
ADDIS ABABA UNIVERSITY

SCHOOL OF COMMERCE

DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT

# VACCINE COLD CHAIN MANAGEMENT PRACTICE: THE CASE OF PUBLIC HEALTH FACILITIES AT NORTH SHOA ZONE, AMAHARA REGION, ETHIOPIA

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May, 2018

Addis Ababa, Ethiopia

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A THESIS SUBMITED TO ADDIS ABABA UNIVERSITY SCHOOL OF COMMERCE, DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT IN PARTIAL FULFILMENTS OF THE REQUIRMENTS FOR MASTER'S DEGREE IN LOGISTICS AND SUPPLY CHAIN MANAGEMENT.

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By: Solomon Yetwale Dememew

**Approved by Board of Examiners**

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| **Internal Examiner** | **Signature** | **Date** |
| **External Examiner** | **Signature** | **Date** |

## Declaration

I, the undersigned, declare that this study is my original work and has not been presented for a degree in any other university, and that all sources of materials used for the study have been dully acknowledged.

Declared by:

Name_____

Signature_____

Date_____

**Letter of Certification**

This thesis has been submitted to Addis Ababa University Department of Logistics and Supply Chain Management for examination with my approval as a University advisor.

Advisor: Dr. Matiwos Ensermu

Date: _____

**Acknowledgements**

Firstly I would like to give my gratitude to the almighty God because this work would not be get completion without the blessings of him. Next to God my deepest appreciation goes to my beloved family especially to my wife (S/r Emebet Molla), children (Eyuel Solomon and Ehite Solomon) without them it is impossible to do so. In addition my parents, brothers and sister had a great contribution to my study.

I wish to my deepest gratitude to my advisor Dr. Matiwos Ensermu for his invaluable support and advice to be successful and come to the final. During my academic career the contribution of my friend, Mr. Yehun Telila was great I really thank him for his unreserved support that give me from his bottom of heart.

Also I would like to forward my deepest gratitude to my friends who give me any kind of support. Lastly, I would like to thank North Shoa Zonal Health Department heads and colleagues for their support and for those participants who have been involved in completing the questionnaire.

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## ACRONYMS AND ABBREVIATIONS

**BCG-** Bacilli-Calmette-Guarein

**CDC** – Center for Disease Control and Prevention

**DTP-** Diphtera, Tetanus, Pertusis

**EPI** – Expanded Program on Immunization

**EVM** – Effective Vaccine Management

**FMOH** – Federal Ministry of Health

**HC** – Health Center

**HepB-** Hepatitis B

**HIV-** Human Immuno-Deficiency Virus

**ILR-** Ice lined Refrigerator

**ISCL** – Immunization Supply Chain and Logistics

**LIAT** – Logistic Indicator Assessment Tool

**LSAT** – Logistics System Assessment Tool

**MDVP -** Multi-Dose Vial Policy

**MOH** – Ministry of Health

**NIP** – National Immunization Program

**OPV-** Oral Polio Myletis Vaccine

**PATH -** Program for Appropriate Technology in Health

**PFSA** – Pharmaceuticals Fund and Supply Agency

**PHAC-** Public Health Agency of Canada

**SCM** – Supply Chain Management

**SNNP-** Southern Nations and Nationalities People

**SOP-** Standard Operating Procedures

**TT-** Tetanus Toxoid

**UNICEF** – United Nation Children's Fund

**VRF** – Vaccine Requisition Form

**VVM -** Vaccine Vial Monitors

**WHO**-World Health Organization

**WoHO** – Woreda Health Office

**ZHD** – Zonal Health Department

***Abstract***

***Introduction:*** *Vaccines are the only essential commodities that required their own specific supply chain system with storage of 2 $^{o}C$ to 8 $^{o}C$. It is critical that they should be kept at appropriate temperatures during transit and storage.*

***Objective****: The purpose of this study was to assess vaccines' cold chain management practice at public health facilities under North Shoa Zone, Amhara Region, Ethiopia.*

***Methods****: descriptive research design with time dimension of cross-sectional study was used to assess the status of cold chain management practice at health facilities in North Shoa Zone Amhara Region, Ethiopia.*

***Results:*** *81.7% (n=49) out of 60 facilities monitored the cold chain in twice daily bases at the time of visit. Taking the last six month temperature monitoring status of the facilities, 51.7% (n=31) of the facilities had complete set of twice daily manual temperature monitoring chart. In 38.3% (n=23) of the facilities one or more refrigerators were non functional. All receipts and dispatches were recorded in 58.3% (n=35) of facilities. The vaccines were not packed with air circulating and appropriate gap between them in 38.4% (n=23) of the facilities.*

***Conclusion****: Overall from the findings of the study, it can be conclude that there were vaccine cold chain management practice problems.*

***Recommendations:*** *30 day continuous temperature monitoring device should be installed at facilities and standardized vaccine storage room should be ready for proper vaccine management.*

***Key words****: vaccine, cold chain, cold chain management practice, temperature monitoring, vaccine storage and handling, recommended range.*

# CHAPTER ONE

# INTRODUCTION

## 1.1. Background

Immunization is recognized as one of the most successful public health interventions in history. Vaccines save millions of lives every year from preventable diseases. They are distributed nationally and are available for free in public health facilities (WHO & UNICEF 2014). The system used for storing vaccines in good condition is called the cold chain (WHO 2015). The cold chain is the system of transporting and storing of vaccine at the recommended temperature range which is (+2 $^0$C to + 8$^0$C for refrigerator vaccines) and (-15$^0$C to -25$^0$C for freezer vaccines). Cold chain begins from the time the vaccine is manufactured, stored, distributed and ends when it is administered to client (Mugharbel et al., 2009). It consists of a series of storage and transport links, all designed to keep vaccines within an acceptable temperature range until it reaches the users. The success of the EPI is therefore highly sensitive to the cold chain status and hence its management should not be taken lightly (Yakum et al., 2015). An effective cold chain management relies on three main elements as mentioned by CDC 2018, PHAC 2015, WHO, USAID, UNICEF 1998: Trained Personnel, who use and maintain the equipment and provide the health service; Equipment for safe storage and transportation of vaccines; and Procedures to providers used to ensure they monitor the vaccine storage conditions and actions taken if the vaccines are exposed to temperatures outside the required range.

Due to the fact that most vaccines maintain their potency for a short period of time at room temperature, the cold chain is the core of the system used for managing the quality and safety of vaccines. In addition, the principles related to management of vaccines such as installation of thermometers, maintenance of appropriate temperatures, recording temperatures, location of the vaccines inside a refrigerator, defrosting a frozen vaccine, as well as using the refrigerator exclusively for vaccine storage must be followed in order to finally administer the vaccine at full titer (Lee S. et al. 2012). Therefore, to ensure that the vaccines are viable, it is critical that they are kept at appropriate temperatures during transit and storage (Anderson R. et al., 2014). Temperatures falling outside the recommended range require immediate action to avoid loss of product. An immediate loss of potency of cold-sensitive vaccines may occur following freezing. For vaccines exposed to temperatures above the recommended temperature range, there is some loss of potency with each episode of exposure.

Repetitive exposure to heat episodes could result in a cumulative loss of potency that is not reversible. Therefore administration of vaccines that are not potent will lead to failed immunization of the individual against vaccine preventable diseases (Ogboghdo et al., 2017).

The cold chain management of vaccines is important for several reasons. In the past, many studies have shown that health care providers accidentally expose vaccines to improper storage temperatures outside of the +2°C to +8°C (+35°F to +46°F) range and do not monitor refrigerator temperatures regularly. Hence, there is a need to ensure that an effective product is being used, otherwise recipients may not be protected against vaccine-preventable diseases; this could result in the re-emergence or occurrence of those diseases. Since, Loss of vaccine effectiveness due to cold chain exposures to adverse conditions is cumulative, permanent and irreversible; it may result in the cancellation of immunization clinics and lost opportunities to immunize, as well as increased costs to the program (PHAC 2015).

In addition, revaccination of people who have received an ineffective vaccine may cause a loss of public confidence in vaccines and/or the health care system. A shortage of vaccine supply could be created by increased demand in a mass revaccination scenario. Freezing refers to a situation where vaccines experience temperatures at or below 0 °C. Vaccines may not appear frozen but may have been damaged at these temperatures. Most vaccines are considered to be damaged at 0°C. Therefore, failure to adhere to cold chain requirements may reduce vaccine potency, resulting in lack of protection against vaccine preventable diseases and/or increased local reactions after administration of vaccine (Ontario 2012). According to vaccine storage and handling tool kit (CDC 2018), a good vaccine storage and handling include storage of vaccines between 2 and 8 $^{o}$C with a temperature monitoring twice daily, use of stand-alone refrigerator, dedication of the vaccine storage for vaccine only (no food, beverages, or other substances), keeping vaccines 2-3 inches away from walls and other boxes.

After reviewing literatures, it has been discovered that there was a limited study that focuses on the cold chain management of vaccines in North Shoa Zone, Amhara Region, Ethiopia. As a result, this study aims to add to the existing knowledge on the cold chain management practice of vaccines from Ethiopia's perspective especially at North Shoa Zone, Amhara Region, Ethiopia. Results and recommendations derived from the study can help to reinforce knowledge of cold chain management of vaccines, to carry out strategies for improvement of vaccine management

in Ethiopia. In addition to highlighting Positive aspects of the study, the possible gaps that existed in the cold chain system and practice were addressed.

### 1.2. Statement of the problem

For cold chain management to be efficient, three major elements are required. These include well trained personnel, reliable transport/storage equipment and efficient management procedures. An absence of any of these would lead to a deficient cold chain system (Ogboghdo et al., 2017).

There were a number of basic cold chain management problems for vaccines. The major was maintaining the cold chain to keep vaccines in a safe temperature range. The temperature readings were out of the recommended range in 27.7% of the facilities in three districts of Oromiya, Amhara and SNNP; and 25.9% of facilities in eight districts of Cameroon. According to the WHO guideline, vaccines should not be exposed to temperatures of less than -0.5 $^{o}$C for more than one hour, or temperatures of more than 8 $^{o}$C for more than 10 hours (Richard et al., 2014). Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless (CDC 2018).

The other problem in vaccine cold chain management was failing of health facilities to store vaccines with in a recommended temperature range and to monitor them according to the WHO storage guideline (Richard et al. 2014). Assessments done in central Ethiopia there was temperature outage in 10.9% of the facilities (Berhane et al. 2000), whereas assessments done in three districts of Ethiopia, 27.3% of the facilities had temperature outage during data collection (Roggie et al., 2013). There was temperature outage in 10% of the health facilities at North West Region of Cameroon (Yakum et al., 2014). Data collected from a nationally representative sample of 661 health facilities in Ghana, Kenya, and Uganda had shown that 16.6% of the facilities registered temperature outage (Emily et al., 2013). In 15.79% of the facilities found in Southern Benin Rural Health district, temperature outage was documented (Agueh et al., 2016). From the above assessments done different findings were obtained from different researches and

it shows that there was a considerable research gap at the facilities during the study. Hence, the study focused on the temperature monitoring practice.

Studies also reported that improper vaccine storage leading to the administration of sub-potent vaccines were associated with outbreaks of vaccine preventable diseases in Israel and several developing countries (Dairo 2016). Proper vaccine storage and handling has been an important factor in preventing and eradicating many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they have to be revaccinated because the vaccines they received may have been compromised (CDC 2018). In assessments done at central Ethiopia, 2013, and North West region of Cameroon, 2014; vaccines were not properly stored in 54.5% and 20.69% of health facilities respectively. This was another research gap that should be studied. Also refrigerator functionality status, there was a problem in proper functioning of the cold chain equipments (FMOH 2015). From the assessments of 116 facilities in central Ethiopia, 81% of the facilities had non functional refrigerators (Roggie et al., 2013) and 14.3% of the refrigerators were not functional in Gambella region. The remaining facilities transported vaccines from nearby facilities having functional refrigerators (Asres et al., 2013). This was another research gap identified from the researches done.

Overall because of the research gaps identified and limited research carried out in North Shoa Zone, Amhara Region, Ethiopia with regard to cold chain management practice of vaccines, the study assessed the cold chain management of vaccines in temperature monitoring, vaccine storage and handling practices and cold chain equipment status in facilities at North Shoa Zone Amhara Region, Ethiopia.

### 1.3. Research Questions

The following questions were considered:

- Who is responsible for managing cold chain commodities at woreda and health center?
- How is vaccine storage condition maintained and monitored at woreda and health center?
- What is the cold chain equipment status at woreda and health center?
- How are vaccines arranged within the refrigerator?

### 1.4. Objective of the Study

The purpose of this study was to assess vaccines' cold chain management practice at public health facilities within Ethiopia's vaccine cold chain system. Studies into the cold chain management and practices of vaccines have been conducted in many countries found in Africa, Europe, America, etc. However, there was limited number of studies that address the cold chain management practice of vaccines in Amhara region specific to North Shoa Zone. This assessment gives the opportunity for a study into the cold chain management of vaccines in health center and woreda health offices which have been existed in North Shoa Zone, Amhara region, Ehiopia.

#### 1.4.1. General Objective

The general objective was to assess the cold chain management practice of vaccines in public health facilities at North Shoa Zone, Amhara Region, Ethiopia.

#### 1.4.2. Specific Objectives

The specific objectives of the study are:

- To assess the temperature monitoring practice of vaccines at woreda and health center.
- To assess the cold chain equipment status at woredas and health centers.
- To assess the vaccine management activities of vaccines at woredas and health centers.
- To assess the vaccine storage and handling practice at woreda and health center.

## 1.5. Significance of the Study

The study aims to add and reinforce to the existing body of knowledge on the cold chain management of vaccines. Identification of the positive aspects of the study and possible gaps that exist in the cold chain system help for further analysis of the cold chain management practice. Recommendations made from the study help managers for improvement of vaccine management strategies and smooth operations. This assessment also helps professionals how vaccines must be maintained according to the storage guidelines set by World Health Organization. The results give a baseline data for any public health facilities to take an appropriate measure to improve the cold chain management practice of vaccines and further studies. Managers, EPI focal persons and cold chain managers at all levels benefit from the study and helps them to be involved in the decision of improving the cold chain management practice of vaccines from recommendations especially on using of new technologies and procedures.

## 1.6. Scope of the Study

The vaccine cold chain management covers the effective vaccine management practice towards the nine criteria namely; vaccine arrival, temperature monitoring/control, storage capacity, infrastructure/equipment, maintenance, stock management, distribution, vaccine management, and logistics management information systems with the three important elements of trained staff, equipment and procedures. But the current study focused on few of the effective vaccine management activities. These were temperature control, equipment status, stock management and vaccine management together with the three important cold chain elements. This study didn't consider procurement, cost related issues and the remaining five criteria of effective vaccine management activities. In addition to this immunization coverage and practice were not considered in the study. The geographical scope of the study includes woredas and health centers under North Shoa Zone, Amhara Region. It didn't consider cold chain management activities at zonal health department and health posts.

### 1.7. Limitation of the Study

The limitation of this study was resource in terms of time and financial. The time for data collection and budget for different expenses during the data collection was not enough. In addition, the geographical location of woredas and health centers was another limitation because there were facilities which are remote.

### 1.8. Organization of the Study

The Study was organized in to six chapters each dealing with different ideas for one common purpose. In chapter one; background of the study, statement of the problem, objective of the study both general and specific objectives, research questions, significance of the study, scope of the study, limitation of the study, conceptual frame work and study variables were included. In chapter two, reviews of theoretical and empirical literatures were included to support the study. In chapter three; research design and methodology was briefly discussed including the research type, population of the study, sampling method, sample size, data collection instrument, pilot test and method of data analysis. Questionnaires and other documents used in the study annexed in the appendices.

## DEFINITION OF TERMS

**Temperature control: -** All vaccines and their diluents are stored and distributed within a cold-chain system that maintains, at all times, the WHO-recommended temperatures ranges for all types of vaccines.

**Vaccine management**:- All recommended policies for vaccine management are adopted and implemented, including the use of vaccine vial monitors (VVMs), the shake-test, the multi-dose vial policy (MDVP), the use of diluents and the monitoring of vaccine wastage rates.

**Stock management Systems:-** and procedures for managing the stocks of vaccines are effective, in terms of vaccine handling, physical inventory, stock-control systems, adequate stock-level policy, good warehousing practice, and disposal procedures for damaged and expired vaccines.

**Maintenance:-** Preventive and curative maintenance systems are standard and operational for storage buildings, cold-chain equipment and vehicles used to distribute vaccines.

**Cold Chain: -** The system used for storing vaccines in good condition and it consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges, from the point of manufacture to the point of administration.

**Cold Chain Management**: - is an effective vaccine storage, handling, and stock management; rigorous temperature control in the cold chain; and maintenance of adequate logistics management information systems to ensure the uninterrupted availability of quality vaccines from manufacturer to service-delivery levels.

