



**ASSESSMENT OF COLD CHAIN LOGISTICS MANAGEMENT OF
PHARMACEUTICALS THE CASE OF EPSS: A DESCRIPTIVE CROSS-
SECTIONAL STUDY**

**BY
THEWODROS LEMESSA (B. PHARM)**

ADDIS ABABA UNIVERSITY

ADDIS ABABA, ETHIOPIA

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Addis Ababa University
College of Health Sciences
School of Pharmacy
Department of Pharmaceutics and Social Pharmacy

**Assessment of Cold Chain Logistics Management of Pharmaceuticals the Case
of Ethiopian Pharmaceuticals Supply Services: A descriptive cross- sectional
study**

By: Thewodros Lemessa (B. Pharm)

Advisor: Arebu Issa (B. Pharm, MSc, Ass. Prof)

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This is to certify that the thesis prepared by Thewodros Lemessa entitled: Assessment of cold chain logistics management of pharmaceuticals the case of Ethiopian Pharmaceuticals Supply Service: A cross-sectional study and submitted for partial fulfillment of the requirements for the Degree of Master of Science in Health Supply Chain Management complies with the regulations of the University and meet accepted standard concerning originality and quality.

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ABSTRACT

Assessment of Cold Chain Logistics of Pharmaceuticals the Case of Ethiopian Pharmaceuticals Supply Service.

Thewodros Lemessa

Addis Ababa University, 2023

Background: Cold Chain Management is a network of facilities and distribution options that performs the usual functions of a standard supply chain cycle but with temperature and humidity control throughout the supply chain stages and entities. A cold supply chain is important within the changing global economy today due to the huge increasing need for the products of temperature controlled industries.

Objectives: The main objective of this study was to assess cold chain logistics of temperature sensitive pharmaceuticals including vaccines in Ethiopian Pharmaceutical supply service.

Result: In this study, it was identified that factors that influence cold chain logistics of pharmaceuticals; are inadequate vehicles for the distribution of cold chain pharmaceuticals to public healthcare facilities, lack of sufficient storage area for storage of cold chain pharmaceuticals, poor record keeping for unfit for use pharmaceuticals and lack of knowledge among some of staffs working on storage and distribution directorate Ethiopian Pharmaceuticals Service.

Methodology: An institution based cross-sectional study was conducted between December 2021 to February 2023 in EPSS central and Addis Ababa no2 which are located in Addis Ababa, Ethiopia, data was collected from 69 respondents working on storage and distribution directorate of EPSS. Descriptive and inferential statistics were carried out to analyze the data.

Conclusion and Recommendations:, Insufficient storage space, Lack of cold chain vehicles ,lack of knowledge among some staffs and poor documentations for unfit for use pharmaceuticals were challenges observed at Ethiopian Pharmaceutical supply service and recommendations were given to improve storage conditions and facilities of by availing sufficient storage area and equipment by expanding and constructing additional centralized warehouses, availing sufficient cold chain vehicles, providing on job training for staffs working storage and distribution and improving documentation for unfit for use pharmaceuticals

Keywords: Cold chain, logistics, Pharmaceuticals, Time and Temperature sensitive

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ABBREVIATIONS AND ACRONYMS

EPMSC:	Ethiopian Pharmaceutical and Medical Supplies Corporation
EPI:	Expanded Program on Immunization
EPSA:	Ethiopian Pharmaceuticals Supply Agency
EPSS:	Ethiopian Pharmaceutical Supply Service
EFDA:	Ethiopian Food and Drug Authority
FEFO:	First Expire-First-Out
FIFO:	First-In-First-Out
FMOH:	Federal Ministry of Health
ISO:	International Standard Organizations
IT:	Information Technology
PFSA:	Pharmaceutical Fund and Supply Agency
PHARMED:	Pharmaceutical and Medical Supplies Importer and wholesale Distributor
RH:	Relative Humidity
TTSP:	Time and Temperature-Sensitive Pharmaceutical Product
UPS:	Uninterrupted Power Supply

CHAPTER ONE: INTRODUCTION

1.1. Background

Cold Chain Management (CMM) can be expressed as the network of facilities and distribution options that performs the usual functions of a standard supply chain cycle but with temperature and humidity control throughout the supply chain stages and entities (Last, 2009). The cold supply chain has become more and more crucial within the changing global economy today due to the huge increasing need for the products of temperature-controlled industries, particularly medical vaccines, fresh agricultural products, manufactured food, chemicals, and military services. Cold chain logistics is considered a huge competitive advantage as it causes a valuable extension to product shelf life which gives the suppliers the ability to access overseas markets and to meet the huge local demand caused by population growth as well (Taylor, 2006).

The reason for studying cold chain logistics is cold chain logistics of drugs or temperature-sensitive products such as proteins, peptides, biologics, vaccines, enzymes, microorganisms, and monoclonal antibodies have a short shelf life, high cumbersome storage, handling, and distribution requirements, high shipping costs, and demand for cold storage environments (Gore *et al.*, 2006). Without efficient cold chain management, many valuable therapeutic products would be perished (Albert, 1997).

Despite the changes in the market for cold supply chains, the importance of the role of logistics seems to be downgraded. The previous studies related to cold chain also depict similarities of either focused on technologies of maintaining the product at a set temperature (Park and Kim, 2010; Singh and Saha, 2012) or on the domestic pharmaceutical industry and its development (Bishara, 2006; Chung and Chung, 2005) in relation to other policies and regulations.

Cold chain monitoring is still a major challenge in Africa, including Cameroon. study done in 65 health facilities found in North West region of Cameroon, past studies suggest that only about 56% of health facilities fill their temperature charts systematically twice a day as recommended. In 26 (50%) of the health facilities with a temperature recording sheet, a total of 409 days were skipped without recording the temperature twice daily as recommended. Temperature chart was properly filled in 25(50%) of the 50(96.2%) facilities having it. About 14 (26.9%) of the health facilities

record at least one inappropriate temperature during the last 2 months following data collection.17 (28.3%) personnel did not know the correct vaccine storage temperature (Yakum et al., 2015). Therefore, the study of cold chain management from a logistics perspective seems to be much required. The objective of this study is to review cold chain logistics and its characteristics regarding the pharmaceutical industry, particularly of the pharmaceutical distributor; like storage, transportation, packaging, and technical capacity.

This study mainly focuses on the assessment of cold chain logistics of pharmaceuticals in the Ethiopian Pharmaceutical Supply Service. Cold chain logistics elements under study are storage, temperature monitoring, transportation, distribution, and knowledge of staffs working in the cold chain.

In Ethiopia, there is regulation and standard guideline to control the quality of drug during storage, transportation and distribution including the distribution and transportation of cold storage drugs. The quality of cold chain management is the responsibility of each distributor. But there are gaps during the management of cold chain pharmaceuticals at central EPSS and branches even though good transformations in recent years; like shortage of cold chain warehouses, lack of cold chain vehicles, and technical gaps of staffs working in the cold chain this is also depicted in previous studies(Tesfamichael,2018;Temesgen,2020). This study assesses how the above factors or problems like storage, distribution, temperature monitoring and technical capability affect cold chain logistics at Ethiopian pharmaceutical supply service and recommend solutions.

1.2. Statement of the Problem

Management of cold chain is a major challenge in developing countries and weaknesses are often seen during the storage and transportation of cold chain pharmaceuticals (Akoh *et al.*, 2016).Factors contributing to weaknesses of the cold chain are delays during transportation, quality of refrigerators, a method of storage, too long storage at the health unit, improper use of refrigerators, power interruption, equipment breakage, and lack of trained personnel on cold chain management (Nelson *et al.*,2004). Similar problems are being faced in Ethiopia where cold chain medicines are losing their

potency at the storage centers even if they arrive with their full potency (Bogale *et al.*, 2019).

Globalization has made the relative distance between regions of the world much smaller, but the physical separation of these same regions is still a very important reality. The greater the physical separation, the more likely freight can be damaged in one of the complex transport operations involved. Some goods can be damaged by shocks, while inappropriate temperature variations can damage others. To ensure that cargo does not become damaged or compromised throughout this process, businesses in the pharmaceutical, medical, and food industries increasingly depend on the cold chain (Rodrigue, 2020).

The reason for studying cold chain logistics is it is a \$10 billion component of the \$1 trillion global pharma industry from the economic aspect. Around 80% of drugs require temperature-controlled transportation and the practice is particularly increasing from a therapeutic aspect. In some drug categories, the proportion is even higher. For example, according to the World Health Organization, more than 90% of all vaccines require a temperature-controlled supply chain. The need for these controls is driven by the increasing sensitivity of modern drugs, particularly those of a 'large-molecule' i.e. biological nature. It is a requirement that is accompanied by tight regulatory controls and compounded by factors such as globalized production, new market development, and new systems of transportation. And the problem of maintaining the correct product temperature during shipment is significant. According to industry sources, the incidence of temperature excursions during pharma transportation may be as high as 5% of the total and the World Health Organization reports that the Effective Vaccine Management assessment carried out in more than 70 countries between 2010 and 2012 found that only 29% of countries met its minimum recommended standards for temperature control (Tobescu, 2017).

In Ethiopia there are anticipated challenges while storing, packaging, transporting, and distributing cold chain pharmaceuticals for pharmaceutical distributors like EPSS since it supplies the majority of health commodities of the country and as these products are temperature sensitive.

From past studies, different gaps were identified and different solutions were recommended. From those recommendations, EPSS tried to solve some of its cold chain logistics by building cold chain warehouses and by providing on job training to its staff but it is anticipated that there are still gaps or problems while handling cold chain pharmaceuticals, for instance, public health facilities procure and transport cold chain products by their vehicles in which cold chain is not maintained this is due to shortage cold chain vehicles in EPSS. Moreover, technical capability and cold storage area are also other challenges.

Proper packaging, regulatory and compliance issues relating to transportation, storage, packaging, and technical compliance, influence the safety of cold chain items at the user level are critical in this process to avoid degradation.

In the pharmaceutical industry, the importance of the cold chain is clear to the government and key stakeholders based on their impact on health, there is a gap or a problem to control the effects of supply chain logistics such as transport, storage, packaging, technical capacity and many other sensitive activities that help keep such products safe and in good quality. This is confirmed by Bishara, (2007) who asserts that pharmaceutical cold chain items like vaccines are particularly sensitive materials that, if not manufactured and shipped under stringent controls, can become ineffective or even hazardous to the consumer due to reduced potency.

Kamau and Mukui, (2005), noted that a lack of awareness by distributors in the control of storage and transportation temperatures can have a major impact on product quality by non-observance of the cold chain or inefficiency in its monitoring mechanisms. This may affect the products' therapeutic properties and consequently generate deficiency quality risks such as loss of therapeutic effects and intoxication with direct effects on the health of the users. Storage conditions and facilities are not up to standard and there lacks a fleet of specialized transport systems to ensure no cold chain breaks during transport by doing proper monitoring of temperatures. Packaging materials used are questionable to maintain the correct temperatures and conditions to ensure the safety of cold chain pharmaceuticals. Most firms also seem not to be technically capable to handle cold chains effectively to ensure their safety.

Khurana and Gupta, (2019) stated insulin the common antidiabetic agent being a protein is liable to get denatured. Insulin due to its colloidal nature is highly prone to precipitation induced by changes in the environmental pH and temperatures. Instability in the proteins is attributed to the differential level of changes in the protein structure. It deaminates and degrades which causes this medicine therapeutically ineffective.

This study is crucial in analyzing the influence of cold chain logistics on the supply of safe cold chain products. From the public health and patient aspect also proper cold chain management of pharmaceuticals is important as these pharmaceuticals are lifesaving and prevent disease. From an economic aspect, cold chain management is important as high-value pharmaceutical products transact through cold chain so its good management is very important to save the economy of the country and nation.

1.3. Research Questions

1. How does cold chain storage practice of cold chain pharmaceuticals look in EPSS central and EPSS Addis Ababa no 2?
2. How does temperature monitoring and transport systems of cold chain Pharmaceuticals look in EPSS central and EPSS Addis Ababa no 2?
3. How does knowledge of staffs look regarding cold chain pharmaceuticals in EPSS central and EPSS Addis Ababa no 2?

1.4. OBJECTIVE OF THE STUDY

1.4.1. General Objective

To assess cold chain logistics of pharmaceuticals at Ethiopian Pharmaceuticals Supply Service

1.4.2. Specific Objectives

- To assess the cold chain storage practice of pharmaceuticals at EPSS central and EPSS Addis Ababa no 2.
- To assess temperature management, transportation means and adequacy of the fleet for transportation of cold chain pharmaceuticals at EPSS central and EPSS Addis Ababa no 2.

- To assess the knowledge of staffs engaged in cold supply chain management practice at EPSS central and EPSS Addis Ababa no 2.

1.5. Definition of Terms

The terms listed below have multiple meanings, but for this thesis, they are defined as follows:

- **Supply Chain Management:** is the art and science of integrating the flows of products, information, and financials through the entire supply pipeline from the supplier's supplier to the customer's customer.
- **Pharmaceutical:** a drug used to diagnose, cure, treat, or prevent disease. Drug therapy is an important part of the medical field and relies on the science of pharmacology for continual advancement and pharmacy for appropriate management. Drugs are classified in multiple ways
- **Cold Chain:** is the system of transporting and storing pharmaceuticals at the recommended temperature range.
- **Calibration:** is the process of configuring an instrument to provide a result for a sample within an acceptable range.
- **Freezer:** Storage area of -15°C to -25°C temperature
- **Logistic:** is part of supply chain management that plans, implements, and controls the efficient, effective forward and reverse flow and storage of goods, services, and related information between the point of origin and point of consumption to meet customers' requirements.
- **Probes:** Probes are instruments used to record temperature and humidity
- **Refrigerator** Storage area of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ temperature
- **Walk-in units:** Walk-ins are medium-term cold storage with standard refrigerators acting as short-term storage and refrigerated warehouses acting as long-term storage. Just like any refrigeration system, walk-ins use an evaporator inside the unit and a condenser outside the unit to move heat outside, thus cooling the inside.
- **Temperature Excursion:** Temperature excursion is an excursion event in which time and temperature-sensitive products are exposed to temperatures outside the

range(s) prescribed for storage and/or transport. This temperature range may be the same or different which is determined by the manufacturer, based on stability data.

1.6. Significance of the Study

The world's pharmaceutical cold chain logistics industry isn't similar to other logistics markets. It's large and complex with the majority of the cargo being life-saving. It has a value of around \$73bn, the sector of cold chain logistics requires coordinated handling procedures, specific transport equipment, and great requirement of regulatory compliance. Moreover, it's continuing to grow the demand for all kinds of drugs that help to fight an increasing number of chronic and lifestyle-related diseases (VRR, 2020)

As our list of common and rare diseases increases, so do our anticipation for remedies and therapies. The pharmaceutical sector is growing to the challenge by providing us with a wide range of pharmaceuticals, a large portion of them requiring temperature-monitored transportation under the umbrella of proper cold chain management. With a large array of pharmaceuticals circulating the world, for instance, the current distribution of the COVID-19 vaccine, the pharmaceutical cold chain is an interesting logistics sector (VRR, 2020).

This study is important for EPSS to strengthen its cold chain logistics due to increased demand for temperature-sensitive pharmaceuticals by the health sector and to satisfy its customers' needs. Robust cold chain logistics of EPSS are also important for academia for training students during internship programs and research areas for specialization since it serves as a training center for students. For policymakers like MOH and EFDA cold chain logistics are important as a strategic plan in public health issues and to strengthen the cold chain logistics of EPSS since it is the major supplier of pharmaceuticals in the country.

1.7. Scope of the Study

The study is limited to EPSS central and EPSS Addis Ababa branch no-2 which are found in Addis Ababa Gullele sub city around St Paul Millennium Medical College and Bole sub city around Jacros respectively. The reason for selection of EPSS central for this study is, it is a major supplier and distributor of majority of pharmaceuticals in the country so it needs attention and its cold chain management should be assessed. EPSS Addis Ababa no 2 is selected for this study because it is a new branch inaugurated in October 2017 and there is no study done in this hub previously regarding cold chain

management. The research will not include health institutions, i.e. hospitals and health centers, and direct-to-patient logistics. The study will focus on cold chain logistics parameters like storage, transportation, packaging & distribution of cold chain Pharmaceuticals. The study will include Pharmacists and Druggists working in EPSS central, and EPSS Addis Ababa no 2.

1.8. Limitations of the study

This study had not addressed cold chain logistics of pharmaceuticals at health facilities and patient side; in addition, the research is limited to Ethiopian Pharmaceutical Supply Services and EPSS Addis Ababa branch No 2, this is due to time and resource limitations. But to find more challenges and get a complete conclusion at the country level, a deep investigation of cold chain logistics of all EPSS branches will be required because this study covered small sample size which has impact on the generalizability of the result. Moreover this study used cross-sectional study design it is at certain point of study period and doesn't show long term practice. Finally, the factors that affect cold chain logistics presented in this study are only part of the potentially relevant variables that might have been incorporated in to the cold chain logistics study. Due attention also must be given to other variables that affect cold chain logistics of pharmaceuticals, and therefore it is important to consider that the results of this study can only be utilized for reference or comparison not to generalize.

1.9. Organizations of the paper

This study is organized into five chapters: Chapter one contains background of the study, statement of the problem, basic research questions, objective of the study, definition of terms, significance of the study, delimitation/scope of the study and limitation of the study. The second chapter deals with the literatures relevant to the study and conceptual frame work adapted from previous studies. Under the third chapter, the methodology and design of the research, the subjects/participants of the study, the sources of data, the data collection tools, the procedures of data collection, and the methods of data analysis used are described. Chapter four summarizes the results/findings of the study and interprets and/or discusses the findings. Finally chapter five comprises four sections, which includes summary of findings, conclusions, recommendations and suggestions for future study.

CHAPTER TWO: REVIEW OF RELATED LITERATURE

2.1. Theoretical Literature Review

2.1.1 Supply Chain

In its most inception form, a supply chain is the series of events and procedures that transport a product from dirt to dirt, sometimes literally. It refers to various activities that have presented since the birth of business (Blanchard, 2021). Blanchard (2021), in other terms, asserts that a supply chain goes from the initial supplier or source to the final client/consumer. According to Izikki et al. (2021), a supply chain is a network that connects a corporation with its suppliers to manufacture and deliver a specific product to the consumer. Various activities, individuals, organizations, data, and assets are all part of this network. This indicates that the supply chain comprises all the stages of getting a product or service from its initial condition (manufacturer) to its final destination (consumer). According to Izikki et al. (2021), supply chains are now complex due to demanding customers need regarding quality, time, and sustainability as the industrial and business world continuously undergoes tremendous changes and faces new difficulties. Supply chain management was coined in the early 1980s, when transportation, distribution, and materials management merged into a single term (Blanchard, 2021). It was conceived by Keith Oliver, a Booz Allen consultant, and first appeared in print in 1982. The book *Competitive Advantage*, by Harvard professor Michael Porter, was published in 1985 and explained how a company might become more successful by carefully analyzing the five primary processes that make up its supply chain.

1. Inbound logistics: This refers to the actions involved in receiving, storing, and dispersing product inputs (material handling, warehousing, inventory control, transportation scheduling, and returns to suppliers).
2. Operations: This refers to the actions involved in changing raw materials into finished goods (machining, packaging, assembly, equipment maintenance, testing, printing, and facility operations).
3. Outbound logistics: These are the actions involved in gathering, storing, and physically distributing commodities to customers (finished goods warehousing, material handling, freight delivery, order processing, and scheduling).

4. Sales and marketing: In the context of a supply chain, these tasks help and enable purchasers to acquire a product (advertising, promotions, sales force, quoting, channel selection, channel relations, and pricing).

5. Service: This refers to the activities involved in delivering service to improve or keep the product's value (installation, repair, training, parts supply, and product adjustment)

2.1.2. The Cold Chain

Cold chains consist of several components that usually comprise at least pre cooling, cold storage, and refrigerated transport. For the medical sector, the cold chain is typically important for the transportation and storage of temperature-sensitive health commodities that include but are not limited to vaccines, blood products, and a range of medicines that support common health services. These commodities are usually handled by medical staff logisticians in the cold chain and at the point of delivery but may also involve consumers if and when these products are to be taken home and kept cool for use over time. (Analytics et al., 2020). For instance, Vaccines are highly thermosensitive biological substances which have a limited shelf-life and lose potency over time. The loss of potency is irreversible and accelerated if proper storage and temperature conditions are not kept. A vaccine vial must be kept between 2 and 8 degrees Celsius throughout the entire cold chain system which is when it is transported, when it is stored in a refrigerator or cold store, and when it is used at an immunization session. Although many sensitive drugs fall into the nominal 2-8 degrees temperature band others need very specific storage conditions and these conditions must be kept until the point of administration. The HPV vaccine for instance, can withstand higher temperatures but is extremely sensitive to freezing and cold conditions. (World Health Organization 2010)

2.1.2. Cold Storage

2.1.2.1. Temperature Controlled Storage

Temperature controlled storage should ensure that TTSPPs are stored in temperature controlled rooms, cold rooms, freezer rooms, refrigerators, and freezers that comply with the following requirement; Temperature-controlled rooms, cold rooms, and freezer rooms. This requirement must be capable of keeping the temperature range indicated by the system set points over the full annual room temperature range faced at the store location. The rooms must also be equipped with an auto-defrost circuit which has a

minimal effect on the temperature within the unit during the defrost cycle and keeps the temperature within specification for this period. In addition, the cold rooms must be equipped with a low-temperature protection circuit in cold climates where there is a risk of breaching the low-temperature set point for TTSPPs that are damaged by exposure to low temperatures. To protect against power interruption the cold rooms must be connected to a UPS. The cold rooms also must be equipped with a calibrated continuous temperature controlling system with sensors located at points representing the greatest temperature variability and temperature extremes. Moreover, the cold rooms must also be equipped with continuous humidity monitoring devices with sensors located at points representing humidity extremes. Finally, the cold rooms must be equipped with alarms to indicate temperature excursions and/or refrigeration failure, fitted with lockable doors, or an access control system, as necessary and locks must have a safety device so that doors can be freely opened from the inside (Ziehr, 2011).

Refrigerators and freezers must be purpose designed for the storage of TTSPPs Capable of keeping the temperature range specified by the TTSPP manufacturer over the full annual room temperature range faced at the storage site. In addition, