Vaccine and cold chain Management

Training Manual

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Acronym

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 Haemophilus influenzae type b
FEFO	First-Expiry-First-Out
EPI	Expanded programme 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
EPSA	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

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. During the inception of EPI the objective was to increase immunization coverage by 10% annually. However, the coverage in the first 20 years remained low although during the 1990's good progress was observed through Universal Child Immunization (UCI). Since 2004, the reaching every district (RED) approach has been implemented in Ethiopia in districts with poor immunization coverage and high dropout rates. As a result, the coverage showed marked improvement.

In Ethiopia, EPI was launched in 1980 with six antigens (BCG, Polio, DPT and Measles vaccines). Several new vaccines have been introduced over time (HepB and Hib in combination with DPT as Pentavalent in 2007, PCV10 in 2011, Rota in 2013, IPV in 2015 and switch from tOPV to bOPV in 2016, HPV in December 2018, and MCV2 in February 2019). The switch from PCV10 to PCV13 and TT to Td is completed in 2020. Currently, 12 antigens are provided through routine EPI. In addition, piloting is under implementation for Hep B birth dose in four woredas in the country. The use of static sites, outreach sites and mobile teams are recommended as appropriate strategies for delivering immunization services. All public hospitals, health centers and health posts are expected to provide immunization service; some private health facilities also provide immunization service.

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Vaccine management

Vaccine management can be defined as the main component in all immunization efforts including accelerated disease control activities as well as improving coverage and introduction of new vaccines.

The high level of vaccine wastage, and 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 also highlighted the need for improvement of the immunization human resources capacity for better vaccine management and immunization practices. Adverse events due to inappropriate vaccine distribution practices are, partly, also believed to impact negatively on vaccine management.

Based on the estimated total cost of vaccine per fully immunized child in a developing country, Ethiopia is investing about $136.8 million USD (3 billion ETB) annually and this cost is allocated both by partners and the government of Ethiopia each year. This huge amount of money for procurement of vaccines will be expected to be ultimately covered

by the government of Ethiopia in the long run. Despite huge vaccine costs to vaccinate more than three million cohorts of children annually, there is no vaccine wastage monitoring system in place and thus the vaccine wastage for the vaccines in the EPI program is unknown. A vaccine wastage even as small as 5% corresponds to a loss of 150,447,000 Birr annually in Ethiopia for the current vaccines and it will increase as more expensive vaccines are introduced into the EPI program. Therefore, proper cod chain and vaccine management is important to reduce the high cost of vaccine wastage and ensure that children are vaccinated with safe and potent vaccines at reasonable cost.

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, the need for training in better vaccine management practices has become a priority.

Cold chain management

Cold chain equipment (CCE) is an essential component of the supply chains that ensure life- saving vaccines reach every child. Reliable, well-maintained, and cost-effective cold chain equipment to ensure adequate, sustainable vaccine storage for current and planned vaccines, with low maintenance requirements and reduced running costs.

However, according to National Cold Chain Equipment inventory (2020), it is estimated that more than 30% of counted available refrigerators and freezers are not functional. At all levels of the health system, the absence of cold chain equipment, obsolete and aging technologies, and non-functional equipment constrain the effectiveness of delivering services and limit the overall coverage and quality of the immunization program. The Ministry of Health have been doing a lot in replacing old and obsolete equipment through deploying and installing optimal and highly efficient CCE to all regions focusing in hard to reach areas through the support of GAVI cold chain equipment optimization platform and government finance. The Ministry of health distributed more than 10,000 optimal solar direct Drive refrigerators and on grid refrigerators and will continue deploy new technology CCE to all health facilities.

Moreover Ethiopia conduct effective vaccine management assessment in 2019 which shows weakness in at national level in Pre–shipment and arrival procedures (57%), storage temperatures (40%), stock management(64), distribution(60%), vaccine management(50%)and MIS, and supportive functions(59). The below are the major recommendation for improvement:

- A systematic temperature monitoring study should be done, and a complete set of temperature print out or recorder traces for the refrigerated vehicles
- Expand storage capacity of +2 to +8 degrees
- Develop a Planned Preventive Maintenance Program for the buildings and refrigeration equipment
- Ensure that Stock records include diluent information and all the vital information such as expiry, etc
- Use of freeze indicators for transportation
- More investments need to be done at the Lowest Distribution Point (Woreda) and Service Point (Health Facility) and this should be done in all categories from E2 to E9

The temperature monitoring study (2010) revealed that 50% of vaccine storage and 21% of vaccine shipments were at risk of freezing with the most significant challenges at health facility level. Thus in addition to the key challenge for potency of vaccines administered, suboptimal equipment have implications for efficiency of the supply chain in terms of recurring maintenance and fuel costs which have diverted funding from preparations for New Vaccine Introduction (NVI).

Newer optimal technology, such as solar direct drive refrigerators show promise in minimizing these costs and 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 through the use of equipment that is better adapted to needs; and

The CCE optimization platform will help to make vaccine supply chains more effective, efficient and sustainable, which will in turn help the Alliance to progress towards its 2020 goal of immunizing an additional 300 million children.

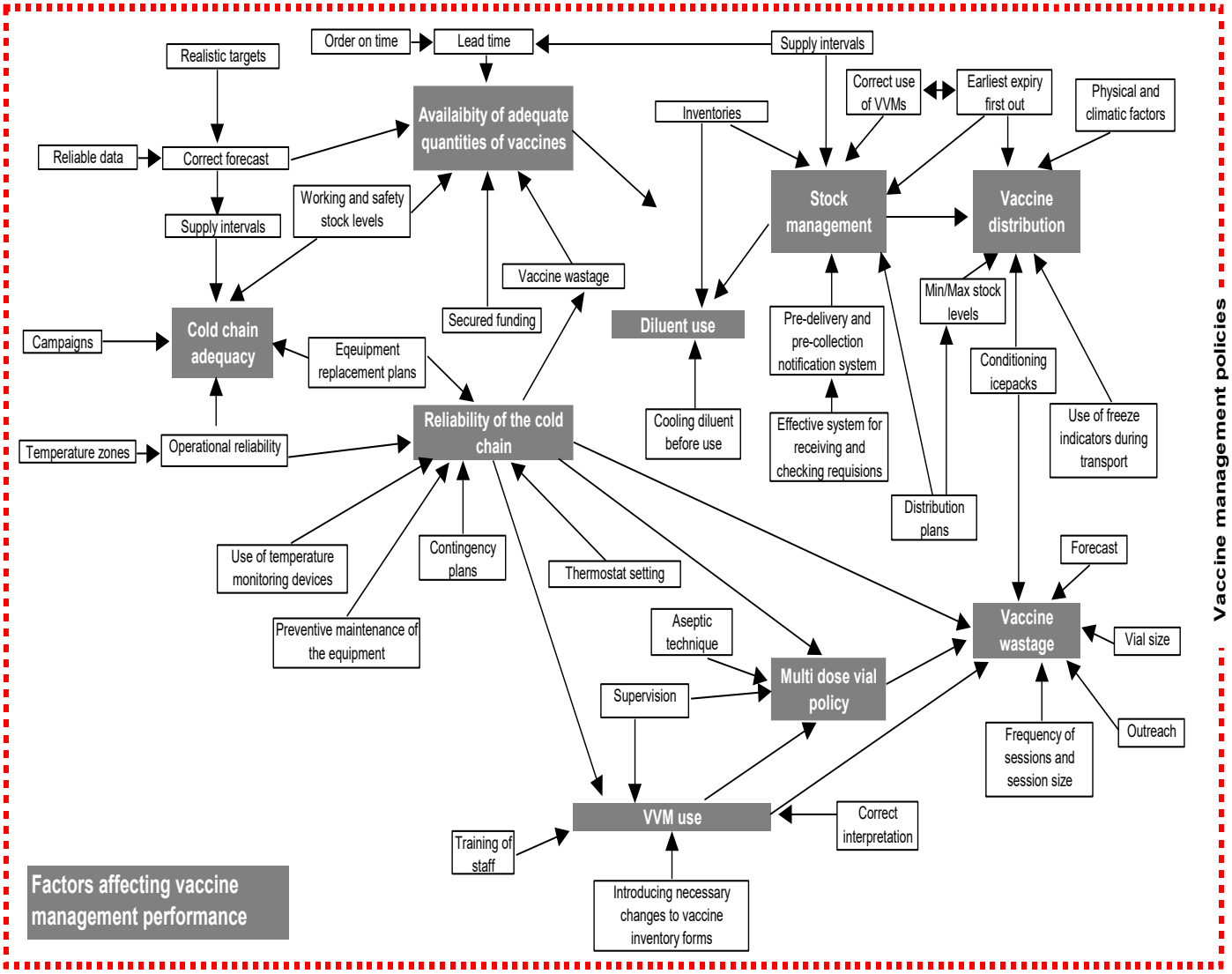
Strong and efficient supply chains – equipped with reliable cold chain equipment (CCE) are vital to helping countries increase immunization coverage and equity, reaching children with lifesaving vaccines and protecting them against deadly diseases. To ensure that vaccines are widely available and remain cold, safe and effective throughout the entire supply chain, each country's immunization programme 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.

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.

In realization of goal of immunization program, as any other health program, availability of adequate and well trained human resource is vital. With this regards, training of

immunization supply chain officers at different level and immunization officers at service delivery points based on the standard training manual to enhance their knowledge and skill of vaccine and cold chain management is important.

Factors affecting Vaccine management performance and the big picture



Purpose of the manual

This manual provides vaccine and cold chain management officers/supply chain officers with up-to date information about the vaccine management and cold chain.

It is a practical teaching tool for health staff working in immunization supply chain, whatever their level, to manage logistics support for EPI and to provide quality services to the target populations.

Target audience

This manual provides FMOH, EPSA, regional, zonal, woreda and health Facilities immunization & cold chain and vaccine management officers and the immunization management team, up-to-date information about the cold chain concept and techniques of vaccine management. It is a practical guiding tool for health staff working in vaccine management, whatever their level, to manage logistics support for EPI and to provide quality services to the target population. The manual will also help the EPI officer to renew the immunization logistics support system in order to address operational weaknesses.

Learning objectives

Vaccine management training was designed to enable the participants

- To understand vaccine management requirements in the light of the new global and adjusted national policies;
- To understand the basic concepts and practical approaches for optimum performance in vaccine management;
- To learn about the tools and techniques used specifically to improve the entire spectrum of vaccine management;
- To exchange and consolidate vaccine best practice management among the participants;
- To gain hands-on experience in critical aspects of vaccine management.

Contents of the manual

The content of vaccine management training manual were organized to follow of the information during the training.

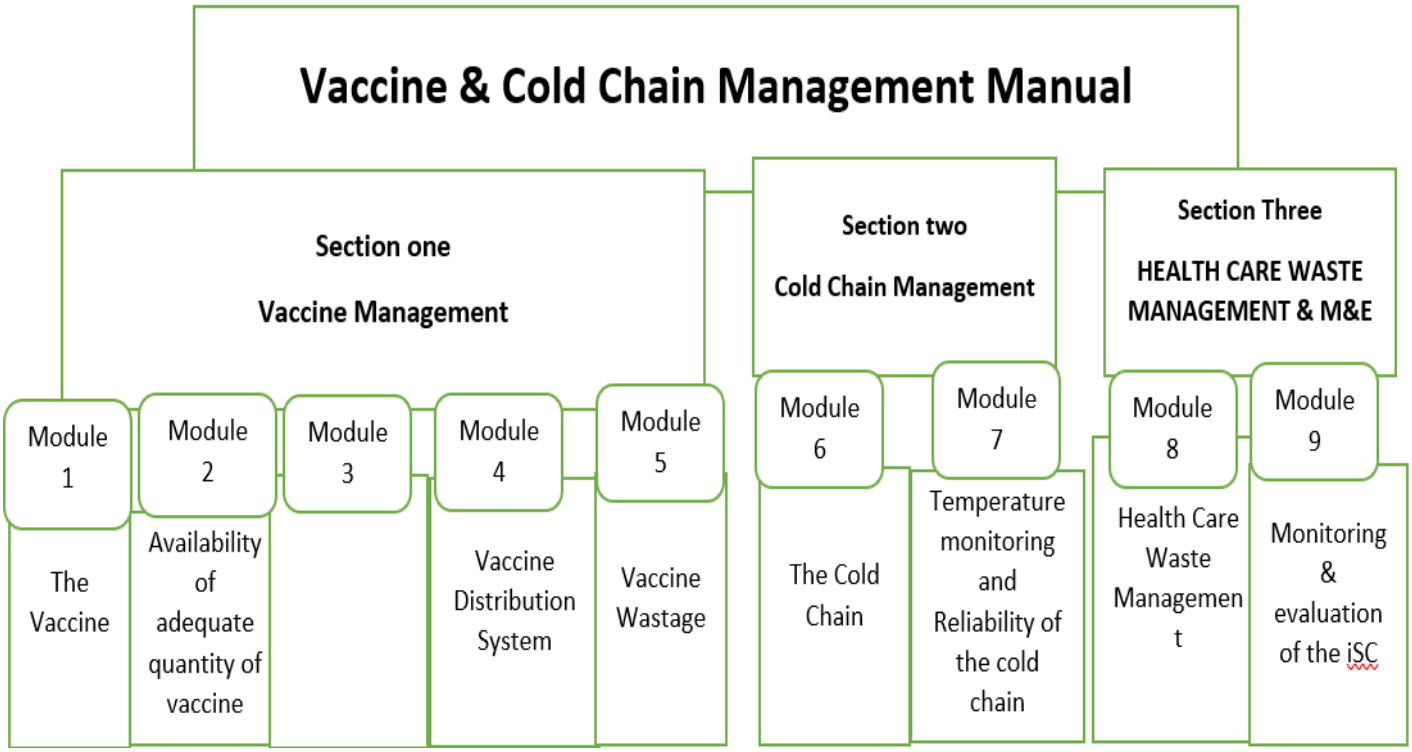


Figure 1: Vaccine and Cold chain manual components and modules

How to use the manual

The manual has 9 modules grouped in to 3 blocks (vaccine management, cold chain management and Health care waste management and monitoring and Evaluation) and after discussion of the main concepts of the each modules and consideration of the various approaches suggested, each participant will proceed to the practical exercises. With the help of the facilitator, the working group or plenary session will discuss and comment on the exercise. At the end short summary will be presented by facilitators. Similar methods will be implemented for all modules.

Section I: Vaccine Management

This section of the training manual provides technical guidance on the vaccine management policies, procedures and standard practices for workers at health facility and cold chain managers at different levels. It covers characteristics of the vaccines, forecasting of the vaccines, proper stock management, vaccine distribution and the concept of vaccine wastage which are organized into five modules which arranged in logical orders.

The vaccine management section modules are,

Module 1: The vaccines
Module 2: Availability of adequate Quantity of vaccines
Module 3: Stock management
Module 4: Vaccine distribution system
Module 5: Vaccine wastage

Module 1: Vaccines

Learning Objectives

At the end of this module, the trainees should be able to:

1. Describe vaccines and their characteristics
2. Identify the type of vaccine needed for each vaccine preventable diseases
3. Discuss the vaccine schedule for the routine EPI program
4. Identify the dose, route of administration and storage of each vaccine

Training methods

The training will be conducted through presentations, small group work exercises, and plenary discussion. The estimated total time allocated is -120 minutes.

1.1. Introduction

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.

1.2. Types of Vaccine and Characteristics

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

Inactivated vaccines: are produced by growing viruses or bacteria and then inactivating them with heat or chemicals. Because they are not alive, they cannot grow in a vaccinated individual and therefore cannot cause the disease. They are not as effective as live vaccines, and multiple doses are required for full protection.
Inactivated vaccines may be whole-cell or fractional. Whole-cell vaccines are made of an entire bacterial or viral cell. Fractional vaccines, composed of only part of a cell, are either protein- or polysaccharide-based. Polysaccharide-based vaccines are composed of long chains of sugar molecules taken from the surface capsule of the bacteria. Unless coupled with a protein, pure polysaccharide vaccines are generally not effective in children under the age of two years. This coupling process is known as "**conjugation**."

Recombinant vaccines: are produced by inserting genetic material from a disease-causing organism into a harmless cell, which replicates the proteins of the disease-causing organism. The proteins are then purified and used as vaccine. For COVID 19 vaccines like AstraZeneca and Jansen, a viral vector encoding the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralizing antibody and cellular immune response

Nucleic acid vaccines: are RNA or DNA vaccines which include 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.

Summary of types of vaccines

- **Live attenuated**
  - Virus: Oral Polio Vaccine (OPV), Measles, Yellow fever, rotarix, Bacteria: BCG
- **Inactivated:**
  - Whole Cell:
    - Virus : Inactivated polio vaccine (IPV), COVID -19 Vaccines (Sinopharm, Sinovac)
    - Bacteria: Whole cell pertussis, Oral Cholera Vaccine (Shanchol™, Euvichol® and mORCVAX™)
  - Fractional:
    - Protein based
      - Sub unit: acellular pertussis
      - Toxoid : Tetanus, diphtheria
    - Polysaccharide based:
      - Pure: meningococcal
      - Conjugated: Haemophilus influenza type b (Hib), Pneumococcal conjugate vaccine ((PCV), Meningococcal conjugate vaccines (e.g. MenA)
- **Recombinant:** Hepatitis b, HPV, COVID -19 vaccines (AstraZeneca, Janssen, Gamaliya)
- **Nucleic Acid:** COVID -19 vaccines (Pfizer, Moderna)

All vaccines are sensitive biological substances that progressively lose their potency (i.e. their ability to give protection against disease). This loss of potency is much faster when the vaccine is exposed to temperatures outside the recommended storage range. Once vaccine potency has been lost, returning the vaccine to correct storage condition cannot restore its potency. Any loss of potency is permanent and irreversible. Thus, storage and transportation of vaccines at the correct recommended temperature conditions is vitally important in order that full vaccine potency is retained up to the moment of administration.

All vaccines particularly heat sensitive vaccines suffer much faster loss of potency when exposed to temperature above $+8^0$C. Some vaccines are also highly sensitive to being freeze. Such vaccines will lose their potency entirely if frozen although others can sustain freezing without any damage whatsoever. It is, therefore, vitally important to know the correct storage condition for each vaccine and to ensure that each is kept always at the recommended conditions. Attention to maintaining correct temperatures during storage

and transport of vaccine is thus a major task. Some vaccines are also highly sensitive for light.

1.3. Vaccines in use for routine immunization, outbreak response and SIA in Ethiopia

i. Diphtheria-containing vaccines

There are different combinations of diphtheria-containing vaccines including, combination with tetanus toxoid (Td) and the combination with tetanus, pertussis, hepatitis-B and Haemophilus influenza type B known as Pentavalent. Pentavalent vaccines are supplied in single- and multi-dose presentations. They must be stored between +2°C and +8°C without being frozen. Pentavalent is freeze-sensitive. Pentavalent is administered as 0.5 ml doses given intramuscularly in the left anterolateral (outer) thigh in infants.

ii. Pertussis-containing vaccines

Pertussis vaccine is most often given in pentavalent combination (tetanus, hepatitis-B, and Diphtheria and Haemophilus influenza type B) form. Pertussis-containing vaccines must be stored between +2 °C and +8°C without being frozen. Pertussis-containing vaccines are administered as 0.5 ml doses given IM in the anterolateral (outer) thigh in infants

iii. Tetanus toxoid-containing vaccines

In Ethiopia Tetanus toxoid vaccine is available as Td, **which protects against tetanus and neonatal tetanus**. It is also available in pentavalent combinations. Td vaccine is supplied as a liquid in multi-dose vials. Tetanus toxoid-containing vaccines must be stored between +2°C and +8 °C without being frozen. They are freeze-sensitive. Tetanus toxoid-containing vaccines are administered as 0.5 ml doses given IM in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of older children and adults.

iv. Hib-containing vaccines

Hib-containing vaccines prevent pneumonia, meningitis, epiglottitis, septicemia and other Hib disease. They do not protect against other types of Haemophilus influenza or other bacteria that cause similar diseases. In Ethiopia Hib containing vaccine is available in the form of Pentavalent.

v. Hepatitis B-containing vaccines

Hepatitis B vaccines are available as monovalent formulations for birth doses or for vaccination of adult persons at risk, and in combination with other vaccines for infant vaccination, including diphtheria–tetanus–

pertussis (DTP), Haemophilus influenzae type b (Hib) (Pentavalent) and inactivated polio vaccine (IPV). Additionally a combined hepatitis B and hepatitis A vaccine is also available.

The standard pediatric dose contains 5 μg–10 μg HBsAg, and the standard adult dose is 10 μg–20 μg; a 40 μg dose vaccine is used for immune compromised and dialysis patients. HepB-containing vaccines are administered as 0.5 ml doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle of adults (pregnant women and high risk populations). Hepatitis B vaccine is to be administered by intramuscular injection into the anterolateral aspect of the thigh for infants or into the deltoid muscle for older children and adults. Administration into the gluteal muscle is not recommended as this route has been associated with decreased concentrations of protective antibody and injury to the sciatic nerve. Four doses of hepatitis B vaccine may be given for programmatic reasons (e.g. 1 monovalent birth dose followed by 3 monovalent or hepatitis B-containing combination vaccine doses) administered during the same visits as the 3 doses of DTP-containing vaccines.

HepB-containing vaccines must be stored between +2°C and +8ºC. They are freeze-sensitive. If freezing is suspected, the "shake test" should be performed. If HepB vaccine vials stand for a long time, the vaccine may separate from the liquid. When separated, the vaccine looks like fine sand at the bottom of the vial. Shake the vial to mix it before using.

vi. BCG vaccine

BCG vaccine protects infants against tuberculosis. The letters B, C, G stand for bacille Calmette -Guérin. Bacille (describes the shape of the bacterium. Calmette and Guérin are the names of the individuals who developed the vaccine. BCG vaccine is supplied in freeze-dried powder (also called lyophilized) form. It must be reconstituted with a diluent before use. BCG vaccine must be stored between +2°C and +8°C after reconstitution & should be discarded after six hours.

vii. Pneumococcal conjugate vaccine

Pneumococcal vaccines have been developed based on the serotypes frequently found in severe pneumococcal disease patients. There are two categories of pneumococcal vaccines: Pneumococcal polysaccharide vaccines and Pneumococcal conjugate vaccines (PCV). PCV-13 is used in the EPI schedule. Ethiopia switched from PCV 10; 2 dose vial to PCV 13;4 dose vial presentation in 2020. The number indicates how many pneumococcal serotypes the vaccine contains (for example, PCV13 protects against 13 serotypes of pneumococcus).

Each pneumococcal vaccine protects against disease caused by the pneumococcal serotypes that it contains; it is unlikely to protect against serotypes that it does not contain. It does not protect against other bacteria that cause the same types of infections (pneumonia, meningitis, etc.) as the pneumococcus, a fact that should be emphasized in health education. For infants and children, 0.5 ml of PCV is administered by IM injection in the right anterolateral thigh.

PCV vaccine should be given on the right outer thigh after pentavalent vaccine is given on the left outer thigh. This is done for monitoring purpose only.

viii. Rotavirus vaccine

There are two types of rotavirus vaccines (RV) that contain one or more live attenuated virus strains given orally to protect against rotavirus gastroenteritis. They do not protect against other causes of diarrhea, a fact that is important to emphasize in health education. In Ethiopia (Rotarix®), also known as RV1 or monovalent RV which contains one strain, is available in the routine program. RV 1 comes in liquid form in an oral applicator or a squeezable tube which is ready to use. Rotarix® must be stored between +2°C and +8 °C without being frozen.

ix. Polio vaccine

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). It is supplied in multi-dose vials. It is very heat-sensitive and must be kept frozen during long-term storage. After thawing, it can be kept at a temperature of between +2 °C and +8 °C for a maximum of six months or can be refrozen. In Ethiopia tOPV is switched to bOPV in 2016. In addition, monovalent oral polio vaccine (mOPV2) is being used to manage circulating vaccine derived poliomyelitis (cVDP).

The novel oral polio vaccine (nOPV2) is also 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 = 0,55cm^3 (same as mOPV2) or 27.5 cm3 per vial. Expected wastage factor for 50 dose vial = 1.67 (wastage rate = 40%) – 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^{0}C; this is subject to change as additional data is submitted and reviewed in line with EUL recommendations.

	bOPV	mOPV2	nOPV2
Doses per vial	20	20	50
Vial size	2ml	2ml	5ml
Packed volume per dose	0,55cm³	0,55cm³	0,55cm³
VVM	Yes – Type 2	Yes – Type 2	Yes-Type 2
MDVP during house to house campaigns	Yes	Not recommended	Not recommended
Heat sensitivity	similar to mOPV2	similar to bOPV	similar to bOPV and mOPV2
Wastage factor	1,15	1,15	1,67 To be adjusted after "initial use" period
Passive Cold Chain Equipment	Standard Cold Box and Vaccine Carriers	Standard Cold Box and Vaccine Carriers	Standard Cold Box and Vaccine Carriers
Temperature Monitoring in the field	VVM only	VVM only	VVM only
Containment	Not required	Required	Required
Reverse logistics	Not required	Required for all vials (Usable and Unusable) after each round	Required for all vials (Usable and Unusable) after each round
Disposal of empty vials	Local (as per national guidelines)	National or Regional (as per national guidelines)	At National or Regional level (as per national guidelines)
Disposal of unopened vials	Not required, can be used for RI	OPRTT decides	OPRTT decides
Verification of vial collection	Not Applicable	Yes, by supervisors	Yes, by supervisors
Validation of collection	Not Applicable	OPRTT will decide after concluding the OB	OPRTT will decide after concluding the OB

Figure 2: Comparison of bOPV2, mOPV2 and nOPV2

IPV is an inactivated virus vaccine available as a stand-alone product or in combination with diphtheria, tetanus, pertussis, hepatitis B and/or Hib. It should be stored between +2°C and +8°C. It must not be frozen. It is supplied in one-, five- or ten-dose vials. Ethiopia will introduce second dose IPV after 2022. OPV is given orally and IPV is injected intramuscularly as a 0.5 ml dose.

x. Measles-containing vaccines

Measles-containing vaccines include measles only (M) or a combination of measles with rubella (MR), mumps (MM, MMR) and varicella (MMRV) vaccines. MCVs can be used interchangeably in immunization programs. M, MR and MMR are supplied as freeze-dried powders (also called lyophilized) with diluents in separate vials. They must be reconstituted before use with only the diluent supplied from the same manufacturer. Measles-containing vaccines must be stored between +2 °C and +8 °C and protected from sunlight since they are sensitive to both heat and light. MCVs are administered by subcutaneous injection. In countries where vitamin A deficiency is common, vitamin A supplements are often given at the same time as the vaccine.

xi. HPV vaccine

Two HPV vaccines are currently available worldwide: a bivalent vaccine, Cervarix ®, which protects against HPV types 16 and 18, and a quadrivalent vaccine, Gardasil ®, which protects against four HPV types (6 and 11 (which cause genital warts), and 16 and 18). In Ethiopia, the currently available HPV is quadrivalent vaccine, Gardasil ®. Both are available in single-use vials or prefilled syringes. The bivalent HPV vaccine (Cervarix ®) also comes in two-dose vials. These vaccines do not require reconstitution. They must be stored between +2 °C and +8°C. Both vaccines are administered intramuscularly in two separate 0.5 ml doses.

xii. Meningococcal vaccine

There are two categories of meningococcal vaccine :polysaccharide vaccines with specific capsule serogroup antigens and polysaccharide-protein conjugate vaccines, which have serogroup antigens bound to a protein that helps increase the immune system response to the vaccine. Conjugate vaccines result in better protection in infants and longer lasting effect in all (this is similar for pneumococcal conjugate vaccines).

Table 1: Available formulations of Meningococcal vaccines

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

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

xiii. Yellow fever vaccine

Yellow fever (YF) vaccine live attenuated vaccines for preventing yellow fever are currently in use. They are supplied in freeze-dried (also called lyophilized) form and must be reconstituted be with the diluent supplied by the manufacturer before use: YF vaccine must be stored between +2 °C and +8 °C. It is not damaged if accidentally frozen. It is administered as a single 0.5 ml dose either subcutaneously in the upper arm or intramuscularly in the anterolateral thigh.

xiv. Oral Cholera Vaccine (OCV)

Two types of oral cholera vaccines (OCVs) are currently available at: (i) WC-rBS, killed whole cell monovalent (O1) vaccines with a recombinant B subunit of cholera toxin (Dukoral®) and (ii) WC, killed modified whole cell bivalent (O1 and O139) vaccines without the B subunit (ShancholTM, Euvichol® and mORCVAXTM); the 3 WC vaccines are based on the same cholera strains.OCV must be stored between +2 °C and +8 °C.

xv. COVID -19 Vaccines

Following the COVID -19 pandemic, efforts have been taken to develop safe and effective vaccines to combat the COVID-19. In the case of pandemic response, WHO developed an EUL (Emergency use listing) approach to authorize the use of COVID 19 under development. The WHO Emergency Use Listing (EUL) is a procedure for assessing unlicensed vaccines, therapeutics and in vitro diagnostics during public health emergencies. As of 1 July 2021, six vaccines across two different platforms have registered under WHO EUL approval. The EUL procedure assesses the suitability of novel health products during public health emergencies. The objective is to make medicines, vaccines and diagnostics available as rapidly as possible to be able to address the emergency.

There are multiple COVID-19 vaccines under development. The Nine Pioneer COVID-19 vaccines are;

1. Pfizer-BionTech – mRNA Comirnaty
2. Moderna- mRNA-mRNA-1273
3. Oxford-AstraZeneca – Adenovirus Based (AZD1222 or Covishield)
4. Johnson & Johnson – Adenovirus Based (Ad26.COV2.S)
5. Gamaleya Adenovirus-Based Sputnik V or Gam-Covid-Vac

6. Novavax Protein-Based (NVX-CoV2373)
7. Sinopharm (Inactivated Coronavirus Vaccines) -BBIBP-CorV
8. Sinovac Inactivated Coronavirus Vaccines-CoronaVac
9. Bharat Biotech- Inactivated Coronavirus Vaccines-Covaxin~~,~~

Table 2: Summary of COVID19 vaccines characteristics, presentation and recommended storage temperatures

COVID-19 Vaccine Type	Target age group	Characteristics	Route	Formulation, Presentation	Dosage	Number of doses	Schedule	Handling procedures	Storage temperature	Shelf life
AstraZeneca	18 years and above	Recombinant	IM	Liquid, preservative free. Multi dose suspension.	0.5ml	2 doses	1st dose at start 2nd dose after 8-12 weeks	Freeze and light sensitive. The vaccine has no VVM.	+2°C to +8°C	Unopened vials kept at +2°C to +8°C until expiry date. Opened vials at +2°C to +8°C for six hours.
SinoPharm	18-59	Inactivated vaccine	IM	Liquid, adjuvanted. Preservative-free suspension.	0.5ml	2 doses	1st dose at start date 2nd dose 3 to 4 weeks after the 1st dose	Freeze and light sensitive. The vaccine has no VVM.	+2°C to +8°C	Unopened vials kept at +2 to +8 °C: 24 months or _until expiry date.
Janssen	18 years and above	Recombinant	IM	Preservative-free Multi-dose suspension.	0.5ml	Single	Single	Light sensitive. Never refreeze thawed vials. The vaccine has no VVM.	Frozen vaccine - in the original carton at -25 to -15 ° If thawed store at +2 to +8 °C in the original carton	Frozen at -15 to -25 for 24 months Thawed un opened at +2 to +8 °C for three months Opened at +2 to +8 °C for 6 hours
Sinovac	18-59	Inactivated	IM	Liquid, inactivated, adjuvanted. Milky-white suspension.	0.5ml	2 doses	1st dose at start date 2nd dose 2 to 4 weeks after the 1st dose	Freeze and light sensitive. The vaccine has no VVM.	+2°C to +8°C	12 months, Stored at +2°C to +8°C
Moderna	18 years and above	mRNA vaccine	IM	Frozen, sterile. Preservative-free Multi-dose suspension.	0.5ml	2 doses	1st dose at start date 2nd dose 4 weeks after the 1st dose	Never refreeze thawed vials. Do not store in freezer below -40 °C Light sensitive Has no VVM	Store in the original carton in a freezer at -25 to -15 °C	Thawed punctured vial at +2 to +25 °C 6 hours after the first dose has been withdrawn For unopened vial see the manual
Pfizer	12 years and above	mRNA vaccine	IM	Frozen, sterile Preservative-free Multi-dose concentrate	0.3ml	2 doses	1st dose at start date 2nd dose 3-4 weeks after the 1st dose		At -80 to -60 °C in freezer	Undiluted vaccine at storage temperature -90 to -60 °C: 6 months For THAWED vaccine see the manual

From the above list of COVID 19 vaccines, Pfizer-BionTech must be stored at -80 to -60 °C in freezer (ultra-cold chain), Moderna requires a freezer at -25 to -15 °C, and the rest of the vaccines must be stored between +2 °C and +8 °C. As of July, /2021, all of the above COVID 19 vaccines are supplied without VVM.

The shelf life for some of the COVID 19 vaccines depends on the storage location at the respective storage points. The time transferred from its original storage requirement to the next storage level will be used as its shelf life in lieu of the expiry date. For instance, for Pfizer vaccine, before mixing, the vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F) for 6 months after the time of manufacturing. Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. Vaccine stored in the freezer can be transferred to refrigerator storage where it can be stored for up to 1 month (31 days). Undiluted thawed vaccine at temperatures up to +30 °C, for up to 2 hours. Diluted vaccine shall be discarded after 6 hours or at the end of immunization session whichever comes first.

Vaccines can be given in a routine and/or SIA forms. In Ethiopia, new vaccine is introduced based on the diseases epidemiology and other parameters. From the above list of vaccines, Yellow fever, OCV, MenA, Covid 19 are provided only for vaccine preventable disease outbreak response and follow up campaigns.

1.4. Target diseases and vaccine schedules

Table 3: Summary of different vaccines, their characteristics, presentation and recommended storage temperatures in Ethiopia

Vaccine	Characteristics	Route and site of inoculation	Formulation, Presentation	Dosage	Number of doses	Schedule	Handling procedures	Storage temperature	Preventable Disease	Purpose
BCG	Live attenuated vaccine	ID (Right upper arm (deltoid)	Lyophilized with diluents; Multi- dose ampoules	*0.05ml*	One	At or as soon as possible after birth	Avoid exposure to sunlight. Diluents should be refrigerated previous to mixing with vaccine. Diluents should never be frozen	+2°C to +8°C	*Tuberculosis*	*RI*
DPT-HepB+Hib (Pentavalent vaccine or Penta)	Hib conjugated vaccine, Hep.-B is recombinant vaccine and DPT (inactivated, vaccine toxoid)	IM (Left (outer) mid-thigh)	Liquid ; Multi-dose/ single- dose vial	*0.5ml*	three	6, 10, 14 weeks of age	Never Freeze Diluents should be refrigerated previous to mixing with vaccine. Diluents should never be frozen	+2°C to +8°C	Diphtheria, Pertussis, tetanus, Hepatitis B, and H.influenza B diseases	RI
HepB-birth dose	Recombinant vaccine	IM	Liquid; Multi-dose/Single-dose	*0.5ml*	one	At birth	Never Freeze	+2°C to +8°C	Hepatitis B	RI
Oral Polio (OPV)	Live attenuated virus vaccine	Oral	Liquid; Multi-dose vial or plastic tube	*2 drops*	four	At birth, 6, 10, 14 weeks of age	Avoid exposure to Heat	2°C to +8°C or (-20°C)	*Poliomyelitis*	*RI/SIA*
Inactivated Polio Vaccine (IPV)	Inactivated vaccine	IM(Right (outer) mid-thigh, 2cm away form IPV)	Liquid; Prefilled Syringes/Multi- dose vial	*0.5ml*	One	14 weeks of age	Never Freeze	+2°C to +8°C	*Poliomyelitis*	*RI*

Table 2: ……..continued

Vaccine	Characteristics	Route of inoculation	Formulation, Presentation	Dosage	Number of doses	Schedule	Handling procedures	Storage temperature	Preventable Disease	**Purpose**
Rotavirus	Live attenuated virus vaccine	Oral	Liquid ; Single-dose plastic tube or applicator	1 tube (1.5ml), only for oral use	two	6, 10, weeks of age	Avoid exposure to sunlight, prefilled syringe and lyophilized vaccine should be refrigerated but never be frozen	+2°C to +8°C	Rota virus	Routine immunization **(RI)**
Measles	Live attenuated virus vaccine	SC (Left upper arm)	Lyophilized with diluents; Multi-dose/Single-dose	0.5ml	two	9 and 15 months	Avoid exposure to sunlight; diluents should be refrigerated previous to mixing with vaccine but never be frozen.	2°C to +8°C or (-20°C)	Measles	RI & SIA
Pneumococcal Conjugated vaccine	Conjugated vaccine and Polysaccharide	IM	Liquid; Multi-dose/Single-dose Prefilled syringes	0.5ml	three	6, 10, 14 weeks of age	Never freeze	+2°C to +8°C	*Pneumococcal diseases*	*RI*
Yellow Fever	Live attenuated virus vaccine	SC	Lyophilized with diluents; Multi-dose/Single-dose	*0.5ml*	One	9 months	Avoid exposure to sunlight Diluents should be refrigerated previous to mixing with vaccine but never be frozen	2°C to +8°C or (-20°C)		VPD [1]outbreak response
Human Papilloma Virus	Recombinant Vaccine	IM	Liquid; Single-dose vial	0.5ml	two	girls of (9-14) years old	Never freeze	+2°C to +8°C		RI
Td*	Toxoid	IM	Liquid; Multidose (10 or 20)	0.5ml	Five	*	Never freeze	+2°C to +8°C		RI
Men A	Conjugated	IM (Upper arm)	Liquid multi dose	0.5m	one	1-29 years and single	Never freeze	+2°C to +8°C		SIA
OCV	Inactivated	Oral	Liquid, single dose –	2 drops	two	14 days	Never freeze	+2°C to	Cholrea	VPD outbreak

VPD: Vaccine preventable disease.

			vials			apart for age>1year		+8°C		response
COVID - 19 Vaccine (AstraZeneca/Covishield)	Recombinant	IM (left Upper arm)	Liquid, preservative free. Multi dose solution.	0.5ml	two	1st dose at start 2nd dose after 8-12 weeks	Freeze and light sensitive. The vaccine has no VVM.	+2°C to +8°C	COVID -19	VPD outbreak response
COVID - 19 Vaccine (Sinopharma)	Inactivated	IM (left Upper arm)	Liquid, adjuvant. Preservative-free suspension.	0.5ml	two	1st dose at start date 2nd dose 3 to 4 weeks after the 1st dose	Freeze and light sensitive. The vaccine has no VVM.	2°C to +8°C	COVID -19	VPD outbreak response
COVID - 19 Vaccine (Pfizer	Nucleic Acid	IM (left Upper arm)	Frozen, sterile Preservative-free Multi-dose concentrate	0.3ml	two	1st dose at start date 2nd dose 3-4 weeks after the 1st dose		-80 to -60 °C in freezer[2]	COVID -19	VPD outbreak response

Td schedule - *Td_1 (as early as possible after 15 years of age); 4 weeks after Td2; 6 months after Td2 or subsequent pregnancy; 1 year after Td2 or subsequent pregnancy, 1 year after Td3 or subsequent pregnancy.)

Exercise:

Exercise 1

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

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

Exercise: 2

- Describe the difference between, Vaccination and immunization
- What are the two types of immunity?
- What are the advantages of understanding vaccine characteristics?

Module 2: Availability of adequate quantity of vaccines

Learning Objectives

By the end of this session you will be able to:

1. Define immunization target population and supply period for your administrative levels (health facility, woreda, EPSA hub and central/national levels)
2. Estimate the vaccine needs for supply period
3. Forecast vaccines and supplies required for emergency/outbreak/pandemic responses.
4. Compare immunization coverage with vaccines distributed, utilized for supply periods.

Training methods

The training will be conducted through presentations, small group work exercises, and plenary discussion. The estimated total time allocated is - 4:30 hours.

2.1. Introduction

It is very essential to have adequate stock of vaccines at every level of the supply chain. If it is in less quantity the immunization programme may suffer and in the case of excess quantity, the chances 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.

WHO and UNICEF recommend 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. Thus,

Accurately estimating stockholding is essential to the success of the EPI programme and can be done the estimate using

- The target population,

- The consumption method based on historical vaccine usage and
- The session size and frequency of immunization at the service delivery point.

One should become more vigilant in forecasting and management of these vital items and address the following three major issues in storage and distribution of vaccines and logistics:

1. Stock out – A condition when no vaccine/logistics available.
2. Inadequate stock – Less than buffer stock i.e., less than 25% of vaccine/Logistics required.
3. Excess stock – More than requirement of supply period and buffer stock i.e., more than 125% of vaccine.

The Target Population

In Ethiopia the vaccines and EPI supplies forecasting considered the following health administrative levels or catchment areas; community and health facility, woreda, EPSA hubs and national levels. Sources of information for population size to conduct forecasting exercise includes; census data, birth registrations, and head counts at the local levels all under one children, second year of life and pregnant and child bearing age women, girls of (9-14) years old, etc. for routine immunization program. While supplementary and outbreak responses vaccine needs determined based on the target population affected using epidemiological data and programme directions. For COVID 19 vaccination rollout in 2021, the SAGE framework of target prioritization was used to select priority targets for the most at risk and vulnerable population.

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 programme guidelines determine the target population, coverage, number of dose per target, wastage rate, supply 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

Vaccine type, formulation, and presentation

In Ethiopia, there are 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.

Vaccine Storage Requirement

The presentation and formulation of vaccines determines the storage requirement, maximum storage time 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 rage storage requirements at central and EPSA hub level. A negative storage temperature is required (-25 ^{0}C to -15^{0}C) 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 8^{0}C) for the rest of the vaccines at all supply chain level. BCG and measles can be stored at (-25 ^{0}C to -15^{0}C) at central and ESPA hub level if there is adequate negative storage capacity. The maximum recommended storage period at Central and EPSA hub level is six and three months respectively. All vaccines and diluents in woreda and health facilities should be store in a temperature range of 2 ^{0}Cto 8^{0}C for a maximum of one month period.

Cold Chain Capacity

Cold chain is the backbone of a vaccine supply chain system. The cold chain capacity at all level 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.

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.

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.

Supply Interval

It is the period of time 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:

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

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 proportion of

$$\text{Vaccine Usage Rate} = \frac{\text{Children vaccinated (Dose used)}}{\text{(Beginning Balance +Received During the Month) - End Balance}} \times 100$$

Vaccine wastage = 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.

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 needs

The number of doses required traditionally been calculated on the basis of population, coverage and wastage factor, and increasing annually in order to allow for programme growth.

Estimation of Requirements

The availability of adequate vaccines supply, diluents and safe-injection equipment of assured quality is critical to every immunization service. Effective management and storage of supplies can help save on programme costs, prevent high wastage rates and stock-outs, and improve the safety of immunizations.

There are three methods of forecasting (target population, previous consumption, and size of immunization sessions) that are commonly used to estimate vaccine and safe-injection equipment needs. Target population method is suitable for higher level (Central ESPA and hubs woreda level), whereas number and type of sessions planned is more suitable for planning at lower levels health-facility level.

a. Formula to be used in target population method

Annual need of vaccine in dose
= (Annual target population X Annual coverage planned X Number of doses per child X Wastage Factor)

***[3]

During new vaccine introduction and initial forecasting for newly established health facility of cold store, the forecasting of vaccine and other related supplies should include the buffer stock which is expected to be 25% of the requirement for the supply period

Table 4: WHO indicative Wastage rate and Wastage factor commonly used for forecasting

Vaccine and Supplies	Wastage Rate	Wastage Factor
BCG	**50%**	**2**
Measles	**35%**	**1.54**
Td, OPV, IPV, PCV	**10%**	**1.11**
Pentavalent, Rotarix, HPV, HepB	**5%**	**1.05**
AD Mixing syringes	**5%**	**1.05**
Safety Box	**5%**	**1.05**

To calculate:

- BCG Mixing syringes (2ml) – divide the calculated doses of BCG vaccine by 20 and multiply by wastage factor 1.05 (5%)

[3] *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.*

- Measles Mixing syringes (5ml) - divide calculated doses of Measles vaccine by 10 and multiply by wastage factor 1.05 (5%)
- Safety box – Divide the sum of all AD and mixing syringes by 100 and multiply by wastage factor 1.05 (5%)

b. Formula to be used in size of immunization sessions method

Vaccine need based on size of immunization sessions method
= 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

c. Estimating vaccine needs based on previous consumption

Each parameter relative to previous consumption can be affected by many factors, especially programme performance, during the supply period in question. Estimating needs based on previous consumption may, therefore, not be as reliable as the method based on target population.

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

- Beginning stock at the beginning of the given period/beginning balance (B);
- Stock received during the period (R) and
- Ending balance at the period/stock (E).
- Number of unopened vaccines vials lost/loss adjustment (damaged, 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 in order to compensate the given wastage rate. The vaccine wastage rate can vary greatly according to several characteristics of the programme 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

$$\text{Wastage factor} = \frac{100}{(100-35)} = \frac{100}{65} = 1.54$$

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 4 for quick reference guide wastage rates and their corresponding WMFs.

Table 5: 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

Forecasting vaccines for outbreak responses

Substandard and 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. In such instance factors required for vaccines forecast are similar with routine vaccines except changes in target age, wastage rate and supply lead time. Assessing the cold storage capacity, distribution plan including transport should be considered.

2.4. Vaccine Stock levels

2.4.1 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

Formula: Minimum stock (S_{mini}) = Quantity for the supply period (Q period) x 25%

E.g.:- If the number of doses required for a given period is 10,000 and percentage of desired minimum stock is 25%, then

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

2.4.2 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 loosing vaccines to expiration 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

2.4.3 Re-Order Point(Critical Stock) (Time to Order)[4]

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 dose (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.

