St. Mary's University School of Graduate Studies

A DESCRIPTIVE STUDY INTO THE COLD CHAIN MANAGEMENT OF CHILDHOOD VACCINES BY PHARMACISTS AT CENTRAL AND REGIONAL LEVEL IN ETHIOPIA

By

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January 2016

Addis Ababa, Ethiopia

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A thesis submitted to St. Mary's University School of Graduate Studies in compliance with the requirements for the Master's Degree in Business Administration

January 2016

Addis Ababa, Ethiopia

DECLARATION

This is to certify that the work is my own and not of any other person,The work has not previously been submitted in any form to other institution for assessment or for any other purpose.

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Signature of student

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Date

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To my Parents, who continuously supported and believed in me. I thank them for their patience and understanding during this time, they were the sources of inspiration and motivation during this study..

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ABSTRACT

INTRODUCTION

This research was a a descriptive study into the cold chain management of childhood vaccines by pharmacists at central and regional level in Ethiopia It is imperative for health professionals to follow the procedures and policies set out by the health manuals and by of the World Health Organization. The success of any childhood vaccination programme depends on how well pharmacists and health professionals are able to adhere to the laws, regulations and procedures. There is also a need for cold chain to be flexible enough to deal with certain constraints so that the vaccination programmes are not interrupted for extended periods of time but rather run efficiently and benefit the intended population. As a result pandemics are easily avoided and a healthy generation of children will bring about a better society.

The study was carried out in two phases i.e. an observational study and a self-administered questionnaire. In the first phase, the observational study was carried out at 5 different Cold chain Facilities. In the second phase, the cold chain management of vaccines was explored by means of a self-administered questionnaire.

The key findings of the observational study include that on most occasions policy was not being implemented. Furthermore there were no contingency plans to deal with equipment and electricity issues, no monitoring and evaluation systems, poor recording keeping, poor management of the cold box, access to stock and the actual management of the cold chain for vaccines. The self-administered questionnaire was completed by 43 respondents. The most noteworthy aspects of the research in this phase of the study revealed that education and experience are crucial to the sustainability. Not surprisingly, some of the findings were similar to that of the observational study. Issues surrounding equipment and electricity, monitoring and evaluation systems, poor recording keeping, poor access to stock and ordering of stock were prevalent in this phase of the research as well.

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ACRONYMS

BCG - Bacillus Callmete Guerin

DPT - Diphtheria Pertussis Tetanus

EPI - Expanded Program on Immunization

GIVS - Global Immunization Vision and Strategy

GPHC - Government Primary Health Care

PHCF - Private Health Care Facilities

HIV - Human Immunodeficiency Virus

HBV - Hepatitis B Vaccine

MDG - Millennium Development Goal

OPV - Oral Polio Vaccine

UNICEF - United Nations Children's Fund

VMAT - Vaccine Management Assessment Tool

VVM - Vaccine Vial Monitoring

WHO - World Health Organization

MOH – Ministry of Heath

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APPROVED BY BOARD OF EXAMINERS

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CHAPTER 1: BACKGROUND TO THE STUDY

1.1 INTRODUCTION

The focus of this descriptive study is on the cold chain management of vaccines at central and regional level cold chain's. The cold chain is the system of transporting and storing vaccines within the safe temperature range of two to eight degrees Celsius (National Vaccine Storage Guidelines Strive for 5, 2013). The vaccine cold chain begins with the cold storage unit at the vaccine manufacturing plants and extends through the transport of vaccine to the distributor, then the delivery provider and ends with the administration of the vaccine to the patient (Vaccine Storage and Handling Toolkit, 2012).

A vaccine must have two characteristics, one is safety and the other is potency. Vaccines lose their potency if they are not stored or transported at an appropriate temperature range. Once the potency is lost, it cannot be regained. The damaged vaccine must be destroyed. This leads to inadequate stock and wastage of expensive vaccines. Furthermore, children who receive vaccines that are not potent will not be protected from diseases (Handbook for Vaccine and Cold Chain Handlers, 2010).

Therefore Facilities handling vaccines must adhere to the five rights of vaccine handling and Storage (Rittle, 2008). All facilities within the vaccine cold chain must ensure they have the right Pharmacist in charge of vaccine management use the right procedures to maintain the cold chain, ensure the right vaccine storage unit is available, the right temperature monitoring tool is used and the vaccine is stored at the right temperature. If these five rights are adhered to vaccine efficiency will be maintained and disease will be prevented (Rittle, 2008). Therefore it is imperative for health professionals to follow the procedures and polices set out by the immunization and health manuals by the World Health Organization in order to ensure effective management of the cold chain for vaccine safety.

After reviewing literatures, it was discovered that there were a limited number of studies that focus on the cold chain management of vaccines in Ethiopia. As a result, this study aims to add to the existing body of knowledge on the cold chain management of vaccines from Ethiopia's perspective.

The research study will be conducted in two ways. In the first one, an observational study will be conducted by the researcher using a structured observation guideline. Six cold chain facilities are selected, using the simple sampling technique. At these sites the researcher will observe whether the cold chain for vaccines is being maintained according to National and Operational guidelines. In the second phase, the cold chain management of vaccines by the pharmacists will be explored by means of a self-administered questionnaire.

Results and Recommendations derived from this study can help to reinforce knowledge of cold chain management of vaccines, to carry out strategies for improvement of vaccine management in Ethiopia and empower those within the cold chain system(Pharmacists and cold chain managers) to obtain greater job satisfaction, knowing that they are knowledgeable and can be confident when managing their vaccine. In addition to highlighting Positive aspects of the study and the possible gaps that exist in the cold chain system and processes.

1.2 STATEMENT OF THE PROBLEM

According to the Vaccine Handling and Storage Toolkit (2012) vaccines must be stored correctly from the time they are manufactured until the time they are administered to children. The exposure of vaccines to heat or cold can reduce the vaccines potency, thus increasing the risk of children not being protected against vaccine-preventable diseases (Vaccine Handling and Storage Toolkit, 2012). A study conducted in eight health districts in Cameroon revealed that the targeted health districts were not compliant with the standard operating procedures. Almost 25% of health facilities were conducting EPI activities without cold chain equipment resulting in a threat to the cold chain for vaccines (Ateudjieu *et* al., 2008).

When children are immunized with vaccines exposed to inappropriate temperatures they need to be re-vaccinated. Vaccine recalls result in extra doses of vaccines for children, increased costs for providers, damage to public confidence in vaccines and can also be a liability for providers' practices (Vaccine Handling and Storage Toolkit, 2012).

Evidence from studies conducted in Australia (Carr, Byles, and Durrheim, 2009), Matthias, (2007) in Mozambique (De Timoteo Mavimbe and Bjune, 2003), in Indonesia (Nelson *et al.,* 2004), in China (Ren *et al.,* 2009), in Thailand (Techatawat, Varinsathein and Rasdjarmrearnsook, 2007) and in Papau New Guinea (Wirkas *et al.,* 2007) indicate that good vaccine practices are lacking even in developed and still developing countries. Examples of these include inadequate temperature monitoring, unreliable equipment and use of incorrect fridges.

Limited research has been carried out in Ethiopia with regard to cold chain management of vaccines. Thus, this study assessed how cold chain for vaccines was maintained on receipt, storage and delivery in the Ethiopian Vaccine cold chain system.

1.3 RESEARCH OBJECTIVE

The purpose of this study is to investigate the management of the cold chain vaccines by Pharmacists operating within Ethiopia's vaccine cold chain system.Studies into the cold chain management and practices of vaccines have been conducted in many countries e.g. India, China, New Zealand, Australia and Indonesia. However, there are a limited number of studies that address the cold chain

management of childhood vaccines in an Ethiopian context. This presented the opportunity for a study into the cold chain management of childhood vaccines in cold chain facilities of the country.

There are numerous challenges in the management of the cold chain vaccines despite the many promising advances in immunization. In Ethiopia some of these challenges include insufficient financial resources, a shortage of human resources and a lack of knowledge of Trained pharmacists regarding vaccine management. These inefficiencies will lead to vaccines becoming compromised and losing their potency (Craig, 2008). As a result, these vaccines will not be beneficial to children. The WHO has created a set of practice guidelines for different service levels. These guidelines address immunization techniques, vaccine monitoring, cold chain management and reporting systems, providing a framework that healthcare personnel can follow to ensure vaccines are delivered as intended. In order to address the above mentioned challenges, it is imperative that pharmacists maintain the cold chain for vaccines as guided by WHO, as these are an essential part of successful immunization programs (Wiysonge *et al.*).

A quantitative descriptive survey design was used for this study. To achieve this, a self-administered questionnaire will be handed out to selected Cold room Pharmacists and managers involved at all central and regional cold rooms. The study was also be supported by observations using a structured observation guide. Data obtained from both the questionnaires and observations will be analyzed and used to draw appropriate conclusions.

In Ethiopia, there are 15 regional and one central cold chain facilities under MOH, in which 64 employees have direct daily involvement, one EPI officer handling the receipt, issuance and storage of vaccines and two EPI coordinator's\Focal person handling the forecasting and planning activities with one manger as supporting staff and others involved in unrelated activities.

The study take place in two phases:
Phase one: An observation study was conducted using a sample size of Ten in the cold chain activities (EPI co-ordinator and EPI Officer\Cold room manager), from five regional Cold rooms.

Phase two: A survey was conducted using a self-administered questionnaire. A random sample size of 48 will be selected to complete a self-administered questionnaire.

1.4 SPECIFIC OBJECTIVES OF THE STUDY

- The objectives of this study is: To Assess current processes of the cold chain management of vaccines by those involved in the cold chain and
- To compare current processes of the cold chain management of vaccines against best practice and in accordance with global, national and operational guidelines;

1.5 SCOPE OF THE STUDY

There are five supply chain levels: Central, Sub-National 1 (regions), Sub-National 2 (zones), Lowest Distribution (woredas and Service Delivery Points (vaccination providers such as health centres, health posts, hospitals, etc.),this study will focus on Central and Regional(Sub-National level)

1.6 SIGNIFICANCE OF THE STUDY

After reviewing the literature, as presented in Chapter 2, it was found that there are a limited number of studies that focus on cold chain management in an Ethiopian context. As a result, this study aims to add to the existing body of knowledge on the cold chain management of vaccines from Ethiopia's perspective. It is intended that the results of this study could be used to reinforce Existing knowledge on the cold chain management of vaccines. Positive aspects of the study will be highlighted and possible gaps that exist in the cold chain system and processes of cold chain management will be identified. Recommendations will be made to managers for improvement of vaccine management strategies and smooth operations. The results of this study can also assist in empowering those involved in the cold chain system to obtain greater job satisfaction, knowing that they are knowledgeable and can be confident in managing vaccines.

1.8 SUMMARY

Effective cold chain management is vital to ensure that vaccines are administered in a potent state to their recipients, thus providing necessary protection against diseases. Due to limited research carried out on cold chain vaccine management in Ethiopia, the quality of the vaccine management is unknown, presenting an opportunity to investigate the system in Ethiopia's context.

The following chapter discusses existing literature on the management of the cold chain system, in order to gain a broader view on the topic under investigation.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

The reviewing of literature is 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 (Burns and Grove, 2007). According Polit and Beck (2008) a literature review is a critical summary of the research on a topic of interest, often prepared to put a research problem in context.

This chapter focuses on previous research studies conducted globally, in African countries and in Ethiopia and evaluates the available literature to give a wider perspective on the cost effectiveness and benefits of immunization, the introduction of EPI in Ethiopia and how the cold chain for vaccines is maintained from the time of receipt in the facility until the time of distribution.

2.2 IMMUNISATION GLOBAL STRATEGY

Immunization programmes are globally recognized as the most effective type of health intervention (Ngcobo, 2008). Since the launch of the EPI in 1974, millions of deaths have been prevented every year by delivery of infant immunization through national immunization programmes (Cold Chain for Vaccines: WHO 1998). In 2005 the World Health Organization (WHO) and the United Nations children's Fund (UNICEF) endorsed the Global immunization Vision and Strategy (Wolfson *et al.*, 2008). The primary objective of GIVS is to reduce vaccine-preventable disease mortality and morbidly by two-thirds by the year 2015. This is aligned with the achievement of Millennium Development Goal Four, which calls for a two thirds reduction of under-five mortality rate by the year 2015 (Wolfson *et al.,* 2008).

The effectiveness of immunization programs is related to the quality of the practice of those who implement them (Cold Chain for Vaccines WHO, 1998). To maintain vaccines perfectly from the time they are made to the time they are administered requires an adequate cold chain infrastructure, compliance to national guidelines, and effective management of cold chain (Cold Chain for Vaccines WHO, 1998). However, in most countries the delivery of potent vaccines and the practice of quality vaccine maintenance remains a challenge.
Some of these challenges include insufficient financial resources, a shortage of human resources and a lack of knowledge regarding vaccine management.

These inefficiencies will lead to vaccines becoming compromised and degraded. As a result these vaccines will no longer be potent and will not be beneficial to children. To overcome this challenge the cold chain for vaccine must be effectively managed (Cold Chain for Vaccines WHO, 1998).

2.3 THE HISTORY OF VACCINES

In the pre-vaccine era, epidemics were greatly feared as the majority of people died from diseases due to the fact that very little was known about diseases. In the 17th century it is estimated that smallpox caused 60 million deaths (Baker, 2010).

The vaccine era started in 1796 with Edward Jenner developing a vaccine against smallpox. The ultimate success of Edward Jenner's efforts was realized in 1979 when WHO certified that smallpox had been eradicated (Henderson *et al.*, 2008).

