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UNIT

COLD CHAIN MANAGEMENT PRACTICES AND CHALLENGES: THE CASE OF PRIVATE HEALTH FACILITIES PROVIDING EXPANDED PROGRAM OF IMMUNIZATION (EPI) SERVICE IN ADDIS ABABA

By

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Declaration

I, Alemtsehay Berahnu, declare that this thesis work entitled "**Cold Chain Management Practices and Challenges: The Case of Private Health Facilities Providing Expanded Program Of Immunization (EPI) Service in Addis Ababa"** is my original work in partial fulfillment of the requirement for the award of Degree of Masters' of Art in Logistics and Supply Chain Management. I also declare that it has never been presented in this or any other university and that all resources and materials used in the thesis have been duly acknowledged.

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Statement of Certification

This thesis entitled as **Cold chain management practices and challenges: the case of private health facilities providing Expanded Program of Immunization (EPI) service in Addis Ababa** has been submitted for examination with my approval as a university advisor. In my opinion, this thesis is suitable for submission in partial fulfillment of the requirements for the award of Degree of Masters' of Art in Logistics and Supply Chain Management.

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ACRONYMS AND ABBREVIATIONS

AACAHB - Addis Ababa City Administration Health Bureau

BCG - Bacillus Calmette-Guerin

CCE - Cold Chain Equipment

CCP - Cold Chain Point

CCT- Cold Chain Technician

CDC- Centers for Disease Control and Prevention

CHAI - Clinton Health Access Initiative

DDL - Digital Data Logger

DPT - Diphtheria-Pertussis-Tetanus Vaccine

DTR - Daily Temperature Reading

EDHS- Ethiopian demographic health Survey

EPI - Expanded Program on Immunization

EVM - Effective Vaccine Management

FMOH - Federal Ministry of Health

GAVI - Global Alliance for Vaccine Initiative

HEW - Health Extension Workers

Hib - Haemophilus Influenza Type B

MCV - Measles Child Vaccine

MNCH - Maternal Neonatal and Child Health

OPV - Oral Poliovirus

PCV - Pneumococcal Conjugate Vaccine

PIS - Product Information Sheets

PQS –Performance Quality Safety

RV - Rotavirus Vaccine

SARA - Service Availability and Readiness Assessment

SNNP - Southern Nations and Nationalities People

SOPs - Standard Operating Procedures

TMD - Temperature Monitoring Device

TT- Tetanus Toxoid

TTSPPS - Time and Temperature Sensitive Pharmaceutical Products

UNICEF – United Nation Children's Fund

VAP - Global Vaccine Action Plan

VPDS - Vaccine Preventable Diseases

VRF - Vaccine Requisition Form

VVMs - Vaccine Vial Monitors

WHO - World Health Organization

Abstract

Vaccines are essential health commodities which need their own specific supply chain system with storage of 2 ^{o}C to 8 ^{o}C from manufacturing up to final use. It is recommended and critical that they should be kept in appropriate temperatures during transport, storage and use. The purpose of this study was to assess the cold chain management practice of private health facilities and related challenges on providing EPI service in Addis Ababa, Ethiopia. Cross-sectional descriptive study was used to assess the cold chain management practice of private health facilities and related challenges on providing EPI service in Addis Ababa, Ethiopia. Based on this study, the overall cold chain management practice was good at 60% (n=30) out of 50 facilities visited. The overall storage condition of 16% (n=8) facilities was good. The overall transport trend of only 12% (n=6) facilities was good. The overall technical capacity of EPI focal persons was good at 42% (n=21) facilities was good and the overall logistics information system of 24% (n=12) facilities was good. Overall from the findings of the study, it can be concluded that there were vaccine cold chain management practice gaps and there were challenges related to lack of vaccine standard fridge for vaccine storage. Majority 44(88%) of facilities have been using domestic fridges to store vaccines. Federal Ministry of Health (FMoH) and Addis Ababa City Administration Heath Bureau have vital role to improve the challenge related to availability of the standard fridges at private health facilities.

***Key words**: Vaccine, Cold chain, Cold chain management practice, Temperature monitoring, Vaccine storage and handling, Vaccine transport.*

CHAPTER ONE: Introduction

1.1 Background of the study

Vaccination is a simple and effective way of protecting people against harmful diseases, before they come into contact with them. It uses human body's natural defenses to build resistance to specific infections and makes your immune system stronger. Vaccines train human immune system to create antibodies, just as it does when it's exposed to a disease. However, because vaccines contain only killed or weakened forms of germs like viruses or bacteria, they do not cause the disease or put people at risk of its complications. Most vaccines are given by an injection, but some are given orally (by mouth) or sprayed into the nose (WHO, 2018) and (Global action plan, 2011-2020).

Vaccination is a global health and development success story, saving millions of lives every year. Since 2010 to 2017, 21 million deaths were prevented by only measles vaccination. The annual number of infants vaccinated were more than 116 million, 86% of all babies born has reached the highest level ever reported. By now more than 20 life threatening diseases can be prevented by immunization. Since 2010, 116 countries have introduced new vaccines that they were not previously using including vaccines against major killers, such as pneumonia, human papillomavirus, rotavirus, typhoid and cholera. In addition, this is an era of much innovation in vaccine development. The first vaccines have been developed for malaria, dengue and Ebola, and promising vaccines for respiratory syncytial virus, universal influenza vaccines and tuberculosis are in the pipeline. Promising new research on broadly neutralizing antibodies and therapeutic vaccines has the potential to open new prospects. Vaccines are protecting health beyond infancy in adolescence, adulthood, during pregnancy and in older age groups in increasing trend (Vaccination agenda, 2030).

Using immunization as a priority means recognizing the importance of immunization as a vital public health intervention and the value that immunization represents in terms of health and economic returns. Majority of countries demonstrate a commitment to immunization by setting ambitious but attainable national targets and allocating adequate financial and human resources to programs to achieve these targets ensuring that their national immunization plans are fully integrated into national health plans. National policies and resource allocation decisions should be informed by current evidence regarding the direct and indirect impact of immunization. Most of the evidence base exists but does not reach policy makers, as those who generate the evidence are not always those who interact with these decision makers. The cooperation between technical experts who generate the evidence and the champions of immunization who construct context-specific messages that highlight the importance of immunization within health and social services, can clearly articulate the value of immunization and how immunization supports equity and economic development (Global action plan, 2011-2020).

Immunization through vaccination is globally acknowledged as one of the most successful and cost effective public health interventions in history, which enables in saving two to three million lives every year. Recently discovered vaccines such as pneumococcal conjugate vaccine (PCV) and rotavirus vaccines could save an additional million lives per year. Though, national immunization programs continue to face delivery challenges in terms of sustainably closing the immunization coverage gap. Introducing new vaccines and securing sustainable funding is not easy task. If immunization specific goals are achieved, hundreds of millions of cases and millions of future deaths will be prevented by the end of the decade, billions of dollars of productivity will be gained and child mortality rate become reduced(Global action plan, 2011-2020).

In 2018, an estimated 19.4 million infants living globally were not received routine immunization services such as 3 doses of DTP vaccine. Around 60% of these children live in 10 countries; Ethiopia, Angola, Brazil, the Democratic Republic of the Congo, India, Indonesia, Nigeria, Pakistan, the Philippines and Viet Nam (WHO, vaccine cold chain 2018).

The base of successful immunization programs is built on functional, end-to-end supply chain and logistics systems. The role of the supply chain is to ensure effective vaccine storage, handling, and stock management; rigorous temperature control in the cold chain and maintenance of adequate logistics management information systems. The final goal is to ensure the uninterrupted supply of quality vaccines from manufacturer to service delivery points. Therefore, opportunities to vaccinate are not missed because vaccines supply unavailability. This requires a system to achieve the six rights of supply chain management, namely; the right product, the right quantity, with the right cost, in the right condition, at the right place and right time (WHO 2018).

In spite of the success of routine immunization programs, national vaccine supply chains are now tensed to effectively manage the flow of new vaccine introductions, adaption for the needs of new delivery strategies or benefit from new technological advances in cold chain equipment to increase their effectiveness. Putting pressure to improve performance is pushing the limits of what can be achieved. Due to this, WHO has prioritized this area of work as a key building block of the Global Vaccine Action Plan (GVAP). Cold chain management for pharmaceuticals is an extension of Good Manufacturing Practice. The entire supply chain system is expected to keep this practice throughout the chain starting from the moment the pharmaceuticals/ vaccines and other medicines released from the manufacturer until they reach to the final beneficiaries. Safety and efficacy of these medicines depends on the proper maintenance of the system (Global action plan, 2011).

Due to the rising cost of vaccines and the greater storage capacity required at every level of the cold chain, countries must maintain lower stock levels, reduce wastage, accurately forecast vaccine requirements, and prevent equipment breakdowns. This requires a consistently high standard of supply chain management, which can only be achieved if all the links in the supply chain comply with current standards for storage and distribution. The controlled temperature

chain (CTC) is an innovative approach to vaccine management allowing vaccines to be kept at temperatures outside of the traditional cold chain of +2°C to +8°C for a limited period of time under monitored and controlled conditions which is appropriate to the stability of the antigen. A CTC typically involves a single excursion of the vaccine into ambient temperatures not exceeding +40°C and for duration of a specific number of days, just prior to administration.

CTC is not currently recommended for immunization through routine delivery, the vaccine must be able to tolerate ambient temperatures of at least +40°C for a minimum of three days and should be accompanied by a vaccine vial monitor (VVM) on each vial, and a peak threshold indicator in each vaccine carrier. The vaccine must be licensed for use in a CTC by the relevant regulatory authorities, with a label that specifies the conditions (WHO 2018) and (Challenge and solutions CHAI, 2017).

Vaccine cold chain and logistics systems are critical issues for the success of immunization. However, a number of new vaccines have been rolled out across the developing world; with more vaccines in the pipeline in recent days, cold chain systems are struggling to support national immunization programs. This leads to risks of reduced potency of vaccines administered (such as, due to poor temperature control, nonfunctional cold chain equipment), low availability of immunization supplies (due to inadequate storage capacity, disrupted service delivery, vaccine stock outs, etc.) and inefficient use of limited financial and human resources (e.g. through losses from vaccine wastage). Therefore, improving cold chain systems can expand effective immunization coverage and further decrease the number of deaths caused by vaccine preventable diseases. For instance, in Ethiopia, the introduction of the pneumococcal, rotavirus and pentavalent vaccines has increased the volume of antigens delivered by more than fivefold. On the other hand, the value of vaccines delivered has increased tenfold which means any vaccine wastage due to cold chain weaknesses will incur significant costs. Therefore, ensuring the safety, sufficiency and efficiency of the cold chain is critical. (Ethiopia Immunization, 2015) and (Global action plan, 2011-2020).