**Wastage Rate**: A measurement of the amount of vaccine that is not administered (due to both open and unopened vial wastage), compared to the amount of vaccine issued.

**Vaccine Vial Monitors (VVMs)**: are small stickers that adhere to vaccine vials and change color as the vaccine is exposed to heat, letting health workers know whether the vaccine can be safely used for immunization.

**Cold Chain Capacity**: The total volume of functional temperature controlled storage including fridges, cold room, vaccine carriers, or other temperature controlled storage equipment.

**Cold Chain Equipment**: - All equipments used for storing, transporting and monitoring vaccines.

**Cold Chain Managers**:- are health professionals who are assigned at administrative level of zone and woreda to manage vaccines and other pharmaceuticals that need cold chain.

# CHAPTER TWO

# LITERATURE REVIEW

## 2.1. Introduction

The reviewing of literature was a key step in the research process. Literature reviews enable the researcher to gather information about current theoretical and scientific knowledge regarding particular phenomena under study and allows deductions to be made on what is known and what is unknown. It is a critical summary of the research on a topic of interest, often prepared to put a research problem in context. Various empirical and theoretical studies were reviewed on effects and consequences brought about by improper vaccine cold chain management, storage and handling. This chapter focused on previous research studies conducted globally, in African countries and in Ethiopia and has evaluated the available empirical studies to give a wider perspective on the cold chain management in Ethiopia and how the cold chain for vaccines was maintained from the time of receipt in the facility until the time of administration. In addition, in this chapter, various vaccine storage guidelines and policies regarding vaccine cold chain management was examined (Makuru 2012).

## 2.2. Expanded Program on Immunization

Immunization is unquestionably one of the most cost-effective public health interventions available. In order to improve its accessibility to children worldwide, WHO launched the Expanded Program on Immunization (EPI) in 1974 with as objective to prevent seven of the most serious diseases (Ateudjieu et al., 2013). One of the cornerstones of an effective national immunization programme is for its supply chain to ensure a continuous and uninterrupted availability of essential vaccines up to the point of vaccination. If vaccine availability is interrupted for any reason, missed opportunities to vaccinate will occur and populations run the risk of not being protected against deadly preventable diseases (Lydon et al., 2017).

Successful immunization programmes are built on functional end-to-end supply chain and logistics systems. The role of the supply chain is to ensure effective vaccine storage, handling, and stock management, rigorous temperature control in the cold chain, maintenance of adequate logistics and information system management (Agueh et al., 2016). The cold chain is important for national immunization programs in tropical climates countries. Ideally, high coverage of

vaccination resulted in high immunity. So, primary health care must have adequate knowledge to manage the cold chain because vaccine as main component to yield immunogenicity toward program of diseases that can be prevented by immunization need specific cold chain (Saraswati et al., 2018).

### 2.3. Vaccine Cold Chain

Vaccines are the only essential commodity that required their own specific supply chain system – with vaccines needing to be kept in a 2 $^{o}$C to 8 $^{o}$C cold chain unlike any other essential medicines (WHO & UNICEF, 2014). To ensure that the vaccines remain viable, it is critical that they are kept at appropriate temperatures during transit and storage. This is done with refrigerators and freezers at storage locations, and refrigerated trucks and cold boxes for transit. These are collectively referred to as the vaccine cold chain (Richard et al., 2014).

The chain begins with the refrigerator or freezer at the vaccine manufacturing plant, vaccine distributor and then to the provider's office (immunization clinic) and ends with the administration of the vaccine to the recipients. Cold chain components include equipment transport and storage, trained personnel, and efficient management procedures. All three elements must be maintained at every link in the chain to ensure that the administration of the vaccine is safe. Any alteration in temperature such as exposure to excessive heat or cold damages the vaccines, resulting in loss of potency. Vaccines are powerful public health tools that require a conscious effort to evaluate the cold chain at different levels. Managers of immunization services have to organize staff training and plan for the physical and budgetary implications of any problems of storage or handling (Mugharbel et al., 2009).

To ensure the optimal potency of vaccines, careful attention is needed in handling practices at all levels of the cold chain. These include storage and transport of vaccines from the manufacturer through the primary vaccine store down to the end user at the health facility and further down at the outreach sites. A cold chain is the integrated system of equipments (e.g., cold rooms, shipping containers, refrigerators, vehicles), procedures, records, and activities used to handle, store, transport, distribute and monitor temperature-sensitive products (Kartoglu and Milstien 2014).Preventing loss of vaccine potency during storage and handling is increasingly important

as new, more expensive vaccines are introduced, in at least one case requiring a different approach to storage (Bell KN et al., 2001).

The quality of vaccines can only be ensured by a functional cold chain system (Esohe et al. 2017) because vaccines are temperature sensitive and need to be kept in a cold chain, between 2 °C and 8 °C, to remain potent (Lennon et al., 2017). Vaccines have a fixed shelf life that loses viability over time. This loss is irreversible and accelerated if proper storage and temperature conditions are not maintained. Freezing or heat exposure can totally or irreversibly damage the efficacy of vaccines and increase the risk of side effects (Ogboghdo et al., 2017).

The maximum vaccine potency is preserved by, among other things, maintaining its functional cold chain system at all levels. It implies for those involved, mastering vaccines sensitivity to temperature and being adequately skilled and equipped regarding conditions of storage and transportation for each vaccine as well as cold chain and power supply monitoring. The monitoring of cold chain at each level is to be insured by trained personnel. Each health facility in charge of storing vaccines or organizing vaccination sessions should have adequate functional cold chain equipment. To monitor the temperature in the freezer or refrigerator used to store vaccines, temperature should be read twice daily and recorded on the temperature sheet pasted on it (Ateudjieu et al., 2013).

### 2.4. Vaccine Stability

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 it. Any loss of potency is permanent and irreversible. Thus, storage of vaccines at the correct recommended temperature conditions is very important in order that full vaccine potency is retained up to the moment of administration (WHO, USAID, UNICEF, 1998). Classically, there have been two general types of vaccines (Kartoglu and Milistien 2014):

1. live viral and bacterial vaccines: which do not require adjuvant to boost the immune responses but are more sensitive to potency loss during storage and distribution, especially at elevated temperatures, and

2. Non-replicating vaccines: such as inactivated viruses and bacteria, purified protein and carbohydrate antigens, which often require adjuvant to boost the immune response. They are typically stable to moderate heat exposure, but mostly due to adjuvant, are sensitive to freezing.

The live vaccines contain weakened, attenuated versions of infectious viruses and bacteria that can replicate *in vivo* (and, therefore, mimic natural infection). Live vaccines require careful maintenance of the vaccine cold chain. For example, the varicella-containing vaccines may even require frozen storage to ensure long stability, even in the lyophilized state, and thus can rapidly lose potency under refrigerated storage (Kartoglu and Milistien 2014).

The second category, non-replicating vaccines (as they cannot replicate in vivo), usually require adjuvants in lieu of prohibitively high doses to provide sufficient levels of protective immunity in humans. From stability viewpoint, inactivated and subunit vaccines are generally more stable and are typically available as liquid formulations. These vaccines, however, can be freeze sensitive, especially if adjuvant with aluminum salts, which may collapse on freezing, lowering the adjuvant effect (Kartoglu and Milistien 2014).

**Table. 2.1. Freeze Sensitivity of Vaccines**

| Category | Antigen (Vaccine) Stability |
|---|---|
| Group A | Diphteria-Tetanus-acellular Pertussis-hepatitis B-Haemophilus influenza type b -Inactivated Poliovirus Vaccine (IPV) (hexavalent), Diphteria-Tetanus-acellular Pertussis - hepatitis B- Haemophilus influenza type b (pentavalent), Hepatitis A, Hepatitis B, Human papillomavirus, Meningitis C (polysaccharide-protein conjugate), Pnumococcal (polysaccharide-protein conjugate), tetaus, diphtheria-tetanus, low dose tetanus |
| Group B | Cholera (inactivated), influenza (inactivated, split), Haemophilus influenza type b (liquid), inactivated poliovirus, typhoid polysaccharide, Rotavirus (liquid). |

**Table. 2.2. Heat Sensitivity of Vaccines**

| Category | Antigen (Vaccine) Stability |
|---|---|
| Group A | Oral Polio Myletis |
| Group B | Influenza (Inactivated) |
| Group C | Inactivated Poliovirus, Japanese Encephalitis (live freeze dried), measles, or measles-rubella, measles-mumps-rubella, cholera (inactivated) |
| Group D | Cholera, Diphteria-Tetanus-acellular Pertussis-hepatitis B-Haemophilus influenza type b -Inactivated Poliovirus Vaccine (IPV) (hexavalent), Diphteria-Tetanus-acellular Pertussis - hepatitis B- Haemophilus influenza type b (pentavalent), Haemophilus influenza type b (liquid), Measles (freeze dried), Rotavirus (liquid and freeze dried), Rubella (freeze dried), Yellow fever (freeze dried). |
| Group E | Bacillus Calmette-Guerin (BCG), Human papilomavirus (HPV), Japanese encephalitis (JE), Tetanus, Diphteria tetaus (DT), dT (low dose tetanus). |
| Group F | Hepatitis A, Hepatitis B, Haemophilus influenza type b (Hib-freeze dried), Meningitis A (polysaccharide-protein conjugate), Meningitis C (polysaccharide-protein conjugate), Pneumococcal (polysaccharide-protein conjugate), Rabies, Typhoid Polysaccharide. |

## 2.5. Activities Regarding Cold Chain

According to annual Cold Chain Management guide and record report of 2012, show the EPI cold chain system activities in order to ensure quality cold chains in the program to keep vaccines potent until administration to the clients (Ramadhani 2015).

i. Regular monitoring and recording of vaccine temperature**:** vaccine temperature should be recorded two times per day including weekends by the cold chain person on the cold chain recording chart found on the door of the refrigerator in facilities with the refrigerator. It is one of the best indicator for the availability of quality cold chain.

ii. Appropriate storing and transporting of vaccines: vaccines are stored in the refrigerator main compartment to keep them with acceptable temperature range. There should be fifty per cent space within the vaccines for cold air to circulate. Thermometer that measures the temperature also should be there in order to monitor its temperature.

iii. Cold chain equipment cares and maintains: cold chain equipment must be handled and used with care to avoid damages. Once damage is occurred it should be maintained timely to avoid vaccine damage because of cold chain break.

iv. Production of ice packs: vaccine icepacks are important to keep vaccine cold chain during power breaks, transportation and vaccination sites. Therefore production and availability of adequate ice packs is the important task of cold chain management.

v. Immediate transferring of vaccine to cold box during power interruption: This is the transfer of vaccines from the refrigerator to the cold box until power comes. For this activity free zed icepacks are necessary.

vi. Maintaining cold chain of the static and outreach sites: static and outreach sites are the most dangers time for the exposure of vaccines for heats. In order to keep vaccines temperature cold chain person must use adequate ice packs at the vaccination sites.

## 2.6. Effective Vaccine Management (EVM)

Effective Vaccine Management (EVM), launched by WHO and UNICEF in 2010, is a quality improvement process for ISCL systems to compare their effectiveness against best-practice benchmarks. It is both a consultation and a survey tool, designed to identify the strengths and weaknesses of immunization programmes. By periodically repeating the process, programme

managers can measure their programme's health, chart a course for improvement and measure progress against their improvement plans (WHO & UNICEF 2014).

**EVM measures a wide spectrum of programmatic activities, including the following:**

1. Vaccine Arrival: All pre-shipment and arrival procedures ensure that every international shipment of vaccines from a manufacturer reaches its first destination in a country (a primary vaccine store or central medical store) in satisfactory condition (no breaks in the cold chain and no damaged vaccines) and is accompanied with all the recommended paperwork.
2. Temperature Control: All vaccines and their diluents are stored and distributed within a cold-chain system that maintains, at all times, the WHO-recommended temperatures ranges for all types of vaccines.
3. Storage Capacity: The national supply chain system has sufficient and quality cold storage, dry storage and transport storage capacity to accommodate all vaccines, diluents and injection supplies needed for the national immunization programme.
4. Infrastructure: The status and the layout of storage buildings, cold-chain equipment and vehicles enable the supply chain system to function effectively.
5. Maintenance: Preventive and Curative Maintenance Systems are standard and operational for storage buildings, cold-chain equipment and vehicles used to distribute vaccines.
6. Stock Management: Systems and procedures for managing the stocks of vaccines are effective, in terms of vaccine handling, physical inventory, stock-control systems, adequate stock-level policy, good warehousing practice, and disposal procedures for damaged and expired vaccines.
7. Distribution: The transport of vaccine between each level in the supply chain is effective, including the correct use of passive containers (cold boxes), packing practices with coolant packs (conditioned ice-packs or cool water packs), temperature indicators and maintaining transport contingency plans.
8. Vaccine Management: All recommended policies for vaccine management are adopted and implemented, including the use of vaccine vial monitors (VVMs), the shake-test, the multi-dose vial policy (MDVP), the use of diluents and the monitoring of vaccine wastage rates.

9. Information Systems: Logistics Management Information Systems (LMIS) and supportive management functions are effective, including standard operating procedures and vaccine-needs forecasting (WHO 2014).

Based on the study questions and objectives set, from the above nine criteria of effective vaccine management; vaccine temperature storage condition, vaccine stock management, vaccine management and vaccine storage and handling have been discussed.

### 2.6.1. Vaccine Storage Condition and Monitoring

The World Health Organization (WHO) has issued guidelines recommending that all vaccines used in routine immunization be kept between two and eight degrees Celsius during in-country distribution (the ‘‘cold chain”) (Eriksson et al., 2017). Vaccines are biological products that can be damaged by high temperatures, freezing temperatures, and excessive light. They are generally effective for a limited period of time at room temperature (PATH 2011). Cold chain is a procedure to maintain vaccine in certain temperature, in order to ensure the vaccine has potent state, from the manufacturer to the person being immunized (Saraswati et al., 2018). Most live virus vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to temperature fluctuations (e.g., extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions (out-of-range temperatures) that can have a cumulative negative effect. (Kausar et al., 2013).Thus, WHO recommends the following vaccines be stored and transported at 0–10 $^{o}$C: Diptheria-tetanus containing vaccines, tetanus toxoid (TT), hepatitis A and B, human papillomavirus (HPV), meningitis C, pneumococcal (PCV), cholera, influenza, haemophilus influenza b (Hib), typhoid and inactivated poliovirus (IPV) (Hanson et al., 2017).

Inappropriate transportation and improper storage of vaccines might lead to a decrease in vaccine effectiveness. For example, according to the product information sheets, inactivated polio vaccine, diphtheria-tetanus-pertussis vaccine (DTP), diphtheria and tetanus toxoids vaccine, hepatitis B vaccine (HepB), and tetanus toxoid vaccine (TT) are seriously damaged at temperatures less than 0°C. Hepatitis B vaccine freezes at temperatures less than -0.5°C. Once potency has been lost through exposure to excessive heat or freezing temperatures, returning the vaccine to the correct storage temperature will not cause the vaccine to regain its potency. If

potency is lost through heat exposure, the vaccine's appearance will not change. Without performing a laboratory test, it is not possible to know whether a vaccine has lost its potency (PATH 2011).

According to vaccine storage and handling toolkit and guideline, vaccines must be stored correctly from the time they are manufactured till they are administered to the patient. Excessive exposure of the vaccine to heat or cold will reduce its potency. Thus, children will not be protected against vaccine preventable diseases. The vaccine cold chain relies on three main elements. These elements include effectively trained personnel, appropriate transport and storage equipment and effective management procedures. These factors ensure a safe cold chain and potent vaccines. Maintaining correct temperatures during storage and transport of vaccines is a critical task for the health worker. Temperatures must be regularly measured and recorded in order to ensure storage of all vaccines at the correct temperature conditions, and ensure the correct operation of your cold chain equipment. Monitoring of temperatures should be a routine activity, and a task that is carried out at the start and end of each working day (CDC 2018).

A standard manual temperature-recording chart should be attached to the door or lid of every vaccine refrigerator. Readings should be taken twice a day at least five days per week and preferably every day, including weekends and holidays. Daily readings should be taken from the same temperature monitoring device each time. The health worker should read the 30 daily monitoring recording (DTR) and write the data on the chart. Recording temperatures in this way provides evidence that the refrigerator is being monitored and that regular readings are being taken. This can help identify performance trends, sometimes even before automatic alarms are generated. Manual readings should be recorded on a temperature chart attached to the refrigerator door using the following procedure: Check the refrigerator temperature first thing in the morning and at the end of the working day and record the temperature by date and time on the temperature chart specifically designed for 30 DTRs. When a chart is completed, replace it with a new one. Keep completed charts together in a file for future reference and action should be taken when the temperature goes out of range (PHAC 2015).

Checking and recording the minimum and maximum temperature of the vaccine refrigerator is an essential element of ensuring that vaccines remain safe and effective. Checking and recording

temperatures before using vaccine enables the identification of problems before vaccine (which may be damaged) is given. Twice daily checks give a better indication of any problems in the refrigerator's function and temperature fluctuations over the course of the day. However, the temperature needs to be viewed and considered every time the refrigerator is opened (Green Book 2013). In addition to twice daily monitoring and recording the temperature of the vaccine refrigerator, the health facility ensures safe and effective vaccines by checking minimum/maximum temperatures and VVM on vaccines during receiving of vaccines, every day before the facility commences and at the end of the working day, twice a day even on weekends and public holidays. Record temperature, comments and any action taken including if minimum and maximum temperature ranges are exceeded the recommended range of +2°C and +8°C, e.g. if restocking or defrosting the refrigerator. Record all temperatures on the Refrigerator Monitoring Chart (Fiji's MOH 2016).

### 2.6.2. Vaccine Stock Management

According to vaccine storage and handling tool kit 2018, vaccines are expensive, so it's important to make sure they are unpacked and stored correctly and to account for every dose received and used by your facility, whether administered, wasted, compromised, expired, or transferred. Keeping accurate records to assist you in ordering and rotating stock on a regular basis will ensure that your facility has available the vaccines your patients need (CDC 2018). The stock keeping tools record the following information for all vaccines and diluents. For the vaccines; Vaccine presentation (vial size), Quantity received in doses, Vaccine manufacturer, Manufacturing batch or lot number, Expiry date of each vaccine batch, VVM status where applicable, Location in the store and for diluents; Diluents presentation (vial size), Quantity received in doses, Diluent manufacturer, Manufacturing batch or lot number, Expiry date of each batch should be recorded on the stock record log book. When vaccines are received the shipment must be checked immediately for exposure to heat or freezing, stock that was ordered was received, damage to vials, expiry date. After the vaccines have been received, transfer them to the refrigerator immediately, minimizing the time that the refrigerator door is open. Fresh vaccines should be placed to the rear of the current stock if the expiry dates are longer than the current stock. If you have any concerns about your vaccine delivery, isolate the vaccines in the

vaccine refrigerator and contact the supplier. Stock must be rotated with the first expired, first out rule (WHO and UNICEF 2014).

According to the Western Cape Government Health of minimum standards on cold chain management, VVM status must also be taken into consideration. Vaccines with VVMs in stage 2 should be used before those with VVMs in stage 1. Diluents do not require refrigeration (only 24 hours before use). Diluents can be taken out of the cold chain to make space for vaccines where cold chain capacity is limited. It is vital that diluent is paired with its respective vaccine and diluent be clearly marked as such. In addition regarding the Vaccine Inventory Control; conduct a vaccine inventory at least once per week and when vaccine is delivered. Avoid stocking excessive vaccine supplies with a Limit of inventory to a 60-90 day supply for monthly vaccines and two to four weeks for flu vaccines. Moreover monitor expiration dates and rotate stock and use vaccines that expire sooner first. But the cold chain manager should never use expired vaccine or diluents (Western Cape Government Health 2003).

Regarding the vaccine distribution system in Ethiopia, the PFSA management of vaccine supply chain is also creating new opportunities to improve how vaccines are distributed throughout the country, focused on improving the delivery of vaccines. In the past, regional, zonal, woreda, and health facility staff collected vaccine supplies from the level above. Now PFSA is delivering vaccines from the central cold room to the regional hubs, ZHD, and then to woreda using refrigerated trucks. Existing Country Context for Vaccine Distribution Cold Chain system for vaccines and other cold storage requiring health commodities consists of four levels, following the FMOH administrative structures (Paul et al., 2015):

### 2.6.3. Vaccine Management

According WHO and UNICEF 2014, vaccine management is the policies and procedures related to the effective implementation of the cold chain. These include the use of vaccine vial monitors (VVM), the shake test, the multi dose vial policy (MDVP), the use of diluents, and the monitoring of vaccine wastage.

#### 2.6.3.1. Multi-Dose Vial Policy of Vaccines

The cold chain and immunization operation manual on the revised opened multi-dose vial policy states that: Opened vials of DPT, TT, DT, Hepatitis B and OPV vaccines may be used in subsequent immunization sessions for a maximum of one month and Opened vials of measles, BCG & yellow fever vaccines Reconstituted vials of measles, BCG and yellow fever vaccines must be discarded at the end of each immunization session or at the end of six hours; provided that each of the following conditions has been met: the expiry date has not passed, the vaccines are stored under appropriate cold chain conditions (2°C to 8°C with temperature monitoring and recording), the vaccine vial septum has not been submerged in water, aseptic technique has been used to withdraw all doses, if one of these vaccines has a VVM e.g. OPV, the VVM will indicate the potency of the vaccine and the vaccine may be used for any length of time as long as the VVM has not reached discard point, and the other conditions above apply. Whichever comes first, all opened vials must be discarded immediately if: Sterile procedures have not been fully observed, there is even a suspicion that the opened vial has been contaminated, **or** there is visible evidence of contamination such as a change in appearance, floating particles, etc. (Cold Chain and Immunization Manual 2003).

#### 2.6.3.2. Vaccine Vial Monitors (VVMs):

Excessive heat exposure can damage vaccines and result in reduced potency, which can impair development of individual and population immunity. The vaccine vial monitor (VVM) is a technology that registers cumulative heat exposure on vaccines over time. The technology was developed as a temperature-monitoring device to help health workers know whether a vaccine was still effective and could be used following exposure to potentially damaging heat during, for example, a cold-chain break, or whether it should be discarded. The VVM label provides an indication of the integrity of the cold chain, both in routine storage, and when vaccines are removed from storage for final distribution prior to vaccination sessions. This temperature management recommendation has been standardized for programmatic simplicity. VVMs contain a heat-sensitive material that registers the cumulative heat exposure of the vial over time (Eriksson et al. 2017). The VVM solved a major problem presented by the absence of temperature monitoring (Lioyd et al., 2017). The combined effects of time and temperature cause

the inner square of the VVM to gradually darken irreversibly. This ensures that health care workers can clearly identify which vaccine vials have reached their preset limit for cumulative heat exposure and should not be used. VVMs offer a wealth of benefits in addition to being able to track a vaccine vial's exposure to heat, such as (WHO and Path 2011) Quality Control. In the past, heat-damaged vaccines were sometimes unknowingly delivered to children, or good vaccines were thrown out because health care workers feared they had gone bad. Through using VVMs, health workers can tell just by looking at the color of the inner square which vaccines have not been exposed to too much heat and are therefore okay to use for immunization (WHO and Path 2011). VVMs can facilitate immunization program efforts to expand coverage, especially to difficult and remote locations. Some countries use VVMs to take vaccines beyond the reach of the cold chain (Eriksson et al., 2017). The availability of VVMs on vaccines helped WHO to create new policies on the handling of multi-dose vials of vaccines allowing open vials of some liquid vaccines to be used for more than a single day, saving millions of dollars. In addition, VVM allow countries to safely use vaccines, despite cold chain interruptions (WHO and Path 2011). It enables health care workers to make informed decisions about which vaccines to use. By reading the VVMs, health workers can identify vaccines that have received some heat exposure but are still good and preferentially select those vaccines to use first (WHO and UNICEF 2014). VVM measures the cumulative heat exposure of the vial they are adhered to (Eriksson et al., 2017). It is dangerous and inaccurate to generalize the reading from one vial to another. VVMs are quick and easy to interpret. After confirming that the expiry date has not passed, health workers follow two simple rules (WHO and Path 2011):

Rule 1: If the inner square is lighter than the outer circle, the vaccine may be used.

Rule 2: If the inner square is the same color as or darker than the outer circle, do NOT use the vaccine.

Start point Square lighter than circle. If the expiry date has not passed, USE the vaccine.

End point Square matches the circle. Do NOT use the vaccine.

End point exceeded Square darker than the circle. Do NOT use the vaccine.

There are four different VVMs, each designed for different types of vaccines depending on the vaccine's heat stability (WHO and UNICEF 2014).

**Table 2.3. VVM Stability**

| Category | Days to end point at +37°C | Days to end point at +25°C | Time to end point at +5°C |
|---|---|---|---|
| VVM 30: high stability | 30 | 193 | >4 years |
| VVM 14: medium stability | 14 | 90 | >3 years |
| VVM 7: moderate stability | 7 | 45 | >2 years |
| VVM 2: least stability | 2 | N/A | >225 days |

### 2.6.4. Cold Chain Equipment

Infrastructures of cold chain consist of cool room, freezer, refrigerator, cool box, cool pack, vaccine carrier, and generator (Saraswati et al., 2018). All cold chain equipment has to comply with a set of performance standards defined by the WHO EPI program and UNICEF, or national policy. Only proven methods should be used to transport or store vaccines: for example, insulated containers proven through electronic temperature logging as reliable in maintaining the recommended temperature (solid wall transport containers, double walled transport containers and polystyrene containers) (Kausar et al., 2013). There are different vaccine storage conditions appropriate to each level of the cold chain. Thus, each level requires different storage equipment depending on the quantity of vaccine to be stored, the duration of storage and the temperature necessary. All equipment must be able to keep vaccines safely whatever the outside temperature, and however the climate varies at different times of the year. There are also different types of equipment designed for transporting vaccines between the various levels of the cold chain, and for use during immunization sessions (WHO 1998). The recommended equipments typically used for vaccine storage are Cold rooms, Refrigerators, and Freezers. For transporting vaccines equipment such as are commonly used are Cold boxes, Vaccine carriers and International containers (Kausar et al., 2013).

### 2.6.5. Vaccine Storage and Handling Practice

Vaccine effectiveness cannot be guaranteed unless the vaccine has been stored correctly. Vaccines should be stored in the original packaging, retaining batch numbers and expiry dates. Vaccines should be stored according to the manufacturer's summary of product characteristics usually at +2˚C to +8˚C and protected from light. Prolonged exposure to ultraviolet light will cause loss of potency. Within the refrigerator, sufficient space around the vaccine packages should be left for air to circulate. Vaccines should be kept away from the side and back walls of the refrigerator; otherwise the vaccines may freeze rendering them inactive and unusable. Good practices to maintain proper vaccine storage and handling can ensure that the full benefit of immunization is realized (Saraswati et al., 2018). The CDC has estimated that each year, 300 million pounds worth of vaccines alone are destroyed globally due to improper storage and distribution. This scenario of failure of cold chain management has an end effect of causing wastage of vaccines which can be expensive and be in short supply (Ogboghod E.O et al., 2017).

Vaccines must be stored properly from the time they are manufactured until they are administered. Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacture to administration of the vaccine. By following a few simple steps and implementing best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive (CDC 2018).

Proper vaccine storage and handling procedures include monitoring the minimum and maximum temperature of the refrigerator(s) and freezer(s), as well as the room temperature, for a minimum of twice daily or if using an automated recording system with alarm, downloading temperature data for a minimum of once weekly. The temperature should be viewed every time the refrigerator is opened. This will allow for troubleshooting if required. Since temperature monitoring and recording devices (e.g., data loggers) and equipment (e.g., temperature alarm systems) are required, these devices do not eliminate the need for staff intervention and monitoring of the cold chain (Strive for five 2013).

Regarding the arrangement of vaccines within the refrigerators, vaccines should be organized by product; Placing vaccines of the same type together, leave space between the vaccine packages in the refrigerator to allow air to circulate. The expiry dates of vaccines should be checked regularly and after every vaccine order, always moving vaccines with shorter expiry dates to the front of the refrigerator so that they can be used first removing expired vaccines if available. Vaccines should be away from the refrigerator walls, floors and cold-air vents; storage of vaccine against refrigerator walls, floors and cold air vents because doing so increases the risk of exposing vaccines to temperatures below +2ºC. When storing vaccine in domestic or bar style refrigerators, always store vaccines on the middle internal shelves. Never store vaccines in refrigerator door shelves or drawers as they may be exposed to warmer temperatures. Since vaccines are heat and light sensitive, they must be protected from light by storing vaccines in their original packaging. (Ontario 2012).

Vaccine refrigerator must be dedicated for storage of vaccines only. Food, beverages or medical/laboratory specimens should not be stored in a vaccine storage unit because this practice results in frequent door openings and destabilization of the temperature. Storing filled water bottles on the lower shelf and the door of a kitchen or bar refrigerator used to store vaccines will help maintain an even, stable temperature inside the refrigerator. Diluents should be stored with vaccines and be kept within +2 °C to +8 °C. The refrigerator capacity should be large enough to store vaccine supply. There must also be enough room to allow air to circulate around the vaccine packages (CDC 2018).

Organizing staff to minimize the number of times the refrigerator is opened during the course of the day. Vaccines must be secured away from public access. Vaccine refrigerators should be equipped with a lockable door or the vaccine refrigerator should be stored in a room with a lockable door. Designated staff must lock the refrigerator and/or the room that vaccine is housed in after office hours. Always ensure that the refrigerator door is closed tightly. Installing an inexpensive Velcro latch from a hardware store can help ensure that the door is not accidentally left ajar during the day, or by cleaning staff after hours. To minimize the door opening of refrigerators, take vaccines out of the refrigerator only when ready to administer and protect vaccines from light and return unused vaccine to the refrigerator immediately after the required

dose has been drawn up. Vaccines that have not been stored between 2°C and 8°C should not be used until an assessment has been made. The refrigerator should be optimally placed in an area that is well ventilated, out of direct sunlight and away from external walls and ensure that the electrical outlet and refrigerator plug are secured to prevent the refrigerator from accidentally being unplugged or turned off. Place a highly visible sticker by the electrical outlet to make sure that the refrigerator is not unplugged (e.g., to plug in a vacuum) or cover outlet with a cage to prevent accidental disconnection (plug sticker is available from your public health unit) (PHAC 2015).

Since multi dose vial policy has been adopted and implemented, reconstitute vaccines immediately prior to use and only with the diluent provided by the manufacturer. For multi-dose vial, print the date opened on the label after opening. For reconstituted products, refer to the manufacturer's package insert for stability information following reconstitution. Mark the date on all multi-dose vials when the first dose is withdrawn. Once opened, multi-dose vials must be used within the time indicated on the product monograph. Aseptic technique for the withdrawal of vaccines must be followed at all times (Hyun-Sul Lim et al., 2012).

### 2.7. Cold Chain Status Globally

In the United States, a temperature study was conducted of refrigerators used to store vaccines in medical clinics. Thermometers were used to measure the minimum and maximum temperatures for a 24-hour period. The results indicated that only 2 of the 21 clinics studied had refrigerator temperatures that fell within the acceptable range. About 63% of the samples had temperatures that fell below the acceptable range, 59% reached temperatures higher than the acceptable range, and 93% were both higher and lower than the acceptable range. Since the study measured only the minimum and maximum temperatures, it is impossible to know how long the temperatures remained outside the acceptable range. During a three-day monitoring period, a study in New South Wales used data loggers to measure the temperature of 53 vaccine refrigerators in pharmacies and found that only 19% of the refrigerators studied had temperatures that fell within the acceptable range, while 23% of the refrigerators had temperatures that fell to less than 0°C and 29% had temperatures higher than 8°C. The assessment done in Thailand showed that vaccines were stored at a temperature lower than 0°C on 32 out of 43 facilities, the major

problems reported were that the refrigerator temperature was not in the range of 2°C to 8°C in 22% of the health facilities. Also vaccine freezing was detected at the provincial level (50%), the district level (29%), and health centers (28%) (WHO and PATH 2011). Assessments done in 440 storage units found in developed and developing countries, the percent of storage units where vaccines were exposed to temperatures below recommended ranges were 33.3% in wealthier countries and 37.1% in lower income countries (Hanson et al., 2017).

### 2.8. Cold Chain Status in Africa

Cold chain monitoring is still a major challenge in developing countries, including Cameroon. Assessments done in 65 health facilities found in North West region of Cameroon, Previous studies suggest that only about 56% of health facilities fill their temperature charts systematically twice a day as recommended. In 26 (50%) of the health facilities with a temperature recording sheet, a total of 409 days were skipped without recording the temperature twice daily as recommended. Temperature chart was complete/correctly filled in 25(50%) of the 50(96.2%) facilities having it. About 14 (26.9%) of the health facilities record at least one abnormal temperature during the last 2 months following data collection. 17 (28.3%) personnel did not know the correct vaccine storage temperature (Yakum et al., 2015). Concerning the 60 days preceding data collection, electricity outage was registered on the temperature recording sheet of 5(10%) health facilities. A total of 239 abnormal temperatures were recorded in 14(26.9%) health facilities. A total of 14(26.9%) vaccine fridges were exposed to overheating (temperature higher than 8°C) and 6(12%) exposed to cold (temperature lower than +2°C) in the two previous months to data collection. It is worth noting that all the vaccine refrigerators that were exposed to cold during the two months were equally exposed to overheating. Concerning the 60 days preceding data collection, electricity outage was registered on the temperature recording sheet of 5% of the health facilities (Yakum et al., 2015).