According to Baker (2010) new targets have been set by WHO to eradicate polio and measles. Furthermore, Hadler *et al.*, (2008) state that prior to 1974 vaccination programmes in developing countries were restricted to the urban elite and children of school-going age were the main target, in spite of the fact that younger children are often more vulnerable to the diseases. According to Baker (2010) less than 5 percent of children under the age of one year were being vaccinated against six killer diseases namely, polio, diphtheria, tuberculosis, pertussis, measles and tetanus.

2.3.1 EXPANDED PROGRAMME OF IMMUNISATION, PHARMACEUTICAL SERVICES PROVISION AND POLICY IN ETHIOPIA

The EPI was introduced by WHO in 1974 with the aim of vaccinating all children below the age of one year against the six killer diseases (Baker, 2010), It was introduced and launched in Ethiopia in 1980 with the objective of achieving 100% immunization coverage of all children under two years old by 1990.

All vaccines for Ethiopia arrive by air to Bole International Airport in Addis Ababa. UNICEF sends a copy of the airway bill to PFSA. PSFA clears vaccines from the customs and transports them to the store. Vaccines are totally exempted from taxes and customs charges. Vaccines usually go through five storage levels before reaching the recipients (excluding the central PFSA store). Difficult terrains and geographical situations sometimes require having a number of intermediate stores.

There are five supply chain levels: Central, Sub-National 1 (regions), Sub-National 2 (zones), Lowest Distribution (woredas and Service Delivery Points (vaccination providers such as health centres, health posts, hospitals, etc.),this study will focus on Central and Regional(Sub-National level).

Immunization Service Delivery Under Ethiopia's bicameral parliament, the Committee on Social Affairs in the House of People's Representatives has responsibility for overseeing immunization and immunization financing, along with various other health-related activities. Vaccines are placed under government regulation through the Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009 (Federal Democratic Republic of Ethiopia Ministry of Health, 2010).

2.3.2 THE COLD CHAIN SYSTEM

Vaccines are sensitive biological substances that with time lose their potency, especially when exposed to heat, sunlight and cold (Safe Vaccine Handling, Cold Chain and Immunisation WHO, 1998). Once a vaccine's potency has been lost, it cannot be restored and these vaccines will no longer provide protection against the target disease (Mugharbel and Wakeel, 2009).

In light of this, the cold chain system provides an effective means for storing and transporting vaccines in a potent state, from the manufacturer to the person being immunized (Guidelines for Vaccine Storage and Distribution: New Zealand, 2012).

The common elements of all cold chain systems are a series of storage and transport links through a network of fridges, freezers and cooler boxes that keep vaccines at an optimum temperature, which is two to eight degrees Celsius (Safe Vaccines Handling, Cold Chain and Immunisation WHO1998; Guidelines for Vaccine Storage and Distribution: New Zealand 2012, Vaccine Storage and Handling Guidelines Milvax 2012; The Cold Chain, WHO 1988).

In the cold room facilities, there are a number of ways of checking that the temperature in the vaccine fridge remains within a safe range. These include

- A working dial thermometer hanging vertically in the middle of the vaccine fridge or,
- A fridge tag could also be placed in the middle shelf of the fridge to monitor the temperature of vaccines.

The temperature should be read and recorded twice a day on a temperature chart. If the temperature stays outside the safe temperature range or if the fridge tag alarms, then immediate action is necessary.

According to the Guidelines for Vaccine Storage and Distribution New Zealand, (2012) freezing and subjecting vaccines to heat are the most common reasons for vaccine damage and ultimately, wastage. According to these guidelines, the following vaccines are freeze-sensitive:

- Diphtheria;Tetanus and cellular pertussis;
- Hepatitis B;
- Haemophilus influenza type B;
- Inactivated polio (IPV);
- Meningococcal;
- Pneumococcal;
- Human Papillomavirus;
- Rotavirus; and
- Vaccine Diluents.

The most heat-sensitive vaccines are:

- Measles Mumps Rubella;
- IPV;
- Bacille Calmete Guerin (BCG); and
- Chicken pox.

From the above, it is evident that vaccines can be damaged through both heat and cold. This emphasizes the importance of the cold chain system within an immunization programme as it ensures that vaccines are maintained at the correct temperatures and thus, guarantees the effectiveness of vaccines in such programmes.

According to the study conducted by Carr, Byles, and Durrheim (2009: 34), in order to ensure the success of immunization programmes, it is imperative to ensure the maintenance of vaccines in their original state, through the cold chain system.

Many global studies, such as those conducted in Vietnam by Hipgrave *et al.*, (2006), in China by Wang *et al.*, (2007), and in Indonesia by Nelson *et al.*, (2004), have found that attention to maintenance of correct temperatures during storage and use of vaccines is a challenge for staff. According to these studies challenges that staff face were due to non-competent personnel managing the vaccines, equipment used for vaccine management not being effective and procedures not being efficient.

Evidence from studies conducted in Australia by Carr, Byles and Durrheim (2009) and Matthias *et al.*, (2007), in Mozambique by De Timoteo Mavimbe and Bjune (2003) indicate that good vaccine practices are lacking even in developed countries. Examples from these studies include use of incorrect and faulty refrigerators, vaccines being subjected to extreme cold and heat during transportation and storage in the refrigerator, lack of knowledge amongst staff who manages vaccines and failure to follow policy, guidelines and procedure regarding cold chain management.

- According to the Cold Chain Manual (WHO 1998) an effective cold chain system comprises of three major elements: Personnel, who use and maintain the equipment and provide the health service;
- Equipment for safe storage and transportation of vaccines; and
- Procedures to manage the programme and control the distribution and the use of vaccines.

Craig, (2008) states that there are several important reasons to maintain the cold chain. These include:

- Vaccines are biological products that lose their potency over time and this will result in reduced immune responses and inadequate protection against disease;
- Pharmacist and managers have a professional responsibility to ensure that vaccines are potent, safe and effective when children are being immunised in order to ensure high levels of disease control and public confidence in vaccine programmes; and
- Vaccines are expensive and Pharmacists have a responsibility to not waste this scarce resource.

Therefore, competent personnel, effective equipment and efficient procedures are vital parts of the cold chain system. Potency of vaccines should be maintained in order to obtain full benefit of immunization programmes. The safety of the vaccine is linked to the adverse events following immunization (AEFI) programme (Craig, 2008). Therefore cold chain store employees and managers involved in the cold chain system must ensure every effort is made to retain the safety of vaccines.

2.4 THE COSTS AND BENEFITS OF IMMUNISATION

Vaccine preventable diseases result in significant costs to individuals, the health care system and society. These include saving costs related to: repeated visits to health care providers, hospitalization, premature deaths, loss of time from work for parents to care for sick children and sick children lose

time from school (Canadian Immunization Guide, 2013).Therefore immunization against vaccine preventable diseases e.g. measles, and tetanus is a good investment and is offered free of charge.

Brenzel *et al.,* (2006) conducted a study that analyzed the cost, the scaling up and the introduction of new vaccines into programmes. The study also focused on the epidemiology of diseases preventable through immunization and estimates the disease burden with and without immunization. During this study the authors reviewed 102 estimates of total immunization programme costs of 27 countries. They concluded that immunization with the vaccines is a highly cost effective public health intervention (Brenzel *et al.,* 2006: 408). They further state that immunization has a significant effect on reducing mortality and morbidity from childhood diseases (Brenzel *et al.,* 2006).

Ethiopia is committed to ensuring that children receive effective vaccines and high vaccine coverage levels and these will reduce death and disease also leads to productivity gains, contributing to Ethiopia's economic development and also benefit unvaccinated children.

2.5 THE VACCINE MANAGEMENT ASSESSMENT TOOL

According to WHO (2005) the purpose of the Vaccine Management Assessment Tool (VMST) is to investigate the knowledge and practice of vaccine management by health staff at levels of the cold chain. The tool comprises 11 key indicators which are scored zero for a response of "No" and one for a response of "Yes" or "Not applicable" which are scored zero. The sum of these scores is normalized to give an overall score for each criterion on a scale of zero to five. The 11 indicators are:

Vaccine arrival procedures;

- Vaccine storage temperatures;
- Cold storage capacity;
- Buildings, cold chain equipment and transport;
- Maintenance of cold chain equipment and transport;
- Stock management;
- Effective vaccine delivery;
- effective use of Vaccine Vial Monitors(VVM);
- policy; and
- Vaccine waste control.

The scores are then used to graphically demonstrate the strengths and weaknesses of a country's cold chain management for vaccines and to stimulate necessary changes wherever needed. Support and

training can then be provided to the identified areas to overcome these deficiencies (VMAT WHO, 2005).

The Vaccine Storage and Handling Guidelines Ontario (2012) and Vaccine Storage and Handling Guidelines (2011) emphasize's the importance this tools for inspection of facilities by Public Health Units. This is to ensure proper management of vaccine inventories, reduce vaccine wastage, provide education strategies to minimize vaccine wastage and ensure vaccine safety and effectiveness (The Vaccine Storage and Handling Guidelines Ontario, 2012).

2.6 ADHERENCE TO NATIONAL POLICY AND GUIDELINES ON VACCINE MANAGEMENT

According to the National Guidelines for Vaccine Storage and Distribution – New Zealand (2012: 15) and the Vaccine Storage and Handling Toolkit (2012) immunisation programs and practices must have written protocols for routine storage and handling and emergency procedures for the cold chain management of vaccines.

The Vaccine Storage and Handling Guide (2011) states that staff should be knowledgeable regarding vaccine storage and handling. There should be at least two staff members who are responsible for vaccine management.

In the study conducted by Bankole *et al.*, (2010) in Nigeria the authors visited 1000 privately owned health facilities. During the first visits they interviewed the health care workers on cold chain for vaccines activities e.g. storage of vaccines, reading the vaccine vial monitor and vaccine monitoring. They found knowledge amongst health care workers was poor. On-the-spot training according to WHO guidelines was given to staff on vaccine management. A vaccine audit was also conducted. During the audit they found that 90 percent of the 900 fridges were faulty and were being shared with laboratory reagents and drugs. The fridge temperatures were not monitored, no recordings were done and fridges were without electricity. They revisited these health facilities in 2009 and found great improvement in the cold chain management and knowledge of staff was noted. In 92 percent of the facilities it was noted that the cold chain for vaccine fridges was greatly improved. This study concluded that in order to maintain vaccines perfectly conserved from manufacturer to administration an adequate cold chain infrastructure, compliance to standards and effective management are required. Similar studies were conducted by Carr, Byles, and Durrheim (2009), Mathias *et al.*,

(2007:) and Samyant, *et al.*, (2007) prove adherence to these guidelines are often lacking therefore resulting in vaccines losing their potency.

Thakker and Woods (1992) conducted a study in the United Kingdom on the storage of vaccines in five health clinics and 45 general practices. Questionnaires were handed out to staffs in the clinics. The refrigerator temperatures were monitored in eight practices for a period of two weeks. The results of the study revealed that in six of the eight practices selected for monitoring of the refrigerator temperature, the vaccines were either exposed to subzero temperatures or temperatures as high as 16 degrees Celsius. Furthermore, there was no evidence of bi-daily refrigerator temperature recordings and no written procedures or polices to indicate the action to be taken when vaccines were compromised. In this study a total of 40 staff responded to the questionnaire and only 16 of the staff were aware of the National Storage Guidelines for vaccines. The study also revealed a lack of knowledge on vaccine management which ultimately leads to vaccines being exposed to a wide range of adverse temperatures.

Thakker and Woods (1992) expressed the need for staff responsible for vaccine management to be trained in order to adhere to National Guidelines and standard operating procedures on vaccine management. Although this study was conducted in 1992, similar weaknesses are still observed in the cold chain management of vaccines today, due to lack of adherence to guidelines and policy.

2.7 THE STORAGE AND HANDLING OF VACCINES

According to the Cold Chain Module (WHO 1998), the cold chain system is a means for storing and transporting vaccines in a potent state, from the manufacturer to the person being immunized. The cold chain system comprises of three major elements:

- personnel, who use and maintain the equipment and provide the health service;
- equipment, for the safe storage and transportation of vaccines; and
- procedures, to manage and control the distribution and use of vaccines.

One of the very first studies conducted on cold chain management of vaccines was in Ohio by Lerman and Gold (1971). In this study the researchers questioned whether the storage of vaccines had any link to the outbreak of measles in previously immunized children in Ohio. The study revealed that 14 of the children immunized with the measles vaccine by a particular physician, had presented with an attack of measles. Upon further investigation it was discovered that the measles vaccine in the physician's practice was stored in the refrigerator door. Variations in refrigerator

temperature occurred due to the opening and closing of the door. The vaccines were subjected to temperatures of between zero to eighteen degrees Celsius. These findings suggested that vaccines were not maintained at the proper temperature throughout the cold chain and subsequently lost their potency, possibly resulting in measles outbreak.

A study carried-out in eight health districts in Cameroon by Ateudjieu *et al.*, (2008) revealed that the targeted health districts were not compliant with the standard operating procedures. Almost 25 percent of health facilities were conducting EPI activities without cold chain equipment resulting in a threat to the cold chain for vaccines.

2.8 VACCINE STORAGE EQUIPMENT

At the Cold room Facilities vaccines are stored in a refrigerator dedicated for storage of vaccines only. During Transportation vaccines required to be stored in the cold box. The cold box is lined with ice packs. A thermometer is used in the refrigerator and the cold box to monitor the temperature. A temperature of two to eight degrees Celsius must be maintained in the refrigerator and the cold box to ensure vaccine potency (Vaccine Storage and Handling Toolkit, 2012).

2.8.1 REFRIGERATOR, COLD BOXES AND THERMOMETERS

The Vaccine Storage and Handling Toolkit (2012) recommend stand-alone refrigerators or freezers and purpose built refrigerators for storing of vaccines. The bar refrigerator is not suitable for vaccine storage as it is a very small combination unit (Vaccine Storage and Handling Toolkit, 2012).

Study was conducted by Carr, Byles, and Durrheim (2009) in New South Wales in which 256 pharmacists participated by filling in a questionnaire. During the site visits the researchers conducted an audit using a checklist on all refrigerators used for vaccine storage. The results from the study showed that of the 49 (19 percent) of general practices that used bar type refrigerators, the temperature fluctuated between being too high or too low. The authors recommend that bar-type refrigerators for storing vaccines be outlawed as they pose a threat to vaccine integrity. Similar concerns were raised about the bar-fridge for vaccine storage in a study conducted in Australia by Page *et al.* (2008). This study supported the use of the purpose built refrigerators as the best method for vaccine storage, as recommended by the Vaccine Storage and Handling Toolkit (2012).

The National Vaccine Storage Guidelines Strive for Five (2005) states that vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to get

too hot or if they are exposed to direct sunlight and it is recommend that vaccines must be stored at a temperature range between two to eight degrees Celsius.

Recording of the fridge temperature must be done twice daily. If at any time, the temperature is outside the normal range of two to eight degrees Celsius, immediate corrective action is necessary as recommended by The National Vaccine Storage Guidelines Strive for Five (2005).

The correct number and placement of icepacks inside the cold box is important as too few ice packs can fail to maintain the internal cold box temperature and too many icepacks have the potential to harm the vaccines (Rogers *et al.*, 2010). The authors state that a thermometer must be placed in the cold box next to the vaccines and the temperature of the cold box must be monitored hourly and displayed outside the cold box (Rogers *et al.*, 2010). By monitoring the temperature hourly the pharmacist will be able to identify if vaccines are still potent and safe to use.

Barber-Hueso *et al.,* (2009) conducted a cross-sectional study in Spain. This study reviewed 50 immunisation points and 68 refrigerators using a structured questionnaire. The results revealed that for 75 percent of the vaccine refrigerators, the correct temperature was not maintained. In addition, no refrigerator temperature recordings were documented.

A similar cross sectional study was conducted in health facilities in three African countries, namely, Ghana, Kenya and Uganda. The study was conducted by Burstein, *et al.* (2012) to assess the quality of cold chain for vaccine storage from mid-2012 to late 2012. A total of 661 facilities were surveyed. During the study, the temperatures of the cold boxes and fridges at these facilities were recorded and compared to the National Vaccine Storage Guidelines Strive for Five (2005). In most of the health facilities surveyed the temperatures of the fridges and cold boxes were four degrees Celsius outside the normal range. There was no documentation of temperature or cold chain equipment. The authors state that there remains significant room for improvement in vaccine storage management in Ghana, Kenya and Uganda (Burstein *et al.*, 2012).

Goel *et al.,* (2008) compared the state of cold chain maintenance during a polio immunization campaign in Chandigarh India from the year 2001 to 2006.The results revealed that in 2006, monitoring of the cold chain, with regards to recording of fridge temperatures and countersigning by supervisors, improved to 95.5 percent as compared to 23 percent in 2001. The results from this study showed that temperature maintenance improved over time. This was evident by the adequate

maintenance of temperature charts. However, the authors stated there was still room for improvement and constant efforts are required to maintain the cold chain for vaccines.

Similar concerns were raised by a study conducted in Western India by Naik, Rupani and Bansal (2013: 1395). Concerns noted by them included, use of expired vaccines, lack of backup generators, lack of knowledge by staff on how to read the vaccines vial monitors, conduct the shake test for frozen vaccines and record the temperature of the fridge. The authors recommended periodic training, capacity building supervision and monitoring for cold chain handlers,

The National Vaccine Storage Guidelines Strive for Five (2005) state that no food or any other goods must be stored in the refrigerator. This ensures that staff do not continuously open and close the refrigerator door unnecessarily, causing fluctuation in fridge temperatures, ultimately causing vaccines to become compromised. A study conducted by Barber-Hueso *et al.,* (2009) showed that 33.8 percent of fridges evaluated, stored food, suggesting that the vaccine cold chains in immunisation centres were not being maintained according to National Vaccine Storage Guidelines.. In addition, this study revealed that vaccine fridges also stored laboratory reagents and various other drugs.

A cross-sectional study was conducted in Saudi Arabia by Mugharbel and Wakeel (2007). The authors compared the use of vaccine chain tools in ten Governmental Primary Health Care (GPHC) facilities to the use of these tools in five Private Health Care Facilities (PHCF). To enable the comparison, the authors used a checklist based on the World Health Organization criteria for vaccine management. The study revealed that less than 20 percent of PHCFs maintained proper vaccine temperatures during storage as compared to 100 percent in GPHC facilities. Better cold chain practices were maintained in GPHCs with regard to the placement of the fridge away from direct heat and sunlight, recording of fridge temperatures twice daily, packing of vaccines in the fridge and in a cold box according to guidelines of WHO and the knowledge of staff regarding backup systems in case of cold chain failure. The overall results of this study revealed that PHCFs did not comply with standards defined by WHO and that the PHCF staff needed constant supervision and training regarding cold chain tools. A similar study was carried-out by Gazmararian *et al.,* (2002) in which a comparison of primary care physicians' offices and paediatricians' offices revealed that paediatric offices had better compliance to guidelines for vaccine management.

A study conducted in eight health districts in Cameroon by Ateudjieu *et al.*, (2008) revealed that the targeted health districts were not compliant with the standard operating procedures related to cold chain management of vaccines. Almost 25 percent of health facilities were conducting EPI activities without cold chain equipment. The authors noted that the electricity supply in Cameroon was unreliable and 79.4 percent of facilities reported interruption of power on a regular basis but had no standby generators available. The study further revealed that vaccines were not stored correctly on the top and bottom shelves of the fridge, vaccines and diluents were not stored together, fridges were over-packed not allowing air to circulate and used vaccines were not marked appropriately. The authors recommend that in order to overcome the gaps identified in cold chain management of vaccines in Cameroon, the health authorities should identify innovative strategies such as computerised temperature monitoring systems for cold chain of vaccines, as recommended in the study conducted by Schlumberger *et al.*, (2011). Schlumberger *et al.*,(2011) recommend that in order for staff to effectively manage the cold chain for vaccines, there should be constant supervision and training in cold chain management, access to guidelines and availability of cold chain tools and equipment for staff.

An outbreak of measles in Cape Town, South Africa, In 1993 prompted Coetzee (1993) to carry-out a study on vaccine storage procedures in General Practitioners' rooms. A standardised questionnaire was used to conduct telephonic interviews. A sample of 103 practitioners was used. The study revealed that 81 percent of practitioners did not monitor the fridge temperature as they did not have appropriate temperature devices. Food and cold drinks were stored in the fridge in 54 percent of the cases and 60 percent of the practitioners' stored vaccines in the doors. These findings are consistent with studies conducted globally and on the African continent.

Thermometers are a critical part of good storage and handling practice. The common types of thermometers used in vaccine fridges are dial and digital (National Vaccine Storage Guidelines Strive for 5, 2013). Thermometers should be placed in the centre of the fridge. The temperature of the fridge must be monitored twice daily and recorded on the temperature chart which is placed on the front of the fridge. If the fridge temperature drops below two degrees Celsius and goes above eight degrees Celsius action needs to be taken to avoid vaccine becoming compromised. (National Vaccine Storage Guidelines Strive for 5, 2013).

Barber-Hueso *et al.*, (2009) conducted a cross-sectional study in Spain. This study reviewed 50 immunisation points and 68 refrigerators using a structured questionnaire. The results revealed that

for 78 percent of the vaccine refrigerators, the correct temperature was not maintained. In addition, no refrigerator temperature recordings were documented. Ateudjieu *et al.*, (2008) in their study conducted in Cameroon stated that innovative strategies such as computerized temperature monitoring of the cold chain for vaccines could be used to protect their potency.

2.9 EVIDENCE OF FREEZING OF VACCINES

According to Immunisation, Vaccines and Biological (WHO-2011), improperly maintained or outdated refrigeration equipment, poor compliance with cold chain procedures, inadequate monitoring and poor understanding of the dangers of vaccine freezing contribute to weakness in the cold chain.

In a study conducted in Indonesia by Nelson *et al.*, (2004) the authors used data loggers to monitor temperatures of the Hepatitis B vaccine from the manufacturer to the point of use. Baseline conditions and three intervention phases were monitored. In 75 percent of the shipment of vaccines, freezing temperatures were recorded. The highest rates of freezing occurred during transport from province to district, storage in district-level ice lined refrigerators and storage in refrigerators in health centres. The researchers concluded by stating that the use of simple strategies, such as the use of selective transport that store vaccines at ambient temperatures and the use of VVM to detect heat damage to vaccines as these could reduce freezing, reduce costs and increase capacity of vaccines in Indonesia.

Nelson *et al.*, (2004: 99), Ren *et al.*, (2009), Techatawat *et al.*, (2007), Turner, Laws and Roberts (2011), Wirkas *et al.*, (2007) and Zipursky *et al.*, (2011) conducted studies in Indonesia, China, Thailand, Papau New Guinea and Chad, respectively, on how vaccines which are exposed to freezing temperatures lose their potency due to the inactivation of key organic components. Such losses in the potency of vaccines results in vaccines becoming ineffective. This poses potential danger to patients who receive these vaccines, as well as a financial loss for immunization programmes.

Matthias *et al.*, (2007) conducted a systematic literature review of studies from January 1985 to June 2006 which investigated vaccine freezing in the cold chain. These authors recommended that more rigorous and comprehensive studies be conducted to examine the exposure of vaccines to freezing temperatures through all transport and storage segments of the cold chain.

When vaccines are subjected to freezing the shake test is done to determine if the vaccine can still be used.

2.10 VACCINE VIAL MONITORS

Studies conducted in India by Samant *et al.*, (2007) and in Gujarat by Patel, Raval and Pundit (2011) focused on the relationship between the Vaccine Vial Monitor (VVM) and the cold chain infrastructure. WHO mandates that all vaccines which have VVMs must indicate the heat exposure that negatively affects vaccine potency (WHO, 1999). Patel, Raval and Pundit (2011) revealed that 98.8 percent of the facilities they visited showed VVMs of stage one and two of freeze vaccines. Furthermore, reconstitution time was not documented on the vaccine vial. Samant *et al., (*2007) in their study concluded that the further away vaccines travelled from the central vaccine stores to sub-health centers, the more likely the VVM changes from stage three to stage four. These stages indicate that vaccines have lost their potency and should be discarded. The VVM remains a cost effective way which ensures that potent vaccines are delivered to children.

2.11 KNOWLEDGE AND PRACTICES OF STAFF HANDLING AND ADMINISTERING VACCINES

The Vaccine Storage and Handling Toolkit (2012) and the National Vaccine Storage Guidelines (2005: 6) recommend that staff who handle and administer vaccines should receive training regarding vaccine storage and handling policies and procedures. Training should also be integrated into the orientation programmes.

Widsanugorn *et al.*, (2011) conducted a cross-sectional study in hospitals and primary health care centers, to assess healthcare workers' knowledge and practices regarding the cold chain system in Thailand. The researchers concluded that nurses' knowledge in hospitals were better than in primary health care centers. These researchers have strongly recommended that continuous training and supervision on cold chain management of vaccines be carried out in order to ensure that immunization is effective and vaccine failures are prevented.

Mallik *et al.*, (2011) conducted a baseline survey on cold chain equipment in Kolkata, India. This study assessed the changes that occurred in cold chain management after an intervention undertaken to improve the cold chain management status. The intervention involved the reorganizing of cold chain points and training in cold chain management based on the guide of the Government of India. Prior to the intervention there were gross discrepancies in availability of cold chain equipment, lack of knowledge amongst staff on cold chain guidelines and lack of monitoring and supervision. The success achieved through the intervention resulted in significant improvement in care of cold chain

equipment, placement of vaccines in the refrigerator and appointment of a cold chain handler at every immunization centre. Other gaps identified in cold chain systems in this study included non-availability of backup generators and a separate cold chain room, which is mainly dependent on policy makers and funding.

2.12 CHALLENGES COLD CHAIN HANDLERS FACE WITH VACCINE MANAGEMENT

There are numerous challenges in the management of the cold chain of vaccines despite the many advances in immunization in Ethiopia. These include insufficient financial resources, a shortage of trained staff and a lack of knowledge regarding vaccine management. These challenges will lead to vaccines becoming compromised and less potent. As a result, these vaccines will not be beneficial to children. Some solutions to overcome these challenges May be training, supervision and regular auditing to improve performance of vaccine management.

2.13 VACCINES WASTAGE

Improving the use of vaccine supplies and avoiding unnecessary wastage often depends upon better management. Wastage of vaccines can occur form central stores, during transportation and at immunization sessions (Cold Chain Vaccines and Safe Injection Equipment management WHO, 2008: 46). The factors associated with vaccine wastage can be classified as unavoidable or avoidable. Unavoidable wastage includes reconstituted vaccines that have to be discarded at the end of the immunization session. Avoidable vaccine wastage factors include poor stock management, cold chain failure that exposes vaccines to high or low temperatures, loss breakage and theft of vials (Cold Chain Vaccines and Safe Injection Equipment management WHO, 2008).

In a study conducted in New Zealand between 2002-2008 the researchers randomly included temperature monitor cards in vaccines that were distributed from the national stores to delivery sites. During this time six monthly reports were documented and analysed to identify changes in freeze and heat exposure failures for vaccines. When cold chain failures were identified a range of changes were implemented such as improving equipment, systems, policies and procedures, education and training and increased provider attention, in order to strengthen the cold chain for vaccines (Turner, Laws and Roberts, 2011: 280). The study revealed that the heat failure in vaccines was reduced from 3 to 0.3 percent, freeze failures in vaccines decreased from 16 to 2 percent and overall vaccine wastage was reduced from 17 to 2 percent. Therefore this study concludes that through improving equipment,

systems, policies and procedures and education and training, vaccine wasting can be reduced thus reducing costs for the country (Turner, Laws and Roberts, 2011).

2.14 RECORD KEEPING FOR VACCINES

All facilities must have written policies, procedures and protocols in place regarding vaccine management. Maintaining stock records are critical for vaccine inventory management (Vaccine Storage and Handling Toolkit, 2012). Records must be maintained on vaccine balances, waste, fridge temperature, fridge servicing and records of training of staff on vaccine management. Records must be kept for a period of three years. Proper documentation helps to prevent wastage of vaccines (Vaccine Storage and Handling Toolkit, 2012).

A study was conducted in seven regional vaccine depots, eighteen health clinics and central vaccine stores in Swaziland. At the health clinics the authors found that documentation for vaccine management was poor. They found that vaccine stock levels were not established and physical count of vaccines not documented in 37 percent of the clinics. Furthermore, vaccine wastage was recorded in log books however only 13 percent of the clinics maintained records for calculation of wasted vaccines. The authors recommend that staff be trained on vaccine management and recording (Nxumalo *et al.,* 2006).

2.15 CONCLUSION

It is evident from the literature reviewed, that many gaps and weaknesses are present at every stage of the cold chain such as Staffs who lack knowledge on the management of vaccines, lack of electricity, the mismanagement of equipment and the poor transportation infrastructure. Due to these gaps vaccines lose their potency, thus, making children more vulnerable to childhood vaccine preventable diseases. Therefore, Staff with in the cold chain must have adequate knowledge and regular in-service training on vaccine management, ensure availability of generators in case of power failure, and ensure proper management of vaccine fridges and cold boxes in order to maintain an effective cold chain for vaccines.

Chapter 3 presents the research methodology used to guide the study. It describes 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 analysing the data collected. In addition to this, the chapter presents the conceptual framework that was used to guide the study.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter presents the research methodology used to guide the study. It describes 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. In addition to this, this chapter presents the theoretical framework that was used to guide the study.

The researcher will collect data from 15 Regional and one Cold chain central facilities operated by Ethiopian Ministry of Health. The facilities are found disbursed around Ethiopia in Addis Ababa, Jimma, Bonga, Nekemet,Dukem, Chiro, DireDawa, Harar, Somalia, Dessie, Bahirdar, Hawassa, Afar, Assosa, Gambella. All Vaccines flows through these facilities trough out Ethiopia first.

3.2 RESEARCH DESIGN

Polit and Beck (2012) describe the research design 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 provide the answer to questions and guides the comparisons that will be made. From this it can be deduced that the research design has a strong influence on the reliability and relevance of the results attained and thus provides a solid base for the research study.

According to Burns and Grove (2009) quantitative research is a formal, objective, systematic process in which numerical data is used to obtain information. Burns and Grove (2009) also state that descriptive studies offer researchers a way to discover new meaning to describe what already exists, determine the frequency with which something occurs and to categorize information.

In light of this, a quantitative descriptive survey design was selected for this study and will be conducted in two ways . In the first , an observational study will be carried out by the researcher using a structured observation guideline. At the **Five** of the 15 cold chain facilities selected, using interval sampling technique, the researcher will observe if the cold chain for vaccines was maintained according to National/reginal and Operational guidelines. Observations will be recorded on a pre-planned checklist that containes the aforementioned guidelines.Second , the cold chain management of vaccines by Pharmacist will be explored by means of a self-administered questionnaire. staff working in the the cold chain system will be included in both phases of this research study.

3.3 CONCEPTUAL FRAMEWORK

The purpose of the cold chain system is to ensure effective transport and storage of vaccines to enable their administration in a potent state to the person being immunized. The WHO proposes a framework (Figure 1) for effective cold chain management of vaccines in addition to National and operational guidelines. This framework was adapted for this study, to aid in investigation of the cold chain for vaccines. This framework is made up of nine constructs, split into five strategic steps. As recommended by WHO, these five steps should be followed to ensure quality vaccine Managment.

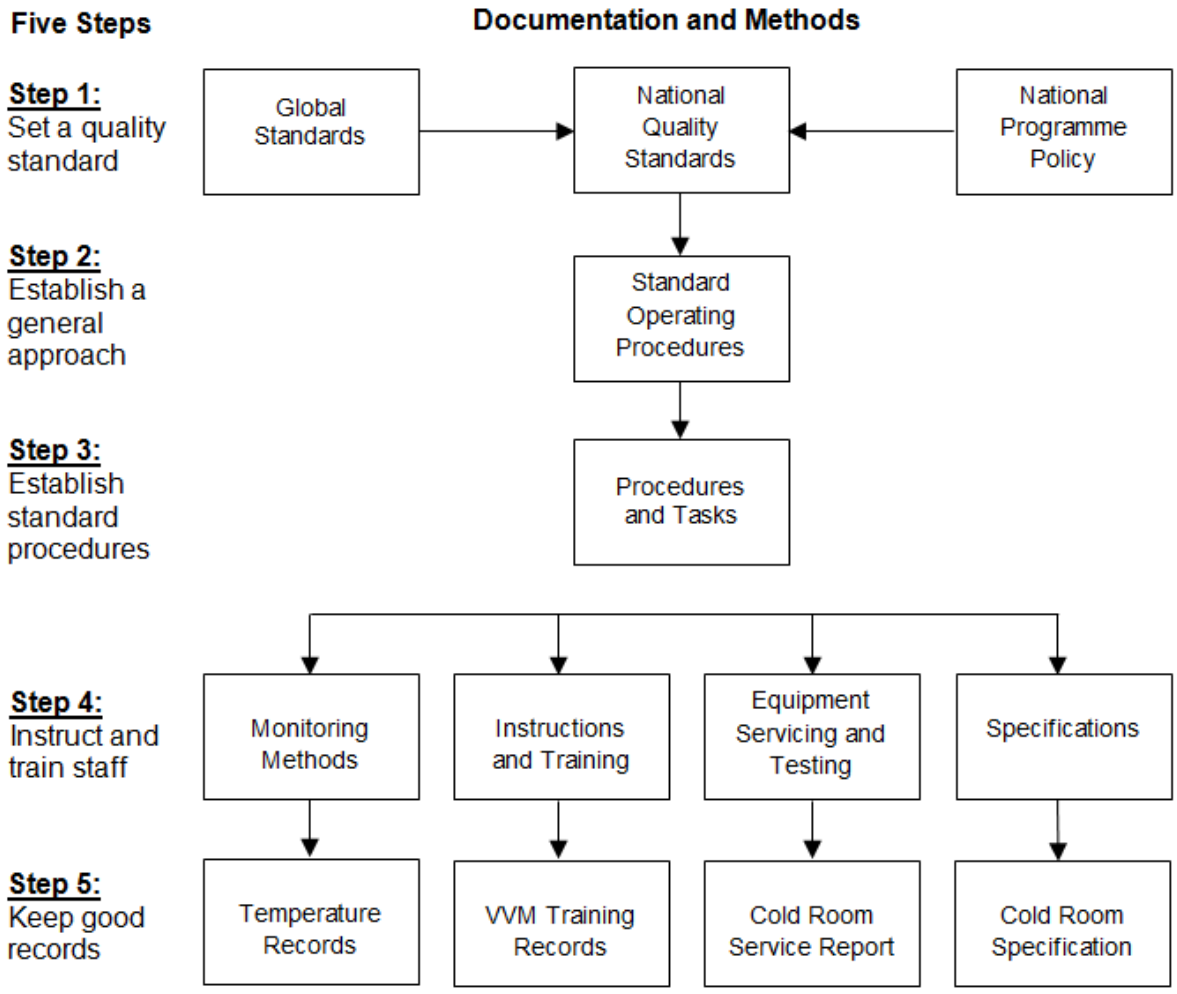


Figure 1.1: Conceptual Framework Adapted from Vaccine Management (WHO, 2005) immunization, vaccine guidelines.

The first step is setting the quality standard.
This is the step in which quality models available for vaccine management are identified. Staff allocated to Cold Room facilities must practices duties regarding the management of vaccines based on national programme policy guidelines as recommended by WHO and UNICEF. Following the policy guidelines in the selected quality model ensures that the integrity of vaccines is maintained.

In step two, a general approach to vaccine management is established. Overall requirements for vaccine management are identified. Thereafter, standard operating procedures are prepared and adopted.

Step three entails establishing standard procedures. Specific tasks and procedures for vaccine management are identified. These tasks and procedures are set out to ensure that standard of performance prepared in step two are achieved. Instructing and training staff is a vital step in this process. In order to carry out each task competently, staff are instructed and trained during orientation programmes and in-service training. It is also important to ensure sufficient equipment for cold chain management. Equipment servicing and testing should be done on a regular basis.

Lastly, it is suggested that good records are kept. This will ensure that the task has been carried out effectively, in doing this, vaccine programme managers can verify that sound vaccine management is in place and has been maintained over a period of time.

This framework provides the foundation for determining the level of quality of the management of vaccines at the selected Facilities with in the cold chain system. In addition, assessing vaccine management using this framework enables staff to highlight the strengths and weaknesses of vaccine management and introduce the changes where necessary.

3.4 STUDY SETTING

The study setting for this research will be naturalistic in order to ensure that the obtained results mirror the reality of managing the cold chain for vaccines in the daily workings of the Facailites with in the selected cold chain system of the regional cold chain facilities.

There are 15 regional cold chains and one Central Cold chain facility. These facilities cover Millions of children's vaccination need. These Facilities are at sub-National\region level and are the first entry

for vaccines into the health system. The study is carried out at all 15 cold chain facilities found in Addis Ababa, Jimma, Bonga, Nekemet,Dukem, Chiro, DireDawa, Harar, Somalia, Dessie, Bahirdar, Hawassa, Afar, Assosa, Gambella.where Selected participants pharmacists will complete the questionnaires.

3.5 SAMPLING PROCESS

A sample can be described as a sub-selection of the research population. According to Polit and Beck (2012: 275) samples characteristics should closely resemble those of the entire population, to be considered as representative of the population. There are 15 Cold chain Facilties in Ethiopia and they are:

Addis Ababa
Jimma
Bonga
Nekemet
Dukem
Chiro
DireDawa
Harar
Somalia
Dessie
Mekele
Bahirdar
Hawassa
Afar
Assosa
Gambella

There are approximately 1950 staff employed at these Facilities representing the total research population for this study. For the purpose of this study,all the cold chains at the Sub National Level\reginal level will be utilized.

3.5.1 PHASE ONE

For the observation study 30 percent of the 15 Cold chain facilities were chosen, which equated to 5 Facilities. Thus, the sample comprised of 5 Staff members who are directly involved in the daily operations were randomly selected, Two from each Facility. The facilities were semi randomly selected by using interval sampling. All 15 were listed on a page and every third facility will be chosen for the observation study. The observation study will be conducted using a structured observation guide.

3.5.2 PHASE TWO

A self-administered questionnaire will be distributed to a representative sample of 45, Two who are directly involved in daily operations EPI co-ordinator(Responsible for planning, approving distributions and forecasting need) and EPI officer(Cold Room manager: responsible for managing the vaccines in their cold room\refrigrator) and one support staff the cold chain manager .

A sample is chosen to be representative of the research population. Inclusion and exclusion criteria ensure that there is accuracy in the sampling process therefore inclusion criteria are applied to choose applicable participants for the study also exclusion criteria guide who will be excluded from the study. The following criteria where applied to the study:

INCLUSION CRITERIA:

- All full-time staff directly involved in cold chain system and employed at Regional and central level and important support staff for the smooth operation of the activities.

EXCLUSION CRITERIA:

- Partner organization staff seconded at the facilities for support
- Staff members who are not directly involved in the daily activities
- Student Pharmacists Practicing at facilities.

3.6 DATA COLLECTION PROCESS

According to Burns and Grove (2009), data collection is the process of acquiring participants and collecting information from these participants that is relevant to the study. The authors further state that ensuring consistency and controls during the data collection process ensures the integrity and validity of the study. With that in mind the data collection process will occur in two phases. The first phase will be an observation study which uses a structured observation guide as a means of recording the researcher's observation. The second phase warrants the use of a questionnaire which 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 includes items regarding Policy, procedures and guidelines as well as cold chain maintenance, Equipment and stock availability.

3.9 RELIABILITY AND VALIDITY OF THE INSTUMENT

According to Polit and Beck (2008) reliability is the degree of consistency or dependability with which an instrument measures an attribute. In addition Polit and Beck (2008) state that the reliability of a quantitative measure is an important criterion for assessing its quality. The researcher will ensure that the same questionnaire will be administered to all participants for this study and the same structured observational guide will be used in all Selected facilities with in the cold chain.

Validity, according to Polit and Beck (2008), is the degree to which the instrument measures what it is intended to measure. Content validity was tested by choosing experts in the field of vaccine management and seeking their profesinal input in order to test the validity of the data collection tool. The researcher ensured validity by including questions pertaining to this study only.

3.11 SUMMARY

This chapter detailed the research methodology and the conceptual framework that were employed in the study.

CHAPTER 4: PRESENTATION OF THE RESULTS

4.1 INTRODUCTION

The previous chapter outlined the methodology adopted in conducting this study. This chapter presents the data obtained from the study. An observation guideline checklist and a self-administered questionnaire were used to collect the data from the Cold rooms facilities. The objectives of the study and the observation guidelines were used to guide the findings.

Section A1 presents the findings related to the observation guidelines checklist. This is followed by Section A2, which presents the findings of the self-administered questionnaire

SECTION A1: PHASE ONE – OBSERVATION STUDY

4.2.1 DEMOGRAPHIC DATA

The observation study was conducted in five cold room facilities, A total of ten cold Room employees were observed. Both the employee's and the cold room facilities to which they belonged were evaluated against the criteria discussed below.

4.2.2 CURRENT PROCESSES OF COLD CHAIN MANAGEMENT

4.2.2.1. POLICIES, PROCEDURES AND GUIDELINES OF COLD CHAIN MANAGEMENT AS SUGGESTED BY NATIONAL/GLOBAL STANDARDS OF WHO

An observation guideline checklist with Eleven criteria was used to observe whether Employees in the cold room followed policy, procedures and guidelines in the management of the cold chain for vaccines.

	YES	NO
1.1 Policies, procedures and guidelines available for vaccine management.	40	60
1.2 Are contingency plans in place for problems with equipment/electricity used in th cold chain management of vaccines?	40	60
1.3 Is there evidence of maintenance to cold chain equipment available?	40	60
1.4 Is there evidence of filling in of stock cards for vaccines?	60	40

1.5 Is there evidence of physical inventories of vaccine stock?	100	1
1.6 Is there evidence of dedicated room for vaccine Storage ?	80	20
1.7 Is vaccine wastage managed according to policy?	40	60
1.8 Are there vaccine wastage reports available?	40	60
1.9 Is their evidence of shake test for frozen vaccines?	80.	0.
1.10 Is there evidence of records of in case of recall /batch numbers for vaccines?	40	60
1.11 Is there evidence of good vaccine records .i.e. temperature records .training record, cold room service reports?	40	60

As can be seen in Table 4.1, there are eleven criteria relating to policy, procedure and guidelines of cold chain vaccine management. In three of the ColdRooms observed there was no written evidence of contingency plans for faulty equipment and electricity failure, maintenance of equipment, management of vaccine waste. There was evidence of filling in of stock cards in 60% (n=3) ColdRooms and in 40% (n=2) this was not evident.

In 80 (n=4) of ColdRooms there was compliance with having a dedicated room for vaccine storage and procedures. There was non-compliance in 20% (n=1) of the ColdRooms observed.

Record keeping regarding in-service training for cold room pharmacists\employees, cold room service reports, and records for recall of batch numbers were only documented in 40% of the cold rooms.

4.2.2.2. STANDARDS OF COLD CHAIN MANAGEMENT

The criterion used for standards of cold chain management during the observation study was based on the National/Global standards of vaccine management according to the WHO.

The observation guideline checklist was used to observe whether Cold Room employees\ pharmacists maintained the standards of cold chain for vaccine management regarding vaccine arrival procedures, refrigerator, cold box and availability of vaccine stock and equipment.

4.2.2.3. VACCINE ARRIVAL PROCEDURE

Four criteria, as seen in Table 4.2, were used in the observation study to observe how the cold room employee's \pharmacist responded to and stored vaccines when they arrived.

Table 4.2: Vaccine arrival procedure

	No	Yes
2.1 Does the cold room employee's \pharmacist respond immediately when vaccines arrive ?	40.0	60.0
2.2 Does the cold room employee's \pharmacist check vaccines for discrepancies, leakage and breakage before receipt?	60.0	40.0
2.3 Are vaccines stored immediately on receipt?	40.0	60.0
2.4 Are vaccines stored according to the first in first out principle?	80.0	20.0

Table 4.2 shows results for each of the criteria on vaccine arrival procedures

4.2.2.4. REFRIGERATOR

During the observation study fourteen criteria as indicated in Table 4.3 was used to observe the refrigerator in which vaccines were stored.

Table 4.3: Refrigerator

	Yes	No
3.1 Is the refrigerator appropriate to store vaccine? Size, freezer compartment for icepacks?	80.0	20.0
3.2 Is the refrigerator is dedicated for vaccines only?	100.0	0.0
3.3Is the refrigerator temperature between (2 - 8 °C)?	60.0	40.0
3.4 Is the temperature of the refrigerator recorded on chart twice daily?	20.0	80.0
3.5 Is the refrigerator packed correctly ?	20	80
3.6 Is the refrigerator overstocked?	60.0	40.0
3.7 Is there enough air circulating between vaccines?	20.0	80.0
3.8 Are there vaccines on the door?	20.0	80.0
3.9 Is the refrigerator in a locked room or does the fridge has a lock and key?	0.0	100.0
3.10 Is there a working thermometer hanging in the correct place?	0.0	100.0
3.12 Do not unplug refrigerator signage on plugs	0.0	100.0
3.13 Do not open vaccine fridge signage on fridge door	0.0	100.0

Table 4.3 - shows that for criteria 3.9- 3.13 100% (n=5) of the cold rooms scored “No”, indicating non-compliance. In the first eight criteria it was observed that cold rooms were partially complaint. The “Yes” scores ranged between 20% -80 % and the “No” ranged between 20-80% .

4.2.2.5. EQUIPMENT AND STOCK AVAILABLE

During the observation study one criterion was used as indicated in Table 4.4 to observe the availability of vaccine equipment and stock.

Table 4.4 :equipment and stock availability		
	Yes	No
8.1 Are sufficient EQUIPMENT AND STOCK AVAILABLE for smooth operations?	40	60

As seen in the above Table 4.4 only one criterion was used to observe the availability of equipment and stock . It was observed that 40% (n=2) were compliant with availability of stock and equipment and 60% (n=3) were non-compliant with this criteria.

4.3 SECTION A2: PHASE TWO – SELF-ADMINISTERED QUESTIONNAIRE

4.3.1 INTRODUCTION

The questionnaire was the primary tool used to collect data for phase two of the study. The questionnaire was distributed to Pharmacists\Cold Rooms employee's Through Out Ethiopia.The responses from the questionnaire were captured on Microsoft Excel and then transported into the Statistical Package for the Social Sciences (SPSS) database. This data was analysed using SPSS version 17.0.

4.3.2 THE SAMPLE

The sample consisted pharmacists and managers directly involved in the cold chain trough out ethiopia. In total, 45 questionnaires were administered and 43 were returned which gave a response rate of 95.6% .

4.3.3 THE RESEARCH INSTRUMENT

The questionnaire was divided into three main sections which measured various themes as illustrated below:

Section A : Biographical data

Section B : Vaccine Management

Question B1 : Policy

Question B2 : Vaccine Management

Question B3 : Vaccine Refrigerator

Question B4 : Cold Boxes

4.3.4 PRESENTATION OF THE RESULTS

This section presents the results of the self-administered questionnaire.

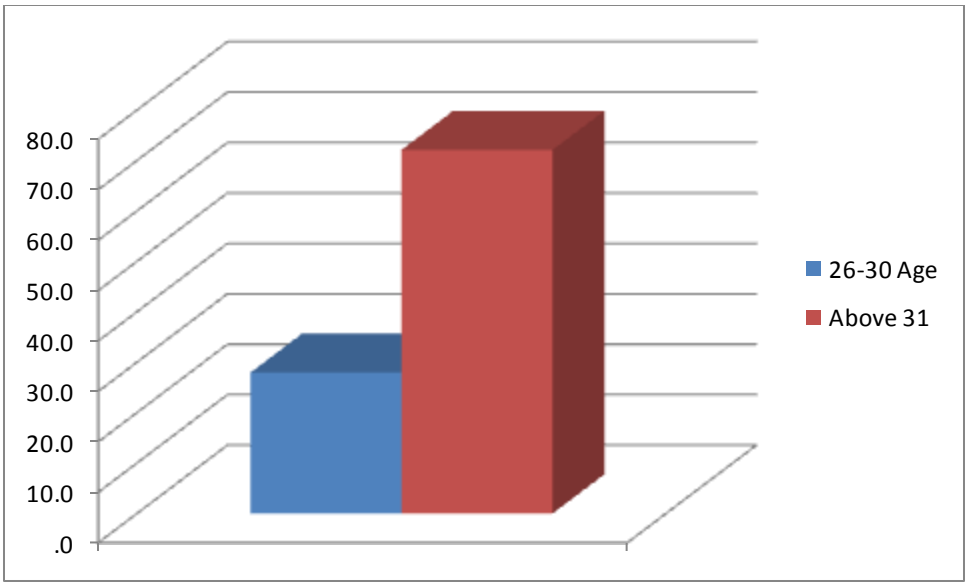
4.3.4.1. SECTION A – BIOGRAPHICAL DATA

This section summarizes the biographical characteristics of all respondents who participated in this study. This included: age, gender and experience.

4.3.4.1.2. AGE AND GENDER DEMOGRAPHY

Table:4.5 age and gender demography

Age	
Age	Percent
26-30 Age	27.9
Above 31	72.1



Gender	
	Percent
Male	90.7
Female	9.3

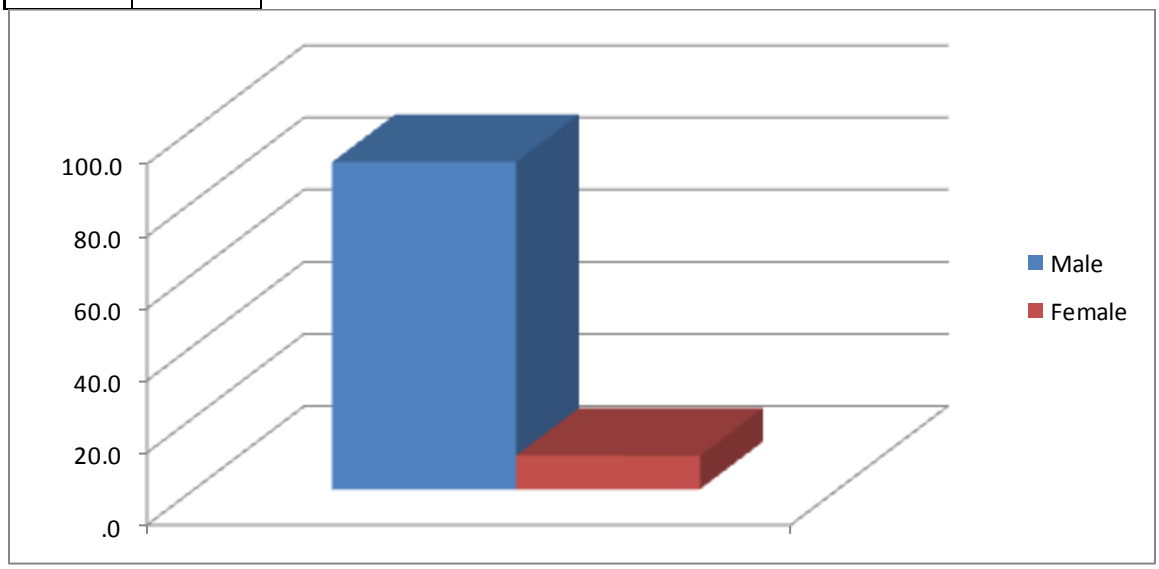


Figure 4.1: Age and Gender

The ratio of females to males who participated in this study was approximately 1:10, with males forming 90.7 % (n=39) and females forming 9.3% (n=4) of the population, respectively. The age of participants in this study ranged from 26 to above 31 years, with 2.9% (n=8) of the participants between 26 and 30 years old, 27.9 % (n=12) of participants between 26 and 30 years of age and the majority of participants older than 31 years old, forming 72.1% (n=31) of the total.

4.3.4.1.3. EXPERIENCE

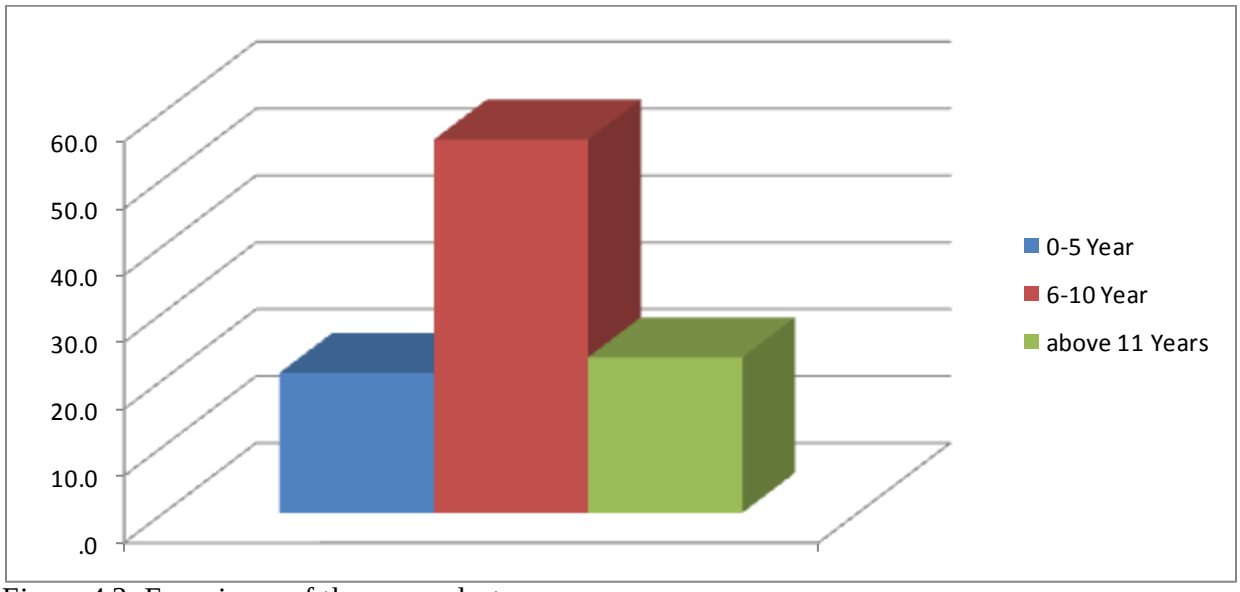


Figure 4.3: Experience of the respondents

23.3 % (n=10) of the sample had more than 10 years of work experience. The majority of participants 55.8% (n=24) had between six and ten years of work experience, with only 20.9% (n=9) of participants having worked for less than 5 years. The cumulatively the sample indicates a mature and experienced grouping of respondents. This is useful as the responses can be regarded as informed opinion.