1.1.1 Dimensions of Cold Chain Management Practice

Pillars of vaccine cold chain management practices include practices of vaccine storage, technical capacity of personnel involved in vaccine management, logistics information system for vaccine commodities and the distribution system. Based on these pillars, there are cold chain management practices expected to be performed at EPI service provider facilities for effective cold chain management practice. These are; carrying out deliveries and sorting of vaccines and immunization-related equipment as appropriate, updating stock records, monitoring storage temperatures, conducting first level maintenance of cold chain equipment, estimating needs for vaccines and immunization related equipment in accordance with program plans and projections and establishing standard operating guidelines for the clearance and receipt of vaccines and immunization related equipment including completion of vaccine arrival reports (Reeves, T., et.al, 2017).

The aim of this study is to examine cold chain management practices and challenges at private health facilities providing Expanded Program of Immunization (EPI) service in Addis Ababa.

1.2 Statement of the problem

Now a days, the significance of cold chain management is clear enough in vaccine supply chain. However, in many low-income countries vaccine delivery systems have remained largely unchanged due to challenging contextual factors that have limited their ability to meet immunization program requirements. Geographically, the scale and environmental spread of cold chain systems have been demanding, given the need to consistently reach the whole population. Clinton Health Access Initiative (CHAI) has identified three key issues limiting cold chain performance: insufficient cold chain capacity, lack of up-to-date technology or 'optimal' equipment and inadequate temperature monitoring and maintenance systems (LeTallec, Y., *et.al* 2017).

Cold chain assortment in many countries is characterized by old and obsolete technologies; between 15% and 50% of equipment are older than the recommended 10 years, after which they are more susceptible to breakdown and poor temperature control. Infrastructure of cold chain system is a small cost as compared to the value of vaccines it safeguards, so there is a strong case for Global Alliance for Vaccine Initiative (GAVI) and other stakeholders to ensure timely and sufficient funding to implement cold chain system improvements to protect the vaccines that were also procured through their investments (LeTallec, Y., *et.al* 2017) and (WHO, 2018).

The value of vaccines delivered has increased tenfold, meaning that any vaccine wastage due to cold chain weaknesses (e.g. poor temperature control, insufficient storage capacity, etc.) will incur significant costs. Therefore, ensuring the safety, sufficiency and efficiency of the cold chain is critical (LeTallec, Y., *et.al* 2017).

Domestic fridges; which is household refrigerators are cheaper, extensively available and easily purchased. However, they are not safe for vaccine storage, as they do not reliably maintain optimal temperature ranges. Absorption type fridges are fridges fueled by kerosene or bottled liquid petroleum gas are widely used (60–80% of CCE in some countries), but are no longer approved by the World Health Organization (WHO) Product Quality and Safety (PQS) system (LeTallec, Y., *et.al* 2017) and (WHO, 2017).

In Ethiopia, there is a real problem of vaccines losing their potency during storage at health facilities even if they were potent on arrival. In the study area of Addis Ababa, there are high immunization coverage rates, but there are still a number of gaps at EPI service provider facilities. From daily routine observations the researcher observed that currently the cold chain fridges used to store vaccines at public health facilities and private health facilities are different. Most of the fridges used by private health facilities providing EPI service are commercially bought domestic fridges and fridges of public health facilities are different from those used by private health facilities. There is neither clear justification reported from responsible bodies nor

investigations conducted for this variation among same service providing facilities. This is a factor which leads the researcher for the arousal of research problem.

In addition, there is only a single study conducted at private facilities of Addis Ababa, Ethiopia to assess the cold chain management practices on availability of vaccine. The research report revealed that the storage system, the distribution system, the technical capacity and the information system with regard to vaccine is on average performance. Which means cold chain management system is on average performance which needs improvement to render quality service for the public. It also explained that the storage system, the distribution system, the technical capacity and the information system have a combined significant positive effect on availability of vaccine. However, the research did not address the cold chain standard used by private health facilities providing EPI service and challenges related to the cold chain management.

Therefore, the aim of this research proposal is to assess the cold chain management practices of private health facilities providing EPI service in Addis Ababa including the challenges which was not entertained in previous researches.

1.3 Basic Research Questions

For cold chain management to be efficient, three major dimensions are required. These include well trained personnel, reliable transport/storage equipment and efficient management procedures. An absence of any of these would lead to a deficient cold chain system. Health workers play an important role in maintaining an undisrupted cold chain as they are the last point of contact between the vaccines and the recipient. Hence, it is very pertinent that they be trained regularly in order to ensure efficient practice of cold chain management. Based on the dimensions of cold chain management practice, below listed are the research questions;

- How is the cold chain management practice of private health facilities providing EPI service in Addis Ababa?
- How is the cold chain standard of vaccine fridges at private health facilities providing EPI service in Addis Ababa?
- What are the challenges related to the cold chain management practice of private health facilities providing EPI service in Addis Ababa?

1.4 Objectives of the study

1.4.1 General Objective

The general objective of this research is to assess the cold chain management practice and challenges related to cold chain management at private facilities providing EPI service in Addis Ababa.

Storage condition, technical capacity and supervision of EPI focal persons and transport trend of vaccines are components of cold chain management practice.

1.4.2 Specific Objectives

The specific objectives of the study are

- ✓ To assess the cold chain management practice of private health facilities providing EPI service in Addis Ababa.
- ✓ To assess the cold chain standard of vaccine fridges of private health facilities providing EPI service in Addis Ababa.
- ✓ To assess challenges related to the cold chain management practice of private health facilities providing EPI service in Addis Ababa.

1.5 Definition of Terms

1.5.1 Conceptual definition

WHO Standard Cold Chain: is a supply system which is used to store, transport and distribute vaccines in a controlled temperature of +2 to +8 degree Celsius Using refrigerators, cold stores, freezers and cold boxes from the factory to the point of use without fluctuations.

Technical capacity of EPI focal persons: is determined by staff that is trained in EPI and handling standard operating procedures (SOPs) to ensure vaccine supply potency and patient safety.

Logistics information system: The practice of the focal person to make the inventory management and stock movement of vaccines (vaccine forecasting, consumption report preparation and use of vaccine requisition forms).

Challenges related to cold chain management practice: are internal and/or external that affect the performance of cold chain practice negatively.

1.5.2 Operational definition

Cold chain management practice:

- The overall cold chain management practice were assessed using a total of three questions. A score of one was given for correct responses and zero for incorrect responses and focal persons who score three were considered as performing good practice and focal persons who score below three were considered as performing poor cold chain management practice in EPI service provision

Standard Cold Chain:

- Facilities using domestic refrigerators are considered as they do not have WHO standard cold chain since they lack keeping vaccines with in controlled temperature of +2 to +8 degree Celsius without fluctuations. These units are not specifically built or designed to

store vaccines. For this reason, domestic refrigerators are not recommended by WHO for vaccine storage.

Storage condition of vaccines:

- To assess the storage condition of vaccines, 8 questions were administered and focal persons who score eight were considered as proper storage condition of vaccines and focal persons who score below eight were considered as the storage condition for vaccines is not proper.

Transport trend of vaccines:

- To assess the transport trend of vaccines, six questions were administered and focal persons who score six will be considered as proper transport trend of vaccines and focal persons who score below six were considered as the transport trend is not proper.

Technical capacity of EPI focal persons:

- To assess the technical capacity of focal personnel; four questions were administered and focal persons who score four were considered as technically capable and focal persons who score below four were considered as technically incapable in EPI service provision.

Logistics information system:

- To assess the existence of logistic information system; four questions were administered and focal persons who score four were considered as performing good logistics information system and focal persons who score below four were considered as performing poor logistics information system in EPI service provision.

1.6 Significance of the study

This study provides use full evidence on the overall cold chain management practice on vaccines and challenges related to cold chain management practices of private facilities providing EPI service. Therefore, helps all stake holders in this area including policy makers, international organizations working on immunization, regulatory authorities, health care providers and donors in guideline development and implementation, compliance with minimum standard, in providing technical and financial support on private health facilities. It enables the health sector to get important information on the current practice of private health facilities on cold chain management including the gaps and challenges. It also fill the literature gap which was not addressed in previous studies involving private health facilities.

1.7 Delimitation/scope of the study

This study is limited to private health facilities providing EPI service in Addis Ababa City Administration. The study addresses the cold chain management practices; technical capacity, information system, storage, transport and challenges related to cold chain management of private facilities managing vaccines in Addis Ababa City Administration.

1.8 Limitation of the study

The study was carried out among health professionals working in the private health facilities only. Therefore, the findings cannot be generalized to all health professionals working in Ethiopia.

1.9 Organization of the paper

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

CHAPTER TWO: Literature Review

2.1 Introduction

This chapter reviews relevant literatures on the key areas that the study focuses. It presents related theoretical literature with a focus on the objectives and theoretical inceptions of the study. It also reviews related empirical literature, conceptual frame work and literature gap. Only few vaccines were available in the early 1960s, and few children around the world received them. Smallpox was among the infectious diseases that were widespread and the World Health Assembly received numerous reports of the catastrophic consequences of smallpox among its Member States. However, vaccine technology existed for smallpox, offering the potential for protection. In 1966, the World Health Organization WHO launched a global campaign to eradicate smallpox. This successful campaign demonstrated both the power and portability of vaccines. Within less than two decades, smallpox had been eradicated, a public health achievement that still stands as one of the greatest in history. Encouraged by the success of the smallpox campaign, health officials advocated for an expanded range of vaccines to be given routinely to infants under one year and women of child-bearing age. In 1974, WHO established the Expanded Program on Immunization (EPI). EPI was initially piloted in Ghana to assess the feasibility of establishing a single, global immunization schedule incorporating six antigens: tuberculosis, polio, diphtheria, pertussis, tetanus, and measles. The schedule was optimized to provide maximum protection for a minimum number of contacts through what was then a promising primary health care system. One of the key challenges of the early EPI work was to find a way to safely deliver vaccines, which are temperature-sensitive biological products, from the point of manufacture to the point of administration. Smallpox eradication established stepped vaccine distribution systems based on existing health services infrastructures but separate from the routine distribution of medicines. Recognizing the managerial weaknesses of medicine

distribution at that time, WHO helped build the capacity of countries by developing the technologies, systems, and guidance towards a vaccine cold chain to distribute vaccines routinely (Cheyne, J., and Lloyd, L., 2017).

2.2 Theoretical Review

2.2.1 Cold Chain Management Practice

Cold chain is the system used for storing vaccines in good condition. It is sometimes referred to as the vaccine supply chain or the immunization supply chain. The cold chain consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges; from the point of manufacture to the point of administration. Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and others to light. Vaccine potency, meaning its ability to adequately protect the vaccinated patient, can weaken when the vaccine is exposed to unsuitable temperatures. Once lost, vaccine potency cannot be regained. To maintain quality, vaccines must be protected from temperature extremes. Vaccine quality is maintained using a cold chain that meets specific temperature requirements. It is essential that all those who handle vaccines and diluents know the temperature sensitivities and the recommended storage temperatures for all the vaccines in the national schedule (WHO 2018).

Cold chain management practice is a system which is used to store, transport and distribute vaccines in a controlled temperature of +2 to +8 degree Celsius Using refrigerators, cold stores, freezers and cold boxes from the factory to the point of use. Proper vaccine storage and handling play critical roles in efforts to prevent vaccine-preventable diseases. Vaccines exposed to storage temperatures outside the recommended ranges may have reduced potency, creating limited protection and resulting in the revaccination of patients and thousands of dollars in wasted vaccine. Proper storage and handling begin with an effective vaccine cold chain. A cold chain is a temperature controlled supply chain which includes all vaccine related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the client (CDC 2019).

2.2.2 WHO Standard Cold Chain Fridges

As per the WHO recommendation, health facility refrigerators should be equipped with a 30-day temperature logger and facility staff should be trained in their utilization. These devices provide a complete history of the refrigerator temperature. Thermometers cannot do this; they only indicate the temperature at the time when a reading is taken. An electronic freeze indicator and a stem thermometer is the next best choice. The freeze indicator shows whether freeze sensitive vaccines have been exposed to subzero temperatures which is the most common cause of damaged vaccine. However, a freeze indicator cannot be used again once it has been triggered; it must be replaced immediately with a new one. The worst choice is a stem thermometer on its own. As mentioned above, a thermometer only indicates the temperature at the time a reading is

taken, which is no more than 14 times per week. A 30 day temperature logger takes at least a thousand readings a week (WHO 2018).

WHO always warns that domestic compression refrigerators and freezers should never be used to store vaccines unless they have been tested against the relevant PQS verification protocol and found to be satisfactory for the setting in which they are intended to be used. Many countries purchase locally manufactured standard front opening domestic refrigerators for storing EPI vaccines. This has procurement and maintenance advantages, but a number of serious performance shortcomings can compromise the cold chain and cause loss of vaccine (WHO 2017).

As per WHO recommendation, categories of vaccine refrigerators are; electric, solar energy and bottled gas (or kerosene) fridges. Solar refrigerators are more expensive to buy and install than electric refrigerators, but they have no running costs, apart from cleaning and preventative maintenance. The two types are: a) solar-battery units connected to a battery bank, which is charged by the solar panels and b) solar direct drive units that are powered directly by the solar panels. Bottled gas (or kerosene) refrigerators may be necessary in places where there is insufficient sunshine for a solar-powered unit. Gas-powered units are better than kerosene models because they need less maintenance and have better temperature control. Bottled gas and kerosene refrigerators can expose vaccines to freezing temperatures. Keeping vaccines in the +2˚C to +8˚C range is particularly difficult with kerosene refrigerators (WHO 2017).

2.2.3 Vaccine Temperature Monitoring

It is essential to monitor and record the temperature of vaccines throughout the supply chain. It is the only way to prove that vaccines have been kept at the right temperature during storage and transport. Temperature monitoring also shows up any problems with equipment and procedures. A standard manual temperature recording chart should be attached to the door or lid of every vaccine refrigerator. Readings should be taken twice a day at least five days per week and preferably every day, including weekends and holidays. Daily readings should be taken from the same temperature monitoring device each time. The health worker should read the 30 days temperature reading (DTR) and write the data on the chart. If there is no 30 DTR, focal persons should check the integrated dial thermometer or, where necessary, the stem thermometer. Recording temperatures in this way provides evidence that the refrigerator is being monitored and that regular readings are being taken. This can help identify performance trends, sometimes even before automatic alarms are generated. Manual readings should be recorded on a temperature chart attached to the refrigerator door using the following procedure: refrigerator temperature should be checked first in the morning and at the end of the working day and temperature should be recorded by date and time on the temperature chart (WHO 2018 and WHO 2017).

Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. The software or website may also allow to set the frequency of

temperature readings. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility. WHO recommended to keep the data for three years so it can be analyzed for long term trends and/or recurring problems. Those receiving public vaccine may need to keep records longer as required by state regulations. In addition, using a DDL or other appropriate Temperature Monitoring Device (TMD) for each vaccine storage unit and each transport unit (emergency or non-emergency). In addition, have at least one backup TMD in case a primary device breaks or malfunctions and use DDLs with the following features: detachable probe that best reflects vaccine temperatures, alarm for out-of-range temperatures and low-battery indicator (WHO 2018 and WHO 2017).

2.2.4 Controlled Temperature Chain (CTC)

An increasing number of vaccines are being examined to determine their compatibility with a Controlled Temperature Chain (CTC), which would allow their use at ambient temperatures. WHO defines a CTC as the on label use of a WHO prequalified vaccine out of the traditional +2 °C to +8 °C cold chain for a limited period of time, at temperatures of up to 40 °C, just before administration. Vaccines licensed accordingly can be used in a CTC. The CTC approach can be adopted by countries for carefully chosen circumstances, such as for special strategies or mass vaccination campaigns (WHO 2018 and WHO 2017).

2.2.5 Sensitivity to Heat and Freezing

Vaccine storage and handling condition have significant roles in determining the efforts to prevent vaccine preventable diseases. Exposure of vaccines to storage temperatures beyond the recommended ranges may lead to reduced potency. Limited protection of vaccines results in the revaccination of patients and increased expenses due to wastage of vaccines. The right storage and handling of vaccines begin with an effective vaccine cold chain. A cold chain is a temperature controlled supply chain which includes the entire vaccine related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing firm, including the transport and delivery of vaccines and correct storage at the provider facility and ends with administration of the vaccine to the client. The vaccine potency is maintained only if the cold chain is properly maintained otherwise, potency of vaccine may be lost due to a useless vaccine supply. Proper vaccine storage is mandatory from vaccine manufacturing up to administration to clients. Vaccine potency is reduced every time as a vaccine is exposed to an improper handling and condition. This includes overexposure to heat, cold or light at any stage in the cold chain. It’s not possible to restore vaccine potency if once lost. Exposure of vaccines to inappropriate conditions can affect potency of any refrigerated vaccine, however a single exposure to freezing temperatures (0° C [32° F] or colder) can actually destroy potency. Exposure of vaccines in liquid state containing an adjuvant to freezing temperature can lead to everlastingly lose their potency (CDC 2017).

2.2.6 Sensitivity to light

Some vaccines are very sensitive to light and lose potency when exposed to it. Such vaccines should always be protected against sunlight or any strong artificial light, and exposure should be minimized. Vaccines that are as sensitive to light as they are to heat include BCG, measles, measles-rubella, measles-mumps-rubella and rubella. These vaccines are often supplied in dark glass vials that give them some protection from light damage. However, they should be kept in their secondary packaging for as long as possible to protect them during storage and transportation (WHO 2018).

2.2.7 Cold chain equipment

Guaranteeing vaccine quality and maintaining the cold chain are shared responsibilities among manufacturers, distributors, public health staff, and health care providers. An effective cold chain depends on three main elements: A well-trained staff, reliable storage and temperature monitoring equipment and accurate vaccine inventory management. Results of a cold chain failure can be costly. A break in the cold chain can mean extra doses for patients, increased costs for providers and damage to public confidence in vaccines. More importantly, patients refusing revaccination can remain unprotected from serious, vaccine-preventable diseases (CDC 2019).

2.2.8 Staff and training

Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well-trained in general storage and handling principles and organization specific storage and handling standard operating procedures (SOPs) is critical to ensure vaccine supply potency and patient safety. All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine related practices and be familiar with your facility's storage and handling SOPs.

As per the WHO's recommendation from the vaccine storage tool kit, personnel involved in vaccine cold chain responsibilities which includes ordering vaccines, overseeing proper receipt and storage of vaccine deliveries, documenting vaccine inventory information, organizing vaccines within storage units, setting up temperature monitoring devices, temperature monitoring and recording Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends, removing expired vaccine from storage units, responding to temperature excursions (out-of-range temperatures), Maintaining all documentation, such as inventory and temperature logs and overseeing proper vaccine transport per SOPs.

2.3 Empirical Review

2.3.1 Cold chain management practice

High level of concern is placed on major cold chain management practices; the storage, handling, transportation and distribution of vaccines and other pharmaceutical products which are temperature sensitive. Active and passive cooling equipment and monitoring devices are important tasks in vaccine cold chain. It is the assigned personnel responsible for executing and writing procedures, designing and operating systems and investigating problems to prevent them

who are paramount in establishing and maintaining a cold chain for time and Temperature Sensitive Pharmaceutical Products (TTSPPs). These concerned professionals must have the required competencies, knowledge, skills and abilities to effectively perform these activities with appropriate levels of expertise. These are multifaceted tasks that require the development of higher cognitive skills that cannot be adequately addressed through professional development opportunities based on simple information delivery and content acquisition (WHO 2018).

One of the major risks to vaccine in EPI cold chains is exposure to freezing temperatures. Though there are vaccine vial monitors to indicate whether vaccines have been exposed to excessive heat, freeze damage can be invisible, especially if the temperature exposure is never detected UNICEF conducts temperature monitoring studies in several countries annually, and freezing temperatures are frequently found in these studies. In a 2007 review of vaccine temperature-monitoring studies, authors found between 75% and 100% of the vaccine shipments were exposed to freezing temperatures in studies that examined all segments of distribution. For these reasons, the immunization community has been interested in the development of freeze-prevention features for all vaccine cold chain equipment (Maire, D., et.al, 2017).

Accidental freezing still occurs in 33% of storage facilities in wealthy countries and 37% of facilities in lower income countries and cold chain equipment is failing and underperforming in 20 and 50% (respectively) of 55 GAVI (Global Alliance for Vaccine Initiative) eligible countries. Solutions to these problems are being developed at many different levels and with different time perspectives. Vaccine manufacturers may be interested in formulations that can withstand freezing and program managers my want to know how to use vaccines in a controlled temperature chain. Global immunization experts and procurement officers may consider the value of cold chain equipment that is designed to avoid freezing and to operate successfully in areas without reliable access to electricity. Program managers may find it surprising to know that their investigations of equipment failures can yield valuable and actionable information for technicians, procurement officers, equipment manufacturers, and international partners (Immunization supply chains 2017).

2.3.2 Challenges in cold chain management practice

According to the World Health Organization (WHO), the success of efforts against vaccine-preventable diseases (VPDs) is largely attributed to proper storage and handling of vaccines. Some vaccines exposed to temperatures outside the recommended ranges can have reduced effectiveness and protection. Storage and handling faults cause great economic consequences as they can cost millions for replacement and lead to wastage of the vaccines (WHO 2018).