An external EPI review in 2012 done in provinces at Democratic republic of Congo, which found that 32% of health facilities had to interrupt immunization services during the six month preceding the review due to issues with the cold chain (Village Reach 2015). Evaluation of the Performance of Expanded Immunization Programme Supply Chain and Logistics Management in Southern Benin Rural Health District shows that in the 19 health centers, vaccines and liquid for dilution were stored at a temperature between 2 °C and 8°C on the day of the survey in 17

centers (89.47%), a temperature monitoring device was placed in the refrigerator in 18 (94.74%) centers, the recommended standards of vaccines storage were met in 15 (78.95%) health centers and effectiveness of twice-daily temperature monitoring of refrigerators was noted in 17/19 centers (89.47%). In addition vaccines have been exposed to freezing in 15.79% of the facilities at Benin (Agueh et al., 2016). Assessments done in the North West region of Cameroon, 53 out of 65 health facilities (81.5%) had at least one functional vaccine refrigerator. In addition 43.8% cold chain managers in the facility did not know the recommended vaccine temperature storage range. A total of 13 vials of OPV were found with the vaccine vial monitor at a discard point in 2% of the health facilities and 6 (11.3%) health facilities reported to have had a technical break down of refrigerator during the last 2 months (Yakum et al., 2015).

Data collected from a nationally representative sample of 661 health facilities in Ghana, Kenya, and Uganda was surveyed. From 661 health facilities in the three countries 441 claimed to regularly store vaccines. Only 4% of facilities stored vaccines in cold boxes, while the remainder (96%) used refrigerators. In total, it was observed that storage outside the recommended range in 16.6% (71 of 429) of the sampled facilities, though significant variation was observed between countries (26·2% [34 of 130], 16·3% [26 of 160], and 7·9% [11 of 139] for Ghana, Kenya, and Uganda, respectively). Of those facilities that were not compliant with the guidelines, half were 4°C or more outside the recommended range. While most facility-level characteristics, such as size, management, and location, were not found to be associated with vaccine storage temperature, facilities that had a written chart to monitor their storage equipment were associated with 6·42 (95% CI 3·09–13·32) times higher odds of storing their vaccines within the recommended range compared with those without a chart (Emily et al., 2013).

### 2.9. Cold Chain Status in Ethiopia

Cold chain status assessment conducted at 67 peripheral store facilities in Ethiopia showed that complete temperature record was observed in 37/64 (57.8%) of the health centers. Thermometer was not available in 4/64 (6.3%) and temperature reading was found to be outside the optimal range in another 7/64 (10.9%) of the health centers. Vaccine storage in the refrigerator was not proper in 47/64 (73.4%) health centers. Majority of the health centers had neither trained personnel nor budget for maintenance of the cold chain (Berhane et al., 2000).

Assessments done in three districts of Oromiya, SNNP and Amhara regions of Ethiopia, of 116 visited facilities, only 22 (19%) had functional refrigerators. The remaining facilities transported vaccines from nearby facilities having functional refrigerators. Complete temperature recording of the last month was observed in 13 (59.1%) facilities. Of 22 functional fridges, the thermometer reading was found to be outside the recommended range in 6 (27.3%) on the date of data collection. Vaccine storage in the refrigerator was not proper in 12 (54.5%) facilities and 65/116 (56%) health workers had satisfactory knowledge on cold chain management (Roggie et al., 2013). The research done for the status of surveillance and routine immunization performances in Amhara region, there had been vaccine stock out in the 3 months before assessment in 28/82 (34%) of the sites (Lakew GA et al., 2017).

In addition to the above, many of the typical supply chain challenges are exacerbated including improper storage of vaccines, and unsatisfactory knowledge in cold chain management at health facility levels. These have been supported by researches done at Health facility in Gambella region, Ethiopia only 7/28 (25%) of health facilities provided routine EPI service regularly while the rest 21/28 (75%) health facilities did not offer routine EPI regularly. The reasons given for not providing EPI services regularly were lack of refrigerator in 9/28 (32.1%) health facilities, shortage of kerosene in 7/28 (33.3%), the refrigerators were dysfunctional in 3/28 (14.3%), had no vaccine in 1/28 (3.6%) health facilities (Asres & Fantahun 2013).

## 2.10. Conceptual Frame Work of Cold Chain Management Practice

Conceptual Framework on Quality Vaccine Management

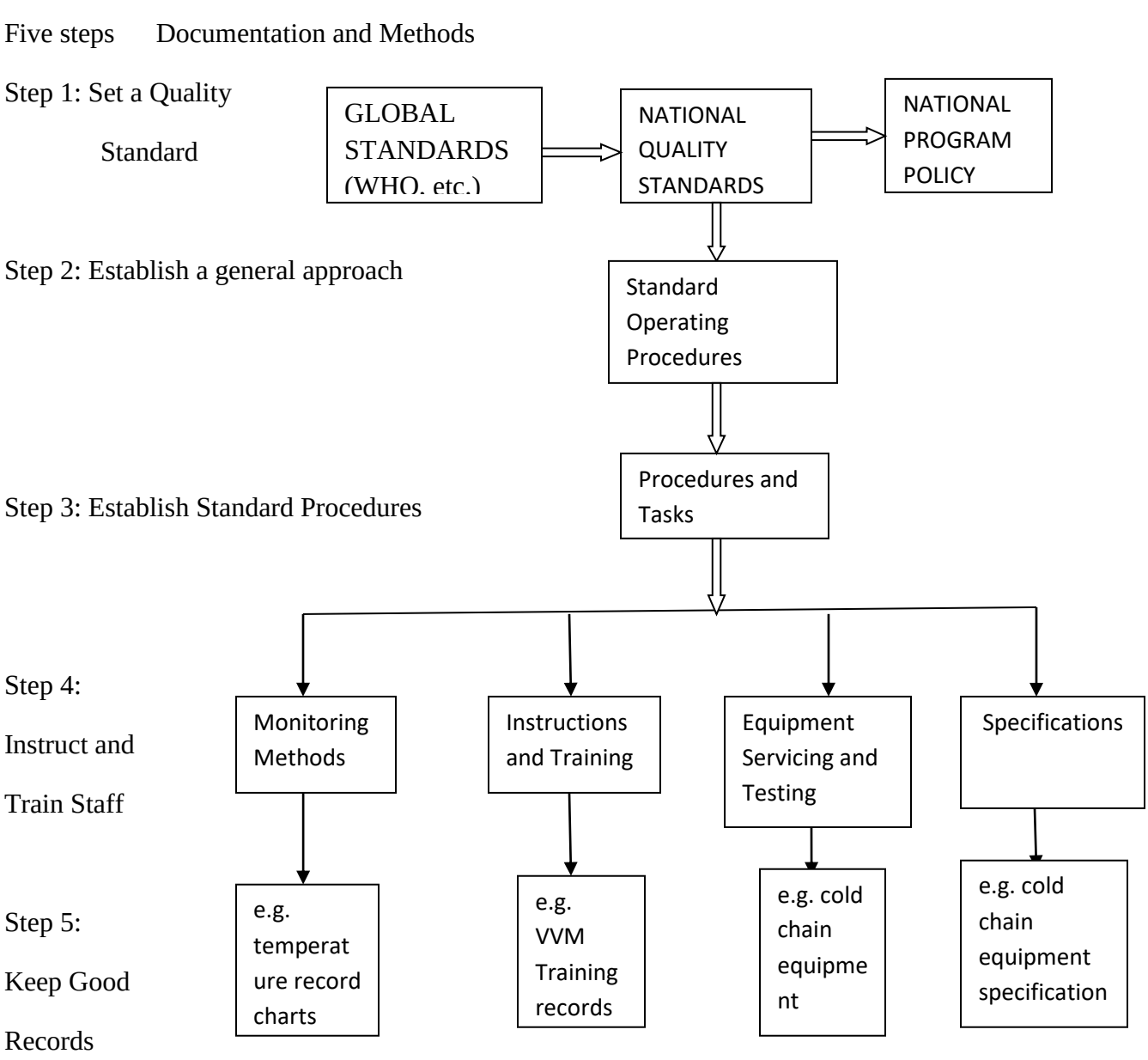


Figure 2.1. Source: conceptual frame work adopted from Effective Vaccine Management Assessment Tool (VMAT module 2, WHO 2005).

# CHAPTER THREE

# RESEARCH DESIGN AND METHODOLOGY

## 3.1. Introduction

Following the background, problem, research questions, objective, literature reviews, and conceptual framework, this chapter has presented the research methodology used to guide the study. In the study, the research design, the research instruments used to obtain data, the validity and reliability of the research instruments, the data collection process, the method for analyzing the data collected were described.

## 3.2. Study Area and Population

The study was conducted in public health facilities (health centers and woredas) at North Shoa Zone Amhara Region, Ethiopia. According to the Amhara Region Bureau of Finance and Economy Development (BOFED), North Shoa Zone is estimated to have 2,226,685 population. There are 95 health centers and 24 districts (woreda). The study or sampling units were health centers, woredas and north shoa zone. The study population was health professionals from health centers and woreda health offices under the zone. For the purpose of this study, the health centers and woreda vaccine stores were included. The data was collected from February to April 2018 G.C in selected woredas and health centers. The population was respondents from cold chain managers assigned at woreda and facility level as shown below the table. The total population of the study was 119 respondents (95 health centers having one EPI focal person each with a total of 95 respondents and 24 woredas having one cold chain manager each with a total of 24 respondents). The number and name of each woreda and facility under zone is annexed (annex 1). In preparing the sampling frame, the zonal health department was removed because at the time of study vaccines were not managed.

**Table 3.1. Number of Health facilities and respondents (Sampling Frame)**

| Level | Respondent | Number of Study Unit | Number of Respondents (Study Population) |
|---|---|---|---|
| Woreda (district) | Cold chain manager | 24 | 24*1=24 |
| Health Center | EPI Focal Person | 95 | 95*1=95 |
| **Total** | | **119** | **119** |

**Data Sourec: Researcher Data Survey 2018**

### 3.3. Research Design

Research design is an advance planning of the methods to be adopted for collecting the relevant data and the techniques to be used in their analysis, keeping in view the objective of the research and the availability of staff, time and money. It has a great effect on the reliability of the results as being the architectural backbone of the study in that it allows the researcher to identify measures to reduce bias, stipulate the frequency of data collection, and provides the answer to questions and guides the comparisons that will be made. Therefore, descriptive research approach was used to assess the status of cold chain management practice at health centers and woredas under North Shoa Zone, Amhara Region, Ethiopia.

### 3.4. Sampling Design, Sample Size determination and Sampling procedures

The sample size was determined before data have been collected. Therefore, the sampling method used for the study was probability. A multi-stage cluster sampling was used where health centers were selected from woredas. However, a consideration with regard to sample size was addressed using the “design effect” where the number of facilities was multiplied to account for differences between clusters. Hence, the sample size was calculated according to the guide for conducting supply chain assessments using the LSAT and LIAT. To generate representative sample a confidence level of 90% with a margin error of 10% was used. The sample size was calculated using formula for calculating sample sizes in finite population bases (John Snow Inc. 2011).

**Step 1: Calculating the General Sample Size**

The general formula for calculating a sample size is: $n = t^2 * p (1-p)/ m^2$ where:

n = required sample size

t = the value of the confidence level chosen (at 90 percent = 1.64)

p = estimated prevalence of the indicator.

(The product of p and [1-p] is maximized when p = 0.5. Therefore, when prevalence is unknown, 0.5 should be used)

m = margin of error I wish to allow in estimating the prevalence, expressed as a decimal at 10 percent, m = 0.1).

Therefore, $n= (1.64)^2 (0.5)(0.5)/(0.1)^2 = 67$

**Step 2: Accounting for Finite Population Correction Factor:**

Where there is a predetermined population, in this case, 119 total number of facilities in North Shoa Zone including 24 woredas and 95 health centers, the sample size generated from the above equation needs to be multiplied by the Finite Population Correction (FPC) factor. For our purpose, the formula can be expressed as: New n = n/ 1+[(n-1)/N]

Where:

New n = the adjusted new sample size

N = the population size = 119

n = the sample size (67) obtained from the general formula using the example above, ensuring a 10 percent margin of error and a 90 percent confidence level would require:

n= 67/1+[67-1]/119 = 67/1.55=43

**Step 3: Determining number of Facilities to be Selected from Each Cluster**

The sample size equations given above are for simple random sampling or, in other words, when it is possible to select the respondent (e.g., health facility) from the entire population (e.g., the whole facilities in the zone). However, due to travel or resource constraints (e.g., logistics, funding), it is necessary to use cluster sampling to obtain results, where the total population is divided into smaller groups (or clusters) and a sample of the groups is selected. For example, using the study sampling frame developed earlier, woredas were selected randomly and then within those randomly selected woredas, sample facilities were selected. In these situations, in order to produce survey estimates with the same precision as in a simple random sample, the sample size was multiplied by the design effect (DEFF). When no information is available, the default value of DEFF of 1.2 is recommended with facility-based assessment. Thus, the sample size from the above equations was multiplied by the DEFF (1.2) and then divided by the number of clusters to be sampled to determine the number of observations needed per sampled cluster (or district):

n per cluster sampled = (New n * DEFF)/ Number of clusters sampled

Therefore, number of facilities within each woreda assumes that it is feasible to go to 20 woredas where there are a total of 43 health centers will be calculated as:

Where
- DEFF=1.2
- New n=43
- Number of Clusters Sampled=20

n per cluster sampled= $\frac{(43)*(1.2)}{20}$ = 2 to 3 health centers per woreda will be selected

Hence, 20 woredas and 43 health centers with a total of 63 public health facilities were included in the study using multi stage cluster sampling.

**Step 4: determining the specific list of sample facilities**

Once the number of woredas and number of health centers within each woreda has been determined, the specific list of facilities were determined using simple random sampling since

the health centers within each selected woredas were homogeneous in the population and they had an equal chance to be included in the study. The selected woredas and facilities have been annexed (annex 2).

### 3.5. Data Sources and Types

The main data sources of this study were primary and secondary data. Primary data was obtained from either through direct communication with respondents or through observation. Self administered questionnaire for cold chain managers was used for this particular study. In addition to primary data, secondary data source was used. These data are already available which have been collected and utilized by someone else. Secondary data source used for the study include literature reviews from books, journals, various publications, reports and other relevant documents related to vaccine cold chain management.

### 3.6. Instruments and Data Collection Procedures

The data collection instrument was self administered questionnaire. The cold chain management practice of vaccines by the health facilities was explored by means of a self-administered questionnaire with likert scale of five. Staff working in the cold chain management was included in the research study. Questionnaire was developed through careful review of the existing literature and in accordance with the framework suggested by WHO for effective cold chain vaccine management. The questionnaire included items regarding Policy, procedures, vaccine storage and handling guidelines, storage and handling practices, cold chain equipment status. Effective vaccine management assessment tool (VMAT – Module 1) WHO 2005) and vaccine storage and handling tool kit (PHAC 2018) was used to develop data collection tool. A self-administered questionnaire was distributed to a representative sample of 43 health centers and 20 woredas. From health centers and woredas, 43 EPI focal persons and 20 cold chain managers respectively was participated as a respondent in the study. Hence a total of 63 respondents were expected for the study. Regarding data collection procedure the data was collected by the principal investigator using self administered semi-structured questionnaire (annex 1).

### 3.7. Criteria for Inclusion and Exclusion

#### Inclusion Criteria

Woreda and health center cold chain managers were considered in the study. All full-time health professionals directly involved in cold chain management employed at woreda and health center level was considered. In addition, all health professionals who have a full time delegation for the position of cold chain management were included in the study, in case if the designated personnel were absent.

#### Exclusion Criteria

Regarding the staffs, staff members who were not directly involved in the daily activities, student health professionals practicing at facilities, those healthcare personnel who were unwilling to participate and those who were on leave during the study was excluded from the study. In addition health professionals who didn't handle vaccines and absent during collection was excluded.

### 3.8. Validity and Reliability

Questionnaire design is only one step in the process that ultimately leads to generating answers to research questions of interest. After the questionnaire was designed, a pilot test was run to make sure it was understandable and acceptable to the intended audience; to increase the clarity of the questions for respondents' understanding and to ensure the appropriateness of the questions, before launching the full scale study.

Hence, before starting upon data collection, pretest of the prepared questionnaires was performed in two HCs and woreda at Basona Werana, which was found around Debre Berhan. The principal investigator was involved in the data collection process and review completed questionnaires to clarify any data inconsistencies. In order to assure the quality of data, the same questionnaire was administered to all participants for the study in all selected facilities. During the study measures were taken in order to ensure consistence of data quality including verification of filled questionnaires and Coding of the questionnaires. Reliability of data was confirmed using SPSS tool, after all the data had been entered in to the software, reliability analysis was done. Reliability is considered to be good if the reliability analysis test value is

greater or equal to 0.7. Accordingly the study was reliable based on the analysis obtained with a Cronbach's Alpha result of 0.845.

### 3.9. Data Analysis

The quantitative data was entered and analyzed using SPSS version 20 and Microsoft Excel 2010 and statistical method used was descriptive. Study results have been presented by using tables, Pie charts, and histograms.

### 3.10. Ethical Considerations

Before commencing data collection, ethical clearance was obtained from Addis Ababa University School of Commerce where by written letter was given to the host organization (North Shoa Zone Health department) so as to accept the data collection activity at the area. Then ZHD wrote ethical clearance to the respective woredas and health centers for smooth communication and data collection activity. Participants of the study were asked for consent before participating in the study. During the consent process, they were provided with information regarding the purpose of the study, why and how they were selected to be involved in the study, and what was expected from them and that they can withdraw from the study at anytime. Participants were also assured about confidentiality of the information obtained in the course of the study by not using personal identifiers and analyzing the data in aggregates. Consent claims that participants were not be at risk by refusing to participate in the assessment or stopping their collaboration during the study. Confidentiality was maintained throughout the process of data collection.

# CHAPTER FOUR

# RESULTS AND DISCUSSIONS

## 4.1. Introduction

The previous chapter outlined the methodology adopted in conducting this study. This study gives attention on cold chain management practice in health facilities based on standard storage and proper handling of vaccine at north shoa zone and presents the data obtained from the study. A self-administered questionnaire was used to collect the data from the facilities who manage vaccines at woreda and facility level. This chapter presents the answer in a logical way to assess the cold chain status of vaccines, to assess the effective vaccine management activities, and to assess the cold chain equipment status at facility. This chapter will present the findings of the self-administered questionnaire and provides a detailed analysis of the data collected from the survey. It starts by analyzing data according to the research questions which guided this study. The questionnaire was the primary tool used to collect data for the study. The questionnaire was distributed to cold chain mangers at woreda and EPI focal persons at health centers.

## 4.2. Response Rate

From the selected 63 public health facilities (i.e. 20 woredas and 43 health centres), 60 facilities have been participated in the study. Based on inclusion and exclusion criteria, a total of three facilities (two woredas and one health center) have been excluded from the study since the two woredas were not managing vaccines and the health center is not available at the time of assessment. All 60 public health facilities' respondents agreed and participated in the study. Therefore, the overall response rate of the interview that was conducted was 100%.

### 4.3. Demographic Variables

**Table 4.1. Demographic Variables**

| Age in years f(%) | | Work experience in years f(%) | | Educational status f(%) | | Profession f(%) | |
|---|---|---|---|---|---|---|---|
| 20 to 25 | 18(30%) | < 1 | 6(10%) | degree | 8(13.3%) | Druggist | 15(25%) |
| 26 to 30 | 30(50%) | 1 to 5 | 37(61.7%) | diploma | 51(85%) | clinical nurse | 34(56.7%) |
| >31 | 12(20%) | 6 to 10 | 13(13.7%) | certificate | 1(1.7%) | health officer | 4(6.7%) |
| | | 11 to 15 | 3(5%) | | | health extension worker | 1(1.7%) |
| | | >15 | 1(1.7%) | | | Midwifery | 2(3.3%) |
| | | | | | | BSC nurse | 4(6.7%) |
| total | 60(100%) | total | 60(100%) | total | 60(100%) | total | 60(100%) |

**Data Source: Survey Result, 2018**

Gender, sex, experience at work and educational background of the participants were examined and their distribution is summarized in the table. Regarding gender 41.7% (n=25) respondents were male and 58.3 % (n=35) were female. The majority of participants were from 26 to 30 years old (50%, n=30). Regarding the educational status 85% (n=51) of the respondents were diploma. The professional mix of the respondents have shown that the majority of professional who were involved in vaccine cold chain management practice were clinical nurses with 56.7% (n=34) followed by pharmacy technicians 25% (n=15). In addition the majority of respondents i.e. 61.7% (n=37) were between 1 to 5 years of work experiences.

### 4.4. Assessment on Vaccine Storage Condition and Monitoring

**Table 4.2. Assessment on Vaccine Storage Temperature**

| Vaccine Storage Temperature | strongly agree | agree | undecided | disagree | strongly disagree |
|---|---|---|---|---|---|
| the cold chain manager can give the correct temperature range for each of the vaccines | 88.30% | 11.7 % | 0% | 0% | 0% |
| the cold chain manager can give the correct freezing temperature of the freeze sensitive vaccines | 0% | 0% | 0% | 43.30% | 56.70% |
| For the past six months, there is a complete set of twice-daily manual temperature records for each refrigerator | 8.30% | 43.30 % | 0% | 38.30% | 10% |
| the temperature of the refrigerator has been recorded twice a day when the facility is open | 0% | 81.7 % | 0% | 16.70% | 1.70% |
| the contact numbers to report a cold chain breach is easily accessible | 0% | 0% | 0% | 98.30% | 1.70% |
| the responses to all deviations outside +2°C and +8°C has been documented and actions taken | 5% | 56.70 % | 0% | 33.30% | 5% |
| The refrigerator temperature is within correct range of 2ºC to 8ºC at the time of visit. | 0% | 70% | 3.30% | 20% | 6.70% |
| vaccines have been exposed to overheating in the past six month (higher than 8ºC) | 0.00% | 40% | 15% | 45% | 0% |
| vaccines have been exposed to lower than 2ºC in the past six month | 0% | 11.70 % | 15% | 73.30% | 0% |
| during the past six month there was a cold chain breach and alarms have been documented | 0% | 43.3 % | 15% | 41.70% | 0% |
| there is a satisfactory contingency plan | 0% | 0% | 0% | 96.7% | 3.3% |

**Data Source: Survey Result, 2018**

In order to assess the cold chain status of the health facilities some variables were used. From 60 facilities involved in the study, 51.7% (n=31) of the facilities had complete set of twice daily manual temperature monitoring chart where as 48.3 % ( n=29) facilities were not monitoring the cold chain status in twice daily bases considering the last 6 month monitoring. Regarding the daily temperature monitoring activity, 81.7% (n=49) of facilities monitored the cold chain in twice daily bases using temperature monitoring but 19.3% (n=11) didn't monitor the cold chain at the time of visit. In 66.7% (n=37) facilities, the responses to all deviations outside 2ºC and 8ºC had been documented and the recommended actions were taken by the facility. In addition, at the time of visit in 26.7% (n=16) facilities the refrigerator temperature readings were outside the recommended range. Regarding the knowledge on vaccine storage temperature range, all of the respondents knew about normal vaccine storage temperature range to be from 2ºC to 8 ºC (100%, n=60) on contrary all of them didn't know about the freezing vaccine temperature range to be -15ºC to -25ºC (100%, n=60).

The above results indicate that facilities are not monitoring the vaccines appropriately in a continuous manner. It is expected that the facilities should monitor the storage condition of the vaccines in twice daily bases but the facilities lack this practice. Not only there is a gap in monitoring the storage condition of vaccines but also there is poor documentation practice of the temperature monitoring chart in the facilities. In addition the result has shown that the facilities' refrigerators has considerable problem in maintaining appropriate storage condition since vaccines should be stored with in recommended temperature range during storage and transportation.

**Discussion on Vaccine Temperature Storage Condition**

According to the National Standards for Vaccine Storage and Transportation for Immunization Providers of New Zealand, 2017, maintaining correct temperatures during storage and transport of vaccines is a critical task for the health worker. Temperatures must be regularly measured and recorded in order to ensure storage of all vaccines at the correct temperature conditions, and ensure the correct operation of your cold chain equipment. Monitoring of temperatures should be a routine activity, and a task that is carried out at the start and end of each working day (MOH New Zealand 2017).

Regarding the temperature monitoring status of facilities a document review of a period from September to February was done. Regarding the daily temperature monitoring activity, 81.7% (n=49) of facilities monitored the cold chain in twice daily bases using temperature monitoring but 19% (n=11) didn't monitor the cold chain at the time of visit. Taking the last six month temperature monitoring status of the facilities, from 60 facilities involved in the study, 51.7% (n=31) of the facilities had complete set of twice daily manual temperature monitoring chart where as 48.3 % (n=29) facilities were not monitoring the cold chain status in twice daily bases i.e. 1158 days were missed in those facilities during the last six month review period and 40 records were once times daily. Similar assessments done in North West region of Cameroon revealed that 49% of the facilities didn't have complete set of twice temperature monitoring records. The reason probably was some of the facilities in the current study didn't have monitoring chart to record the temperature as it has been revealed by 16.7% (n=10) of the facilities. Assessments done at North West region of Cameroon, only 50% (n=26) of the facilities have temperature monitoring chart (Yakum et al. 2015). The other reason for incomplete temperature recording mentioned was some of them didn't have any temperature monitoring device. The current study with regard to temperature monitoring device revealed that 15% (n=9) facilities didn't use any temperature monitoring device which was higher than 6.3% (4/64) in peripheral stores in Ethiopia (Berhane and Demissie 2000) and 5.26% (1/19) facilities in provinces at Democratic Republic of Congo (Agueh et al. 2016). Another reason probably was they didn't take the training or orientation how they could monitor the cold chain especially how to read the fridge tag and even in some of the facilities there was no any knowledge and skill transfer from the previous cold chain manager. In addition to the above reasons mentioned above the probable reason could be in the previous years there was technical support from zonal immunization technical assistant recruited by UNICEF in order to strengthen the routine EPI activity but in this Ethiopian fiscal year the contract of the technical assistant was terminated and hence due to this the regular and continuous support was not available.

The result obtained from the current study was lower than similar assessments done in 65 facilities at North West region of Cameroon about 56% (Yakum et al. 2015) and 57.8% (37/64) of the health facilities at 67 peripheral stores in Ethiopia (Berhane and Demissie 2000). The reason mentioned on the assessment at North West region of Cameroon was even though the

SOP in Cameroon recommends that the temperature should be registered twice daily every day including weekends and holidays, there was lack of motivation, training and supervision of health personnel. The reason to be lower at peripheral stores in Ethiopia was lack of training and regular supervision from the higher level. Hence, the reason given by both assessments were aligned to the current study. But the result obtained from the current study was lower than when compared to an effective twice-daily temperature monitoring of refrigerators in 17/19 centers (89.47%) at facilities in southern Benin. This could be justified by the frequency of supervision and evaluation in all health facilities from the higher level (Agueh et al. 2016). Hence from the above assessments and findings we can imagine that in order to improve the temperature monitoring and cold chain management practice there should be regular supportive supervision, training, monitoring and evaluation.

Regarding the outage temperature readings, at the time of visit, from the facilities that monitor the cold chain, 70% (n=42) of facilities had a temperature reading within the normal range of between 2$^{o}$C and 8$^{o}$C but in 26.7% (n=16) facilities the refrigerator temperature readings were outside the recommended range. The preceding six month temperature recording, taking from September to February, had shown that 26.7% (n=16) of the facilities registered abnormal temperature out of the recommended range. A total of 419 records were less than 2$^{o}$C (38.3%, n=23) and 409 records were above 8$^{o}$C (40%, n=24), also there was negative temperature readings less than 0 $^{o}$C in 11.7% (n=7) of the facilities with 13 records. The reason probably was frequent power interruption/fluctuation in most of the facilities which had temperature outage records. Most of the health facilities didn't have adequate contingency plan in case of power interruption even the respondents replied that when the power was interrupted they wait for some period of time until the coming of electric power. Most of them didn't have a stand by generator or the generator was non functional or even though there was available, the refrigerators were not connected to the generator. The other reason that the respondents replied was they didn't know how they can correct in case of temperature outages i.e. lack of training. The refrigerator failure in some of the facilities was frequent and there was no immediate response from the responsible body probably from woredas who have the capacity to maintain and from zone technician especially those equipment failures that need the expertise.

The result obtained from the current study (26.7%) was similar with the assessments done in three districts of Oromiya, SNNP and Amhara regions of Ethiopia on 2013, the thermometer reading was found to be out of the recommended range in 6 (27.3%) on the date of data collection (Roggie et al. 2017) and better than the assessments done in North West region of Cameroon, at the moment of data collection, 33.3% of the facilities documented temperature outage during the visit. A total of 239 abnormal temperatures were recorded in 14(26.9%) health facilities. A total of 14(26.9%) vaccine fridges were exposed to overheating (temperature higher than 8°C) and 6(12%) exposed to cold (temperature lower than +2°C) in the two previous months to data collection. The possible reasons to be lower, explained by North West region of Cameroon were the low proportion of the health workers having access to national guidelines, trained on how to monitor the cold chain, supervised, and using the contingency plan, frequency of power outage (Yakum et al. 2015). The reason for the assessment done in Ethiopia, there was frequent interruption of power supply and insufficient kerosene supply. Hence the reason behind temperature outage in most of the facilities was power interruption. Some of the reasons were in line with that of the current study especially the lack of training, power fluctuation and absence of contingency plan. But the result obtained from the study was totally different from the cold chain assessment done at peripheral vaccine stores in Ethiopia in which it revealed that thermometer reading was found to be outside the optimal range in 10.9% (7/64) centers (Berhane and Demissie 2000) i.e. the result of cold chain assessment from peripheral vaccine stores was better than the current assessment in that in the former there was better vaccine storage practice and securing funds for cold chain maintenance especially in the rural sites and also the record keeping and temperature monitoring was better especially the urban sites when it has been compared to the current study.

In addition, in the temperature monitoring chart, appropriate documentation was checked during the assessment in relation to alarms and the actions taken to resolve the problems. Hence in this regard, in 61.7% (n=37) facilities, the responses to all deviations outside 2$^{o}$C and 8$^{o}$C had been documented and the recommended actions were taken by the facility. A total of 133 alarms in 43.3% (n=26) of the facilities were recorded from September to February six month review. When the alarms happened the facilities took one or more of the following actions: VVM check, Conducting of Shake test, Thermostat adjustment, and Refrigerator maintenance, Vaccine

transfer to other sites or other monitored cold chain equipments, report to higher level. But the problems in documenting the alarms were due to the temperature monitoring device (fridge tag) were not available in some of the health facilities. In addition some facilities didn't have temperature monitoring chart containing minimum and maximum temperature recordings together with actions taken to alarms i.e. the monitoring chart was not suitable to register the minimum and maximum recordings. Similar assessment done in Nepal shown that 14(74%) of health care workers didn't comply and practice by keeping out of range record on temperature monitoring chart because the temperature record form does not include space for entering alarm events. But the challenge was on weekend that is, Saturday and Sunday when most of staff were out of their working station and even if the power breakdown appear was difficult to monitor the out of range temperature (WHO and UNICEF 2014). The current study (61.7%) was less than that of the study in Nepal (74%); the reason for poor performance could be the temperature monitoring format and the monitoring device to track the minimum and maximum readings.

Regarding the knowledge on recommended vaccine storage temperature range, all of the respondents knew about the recommended vaccine storage temperature range to be from 2$^{o}$C to 8 $^{o}$C (100%, n=60) the result of the current study was in line with similar assessment done in Nepal and different from the study found at democratic republic of Congo which was 43.8% cold chain managers in the facility didn't know the recommended vaccine temperature range (Village Reach, 2015). But all of the respondents in the current study didn't know about the freezing vaccine temperature range to be -15$^{o}$C to -25$^{o}$C (100%, n=60) which was different from the result from similar assessment done in Nepal in which the correct storage temperature ranges (for each of the vaccines in the national immunization calendar) were known by 100% of health workers interviewed at all levels. All storekeepers or health workers knew which vaccines on the schedule can be damaged by temperatures below 0°C at all levels (WHO and UNICEF 2014).

Regarding the contingency plan, health facilities should develop and adhere to detailed written routine vaccine storage and handling plan that is updated annually. A written plan helps vaccine providers to remain organized and serves as a reference and training tool as well as providing assurance of proper vaccine management and prevention of vaccine wastage (CDC 2018). The current study on the contingency plan for cold chain breach and equipment failure, all facilities

had no a written and documented satisfactory contingency plan in the event of equipment failure and there was no any emergency contact detail posted in the vaccine storage room in case of cold chain breach. The current study was similar with assessments done on effective vaccine management in Maharashtra, India (UNICEF 2011) and assessments done on effective vaccine management in Nepal (WHO and UNICEF 2014). In all of the studies done even though a standard operating procedure which sets out a contingency plan in the event of equipment failure or other emergency should be prepared, none of them had a written plan on contingency. The reason was probably a limited knowledge on preparing and implementing the plan. On the current study some of them verbally communicated what actions would be taken in an emergency situation to ensure vaccines were not compromised and the cold chain system was still managed effectively. The respondents replied that transferring the vaccine to alternative storage in cold box or nearby facility in case of equipment failure, use kerosene or adjusting the refrigerators for minor correction, but there was no evidence of written documentation in this regard. According to the vaccine storage and handling guideline, each health care provider's premises should have a contingency plan for vaccine storage in the event of a refrigerator malfunction and electricity disruptions. If there is no access to a backup power supply (i.e., generator) at the premises, arrangements should be made in advance with an alternate storage site that has an emergency backup power supply and appropriate vaccine storage capacity. However, if this cannot be arranged, insulated containers and packaging materials should be made available to temporarily and safely store the vaccines at the premises.

### 4.5. Assessment on the cold chain equipment status

**Table 4.3. Assessment on cold chain equipment status**

| | Cold Chain Equipment Status | strongly agree | Agree | undecided | Disagreed | strongly disagree |
|---|---|---|---|---|---|---|
| | Where applicable, are there adequate reserve supplies of kerosene and/or gas | 0.0% | 15.0% | 76.7% | 6.7% | 1.7% |
| | there is sufficient icepack freezing and storage capacity to meet peak demand | 0% | 53.3% | 0% | 45 % | 1.7% |
| | there is sufficient refrigerator for vaccine storage | 3.3% | 51.7% | 0% | 33.3% | 11.7% |
| | all refrigerators are fully functional at time of inspection | 5 % | 56.7% | 0% | 26.7% | 11.7% |
| | facilities have at least one functional refrigerator | 0 | 93.3% | 0 | 6.7% | 0 |
| | all refrigerators have a working temperature monitoring device stored with the vaccine (dial thermometer or fridge tag) | 56.7% | 28.3% | 0% | 0% | 15% |
| | there are sufficient cold boxes and vaccine carriers | 0% | 83.3% | 0% | 16.7% | 0% |
| | staff know how to condition icepacks and how to pack transport boxes | 15% | 70% | 0% | 15 % | 0% |
| | there is a planned preventive maintenance, and replacement plan, and is being followed | 0% | 5% | 0% | 95% | 0% |
| | During the past six months vaccine refrigerator fail to the extent that vaccine was damaged | 3.3% | 21.7% | 0% | 73.3% | 1.7% |
| | During the past six months, a shortage of spare parts or consumables cause refrigerator to be removed from service for longer than seven days | 1.7% | 21.7% | 0% | 76.7% | 0% |
| | There are records of regular refrigerator servicing, defrosting and cleaning available. | 0% | 1.7% | 0% | 98.3% | 0 |

**Data Source: Survey Result, 2018**

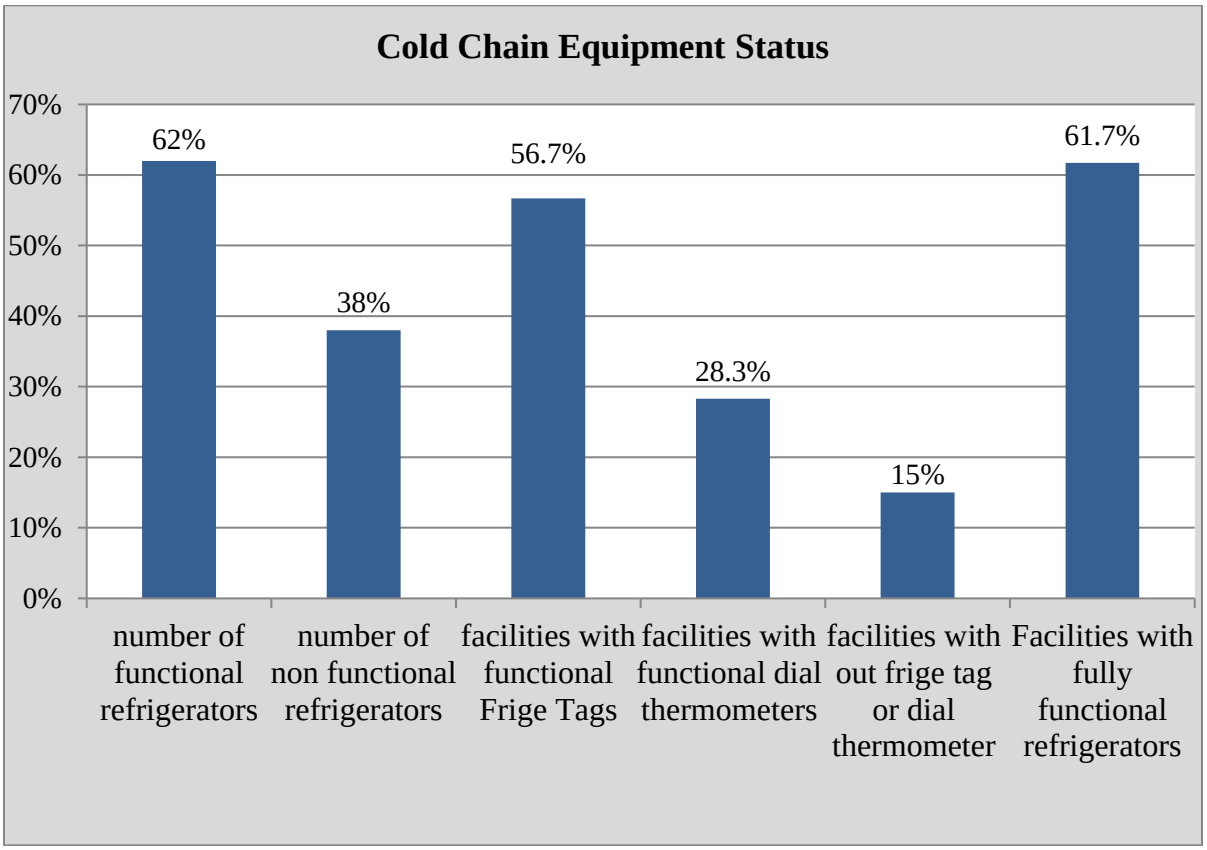


**Figure 4.1. Cold Chain Equipment Status**

**Data Source: Survey Result, 2018**

Assessment conducted on the cold chain equipment status of facilities revealed that 46.7% (n=28) facilities had not sufficient ice pack and icepack freezing capacity and also 45% (n=27) facilities didn't have sufficient refrigerator for vaccine storage. Regarding the refrigerator status, in 38.3% (n=23) of the facilities all the available refrigerators were not functional. At the time of visit we had counted 128 refrigerators within the facilities of which 62% (n=79) were functional and 38% (49) were non functional. In the assessment the temperature monitoring devices that are used were included. Hence, 56.7% (n=34) facilities used fridge tags as temperature monitoring device, 28.3% (n=17) facilities used dial thermometer as monitoring device but 15% (n=9) facilities didn't use any temperature monitoring device. Regarding the cold chain equipment maintenance status, none of the facilities had documented preventive maintenance plan and records of refrigerator servicing, defrosting and cleaning available. During the past six months, in 23.4% (n=14) facilities, there was a shortage of spare parts or consumables cause refrigerators

to be removed from service longer than seven days. Some facilities used kerosene incase of power interruption and 15% (n=9) facilities had adequate kerosene supplies whereas 8.4% (n=5) facilities didn't have adequate kerosene supplies.

The assessment results indicate that there is considerable number of refrigerators which are out of service which minimizes the capacity of the cold chain with in the facilities. Whenever there are non-functional refrigerators, the facilities are compelled to store vaccines to non-standardized refrigerators and it affects proper storage condition of vaccines. For those facilities which don't have temperature monitoring devices, it is difficult to know the status of the vaccines and whether the refrigerators can maintain the recommended temperature or not.

**Discussion on Assessment of the cold chain equipment status of the facilities**

Cold chain equipments are very important parts to maintain the cold chain of vaccines within the recommended storage range. An acceptable functioning cold chain is defined as a cold chain that does not have refrigerators that have stopped working for seven or more days (Van den Ent et.al. 2017). Regarding the vaccine refrigerator, 45% (n=27) facilities didn't have sufficient refrigerator for vaccine storage and in 38.3% (n=23) of the facilities one or more refrigerators were non functional. In addition 93.3% (n=56) of the facilities had at least one functional refrigerators which was very different result when compared to similar assessment done in the North West region of Cameroon, 53 out of 65 health facilities (81.5%) had at least one functional vaccine refrigerator (Yakum et al. 2015), the assessments done in three districts of Oromiya, SNNP and Amhara regions of Ethiopia, of 116 visited facilities, only 22 (19%) had functional refrigerators (Roggie et al. 2013) and assessments done at Health facility in Gambella region of Ethiopia revealed that the refrigerators were dysfunctional in 3/28 (14.3%) (Asres & Fantahun 2013). The better result of the current study was probably due to there were refrigerator distributions from the government of Ethiopia in the recent years especially there were solar refrigerators distributions for facilities and there was time gap between the current assessment and the assessments done in Cameroon (2013), Ethiopia (in 2011 and 2012) and Gambella (2011).

At the time of visit 128 refrigerators were assessed within the facilities of which 62% (n=79) were functional and 38% (n=49) were non functional. The study shows that the non functional refrigerators were not few in numbers probably the reason mentioned here was poor maintenance

capacity, limited knowledge on maintenance (both preventive and corrective) and availability of outdated refrigerator types (sibir refrigerator) in the facilities. From 277 vaccine refrigerators and vaccine freezers identified in Nepal (all types, including solar) 172(62%) were fully operational at the time of inspection (WHO and UNICEF 2014). There was no difference between the two assessments regarding the functional status of refrigerators. Regarding the cold box availability, 83.3% (n=50) of the facilities had functional cold box and it was comparable with that of the assessment in three districts of Ethiopia (86.6%, 33/38) (Rogie, et al. 2013). Regarding the icepacks, 46.7% (n=28) facilities didn't have sufficient ice pack and icepack freezing capacity. Similar assessments done in Nepal shown that 80% at service delivery point level, the available icepack freezers have sufficient capacity to meet the maximum daily demand for icepacks (WHO and UNICEF 2014).

### 4.6. Assessment on vaccine stock management and vaccine management activities

**Table 4.4. Assessment on Stock Management**

| Stock Management | strongly agree | Agree | undecided | disagree | strongly disagree |
|---|---|---|---|---|---|
| all receipts and dispatches are recorded and balances are updated using below listed criteria | 3.3% | 55.0% | 0.0% | 33.3% | 8.3% |
| all receipts and dispatches are recorded and balances are updated on receiving and issuing voucher | 3.3% | 71.7% | 0% | 23.3% | 1.7% |
| vaccine requisition forms are used for ordering and receiving vaccine | 3.3% | 95% | 0.0% | 1.7% | 0.0% |
| vaccine distribution generally made according to the "first expiry – first out" (FEFO) principle | 5% | 95% | 0.0% | 0% | 0.0% |
| the vaccine managers make exceptions to the 'FEFO' rule (e.g. because of VVM status) | 5% | 95% | 0.0% | 0% | 0.0% |
| vaccines are delivered by PFSA | 33.3% | 0.0% | 0.0% | 0.0% | 70.0% |
| Vacines are delivered by or collected from woreda health office | 66.7% | 0.0% | 0.0% | 0.0% | 30.0% |
| physical counts have been carried out and recorded | 5% | 95% | 0% | 0% | 0% |

**Data Source: Survey Result, 2018**

As it has been mentioned in the table**,** all facilities (100%, n=60) used first expiry first out principle and VVM status for those vaccines at 2nd stages. Regarding the inventory management all receipts and dispatches were not recorded in 41.7% (n=25) of facilities and 25% (n=15) of the facilities didn't use receiving and issuing voucher for receiving and issuing purposes. In addition the majority of facilities about 98.3% (n=59) used vaccine requisition form for reporting and requesting of vaccines.

The results indicate that there is a good practice in implementing FEFO principle but facilities didn't have a good practice of using vouchers. Facilities should have a good practice in using receiving and issuing vouchers because even though vaccines are donated, using of vouchers facilitates the accountability and transparency of vaccine distribution. Unless and otherwise it is not possible to make auditing the vaccines' transactions.

**Discussion on Assessment of Vaccine Stock Management**

In this assessment the variables related to systems and procedures for managing the stocks are effective in terms of vaccine physical inventory, stock control system, adequate stock level policy and good storage practice were assessed. Regarding on good storage practice, all facilities (100%, n=60) used first expiry first out principle and VVM status for those vaccines at 2nd stages. Regarding the inventory management, all receipts and dispatches were recorded in 58.3% (n=35) of facilities and 75% (n=45) of the facilities used receiving and issuing voucher for receiving and issuing purposes. In addition the majority of facilities about 98.3% (n=59) used vaccine requisition form for reporting and requesting of vaccines in every month. Assessments done in Nepal had shown that 24 out of 47 (51%) of stores all vaccine arrivals and vaccine dispatches recorded and stock balances updated within one working day of the transaction, 35 out of 47 (74%) stores reported regular use of vouchers, vaccine is issued according to the 'First-Expiry-First-Out' (FEFO) principle in 27 out of 47 (57%) assessed stores, the storekeeper can make exceptions to the FEFO rule (e.g. because of VVM status) in all (100%) stores, 29 out of 47(62%) stores carried out a physical inventory of vaccine, diluent and dropper stocks at least equal to the planned supply frequency at lower levels. 16 out of 47 (34%) stores had stock count and records match exactly (WHO and UNICEF 2014).

Comparing the current study with the assessment in Nepal, the current study was better in applying FEFO rule, conducting physical inventory and preparing vaccine requisition to the

supplying facility and recording and updating the stocks in the stock record book. This was probably due to better awareness in FEFO principle; every health professional who manages pharmaceuticals follows 'First-Expire-First Out' rule. There was better implementation in vaccine requisition form because of the principle that without report no product, the higher supplying facility didn't issue without the vaccine requisition form. In using receiving and issuing voucher and applying VVM status, the result had no significant difference. The reason probably for stock record was unavailability of stock record book in the facility, giving low attention for the recording and updating activity. Regarding the receiving and issuing on vouchers there was lack of awareness because they assume that it was enough to register on the stock record log book rather than using the vouchers.

**Table 4.5. Assessment on vaccine management activities**

| Vaccine Management | strongly agree | Agree | undecided | disagree | strongly disagree |
|---|---|---|---|---|---|
| written instructions are on the use of VVMs, such as posters and stickers, available to health workers | 5% | 51.7% | 0.0% | 43.3% | 0.0% |
| vaccine managers use VVM status for vaccine management purposes | 13.3% | 81.7% | 0.0% | 5% | 0.0% |
| the cold chain manager know how to read VVMs | 15.00% | 70.00% | 1.7% | 13.3% | 0.00% |
| The multi-dose vial policy has been adopted and correctly implemented by the facility | 20% | 80% | 0% | 0% | 0% |
| opened vials vaccines are discarded within the recommended period after reconstitution | 5.0% | 51.7% | 25.0% | 15.0% | 3.3% |
| opened vials of liquid vaccines are kept and labeled for the next immunization sessions | 6.7% | 58.3% | 30.0% | 5.0% | 0.0% |
| vaccine managers/health workers can explain how to use the MDVP | 11.70% | 56.70% | 0.00% | 30% | 1.7% |

**Data Source: Survey Result, 2018**

The assessment on vaccine management focuses on the activities related with multi dose vial policy, VVM, shake test, inventory management, wastage rate and management. With this regard some variables had been used to assess mentioned above activities and is presented in the table above. For multi dose vials, opened vials were not properly recorded and labeled in 18.3% (n=11) facilities and were not discarded within recommended period of time in 5% (n=2) of the health facilities. The cold chain manager didn't know how to read VVMs on vaccine vials in 13.3% (n=8) of the facilities. 31.7% (n=19) of cold chain managers/EPI focal persons didn't know and explained how to use the multi-dose vial policy.

The results have shown that for multi-dose vials the cold chain managers should know about the multi-dose vial policy and not to use the opened vials after the vials have been opened for longer than the recommended period of time. They should be discarded within the recommended period of time because if the vaccines don't discarded, they might endanger the children.

**Discussion on Assessment of Vaccine Management**

The assessment on vaccine management focuses on the activities related with policies and procedures for an effective vaccine management at every stage within the cold chain system. Those policies and procedures include multi dose vial policy, VVM, shake test, inventory management, wastage rate and management. With this regard some variables had been used to assess mentioned above activities. For multi dose vials, opened vials were discarded within recommended period of time in 98% (n=58) of the health facilities. The cold chain manager knew how to read VVMs on vaccine vials in 86.6% (n=52) of the facilities. 68.3% (n=41) of cold chain managers/EPI focal persons explained how to use the multi-dose vial policy. Written instructions on the use of vaccine vial monitors (VVMs), such as posters and stickers were available to health workers in 56.7% (n=34) of the facilities. Similar assessment done in Nepal revealed that 20 out of 20 (100%) opened vials of freeze-dried vaccines discarded within six hours of reconstitution, or at the end of each immunization session. Written instructions on the use of VVMs, such as posters and stickers, were available to storekeepers and health workers in 43 out of 47 (91%). 47 out of 47 (100%) storekeepers/health workers knew how to read VVM status. During assessment, the VVMs on all vaccines in the health facility refrigerator, cold box or vaccine carrier were observed at VVM stage 1 or stage 2 in 20 Service delivery Points out of 20 (100%). 46 out of 47 (98%) health workers knew how to use VVM status for vaccine

management purposes (WHO and UNICEF 2014). NIP adopted the MDVP and 18 out of 20 Service delivery points (90%) health workers were able to explain how to apply the MDVP. In 43 (91%) stores the storekeeper/health worker received on-the-job or classroom training in vaccine management during the review period. In 23 (53%) locations records of training were given. 35 out of 47 (39%) locations reported that facility received supervisory visits during review period. 16 (46%) stores provided supervision records (WHO and UNICEF 2014). The majority of results under the current study on vaccine management were less than that of the assessment in Nepal. This was probably unavailability of updated manual, VVM posters, limited supervisory role specific to vaccine management, lack of training and orientation, lack of skill and knowledge transfer in case of turnover.