4.3.4.1.4 TRAINING IN VACCINE MANAGEMENT

Table 4.6: Training in vaccine management and involvement in vaccine management

	Yes	No
Training in vaccine management vaccine management	70%	30%

Table 4.6 reveals that 70% of participants are trained in vaccine management whereas 30 % of participants are not trained in vaccine management.

4.3.4.2. SECTION B – VACCINE MANAGEMENT

The section that follows analyses the scoring patterns of the participants per variable per section. Negative statements were categorised as "Never" and positive were labelled "Always". The results are presented using percentages for the variables that constitute each section..

4.3.4.2.1. QUESTION B1: POLICY

This section deals with cold chain policies. The scores are represented in Table 4.7

The coldroom has an up to date cold chain policy			
		Frequency	Percent
	Never	15	34.1
	sometimes	0	0
	Always	28	63.0
	Total	43	97.7

All staff are trained to follow policies that ensure cold chain compliance for vaccines.			
		Frequency	Percent
	Never	5	11.4
	sometimes	8	18.2
	Always	30	68.2
	Total	43	97.7

All new staff allocated to the coldroom are oriented to the vaccine policy and procedures.			
		Frequency	Percent
	Never	6	13.6
	sometimes	6	13.6
	Always	31	70.5
	Total	43	97.7

There is at least one trained individual, responsible for the receipt, Storage of vaccines and the recording of vaccines.			
		Frequency	Percent
	Never	5	11.4
	sometimes	1	2.3
	Always	37	84.1
	Total	43	97.7

Table :4.7 Cold chain policies

Tables 4.7 shows that a Sizable number of participants, 50% (n=22) agree that the coldrooms always has an up to date cold chain policy while 34.1% (n=15) indicate that the coldrooms never has an up to date cold chain policy and a small number 13.6% (n=6) have indicated that the coldrooms sometimes has a cold chain policy that is up to date.

The results show that 68.2% (n=30) believe that all staff are trained to follow polices that ensure cold chain compliance for vaccines whereas only 11.4% (n=5) believe that staff are not trained and 18.2% (n=8) believe that staff are sometimes trained to follow these policies.

The results further show that 70.5% (n=31) of all new staff allocated to the clinic are always oriented to the vaccine policy and procedures, 13.6 (n=6) indicated that staff are sometimes trained and 13.6% (n=6) stated that new staff are never oriented to the vaccine policy and procedures.

In addition to the above, the results show that 84.1% (n=37) of participants indicate that there is one trained individual responsible for the receipt and storage of vaccines and the recording of vaccines while 11.4 (n=5) state that this is never the case and 2.3 % (n=1) indicate that this is sometimes the case.

4.3.4.2.2. QUESTION B2: VACCINE MANAGEMENT

This section deals with management of vaccines as listed in the sixteen criteria below. The summarised scores are shown in Table 4.8.

2.Vaccine Management	Never	Sometimes	Always
2.1. Stock cards for vaccines are kept.	4.5%	11.5%	81.8%
2.2. Vaccines are checked for discrepancies and leakage or damage before receiving them.	22.7	15.9	59.1
2.3. Procedures are followed for recording the date and time, vaccine types, brands, quantities, batch numbers and expiry dates when received.	18.2	9.1	70.5
2.4. Staff are aware of the urgency of storing vaccines immediately on receipt.	11.4	0	86.4
2.5. Staff are aware of how to read and check the cold chain monitor when unpacking vaccines.	9.1	0	88.6
2.6. There are times when vaccines are out of stock.	6.8	77.3	13.6
2.7. Vaccines are ordered by a designated person.	4.5	22.7	70.5
2.8. Vaccine stock is monitored prior to ordering	4.5	11.4	81.8

2.9. The first in first out principle applies when using and packing vaccines.	6.8	18.2	72.7
2.10. There is a record of vaccine batches in case of recall.	15.9	27.3	54..5

Table 4.8 Vaccine Management.

Findings were as follows:

- A large majority of participants, 81.8(n=36) indicate that stock cards for vaccines are always kept with only 11.5% (n=5) indicating that this is sometimes the case and a small number 4.5% (n=2) indicating that this is never the case.
- A large majority 72.7 (n=32) indicated that the first-in first-out principle applies when storing and using vaccines. 18.2% (n=8) stated that this principle is sometimes applied with a small percentage and 6.8% (n=3) stated that this principle is never applied.
- 54.5% (n=24) of participants stated that in the case of recall, there is a record of vaccine batches, while 27.3% (n=12) stated that records are sometimes kept and 15.9% (n=7) stated that records are never kept in case of recall. .
- 70.5% (n=31) stated that procedures for recording the date and time, vaccine types brands, quantities, batch numbers and expiry are always followed when vaccines are received, while 18.2% (n=8) stated that these procedures are never followed and 9.1% (n=4) stated that these procedures are sometimes followed.
- 86.4% (n=37) of participants indicated that staff are always aware of the urgency of storing vaccines immediately on receipt. 11.4 (n=5) of ColdRoom Employees\pharmacists stated that staff sometimes store vaccines on receipt.
- A small number of participants 13.6% (n=6) stated that there are always times when vaccines are out of stock whereas 77.3% (n=34) stated that this is sometimes the case and 6.8% (n=3) stated that this is never the case.
- The majority of the participants, 81.8% (n=36) stated that vaccine stock is always monitored prior to ordering. 11.4% (n=5) stated that vaccine stock is sometimes monitored before ordering and a small percentage of respondents 4.5% (n=2) stated that vaccine stock is never monitored prior to ordering.

QUESTION B3: VACCINE REFRIGERATOR

This section is concerned with maintenance of the cold chain for vaccines in the refrigerator. As listed below, 23 criteria were used in the questionnaire for the vaccine refrigerator. In order to present these results the criteria was divided into different themes: criteria pertaining to the refrigerator, signage on refrigerator, temperature monitoring, storage of vaccines, interruption in electricity supply and power failure. The summarised scores are indicated in Table 4.9.

3. Vaccine refrigerator	Never	Sometimes	Always
3.1. The refrigerator is in working order.	93	2.3	4.3
3.2. A dedicated refrigerator is used for the Storage of vaccines only.	0	0	100
3.3. The refrigerator is situated in a well-ventilated area, away from sunlight and heat.	2.3	0	97.7
3.4. The refrigerator type is correct for vaccines.	4.7	2.3	93.0
3.5. The refrigerator is the right size to store adequate vaccines when the demand increases.	7.0	16.3	76.7
3.6. The refrigerator temperature is within correct range of (2 - 8ºC) all the time.	0	16.3	83.7
3.7. The responses to all deviations outside (2 - 8ºC) have been documented and the recommended actions taken.	30.2	11.6	58.1
3.8. There is a “do not unplug the refrigerator” sign next to the refrigerator.	100.0	0	0
3.9. Vaccines are stored on the door.	72.1	18.6	9.3
3.10. Food or cool drinks are stored in the same refrigerator that is used to store vaccines.	90.7	9.3	0
3.11. The refrigerator is either lockable and locked or stored in a locked room.	100.0	0	0
3.12. Vaccines are stored in the door, bottom drawer or adjacent to the freezer.			
3.13. Refrigerator door opening during is minimised.	4.7	11.6	83.7
3.14. A refrigerator temperature chart is present with recording.			

3.15. The temperature chart is filled in twice daily.	14	55.8	30.2
3.16. Electricity supply to the refrigerator is safe examples- switchless plugs, cautionary notices are in place.	34.9	0	65.1
3.17. Arrangements are in place in the event of a refrigerator or power failure.	32.6	4.7	62.8
3.18. There are records of regular refrigerator servicing, defrosting and cleaning available.	30.2	0	69.8
3.19. A working dial thermometer is present in the centre of the refrigerator.	79.1	7	14
3.20 There are no expired vaccines in refrigerator.	60.5	11.6	27.9
3.21. There is a sticker on the door to remind staff to open the door only when necessary.	93.0		7.0
3.22. The ColdRooms have a back-up system in case of power failure.	48.8	0	51.2
3.23. The refrigerator has an alarm which is activated when the temperature exceeds 8 degrees Celsius (8ºC) and falls below 2 degrees Celsius (2ºC).	55.8	0	44.2

Table 4.9 :criteria related to the refrigerator

4.3.4.2.2.1. CRITERIA RELATED TO THE REFRIGERATOR

- 93 %(40) of participants agreed the correct type of refrigerator is always used to store vaccines, 2.3 %(n=1) indicated that this is sometimes true and 4.7% (n=4) that this never the case.
- 76.7 (n=33) of participants agreed that the refrigerator is the correct size for storage of vaccines, 15.3 (n=7) indicated that this is sometimes and 7% (n=3) that this is never the case.
- A large majority of participants, 93% (n=40) indicated that the refrigerator is always in working order, 2.3 (n=1) indicated that this is sometimes and 4.3% (n=2) that this is never the case.
- 100 (n=43) of participants agreed that the refrigerator is always dedicated for storage of vaccines only, with No participants indicating otherwise.
- 69.8% (n=30) of participants agreed that there are always records of regular servicing, defrosting and cleaning of the refrigerator, while the rest 32.2 (n=13) agreed that this is never the case .
- 97.7% (n=42) responded that the refrigerator is situated in a well-ventilated area, away from sunlight and heat. 2.3% (n=1) agreed this is never the case.
- 44.2% (n=19) of participants agreed that the refrigerator is always fitted with an alarm to detect cold chain breaches, 55.8% (n=24) responded never and No one responded sometimes.
- 100% (n=43) of participants stated that the refrigerator is always either locked or stored in a lockable room.

4.3.4.2.2.2. CRITERIA RELATED TO THE TEMPERATURE OF THE REFRIGERATOR

- 69.8% (n=30) responded that the temperature chart is always placed on the refrigerator and recordings were kept. 6.5% (7) responded sometimes and 6 (n=6) responded never.
- 60 % (26) of participants responded that the temperature of the fridge's always documented twice daily on the temperature chart. 20% (n=9)responded sometimes and 18.5% (n=8) responded never.
- 83.7% (n=36) of the participants responded that the refrigerator is always within the correct temperature range of two degrees to eight degrees Celsius 16.3% (n=7) responded sometimes.
- 58.1% (n=25) responded that deviations in the refrigerator are documented and necessary actions are always taken. 11.6% (n=5)responded sometimes and 30.2% (n=13) responded never.

4.3.4.2.2.3. CRITERIA RELATED TO SIGNAGE ON REFRIGERATOR

- None of the participants responded that there is always signage on the refrigerator informing staff not to open "vaccine fridge".7% (n=3) of the participants responded sometimes and 93% (n=40)responded never.
- In 100% (n=43) of the cold rooms participants responded that there is never been a"do not unplug"

4.3.4.2.2.4. CRITERIA RELATED TO INTERRUPTION IN ELECTRICITY SUPPLY AND POWER FAILURE

- 65.1% (n=28) of participants in responded that the electricity supply to the refrigerator is always safe. No one responded sometimes but 34.9% (n=15) responded never.
- At the Cold Rooms 51.2% (n=22) of participants responded that there is a backup system in place for vaccine management in case of power failure. 48.8% (n=21) responded never.

- 62.8% (n=27) of participants responded that arrangement were in place in case of refrigerator failure or power failure. 4.7% (n=2) responded sometimes and 32.6% (n=14) responded never.

4.3.4.2.3. CRITERIA RELATED TO STORAGE IN REFRIGERATOR

- The majority of participants, 72.1% (n=31) responded that there is always no vaccines stored on the door of the refrigerator. 18.6 (n=9) of participants responded sometimes and 9.3 (n=4) responded never.
- 90.7 (n=39) of participants agreed that no food or cool drinks were ever stored in the refrigerator. 9.3% (n=4) responded sometimes and None responded always.
- 27.9 (n=12) of participants responded that there is always no expired vaccines in the refrigerator while 11.6% (n=5) responded sometimes and 60.5% (n=26) responded never.

4.3.5.2.4. QUESTION B4: COLD BOXES

This section deals with the management of vaccines in the cold box during an transport. These results are presented in Table 4.10.

4. Cold boxes	Never	Sometimes	Always
4.1. An adequate number of cooler boxes are available.	7	39.5	53.5
4.2. Cooler boxes are in a good condition and not damaged.	0	27.9	72.1
4.5. The temperature in the cooler box is between 2-8 degrees Celsius (2 - 8ºC).	2.3	32.6	65.1
4.8. Vaccines are correctly packed in the cooler box.	7	20.9	72.1
4.9. A dial thermometer is available for cooler boxes and is working.	11.6	18.6	69.8

Table 4:10 Cold boxes

- In regard to cold boxes, the results show that 53.5 % believe that there is always an adequate number of cooler boxes available while 39.2% believe that there is sometimes an adequate number of cooler boxes available and 7% believe that there is never an adequate number of cooler boxes available.
- None of participants believe that cooler boxes are in a bad condition.