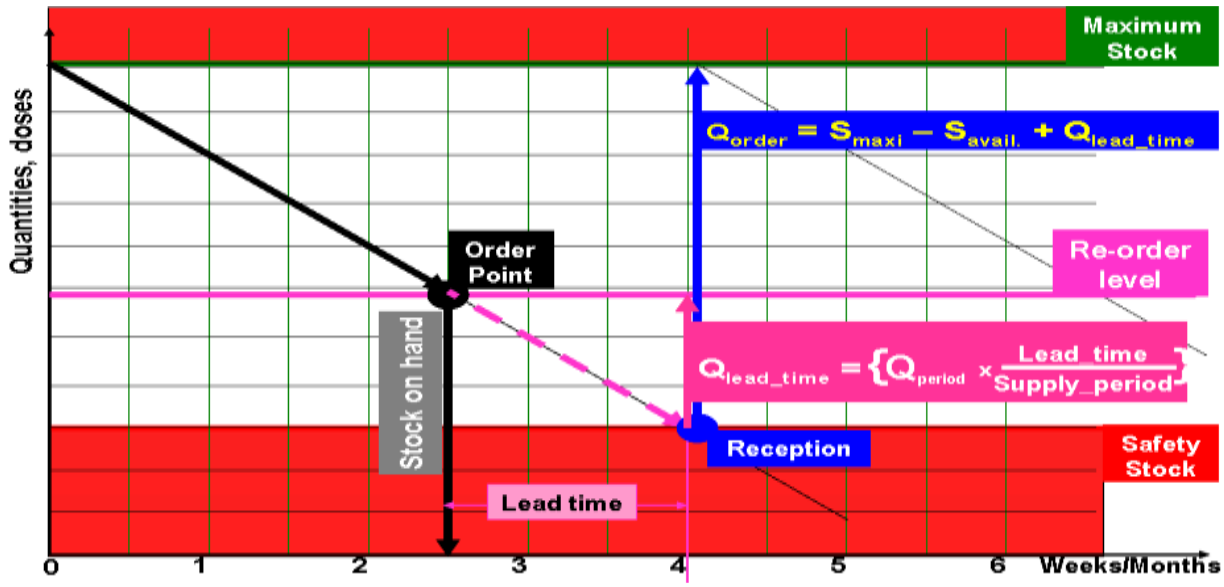


Figure 3: Different stock levels

Exercise1: Vaccine Forecast

It is August 2021, and the forecast for 2022 is being prepared for EPSA 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 EPSA 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 EPSA center is one week. In small groups, 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

Exercise 2: The following data refer to X health center

Vaccine	Target population	No of doses	Coverage	Wastage factor	Stock on hand (doses)	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%	1.05	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:

a) Quantity that you intend to use for supply period

b) Minimum stock

c) Maximum stock

Module 3: Stock management

Learning Objectives

By the end of session you will be able to:

1. Understand and list the required stock records to be kept
2. Know how to properly complete vaccine and other EPI supplies' stock control book (during vaccine arrival, issuing and loss adjustment) forms.
3. Know how to plan and conduct regular stock monitoring (physical inventory)
4. Identify and manage factors affecting vaccine stock level
5. Know how to manage damaged and expired vaccines and supplies
6.

This module is going to be covered by a brief introduction, a small group discussion, demonstration and plenary presentation and discussion. Vaccine and other EPI supply ledger book (used and unused pages), stock cards if available will be used as a training material.

3.1 Introduction

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.

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: take into account 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, in the rare situation that there is a serious adverse event, it will be useful to know the exact description of the vaccine (manufacturer, batch number etc.).

Vaccines and supplies stock monitoring is an integral part of the overall EPI management system and should

take place regularly. Monitoring vaccines:

- 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 planning process

The responsible officer 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 diluent bundled
- Monitoring the use and wastage of vaccines

3.2. Effective stock management

3.2.1. 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 diluent (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. OPV 20 dose), 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 diluent 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 diluent. Where books are used, label each book or ledger section clearly with the vaccine and diluent type. Label it clearly – e.g. 'diluent 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 diluent type or keep separate sheets for each vaccine and diluent type in the same file.

At national and sub-national level there is a computer-based logistics management information system. EPSA central and its hubs used health commodities management information system to monitor stock and manage transactions. At Woreda Health office and health facility level, mobile based application is deployed to control inventory and transactions. It also generates monthly vaccine request.

International vaccine shipment arrival

The 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. 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. It is a basic and important document for claims in cases of litigation.

It is critical to monitor when vaccines remain in storage; regularly check the expiry dates of the stock to ensure no older batches are present which should have been distributed before recent arrivals. Also regularly check the integrity of the stocks by reviewing the status of the VVMs for each batch or lot.
Only vaccine stocks which are fit for use should be included in stock records. Any expired vials, damaged vials or vials with VVMs at and beyond their discard point should not appear in the available stock balance. If such vaccines need to be kept until accounting or auditing procedures have been completed for example, they should be recorded on a separate page or card until disposal.

All records should be kept safe for at least 3 years and available for review and archive afterwards following the organization procedures for such documents.

3.2.2. Issuing vaccine and supplies

Vaccines and supplies can be delivered to health facilities through push or pull system. In case of push system, the mode of delivery determines the communication with health facilities focal persons..

1. **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, 'promoting' vaccine in this way should be done with care because it may cause a 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 diluent 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 diluent is always kept and distributed with each vaccine type and batch.

3.2.3 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 to ensure that all details are correctly recorded. For each consignment that is distributed, record:

- **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 diluent; quantity distributed (in doses); vaccine/diluent 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).

- 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 at least 3 years and archive following the organizations procedures.

Factors affecting vaccine stock level

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

3.3. Physical inventory

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 vaccines, diluent 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

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
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

a. detail plan with schedule
b. arranging required staffs
c. organize the cold and dry store

d. Count all the products (vaccines, diluents, syringes etc.)
e. Update the stock keeping records
f. Take action based on the results of the inventory.
g. discuss the findings of the inventory with the facility staff members
h. Prepare detailed report of the inventory findings

Note:

1. Recommendation: Central EPSA should conduct inventory biannual while EPSA hubs and health facilities to conduct quarterly and monthly respectively.
2. At all level – conduct a physical inventory and update the stock recording formats whenever you prepare VRF for resupply.

3.4. Managing expired and damaged stock

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 have 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 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.

Exercise

Exercise 1: Factors affecting stock levels

You will receive blank cards/sticker and markers for this exercise.

- Think about factors effecting stocks. Write down these factors on note book. You can write as many factories you want. When writing down, be specific.
- When all participants are done with writing, discuss and write down all participants idea on the flip chart
- When doing this, discuss your reasoning with the group. Discuss the whole picture when it is complete

Exercise 2

Complete vaccine ledger based on the following data found at Woreda "X" cold store. On 20/03/2013 "X" Woreda received the following vaccines from "Z" EPSA hub:

Antigen	Formulation/ Presentation	dose	VVM status	Expiry date	Batch#	Remarks
BCG	20	2000	1st	Nov. 2023	004N0128	
DPT-HepB-Hib	1	1800	2nd	March. 2023	044N0130	
Measles	10	1800	1st	Aug .2023	004N0141	
PCV13	4	1800	2nd	June. 2023	004G0128	
OPV	10	1800	1st	June .2023	054N0133	
Td	10	2000	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 "K" HC received 200 doses of Td of Batch # 064L0145 with the 1st VVM status and **July. 2014** expiry date. After 2 days "K" HC issued 20 doses of Td of Batch # 064L0146 to "L" health post with the 1st VVM status and July. 2014 expiry date. On the same day afternoon "L" HP after vaccinating 8 girls returned 10 doses of Td of Batch # 064L0146 to "K" health Centre with the 2nd VVM status and July. 2014 expiry date. All the transactions are for routine EPI purpose.

Module 4: Vaccine distribution systems

Learning Objectives

By the end of session you will be able to:

- Describe the concept of good storage and distribution practice
- Perform distribution planning
- List the information needed on receipt and distribution forms
- Identify and minimize potential risks to transported vaccine
- Able to Conduct and interpret shake test.
- Identify pre and post-delivery notification requirements

This module is going to be covered within 3 hours by a brief introduction, a small group discussion, group exercise, demonstration and video, plenary presentation and discussion. Vaccine requisition format, shake test poster/ job aid and shake test video will be used as a training material.

4.1. Introduction:

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 distribution chain. In addition, good stock 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 system

A well-run vaccine storage and distribution system should:

- Maintain a constant supply of vaccine, injection equipment and waste management supplies;
- Keep vaccines, injection equipment and waste management supplies in good condition;
- Ensure timely vaccine distribution using VRF
- Ensure bundling of vaccine is practiced at all level
- Minimize vaccine wastage attributable to spoilage and expiry;
- Maintain accurate and up to date inventory records using stock monitoring tool
- Use temperature monitoring tool during transportation
- Rationalize the locations where vaccine and other supplies are stored;
- Use available transport as efficiently as possible.
- Ensure safe disposal of used injection equipment, discarded vials and other toxic and hazardous waste generated by the distribution system;

A good distribution system is cost-effective. This requires systematic cost-effectiveness analysis and operational planning. Once the system is in place, regular performance monitoring is needed in order to

ensure that it functions as intended and can adapt to changing circumstances.
In designing or redesigning a vaccine distribution system it is necessary to:

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

Table 6: Recommended stock level and supplies distribution at each level

Level	Recommended Reorder Period	Maximum Months of Stock	Minimum Months of Stock
Central	**3 months**	**6 Month**	**1 Month**
EPSA 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 system, 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 vaccine and other EPI supplies distribution and/or collection planning is very important. The vaccine distribution plan has to be agreed plan among the issuing and receiving stores. The same copy of distribution plan should be available at both stores. The plan should include;

- Time table or schedule of the distribution,
- mode of transportation and available transportation capacity,
- required and available storage capacity,
- Human resource required and
- List of item to be bundled (vaccine, diluent, AD syringes, mixing syringes, dropper, etc.)

4.4. Planning for vaccine distribution or collection

4.4.1. Ordering vaccines

To avoid vaccine stock out, over stock and excessive ordering, every order for vaccines and other immunization supplies should take into account the following considerations:

- 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 recommended by 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 the WHO and UNICEF's "bundling" strategy is adopted and followed up based on the WHO and UNICEF recommendation on "bundling" the supplies.

Bundling

The term bundling defines the concept of a bundle, which comprises the following items:

- Good quality vaccines[5] , adequate diluents and droppers.
- A-D syringes and mixing syringes
- Safety boxes.
- Printing materials if any.

The implication is that none of the components can be considered alone; each component must be considered as part of a bundle that contains the other two. Bundling has no physical connotation and does not imply that the three items must be packaged together. Since all the annual quantities of vaccine cannot be used or stored at once, divide up the supply and determine separate supply periods for each vaccine store. Stock levels will also be determined and used as indicators when placing orders for vaccines.

4.4.2. Processing Requisitions

Because of cold chain storage limitation vaccine and supplies stored at different level of the immunization supply chain system for specific period of time. Regular inventory of stock and ordering of vaccine based on the acceptable standard review period is very important to avoid stock out and over stock of vaccines and supplies. At all level of the supply chain system 25% of safety stock hold to prevent stock out of vaccines and supplies for unforeseen events.

At all level the immunization supply chain system there is a recommended supply period for each level. Health facilities and districts place order monthly to EPSA hubs place order in every quarter to PFSA central. Responsible staff should know how to process requisitions received from the intermediate stores. The responsible health worker has to place order of vaccine based on the stock at hand and forecasted vaccine plan. All requisitions should be checked against the agreed distribution plan. Where unexpectedly high or low requisitions are received, these should be queried.

4.4.3. Vaccine Requisition Form

Vaccine requisition form is used to place monthly or quarterly order of vaccines and supplies to the next level of the supply chain system. EPSA hubs place vaccine and supplies request to EPSA central office in quarterly basis; and Woreda and health facilities request their monthly demand using VRF from EPSA hubs. The vaccine requisition form should be submitted to next level of the supply chain regularly before the end of the

[5] Not expired, VVM in good conditions

period to avoid stock out because of the lead time. (See the **Error! Reference source not found.**4 below or Annex 1 for the Standard requisition form used in Ethiopia). Regional health bureau or Zonal health departments monitor and evaluate VRF reporting rate, consumption rate, stock levels, and storage conditions and provide feedback to facilities and all Woredas

.

Vaccine Request Form

Ministry of Health

EPSA

Region/Zone/Woreda		Level of cold chain	Date of request:
Name of cold store		● RHB/HUB Cold room	No. of months to supply (S):
Responsible Person		○ Zonal store	For population catchment ser
Contact Address		○ Woreda	Births (BI):
Telephone Number(s):		○ Health facility (H/HC/HP)	Surviving infants (SI):
			Girls of age 9 year

Antigen	Doses/pieces	Waste 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 Dileunt	2	1.54	100%										
Pneumecoocal 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%										
Mixing syringe (BCG)		1.05	100%										
Mixing syringe (Measles)		1.05	100%										
Safety box		1.05	100%										

Figure 4: Standard Vaccine Requisition Forms used in Ethiopia

4.4.4 Establish a pre-delivery or pre-collection notification system

When vaccines are delivered, responsible staff at the receiving store should know well in advance when the shipment is due to arrive. Establish an effective procedure for doing this. Notification may be by post, telephone, email, text message, social media or fax.

- In the case of deliveries, the receiving store may need to prepare the store to receive the shipment, for example by re-organizing existing stock to free space in cold rooms and freezers.
- There must also be an authorized staff member on hand to receive, check and sign for the vaccine.
- If case of pull system, staff should know well in advance when the collection is to be made so that they have time to prepare icepacks and to pack the vaccine in preparation for the collection.

4.4.5. Planning for icepack / cool water pack preparation

You must make your plans in advance and start freezing ice packs several days before you need them, depending on your requirements. You may sometimes need a large number of ice packs such as in a pulse polio campaign or a mop up round. Salt should never be added to the water, as it lowers the temperature to sub-zero level, which is not recommended for Td, DPT-HepB-Hib, PCV, Rota and IPV vaccine. Once the ice packs are fully frozen, fresh set of ice packs can be prepared. For health facility utilization of Cool water pack is recommended.

At Health facility level

1. Calculate the requirement of the chilled 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.
2. Add adequate ice packs for preparation of cold box at the time of emergency. It will be your total requirement.
3. Start freezing five day before the immunization day.

At National, Sub national and Woreda level

1. Calculate the requirement of the icepack or cool water packs based on vaccine distribution and/ collection program. It is also important to consider campaigns.
2. Based on the level of vaccine distribution, and volume of the vaccine add adequate ice packs of cool water at the time of emergency. It will be your total requirement.
3. Stack 20-25 (depending upon the ambient temperature) unfrozen ice packs and allow freezing for 24 hrs in the large compartment of Deep Freezer.
4. The next batch of 20-25 unfrozen packs are to be kept on the top of the frozen ice packs.
5. 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.
6. Continue the procedure till you get required numbers of ice packs.

4.4.6. 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”. The standard advice has been that an icepack is adequately “conditioned” as soon as beads of water cover its surface. Experiments have shown that this is not always the case and that cold-sensitive vaccines -particularly HepB - can still freeze inside the cold box even when icepacks have apparently been conditioned correctly. 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 Ice-Pack has been conditioned by shaking it and listening for water.

Figure 5: *Ice/water pack conditioning*

To make chilled 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. Chilled water can be made in a Vaccine cold room or refrigerator (but avoids contact between the water packs and the vaccines). To use chilled water packs, load chilled water packs into cold boxes and vaccine carriers just as you would load frozen ice packs. But do not condition chilled water packs before loading vaccines.

The intermediate store or the health facility collects vaccine. In this case the store supplying the vaccine provides frozen 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.

The intermediate store or health facility receives vaccine. In this case the store supplying the vaccine provides both the cold boxes/vaccine carrier and the frozen ice packs. The vaccine is delivered and the empty cold boxes /vaccine carrier and the melted ice packs are returned to base. These have to be stored until the next delivery is made.

Remember:

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

Making chilled water packs:

The only way to eliminate the freezing risk entirely is to transport liquid vaccines, other than OPV, in cold boxes lined with cool water-packs which have been pre cooled in a refrigerator to a temperature of +2°C to +8°C. Where it is essential to transport OPV, liquid and freeze-dried vaccines in a single carrier, experiments have shown that cool water-packs may safely be used provided the cool life6 of the carrier is not exceeded. Changing over to the use of cool water-packs involves significant changes in practice. In addition there are equipment implications because additional refrigerators will be needed at primary and sub-national level to cool the water-packs in bulk.

Where to chill water packs:

- Vaccine cold room—but avoids contact between the water packs and the vaccines.
- Refrigerator—but not if the refrigerator is also used to store vaccines

Packing area:

The vaccine packing area should connect to a direct route between 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 so as to encourage a logical flow of work. Vaccines should be moved as little as possible in order to minimize the risk of breakage. There should be a sink in the packing area for hand-washing and provision for hygienic hand-drying.

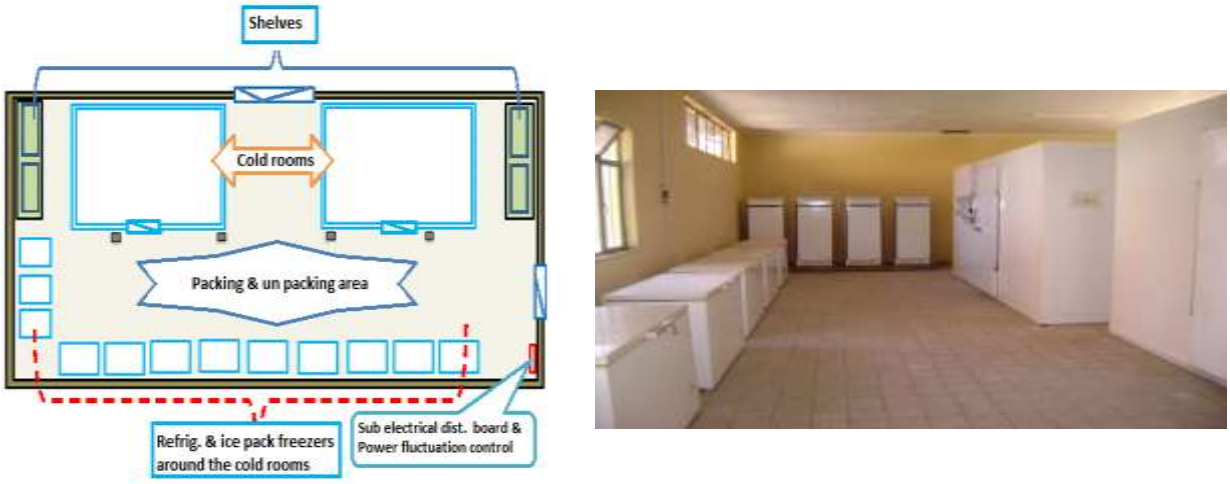


Figure 6: Example of Packing Layout of cold room

[6] *Cool life with cool water-packs at +5°C: Cool life is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches +20°C, at a constant ambient temperature of +43°C. (*http://apps.who.int/immunization_standards/ vaccine_quality/pqs_catalogue/index, accessed May 2016)

4.5. 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 for outreach sessions, 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 -20°C. The practice of immediately placing unconditioned ice packs in well-insulated cold boxes places freeze-sensitive vaccines at the greatest risk. Responsible personnel should ensure that the packing area is correctly organized to process the maximum daily throughput of vaccine and to accommodate the number of personnel employed to pack vaccine for dispatch. 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.

4.5.1 How to pack cold boxes?

1. Place conditioned ice packs 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.
2. Make sure that the cold box is cool to prevent early melting
3. Stack vaccine and diluents in the box.
4. Place conditioned ice packs over the top of the vaccine and diluents.
5. Place the plastic sheet to cover the ice packs kept on top to ensure full hold over time.
6. Secure the lid tightly.
7. Do not open the lid when not required.

4.5.2 How to pack a vaccine carrier

1. Confirm that there are no cracks in the walls of the vaccine carrier.
2. Make sure that the vaccine carrier is cool to prevent early melting
3. 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.
4. 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

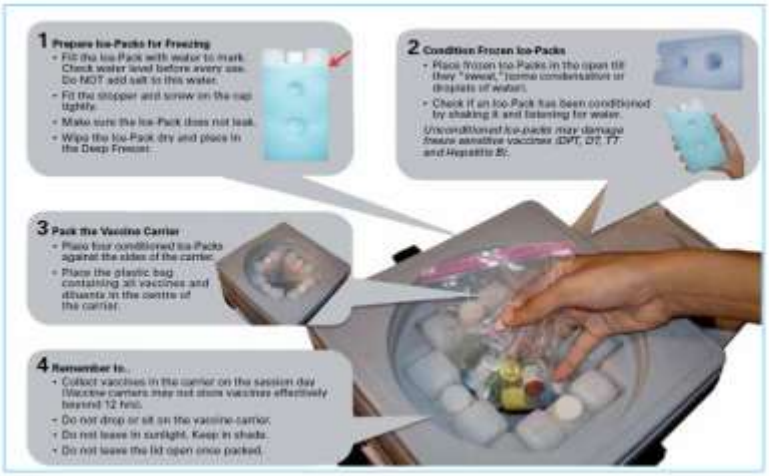


Figure 7: Packing vaccine carrier

- Collect vaccines in the carrier on the session day (Vaccine carriers may not store vaccines effectively beyond 12 hrs).
    - 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.

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.

4.6. Packing and Loading of vaccine and diluents for refrigerated truck

a. Wash your hands and use clean gloves.

b. Pack the vaccine and diluent cartons in the shipping containers or cartons with the vial caps uppermost.

c. Use newspaper or other loose packing to ensure that the load cannot shift during transport.

d. Place a packing list in the container/carton on top of the contents.

e. Place a freeze indicator into at least one container/carton per destination.

f. Label the container/carton with the final destination.

g. Temporary workers: Have the pack-out checked by your supervisor.

h. If there is a lid: Close the lid or seal the carton with packing tape.

i. Keep the shipping containers/cartons in a cold room (+2°C to +8°C) until the vehicle is ready to load. Alternatively, load them into the pre-cooled vehicle immediately after packing.

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 equipment and how to safeguard the vaccine throughout the journey. Details of all journeys must be recorded by the driver in the vehicle log book/route report.

Preparation

- Avail sufficient space in the supplying store to stack delivery crates where these are used to pack vaccines before loading into the vehicle.
- 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 each delivery. If the vehicle has been used for purposes other than the transport of vaccines or pharmaceuticals, disinfect the interior.
- Clean reusable shipping containers before each delivery.
- Maintain 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. If vaccine is being shipped on pallets or in pallet boxes, this is not necessary, because the pallet itself will allow air to circulate.

Pre-cool the refrigerated Compartment

Before loading the vaccine the refrigerated compartment should be the Pre-cooled and to pre-cool:

- Park the vehicle in the shade, and preferably under cover.
- Close the doors and pre-cool the refrigerated compartment to +2°C to +8°C before loading vaccine. Use mains electricity to power the refrigeration unit if this option is available.
- If Vehicles 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 loggers in use securely attach an activated temperature data logger device in the refrigerated compartment. Record the time of activation on the Trip Record.