### 4.7.Vaccine Storage and Handling Practice

**Table 4.6. Vaccine Storage and Handling**

| Vaccine Storage and Handling | strongly agree | Agree | undecided | disagree | strongly disagree |
|---|---|---|---|---|---|
| A trained, designated person is responsible for vaccine storage and handling | 66.7% | 0% | 0% | 33.3% | 0% |
| A trained backup person is available to relieve the designated person when required | 43.3% | 0% | 0% | 56.7% | 0% |
| Orientation has been given for all staff members who may be involved in vaccine storage at any stage | 48.3% | 51.7% | 0% | 0% | 0% |
| The refrigerator is situated in a well-ventilated area, away from sunlight and heat | 1.7% | 88.3% | 0% | 10% | 6.7% |
| the refrigerator is placed in a secure area and is accessible to authorized staff only | 5% | 73.3% | 0% | 11.7% | 10% |
| The refrigerator is placed against an outside wall which may be subject to hot and cold temperatures | 1.7% | 93.3% | 1.7% | 0.0% | 3.3% |
| The refrigerator type is correct for vaccines (standard refrigerator) | 0% | 100% | 0% | 0% | 0% |
| The refrigerator is either lockable or placed in a locked room | 6.7% | 38.3% | 3.3% | 46.7% | 5% |
| there is a standby backup generator in case of unreliable electricity supply or power failure | 15% | 21.7% | 0% | 28.3% | 35% |
| the refrigerator shown evidence of malfunction (e.g. poor seals so that the door opens too easily) | 6.7% | 25% | 0% | 61.7% | 6.7% |
| The refrigerator is correctly packed with air circulating between the vaccines | 3.30% | 58.30 % | 1.70% | 33.30% | 3.30% |
| There are no expired vaccines in refrigerator | 3.30% | 93.30 % | 0.00% | 3.30% | 0.00% |
| vaccines are correctly stored | 5% | 58.30 % | 0 | 30% | 4% |
| there is alternative storage (e.g. cooler, cold box, other monitored refrigerator) available for vaccine storage | 6.7% | 75.0% | 0.0% | 18.3% | 0.0% |
| there are sufficient trays which are used in arrangement | 0% | 88.3% | 0 | 11.70% | 0% |
| there is no mixing of other items in vaccine refrigerator such as other drugs | 5.00% | 61.70% | 0.00% | 30.00% | 3.30% |

**Data Source: Survey Result, 2018**

From the above storage and handling table the following findings were stated:

### 4.7.1. Training status

Based on the results obtained from the assessment, 66.7% (n=40) cold chain managers and EPI focal persons were participated in immunization in practice and cold chain management practice training whereas 33.3% (n=20) participants didn't take any cold chain management training of which 90% (n=18) professionals were from woreda health office and the remaining 10% (n=2) were from health centers. Regarding a trained back up person in case of the absence of cold chain manager or EPI focal person, 43.3% (n=26) were trained and 56.7% (n=34) were not trained of which 53% (n=18) were from woreda health offices and 47% (16) were from health centers. Orientation for those professionals who might be involved in cold chain management practice was given.

### 4.7.2. Refrigerator and Storage Related Variables

In relation with refrigerator situation and placement, some variables were assessed. Refrigerators were not place in a secure area in 21.7% (n=13) of the facilities and is accessible for staffs other than cold chain mangers or EPI focal persons. Also the refrigerators found in 51.7% (n=31) of the facilities were not either locked or placed in a locked room. Refrigerator door opening was minimized in 68.3% (n=41) of the facilities and the majority of the refrigerators (95%, n=57) were not labeled with a sticker on the door to remind staffs to open the door only when necessary. In addition in 58.3% (n=35) facilities, the refrigerators didn't have an alarm which was activated when the temperature exceeds 8$^{o}$C and falls below 2$^{o}$C. Electricity supply to the refrigerator was not safe in 96.7% (n=58) of the facilities. In addition 63.3% (n=38) of the facilities didn't have a standby generator in case of unreliable power supply. Also the refrigerator shown evidence of malfunction (poor seals) in 6.7% (n=4) of the facilities.

The majority of facilities about 71.7% (n=49) had an alternative storage such as cold box or other monitored refrigerator incase of refrigerator failure. All refrigerators in the facilities were standardized with WHO recommendation and trays were available in 88% (n=53) of the refrigerators.

### 4.7.3. Vaccine Handling Variables

Regarding on vaccine handling practices some of indicators had been used for assessment. Vaccines and diluents were properly stored in that according to heat and freeze sensitivity within the refrigerators in 63.3% (n=38) of the facilities. The arrangement of vaccines were good i.e. the vaccines were packed with air circulating and appropriate gap between them in 61.6% (n=37) of the facilities. In addition there was no expired vaccine in the refrigerator in 96.6% (n=58) of the facilities whereas there was expired vaccine in 3.4% (n=2) of the facilities. In the majority of facilities (95%, n=57), vaccines were stored in their original packaging box and include the information leaflet. Regarding on the storage of other pharmaceuticals and vaccines, there was mixing up of storage in 33% (n=20) of the facilities.

From the findings, it has been indicated that there are a number of facilities with poor vaccine arrangements and poor handling practice. There should be proper vaccine arrangements and handling within the refrigerator since poor arrangement and storage of vaccines lead to impotent administration of vaccines to children. When dedicated refrigerator is used for vaccines storage only opening frequency of the refrigerator is minimized thereby minimizing the exposure of vaccines to abnormal temperature conditions.

**Discussion on Assessment of Vaccine Storage and Handling**

According to the vaccine storage-handling tool kit of CDC, Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built. Vaccines must be stored properly from the time they are manufactured until they are administered. Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers. By following a few simple steps and implementing best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive. It is better to not vaccinate than to administer a dose of vaccine that has been mishandled. Cold Chain (a temperature-controlled supply chain) Vaccines must be stored properly from the time they are manufactured until they are administered (CDC 2018).

Regarding on vaccine storage and handling practice training, 66.7% (n=40) of the facilities were managed by trained professionals and 43.3% (n=26) of the facilities had a trained back up person. In addition all of the facilities gave an orientation to the staff who may be involved in the cold chain management practice.

Regarding on the vaccine storage room, the refrigerator was situated in a well ventilated area in 83.3% (n=50) of the facilities and in 78.3% (n=47) of the facilities, the refrigerator was placed in a secured area and was accessible to authorized staff only. The current study was better than cold chain stores in India i.e. only 25% of the institutions had separate and adequate cold chain room (Mallik et.al 2011). The refrigerator was placed in an outside wall (outside room) in 3.3% (n=2) of the facilities. The refrigerator was lockable or placed in a locked room in 45% (n=27) of the facilities which was lower than that of the assessment done in India i.e. as per recommendation that lock and key be provided to a designated worker, stock security was maintained in 70% of the organizations (Mallik et.al 2011). The reason probably was unavailability of sufficient room, even some cold chain rooms were together with other services such as post natal care, human resource, sterilizer room, laboratory room and most of the cold chain stores were in under five service room. The other was probably low attention given by the professionals because some of the refrigerators key was lost and not locked even though the key was available. The good thing was all working refrigerators found in the facilities were the correct type and standard (purpose built refrigerators).

Regarding on vaccine handling practices, vaccines and diluents were properly stored in according to heat and freeze sensitivity within the refrigerators in 63.3% (n=38) of the facilities. The current study was minimal when it has been compared with that of the study in Cold chain status assessment conducted at 67 peripheral store facilities in Ethiopia showed that Vaccine storage in the refrigerator was not proper in 47/64 (73.4%) health centers (Berhane et al. 2000). The reasons in the current study was probably the training gap, lack of supervision and fail to strictly follow the vaccine storage and handling guideline.

The arrangement of vaccines were not good i.e. the vaccines were not packed with air circulating and appropriate gap between them in 38.4% (n=23) of the facilities. In addition there was expired vaccine in the refrigerator in 3.4% (n=2) of the facilities there was no vaccine with an

expired date was found in assessment done at eight districts of Cameroon. In the majority of facilities (95%, n=57), vaccines were stored in their original packaging box and include the information leaflet. Similar assessments done in Ethiopia, 2013, revealed that arrangement of vaccines in refrigerators was not correct in 54.5 % (n=12) health facilities because of not implementing standard storage practices at the facilities. The study tried to point out if the facilities strictly follow good storage practices, vaccine storage and handling practices could be improved. Additionally assessments done in eight districts of Cameroon it was noted that up to 20.69% health facilities had wrong packing of vaccines and diluents in the refrigerator. These included: not arranging vaccines so as to facilitate air circulation and reading of their identification, as well as expired date; not marking and arranging separately vaccines brought back from immunization session; and not storing vaccines in locations appropriate to the style of refrigerator used (e.g.: for ILR refrigerator, storing adsorbed vaccines (DTP, TT, HepB) on the top, OPV and freeze dried vaccines (measles, BCG) on the bottom). The current study was somewhat better than assessment done in Ethiopia but lower than the study in Cameroon. The better result from assessment in Cameroon was due to up to 77.7% of the facilities had got supportive supervision from the responsible body. Still the current study was minimal because in order to deliver safe, effective and potent vaccine to children the vaccine storage and handling practice should be improved at large. The probably reason was training gap, regular supervision from higher level and lack of implementation of SOP guidelines for proper storage and handling by the professionals. The good thing was vaccines were stored in their original package which prevents the vaccines from physical damage as well as for maintaining the storage condition for some period of time in case of power interruption.

Regarding on the storage of other items with vaccines, there was mixing up of storage in 33.3% (n=20) of the facilities i.e. the refrigerator was not dedicated to the vaccine storage only. During the visit other pharmaceuticals like insulin injection, oxytocin injection, ergomethrine injection, tetanus antitoxin (TAT), and laboratory reagents were stored together with the vaccines. Similar assessments done at primary health care in Maharashtra India, Para HIV kit were kept in the cold chain along with the vaccines. While at primary health care, Shembal-Pimpiri transport Media and Insulin Injection was kept in the ILR dedicated for vaccine storage (UNICEF 2011). The current study was relatively better than with that of the assessment done in three districts of

Oromiya, Amhara and SNNP Ethiopia, 2013, the study revealed that 40.9% (n=9) of the facilities store vaccines together with other medicines and laboratory reagents. As it has been mentioned, handling of vaccines with other items has disadvantages. Firstly the problem of wrongly administering drugs that have been packaged in similar color vials as the vaccine vials. Secondly the storage of other items increase the opening frequency and period of the refrigerator door in which it prevents maintaining the recommended temperature range. Thirdly the refrigerator has no enough space for vaccines and the vaccines have been congested to maintain the standard recommended space between vaccines. The reason mentioned by the respondents on the current study, there was no standard and the right type of refrigerator for storing other drugs and reagents, the other was low attention given by professionals to the storage of vaccines with other items, lack of regular supervision, lack of awareness. Therefore it needs attention for the sharing of space between vaccines and other items.

The other important assessment done during the study was the availability of arrangements during equipment and power failure for proper storage and handling of vaccines. Facilities were complaining frequent power interruption and equipment failure. When equipments and power failed, vaccines were transferred to nearby facilities or non-standardized refrigerators probably the domestic ones; hence the proper handling, arrangement and space available for vaccines has been compromised. Regarding such kind of arrangements, only 36.7% (n=22) of the facilities had standby refrigerator. The current study was much better than the result found from the assessment in Ethiopia, 2013, 18.4% (n=7/38) of the health facilities, assessment done in Nepal, 2011, 7% (n=2/8) of the stores (UNICEF 2011) and 20% in 40 cold chain points of India, 2008. Frequent cuts in power supply can have a direct impact on storage temperature and non-availability of standby generators will adversely affect vaccine potency at each level and it makes very difficult to maintain the cold chain. Still the result found from the current study was minimal and needs a big attention by the management units because during the assessment, in most of the facilities, the generator was non functional. Even some of vaccine rooms were not accessible for power supply from the generator, i.e. there was no any electric installation to the room. In addition some of them had shortage of fuel especially if the power interruption was for longer period of time.

# CHAPTER FIVE
# CONCLUSION AND RECOMMENDATION

## 5.1. Conclusion

The basis for any cold chain management activity is maintaining of the product with in recommended storage condition to administer potent and quality vaccines to clients. Without capable personnel to properly manage cold chain equipments guided by stipulated procedures, all cold chain activities end in futility as sub-potent vaccines end up being administered to clients.

This only becomes evident when vaccinated individuals contract with the disease the vaccines were meant to prevent, and is usually not attributed to poor handling of vaccines. Since vaccines are relatively very fragile biological agents, addressing the practice gaps of vaccine handlers cannot be over-emphasized. From the study on vaccine cold chain management practice, a number of problems were identified and possible comments were received from the facilities.

In this regard the major problem encountered was poor monitoring of the cold chain system. The temperatures of the refrigerators were not recorded in twice daily bases even though the guideline should be strictly followed. This was observed in 19.3% of the facilities at the time of visit and 48.3% of the facilities considering the past six month temperature monitoring status under study. In addition 26.7% of the facilities had a temperature outage reading from the recommended range. These findings indicate that if there is no continuous and regular monitoring system about the cold chain, it cannot be sure that we are administering quality and potent vaccines to children.

The other problem was non-functioning of the cold chain equipments at the facility and absence of contingency plan for equipment failures. In 38.3% of the facilities, from the available refrigerators, one or more of them were non functional and 63.3% of the facilities didn’t have backup generators in case of power failure. This finding had shown that if there is no well functioning of the cold chain equipments, there is no efficient cold chain system leading to cold chain failure. This leads to damage of vaccines and interruption of immunization sessions at health center.

The other major finding was if the vaccines are not properly stored and handled, sub potent vaccines are administered and vaccine preventable diseases occur. But there was a remarkable

storage and handling practice problem of vaccines that should be noticed and corrected. The arrangement of vaccines was not good in 38.4% of the facilities and in 33.3% of the facilities vaccines were stored together with other items. Such kind of findings lead the vaccines to abnormal storage conditions in that FEFO principle cannot be implemented, frequent opening of the refrigerator, the VVM status might be changed to discard point even though long expiry date. Therefore, administration of vaccines that are exposed to abnormal storage conditions lead to immunization failure.

Overall from the findings of the study, it can be conclude that there were vaccine cold chain management practice problems in maintaining the recommended temperature range, temperature monitoring, well functioning of the cold chain equipments and vaccine storage and handling practice in public health facilities of North Shoa Zone, Amhara Region, Ethiopia.

## 5.2. Recommendations

In order to have an effective cold chain management practice three things are required. These are personnel, cold chain equipment, policies and procedures. In addition there should be monitoring and evaluation system of the cold chain. Hence the recommendations given will be:

Regarding the personnel; the cold chain will function well if there is a well trained professional. It is expected to train the health professionals who are involved in the management of cold chain and who didn't take the training on cold chain management practice. During the study, all of the cold chain managers at woreda didn't take any training regarding on cold chain management practice. This shows that there is no any cold chain management training prepared for them. Therefore PFSA, Amhara Regional Health Bureau and North Shoa Zonal Health Department should have a plan to incorporate the woreda cold chain managers during training.

Regarding the cold chain equipments, as it has been observed from the assessment done, there are a number of non functional cold chain equipments at facilities. Therefore, there should be supply of refrigerators for those who didn't have functional refrigerator. In addition the non functional cold chain equipments like refrigerators, generators, etc. should be repaired and maintained. For this to be effective medical equipment technician should be assigned at least at woreda for immediate response. Moreover, there should be supply of spare parts for refrigerator maintenance, temperature monitoring devices and charts having minimum and maximum recording space from Ministry of Health, Amhara Regional Health Bureau and PFSA. In addition, woreda health offices and health centers should allocate budget for spare parts and maintenance activities.