According to Clinton Health Access Initiative (CHAI) assessment, and people who have been involved in vaccine supply chains over the years generally agree that the following are the major challenges facing lower and middle income countries the support of local governments and development partners has identified three key issues limiting cold chain performance;

insufficient cold chain capacity, lack of latest technology or ‘optimal’ equipment, inadequate temperature monitoring and maintenance systems (LeTallec, Y., *et.al* 2017).

Availability of cold chain equipment such as refrigerator thermometers, functional refrigerators and temperature logging charts improved the practice of cold chain management (Jennifer, O., *et, al.* 2017).

According to the study conducted at EPI service provider facilities of Addis Ababa, there have been challenges in major components of vaccine supply chain which are related to storage system, distribution system and technical capacity and management procedures. (Firomsa B., 2018).

2.3.3 Vaccine storage and distribution practice

If cold chain is not properly maintained, vaccine potency may be lost resulting in unusable vaccine supply. Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time if vaccines are exposed to improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored. Exposure to any inappropriate conditions can affect potency of any refrigerated vaccine, but a single exposure to freezing temperatures (0° C [32° F] or colder) can actually destroy potency. Liquid vaccines containing an adjuvant can permanently lose potency when exposed to freezing temperatures (CDC 2019).

The research conducted in Cameron found that the cold chain standard is compromised and only 2% of facilities were equipped with devices that are approved for vaccine storage by the WHO PQS system. Among the 4,379 surveyed facilities, only 38% were unequipped with any refrigerator and 14% were equipped with broken refrigerators. Only 2% of facilities were equipped with WHO prequalified refrigerators. The remaining facilities met their cold chain needs with absorption (28%) and domestic (18%) refrigerators. With regard to storage capacity gaps, 45% of health districts had capacity gaps in 2017, a percentage that is projected to reach 75% by 2021. Unlike districts, almost all facilities had cold chain capacity gaps in 2017 and this percentage is expected to reach 99% by 2021 if no intervention is implemented (Divine, N., et.al, 2019).

A complete record of the vaccines stock and up to date refrigerator temperature records taken twice a day were observed in 38 (59.4%) and 37 (57.8%) of the 64 functional immunization centers, respectively. Record keeping was significantly better in the urban centers. Functional freezer necessary to prepare ice packs for outreach services was available in 35 (54.7%) of the functioning centers. Most of the centers were in the rural areas. In four of the rural centers, there was no thermometer to regulate the temperature of the refrigerator and among those found having any, seven were reading outside the recommended temperature of 0 to +8°C for vaccine holding refrigerators. Temperature record keeping was significantly better in the urban centers. Vaccine storage in the refrigerator was observed to be improper at 47 (73.4%) of the functioning 64 centers. Inadequate air circulation between vaccine boxes, vaccines kept in the wrong

compartment of the refrigerator, and absence of water bottles in the spare space of refrigerators were the major reasons for labelling storage inappropriate manner. There was no statistically significant difference regarding vaccine storage between urban and rural sites. Lack of technicians for refrigerator maintenance and budgetary constraints were reported by 41 (61.2%) and 60 (89.6%) of the institutions respectively. These problems were more encountered in the urban centers compared to the rural ones (Rogie, B., Berhane, Y. 2012).

On the other hand, a study conducted in Nekemte, Ethiopia shows that about half of the EPI focal persons asked (44.4%) did not comply with storage temperature as per the national standard. Certainly, all these affect the quality of temperature sensitive medicines and may risk public health and safety he study revealed that less than half of the respondents did not comply with storage temperature as per the national standard. Definitely, all these affect the quality of temperature sensitive medicines and risk for public health. Regarding the guidelines utilization, 60 of the respondents were utilizing the guidelines; majority 33(33.3%) were using the EPI guidelines for vaccine management while 18(18.2%) were using WHO's good storage practice. The remaining 9(9.1%) were using WHO's good distribution practice. About 39(39.4%) of the respondents didn't know what guidelines they are using for managing the quality management system during your practice (Fekadu *et.al* 2018).

2.3.4 Technical capacity

A study conducted in Nigeria revealed that the practice of cold chain management was found to be better among respondents whose health facilities had a functional vaccine refrigerator 214 (79.9%) compared to those whose health facilities did not have a functional refrigerator 10 (47.6%). Though overall good practice of cold chain management exhibited by a higher proportion of the respondents, more than six-tenth of health care workers had poor practice with regards to cold chain monitoring and storage of heat sensitive vaccines (Jennifer, O., *et, al.* 2017).

Provision of regular training to healthcare workers in cold chain management improves practice of cold chain management; developing temperature monitoring and cooling equipment was a great technological challenge. Developing the management skills to operate and oversee the system was and remains an even greater challenge. The problem became evident following the eradication of smallpox, when countries began launching their national immunization programs. There was rarely a single manager in charge of immunization services. In addition, most programs lacked mid-level managers or logisticians and there were no consistent policies, procedures or training materials that could be used as guidance.

In 1976, WHO distributed an EPI loose leaf manual known informally as the Blue Book which became the basis for developing future training and policies. The supply and delivery infrastructure for vaccines was defined to meet the needs of the vaccines and the field operations of the EPI. Responsibility for reliable vaccine distribution was assigned to dedicated EPI managers. A cold chain simulation game was developed and used in several countries to

demonstrate the complexities of vaccine distribution to senior managers in the ministries and to help national EPI offices to develop and agree detailed logistics policies that best suited their needs.

In order to address the global standard operating procedures of the EPI, staff at all levels of national immunization programs received training and support. Starting from 1977, innovations such as participative training by replacing traditional presentations were used to develop training courses for senior program managers and regional and district level staff and courses were developed in collaboration with the US Centers for Disease Control and Prevention. Cascade training was offered to countries, typically starting with national level training from where the participants were paired to manage training in their own regions and districts. Special courses were organized for staff of other organizations that were active in immunization. Managing changes to the supply chain and its continued development will require significantly more skilled managers to improve reliability and performance without any interruption of supplies. Whereas vaccine manufacturers and regulators work towards a future when the vaccine supply chain is without refrigeration, equipment developers and policy makers are now engaged in assessing and introducing improvements to achieve more reliable cooling and less burdensome procedures (Cheyne, J., and Lloyd, L., 2017).

2.3.6 Logistics information system

Incomplete and inaccurate logistics data collection systems have long stymied immunization programs, making it nearly impossible to use data to forecast vaccine requirements and deliver vaccines when and where they are needed. Vaccine stock outs lasting one month or longer occur in one of every three countries globally, and about 89% of these national stock outs compromise vaccine availability at the service delivery level. Countries considering electronic data systems may be interested in learning about new electronic data systems that have been piloted and scaled in developing countries. Procurement staff may wish to learn how data on vaccine wastage and session size is being used to determine optimal dose per vial in specific country situations (Immunization supply chains 2017).

2.3.7 Global perspective on vaccine management

As EPI cold chains were established in the 1970s, absorption refrigerators were the only option for sites with no grid electricity. A number of these devices were prequalified and included in the WHO Product Information Sheets (PIS, the prequalification system that preceded PQS). By the early 1980s, a number of solar battery powered refrigerators were being evaluated in small scale pilot studies in developing country EPIs. Batteries were used in order to even out the availability of power to the refrigerators without them the power would only be available when the sun was shining, while refrigerators need to remain cold throughout the night and during periods of clouds and precipitation as well (Maire, D., et.al, 2017).

Due to the decades of global investment in vaccine development and immunization programs, childhood vaccination now prevents 2–3 million deaths each year. In 2015, an estimated 19.4

million infants worldwide had not been fully immunized, resulting in approximately 1.5 million preventable deaths. To extend the benefits of immunization to all people by 2020, the 194 member states of the World Health Assembly committed in 2012 to an ambitious Global Vaccine Action Plan. This commitment was made amid unprecedented growth in immunization programs. Immunization programs currently deliver more doses of more vaccines to more people in more locations than ever before. Nevertheless, there are too many places in the world where vaccines are still not reaching the people who need them most. In addition, there are circumstances when vaccines are lost, damaged, or expired before they reach local health clinics or other points of use which threatens the efforts to boost coverage. A renewed focus on next generation supply chains that can safely and reliably manage, store, transport, and deliver vaccines to the point of use is vital to closing the immunization gap. Immunization supply chains; the network of staff, equipment, vehicles, and data needed to get vaccines safely from the manufacturer to the people who need them were first developed in the late 1970s with the launch of the Expanded Program on Immunization. They were designed to manage distribution of a small number of vaccines to a limited number of locations. Since then, the immunization program landscape has changed radically due to the growth in the number of vaccines available, changes in storage requirements, increases in vaccine costs and other factors. Among 2010 and 2020, for example, immunization services will require storage and transport capacity to manage four times the volume of vaccines. Health workers will administer six times as many doses per person including older children, adolescents, and adults and in more settings. Storing and transporting a larger number of vaccines to more delivery points requires continuing to update supply chains. Between 2011 and 2015, low and middle income countries had requested US$289 million from GAVI to update and strengthen their immunization supply chain systems, complemented by government and other sources of funding for supply chain improvements. Despite of the many competing budget priorities, finding new funding for further investment for this social good is particularly challenging. The cost effectiveness of investments is compelling; recent research suggests that for every dollar invested in childhood immunization, there is a return on investment of US $16 through savings in health care costs, wages, and productivity due to illness (No product, no program 2017).

A study conducted at health districts and facilities of Cameron shows that of the 189 surveyed health districts, 75% were equipped with WHO prequalified vaccine refrigerators, 7% were unequipped with any refrigerator and 3% were equipped with broken refrigerators. Furthermore, 12% were equipped with absorption refrigerators and the remaining 3% with domestic refrigerators. Among the 4,379 surveyed facilities, 38% were unequipped with any refrigerator and 14% were equipped with broken refrigerators. Only 2% of facilities were equipped with WHO prequalified refrigerators. The remaining facilities met their cold chain needs with absorption (28%) and domestic (18%) refrigerators. Regarding storage capacity gaps, 45% of health districts had capacity gaps in 2017, a percentage that is projected to reach 75% by 2021. Unlike districts, almost all facilities had cold chain capacity gaps in 2017 and this percentage is expected to reach 99% by 2021 if no intervention is implemented (Divine, N., et.al, 2019).

2.3.8 Vaccine Management in Ethiopian Perspective

With a population of 94.1 million, Ethiopia is the second most populous country in Africa, major changes are happening in Ethiopia around how vaccines are distributed throughout the country. Supplying hospitals, health centers, and health posts with safe supplies for routine immunization of the nearly 3 million infants1 born each year is a complex (Notes from field 2016).