Figure 8: 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.
- Use clean gloves.
- 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: give key to driver.
- 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.

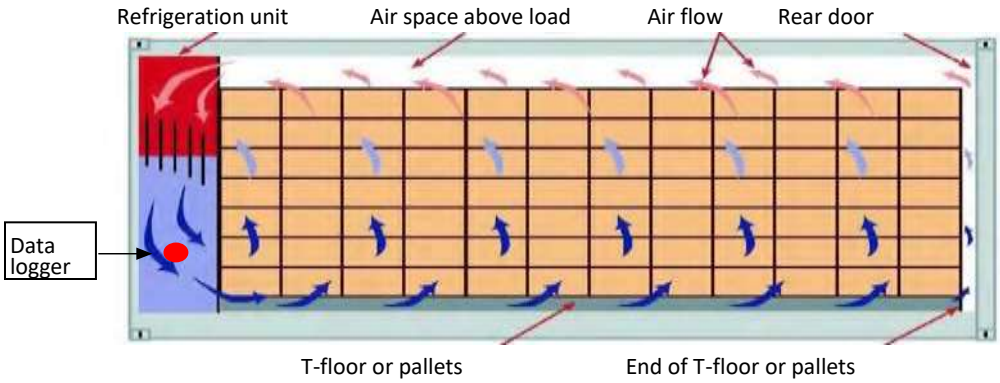


Figure 9: Air flow in cold room

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. Use mains electricity to power the refrigeration unit if this option is available.
- During the unloading operation, keep the loading door open for the minimum time possible
- Use clean gloves.
- Take the shipping containers into the store 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 is kept locked.
- Ensure that one person remains with the vehicle at all times.
- Continue to run the refrigeration unit throughout the overnight stop. Use mains electricity to power the refrigeration unit if this option is available.

- 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.

4.7. Monitoring temperature exposure during vaccine transport

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

4.7.1 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.

4.7.2 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

4.8. Arrival checks and reporting procedures

- Check and record the quantity
- ***Check freeze indicator(s)****:* 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
- ***Check VVMs****:* 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 Issue Voucher (Model 19)****:* 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 EPSA hub level.

- ***Complete and send Returning Voucher (Model 22)****:* Receiving stores should send the completed returning Voucher (Model 22) to the issuing store.
- ***Return the freeze indicators****:* Return devices to the issuing store as soon as possible. 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.

4.9. 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. After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes which gradually settle to the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen. Note that individual batches of vaccine may behave differently from one another. Therefore the test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.

Test procedure:

1. ***Prepare a frozen control sample****:* Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer. Freeze the vial until the contents are solid (at least for 10 hrs), and then let it thaw. This vial is the control sample. Clearly mark the vial so that it cannot later be used by mistake.
2. ***Choose a test sample:*** Take a vial of vaccine from the batch that you suspect has been frozen. This is the test sample.
3. ***Shake the control and test samples:*** Hold the control sample and the test sample together in one hand and shake vigorously for 10-15 seconds.
4. *Allow to rest:* Leave both vials to rest on a flat surface.
5. ***Compare the vials:*** View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample 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 that none of this 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 10: Shake test

The shake test
See the difference in sedimentation rates

The following 4 photographs were taken on 6 August 2003 in Suva, Fiji during the primary vaccine store assessment (Richard Duncan (WPRO) and Diana Chang-Blanc (PATH) on the background). The demonstration was conducted with BioFarma 10 dose TT vaccine. For better visualization, the labels are scrubbed off. The control vial (on the left) was purposely frozen solid at -25oC for 4 hours. In principle, you do not need to wait this long. The moment you are confident that you can tell whether the sedimentation rates are different or same in two vials, you may end the test. In this demonstration, the test vial on the right sediments slower compared to the control vial: The test vial has not been affected by freezing, and may be used safely.

Exercise:

Exercise 1:

Work out the following exercise individually and discuss your answer in small group or during plenary session.

QUESTION	ANSWER
1. How do you avoid freezing during transportation?	
2. Which temperature indicator status should be mentioned on a dispatch form?	
2 . True or false? 15minutes of keeping the frozen icepacks in the room temperature is enough for conditioning.	
3. List at least two vital information that need to be entered in a dispatch form?	
4. What temperature monitoring device should be included in transportation of all freeze sensitive vaccines?	
6. Give one characteristic of a good storage and distribution system?	
7. What are two unsatisfactory delivery conditions?	
8. 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?	
9. What do you do when you receive lesser quantity of vaccines than it is indicated in the dispatch form?	
10. True or false?: Shake test is conducted with a suspected vial and a never frozen sample.	
11. What should you do first if a recipient facility orders a higher quantity than it is expected.	
12. True or False?: Direct sunlight should be excluded from the packing room and ideally there should be no fluorescent lighting.	
13. Give two reasons for short shipments from a primary store to an intermediate store.	
14. When you receive a delivery of vaccine that is heat damaged, where do you register this wastage?	
15. Which vaccine should be transported with frozen ice packs?	

Exercise 2: 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

Considering that the stocks available are taken into account 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

Module 5: Vaccine wastage

Learning Objectives

By the end of this session you will be able to:

1. Understand how to compute and monitor vaccine wastage rate
2. Identify the different types of vaccine wastage at different level supply chain
3. Identify and prioritize the factors that affect wastage rate, what can be eliminated, what can be minimized
4. Ensure the stock control system is designed to record vaccine and diluents in un opened vial
5. Ensure wastage rate is calculated based on the up to date data from the specified facility
6. Evaluate this data to improve the management of vaccines, and minimize wastage
7. Describe the policy or tools that can reduce wastage

This module covers, introduction, small group work, plenary presentation and brief summary, for this vaccine management training manual & flip chart will be used, total time allocated for this module is 3:30hrs

5.1. Introduction[7]

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 programmes; 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 programme to introduce actions whenever necessary.

[7] Monitoring vaccine wastage rate at country level: Guide for program manager: (WHO/V&B/03.18) http://www.who.int/iris/handle/10665/68463

5.2. What is vaccine wastage and how is it calculated?

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, i.e.

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

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

$$\text{Vaccine wastage rate} = 100 - \text{vaccine usage rate}$$

5.3.1. 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.

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

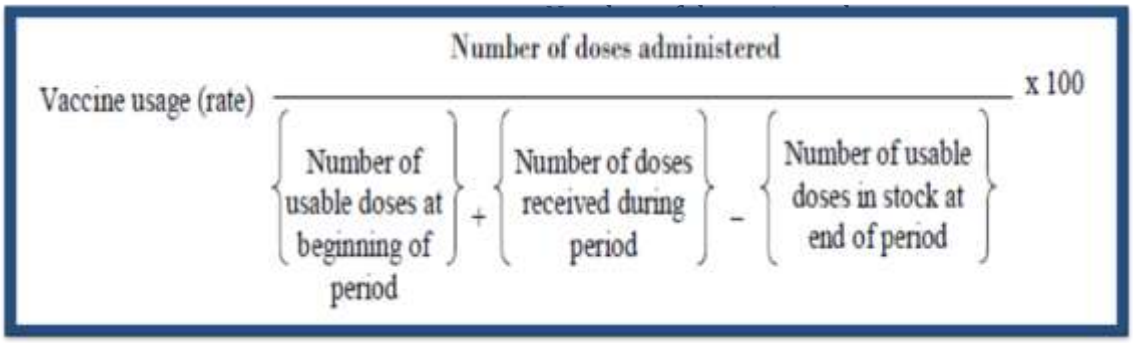
The number of doses discarded includes all discards of unopened vials because of expiry, VVM indication, heat exposure, breakage, freezing, missing inventory and theft. This rate, which is specific for vaccine stores, should not be used for comparison with the vaccine wastage rate explained above. It 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 is the acceptable level for such failures. 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.

5.2.1. Vaccine wastage calculations at service level

All immunization points monitor their coverage rates on a monthly basis. 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.

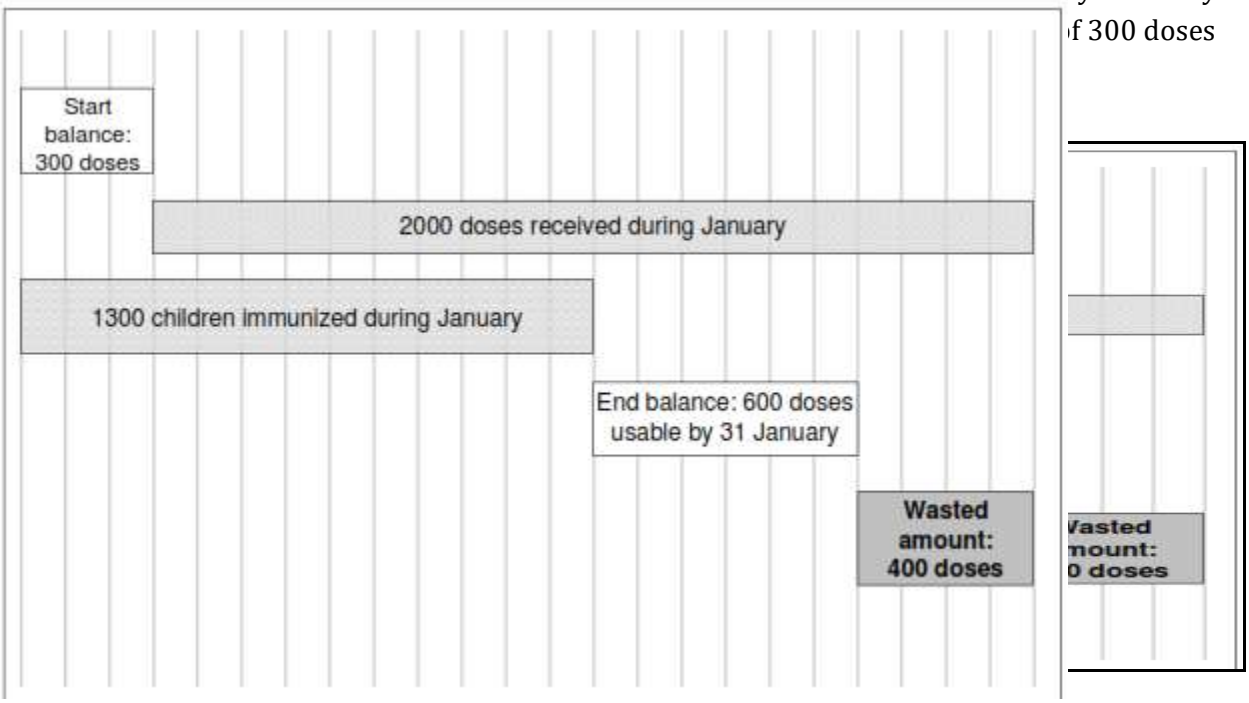
$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{\text{Number of usable doses at beginning of period} + \text{Number of doses received during period} - \text{Number of usable doses in stock at end of period}} \times 100$$



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.

Example

"X" Health Centre received 2000 doses of OPV vaccine in 20-dose vials in January. Monthly



On the basis of the above formulas:

$$\text{Vaccine usage rate} = \frac{1300}{300 + 2000 - 600} \times 100 = \underline{76\%}$$

Vaccine wastage rate = 100 – 76 = 24%.
The vaccine wastage rate can also be calculated without going through vaccine usage rate, as follows.

$$\text{Vaccine wastage (rate)} = \frac{\text{Number of doses wasted}}{\text{Number of doses issued/used}} \times 100$$

In detail this formula can be rewritten as follows:

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

In these calculations 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 programme 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.

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.

5.3. Types of vaccine wastage

No matter how successful a programme is, some vaccine wastage can be expected. Many factors influence vaccine wastage. Improved vaccine management practices are the key to addressing vaccine wastage as a whole.

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 as a consequence 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 programme-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 programme implications but involves unopened vials.

In this manual, vaccine wastage is classified as occurring "in unopened vials" and "in opened vials".

Table 7: 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 not attached	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 (Annex 1).
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.

5.4. Reducing vaccine wastage

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

1. 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.

2. Vaccine stores should monitor their wastage rates on a monthly basis.

3. 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.

4. 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.

5. 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 analysed

5.4.2 Factors contributing to reduction of wastage rate

Immunization managers has consider all factors contributing to reduction of wastage rate when

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

5.4.3 Adopt global policies so as to increase the effectiveness of the system

1. Vaccine vial monitors (VVM)

The effective use of VVMs 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 colour 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 end-point 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 8: Summary of how a vaccine vial monitor works

Questions	Response
What is a vaccine vial monitor?	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 colour 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 colour 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 colour 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 colour reflectance densitometer in order to ensure that the VVM changes colour 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	Vaccine used for emergency response for COVID pandamic have no VVM, Strengent temperature monitoring should be in place using available temperature monitoring devices

2. **Multi dose vial policy**

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 8362-2. (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.

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

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

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

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

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.

FEFO handling is safer than FIFO handling.

3. 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.

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 9: The relationships between immunization coverage and vaccine wastage

Immunization coverage	Vaccine wastage	Where to focus
Same	Same	Types of vaccine wastage should be analysed 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 analysing 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 multidose 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.

Exercises

Exercise 1: Discuss in small groups and classify the following vaccine loss in Wasted **and** Sacrificed **doses:**

1. Doses of Measles administered to children aged 4 years
2. Doses of frozen DPT-HepB-Hib vials
3. Doses in expired vials
4. Doses of Td administered to the informal sector
5. OPV vials with VVM reached discard point
6. Measles vaccine from a 10-dose vial used only for two children
7. Opened OPV vials thrown away at the end of immunization session

Exercise 2: A health center serving a population of 10,000 with surviving infants of 3.6% has one static and three outreach EPI sites. The numbers of children vaccinated for measles in one month were 18 under one year (0-11 months old) and two 12-23 month old children. During the same month the health center has received 10 vials of 10-dose measles vaccine from the district health office and another 5 of the same dose vials carried forward from the previous month. At the end of the same month it was find out that five vials were used for vaccinating children, three vials reported to be discarded because the ice melted during the outreach session, five vials were available at the end of the month in the refrigerator and nothing was known what happened to the remaining two vials.

1. What is the measles vaccine wastage?

   a. Calculate the vaccine wastage rate

   b. And what are the types of vaccine wastage?

2. What are the causes of the vaccine wastage?

3. What can the health center do to decrease its vaccine wastage rate?

Section II: Cold Chain Management

This section of the vaccine management training manual provides technical guidance on the use of cold-chain equipment, types and use of temperature-monitoring devices, the cold chain requirement emergency plan and the basic preventive maintenance of cold-chain equipment. *In addition to this reliability of the cold chain equipment and the significance of temperature monitoring were addressed. Unlike the previous manual, refrigerator truck temperature monitoring devices and its utilization was also in this version of the manual. The section has two modules.*

The vaccine management section modules are,

Module 6: The Cold chain

Module 7: The reliability of the cold chain

Module 6: The cold chain

Learning Objectives

After the training, the trainees should be able to:

1. Understand what cold chain system is
2. Identify cold chain equipment needed, including UCC equipment
3. Calculate cold storage capacity required
4. Describe the different cold chain temperature monitoring tools and their use

Training methods includes reading of the manual, small group discussion and group work, demonstrations of cold chain equipment and temperature monitoring devices, plenary presentations and discussion.

Training materials needed

- Pictorial aid (photo or posters) cold chain equipment
- Cold chain temperature monitoring tools (Fridge tag, freeze tag, CCM, Q-tag® CLm, etc.)
- Cold boxes, vaccine carriers, vaccine samples with different types VVM, foam pads, ice packs

6.1. Introduction

The cold chain system is a means for storing and transporting vaccines in a potent state from the manufacturer of the vaccine to the person being immunized. The cold chain and management system comprises three major elements:

- Personnel who use and maintain the equipment and provide the health service.
- Equipment for safe storage and transportation of vaccine.
- Procedures and information to manage the programs and control the distribution and use of vaccine.

The cold chain consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges, from the point of manufacture to the point of administration. Figure 1 illustrates the complete cold chain. The bottom row of arrows shows the flow of vaccines down to the health facilities; the top row of arrows shows where data are collected, recorded, checked and 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.

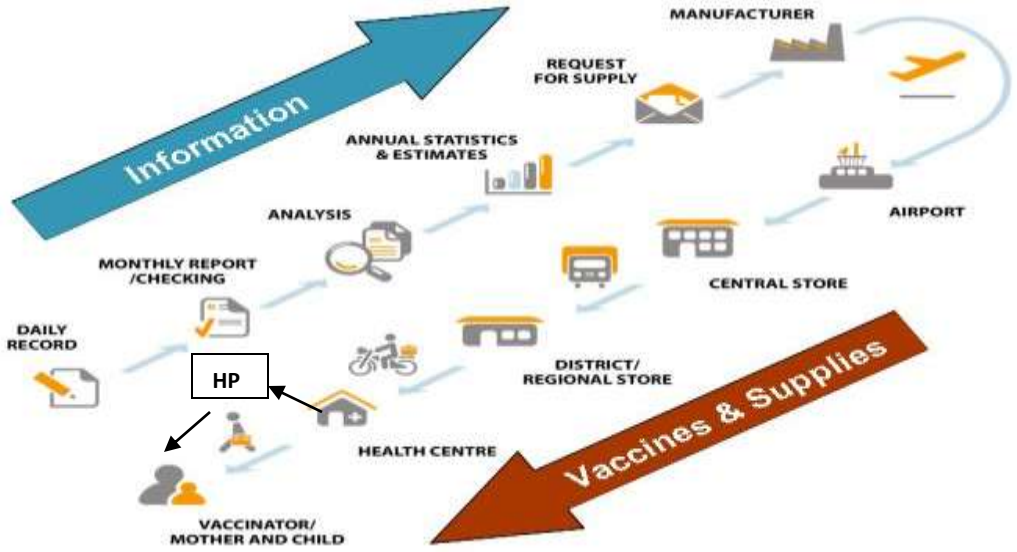


Figure 1: The cold chain system

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 equipments 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.

6.2. Cold chain equipment by refrigeration technologies

There are two common refrigeration systems known as compression and absorption refrigeration.

6.2.1 Compression refrigeration (Compression cycle appliances)

Compression refrigeration uses compressors to drive the cooling process. The compressor is powered by electricity. 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) 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, etc.) developed. (See annex 3 for list of optimal cold chain equipment)

6.2.1.1 Cold Rooms and freezer rooms

These are used for bulk storage of vaccines at EPSA Center and EPSA Hubs stores. They maintain a temperature (+2^{o}C to +8^{o}C cold rooms) & (-25^{o}C to -15^{o}C freezer rooms). They are available in different sizes. These are used for storage of large quantities of vaccines. They have two identical cooling units and standby generator sets with automatic or manual start and stop facilities. They are also provided with temperature recorder and alarm systems.

Figure 2: Clod room/freezer room

6.2.1.2 Refrigerator trucks

A refrigerator truck is a van or truck designed to carry perishable freight at specific temperatures. Like refrigerator cars, refrigerated trucks differ from simple insulated and ventilated vans (commonly used for transporting fruit and vaccines), neither of which are fitted with cooling apparatus. Refrigerator trucks can be ice-cooled, equipped with any one of a variety of mechanical refrigeration systems powered by small displacement diesel engines, or utilize carbon dioxide (either as dry ice or in liquid form) as a cooling agent.

Figure 3: Refrigerated truck for vaccine

6.2.1.3 Deep Freezers

Deep Freezers with top opening lids have been supplied under the immunization programme. The cabinet temperature is maintained between -15°C to -25°C. 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 -15°C to -25°C for 18 & 26 hours at ambient temperatures of 42°C and 32°C 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.

6.2.1.4 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 approved for emergency use requires low temperature as (-80 °C/-60 °C) for storage and transportation and using and using available ULT insulated containers on the market recommended to use for Covid-19 vaccines.

Figure 14: 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.

1. 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.

2. 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 -15°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

6.2.1.5 Ice Lined Refrigerator (ILR)

These type 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 vaccine safe only with as little as 8 hours continuous electricity supply in a 24-hour period. It is available in different sizes. For example; ILR- Model MK 304 of vaccine storage capacity 105 liters or 26000 to 30000 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 start using 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 vaccine safe.

Remember

- Keep all vaccine in 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 basket.

6.2.1.6 Solar Refrigerators (Solar-powered refrigerators)

a. Battery Powered Solar Refrigerators

A solar refrigerator operate on the same principle as normal compression refrigerators but incorporate 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 started.

b. Solar Direct Drive refrigerators

Solar Direct Drive refrigeration systems are the new generation of solar powered refrigeration systems bypassing the use of a battery. Instead of the battery, the power is stored using different non battery based technologies. 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 (SureChill)) 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, more additional optimal SDD refrigerators are expected to be deployed in the country.

Figure 45: Solar refrigerator

6.2.2 Absorption type refrigerators

The absorption system is unique in refrigeration since it involves no moving parts. Continuous absorption types of refrigerators have four main sections: the boiler (generator), the condenser, the evaporator and the absorber.

The four sections are connected by steel tubes. The entire system is welded together. The necessary heat for generation is obtained by using a gas burner, kerosene burner or electric heating element at the boiler (generator).

The system is charged with ammonia, water and hydrogen. The amount of the combined solution is at a pressure which will allow the ammonia to condense at room temperature.

It is important that

- Understand that the entire cycle is carried out entirely by gravity flow of the refrigerant.
- The unit remain in a level, upright position.
- The heat generated in the absorber be removed and that the heat removed by the condenser be carried away by the surrounding atmosphere.

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

- SIBIR – Sibir V170KE, Sibir V110 EK
- Dometics - RCW50KE,
- Zero Refrigerators – PR 245, PR265KE

As all absorption refrigerators are non-optimal and the process of decommissioning and removing them from the system is undergoing, and in the near future all absorption refrigerators will be replaced by optimal CCE.

6.3. Passive Cold Chain devices

Passive device is a technology uses super insulation techniques that designed to keep vaccines at appropriate temperatures for specific period of time and no need for electricity. Vaccine carriers, Cold boxes, and long term passive vaccine storage device (Arktek™), can keep vaccine at appropriate temperature for 24 hours, 5 days and a month respectively.

6.3.1 Cold Box

Cold boxes are big insulated boxes. These are of different sizes- 5, 7.2, 8, 20, 22 and 23.1 liters with requisite number of ice packs. The 5 & 8 liters cold box can transport about 1500 & 2400 doses of mixed antigen vaccines respectively and 20-22 liters cold box has enough space to transport about 6000 – 6600 doses of mixed antigen vaccines respectively. Freeze free vaccine cold boxes which don't need cool water pack or condition Ice packs produced and available in the market. As of July 31st 2021 onne model of freeze free cold box with 15.7 lit storage capacity pre-qualified by WHO on 20th May 2020.

Figure 56: Cold boxes

Figure 17: Freeze-Free Vaccine Cold Box

Uses of cold boxes

1. Collect and transport large quantities of vaccines.
2. 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.
3. Store vaccine in case of breakdown of refrigerators.

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

1. Clean and dry after every use.
2. Do not keep any load over the cold box.
3. The lid of the box should be kept unlocked and opened in the store while box is not in use. This will increase the life of the rubber seal
4. Examine inside and outside surface after every use for cracks.

5. Check that the rubber seal around the lid is not broken; if broken, replace immediately.
6. Knock and sunlight can cause cracks inside the wall and lid of the cold boxes.
7. Lubricate hinges and locks routinely.

6.3.2 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 icepacks; hence only conditioned/chilled waterparks should be used. Different model of freeze free vaccine carriers which don't need cool water pack or condition ice packs produced and available in the market. As of July 31st 2021 about of model of freeze free vaccine carriers with 1.5, 1.7, 1.6 1.511and 1.04 lit storage capacity pre-qualified by WHO on 08 Dec.2017, 28 Aug. 2018, 3 April 2019, 22 Sep 2020 and 30 Sep 2020 respectively.

Figure 18: 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 vaccine carrier containing two ice packs. except Vaccine carriers made for 2 water packs

6.3.3 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 small target population.

6.3.4 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 ºC to -60 ºC) 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:

1. Vaccine rack
2. ULT PCM metal packs

Figure 19: ULT insulated containers (Arktek)

6.3.4 Ice Packs and their use

Ice packs are 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 -15^{o}C to -25^{o}C. 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.

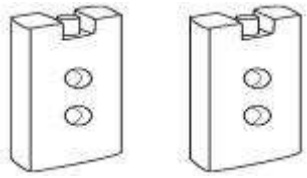


Figure 20: Ice/Water packs

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.

6.3.5 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.

6.3.6 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 Figur below.

Figure 21: Foam pad in use

6.4 Personal Protective Equipment (PPE)

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

6.5 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 23).

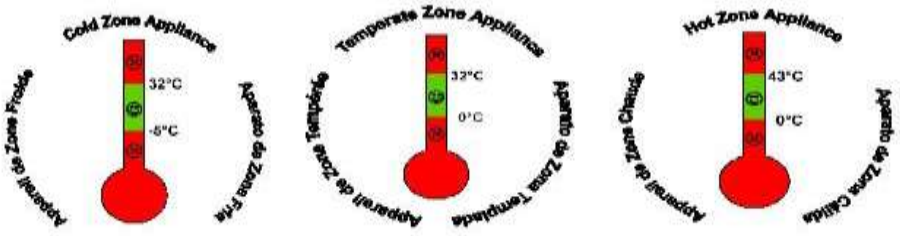


Figure 22: Temperature zones

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.

6.6 Optimal (extended cold chain equipment)

Currently manufacturers are developed optimal cold chain equipment with advanced features. Optimal cold chain equipment means devices designed to make accidental freezing of vaccines very unlikely and contribute to reductions in closed vial wastage. In addition, equipment to this,

- able to keep vaccines cool and safe even if the power is out for multiple days (long hold over time) ; and
- keep vaccines cool using dependable solar-powered devices that do not need batteries. (see annex 3 for list of cold chain equipment recently developed and pre-qualified)

6.7 Cold chain options

A rapid logistics evaluation can determine the status of materials and vaccines management at field level, along with the status of the distribution system. Based on this information, and taking into account the geography of the country, programme managers can decide which option to use. Whatever the chosen immunization strategy, the cold chain structure is based on two options: fast cold chain and slow cold chain.

6.7.1 Fast cold chain

The fast cold chain option is based on equipment that retains cold through chilled water packs for transporting vaccines (vaccine carriers and cold boxes ,A). It does not generate cold. The fast cold chain relies on speed, minimizing possible inconveniences related to storage, distribution and handling of vaccines. The fast cold chain can lead to higher distribution costs, but the costs are compensated for in part by placing smaller quantities of vaccines in circulation.

Fast cold chain may work better if the following conditions are observed:

- Refrigeration at the health facility level is not reliable
- Managerial capacity at the health facility level is inadequate
- Reliable and not expensive distribution system is in place
- Distances between levels of health systems are short

6.7.2 Slow cold chain

The slow cold chain, which relies on cold-generating equipment, will reduce the costs of vaccine distribution, but increase the quantity in circulation. Slow cold chain is recommended if:

- Refrigeration at the health facility level is reliable
- Management skills at the health facility level are adequate
- Vaccine distribution system is expensive and unreliable
- Distances between levels of the health systems are long
- This system uses cooling and freezing equipment (such as refrigerators, freezers or cold rooms).

Table 10: Summary of factors to be considered in selecting a cold chain option

Criteria	Cold chain option	
Technical	Fast	slow
Reliability of energy source	Not reliable	Reliable atrocity
Reliability of transport	Reliable	Not reliable
Distances	Short	Long
Quality of stock control	Poor	Good
Handling of vaccines	Poor	Good
Cost of the vaccines	Increased	Moderate

6.8 Calculating required cold chain storage capacity

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. Donor-dependent countries should ensure that a safe worst-case figure is obtained for each antigen, because the manufacturer of the vaccine may not be known until the shipment arrives.

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 vaccine or from the latest version of the WHO vaccine volume calculator.

6.8.1 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 under stocking caused by seasonal fluctuations in demand, campaigns, NIDs, 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 number of dose per vial, number doses of each vaccine per schedule, packed volume of each vaccine and wastage factor of each vaccine. (See the

Table **1**0 below)

Table 10: Calculation of vaccine storage volume per fully immunized child (including three doses of Td for women)

Table 11: 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	40	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

6.8.2 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 equipments in use have 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 equipments 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

6.8.3 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

1. ***Selecting cold chain equipment for health facilities***

"X" 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 centre.

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. 0.2181Supply period for health facility – monthly

Required Storage Volume in liters per one month – (875* 0. 0.2181)/12= 15.9 lit

Note: In addition to monthly vaccine requirement, 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%= 14.48 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 compared the final required capacity with the gross storage capacity of available refrigerator.

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

2. **Selecting cold chain equipment for EPSA 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. 0.2087 and 0.0078 respectively.
  - Supply period for EPSA hub – Quarterly
  - Required cold Storage Volume in liters per supply period for

    Cold storage (+2^{o}c to +8^{o}c)- (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 requirement, the calculation of required storage capacity take into the storage space needed for safety stock. Hence, the total required cold

storage capacity for the above zone will be,

- Cold storage (+2°c to +8°c) - 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 EPSA hub select TCW 4000 AC of 240 lit, a total of 31 Ice lined refrigerators are required to accommodate the total volume of vaccine needed for supply period. For sub national level (EPSA hubs level) cold stores where multiple cold chain equipments are required it is advisable to select cold chain equipments with large net storage capacity. For this particular hub, it is logical to recommend cold room with cold storage capacity8 of about 15 m3.

For freezing storage two MF314 freezers (storage capacity 264lit) can be used.

[8] The grossing factor for cold room with 15 m^3 storage capacity is estimated to be 3.3. (WHO MLM training manual, Module 7: Cold chain management, 2013)

6.9. Temperature monitoring devices

To ensure the stability, safety, and potency of vaccines, adequate cold chain 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. 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 in the next modules.

6.9.1 Vaccine Vial Monitors (VVM)

Vaccine vial monitors (VVMs) are the only temperature-monitoring devices that routinely accompany the vaccine throughout the entire supply chain. A VVM is a chemical indicator label attached to the vaccine container (vial, ampoule or dropper) by the vaccine manufacturer. As the container moves through the supply chain, the VVM records its cumulative heat exposure through a gradual change in colour (see Figure 64). If the colour of the inner square is the same colour or darker than the outer circle, the vaccine has been exposed to too much heat and should be discarded.

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

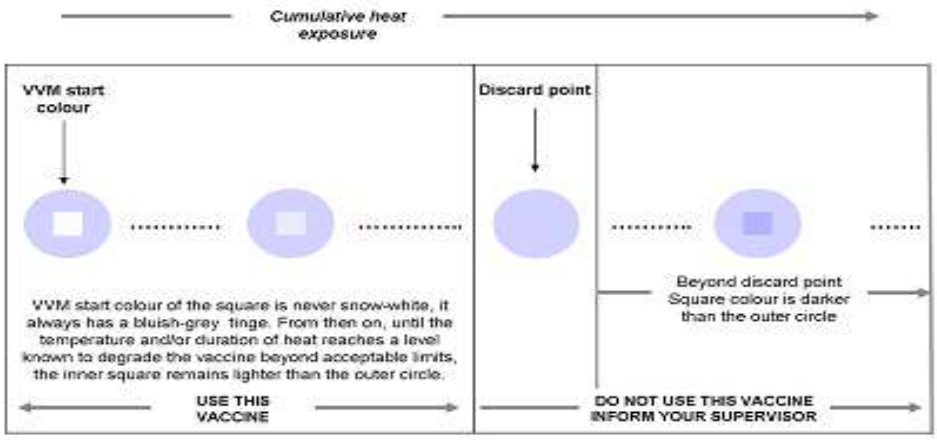


Figure 63: VVM stages

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

Table 22: VVM reaction rates by category of heat stability

Category: (Vaccines)	No. days to end point at +37°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 prevent Covid-19 virus are produced without VVM and to control and monitor their potency and safety, it needs different mechanisms such as continues temperature monitoring devices/data loggers.

6.9.2 Thermometers

Dial Thermometers

Dial thermometers have been provided to record the temperature in the refrigerators/Freezers. It has dial with moving needle to show the temperature of vaccine within the range of -50°C to +50°C. Bi-metallic dial thermometers are no longer recommended because they easily lose their calibration[9].

Figure 74: *Dial thermometer*

[9] http://apps.who.int/immunization_standards/ vaccine_quality/pqs_catalogue/index, accessed May 2020)

Alcohol Stem Thermometers

Alcoholic thermometers are much 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 advice not to use stem thermometer as the primary temperature monitoring device because they do not provide a continuous record of vaccine temperature exposure.

Figure 85: Stem thermometer

6.9.3 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 in to the "alarm" status. Freeze tag and Freeze watch are some of the examples of freeze indicators. For fridge tag with alarm ("×") or activated freeze watch shake test is recommended.

Figure 9: Freeze Indicator

6.9.4. 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 kind 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-sign (✓) is 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.

6.9.5 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 vaccine.

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 10: *Cold chain monitor card (CCM)*

6.9.6 Fridge-Tag

Features of Fridge-Tag2

The electronic data loggers are also being introduced to monitor the temperature of 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 alarm alerts the handlers. This device assists in temperature monitoring through following features:

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

2. It indicates if there was any alarming situation during the past 30 days. The device shows "" (Alarm) on LCD screen if there was any alarming situation in past 30 days. The alarming situation is when the temperature went above +8oc over a consecutive period of ten hours or temperature drops down below -0.5oc for a consecutive period of 60 minutes.
3. It shows the duration of temperature violation for every alarming situation happened in past 30 days on LCD screen. To see the duration of temperature violation, device is equipped with a "Read" button which guides the user through the history of past 30 days starting from "today" till "30 days ago".
4. It shows an "" (OK)" sign if there has been no violation of temperature in past 30 days.
5. It has a shelf life of three years from the date of activation of device. The devise once activated, cannot be stopped through-out its operational life. Hence, it provides round the clock monitoring of refrigerators without any need of intervention of user for three years of time.
6. 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.

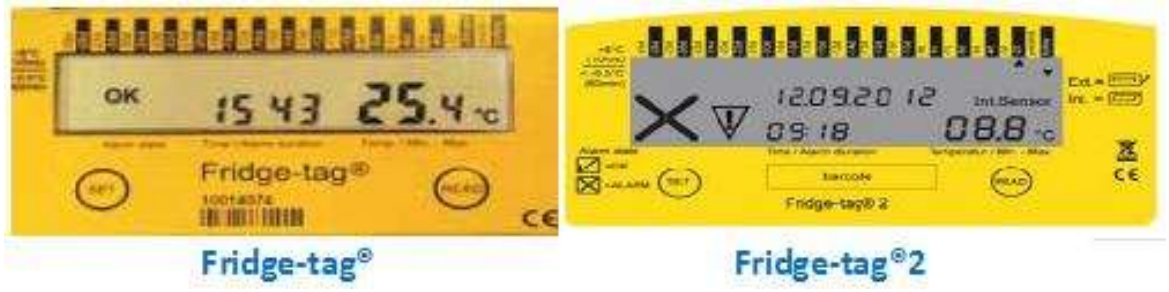


Figure 11: ***Fridge-tag***

6.9.7. 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, over loading, 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 FMOH/EPSA introduced RTMD (FridgeFone) from Beyond Wireless and currently most cold rooms in the country are equipped with remote temperature monitoring device (RTMD).

Figure 12: Fridge-Fone

6.10 Temperature monitoring devices for vaccine transportation[10]

Poorly managed and monitored transport operations place vaccine 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

[10] WHO Vaccine Management Handbook Module VMH-E2-01.1. *How to monitor temperatures in the vaccine supply chain, July 2015*

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 truck 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 13: Dashboard-mounted electronic temperature record

Other temperature monitoring options for refrigerated truck are;

a. **Data logger or electronic temperature recorder** – This is user's programmable temperature loggers 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.

6.10. 1. Temperature monitoring devices for temperature study and cold room/refrigerated truck mapping

To monitor temperature monitoring system WHO recommends conducting temperature monitoring study every 3 year and temperature mapping for cold room in a regular basis. Therefore, data loggers like "Logtag TRIX-8" 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).

Fig _30- Logtag TRIX-8

Exercise:

Exercise 1

Discuss in small groups the advantages and disadvantages of the following refrigeration systems:

- Group 1: Absorption refrigerators, Kerosene
- Group 2: Compression refrigerators
- Group 3: Solar systems (SDD)

Using matrix, rate the three different refrigeration systems on the table. Both advantages and disadvantages should be taken into account. You can add other important criteria as you can. Complete the table using a scale of 1 to 5, where 1 is poor and 5 is excellent.

Comparison Criteria	Absorption refrigerators	Compression ILR	Solar refrigerators (SDD)
Maintenance cost			
Operational cost (running cost)			
Temperature maintaining capacity			
Availability of power option			
Need for higher technical expert for maintenance			

Total the scores and prepare a presentation to the larger group to defend the ratings your group has given.

Exercise 2

Study the list of items given below. Identify the information you think essential to be displayed on the outside of each piece of cold chain equipment at each level. Give reasons for your choices.

List of possible items to be considered to be displayed on Cold Chain equipment at different levels	
1 Mark and model of equipment	2 Serial number
3 Vaccines stored (by Batch number, Expiry date etc.)	4 Ice packs stored
5 Order date schedule	6 Temperature monitoring chart
7 Last defrost date	8 Person responsible maintenance of the equipment
9 Person responsible for repairs to the equipment	10 Last date of cleaning
11 Last date of physical count of vaccine	12 Contingency plan (where to find the plan)
13 List of spare parts available	14 Maintenance schedule
15 Date of installation	

Exercise 3:

A. Calculate the volume of refrigeration or freezing capacity required at national level based on the following information.
   - Target population 1,310, 000 under one year old children (live births)
   - Immunization schedule is as follows:

- BCG (in 20 dose vials) at birth
- OPV (in 10 dose vials) at birth, 6, 10 & 14 weeks
- DPT-Hep B -Hib (in 1 dose vials) at 6, 10 & 14 weeks
- PCV13 (in 4 dose vials) at 6, 10 & 14 weeks
- Measles (in 10 dose vials) at 9 months and 15 months
- Td (in 10 dose vials) 2 doses for girls
- IPV (in 10 dose vial) at 14 weeks
- Rota (in single dose via0) at 6 & 10 weeks
- HepB (in 1 dose) at birth
- Covid-19 (by taking the antigen needs max. storage capacity) with number of doses/person

B. The storage capacity of the national store is 70 m3 refrigeration and 18 m3 freezing capacity. Is this capacity sufficient? If not, how would you adjust the supply periods to ensure that all vaccine received can be stored under optimal conditions.

C. You are to introduce new vaccines (HepB vaccine) into the EPI programme. The country will be using 10 dose of HepB with packed volume of 3 cm3 vaccine which is given at birth. Calculate the changed volume of refrigeration or freezing necessary at country level considering wastage rate 10%.

D. Is the same storage capacity as above in B sufficient, or will you need more of either the refrigerated or the freezing store? What plans would you make to ensure the safe storage of the vaccines in the new immunization schedule?

Exercise 4

The total population and proportion of less than one year old children population and planned coverage of a given woreda is 100,000, 3.5% and 90% respectively.

1. What is required cold chain capacity?
2. Propose appropriate type of refrigerator for this woreda.

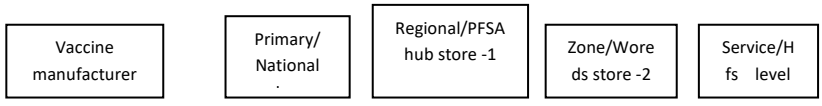
Exercise 5: Temperature monitoring tool

Each participant will receive a mix of a picture of temperature monitoring tool. The pair you have in your hand may not be matching. You are requested to review the wall chart displaying different levels of a

cold chain system in a country.

1. Place the temperature monitoring tool wherever you think appropriate. This could be either on the vertical line indicating that the tool is used in that particular facility or in between vertical lines meaning that it is used when vaccine is transported from one point to the other. When doing this for each different type of temperature monitoring tool use a new row.
2. When all temperature monitoring tools are placed, place the explanation to appropriate row.
3. Discuss the outcome with the group

Level of cold chain



Temperature data logger					
Vaccine cold chain monitor					
Vaccine vial monitor					
Freeze indicator					
Continuous temperature recording system					
Thermometer					

Module 7: Temperature monitoring and Reliability of the cold chain

Learning Objectives

By the end of this session you will be able to:

- Understand the procedures and principles of temperature monitoring to ensure the reliability of the cold chain in maintaining temperature
- Understand correct conditions for loading vaccines
- Prepare a set of contingency plans for use at each level
- Prepare a preventative maintenance plan to increase the reliability of the cold chain.

This module covers, Introduction, group work, demonstration, plenary presentation and summary, it will take 3:30

Materials needed for the training materials

- Pictorial aid (photo or posters) cold chain equipment
- Cold chain monitoring tools (thermometer, fridge tag, freeze tag, CCM card, etc.)
- Cold boxes, vaccine carriers, foam pads, ice packs
- Vaccine samples with different VVM stages
- refrigerators with Burners, wick if possible
- Flip chart

7.1. Introduction

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 2ºC and 8ºC 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 +2ºC and +8ºC to outreach sites and during mobile sessions
- Kept between +2ºC and +8ºC range during immunization sessions; and
- Kept between +2ºC and +8ºC during return to health facilities from outreach sites.
- Kept between -80^{o}c and -60^{o}c in case of Pfizer, Moderna and other COVID-19 vaccine that require ultra-low temprature

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 in those facilities where needed.

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

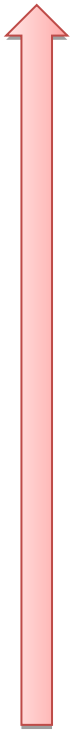
Two important terms used in this module are “alternative” and “contingency”. An alternative cold chain refers to a duplicate system, which is in place to take over the functions of the original cold chain system in cases where the original system fails or cannot be used. On the other hand, a contingency 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. Correct conditions for storing EPI vaccines

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:

Figure 30: Vaccine heat sensitivity

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

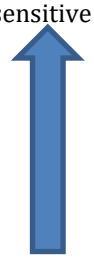
Note:

However, that 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.

Sensitivity to cold (freezing)

Some vaccines are also sensitive to being too cold. For these vaccines, freezing or exposure to temperatures below zero degrees centigrade ($0^{O}C$) can also cause loss of potency, and again, 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:

Figure 31: 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 Rabies Rubella [11]	✓ These vaccines are not damaged by freezing.

[11]Most the listed vaccine are not available in Ethiopia, explain the difference

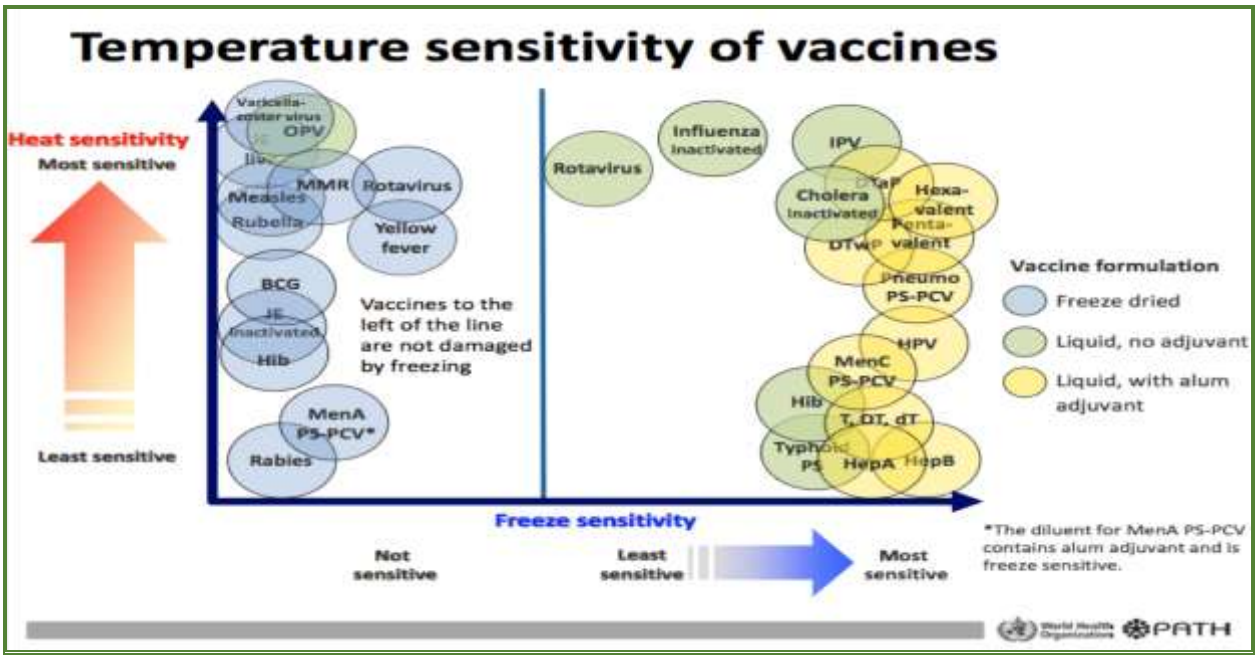


Figure 142: Temperature sensitivity of vaccines

Sensitivity to light

And finally, some vaccines are also very sensitive to strong light. For these vaccines, exposure to ultraviolet light will also cause loss of potency, so they must always be protected against 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, and all vaccines have an expiry date. This is the date by which the vaccine must be used, and will be printed on all vials and packets during manufacture. The expiry date shown on each vaccine vial and on each packet assumes the vaccine has been properly stored and transported at all times, in accordance with the guidelines shown in the above Figure. If the vaccine has been damaged by heat or other causes however, its potency will be reduced even before the expiry date shown on the vial or packet is reached.