Regarding the policies and procedures, there must be a written record of these reviews which identifies problems and records actions taken. Install 30 days continuous temperature monitoring devices (fridge tags). The Swiss company developed an electronic 30-day temperature recorder (30DTR) and is now available at Swiss as both a standalone recording device and a remote recording device providing alarms and data transmission with internet-based reporting (Lioyd and Cheyne 2017). Hence this technology should be adopted to use at facilities and at North Shoa Zonal Health Department, Amhara Regional Health Bureau and PFSA. These organizations must use the technology for monitoring and evaluating purpose because multi-channel temperature loggers with remote alarms and recording capabilities have made it possible to

respond quickly to temperature alarms and use temperature data for analysis of refrigerator performance.

The other gap identified was developing a contingency plan. Therefore facilities should develop a contingency plan designed to deal with emergencies at each store. Contingency plans are context-specific, but should include the following steps: Identify the major sources of risk (e.g. power failure, equipment failure, etc.), prepare a written contingency plan, and post emergency contact details on the notice board in the vaccine store. The other recommendation is vaccine storage and handling guidelines should be properly implemented at each facility. For proper vaccine storage and handling practice, there should be a standardized vaccine storage refrigerator and room at woredas and health centers. Hence, each woreda and health center should prepare dedicated and separate room for vaccine storage.

Regarding the monitoring and evaluation system, there should be program specific regular supportive supervision on vaccine cold chain management practice at facilities from North Shoa Zonal Health Department, Amhara Regional Health Bureau and PFSA; and based on the findings from the supervision, the required action should be taken. There should be a data base (soft ware) available at region, ZHD, and PFSA which helps to track and control the cold chain equipments' status, and to monitor vaccine cold chain status during transportation and storage. This data base also enables the cold chain system to be more responsive and efficient.

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**Annex 1 Questionnaire to Cold Chain Managers and EPI focal Persons**

**Assessment on Vaccine Cold Chain Management Practice on Public health facilities in the case of North Shoa Zone, Amhara Region, Ethiopia.**

**Informed Consent form before administering the questionnaire to the cold chain mangers and EPI focal personnel**

My name is Solomon Yetwale from Addis Ababa University School of Commerce. I am studying masters' degree in Logistics and Supply Chain Management (MLSCM). I am conducting a survey study on the problem of VACCINE COLD CHAIN MANAGEMENT PRACTICE: THE CASE OF PUBLIC HEALTH FACILITIES AT NORTH SHOA ZONE, AMAHARA REGION, ETHIOPIA**.**

The study will examine the current practice on vaccine cold chain management and finally identify challenges encountered in the proper storage, handling and practices of vaccines. If you agree to join the study, you will be required to answer all the questions that will be asked by the investigator in form of interview. All information that will be collected from you will be treated confidential and will not be used for any other purpose other than this study. We do not expect that any harm will happen to you because of joining in this study. Taking part in this study is completely your choice. You can stop participating in this study at any time, even if you have already given your consent and if for any reason you would wish to come back into the study after withdrawal, we will be ready to accept you to continue with the study. Taking part in this study you will contribute towards alleviating the problem of poor vaccines storage and improper vaccines management. Your information and others participating in the study will collectively be used by decision makers in addressing this problem. You will receive the new information about this study upon completion.

May I have your permission? Yes ……. No…… If Yes, Continue

For comments/questions please contact Solomon Yetwale (0911558274), principal investigator for the study

**SEL-ADMINISTERED QUESTIONNAIRES TO ASSESS COLD CHAIN MANAGEMENT PRACTICE OF VACCINES IN PUBLIC HEALTH FACILITIES AT NORTH SHOA ZONE.**

| | | |
|---|---|---|
| **SECTION A: PROFILE DATA (DEMOGRAPHIC AND OTHER BASIC INFORMATION)** | | |
| Professional in-charge of cold chain manager of the facility---------- | | |
| Level of education a. Degree b. Diploma | | |
| Sex | Male | Female |
| | | |
| Experience at work of the cold chain manager (in years) | | |
| a.) less than 1 b.)1 to 5 | c.) 6 to 10 | |
| d) 11 to 15 e.) more than 15 | | |
| Age in years a. 20-25 b. 26-30 c. above 31 | | |
| **Section B: Vaccine Cold Chain Management Practice** | | |
| What type of vaccines do you stock at your health facility | | |
| Bacillus Calmette Guerin (BCG) | | |
| DTP-HepB-Hib or pentavalent (Diphtheria, Tetanus, Pertussis, Hepatitis B, Heamophilus influenzae B) | | |
| BOPV (Bivalent Oral Polio Vaccine) | | |
| Inactivated Polio Vaccine (IPV) | | |
| Measles virus vaccine | | |
| TT (Tetanus Toxoid Vaccine) | | |
| Rota Vaccine | | |
| Pneumococcal Vaccine (PCV) | | |
| if others please specify---------- | | |
| From where do you collect your vaccine---------- | | |
| How often do you collect vaccines from higher level? | | |
| a) monthly b) bimonthly c) quarterly d) biannually | | |
| Available Refrigerator for Vaccine Management | | |
| Functional Refrigerator | | |
| Non Functional Refrigerator | | |

## Section C: Vaccine Cold Chain Management Practice (Likert Scale Type)

| **Vaccine Storage Temperature** | **strongly agree** | **agree** | **undecided (neither agree nor disagree)** | **disagree** | **strongly disagree** |
|---|---|---|---|---|---|
| the cold chain manager can give the correct storage temperature range for each of the vaccines on the schedule | | | | | |
| the cold chain manager can give the correct freezing temperature of the freeze sensitive vaccines on the schedule | | | | | |
| For the past six months, there is a complete set of twice- daily manual temperature records for each and every vaccine refrigerator | | | | | |
| the temperature of the vaccine refrigerator has been recorded twice a day when the facility is open | | | | | |
| the contact numbers to report a cold chain breach is easily accessible (emergency contact details posted in the vaccine) | | | | | |
| the responses to all deviations outside +2°C and +8°C has been documented and recommended actions taken | | | | | |
| The refrigerator temperature is within correct range of 2ºC to 8ºC at the time of visit. | | | | | |
| vaccines have been exposed to overheating in the past six month (higher than 8ºC) | | | | | |
| vaccines have been exposed to cold in the past six month (lower than 2ºC) | | | | | |
| during the past six month there was a cold chain breach and alarms have been documented | | | | | |
| Facilities having minimum and maximum reading monitoring chart | | | | | |
| there is a satisfactory contingency plan in the event of equipment failure | | | | | |
| please list the activities done in the event of equipment failure | | | | | |
| **Cold Chain Equipment** | | | | | |
| Where applicable, are there adequate reserve supplies of kerosene and/or gas | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| there is sufficient icepack freezing and storage capacity to meet peak demand | | | | | |
| there is sufficient refrigerator for vaccine storage | | | | | |
| all refrigerators are fully functional at time of inspection | | | | | |
| facilities have at least one functional refrigerator | | | | | |
| all refrigerators have a working temperature monitoring device stored with the vaccine (dial thermometer or fridge tag) | | | | | |
| there are sufficient cold boxes and vaccine carriers | | | | | |
| there are sufficient cold boxes | | | | | |
| there are sufficient vaccine carriers | | | | | |
| **Maintenance of Cold Chain Equipment** | | | | | |
| there is a planned preventive maintenance, and replacement plan, and is being followed | | | | | |
| During the past six months vaccine refrigerator fail to the extent that vaccine was damaged | | | | | |
| During the past six months, a shortage of spare parts or consumables cause refrigerator to be removed from service for longer than seven days | | | | | |
| There are records of regular refrigerator servicing, defrosting and cleaning available. | | | | | |
| **Vaccine Management (Stock Management, MDVP, VVM)** | | | | | |
| all receipts and dispatches are recorded and balances are updated stock record log book | | | | | |
| all receipts and dispatches are recorded and balances are updated on receiving and issuing voucher | | | | | |
| vaccine requisition forms are used for ordering and receiving vaccine | | | | | |
| vaccine distribution generally made according to the “first expiry – first out” (FEFO) principle | | | | | |
| the vaccine managers make exceptions to the 'FEFO' rule (e.g. because of VVM status) | | | | | |
| physical counts have been carried out and recorded | | | | | |
| vaccines are delivered by PFSA | | | | | |
| Vaccines are delivered by or collected from woreda health office | | | | | |
| written instructions are on the use of vaccine vial monitors (VVMs), such as posters and stickers, available to health workers | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| vaccine managers/health workers use VVM status for vaccine management purposes (e.g. using stage 2 vaccines first) | | | | | |
| the cold chain manager know how to read VVMs (Use dummy VVMs and/or sticker samples to check knowledge) | | | | | |
| The multi-dose vial policy (MDVP) has been adopted and correctly implemented by the facility | | | | | |
| opened vials of liquid vaccines are kept and labeled for the next immunization sessions (Ask health workers to show which opened vials they will use for the next session and verify this information through immunization records | | | | | |
| vaccine managers/health workers can explain how to use the MDVP | | | | | |
| **Vaccine Storage and Handling** | | | | | |
| A trained, designated person is responsible for vaccine storage and handling | | | | | |
| A trained backup person is available to relieve the designated person when required | | | | | |
| Orientation and education on safe and effective vaccine management has been given for all staff members who may be involved in vaccine storage at any stage | | | | | |
| The refrigerator is situated in a well-ventilated area, away from sunlight and heat | | | | | |
| the refrigerator is placed in a secure area and is accessible to authorized staff only | | | | | |
| The refrigerator is placed against an outside wall which may be subject to hot and cold temperatures | | | | | |
| The refrigerator type is correct for vaccines (standard refrigerator) | | | | | |
| The refrigerator is either lockable or placed in a locked room | | | | | |
| Electricity supply to the refrigerator is safe examples switchless plugs, cautionary notices are in place (e.g. the power outlet have a sign ‘Do not disconnect’) | | | | | |
| there is a standby generator in case of unreliable electricity supply or power failure | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| the refrigerator shown evidence of malfunction (e.g. poor seals so that the door opens too easily) | | | | | |
| Vaccines found in domestic refrigerator | | | | | |
| Refrigerator door opening during is minimized. | | | | | |
| The refrigerator is correctly packed with air circulating between the vaccines | | | | | |
| There are no expired vaccines in refrigerator | | | | | |
| There is a sticker on the door to remind staff to open the door only when necessary | | | | | |
| Vaccines are in their original packaging box and include the information leaflet. | | | | | |
| The refrigerator has an alarm which is activated when the temperature exceeds 8ºC and falls below 2º | | | | | |
| vaccines are correctly stored (e.g. no freeze-sensitive vaccine stored close to ice lining in ice-lined refrigerators (ILRs) or stored close to the evaporator plate of service point refrigerators) | | | | | |
| there is alternative storage (e.g. cooler, cold box, other monitored refrigerator) available for vaccine storage, if necessary (e.g. in case of vaccine refrigerator breakdown) | | | | | |
| all vaccines are correctly stored with good arrangement in refrigerator in the manner of first expiry first out or according to their VVM status | | | | | |
| there are sufficient trays which are used in arrangement | | | | | |
| there is no mixing of other items in vaccine refrigerator such as other drugs | | | | | |
| vaccines are found at discard point in refrigerator (frozen vaccines checking with shake test and stage 3rd and 4th checking the VVM) | | | | | |
| staff know how to condition icepacks and how to pack transport boxes | | | | | |
| if any comment on cold chain mangement practice please mention it | | | | | |
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## ANNEX 2. LIST OF SELECTED SAMPLE HEALTH FACILITIES

| S.no | Woreda Name | Health Center Name | No. of Health Facilities Selected | Respondent | No. of Respondents |
|---|---|---|---|---|---|
| 1 | | Chacha HC | | EPI Focal Person | 1 |
| 2 | | Tsigereda HC | | EPI Focal Person | 1 |
| 3 | Angollelana Tara | Angollelana Tara WoHO | 2 | Cold Chain Manager | 1 |
| 4 | | Gorebela HC | | EPI Focal Person | 1 |
| 5 | | Gorgo HC | | EPI Focal Person | 1 |
| 6 | | Aliyu Amba HC | | EPI Focal Person | 1 |
| 7 | Ankober | Ankober WoHO | 3 | Cold Chain Manager | 1 |
| 8 | | Mekoy HC | | EPI Focal Person | 1 |
| 9 | | Ambo Wuha HC | | EPI Focal Person | 1 |
| 10 | Antsokiyana Gemza | Antsokiyana Gemza WoHO | 2 | Cold Chain Manager | 1 |
| 11 | | Ginager HC | | EPI Focal Person | 1 |
| 12 | | Tidesh HC | | EPI Focal Person | 1 |
| 13 | Asagirt | Asagirt WoHO | 2 | Cold Chain Manager | 1 |
| 14 | | Ayer Tena HC | | EPI Focal Person | 1 |
| 15 | | Debre Berhan HC | | EPI Focal Person | 1 |
| 16 | Debre Berhan | Debre Berhan WoHO | 2 | Cold Chain Manager | 1 |
| 17 | | Ataye HC | | EPI Focal Person | 1 |
| 18 | | Jewaha HC | | EPI Focal Person | 1 |
| 19 | | KarakoreHC | | EPI Focal Person | 1 |
| 20 | Efratana Gidem | Efratana Gidem WoHO | 3 | Cold Chain Manager | 1 |
| 21 | | Lemi HC | | EPI Focal Person | 1 |
| 22 | | Salayish HC | | EPI Focal Person | 1 |
| 23 | Ensaro | Ensaro WoHO | 2 | Cold Chain Manager | 1 |
| 24 | | Bulga HC | | EPI Focal Person | 1 |
| 25 | | Sokoro HC | | EPI Focal Person | 1 |
| 26 | Hagere Mariam | Hagere Mariam WoHO | 2 | Cold Chain Manager | 1 |
| 27 | | Abayatir HC | | EPI Focal Person | 1 |
| 28 | | Tere HC | | EPI Focal Person | 1 |
| 29 | Kewot | Kewot WoHO | 2 | Cold Chain Manager | 1 |

| | | | | | |
|---|---|---|---|---|---|
| 30 | | Mehal Meda HC | | EPI Focal Person | 1 |
| 31 | | Ashen HC | | EPI Focal Person | 1 |
| 32 | Menz Gera | Menz Gera Mider WoHO | 2 | Cold Chain Manager | 1 |
| 33 | | Kolako HC | | EPI Focal Person | 1 |
| 34 | | Zemero HC | | EPI Focal Person | 1 |
| 35 | Menz Keya | Menz Keya WoHO | 2 | Cold Chain Manager | 1 |
| 36 | | Kubit HC | | EPI Focal Person | 1 |
| 37 | | Wegere HC | | EPI Focal Person | 1 |
| 38 | Menz Lalo | Menz Lalo WoHO | 2 | Cold Chain Manager | 1 |
| 39 | | Molale HC | | EPI Focal Person | 1 |
| 40 | | Yigem HC | | EPI Focal Person | 1 |
| 41 | Menz Mama | Menz Mama Mider WoHO | 2 | Cold Chain Manager | 1 |
| 42 | | Alem Ketema HC | | EPI Focal Person | 1 |
| 43 | | Fetra HC | | EPI Focal Person | 1 |
| 44 | | Gavezemogn HC | | EPI Focal Person | 1 |
| 45 | Merha betie | Merhabetie WoHO | 3 | Cold Chain Manager | 1 |
| 46 | | Arerti HC | | EPI Focal Person | 1 |
| 47 | | Balchi HC | | EPI Focal Person | 1 |
| 48 | | Bolo HC | | EPI Focal Person | 1 |
| 49 | Minjar Shenkora | Minjar Shenkora WoHO | 3 | Cold Chain Manager | 1 |
| 50 | | Sasit HC | | EPI Focal Person | 1 |
| 51 | | Seladingay HC | | EPI Focal Person | 1 |
| 52 | Mojana Wodera | Mojana Wodera WoHO | 2 | Cold Chain Manager | 1 |
| 53 | | Enewari HC | | EPI Focal Person | 1 |
| 54 | | Jihur HC | | EPI Focal Person | 1 |
| 55 | Moretena jiru | Moretena Jiru WoHO | 2 | Cold Chain Manager | 1 |
| 56 | | Wayu HC | | EPI Focal Person | 1 |
| 57 | | Deneba HC | | EPI Focal Person | 1 |
| 58 | Siya Debirna Wayu | Siyadebirna Wayu WoHO | 2 | Cold Chain Manager | 1 |
| 59 | Shewarobit | Shewarobit HC | 1 | EPI Focal Person | 1 |
| 60 | | Shewarobit WoHO | 1 | Cold Chain Manager | 1 |
| 61 | Tarmaber | Debre Sina HC | 2 | EPI Focal Person | 1 |

| | | | | | |
|---|---|---|---|---|---|
| 62 | WoHO | Mezezo HC | | EPI Focal Person | 1 |
| 63 | | Tarmaber WoHO | | Cold Chain Manager | 1 |
| | **North Shoa Zone** | **Total** | **43** | | **63** |

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