Universal immunization of children against six common vaccine preventable diseases, namely tuberculosis, diphtheria, whooping cough (pertussis), tetanus, polio, and measles, is crucial in reducing infant and child mortality. Other childhood vaccines given in Ethiopia protect against hepatitis B, and Haemophilus influenza type b (Hib). The government of Ethiopia introduced the pneumococcal conjugate vaccine (PCV 13) and monovalent human rotavirus vaccine (RV1) into the nation's infant immunization programmer in November 2011 and October 2012, respectively. The pneumococcal vaccine protects against Streptococcus pneumoniae bacteria, which cause severe pneumonia, meningitis, and other illnesses. Rotavirus causes gastroenteritis, an inflammation of the stomach and intestines. If left untreated, it can lead to severe dehydration and death. Unlike the previous EDHS surveys, the recent EDHS survey has also captured information related to the second dose of measles vaccine (MCV 2) an effort recently launched in early 2019 (Mini EDHS 2019).

In Ethiopia's context, equipment lifespan, working status, the shift from Kerosene refrigerators to electric and solar driven cold chain equipment, the expansion of the immunization services close to community, the introduction of new vaccines and other interventions such as polio, measles and TT campaigns were the key reasons for the development of the cold chain rehabilitation and expansion plans (Ethiopia FMoH 2015).

The performance of cold chains has been affected by large quantities of obsolete equipment, which fails to provide the protective benefit of more recent designs. These previous generation units often have poor temperature control, shorter holdover times and lack freeze protection. This leads to putting new vaccines at risk and limiting the efficiency of cold chains. Temperature damage to vaccines is a known problem in many countries and is often driven by failures in equipment. This causes major risks to national programs in Ethiopia alone, a 1% increase in vaccine wastage due to poor temperature control would result in losses of over US$8 million of vaccines annually (LeTallec, Y., *et.al* 2017).

According to SARA 2018 report, availability of vaccine on the date of survey was below 30 percent for 6 vaccine types, whereas the highest stock out in the last three months prior to the survey was observed for BCG which is 25%, while it ranges (13-18%) for the rest. The availability of adequate temperature refrigerator requirement is low as to 11%, which is below 8% in Oromia, SNNP and Afar regions and rural facilities (SARA 2018).

Vaccine cold chain and logistics systems are vital for the success of immunization. While a number of new vaccines have been rolled out across the developing world with more vaccines in the pipeline, cold chain systems are struggling to support national immunization programs. This has resulted in risks of reduced potency of vaccines administered; due to poor temperature

control, nonfunctional equipment, poor availability of immunization supplies due to inadequate storage capacity, disrupted service delivery, vaccine stock outs and inefficient use of limited financial and human resources; through losses from vaccine wastage. Improving cold chain systems can therefore, expand effective immunization coverage and further reduce the number of deaths caused by vaccine preventable diseases. In Ethiopia, the introduction of the pneumococcal, rotavirus and pentavalent vaccines has increased the volume of antigens delivered by more than fivefold. Simultaneously, the value of vaccines delivered has increased tenfold, meaning that any vaccine wastage due to cold chain weaknesses (e.g. poor temperature control, insufficient storage capacity, etc.) will incur significant costs. Due to this reason, ensuring the safety, sufficiency and efficiency of the cold chain is critical (LeTallec, Y., *et.al* 2017).

The challenges related to immunization performance of were partly contributed by the inadequate access and utilization of routine immunization services due to lack of electricity for vaccines storage refrigerators. As a result, most children were at risk of morbidity and mortality resulting from easily preventable diseases like measles, polio, neonatal tetanus and whooping cough. In addition, due to absence of the vaccine storage refrigerators, the Health Extension Workers (HEWs) were forced to travel more than four hours on foot so as to bring vaccines from the nearest health centers. Thus, the work load was very heavy and beyond description. Wastage of vaccines was also very common since vaccines are easily perishable without cold chain or refrigerator.

2.4 Literature gap

Since vaccination is safe and effective preventive measure, millions of people are vaccinated annually. Preventive vaccination takes place before a disease emerges and aims at preventing a disease outbreak. Besides preventive vaccination, reactive vaccination can take place during an outbreak of an infectious disease or in response to a bioterror attack. Although vaccination is a medical intervention, successful vaccination campaigns are impossible without good logistics. The importance of vaccine logistics is demonstrated by the growing number of studies on the subject. There are a number of empirical literature involving storage and distribution system, Technical Capacity and Information System both globally and in Ethiopia from different perspective. However, the issue didn’t get attention with regard to private health facilities in Ethiopia. As far as the researcher is concerned, previous studies did not fully assess the challenges related to cold chain management practice in the context of private health facilities. Hence this research will help to bridge literature gap in this area.

2.5 Conceptual framework

Vaccine storage and handling practices are vital factors in preventing and eradicating various common vaccine preventable diseases. Nevertheless, inaccuracies result in revaccination of many clients and significant expenses due to vaccines wastage each year. Vaccine potency can be reduced due to failure in to improper storage and handling of vaccines resulting in deficiency of immune responses in clients and poor protection against disease. The requirement of

revaccination may lead to loss of confidence in vaccines and providers by clients. Therefore, ensuring vaccine quality and maintaining the cold chain are shared responsibilities among stakeholders; manufacturers, distributors and health care providers (WHO 2018).

Three main elements are important to ensure an effective cold chain; a well trained staff, reliable storage and temperature monitoring equipment and accurate vaccine inventory management and information system. Failure in a cold chain can be costly. It should be noted that clients refusing revaccination can remain unprotected from serious vaccine preventable diseases. Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For instance, exposure inactivated vaccines to freezing temperatures may not appear frozen with no indication of reduced or loss of potency. Health care providers can ensure clients receive high quality vaccine that has not been compromised through following a few simple steps and implementing CDC recommended storage and handling practices (CDC 2019).

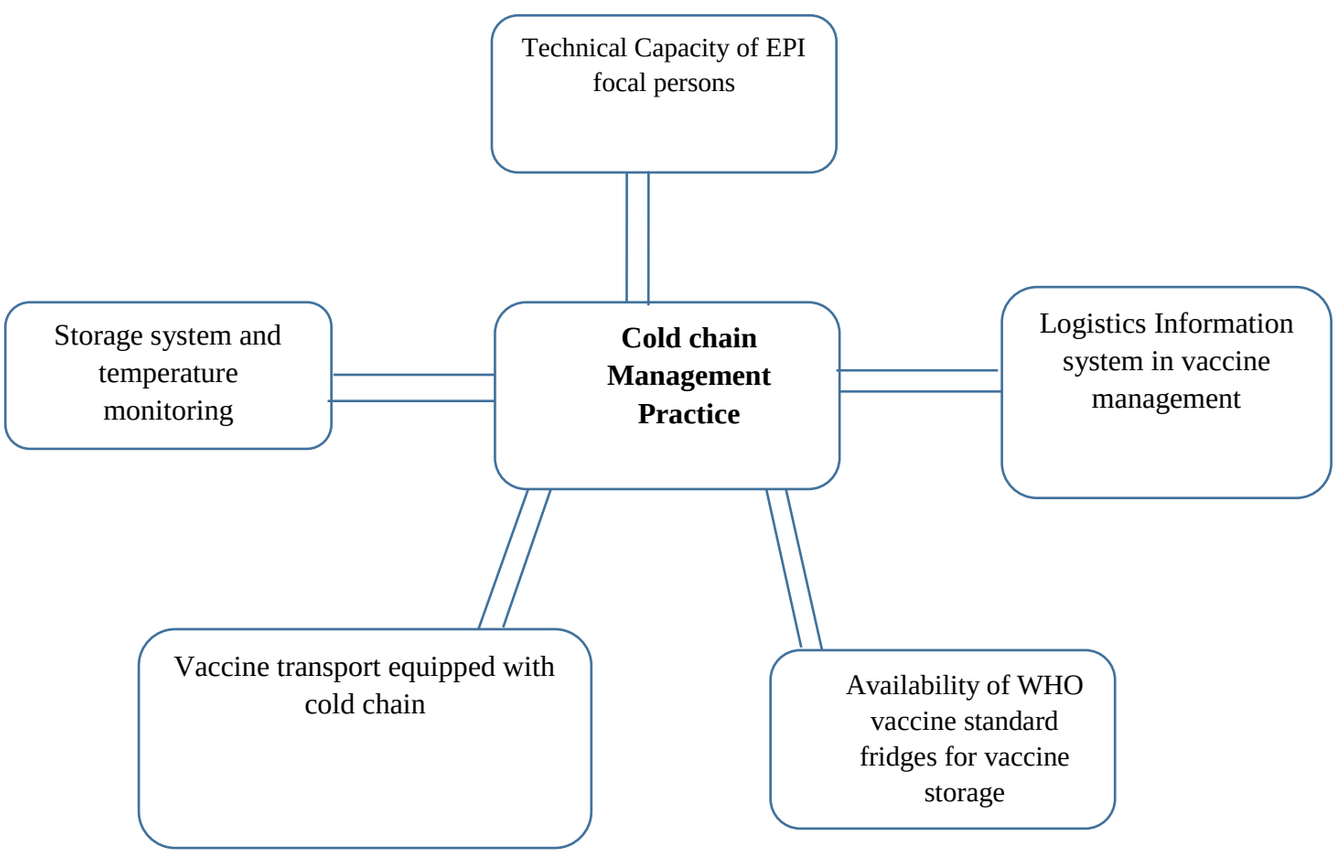

Figure 1. Conceptual framework adopted from (WHO Vaccine tool kit CDC 2019 and Firomsa B., 2018)

CHAPTER THREE: Research Design and Methodology

3.1 Introduction

This chapter describes the procedures followed to carry out the research. It deals with the research design, study population, sample size and sampling procedure, data Sources, data type, data collection procedure and analysis.

3.2 Description of study area

The study was conducted in Addis Ababa City which is the capital city of the country. According to Addis Ababa city administration regional health bureau there were 53 private facilities providing expanded program for immunization among several private health facilities in the city. However, recently three of them were closed and terminated providing EPI service. Therefore, the study was conducted at 50 private facilities providing EPI service.

3.3 Research design/type

A facility based descriptive cross sectional study design was employed for the study at private health facilities providing EPI service in Addis Ababa City Administration. The study was conducted at all the 50 private health facilities providing EPI service in Addis Ababa and a total of 50 EPI focal persons i.e. one EPI focal person per facility was contacted to collect the data.

3.3 Research approach

Both quantitative and qualitative research approaches were fitted. Quantitative approach was suited for capturing those variables narrated in descriptive manner quantitatively and qualitative approach was used to capture and narrate the challenges related to cold chain management practice.