Unlike other routine vaccines, COVID-19 vaccine have short expiry date and shelf-life, even they are stored in recommened temperature range, if there is any temperature excursion at storage of covid-19 vaccine, the shelf-life of COVID-19 vaccine will be shorten.

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, as they may be confused 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 to avoid mistaken use.

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 +2ºC and +8ºC. 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 -5ºC and -15ºC.

Load an vaccineffront 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 have to be stored in the refrigerator compartment. If there is not 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 Keep opened vials of OPV, IPV/ Td , and PCV13 vaccines in the “use first” box for first use during the next session.

5 Keep vials with VVMs showing more heat exposure than others in the box labelled “use first.” Use these vials first in the next session.

6 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.

7 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.

8 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.

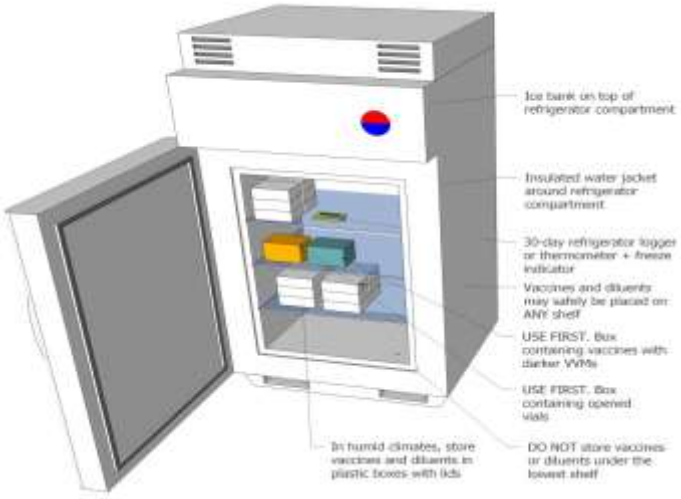


Figure 153: Loading vaccine in Front opening refrigerators

7.3.2. 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.

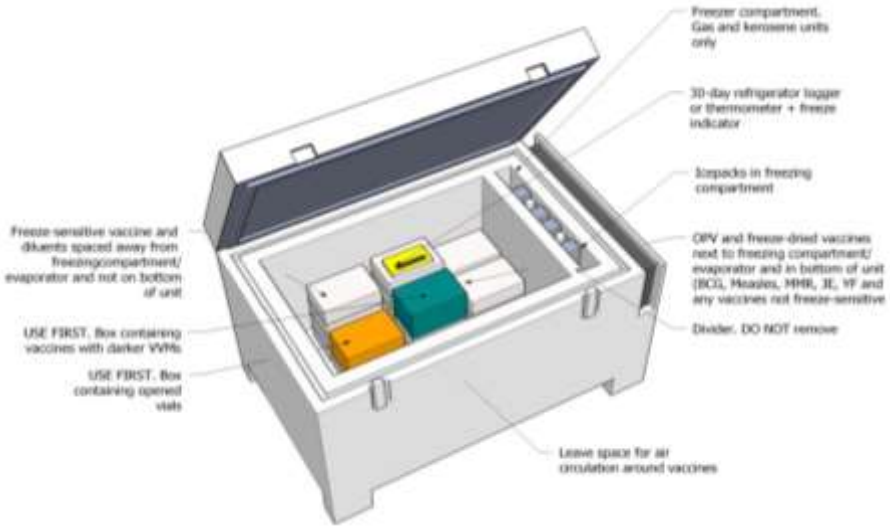


Figure 164: Loading front opening refrigerators

7.3.3. Loading vaccine in cold room

1. Before loading ensure that the internal temperature is in safe range (+2ºC and +8ºC for cold room and -25ºC and -15ºC 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 and the curtains should 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 off the light.

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, be sure to label them clearly and keep them separate from vaccines and diluents.

7.3.4. Correct conditions for storing and using diluents

Proper Handling and use of Diluents:

Diluents for vaccines are less sensitive to storage temperatures than the vaccines with which they are used, but may be kept in the cold chain between +2°C to +8°C 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, /EPSA 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 must never be frozen. This will risk cracking the glass and allowing contamination of the contents, so diluent vials must never be kept in a freezer, or allowed to be in contact with any frozen surface.

Freeze-dried vaccines and their diluents should always be distributed together in matching quantities. The vaccines must be kept in the cold chain between +2°C and +8°C at all times, or optionally, at –15°C to –25°C if cold chain space permits. For each distribution link, the cold chain will normally comprise cold boxes or vaccine carriers with ice packs. The diluents do not need to be kept in the cold chain unless they will be used for reconstituting vaccines within the next 24 hours. However, diluents must travel with the vaccine at all times, and the diluent must always be of the correct type, and from the same manufacturer as the vaccine which it is accompanying. This is essential to ensure that the health worker always has equal numbers of vaccine vials and diluent vials for reconstituting them, and that he/she has the correct type of diluent for the vaccine being used.

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 alkalinity);
- adjuvants to enhance immune response; and
- a separate and different vaccine.

Each vaccine requires a specific diluent and, therefore, diluents are not 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 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 in order 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.

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 programmes, 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.

7.4. 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 take 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 -80^{o}c to -60^{o}c

The most common emergencies in a cold chain are:

- 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
- Destruction of the vaccine store due to natural disasters/accident

What to do when a vaccine refrigerator is not working:

If your 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 a 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 the cold room to below 0°C. In addition when it evaporates it gives off carbon dioxide gas. This 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 staffs 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. There is no point moving stock to another cold room only to find that all your freeze-sensitive vaccine is frozen and destroyed.
- Do not wait until an emergency occurs. Rehearse 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, you risk;

- The destruction of vaccines
- Loss of huge amount of money
- Service interruption
- Discourage the community seeking the service
- Endanger the life of the eligible (children)

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*

Who will act (Name and Designation):

1. _____

2. _____

What to do (Recommendation Action)

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* *3. Contact higher level, for arranging the cold chain space and arrange shifting.*
Deep Freezers	*1. Shift the Ice packs in to cold boxes, if extra cold box available, after shifting of vaccine from refrigerators.* *2. Contact* _____
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* *3. Contact higher level, for arranging another vehicle.*
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.			
5.			

Figure 175: *Sample of emergency plan for vaccine store (to be posted on the wall)*

7.5. Temperature monitoring

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.

7.5.1. Temperature monitoring at storage

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. At the higher levels of the cold chain, i.e., at national Central), and EPSA hubs level, OPV must be kept frozen between minimum -15^{O}C to -25^{O}C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at –15^{O}C to –25^{O}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^{O}C and +8^{O}C. All other EPI vaccines should be stored at between +2^{O}C and +8^{O}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^{o}c-8^{o}c at all level

WHO recommended vaccine storage conditions.

<table>
<tr><th></th><th>Primary</th><th colspan="2">Intermediate</th><th>Health center</th><th>Health post</th></tr>
<tr><th></th><th></th><th>Hub</th><th>District</th><th></th><th></th></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td rowspan="14" colspan="3">+2°C to +8°C</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="3" rowspan="13">+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>
</table>

Diluent vials must 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.

Note: COVID-19 vaccine that require ultra-low temperature (Pfizer& moderna….) are expected to be stored from -80^{o}c to -60^{o}c at vaccine storage level

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 centre 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 temperature map 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 hours;
3. Reading and transferring recoded temperatures (minimum, maximum, mean and mean kinetic[5]) 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;
4. Identifying areas where vaccines and thermo-sensitive pharmaceutical products should not be stored; and,
5. Taking action to reduce the exposure of vaccines and pharmaceuticals to incorrect temperatures.

Its recommended to be conducted bi-annually

7.6.2. Monitoring temperature exposure during vaccine transport

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

7.5.2. 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.

7.5.3 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.

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.

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 analyse 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 13: 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
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
Temperature above +10°C. **VACCINE AT RISK**. Take immediate action to implement the agreed contingency plan and make a report.
For COVID-19 vaccine requiring ultra-low temp, take immidaite action for above -60^{o}c and below -80^{o}c

Respond 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 4 key action steps that you should systematically take 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.

Figure 186: Fridge tag temperature recording tag

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^{o}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.

7.6. Preventive maintenance of vaccine refrigerators

The main objective of maintenance is to ensure that cold chain equipment and transport system 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.

Preventive maintenance: Preventive maintenance is the servicing of equipment according to a pre-defined plan and schedule in compliance of 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 solar panels, topping up batteries, oil/air filter replacement, etc.) at predetermined criteria (age, working hours, transport mileage, etc.)
- **Conditional preventive maintenance:** service task from a checkup or periodic inspection (oil level alarm, subsequent temperature alarms, etc.)

Defrosting:

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. You should defrost the refrigerator when ice becomes more than 0.5 cm thick or once a month, whichever comes first.

To defrost and clean a refrigerator:

- Take out all the vaccines, and diluents and transfer them to cold boxes as follows
  - OPV with frozen 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 or

- Check for functionality of the door (it may need cleaning or replacement)

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

Table 33 Summary of planned preventive maintenance for different types of refrigerators

	Preventive maintenance daily, weekly and monthly Tasks			
	Absorption	Compression	Solar	
			Battery powered	SDDs
Daily	• Record the temperature twice daily • Adjust thermostat • Check color of flame for kerosene refrigerator (Blue flame) • Examine fuel tank contents • Sort vaccine in their correct order • Remove any residual liquid from inner container immediately	Cold / freezer rooms 1. Check the Temperature twice each → *Cold room: - +2 ^{o}C to + 8 ^{o}C* → *Freezing room: -25 ^{o}C to -15 ^{o}C* 2. Check the temperature recorder/monitoring (chart or electronic). The temperature should have remained within the correct limits at all times 3. Listen the cooling equipment (if you notice unusual noise, or if the unit seems to be running for longer than normal) try to find or report 4. At the end of the day, make sure that, → *All lights in the store are switched off* → *There is no body inside the room* → *The door to the room is closed and locked* • Refrigerators • Check and note refrigerator temperature • Remove any residual liquid from inner container immediately	• Record temperature twice daily • Make sure that refrigerator ventilation grill (if fitted) is not blocked	• Check& record temperature
Weekly	• Check the layer on the evaporator • Clean lid sealing & verify the lid is locking tightly • Trim wick using wick cleaner • Examine the holes of burner housing and	1. Change the temperature chart 2. Make sure if the temperature is displayed correct, using additional thermometer inside the cold room • Clean the device inside and outside by use warm water with a slight	• Check the amount of ice forming around the freezer compartment, conduct defrosting. • Clean the solar array	• Wipe clean refrigerator door seals • Wipe refrigerator door seals

	• Examine to ensure the burner is free from soot • Clean burner glass • Examine to ensure the end of the wick reaches the bottom of the tank inlet • Clean the chimney using the brush provided. • opening in the burner inlet must remain free	3. Check ice build-up on the evaporator 4. Check the store if the vaccines and diluents correctly organized 5. Check inside the cold room → *Is there airflow from the evaporator?* → *Is the evaporator fan running quietly?* → *Is there water on the floor? If there is, check the evaporator drain tray and pipe* 6. Check outside the cold room → *Remove any dusts* → *Clean the floor and refrigerator twice a week* → *Change the manual change over switch to other unit.* 7. Record and report maintenance activities by using computerized cold chain equipment, spare parts & maintenance management system or manual templates	cleaning agent. After the cleaning is finished, the device should be dried properly.		• Check for buildup of condensation

Monthly	• Use soft brush to free the unit from dust • Clean the lid sealing / door gasket • Check the hinges & locking for tight fastening & verify that the lid is locking tightly	• Check the room enclosure • Clean and service, the evaporator and the condensing units • Check & run the stand-by generator • Check the electrical duty sharing system • Look for signs of oil stains on the interconnection of piping, pay close attention on (Refrigerant circuit sealing) to areas around solder & flare joints.(*take corrective action if necessary*) • Check the status and tightness of all electrical & ground connections, *take corrective action if necessary*. (Replace any wiring found to be damaged). • Check that each fan rotates freely and quietly. Repair or replace any fan motor that does not rotate smoothly. • Record and report maintenance activities by using computer	• Check the hinges & locking for tight fastening & verify the lid is locking tightly • Clean the condenser use a soft brush	• Clean the parts refrigerator cabinet • Check for shadowing of the array	• Check that the Condenser is clean and air is free to move over condenser • Check that the electrical cable is in good condition and free from damage • Check that the wall socket is in good condition • Clean the solar panel

		ized cold chain equipment, spare parts & maintenance management system or manual templates			

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 mould. Mould 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.

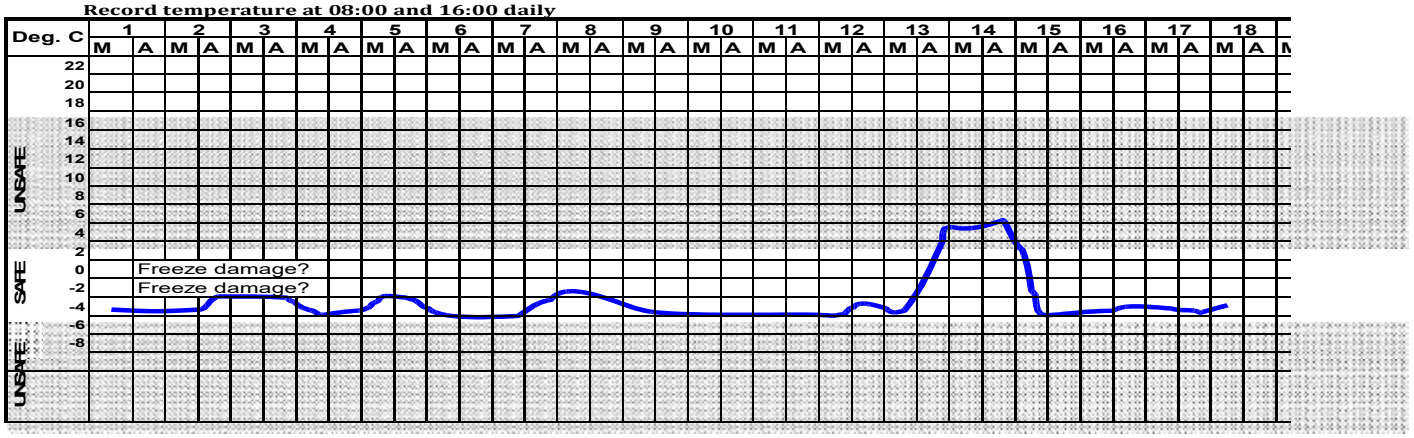
Exercise:

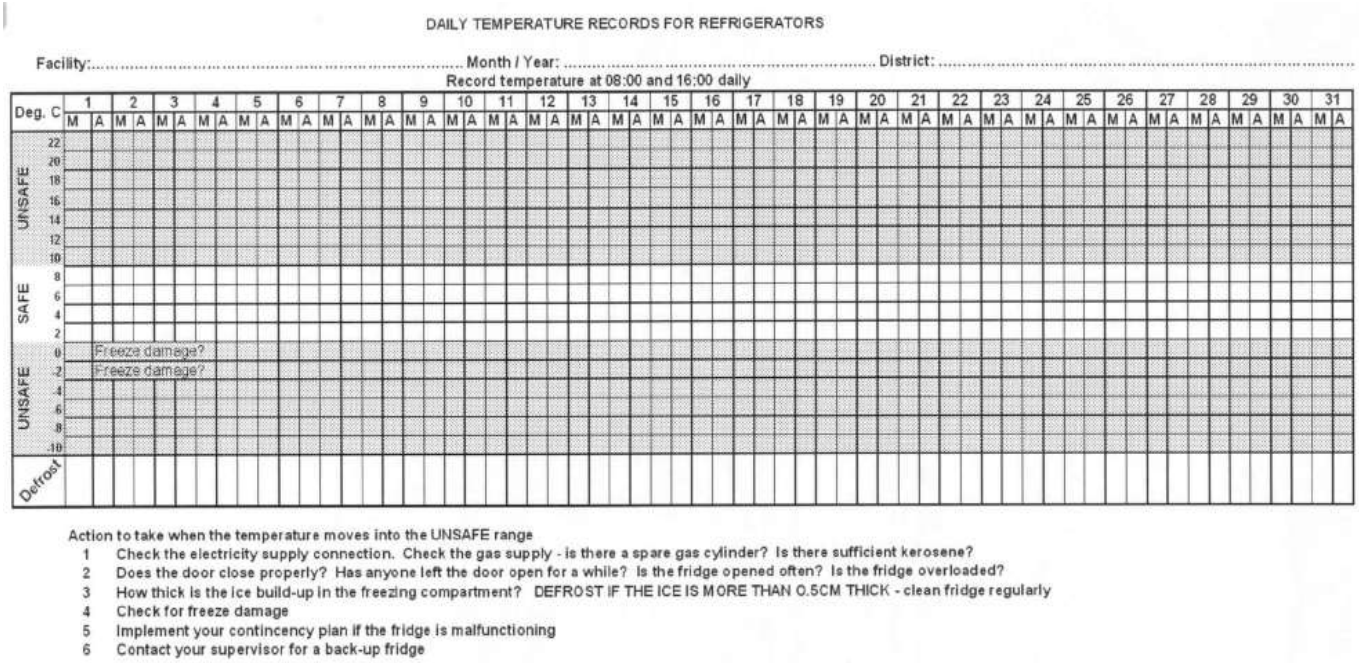
Exercise 1: Heat and freeze sensitivity of vaccines.

1. Which vaccines are highly heats sensitive in the EPI program in Ethiopia? Write them in their heat sensitivity order starting from the most heat sensitive?
2. Which vaccines are freeze sensitive write them in their freeze sensitivity order starting from the most freeze sensitive?.

Exercise 2: **Temperature records**

1. Study the temperature recording chart presented below. Would you prefer to make some adjustments, delete or add some information? Explain why.
2. During supervision to an intermediate vaccine store you have seen the below given temperature chart. What would be your reaction? What questions would you pose?





Action to take when the temperature moves into the UNSAFE range

1 Check the electricity supply connection. Check the gas supply - is there a spare gas cylinder? Is there sufficient kerosene?
2 Does the door close properly? Has anyone left the door open for a while? Is the fridge opened often? Is the fridge overloaded?
3 How thick is the ice build-up in the freezing compartment? DEFROST IF THE ICE IS MORE THAN 0.5CM THICK - clean fridge regularly
4 Check for freeze damage
5 Implement your contincency plan if the fridge is malfunctioning
6 Contact your supervisor for a back-up fridge

Exercise 3:

Using the completed refrigerator fridge tag temperature chart below discuss the following questions in group.

A. Read the fridge tag temperature reading (Morning, Evening, Maximum, and minimum on third, sixth, ninth days of the month).

B. Identify the high alarms and when they occurred?

C. Identify the low from the charts and when they occurred?

D. List the action that the responsible health worker has to take for both low and high alarms observed.

E. 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.

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.

Exercise 4: Alternative cold chain

1. What components of the cold chain have the highest risk of failure in preserving vaccines at +2°C to +8°C?
2. What plans can be made; what can be done with resources available?
3. Where can you spend time and resources to save the most amount of vaccines

possible?

4. Are there changes should be made to how supplies are forecasted; ordered?

Exercise 5: Maintenance

Complete the tables provided on the following page by discussing the following points in the small groups:

1. Identify equipment in cold chain that needs maintenance;
2. List the three most important points to remember for the maintenance of this equipment;
3. Identify the persons responsible for maintenance in your environment;
4. Identify the persons or institutions responsible for repair in case of failure;
5. List at least one question to ask under each heading during an annual audit.

Prepare to present your findings to the large group

Facility equipment	Key maintenance points	Person(s) responsible for mainten	Person(s) responsible for service/repair	Aspects to be assessed during annual audit

SECTION 8: Health Care Waste Management and Monitoring and Evaluation the Supply Chain

This section of the vaccine management training manual provides technical guidance on health care waste management practice and planning and monitoring of immunization chain system with the aim of equipping the participants with the knowledge and skill of identifying and analysing the problems, setting goals and objectives, preparing evidence based improvement plan, monitoring and evaluating the performance and progress based on set indicators. In addition to this the concept of supervision was also introduced.

Module 8: Health Care Waste Management and Disposal Management

Learning Objectives

By the end of this session you will be able to:

1. Understand how to conduct health care waste segregation
2. Identify health care waste types and their hazardous characteristics
3. Understand how hazardous health care wastes and biological waste management
4. Understand procedures for health care waste treatment and disposal
5. Understand the concept of cold chain equipment decommissioning and disposal

This module covers, introduction, small group work, plenary presentation, and brief summary, for this vaccine management training manual & flip chart will be used, total time allocated for this module is 2:00hrs

8.1. Introduction

Health facilities generate waste when providing service to the communities. All Health facilities should have a capacity for regular disposal of waste generated during service provision. Health facilities generate a huge volume of waste during immunization campaign in prevention and control of outbreak. Because of lack of waste disposal infrastructure, health facilities practice substandard waste management such as; disposal of health care waste with general waste, burial of untreated waste and dumping waste in to sewerage and water system. Inadequate health care waste management can cause direct and indirect impact in the community and health care workers by spreading infectious diseases. In addition to health impact it is the major source of environmental pollution.

Highly infectious non-sharp waste, stools from cholera patients, bodily fluids of patients with highly infectious diseases, biological products (live attenuated vaccines and nucleic acid vaccine), used sharp materials (needles, lancet) large quantities of expired or unwanted pharmaceuticals and hazardous chemicals and radioactive, genotoxic or teratogenic wastes requires special and unique precaution during collection, transportation, storage and disposal..

Wastes Management Hierarchy

The waste management hierarchy is the concept of minimizing wastes from its sources. The waste hierarchy mostly presented in an inverted pyramid because prevention of waste generation is very critical component of the cycle.

Figure 37: Waste management hierarchy

8.2. Types of Waste in Health Care Service

Waste can be classified in many ways based on its effect in the environment and human health. In general health care waste can be classified widely in to eight categories.

General Waste

General waste in the health care service is similar with domestic waste not contaminated by infectious body fluid and need not special handling. Waste that does not pose any particular biological, chemical, radioactive or physical hazard. It includes food and drink packaging materials, tissue, paper towel, boxes, disposable cup. A 75% to 90% waste generated in health care system classified as general waste.

Infectious Waste

Waste contaminated with blood and other bodily fluids (e.g. from discarded diagnostic samples), cultures and stocks of infectious agents from laboratory work (e.g. waste from autopsies and infected animals from laboratories), or waste from patients with infections (e.g. swabs, bandages and disposable medical devices) which pose direct hazard in human health and environment.

Sharp Waste

It is highly hazardous waste including used Syringes, needles, disposable scalpels and blades, etc.

Chemical Waste

Solvents and reagents used for laboratory preparations, disinfectants, sterilants and heavy metals contained in medical devices (e.g. mercury in broken thermometers) and batteries.

Cytotoxic Waste

Waste containing substances with genotoxic properties (i.e. highly hazardous substances that are, mutagenic, teratogenic or carcinogenic), such as cytotoxic drugs used in cancer treatment and their metabolites.

Radioactive Waste

Products contaminated by radionuclides including radioactive diagnostic material or radiotherapeutic material.