4.4. CONCLUSION

This chapter presented the results obtained from this study. Section A1 of this chapter presented results of the observation study. Section A2 of this study presented the results of the self-administered questionnaire. The results of the study will be discussed in the following chapter.

CHAPTER 5: DISCUSSION OF THE RESULTS

5.1 INTRODUCTION

In this chapter, the results presented in the previous chapter will be discussed. Conclusions will be drawn and limitations to the study as well recommendations will be discussed later.

Section A1 below discusses the findings related to the observation study. This is followed by Section A2, which discusses the findings related to the self-administered questionnaire.

The discussion is based on the study objectives, namely

- The objectives of this study is: To compare current processes of the cold chain management of vaccines against best practice and in accordance with global, national and operational guidelines;
- To investigate current processes of the cold chain management of vaccines by those involved in the cold chain and
- To contribute to the current body of knowledge and recommend potential solutions to the problems encountered in the cold chain management of vaccines.

5.2. SECTION A1: OBSERVATION STUDY (PHASE ONE)

5.2.1. CURRENT PROCESSES OF COLD CHAIN MANAGEMENT

Cold chain Facilities should evaluate their vaccine cold chain policies and procedures on a regular basis to ensure that best practices are followed. All Cold Room facilities should develop a detailed plan on all aspects of vaccine management. This plan should include vaccine ordering, storing of vaccines and monitoring storage conditions (The Vaccine Storage and Handling Toolkit, 2012: 13).

5.2.1.1. POLICIES, PROCEDURES AND GUIDELINES

The observation study revealed that policy, procedures and guidelines were available. However, on most occasions policy had not been implemented. Each Coldroom facility must have written policies, procedures and protocols in place (National Vaccine Storage Guidelines Strive for 5, 2013: 8).

Health care 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 organised

and serves as a reference and training tool as well as providing assurance of proper vaccine management and prevention of vaccine wastage (The Vaccine Storage and Handling Toolkit, 2012: 13).

It was observed in this study that there were no written contingency plans in place for problems associated with equipment and electricity used for cold chain management of vaccines. Some verbally communicated what actions would be taken in an emergency situation to ensure vaccines are not compromised and the cold chain system is still managed effectively, but there was no evidence of written documentation in this regard.

According to the National Vaccine Storage Guideline Strive for 5 (2013: 8) the following records must be maintained:

- Servicing of the refrigerator and data logger;
- Checking the accuracy of thermometers and batteries;
- Cleaning the refrigerator; and
- Policy in case of power failure.

One can not overemphasize the importance of a backup plan to deal with problems of equipment being affected by electricity. There has to be some kind of a contingency plan in place such as a petrol or diesel generator to overcome the problem of a lack of electricity. It is thus imperative that Pharmacists develop and communicate their backup plans to management so that appropriate allocations can be made in the budget to purchase the required equipment so that it is in place when the need arises for implementation of such plans.

Regular workshops and training on vaccine management is recommended . Such workshops should be compulsory for all so that there is holistic improvement and negligence or carelessness will not be prevalent

This observation study further revealed that 60 percent adhered to filling of stock cards, using these tool more seriously should allow for called rooms to never run out of stock as an out of stock situation means missed opportunities and a breakdown in the System. Pharmacist should fill and monitor their stock card and be able to act quickly before stockout..

5.2.2. STANDARDS OF COLD CHAIN MANAGEMENT

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 (The Vaccine Storage and Handling Toolkit, 2012: 9).

5.2.2.1. VACCINE ARRIVAL PROCEDURES

The results of the study revealed that 60 % percent observed responded immediately to the arrival of vaccines and 40 percent did not respond immediately. The maintenance of the cold chain during distribution and arrival of vaccines to the facility is important to ensure the potency of vaccines (The EPI Cold Chain Standard Operating Procedure Manual, 2009: 4). Therefore it is necessary to carefully examine and check the quantity and quality of vaccines which are received.

This study further reveals that 60 percent of checked vaccines for discrepancies, leakage and breakage and stored vaccines immediately on receipt and 40 percent were not compliant. The EPI Cold Chain Standard Operating Procedure Manual (2009: 4) states that those involved in vaccine management must attend to receive vaccines immediately and record any discrepancies, leakages and breakages on the delivery note.

The results of this study revealed that 20 percent of clinics were compliant with packing the vaccines according to the first-in-first-out principle and 80 percent were non-compliant with this principle. According to the National Vaccine Storage Guidelines-Strive for 5 (2013: 3) the vaccine stock must be rotated so that vaccines with the shortest expiry dates are used first. This practice ensures that vaccines are not wasted as a result of being compromised upon reaching the expiration date (National Vaccine Storage Guidelines-Strive for 5, 2013: 3)

5.2.2.2. REFRIGERATOR

Analysis of the study results showed that 80 percent of the stored vaccines in a refrigerator that was of the correct size, type and had a freezer compartment for icepacks. However, 20 percent of refrigerators used in clinics were not complaint. Some use a bar Type fridge to store vaccines.

According to The National Vaccine Storage Guidelines Strive for 5 (2013: 7) domestic and bar refrigerators are not recommended for vaccine storage as they increase the risk of adverse vaccine storage events. This is supported by the findings in a study conducted by Carr, Byles and Durrheim (2009: 35) in Australia which recommended that bar-type refrigerators should be outlawed for storage of vaccines as they posed an unacceptable threat to vaccine cold chain integrity. In the bar type fridge the temperatures fluctuated between too high or too low, leading to vaccines being subjected to too much heat or cold thus placing vaccines at a risk (Carr, Byles and Durrheim, 2009: 38).

To enable the maintainace of the correct fridge temperature between two to eight degrees Celsius and recording the temperature twice a day the temperature recording chart should be kept on the outside door of the fridge as it is visible to all staff. The National Vaccine Storage Guidelines Strive for Five (2005: 14) recommends that refrigerator temperatures be checked and recorded twice daily. Checking and recording the temperature before administration of the vaccine enables the identification of problems before the vaccine is used. During this study it was observed that temperature charts are available in most coldrooms, however, Pharamcists failed to record findings.

The National Vaccine Storage Guideline-Strive for 5 (2013: 12) recommends that refrigerator shelves must not be overcrowded and there must be space in-between vaccine containers to allow for air to circulate. The guideline further states that overstocking of the refrigerator will prevent air circulation and it will be difficult to maintain stable temperatures within the refrigerator. The results of this study revealed that 64.3 percent of the refrigerators were not overstocked and only 35.7 percent of the coldrooms refrigerators were overstocked. The study also revealed that in 92.9 percent of the fridges there was no circulation of air between vaccines containers and in 7.1 percent of the fridges there was enough air circulating between vaccine packages. It was observed during this study that although refrigerators were not overstocked, vaccines were not packed according to storage guidelines i.e. vaccines were not stored in their original packaging. It is therefore recommended that focus be given to this and regular inspection of the vaccine fridge with respect to checking of the

temperature, vaccine stock and general upkeep of fridge since a properly maintained fridge results in effective management of cold chain vaccines. Hence this aspect must be strictly adhered to and there must accountablity.

According to the results of this study, 80 percent did not store vaccines in the door of the refrigerator. It is important to store vaccines appropriately in the refrigerator in order to maintain their integrity (National Vaccine Storage Guidelines Strive for 5 2013: 12). In 20 percent of the cold rooms, it was observed that vaccines were stored in the door,this storage problem has a direct impacts on the financial constraints since wastage of vaccines results in the wastage of finance.

The observation study further revealed that in all of the cold rooms there was no "DO NOT UNPLUG" signage on the refrigerator plug and no signage on fridge door stating "DO NOT OPEN VACCINE FRIDGE". The National Vaccine Storage Guidelines Strive for 5 (2013: 10) states that the vaccine fridge must be clearly marked "DO NOT TURN OFF OR DISCONNECT THE VACCINE FRIDGE". Accidental disconnection from the power source can cause heat damage to vaccines, especially if this goes unnoticed for a long period. The guidelines further state that vaccine refrigerators must have the sign "VACCINE REFRIGERATOR DO NOT OPEN". Reducing the number of times the fridge door is opened, helps to maintain the internal temperature of the fridge (Nelson *et al.*, 2004; Ren *et al.*, 2009; and Zipursky *et al.*, 2011). It is recommended that the signage be bold so that visibility is not a problem and hence the proper guidelines can be followed.

5.2.2.2.1. COLD BOX

The results of this study revealed that in 72.1 percent cold boxes were in good condition and in 27.9 percent of the cold boxes were not in good condition or were not the right size. The cold boxes should be of a good condition, meaning that it should not be broken or damaged and should have a properly fitting lid (EPI Guidelines WHO-1998: 19). The pros and cons of the cold boxes are listed in (Burstein *et al.*, (2012). It is recommended that the 27.9 percent of the coldrooms purchase better quality cold boxes. An allocation of a budget should be set aside for this.

It was observed in 34.9 percent of the respondents that the temperature range of two degrees to eight degrees Celsius was not maintained and in 67.7 percent the cold box temperature was correctly maintained. In most of cases it was found that thermometers were present and working. In cases it is not working, the pharamcist was not able to identify if the vaccines were subjected to heat or cold. while damage to vaccines due to overheating is gradual, freeze damage is almost instantaneous.

According to the EPI Guidelines (2010: 12) the temperature of vaccines should be maintained between two degrees and eight degrees Celsius in the cold box and a dial thermometer must be used. The correct thermometer should be included in the cold box for hourly monitoring of the temperature. (Rogers *et al.*,2010: 339).

5.2.3. SUMMARY

Section A1 above, discussed the results of the observation study. Following is Section A2, which includes the discussion on results of the self-administered questionnaire.

5.3. SECTION A2: SELF-ADMINISTERED QUESTIONNAIRE (PHASE TWO)

In phase two a self-administered questionnaire was distributed to a representative sample of 45 employees (Appendix 3). All 15 Coldrooms were included in this phases.

Section A2 presents the results of the study related to the self-administered questionnaire. The discussion is based on the objectives of the study, namely to:

- The objectives of this study is: To compare current processes of the cold chain management of vaccines against best practice and in accordance with global, national and operational guidelines;

- To investigate current processes of the cold chain management of vaccines by those involved in the cold chain and

- To contribute to the current body of knowledge and recommend potential solutions to the problems encountered in the cold chain management of vaccines.

5.3.1. AGE AND GENDER DEMOGRAPHY

The current research reveals that more males than females were represented in the sample and age group most represented was between six and ten years of . 20.9% (n=9) of the respondents in this sample were in the age group 20-25 years and 23.3 percent of respondents were in the age group 31 and above. This is indicative of that samples were fairly mature and experienced.

5.3.3. EXPERIENCE

23.3 % (n=10) of the sample had more than 10 years of work experience. The majority of participants 55.8% (n=24) had between six and ten years of work experience, with only 20.9% (n=9) of participants having worked for less than 5 years. The cumulatively the sample indicates a mature and experienced grouping of respondents. This is useful as the responses can be regarded as informed opinion.Thus, one would expect that the results of the self-administered questionnaire would possibly show that the correct practices and policies were in place.

5.3.4. POLICY: COLD CHAIN POLICY

The results revealed a positive finding in that most cold rooms always have an up-to-date cold chain policy. Only few samples disagreed with this being in place in their respective coldroom. We also find that just over 68.2 percent of the sample agreed that all staff are trained to follow policies that ensure cold chain compliance for vaccines whilst 11.4 percent of the sample confirmed that this does not occur. There is comprehensive literature available on cold chain policy such as the EPI Cold Chain Standard Operating Procedure Manual (2009) that can enable the success of implementing the cold chain policy. It is clear from the findings of the research that many staff lack impending the trainings and cold chain policy. Further, only 70 percent of all new staff allocated to the coldrooms are oriented to the vaccine policy and procedures. This is statistics must improve. To ensure the success of vaccine management this must occur at far higher percentages say at 80 to 100 percent of the time. Unfortunately, in this study setting it is not the case, highlighting an area attention that needs to be addressed in order to ensure the effective management of the cold chain system for vaccines.

The EPI Ethiopia Policy (2012) has been specifically written for all health care professionals and hence it is the responsibility of all health workers to educate themselves in the cold chain policy specific to Ethiopia. This is also highlighted in other guidelines as well (Cold Chain Module 3 WHO, 1998, Vaccine Storage and Handling Toolkit, 2012 and National Vaccine Storage Guidelines, 2005). According to the Vaccine Storage and Handling Guide (2011: 5) staff should be knowledgeable regarding vaccine storage and handling and there should be at least two staff members who are responsible for vaccine management. This is imperative for the success of the cold chain policy, so there must be some accountability created and encouraged.

5.3.5. VACCINE MANAGEMENT

The analysis reveals that the areas of strengths within vaccine management include that stock cards for vaccines are always kept; the first-in first-out principle applies when packing and using vaccines; in the case of recall, there is a record of vaccine batches; stock cards for vaccines were correctly filled in; vaccines were checked against the order for discrepancies and leakage; procedures for recording the date and time; staff are always aware of the urgency of packing vaccines immediately on receipt; staff are aware of how to read and check the cold chain monitor when unpacking vaccines and vaccine stock is always monitored prior to ordering since the majority of the respondents agreed that these policies and procedures are being adhered to.