3.3.1 Target Population

The target population of the study is EPI focal person in private health facilities that provide EPI service under Addis Ababa city administration. According to the information taken from Addis Ababa City Administration there are currently 50 private health facilities providing expanded immunization program and hence use vaccine. Hence, the populations of the study are those private health facilities legible to provide the service; one EPI focal person per facility was contacted to collect the data.

3.3.2 Sampling technique

According to Addis Ababa City administration Health Bureau (AACAHB) data, there are 50 total number of private health facilities providing EPI service in Addis Ababa. Thus the study is census which covered all the 50 facilities.

3.4.3 Sources and Time of Data Collection

This study used primary data sources which involved EPI focal persons and by observation of cold chain practice and equipment at facilities. Using primary data sources enhances the reliability of the study finding. The data was collected through two weeks from March 24, 2020 to April 12, 2020.

3.5 Research Methodology

A face to face interview using semi-structured questionnaires was used to collect primary data among EPI focal persons. The tool consists of demographic information of the respondent (gender, age, education and profession) and cold chain management practices of private health facility including storage, distribution, the technical capacity, cold chain standard and the information systems. In addition, questions related to challenges in cold chain management practice were captured using open ended question. Four data collectors were enrolled for data collection. They were briefed on how to collect data for one day. That is to create uniform understanding among data collectors for each question in the questionnaire and hence guide them to provide direction during data collection and also able to check completeness and quality.

3.6 Data Collection Instrument

A face to face interview using semi-structured questionnaires was conducted to collect primary data among EPI focal persons. The challenges mentioned by the EPI focal persons has been narrated in summary.

3.7 Data analysis methods

The data which was obtained from sample facilities analyzed based on objective of the study. In order to ensure logical completeness and consistency of responses, data editing and coding were carried out by the researcher. Finally, the data has been analyzed quantitatively using SPSS version 25 from data obtained through data collection instrument. The researcher analyzed demographic characteristic of participants using frequency, conducted descriptive statistics for all items of storage, distribution, technical capacity, cold chain standard and information system. Further to this regression analysis was conducted to see relationship between variables and finally multiple logistics regression analysis was conducted for those independent variables having significant positive relationship with dependent variable and to identify confounding variables. Regression analysis is a statistical method to investigate relationships between more than one independent variables and only one dependent variable. If the independent variable is one, it is simple regression.

3.8 Research Ethics

Approval to conduct this study was obtained from Addis Ababa University, School of Commerce Ethical review committee. Discussions were held about the purpose of the study to secure permission from each facility management before starting data collection. In addition, verbal consent was obtained from the respondents. Before study participants were requested for consent they were informed in detail about the purpose and procedures of the study, the content of the

questionnaire, its benefit, confidentiality of the information collected from them, the voluntary nature of participation and their right not to respond to questions if they do not want to answer as well as to stop answering and withdraw from the interview at any time.

3.9 Data Quality

To secure data quality, one day training was given for data collectors and the questionnaire was pre-tested in one facility outside of the actual sites. The data collectors were health professionals who are not working in selected health facilities. The trained personnel collect data by face-to-face interview from the study subjects. To assure data quality from the pre-test finding the completeness and consistency of questionnaire were checked at the time of data collection. The researcher controls the overall activities through continuous supervision. All completed questionnaire were examined for completeness and consistency during processing and analysis.

CHAPTER FOUR: Results, Discussion and Interpretation

4.1 Introduction

This chapter presents the findings of the interview and provides a detailed analysis of the data collected from the survey. It begins by analyzing data according to the research questions.

4.2 Response Rate

From the 50 private health facilities providing EPI service all the 50 facilities have been participated in the study. All the 50 facilities' respondents agreed and participated in the study. Therefore, the overall response rate of the interview that was conducted was 100%.

4.3 Socio demographic characteristics of the study population

Table 1. Socio-demographic Characteristics of Respondents in Addis Ababa, Ethiopia 2020

Characteristics (n=50)	Frequency	Percent
Gender		
Female	46	82%
Male	4	8%
Age groups in year		
<25 yrs	2	4%
25-32 yrs	36	72%
33-39 yrs	7	14%
40-48 yrs	4	8%
>48 yrs	1	2%
Educational status		
BA/BSc	21	42%
Diploma	29	58%
Experience in EPI service		
1-5 yrs	28	56%
Greater than 5 yrs	8	16%
Less than 1 yr	14	28%
Respondents profession		
Health officer	1	2%
Nurse/midwife nurse	49	98%
Respondents experience in EPI service		
1-5 yrs	28	56%

Greater than 5 yrs	8	16%
Less than 1 yr	14	28%

Data Source: Survey Result, 2020

Gender, age, educational status, profession and experience in EPI were examined and their distribution is summarized in the table above. Regarding gender majority 82% (46) respondents were female and 8% (4) were male. The majority of participants were from 25 to 32 years old 36 (72%). Regarding the educational status 29(58%) of the respondents were diploma graduated. The professional mix of the respondents have shown that the majority of professional who were involved in vaccine cold chain management practice were clinical and midwife nurses with 49(98%) only one respondent was health officer. In addition the majority of respondents i.e. 28(56%) have 1 to 5 years of experience.

4.3 Training, supervision and availability of equipment in cold chain management

Table 2. Training, supervision and availability of equipment in cold chain management

Training, supervision and availability of equipment in cold chain management (n=50)	Frequency (Yes)	Frequency (No)
Clinic	10%	20%
Hospital	16%	32%
NGO clinic	8%	16%
Specialty center	16%	32%
Type of refrigerator used to store vaccines		
Domestic	44%	88%
WHO standard	6%	12%
Respondents trained on EPI service training		
Trained	42%	84%
Not trained	8%	16%
Respondents trained on IPLS training		
Trained	10%	20%
Not trained	40%	80%
Respondents trained on vaccines related inventory management		
Trained	28%	56%
Not trained	22%	44%
Facilities supervised by National Program of Immunization/or regional health bureau and partners on EPI service with in the last six months		
Yes	18%	36%
No	32%	64%

Data Source: Survey Result, 2020

Majority of the facilities contacted were hospitals and specialty centers. Only 6(12%) facilities have been using WHO standard fridges and the majority 44(88%) have been using domestic fridges for the storage of vaccines. Forty two (84%) of focal persons were trained on EPI service training and 10(20%) focal person s trained on IPLS training and 28(56%) focal persons trained

on vaccine inventory management related trainings. Eighteen (36%) facilities have been get supervised by external body from regional heal bureau or partners working on EPI service support within the last six months.

Discussion Training, supervision and availability of equipment in cold chain management

According to WHO's recommendation, domestic fridges are not intended for vaccines storage purpose globally. Only WHO prequalified fridges are proposed to store vaccines which have specific features considering the perishability and risky nature of vaccines. However, based on this study finding except 6(12%) EPI facilities all 44(88%) facilities have been using domestic fridges for the storage of vaccines. This finding is higher than that of the study conducted in health facilities of Cameroon which were only (18%) facilities were using domestic fridge (Divine N., *et. al,* 2019). Though there are not studies conducted on the potency of vaccines at private health facilities providing EPI service related to the cold chain quality, it will have direct and indirect significant impact on the expected outcomes of success of immunization service quality.

Regarding training, though (84%) EPI focal persons did get trained on EPI service the training coverage of IPLS and vaccines related inventory management is lower which were 10(20%) and 28(56%) respectively. The number of EPI service trained focal persons is higher than the study conducted in health facilities of Addis Ababa and Nigeria which was (66%) and (69.4%) facilities studied respectively.

4.4 Assessment on cold chain management practice of EPI focal persons

Table 2. Assessment on cold chain management practice

Cold chain management practice (observation questions) (n=50)	**Frequency (Yes)**	**Frequency (No)**
Facilities where daily temperature monitoring chart recorded daily for the last week (seven days)	39 (78%)	11(22%)
Facilities with refrigerators thermometer reading +2 to +8 ^{o}C during the visit	38(76%)	12(24%)
EPI focal persons arranged each vaccine record the VVM status of each vaccine	42(84%)	8(16%)
Overall Practice		
Good	30(60%)	
Poor	20(40%)	

Data Source: Survey Result, 2020

In order to assess the cold chain practice of the health facilities some variables were used. From 50 facilities involved in the study, 39(78%) recorded daily temperature monitoring chart daily for the last week (seven days) where 38(76%) of facilities have thermometer reading between +2 to +8 ^{o}C of the refrigerator during the visit and 42(84%) of the VVM status of each vaccine was arranged based on their VVM status.

The above results indicate that facilities are not monitoring the vaccines appropriately in a continuous manner. It is expected that all the facilities should maintain thermometer reading +2 to

+8 ^{o}C all the time. In addition, it's expected that all the facilities were expected to record the daily temperature monitoring chart to observe the temperature pattern and deviations for protective measure.

To measure the overall practice (good or poor), the above three questions were taken and respondents who scored three are considered as having good practice and respondents who scored below three considered as poor practice. Based on this operational definition, 30 (60%) were performing good cold chain practice and 20(40%) were performing poor cold chain practice.

Discussion on assessment of cold chain management practice

Cold chain management practice is a vital indicator for the success of EPI service. It is essential to monitor and record the temperature of vaccines throughout the supply chain at EPI service provider facilities. It's the only way to prove that vaccines have been kept at the right temperature during storage and use. Temperature monitoring also shows up any problems with the cold chain equipment and procedures. This study revealed that EPI focal persons arranged each vaccine record the VVM status of each vaccine was 42(84%) which is lower than the study conducted in North Shewa facilities of Amhara region Yetwale S., (2018) which was (100%).

The study revealed that 39 (78%) facilities recorded daily temperature monitoring chart daily for the last week (seven days) which is higher than that of the study conducted in Addis Ababa which was 57.8% (Rogie, B., Berhane, Y. (2012) and also higher than similar study conducted in Nekemte (Fekadu *et. al* 2018) which was 44%.

According to this study finding, facilities with refrigerators thermometer reading +2 to +8 ^{o}C during the visit were 38(76%) which was lower than the study conducted in Nekemte which was 69.7% (Fekadu G., *et. al* 2018) and same study conducted in Bale (Esmael A., 2018) which was 82.8%. The overall cold chain management practice is good at 30(60%) which is similar to the study conducted in West Gojam (Adam A., 2019) which was 58%. On the other hand this finding is higher than that of Nigeria's study (Jennifer O., *et.al.* 2017) which was 35.1%. This study revealed that the cold chain management performance is better than the previous study conducted on same facilities which was average performance (Firomsa B., 2018). Even though the performance of cold chain management practice is better than the previous study, it's currently 60% of facilities thus needs overall performance improvement.