Biological Waste

It is genetically modified product from bacteria and viruses used as vaccine such as alive attenuated, recombinant and nucleic acid vaccines (oral polio vaccines, mRNA, DNA and viral vector vaccines) for diseases prevention and control. It is highly recommended to properly collect, store, transport and dispose biological products like vaccine as per the standard to avoid environmental hazard and Disease outbreak. One of the best experiences in biological product waste management is the bivalent polio vaccine collection and transportation to national level for disposal. It is important to follow manufacturer recommendation in management of biological products like vaccine during collection and disposal to minimize environmental and health hazardous. The collection and disposal of damaged and expired live attenuated, recombinant and nucleic acid vaccines such as oral polio vaccine (bOPV, mOPV) COVID-19 mRNA and viral vector vaccines need special precaution and imperative to follow national level disposal recommendations.

Oral Polio vaccine waste management and Disposal

The live, weakened virus originally contained in OPV can circulate for an extended period and genetically revert into a form that causes paralysis. This is known as circulating vaccine derived poliovirus (cVDPV). Therefore, proper management of used vials and expired or VVM changed live oral polio vaccines specifically mOPV should be collected, stored, transported and disposed properly to avoid circulating vaccine derived polio virus.

Withdrawal and retrieve of mOPV2

- An Empty and unusable vial returned from the field will be kept in plastics bags, covered up in boxes and properly labeled with the respective district names and amount of the vials.
- All vaccines and empty vials will be sent from HC to woreda cold chain room and from woreda to zonal cold rooms or EPSA hubs. The EPSA HUBS at zonal level/zonal cold rooms are responsible to count and transport to central cold chain with required documentation and recounted on arrival. Unopened vaccines will be kept labeled and, stored in a separate refrigerator /freezer or compartment with proper documentation for all mOPV2 vials at regional and central level

Pharmaceutical Waste

It includes Expired, unused, damaged and contaminated drugs and vaccine.

8.3. Health Care Waste Management

All used health care products should be segregated, collected, and store as per their hazardous characteristics before disposal. It is highly recommended to segregate and label the type of waste in the containers based on their hazardous property to minimize contamination. In health facility waste can be segregated using colored waste segregation bin such as yellow, red and black plastic bag or sealed containers. The color of segregation bin for infectious waste, biological products and laboratory waste, is yellow bag or sealed container with label of infectious waste and sign of biohazard waste. , For general waste and pathological waste a black and red plastic bag or sealed container with proper labeling are used respectively. In immunization program during routine immunization and campaign sharp waste collected and segregated using safety boxes. Health facilities can prepare their own waste segregation bins, If waste segregation bags or containers not available. It is recommended to use only three-forth of the waste collection bag or container to avoid overspill of the waste in to environment and never re-use plastic bags but containers can be used after proper sterilization process.

Segregation: It is collecting wastes by their environmental and health hazardous and physical and biological characteristics,. It is the first and critical step in health care waste management which minimize wastes. The health worker who provides the service in frontline is responsible in segregating wastes based on waste management recommendation. The health worker can use waste segregation bins and bags or locally made containers. The waste containers should be labeled properly about the type of waste, hazardous characteristics, date, estimated volume, health facility name, service provider department and other relevant information.

Collection: It is the collection of waste segregation bins and plastics in to storage or disposal sites. It is important to collect waste segregation bins from service delivery sites timely to minimize waste pollution which compromise service provision. Collection of waste can be done by health worker who generate the waste or trained janitor.

Storage: It is collecting and storing of hazardous wastes in to well ventilated and organized dedicated storage area short period of until it properly disposed without compromising the health and environmental hazard. A dedicated technical officer or store manager should keep updated inventory and manage wastes based on their inherent physical and biological characteristics.

Transportation: The collection and transportation of waste to offsite disposal site or temporary storage can be done daily, twice a day or as required depending on the volume of generated and its hazardous characteristics. Waste collection and transportation can be done by health worker and trained janitor in health care waste management. The transportation of waste can be escorted by law enforcement officers for hazardous waste which can cause serious environmental and health hazard to general public. Example pharmaceutical wastes, biological wastes and waste which can cause explosion.

Figure 38: Color coded waste segregation containers

Recommended practice of health care waste

- Segregate waste to hazardous and general waste
- Collect waste in color coding containers with biohazard sign and labels
- Collect non-sharp infectious wastes in color coding bags
- Transport infectious and hazardous wastes safely and with special precautions with properly labeled containers
- Store infectious and hazardous waste in secure areas
- Ensure availability of personnel protective equipment during collection, transport, storage and disposal
- Immunization of staffs working in waste management against hepatitis B vaccination
- Use high temperature incinerators to minimize environmental and health hazard
- Conduct continuous improvement activities to waste management practice

Poor practice of health care waste

- No practice of waste segregation by infectious and non-infectious waste
- Disposal of waste in unprotected open dumps
- Lack of staff awareness about the risks from potentially infectious materials or blood-borne diseases
- Lack of know-how among staff in waste handling
- Lack of supplies (PPE, Bags, sharp container) and/or improper use of those supplies
- Weak management and supervision of the waste management stream

8.4. Treatment and Disposal Methods

Incineration of Waste

Incineration is a waste treatment process that involves the combustion of waste materials. Incinerators are used to treatment and reduce the volume of waste by burning at a temperature of 800 to 9000C and post combustion at a temperature of 900–1200°C. Incineration of wastes at high temperature in two combustion chambers minimizes the volume of the waste by 95% and emission of environmental and human hazardous chemicals. In most health facilities there is low temperature incinerators with operational temperature of below 500^0C. The process of waste segregation, collection, transportation, storage affects the disposal management. Improper practice in waste segregation and collection makes the disposal process difficult and increase environmental and health hazard. At all level of the heath system where waste generate a presence of dedicate waste mangers and disposal system is important. In health facilities where there is no disposal capacity waste should segregated, labeled, stored and transported by responsible health workers to disposal site with proper documentation which describes the characteristics of the waste, type, volume and related information.

Figure 39: Low temperature incinerator made of bricks

Encapsulation and autoclaving

It is encapsulation of two third of container with hazardous waste using cement mortar, clay and sand. The container buried or landfill.

Safe Burying

It is burial of waste in a pit on site secured and limited access. Used injection equipment may be buried in a disposal pit. The site should be chosen carefully – there should be enough space for a pit large and deep enough for bulky boxes to be buried with minimum risk of contaminated sharps being released into the surroundings and doing harm

If a disposal pit is to be used, several steps must be followed.

- Choose a site where people will not dig or build latrines in the future.
- Choose a qualified staff person to supervise the burn using appropriate equipment.
- Fence off and clear the area.
- Dig a pit at least two meters deep. Make sure that buried materials will not escape from the pit, for example, during the rainy season.

When ready to bury them, take filled safety boxes to the pit site and place them in it. Do not open or empty the boxes.

- After placing the boxes in the pit, immediately cover them with at least 30 cm of soil. If possible, cover the site with concrete when the pit is full. Only qualified staff should perform this task.

Burning in a metal drum

This option should only be considered as a last resort, short term emergency response since low-temperature burning produces toxic emissions and is a public health and environmental hazard.

If contaminated sharps must be destroyed by burning in a metal drum or container, several steps must be followed.

- Choose a site in an unused area that is as far from buildings as possible. The area should be fenced and cleared.
- Choose a qualified staff person to supervise the burn using appropriate equipment.
- Place four bricks on the ground in a square pattern.
- Put a metal screen or grate on top of the bricks.
- Remove both ends of a 210-litre steel drum. This will allow air to flow through the drum and the contents to burn better. If a metal drum is not available, build a cylinder from sheet metal, bricks or clay. A chimney may be added to the removable top of the drum or container.
- Place the drum on top of a metal screen or grate.
- Put filled safety boxes in the metal drum. Mix paper, leaves or other flammable material in among the safety boxes to help them burn.
- Sprinkle a small amount of kerosene, if available, on the boxes and other material in the drum.
- Place a fine metal screen over the top of the drum to reduce flying ashes.
- Put wood, paper or other flammable material under the drum and ignite the material.
- Warn people to stay away to avoid smoke, fumes and ash from the fire.
- Allow the fire to burn until all of the safety boxes have been destroyed.
- Once the fire is out, allow the residue at the bottom of the drum to cool and carefully collect it. Bury it in an unused location. Cover it with at least 30 cm of soil. If possible, seal the residue pit with cement once it is full.

Only qualified staff should perform this task.

Open Air Burning

Burning of wastes in or next to pit where they will be buried using kerosene or similar fuel to maintain combustion. It is not recommended as a permanent solution, but better than burying untreated on site.

This option should also only be considered as a last resort since it produces toxic emissions and is a public health and environmental hazard. It is always preferable to collect safety boxes for later disposal at a more appropriate treatment site.

If burning waste in the open is the only option, several steps must be followed.

- Choose a site in an unused area that is as far from buildings as possible. The area should be fenced and cleared.
- Choose a qualified staff person to supervise the burn using appropriate equipment.
- Dig a pit at least one meter deep, but not so deep that it will be difficult to start the fire. Staff should not have to enter the pit to start the fire.
- Place filled safety boxes in the pit. Mix paper, leaves or other flammable materials with the boxes to help them burn.
- Sprinkle a small amount of kerosene on the boxes, if available, and ignite the fire.
- Warn people to stay away to avoid smoke, fumes and ash from the fire.
- Let the fire burn until all boxes are destroyed and then follow the instructions for burying residue above.

Only qualified staff should perform this task.

8.5. Cold Chain Equipment Decommissioning and Disposal

Cold chain equipment decommissioning is required when the equipment has to be removed from service due to different reasons. If any of the following conditions exist, the equipment must be decommissioned: Unserviceable, obsolete, unsafe, ineffective and costly. In general WHO/UNICEF recommends the total lifetime of CCE to be 10 years to minimize frequent failure and maintenance which increase total cost of ownership. Though WHO and UNICEF recommend five to six service years of CCE, in Ethiopia the service years of CCE is beyond 10 years which requires frequent maintenance and affect continuous functionality of CCE, availability and quality of vaccines. Decommissioning process includes notification, condemnation and removal from service, including safe and secure storage. In Ethiopia out the inventoried xxx refrigerators xxx are above 10 service years and xxx are classified as obsolete technologies for immunization service

8.5.1. Life Cycle of Cold Chain Equipment

The life cycle of cold chain equipment is divided into four phases which are planning, Procurement, lifetime and decommissioning and disposal.

Planning: This phase starts with assessment of the health facility demand in terms of target population, finance and power source.

Procurement: A process of acquiring the CCE based on the specification and demand of the health facilities.

Lifetime: This phase starts with installation and commissioning of CCE, training of users and maintainers, the daily operation and safety for and by users, as well as maintenance and repairs.

Decommissioning and Disposal: This is the stage where the life cycle of the CCE ends and disposed off through appropriate method in the context of international and country environmental protection policies and government agencies rules and regulations.

8.5.2. Reasons for Decommissioning and Disposal of Cold Chain Equipment

The lifespan of refrigeration equipment depends largely on the operational cost of its utilization and its maintenance. Consequently, assets should be estimated based on a cost benefit criterion. In Ethiopia the disposal of public fixed assets should follow directives No. 9/2003 and the government owned fixed assets management manual issued by the Public Procurement and Property Disposal Service and MoFED The five commonly known reasons to start the fixed assets disposal process are the asset is unserviceable, obsolete, surplus Unsafe or Standards not met and abandoned.

Unserviceable: Due to many factors including normal usage of the assets, old age or accident, lack of spare part, the cost of repairing the asset might become much more expensive than the benefit the public body can drive out of it. In such cases it becomes a rational decision to dispose the asset instead of incurring additional repair cost.

Obsolete: Obsolescence could happen due to several factors. An asset could be rendered obsolete due to technological change. It may not fit with other assets in use. The output of the asset might not be accepted by the end user. Similarly, using the asset might not be economical in terms of cost and time. Hence, the asset needs to be disposed.

Surplus: In this case asset is in good condition, and not obsolete, yet the public body might not use it currently and in the near future for some reason such as availability of more than required of such asset or the service of the asset not required as much. Other public bodies might need such assets. In such cases it is generally economical to decommission the asset rather than keeping it and making it obsolete or unserviceable.

Unsafe or Standards not met: This does not comply with safety requirements from manufacturer or international protocols. Cold chain equipment which are absorption type and refrigerators above 10 years' service can be classified as unsafe or not met WHO and UNICEF standard for vaccine management.

Abandoned Assets: These are assets held under police or other legal institute's custody, or assets the owners of which are not known or are unable to satisfy some legal requirements to become the final owner of the assets. This includes assets kept by customs and police. The public bodies that keep these assets are not using the items as fixed assets. Rather the assets are held due to the normal course of operation of those public bodies. Hence the assets can be considered as stock and should be dealt with under consumable stocks management system.

Table 14: Summary of Hazardous Substances in Refrigerators

Hazardous substance	Where to find	How are they released	Why are they dangerous
Lead	Soldered points/joints	Heating up solder	Heavy metal accumulates in body tissue through unprotected contact
Cadmium	Contacts and coloring plastic cases	Burning/ heat treatment	Brain damage even death
Mercury	Switch, sensor, contacts, relays, thermostat and lightning	Heat treatment shredding	Nerve toxin deadly in small doses. severe polluter of air, water and soil
Hexavalent chromium	Plating, anti-corrosion agent, pigment in plastics	Melting and burning plastic	Cause cancer
Flame retardants polychlorinated biphenyls and polychlorinated diphenyl-ether	Plastic casing and housing, plastic wiring and cables, printed wire boards	Melting, burning plastics, shredding	Cause cancer

Figure 40: Components of refrigerator which need precautions during handling

Exercises

A health facility with total target population of 20,000 will conduct polio outbreak response using mOPV2 . In addition the facility will conduct COVID-19 vaccination for target population of 30,000 using AstraZeneca vaccine after one month conducting the polio campaign. The facility requested from the woreda level to develop waste management strategy and disposal plan for both vaccines. Develop waste management plan and strategy for the health facility? Hint (the health facility has low temperature incinerator made from bricks, firs develop the total vials, syringes, safety box and other supplies required before develop your strategies).

Module 9: Monitoring and Evaluation immunization supply chain

Learning Objectives

By the end of this session you will be able to:

- Understand monitoring and Evaluation in immunization supply chain
- Enable to identify and analyze problems in the immunization supply chain
- Utilize standard methodologies and assessment tools in monitoring supply chain system
- Conduct regular monitoring, evaluation and supportive supervision

Training methods, materials needed

- The training methods will be interactive lecture, group discussion, demonstration and plenary presentation which will take a maximum of five hours.

3.1. Introduction

Monitoring of supply chain information involves observing, collecting and examining supply chain data. "Monitoring for Action" is analyzing the data at all levels to direct the programme and measuring progress, identifying areas for specific interventions and making practical revisions to plans.

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.

3.2. Purposes of Monitoring

Monitoring and evaluation of immunization supply chain helps improve performance and achieve targets. More precisely, 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. . Performance is defined as progress towards achievement of results. Traditionally, monitoring and evaluation focused on assessing inputs and implementation processes.

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

9.3. Roles of monitoring in strengthening immunization Logistic System

Collecting monitoring data enables program managers to provide feedback to staff throughout the supply chain to improve system performance; to report results to stakeholders to justify the need for additional resources, when appropriate.. Improving program management and system performance are critical for enhancing customer service and ensuring vaccine and supplies availability.. Monitoring and evaluation can be applied at all components of a supply chain management system., Monitoring and evaluation can therefore ensure continuous quality assurance at all level of the immunization supply management system.

9.3.1 Monitoring Cycle for the Supply Chain System Improvement

Monitoring plays an integral and continuous role in supply chain management and system strengthening. Monitoring must be built into a program from the beginning, or from the launch of a new work plan cycle. **Figure**9 shows a typical program cycle for supply chain systems improvement.

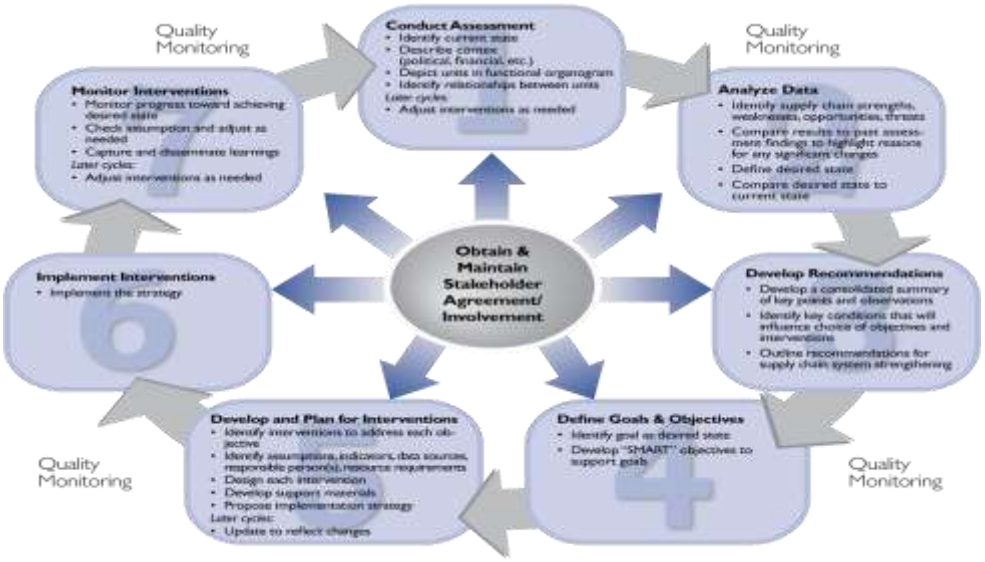


Figure 41: Monitoring cycle for supply chain systems

9.3.2. Monitoring the Immunization Supply Chain

The level of monitoring can be national to Region/ zone/EPSA or from district to health facility. The regularity of monitoring varies, it can be done daily, weekly, monthly, quarterly and annually. Reports from intermediate or peripheral levels can be obtained with **passive** (waiting to

receive) or **active** (asking or visiting health facility to receive) methods. The latter may include visits to the health offices to collect necessary information and extensive monitoring exercise, such as annual review, surveys or focus group discussions may also be applied.

It may be conducted by a single person or a team in an integrated monitoring exercise (joint monitoring), which involves several members from different department. .

The data source for monitoring can be routine administrative report, periodic report (technical, financial, supervisory visits), studies such as Effective Vaccine Management (EVM) or Temperature monitoring study (TMS), Cold chain equipment inventory and program assessments The data source may differ at all level of the health system

At health facility level these may include:

- Cold chain temperature monitoring chart to observe consistency of daily monitoring
- vaccine requisition forms and vaccine ledger book to ensure proper vaccine stock management
- inventory of vaccines, supplies and cold chain equipment to compare what is actually available and conditions of the equipment

At district, zone or national level some of the common sources of information are:

- Immunization coverage survey reports
- DHIS2 report
- supervisory reports
- Cold chain inventory register
- Cold chain review reports
- Program assessment/review reports
- Annual inventory report
- Vaccine reporting and requisition form
- Vaccine arrival report

9.3.3. Indicators For immunization supply chain

To overcome certain weakness of the immunization supply chain system monitoring can be done in specific component which leverage overall performance. for example:

- Availability of vaccines and supplies: this is calculated by dividing the sum of days when each vaccine or supply item was available by total number of days in the period under the reference, and the result multiplied by 100.
- Vaccine wastage rate
- Practice of continuous temperature monitoring
- Adequacy cold chain storage capacity

- Timely delivery of vaccine and supplies
- Vaccine requesting form timelines, completeness and
- Cold chain equipment maintenance and functionality EVM self-assessment score
- Availability and continuity of services (adequate equipment and transport for distribution, outreach and supervision)
- Vaccine stocks (minimum, maximum and critical stocks); Sources of vaccine (quality)

9.3.4 Analyzing and Interpreting Information

. The monitoring process generates data from various sources: routine reporting, special surveys, supervisory reports, personal observations and others, which should be collated and analyzed in order to follow up your programme as per established targets and indicators. Some data are gathered through figures, while others are qualitative and must be followed when they appear in registers and descriptive comments. The collected data is useful only after rigorous cleaning, organize, feeding to analyze for informed decision making.

Table 15 a: Indicators and their interpretations

Monitoring indicators	Issues to look at	Possible interpretations/reasoning
1. Vaccine wastage rates	• Calculate wastage rate for your facility • Specify: the vaccine vial size in use; no. of vials opened for use; no. of closed vials discarded	This is a critical indicator, especially for new vaccines, which are far more expensive that the traditional EPI vaccines. If the analysis shows high wastage rates, there may be various reasons to be considered: • Do the vaccines supplied have a short expiry date? So some vials were discarded without even opening them?! • Is the facility appropriately applying the multi-dose-vial policy (MDVP)? • Have community information program been conducted to bring more children for immunization so that opened vaccine vials can be used more rationally? • There may be even more reasons for a high wastage rate, continue reasoning! Do not respond alone to all questions of your supervisor, involve others too. You will come up with an answer.
2. Vaccine stock out (Health facility lacks all or any one EPl vaccine for a particular period of time	•Are the vaccine needs (annual, monthly) known •Were any vaccination sessions cancelled due to vaccine stock outs •Have vaccines been supplied/ ordered according to needs. •Do the amounts used correlate with vaccinations performed •Have the needs of any particular vaccine •exceeded the supply • Your analysis and physical checks will reveal if there is/has been a real stock out	The issue of vaccine stock out is a reflection of vaccine management problem at various levels, including health facility level, where the problem can be associated with some of the following issues: • Inaccurate calculations and orders of the health facility needs • Other activities have consumed some of the vaccines that were ordered for routine immunization. (Check the health facility annual plan to see if any SIAs were planned in the area and vaccine requirements were included) • The vaccine stock-out may be related to an influx of refugees requiring urgent immunization of target population • There has been a supply problem - fewer vaccines were delivered than requested. If so, this needs to be discussed with your supervisor and the clinic health committee to find a solution • Could be a result of unavoidable high wastage rate (part of the community not respecting vaccination sessions) You may eventually identify the real cause of the stock out in the health facility.

15 b. Indicator for logistics and cold chain component of OPERATIONS

Indicator and definition	What area or function it measures?	Targeted range or optimal	Source of information	Monitoring level
National level wastage rates of DTP and new vaccines (HepB and Hib) The vaccine wastage rate (%) = 100- vaccine usage rate	• This is an indicator in the area of vaccine management especially in relation to introduction of new vaccines, which are much costly than traditional EPI vaccines. It is therefore the centre of attention of GAVI, which is the major supplier of new vaccines to national programmes	The wastage rate of only 10% should be applied to new vaccines which makes the wastage factor 1.1	• Vaccine order form • Vaccine Arrival Report • Vaccine register • Vaccine stock sheets • Physical count of opened and discarded vials	• National • Province • District • Health facility

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15 c. Indicator for vaccine supply and quality component of OPERATIONS

Proportion (%) of districts in the country that had no vaccine stockouts Nominator: No. of districts in the country that had no vaccine stock outs Denominator: Total no. of districts in the country	• This in an input indicator characterizing vaccine supply side of the programme • It is described here in positive terms but can also be used to show districts which had stockouts • It indicates how well districts are doing in vaccine management, storage and handling	All districts (100%) Definition of district stockout: District vaccine store has no remaining doses of any	• Vaccine order form • Vaccine Arrival Report • Vaccine register •	• National • Province/ District (Also useful for health facility level)

9.4. National assessments to evaluate of immunization of supply chain system

9.4.1. Cold chain Equipment Inventory

In our countries, the Ministry of Health have paper based inventory forms and recently developed window based cold chain equipment database to record essential data concerning available cold chain equipment, and the process of developing web-based CCEI database have 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.