The areas that need attention are the shortage are stock out problems, since 77.3 percent of the respondents stated that this sometimes happens. this highlights a stock control issue amongst the coldroom sand a possible way of overcoming this problem is for coldrooms to give due attention to inventory level and properly fill the stock cards.

5.3.6. THE VACCINE REFRIGERATOR

Many of the criteria's were being adhered to. The criteria not being adhered to in the surveyed coldrooms will now be discussed. The study found that 50 percent of the respondents agreed that there were always records of regular servicing, defrosting and cleaning of the refrigerator. The refrigerator is the life of the vaccine and it must be well maintained in the clinics at all times.

Furthermore, it was evident in the surveyed coldrooms that only 44.2 percent of respondents agreed that the refrigerator is always fitted with an alarm to detect cold chain breaches . These issues can be easily solved in the coldrooms by maintaining an efficient refrigerator with proper principles and good technical staff with the traning to fix issues early (WHO 2005: 79; Vaccine Storage and handling Guidelines, 2011: 5). Furthermore, it was evident in these coldrroms that there was no regular inspection and quality control of their refrigerators. This must now be implemented i.e. an inspection audit of the refrigerators where the vaccines are being stored must be conducted regularly.

The current study reveals that in 100 percent of the participants responded that there was No signage on the refrigerator informing staff "DO NOT TO OPEN VACCINE FRIDGE" as well as "DO NOT UNPLUG" sign on the vaccine fridge. These percentages are below the norm indicating that signage on the refrigerators needs to improve. In the observation study it was also highlighted that in all of

the coldrroms there was no “DO NOT UNPLUG” signage on the refrigerator plug and no signage on fridge door stating “DO NOT OPEN VACCINE FRIDGE”. This is indicative of poor cold chain management for vaccines thus indicating that signage on the refrigerators needs urgent improvement. The National Vaccine Storage Guidelines Strive for Five (2005: 10) states that the vaccine fridge must be clearly marked “DO NOT turn off or disconnect the vaccine fridge”. Accidental disconnection from the power source can cause heat damage to vaccines, especially if this goes unnoticed for a long period. The guidelines further state that vaccine refrigerators must have the sign “VACCINE REFRIGERATOR DO NOT OPEN”. Reducing the number of times the fridge door is opened, helps to maintain the internal temperature of the fridge (Nelson *et al.,* 2004). It is recommended that the signage be bold so that visibility is not a problem and hence the proper guidelines can be followed.

Lastly it is noted that at the coldrooms, only 51 percent indicated that there is a back-up system in place for vaccine management in case of power failure. It is evident that the coldrooms do not have generators or a contingency plan like solar power panels in case of a power failure in order to protect their vaccines. Measures must now be implemented to deal with issues such as power failure which is prevalent in Ethiopia). To address this, finances must be allocated in order to purchase generators or solar panels to act as a back-up just in case of power failures.

5.4. CONCLUSION

Pharmacists play a vital role in the maintenance of the cold chain to ensure the efficacy and safety of vaccines administered. Maintaining cold chain standards is vital given the large number of children they services and the cost attached to these vaccines.

The results of the study demonstrate that the cold chain for vaccines is not maintained effectively thus vaccines are compromised. One of the most significant findings of the study is the need for in-service training and refresher courses for pharmacists on cold chain management for vaccines. These courses and in-service training must be based on National, Provincial and Standard Operating Guidelines for vaccine management.

Furthermore, there were no contingency plans to deal with lack of equipment and electricity issues, no monitoring and evaluation systems, poor recording keeping, poor management of the cold boxes and refrigerators and poor access to stock.

Some of the findings were similar to the observation study. These included issues surrounding equipment and electricity, monitoring and evaluation systems, poor record keeping and poor access to stock.

It is recommended that ongoing training for staff on vaccine management be conducted. Regular audits must be conducted by EPI coordinators.

5.5. LIMITATIONS

The cold-rooms visited during the study were very widespread and it was difficult to travel to these remote places and this resulted in time constraint.

Due to the workload and lack of available staff for this study some Cold rooms were not accesed

5.6. RECOMMENDATIONS

One of the most significant findings of the study is the issue of education.Pharamcists need training and refresher courses with respect to the vaccine management.. This education can be in the form of training workshops.

The access to and control of vaccine stock is an imperative issue within the findings of the research. Although stock cards are available at the coldrooms in some they are incomplete or incorrectly filled in. It is recommended that coldrooms appoint and train a member of staff who will monitor and access the vaccine stock on a regular basis. Thus, there has to be a proper inventory system in place in order to facilitate the usage of childhood vaccinations.

Another significant finding in the research is that of the signage on the vaccine refrigerator. There has to be clear and concise signage on the vaccine refrigerator so that proper cold chain policy guidelines can be followed. Thus, it is recommended that a member of staff take the responsibility for placing the correct signage on the refrigerators. This will include signage on the fridge stating "VACCINE FRIDGE DO NOT OPEN" and on the plug on the wall "VACCINE FRIDGE DO NOT UNPLUG" (The National Vaccine Storage Guidelines Strive for Five 2005: 10).

It was also noted that clinics do not have a back-up plan in the event of a power outage. It is recommended that clinics be supplied with generators or install solar panels, in order to ensure that the refrigerators continue to keep running .

The research also reveals that records of regular checking of the cooler box should be visible. In addition, members of staff should be instructed to take the responsibility of keeping these records and they should be constantly checking and validating these records. A thermometer must be placed in the centre of the cold box and the temperature must be monitored and recorded hourly while on transport (Rogers *et al.*, 2010).

Finally, it is evident that the coldrooms do not seem to have any foresight in terms of addressing the current cold chain challenges with the childhood vaccination programme as well as any contingency plans should they be without electricity for extended periods of time. Hence it is recommended that management and MOH meet on a regular basis to discuss certain solutions to the ongoing problems they experience and hopefully this will lead to the implementation of a more effective system.

Future research should be conducted and the research should involve a larger sample and all levels down to health center this will give a more detailed view on traning, practices and access to vaccination stock, inefficiencies in following the cold chain policy.

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APPENDIX A – Questionnaire for the Cold Chain Management of Vaccines

Instructions to be followed in completing this questionnaire:

- Please ensure that you answer all questions.
- Be as honest as possible when answering questions. Note: there are no right or wrong answers.

Section A: Demographic Information

Please select the most appropriate response:

1. Date: _____

2. Your age: 20 to 25 years ☐ 26 to 30years ☐ 31 years and above ☐

3. Work Experience 0 to 5 years ☐ 6 to 10 years ☐ 11 years and above ☐

4. Your Gender: Male ☐ Female ☐

5. Training in vaccine management: YES ☐ NO ☐

6. Involved in vaccine management: YES ☐ NO ☐ SOMETIMES ☐

Section B: Vaccine Management.

Please tick the option that best describes your response to the following statements:

1. Policy	**Never**	**Sometimes**	**Always**
1.1. The coldroom has an up to date cold chain policy			
1.2. All staff are trained to follow policies that ensure cold chain compliance for vaccines.			
1.3. All new staff allocated to the coldroom are oriented to the vaccine policy and procedures.			
1.4. There is at least one trained individual responsible for the receipt, Storage of vaccines and the recording of vaccines.			
2.Vaccine Management	**Never**	**Sometimes**	**Always**
2.1. Stock cards for vaccines are kept.			
2.2. Stock cards for vaccines are correctly filled in.			
2.3. Vaccines are checked for discrepancies and leakage or damage before receiving them.			
2.4. Procedures are followed for recording the date and time, vaccine types, brands, quantities, batch numbers and expiry dates when received.			
2.5. Staff are aware of the urgency of storing vaccines immediately on receipt.			
2.6. Staff are aware of how to read and check the cold chain monitor when unpacking vaccines.			
2.7. There are times when vaccines are out of stock.			
2.8. Vaccines are ordered by a designated person.			

2.9. Vaccine stock is monitored prior to ordering			
2.11. There are more than four weeks of stock in the refrigerator.			
2.12. Vaccines are used when the inner square is as dark as outer circle or darker.			
2.13. The first in first out principle applies when using and packing vaccines.			
2.16. There is a record of vaccine batches in case of recall.			
3. Vaccine refrigerator	**Never**	**Sometimes**	**Always**
3.1. The refrigerator is in working order.			
3.2. A dedicated refrigerator is used for the Storage of vaccines only.			
3.3. The refrigerator is situated in a well-ventilated area, away from sunlight and heat.			
3.4. The refrigerator type is correct for vaccines.			
3.5. The refrigerator is the right size to store adequate vaccines when the demand increases.			
3.6. The refrigerator temperature is within correct range of (2 - 8ºC) all the time.			
3.7. The responses to all deviations outside (2 - 8ºC) have been documented and the recommended actions taken.			
3.8. There is a “do not unplug the refrigerator” sign next to the refrigerator.			
3.9. Vaccines and are stored correctly.			
3.10. Vaccines are stored on the door.			
3.11. Food or cool drinks are stored in the same refrigerator that is used to store vaccines.			
3.12. The refrigerator is either lockable and locked or stored in a locked room.			
3.13. Vaccines are stored in the door, bottom drawer or adjacent to the freezer.			
3.14. Refrigerator door opening during is minimised.			
3.15. A refrigerator temperature chart is present with recording.			
3.16. The temperature chart is filled in twice daily.			
3.17. Electricity supply to the refrigerator is safe examples- switchless plugs, cautionary notices are in place.			
3.18. Arrangements are in place in the event of a refrigerator or power failure.			
3.19. The refrigerator is correctly packed with air circulating between the vaccines.			
3.20. There are records of regular refrigerator servicing, defrosting and cleaning available.			
3.21. A working dial thermometer is present in the centre of the refrigerator.			
3.22. There are no expired vaccines in refrigerator.			
3.23. There is a sticker on the door to remind staff to open the door only when necessary.			
3.24. Vaccines are in their original packaging box and include the information leaflet.			
3.25. The ColdRooms have a back-up system in case of power failure.			
3.26. The refrigerator has an alarm which is activated when the temperature exceeds 8 degrees Celsius (8ºC) and falls below 2 degrees Celsius (2ºC).			
4. Cold boxes	**Never**	**Sometimes**	**Always**

4.1. An adequate number of cooler boxes are available.			
4.2. Cooler boxes are in a good condition and not damaged.			
4.3. Are sufficient packs are available e.g. 6 and more			
4.5. The temperature in the cooler box is between 2-8 degrees Celsius (2 - 8ºC).			
4.6. Records of regular checking of the cooler box are available.			
4.7. Reconditioned ice packs are used.			
4.8. Vaccines are correctly packed in the cooler box.			
4.9. A dial thermometer is available for cooler boxes and is working.			
Comments:			

APPENDIX 4 – Observation Study Guidelines

Date: _____ Time: _____

1.Policies, procedures and guidelines	**Yes**	**No**
1.1 Policies, procedures and guidelines available for vaccine management. *Examples- guidelines for vaccine management according to global, national and standard operating procedures. Evidence of instruction and training on policy and operating procedures on orientation and on-going. Researcher will request this.*		
1.2. Are contingency plans in place for problems with equipment/electricity used in the cold chain management of vaccines? *Examples: Power outages and the break-down of refrigerators. (Gas cylinders, generators available) Policy on what to do if problems encountered.*		
1.3. Is there evidence of maintenance to cold chain equipment available? *Example: Evidence of servicing and testing of equipment.*		
1.4. Is there evidence of filling in of stock cards for vaccines? *Example: Evidence of recording of stock.*		
1.5. Is there evidence of physical inventories of vaccine stock? *Example: Evidence of stock balances.*		
1.6. Is there evidence of dedicated room for vaccine Storage		
1.7. Is vaccine wastage managed according to policy? *Example: Written evidence is available.*		
1.8. Are there vaccine wastage reports available? *Example: Reports are available.*		
1.9 Is there evidence of records of in case of recall /batch numbers for vaccines		
1.10 Is there evidence of good vaccine records i.e. temperature records, training record, cold room service reports?		
2. Vaccine arrival procedure	**Yes**	**No**
2.1. Does the Employee\phrmacist respond immediately when vaccines arrive in Coldroom?		
2.2. Does the Employee\phrmacist check vaccines for discrepancies, leakage and breakage before receipt?		

2.3. Are vaccines stored immediately on receipt?		
2.4. Are vaccines packed according to the first-in first-out principle? **NB. This will be observed when vaccines arrive in the cold room. If no vaccines arrive then the researcher will record not applicable.**		
3. Refrigerator	**Yes**	**No**
3.1. Is the refrigerator appropriate to store vaccine? Size, freezer compartment for icepacks.		
3.2. Is the refrigerator is dedicated for vaccines only? No other drugs		
3.3. Is the refrigerator temperature between (2 - 8ºC)?		
3.4. Is the temperature of the refrigerator recorded on chart twice daily?		
3.5. Is the refrigerator packed correctly with vaccines and diluents?		
3.6. Is the refrigerator overstocked?		
3.7. Are there vaccines in the door?		
3.8. Are vaccines frozen?		
3.9 Is the refrigerator in a locked room or does the fridge have a lock and key?		
3.10 .Is there a working thermometer hanging in correct place?		
NB. When the Employee\phrmacist **opens the refrigerator to take out or pack vaccines the above will be observed.**		
4. Cold box	**Yes**	**No**
4.1. Is the cold boxes in a good condition and right size?		
4.2. Is there a working thermometer in the cold box?		
4.3. Is the temperature of the cold box between 2-8 degrees?		
4.4. Is the cold box packed correctly i.e. 6 ice packs?		