4.5 Assessment on storage condition of vaccines at facilities

Table 3. Assessment on storage condition of vaccines at facilities

Storage condition of vaccines at the facility (n=50)	Frequency (Yes)	Frequency (No)
Facilities which have sufficient storage capacity of vaccines	49(98%)	1(2%)
Standby generator is available in case of unreliable electricity supply or power failure	50(100%)	0(0%)
Vaccines are stored in the correct freezing temperature of the freeze sensitive vaccines on the schedule	46(92%)	4(8%)
The vaccine packing area protected from direct sunlight	50(100%)	0(0%)

EPI focal person use FEFO (First Expire First Out) principle for vaccine use	45(90%)	5(10%)
The refrigerator in the facility has functional thermometer	47(94%)	3(6%)
Anything other than vaccine stored in the refrigerator	14(28%)	36(72%)
There is alternative storage (e.g. cooler, cold box, other monitored refrigerator) available for vaccine storage, if necessary	48(96%)	2(4%)
Overall storage condition		
Good	8(16%)	
Poor	42(84%)	

Data Source: Survey Result, 2020

To assess the storage condition of the health facilities some variables were used. From 50 facilities involved in the study, almost all 49(98%) have sufficient storage capacity of vaccines all the 50 (100%) facilities have standby generator to be used during electric power failure and vaccines storage is protected from direct sunlight. In addition, 45(90%) facilities were implementing FEFO for vaccines arrangement. On the other hand, 14(28%) of facilities stored anything other than vaccines in their refrigerator.

It's not recommended to store anything other than vaccine in vaccines fridge however 14(28%) of facilities violet this recommendation. This considerable problem in maintaining appropriate storage condition since vaccines should be stored in combination with other product in fridges.

Discussion on storage condition of vaccines at the facility

It is important task to monitor and record the temperature of vaccines throughout the supply chain process. This is the only way to ensure that vaccines have been kept in the right temperature range during storage. Temperature monitoring shows up the existence of any problems with equipment and procedures. This study confirms that 47(94%) of facilities have functional thermometer in vaccines fridge. This finding is higher than that of similar study conducted in Nekemte (Fekadu G., et. al 2018) which was 69.7% and study conducted in health facilities of West Gojam which was only (25%) (Adam A., et. al, 2019). On the other hand it's similar to the study conducted in health facilities of Nigeria which were (90.6%) facilities (Jennifer O., *et.al* 2017). In addition, facilities implementing FEFO principle to store vaccines were 45(90%) which is higher than that of the study conducted in health facilities of West Gojam which were (43.3%) facilities lower than the studies conducted in health facilities of Addis Ababa which were (100%) facilities (Zerihun M., 2018). According to this study finding, 48(96%) facilities had alternative storage (e.g. cooler, cold box, other monitored refrigerator) available for vaccine storage which is higher than the previous study conducted in Addis Ababa (Yetwale S., 2018) which was (71.7%). Though it is not expected to store anything other than vaccines in vaccines fridges at all facilities, 14(28%) facilities under the study had stored food and snacks other than vaccines which is higher than that of the study conducted in health facilities of Bale (Esmael A., 2018) which were (2.9%) facilities. All the 50(100%) facilities have stand by generator for to be used during electrical failure. This is higher than the study

conducted in health facilities of Addis Ababa and Nigeria which was (63.3%) and (73.4%) facilities respectively. This may be due to the fear of unintended temperature deviation facility owners and managers due to the nature of domestic fridges used by private health facilities.

The overall storage condition of facilities studied was good at 8(16%) facilities which is lower than that of similar study conducted in health facilities of Addis Ababa (Rogie, B., Berhane, Y. 2012) which was (27%) and also lower than that of the study conducted on health facilities of Bale (Esmael A., 2018) and lower than study conducted in health facilities of Nigeria (Jennifer O., et.al. 2017) which was (77.9%).

4.6 Assessment on transport trend of vaccines in private health facilities

Table 4. Table 3. Transport trend of vaccines in private health facilities

Transport trend of vaccines at the facility (n=50)	Frequency (Yes)	Frequency (No)
Enough vaccine containers (carriers) to meet demand of clients for vaccine transportation purpose	29(58%)	21(42%)
Temperature monitoring system during transportation (thermometer with vaccine carrier)	2(4%)	48(96%)
Temperature readings remain between 2-8^{o}C during transportation	3(6%)	47(94%)
Vaccine collection schedule time table from respective supplier available at the facility	41(82%)	9(18%)
The vaccine delivery from respective supplier done within the regular schedule	41(82%)	9(18%)
SOPs are available at the facility to for cautions to be taken during vaccine transport	36(72%)	14(28%)
Overall transport trend		
Good	6(12%)	
Poor	44(88%)	

Data Source: Survey Result, 2020

Twenty nine (58%) of facilities mentioned that they have vaccine containers (carriers) to meet demand of clients for vaccine transportation purpose. Only 2(4%) facilities have temperature monitoring system during vaccines transportation and only 3(6%) facilities mentioned that the temperature reading range remain between 2-8^{o}C during transportation. Forty one (82%) facilities have vaccine collection schedule time table from respective supplier available at the facility and the vaccine delivery from respective supplier done within the regular schedule.

It's expected that all the facilities should monitor the temperature of vaccines during transportation through thermometer with vaccine carrier but based on this study it is critical that only two (4%) facilities are monitoring the temperature during transportation.

Discussion on Transport trend of vaccines in private health facilities

Regarding the transport trend of vaccines from supplier to health facilities only 2(4%) facilities have temperature monitoring system during vaccines transportation. As displayed on the above table the parameter to this variable includes the availability of thermometer during transport based on WHO recommendation. However, most of facilities used only ice packs during transport and similar studies did not include the availability of thermometer as an indicator. However no one could be sure on maintaining the temperature 2 to 8^{o}C in the absence of thermometer during transportation. This is a critical gap which need improvement to keep the potency of vaccines. According to the study finding, 29(58%) facilities had enough vaccine containers (carriers) to meet demand of clients for vaccine transportation purpose. Therefore, the vaccines containers of 21(42%) facilities still need improvement and the availability of SOPs for cautions to be taken during vaccine transport which was available at 36(72%) facilities is not enough as they are useful guides for health care providers during transportation.

4.7 Assessment on technical capacity of EPI focal persons in private health facilities providing EPI service in Addis Ababa

Table 5. Technical capacity of EPI focal persons

Technical capacity of EPI focal persons (n=50)	Frequency (Yes)	Frequency (No)
Responses to all deviations outside +2°C and +8°C has been documented and recommended actions taken	26(52%)	24(48%)
Written instructions are available on the use of vaccine vial monitors (VVMs posters and stickers, available to health workers	47(94%)	3(6%)
There is assigned staff to handle maintenance of cold chain equipment during failure	21(42%)	29(58%)
The facility have a twice daily temperature monitoring chart	47(94%)	3(6%)
Overall technical capacity of EPI focal persons		
Good	21(42%)	
Poor	29(58%)	

Data Source: Survey Result, 2020

As displayed on the table above 24(48%) facilities did not document deviations in temperature monitoring and 26(52%) of facilities documented temperature deviations outside +2°C to +8°C and recommended actions taken to improve the gap. In addition, only 21 (42%) of facilities have assigned personnel to handle maintenance of cold chain equipment during failure.

It’s expected that all facilities are expected to document responses to all deviations outside +2°C and +8°C and should take action to resolve the gap. However, this finding reveals that there is a critical gap in controlling temperature deviations. In addition, those facilities in absence of maintenance personnel are large in number and needs improvement.

Discussion on Technical capacity of EPI focal persons

It's recommended that the VVM status should always be checked and recorded on the arrival voucher when it first reaches the health facility. The EPI focal person must also check the VVM before the

vaccine is opened to see whether the vaccine has been damaged by heat. This study revealed that written instructions are available on the use of vaccine vial monitors (VVMs), such as posters and stickers, available to health workers at 47(94%) which is higher than the study conducted at health facilities of Addis Ababa (Yetwale S., 2018) which were (56.7%) facilities. In addition, responses to all deviations outside +2°C and +8°C has been documented and recommended actions taken by 26(52%) facilities which was expected at all the facilities visited. Below half 21(42%) of facilities visited had assigned staff to handle maintenance of cold chain equipment during failure which is higher than the study conducted in health facilities of Nigeria (Jennifer O., et.al, 2017) which was (30.6%) and similar to the study conducted in health facilities of Bale (Esmael A., 2018) which was (51.4%). The study also showed that 47(94%) facilities have a twice daily temperature monitoring chart which is better than that of the study conducted in health facilities of Bale and Nigeria which were (20%) and (44.7%) respectively. This study revealed that the overall technical capacity of EPI focal persons was good at 21(42%) facilities which needs intervention through additional trainings and technical supports to EPI focal persons.

4.8 Assessment on logistics information system in private health facilities providing EPI service in Addis Ababa

Table 6. Logistics information system of facilities

Logistics information system(n=50)	Frequency (Yes)	Frequency (No)
All receipts and dispatches of vaccines supply recorded on the receiving and issuing voucher	46(92%)	4(8%)
EPI focal manage and update Bin Cards (BC) or vaccine movement control cards	6(12%)	44(88%)
EPI focal adhere regular report and requisition time/schedule for vaccines	42(84%)	8(16%)
EPI focal use Vaccine Request Form (VRF) to request vaccines from respective supplier	48(96%)	2(4%)
Overall logistics information system		
Good	12(24%)	
Poor	44(88%)	

Data Source: Survey Result, 2020

As narrated on the table above, majority of facilities visited 46(92%) facilities receipts and dispatches of vaccines supply recorded on the receiving and issuing voucher. However, only 6(12%) facilities EPI focal manage and update Bin Cards (BC) or vaccine movement control cards. Even though, 48(96%) facilities use Vaccine Request Form (VRF) to request vaccines from respective supplier the consumption data to be driven from bin cards is low. This indicates that facilities are using vaccine request form without accurate consumption data.

Discussion on Logistics information system of facilities

Vaccines logistics information system is one of the mandatory roles of EPI focal persons. It's enables focal persons to generate accurate vaccine consumption data refill request and to avoid vaccines wastage. This study showed that 46(92%) facilities recorded all receipts and dispatches of vaccines

supply on the receiving and issuing voucher which was higher than the study conducted in health facilities of Addis Ababa which (Yetwale S. 2018) was (75%). This study showed that only 6(12%) facilities' EPI focal manage and update Bin Cards (BC) or vaccine movement control cards which is very minimal as compared to the study conducted in Addis Ababa which were(59%). In addition, 48(96%) facilities' EPI focal use Vaccine Request Form (VRF) to request vaccines from respective supplier which is similar to the study conducted in Addis Ababa which was (98.3%) facilities. The overall logistics information system of facilities was good at 12(24%) facilities. This requires capacity building intervention on focal persons through providing logistics management trainings.