Methods for carrying out an inventory

There are at least 3 methods to carry out cold chain inventory

1st method: Regular visits by cold chain technician to the health facility

2nd method: Inventory by the EPI or logistics manager using inventory form

3rd method: Collect information during distribution of vaccines to the health facilities.

4th Method: Census Method: it is counting each CCE by visiting all health facilities in the country using standard data collection tools. It is conducted in every three to five years at national level because it is resource intensive.

Data to be collected for inventory

Beside the simple physical count, inventory acts as a management tool for the immunization programme. 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/EPSA hubs or central EPSA)

- Type, make, model and serial number of equipment
- Age or year of installation
- Functional status of equipment (working well, need to be repaired, out of order, etc.)
- Source of energy
- 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

As mentioned above, it is critical that cold chain equipment inventory is up to date. It is suggested to update the inventory according to time intervals by using cold chain equipment database or standard forms. The collected data has to be documented, analysed and used for action at all level.

9.4.2. Temperature monitoring study

WHO strongly encourages countries to carry out temperature monitoring study, temperature mapping and route profiling studies because they identify problems and provide the basis for making evidence-based improvements in cold chain quality. Studies in both industrialized and developing countries have revealed that vaccines are commonly exposed to damaging temperatures, especially exposure to sub-zero temperatures. The simplest way to identify these risks is to conduct a systematic temperature monitoring

study of the entire vaccine supply chain designed to identify and locate sources of damaging temperature exposure. Temperature monitoring studies can be used to establish a baseline against which to monitor improvements. They can also be used to validate data being reported through routine temperature monitoring.

Completion of such a study is a critical indicator in an EVM assessment; it should be repeated at least once every five years, preferably more frequently. Guidance on how to carry out a study of this kind is given in the WHO document Study protocol for temperature monitoring in the vaccine cold chain.

9.4.3 Temperature Mapping

Temperature mapping and temperature Monitoring are integral to the storage of vaccine quality and on appropriate storage conditions[12]. Temperature Mapping is the process of recording and mapping the temperature in a three-dimensional (3D) drawing of any cold and freezer rooms and dry storage areas. Any medium-sized cold-room at the central and highly populated sub national level of any country may hold over millions of US dollars worth of vaccines. In order to ensure that a large bulk of vaccines in cold-rooms at the central and provincial levels are not damaged by heat and freezing temperatures, Effective Vaccine Management (EVM)[13] that sets standards for safe vaccine handling requires that all vaccine cold and freezer-rooms are temperature mapped every two years routinely, at the time of commissioning and whenever they undergo major repairs. Vaccines should not be stored in the new cold room or freeze rooms until the temperature mapping exercise has been completed and the results have been analysed to identify and address performance gaps[14].

Temperatures can vary significantly from place to place, and mapping locates the hot spots and cold spots. There are also specific areas within the cold-rooms where the temperature also will differ such as: next to the cooling fans where the temperature will be at its coldest

[12] http://pharmatreasures.blogspot.com/2011/10/temperature-mapping-in-pharmaceuticals.html

[13] One of the critical criteria of EVM assessment (E2)

[14] WHO Vaccine Management Handbook Module VMH-E2-01.1. How to monitor temperatures in the vaccine supply chain, July 2015

or close to the doors where it is likely to be at its warmest. Only when the temperature distribution in the space is known users can be sure that vaccines are always kept in the right temperature range. Refrigerators and freezers can also be temperature mapped.

Increased cost of vaccines justifies temperature mapping of all vaccine cold and freezer rooms on routine basis. The suggested solution to this problem is to empower the program staff, mostly store managers, at the field levels to conduct temperature mapping by themselves.

9.4.4 Vaccine wastage Study

Despite the availability of many tools for reducing vaccine wastage rate, high wastage rates are still occurring in countries. As costly, capacious and freezing sensitive new and underused vaccines are being introduced in to immunization system through the Global Alliance for Vaccines and Immunization (GAVI), countries are looking more closely than before at vaccine wastage. Moreover, GAVI has requested countries to reduce vaccine wastage rates. In Ethiopia there is no maximal vaccine wastage rate monitoring practices at all level. Though newly developed HMIS system captured opened vial wastage reporting, the regularity of the reporting, the quality of the data and culture of analyzing and using for action is not satisfactory. Effective Vaccine Management (EVM) requires regular reporting of the vaccine utilization, analyzing and using as performance measure at all level. To use vaccine wastage rate as key performance indicator at all level availability of well-designed and improved vaccine stock monitoring system is imperative.

9.4.5. Effective vaccine management (EVM)

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.

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. Mention 2013 and 2019 EVMA comparisons

Table 4: Some of the key EVM indicators

Vaccine Arrival • Availability of a VAR for each vaccine procured and information is complete • Vaccine cleared through customs without exposure to extreme temperatures	Storage Temperature • Temperature mapping of cold rooms • Completeness of manual and digital remote temperature monitoring records • Accuracy of manual and digital remote temperature monitoring records • Regular review of temperature records	Capacity • Positive cold storage capacity • Negative cold storage capacity • Dry storage capacity • Contingency plan for equipment failure or other emergency
Infrastructure Quality • Cold rooms and freezer rooms comply with WHO standards • Standby generator installed • Continuous temperature recorders in cold rooms	Maintenance • Preventive maintenance of equipment • Vaccine refrigrators and freezers are repaired quickly	Stock Management • Computerized stock control • Stock records updated on day of transaction • Temperature damage of freeze-sensitive vaccine • Knowledge and adherence to stock level policy
Distribution • Reliability and timeliness of vaccine deliveries/collections • Monitoring of vaccine distribution, reliability and timeliness • Contingency plan for emergency during vaccine transport • Knowledge of how to prevent vaccine freezing and high temperature during transport	Vaccine Management • Application of MDVP • Knowledge of vaccine wastage, types and how to calculate • Ability to properly read and interpret VVMs • Availability of vaccine wastage data	Information Management & supportive • Accessibility and knowledge of SOPs • Up-to-date cold chain equipment inventory • Regular supportive supervision

9.5. Supportive Supervision

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. To ensure their practicality and usefulness, supervision tools must be developed in consultation with the supervised levels. The important component is following up the supervision by sending the supervisory report to the health institutions and by providing the support that has been discussed and agreed upon during the visit.

The key characteristics of supportive supervision are

- Establishes performance objectives
- Focuses on problem solving and monitoring performance objectives
- Empowers supervisees to improve performance
- Emphasizes tem works
- Provides feedback and recommendation
- Motivate and empower staffs
- Encourage participatory decision making

Depending on approaches and purpose supportive supervision can be:

- **Supportive (skills development) supervision:** This focuses on the improvement and/or the enhancement of the skills of the staff to ensure provision of quality services. It requires an assessment of the performance of the logisticians and the staff assigned to it, feedback and necessary remedy. It usually includes on-the-job training.
- **Inspectional/traditional Supervision**

  It is conducted by a supervisor in charge and generally focus on job performance evaluation alone and leaving little time for interacting with supervisees to develop a collaborative approach for addressing issues. and two way communications.
- **Integrated supervision:** This is a direct product of health reform process and is the type of supervision that links immunization supply chain with other immunization priorities and health system. The integrated supervision is carried out with well-trained multi-purpose team using supervision tools which include key issues of essential programmes in line with supply chain strategy.
- **Program Specific Supervision**

It emphasis on evaluation of specific program or project by establishing specific goals and objectives towards continuous improvement.

9.5.1. Why is supervision important?

There are four possible reasons for conducting a supervisory visit:

- To find out what is being done well.
- To help staff identify and solve problems..
- To motivate the staff.
- To improve the skills of the staff.

Supervision action plan

To achieve better results, supervision should be planned and carried out according to a well-elaborated schedule. While supervisory visits ought to be scheduled and known to both the supervisee and the supervisor, no opportunity should be lost to make an extra visit if the supervisory team happens to be nearby and has enough time for it. Moreover, from time to time, it is worth visiting a health facility unannounced.

The supply chain supervisory action plan follows a common format: it consists of the objectives, supervision activities, who must implement them, where, when and with what resources. The plan should be incorporated into the overall EPI/ EPSA plan in order to be included in the budget. The plan can be revised based on information obtained from routine health facility or district reports.

Developed the right tools

It is important to have the right tools available to assist supervisors and to standardize the supervision system. These tools include supervisory checklist, learning materials and job aids to be used by supervisors during supervision visits. All these materials and tools have to be prepared during the planning stage.

Self-assessment check list can prepared to be used by the health facility to enhance regular analysis and use of routine data at point of generation for continuous service improvement. (See the annexed sample self-assessment checklist)

Preparing a supervisory checklist

The supervisory checklist contains priority issues that must be observed and recorded by the supervisor. It helps the supervisor to focus on priority issues and reminds him/her to observe and record them.

The information collected should help the supervisor to decide what corrective action can be taken during the visit, and what issues need to be followed up for action in the longer term.

A checklist contains items to be checked at **every** site visit. However it should not deter the supervisor from recording and following up on other critical issues that he/she has observed but are not included in the

checklist. Three '**S'**s for a good quality checklist are:

Short: should include only priority areas to observe and record during supportive supervision visits.

Specific: items should be specific, with details on what exactly needs to be observed. For example, a question

such as " Does the cold store manager stored vaccine appropriately? " is not specific, but " Does the cold store manager stored vaccine within the safe range temperature (2-8)? " is more specific.The information collected should be critical and should help in taking managerial decisions.

Simple: Questions posed in the checklist should be simple and straightforward without complicated terminology

to avoid confusing the supervisee. To encourage self-assessment sample of the checklist should be given to supervisee to assess their activities by themselves. **(See annex 4 for sample checklist)**

9.5.1 Conducting vaccine Supervision

Visit

Supervisory team can collect information using a number of methods/tools including:

- observing the health facility environment including immunization sessions;
- listening to staff responses to his/her questions;
- reviewing the records like vaccine ledger book, requisition format, temperature monitoring records, cold chain equipment maintenance records, wastage recording format etc.;
- using a checklist;
- reviewing implementation status of the recommendations from past visits;
- conducting a rapid community survey and talking with parents members.

Observing

Even before direct contact is made with staff, the supervisor can obtain much information by simply observing the facility environment.

For example, they may observe the following:

• Are there expired or frozen reconstituted vaccine vials in the refrigerator?

• Are VVM posters, charts, etc. displayed on the walls?

Functionality of cold chain equipment

Temperature monitoring practice

Multi dose vial policy implementation

Observation of vaccine and cold chain activities performed by various staff will provide additional insight into how well the clinic is organized.

The supervisor has to observe the supervisee actually doing the work, but making sure that the supervisee is not put under undue stress. Observation gives the most accurate information about performance. When observing the supervisee look whether he or she:

- loads the refrigerator correctly

- prepares for vaccination session
- completes tally sheets and SMT and vaccine and logistics register

Interview and document review

During the visit, the supervisor may use several methods to collect information, including:

- Talk with logistics officer
- Review available records
- Talk with other members.

During discussions with staff, the supervisor has to explain the purpose of the visit and give staff members the opportunity to express themselves.

Sample questions to ask individual health workers include:

- Are they able to get their work done? If not, why?
- Do they have a special interest in any particular aspect of their job?
- Do they have any ideas about how the facility could be organized so that the community receives a better immunization service?

Try to ask questions that require more than a "yes" or "no" answer by asking open-ended questions.

To learn about ***the cold chain system and vaccine management***, the supervisor may review:

- Refrigerator temperature charts and fridge tag
- Vaccine and other supplies stock records.

9.5.2. Implement immediate corrective measures

The supervisor has to identify and implement immediate solutions that address the root causes of the problem. For example:

If the cause is due to lack of ***skills or knowledge:***

- Simplify task with job aids
- Suggest provision of periodic practice
- Provide training
- Clarify targets/objectives.

On-site training: Six main steps when teaching a skill.

1) Explaining in a simple terms the skill or activity to be learned.
2) Demonstrating the skill or activity using a model, or role-play.
3) Participants practicing the demonstrated skill or activity.
4) Reviewing the practice session and giving constructive feedback.
5) Practicing the skill or activity with clients under trainer's guidance.
6) Evaluating the participant's ability to perform the skill according to the standardized procedure, if possible as outlined in the competency-based checklist.

If the cause is due to lack of ***motivation*:**

- Reduce or eliminate negative consequences of the work. For example, low motivation may be a result of frequent vaccine stock-outs causing high dropout from vaccination. In this situation, the supervisor should take an action to regularize and stabilize vaccine supply.
- Reward good performance
- Discourage poor performance. If it is serious and consistent, suggest disciplinary action. If the poor performance is not serious and happened as a single episode, refer to it and explain consequences (e.g. harm to the client).

If the cause is an ***obstacle:***

- Eliminate the obstacle or reduce its effect.

If the cause of poor performance is due to missing task in the ***job description:***

- Revise the supervisee's job description accordingly and explain the new responsibility to the supervisee.

To provide an effective and immediate feedback, the supervisor has to be specific in his or her comments, which should be based on facts and not on the supervisor's judgment alone.

9.5.3. Preparing a supervision report

After each supervisory visit, the supervisor must prepare a supervisory report. This report is vital for planning non immediate corrective measures. It should inform programme managers and others concerned (e.g. head of facility, departmental heads, other stakeholders, community leaders, partners and health workers) of the situation in the health center and the findings of the visit.

The supervision report must:

- Indicate who has been supervised;
- Describe the tasks and responsibilities of the supervised persons and comment on how well they performed ;
- Assess overall performance of staff (attendance, punctuality, spirit of initiative, creativity, Capacity to work in an independent manner);
- Discuss each item in the supervision checklist;
- Describe what immediate corrective actions were taken during the visit;
- Identify the next steps agreed with the staff members concerned;
- Share with the supervisee (either a copy or written/verbal summary).
- Recommend improvements for EPI performance in between supervisory visits.

9.5.3. Feedback and Follow-up

Feedback must be given to health facility.

Feedback tips:

- Feedback should generate constructive attitude rather judgmental
- Proposed solutions should be workable

- Recognize that tough choices/recommendations will need time and resources
- Feedback must be both strength and weakness of the supervisee
- It must be specific, descriptive, direct, clear and to the point

Follow-up visit

During the next visit:

- Refer to the log/record of items discussed that need action by the supervisor or supervisee
- Refer to the work-plan of the supervisee
- Assess the results achieved using indicators and milestones
- Assess the changes in performance of the supervisee
- Prepare an evaluative supervisory report.

During a subsequent visit, you should always begin with information gathered during the previous visit. If you have not personally conducted the previous visit, then review the supervisor's report in order to continue where he or she left off. Inform the personnel of what you have learned, in order to avoid repeating the same information.

Exercise1

List the most relevant sources of information you will use to verify or interpret each of the following situations:

A. You have received reports from a district whereby the number of children vaccinated for PCV-1, PCV-2 and PCV-3 figure is higher than the PCV vaccine received and no information is given for discrepancy.

B. Review of Vaccine Arrival Reports and vaccination performance reports indicates that the national vaccine store has received 720,000 doses of measles vaccine during the last year. The total number of vaccination performed, however, has been only 130,675 during the same period.

Exercise 2;

- Review definitions of monitoring process

Exercise3: Critically review the indicators and complete the following table

Indicator	Level of use			
	National	Region/PFSA hub	Zone/District	Health facility
Vaccine wastage rate				
Vaccine stock outs				
Availability of Temperature review system				
Proportion of temperature excursion				
Adequacy of Cold chain storage capacity				
Proper vaccine shelving				
Key: Enter XXX- most appropriate level; XX- appropriate but at moderate degree; X- less appropriate level.				

Exercise 4: Role-play on supportive supervision

Assume that you have visited one cold store to assess the performance of vaccine and cold chain

management of the cold store using standard checklist. During supervisory visit to this cold store, you could able to identify the following problems:

- There was OPV vials with VVM at discarding point
- SMT tool was not updated and temperature readings were not recorded
- Vaccines were not properly shelved
- VRF were not properly completed and not submitted timely.

The supervisor observed that the cold store was understaffed. In addition, there was no trace of any supervision during the last 1 year. But, cold store manager was enthusiastic and had a good reputation in the organization.

After the completion of the supervisory activity you are expected to provide feedback to the supervisee and jointly identify action to prepare the improvement plan to improve the performance of the responsible health worker.

The supervisor, supervisee and observer will be instructed about their role during the role play.

After the completion of the role play other group members will provide comment on the supervisory and problem solving skill of the role players.

Note: The causes and recommendations for the identified problems will be discussed in the next exercise.

Exercise 5:

Discuss the causes and possible solutions of the identified problems during supervisory visit (see exercise 3).

1 Identify possible causes of the problem according to the following lines:

- Is there skill or knowledge gap?
- Is there lack of motivation?
- Are there anv other obstacles?
- Was responsibility for the task assigned?

2. Identify possible solutions to address each cause of the problem. Discuss findings and organize an effective feedback

References:

1. WHO Vaccine management training course
2. WHO Immunization in Practice, Modules for health workers, 2013 Update
3. Training for mid-level managers (MLM) - WHO/IVB/08.01; Module 1: Cold chain, vaccines and safe-injection equipment management.
4. WHO Vaccine Management Handbook Module http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index5.html
5. Monitoring vaccine wastage rate at country level: Guide for program manager: (WHO/V&B/03.18) http://www.who.int/iris/handle/10665/68463
6. WHO.Pqs http://apps.who.int/immunization_standards/ vaccine_quality/pqs_catalogue/index, accessed May 2016)
7. WHO Policy Statement: Multi-dose Vial Policy (MDVP): Revised 2014; available at http://www.who.int/immunization/documents/en/
8. FMOH Ethiopia; Immunization in practice, August 2014
9. WHO. EVM website

Annexes: Annex 1: Vaccine Request Format

Vaccine Request Form

Ministry of Health

Region/Zone/Woreda		**Level of cold chain**	**Date of request:**
Name of cold store		◉ RHB/HUB Cold room	**No. of months to supply (S):**
Responsible Person		○ Zonal store	**For population catchment served**
Contact Address		○ Woreda	**Births (BI):**
Telephone Number(s):		○ Health facility (H/HC/HP)	**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%										
Pneumeccocal Conjugate Vaccine (13 Valent)	3	1.11	100%										
Rota Virus Vaccine	2	1.05	100%										
Td (Tetanus and Diphteria) Vaccine	3	1.11	100%										
Human Papilloma Virus (HPV) Vaccine	2	1.05	100%										
Hepatitis B Vaccine (Birth dose)	1	1.05	100%										
Supplies													
Syringe, A-D, 0.5ml	15	1.05	100%										
Syringe, A-D, 0.05ml	1	1.05	100%										
Mixing syringe (BCG)		1.05	100%										
Mixing syringe (Measles)		1.05	100%										
Safety box		1.05	100%										

* Birth Infants (Births for BCG and Td) × B x C x D × (months to supply) ÷ 12 × 1.25 (buffer)

* Surviving Infants (for other vaccines) × B x C x D × (months to supply) ÷ 12 × 1.25 (buffer)

* (Girls of 9 years for HPV) × B x C x D × (months to supply) ÷ 12 × 1.25 (buffer)

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 use*

Requested by: _____

Approved by: _____

Annex 2:

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
B = Name of organization received from or distributed to
C = Reason for receive or distribution (Routine EPI of SIAs)
D = Amount received in dose or unit
E = Amount returned from session or other HFs in dose or unit
F = Amount given to others or lower level or vaccination
G = Discarded to Expiry, VVM, contamination, etc
H = Number of doses per vial or Number of AD/Mixing syringes

I = Name of manufacturer
J = Stage of VVM (1, 2, 3 or 4)
L = Expiry date of material
K = Batch or Lot number of material vaccination session
M = Balance at the beginning or at the end
N = Number children vaccinated with vaccine issued for
O = Any points to be noted such as reasons for discard

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°c to +8°c 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°c to +8°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	ImplementationTimeline	Implementation status

Team Member

1 Name _____ Sign_____ Date_____

2 Name _____ Sign_____ Date_____

3 Name _____ Sign_____ Date_____

Annex 6: Course schedule (five days training schedule)

S. No	Vaccine and cold chain management training agenda and schedule	
Day 1		
	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
	10:50 - 12:30	Vaccine & their characteristics
	12:30 - 13:30	Lunch break
	13:30 - 15:40	Availability of adequate quantity of vaccines
	15:40 - 16:00	Team/Coffee break
	16:00 - 17:30	Availability of adequate quantity of vaccines ….
Day2		
	08:30 - 08:40	Recap of day 1
	08:40 – 09:30	Availability of adequate quantity of vaccines ….
	09:30 – 10:30	Stock management
	10:30 - 10:50	Tea/ coffee break
	10:50 - 12:30	Stock management
	12:30 - 13:30	Lunch break
	13:30 - 13:50	Stock management
	13:50 - 15:40	Vaccine distribution systems …
	15:40 - 16:00	Team/Coffee break
	16:00 - 17:30	Vaccine distribution systems …

Day3			
	08:30 - 08:40	Recap of the day 2	
	08:40 - 10:30	Vaccine wastage monitoring	
	10:30 - 10:50	Tea/ coffee break	
	10:50 - 12:30	Vaccine wastage monitoring	
	12:30 - 13:30	Lunch break	
	13:30 - 15:40	Types of Cold Chain Equipment and temperature monitoring devices	
	15:40 - 16:00	Team/Coffee break	
	16:00 - 17:30	Types of Cold Chain Equipment and temperature monitoring devices ..	
Day 4			
	08:30 - 08:40	Recap of the day 3	
	08:40 - 09:20	Types of Cold Chain Equipment and temperature monitoring devices ..	
	09:20 - 10:30	Reliability of the cold chain	
	10:30 - 10:50	Tea/ coffee break	
	10:50 - 12:30	Reliability of the cold chain	
	12:30 - 13:30	Lunch break	
	13:30 - 14:30	Monitoring & supportive supervision	
	14:30 - 14:50	Tea/ coffee break	
	14:50 - 17:30	Field visit	
Day 5			
	08:30 - 08:40	Recap of the day 3	
	08:40 - 10:30	Field visit finding presentation	
	10:30 - 10:50	Tea/ coffee break	
	10:50 - 12:30	Monitoring & supportive supervision	

	12:30 - 13:30	Lunch break	
	13:30 - 15:30	Monitoring & supportive supervision	
	15:30 - 15:50	Tea/ coffee break	
	15:50 - 16:30	Post course evaluation	
	16:30 - 17:30	General discussion and closing	