tikmit	Hidar	Tahsas	
1	Does the health worker know the correct storage temperature range for each of the vaccines on the schedule known? [Y,N]							
2	Do all vaccine refrigerators have continuous temperature recorders (Fridge tag)? [Y, N].							
3	Do all vaccine refrigerators in use at this level have temperature recording sheet in the last one month? [Y,N]							
4	Is the temperature reading recored on temperature recording sheet similar to the temperature reading on the fridge tag screen in the last one month? (Check all alarms in one month and the last seven days reading)							
5	Does the temperature of all refrigerators recored consitently for the last one month (all days including weekends and holidays?							
6	Did the temperature of vaccine refrigerators remain between +2 oc to +8oc in the last one month?							
7	Total number freezing alarms in the last one month (Check from Fridge tag)							
8	Total number high alarms alarms in the last one month (Check from Fridge tag)							
9	How many temperature alarms have documented corrective measures?							
10	Have correct remedial actions been taken for ***all Temperature excursions*** in the last one months? [Y, N, n/a if there are no excursions or breakdowns]							
11	Are temperature records formally reviewed at least once a month in order to identify temperature excursions and their causes? [Y, N]							
12	Did copy of temperature recording reported to the next higher level for the completed month?							
	Self assessment vaccine Cold Chain management Questions							
13	**Is there sufficient** +2^{o}c to +8^{o}c storage capacity for vaccine storage? [Y, N]							
14	Are emergency contact details (name, phone # etc.) posted in the vaccine store? [Y, N].							
15	Does the facility prepared and posted contigency plan?							

16	Do the responsble health worker know what to do in the event of an emergency? [Y, N].							
17	Are all ice-lined refrigerators fitted with the correct vaccine storage baskets? [Y, N, NA if there is ice-lined refrigerators]							
18	Where applicable, are there sufficient reserve supplies of kerosene for absorption refrigerators or generator **[Y, N, n/a if there is no Absorption refrigerator or generator at this level]**							
19	If standby generator is required and available,is the generator in working order (functional)? [Y, N,NA if standby generator is not required].							
20	Are all refrigrators/freezers attached to a functioning voltage regulator? [Y, N, NA if available refrigerator is woring with kerosene or SDD]							
21	Is there a written planned preventive maintenance (PPM) programme (daily, weekly, monthly) for cold chain equipement. [Y, N]							
22	Is preventive maintenance activities being conducted and recorded according to the PPM [Y, N]							
23	Is there evidence that refrigerators/ freezers have recently been cleaned and defrosted? Check the cleaniness of the refrigerator[Y, N]							
24	Is there evidence that kerosene refrigerator wicks have been trimmed and chimneys cleaned? [Y, N, NA for compression refrigerators]							
25	Are all vaccine refrigrators fully operational at the time of inspection? [Y, N]							
	Self assessment Vaccine management Questions							
26	Is type, presentation (vial size), Quantity in doses, manufacturer, batch or lot number, batch or lot number, VVM status of vaccine and diluent recorded for each vaccine [Y, N]							
27	Are immunization supplies recorded (AD syringe, Mixing sysringe, safety box ….) in vaccine ledger book at all time of transaction (check this month transaction, if no transaction answer NA)?							
28	Was standard vaccine requisition forms used for ordering vaccine in this month? [Y, N]							
29	Does thefacility have a completed arrival and/or issue voucher for every delivery which took place during the last month? [Y, N]							
30	Did the facility properly recorded wasted vaccine (Expired, VVM change, Freezing, etc.) in the ledger book in the last completed one month? [Y, N, NA if there is no wasted vaccine]							
31	was the expired and damaged vaccine clearly labelled and stored out of the cold chain until final disposal? [Y, N, NA if there is no wasted vaccine]							
32	Does the facility have evidence based Vaccine and EPI supply forecasting for the fiscal year?							
33	If there is vaccine and EPI supplies forecasting , is a maximum/minimum/order stock level set for each vaccine ? [Y, N, NA if there is no vaccine forecasting]							

34	During the review period, did the stock of each and every vaccine remain within its recommended maximum/Minimum? [Y, N]							
35	Were vaccine stocks sufficient throughout thecompleted one month (no stockouts)? [Y, N]							
36	Did the facility conducted physical count cin the last completed one month? [Y, N if there is no recorded evidence]							
37	Is the vaccine /diluents stock balance and physical count of sample vaccine equal? (score "Y" if there is exact match)							
38	Did the quantity of vaccine and its respective diluent quantities match, and are vaccine and its respective diluent from the same manufacturer? [Y, N]							
39	Is the sample Dry consumables stock balance and physical count equal? (score "Y" if there is exact match)							
40	Are vaccines correctly stored (as per the recommendation)? [Y, N]							
41	Does the facility have first use box or are the vaccines laid out in in EEFO order, by type and by lot number?							
42	Is the dry store clean, dry and pest-free? [Y, N, N/A if there is no separate dry store]							
43	Does the storekeeper or health worker know how to conduct the shake test? (Y,N)							
44	Has the storekeeper of health worker carried out a shake test for all freezing temperature alarms in the last one month? [Y, N. Score n/a if there were no events that required a shake test]							
45	Are diluents always kept in the cold chain before and during every immunization session? [Y, N].							
46	Are opened vials of freeze-dried vaccines discarded within six hours of reconstitution, or at the end of each immunization session? Does the opening time recorded on the vial [Y, N].							
47	Are the VVMs on all vaccines in the health facility refrigerator, cold box or vaccine carrier at VVM stage 1 or stage 2? [Y, N]							
48	Are opened vials of liquid vaccines (OPV, TT and IPV) correctly kept for subsequent immunization sessions? [Y, N]							
49	Do you calculate wastage rates for each vaccine in the completed month? (Y,N)							
50	Are these data used to monitor vaccine management performance? (Y,N)							

Effective Vaccine Management implementation in Ethiopia

Self-assessment checklist for Health facility and cold stores for vaccine management activities

Summary of major findings of monthly self assessment Month_____

S.No	Identified Problem	Cause	Action points	Responsible person	Implementati onTimeline	Implementation status

Team Member

1Name _____ Sign _____ Date _____

2Name _____ Sign _____ Date _____

3Name _____ Sign _____ Date _____

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Vaccine and Cold Chain Management Participant Training Manual