4.10 Challenges at private health facilities providing EPI service in Addis Ababa

According to this study finding, 28(56%) facilities mentioned that they have challenges related to cold chain management. Among these 24(48%) facilities mentioned that their challenge is related to the standard of cold chain fridges currently used by facilities. All these facilities have been using domestic fridges which need to be changed into WHO standard vaccine fridge. However, the facilities mentioned that it is not easy to find WHO standard fridge supplier and even these type of fridges are available the price will not be affordable. Despite this concern, all the facilities visited which have been using domestic fridge 44(88%) have officially received directive letter from Addis Ababa City Administration Health Bureau to change their vaccine fridges for the sake of improving and maintaining EPI service quality since using domestic fridges are not recommended to use for vaccine storage. The other challenges mentioned by 4(8%) facilities were shortage of vaccines supply from respective suppliers (sub city health offices) and EPI trained staff turnover.

CHAPTER FIVE: Conclusion and Recommendation

This chapter covers summary of the major findings, conclusion and recommendations.

5.1 Summary of the major findings

The aim of this study is to assess the cold chain management practice and challenges related to cold chain management practice on private health facilities providing EPI service in Addis Ababa. Therefore, it targets technical capacity of EPI focal persons, logistic management information system, vaccines transport trend and the standard of vaccine fridges through survey data which was collected from EPI focal persons of private health facilities. Majority of private health facilities 88% have been using domestic fridge for vaccine storage.

The demographic characteristics of participants indicates that participants were educated and experienced on cold chain management. Regarding educational level about 58% of participants hold diploma and nearly about 56% of the participants have 1-5 years of experience and 16% have greater than five years' experience. This will have positive implication on the quality of the research in terms getting of quality data.

This study shows that 60% facilities have overall good cold chain management practice, the storage condition is good at of 16% facilities, the vaccines transport trend of facilities is good at only 12% facilities, the technical capacity of EPI focal persons is good at 42% facilities and the logistics information system of facilities is good at only 12% facilities. This research revealed that the major

challenge mentioned by majority of private health facilities was lack of vaccine standard fridge and shortage of vaccine supply.

5.2 Conclusion

Immunization reaches more target population than any other health and social service and is a key component of primary health care systems. Immunization benefits individuals, communities, countries and the world as a whole. It is an investment in the future that benefits all: saving lives and protecting population health; more productive and a safer, healthier and more prosperous. Nevertheless, there are important challenges to overcome. The benefits of immunization are unevenly shared: vaccine coverage levels vary markedly between and within regions, with some populations having poor access to immunization services often the poorest, the most marginalized or the most vulnerable in fragile and conflict affected settings.

Since the goal of cold chain management practice is maintaining the product with in recommended storage condition to administer potent and quality vaccines to clients. It is not easy task to achieve the goal of vaccination without capable personnel who properly manage cold chain equipment guided by specified procedures. Since vaccines are relatively very perishable biological agents, addressing the gaps of cold chain management practice gaps of EPI focal persons is mandatory. From the study on vaccine cold chain management practice, a number of problems were identified and possible comments were received from the facilities. The overall cold chain management practice of 44(88%) respondents asked facilities was good in terms of storage, transport logistics information system and technical capacity. The major problem encountered at EPI service provider facilities was the absence of WHO standard fridges. The study finding reveals that only 6 (12%) facilities have WHO standard fridges during the visit the rest 44 (88%) use domestic fridges to store vaccines. This is unacceptable practice based on WHO and national EPI service standards. Domestic fridges are totally not recommended for vaccines storage.

Overall from the findings of the study, it can be concluded that there were vaccine cold chain management practice challenges specially lack of vaccine standard fridges to maintain the recommended temperature range, temperature monitoring, vaccine storage and handling practice and to maintain vaccine potency practice in private health facilities providing EPI service in Addis Ababa.

5.3 Recommendation

Three requirements are important in order to have an effective cold chain management practice; personnel, cold chain equipment, policies and procedures. In addition there should be monitoring and evaluation system of the cold chain. Therefore, the recommendations given will be: since majority of private health facilities 44(88%) have been currently using domestic fridges for vaccines storage and as facilities mentioned that it is not easy to find WHO standard fridge supplier and even these type of fridges are available the price will not be affordable and officially received directive letter from Addis Ababa City Administration Health Bureau to change their vaccine fridges for the sake of improving and maintaining EPI service quality since using domestic fridges are not

recommended to use for vaccine storage. Therefore, measures taken by AACAHB was good so far to improve the EPI service quality. However, the researcher recommends that the directive letter is not the only solution for the improvement of EPI service quality. Rather, in order to support this vital public health service which is targeted on prevention, the Ministry of Health (MoH) and AACAHB should work on the availability of standard fridges for private health facilities providing EPI service in affordable manner. Otherwise, the termination of EPI service due to the absence of vaccine standard fridge at private health facilities will lead to public facility centered EPI service (minimized access to vaccination) which will have negative impact of clients who prefer to get the vaccine service at private health facilities. Capacity building of EPI focal persons by providing vaccines inventory management and IPLS training is important to have proper logistics information system.

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Appendices

Appendix 1: Consent Form

ADDIS ABABA UNIVERSITY SCHOOL OF COMMERCE DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT

Thank you in advance

My name is Alemtsehay Berhanu. I am conducting a study on the cold chain management practices and challenges in the case of private health facilities in Addis Ababa city administration for the partial fulfillment of master's degree in logistics and supply chain management in Addis Ababa University, School of commerce. The information that will be collected for this research project will be kept confidential. Taking part in this study you will contribute towards alleviating the problem of poor vaccines vaccine management and challenges. Should you have any query you can contact the researcher at any time.

Alemtsehay Berhanu, Addis Ababa University

Tel: +251911854611

Email: alemtsehayberhanu@yahoo.com

Name _____ Signature _____Date _____

Appendix 2: Research Instrument

Questionnaire for EPI focal persons at private health facilities

Part 1: Demographic characteristics of respondents

The general profile of respondents.

1. Gender:
   a. Male b. Female
2. Age:
   a. <25 yrs c. 33-39 yrs
   b. 25-32 yrs d. 40-47 yrs e. > 48 yrs
3. Educational background:
   a. Diploma c. BA/Bsc d. MA/Msc e. Other Specify……
4. Experience in EPI service provision:
   a. <1 yrs b. 1-5 yrs c. >5 yrs
5. Professional of in charge of facility cold chain management
   a. Nurse/Midwife Nurse b. Health officer e. other(specify)
6. Level of your health facility
   a. Hospital b. Specialty center c. Clinic d. NGO Clinic e. Others

Part 2: Vaccine cold chain management

Part I	**Cold chain standard of the facility**	**Suggested option**	**Remark**
Part	**Training, supervision and availability of equipment in cold chain management**		
1	The facility use WHO standard cold chain fridge or domestic refrigerators (commercially available) vaccine storage?	1. Domestic 2.WHO standard	
2	Does the EPI focal person s who handle cold chain items specifically trained on EPI/cold chain management	1.Yes 2.No	
3	Does the EPI focal person trained on one of the following pharmaceuticals logistics trainings;		
3.1	Integrated Pharmaceuticals Logistics System (IPLS)	1.Yes 2.No	
3.2	Inventory management or storage, distribution and handling procedures of vaccines	1.Yes 2.No	
4	Did the facility get supervised by National Program of Immunization (NPI) or regional health bureau and partners on EPI service with in the last six months?	1.Yes 2.No	
Part II	**Cold chain management practice** (observation questions)		
1	Is the daily temperature monitoring chart recorded daily for the last week (seven days)?	1.Yes 2.No	
2	Is the facility's refrigerators thermometer reading +2 to +8 ^{o}C during the visit? (observe)	1.Yes 2.No	

3	Did the EPI focal person arranged each vaccine record the VVM status of each vaccine? (Observe)	1.Yes 2.No	
Part III	**Storage condition of vaccines at the facility**		
1	Does the facility have sufficient storage capacity of vaccines	1.Yes 2.No	
2	Is there a standby generator in case of unreliable electricity supply or power failure	1.Yes 2.No	
3	Are vaccines stored in the correct freezing temperature of the freeze sensitive vaccines on the schedule?	1.Yes 2.No	
4	Is the vaccine packing area protected from direct sunlight?	1.Yes 2.No	
5	Does the EPI focal person use FEFO (First Expire First Out) principle for vaccine use?	1.Yes 2.No	
6	Does the refrigerator in the facility has functional thermometer	1.Yes 2.No	
7	Is there anything other than vaccine stored in the refrigerator?	1.Yes 2.No	
8	Is there alternative storage (e.g. cooler, cold box, other monitored refrigerator) available for vaccine storage, if necessary (e.g. in case of vaccine refrigerator breakdown)	1.Yes 2.No	
Part IV	**Transport trend of vaccines at the facility**		
1	Are there are enough vaccine containers (carriers) to meet demand of clients for vaccine transportation purpose?	1.Yes 2.No	
2	Is there temperature monitoring system during transportation (thermometer with vaccine carrier)?	1.Yes 2.No	
3	Is temperature readings remain between 2-8^{o}C during transportation?	1.Yes 2.No	
4	Is vaccine collection schedule time table from respective supplier available at the facility?	1.Yes 2.No	
5	Is the vaccine delivery from respective supplier done within the regular schedule?	1.Yes 2.No	
6	Are there SOPs available at the facility to for cautions to be taken during vaccine transport?	1.Yes 2.No	
Part V	**Technical capacity of EPI focal persons**		
1	Are the responses to all deviations outside +2°C and +8°C has been documented and recommended actions taken?	1.Yes 2.No	
2	Are there written instructions on the use of vaccine vial monitors (VVMs), such as posters and stickers, available to health workers?	1.Yes 2.No	
3	Is there assigned staff to handle maintenance of cold chain equipment during failure?	1.Yes 2.No	
4	Does the facility have a twice daily temperature monitoring chart?	1.Yes 2.No	
Part VI	**Logistics information system**		

1	Are all receipts and dispatches of vaccines supply recorded on the receiving and issuing voucher?	1.Yes 2.No	
2	Does the EPI focal manage and update Bin Cards (BC) or vaccine movement control cards?	1.Yes 2.No	
3	Does the facility adhere regular report and requisition time/schedule for vaccines?	1.Yes 2.No	
4	Does the facility use Vaccine Request Form (VRF) to request vaccines from respective supplier?	1.Yes 2.No	
Part VII	**Challenges related to cold chain management**		
1	Is there currently cold chain related challenge at the facility?	1.Yes 2.No	
2	If Yes for Q1, List cold chain related challenges faced at the facility		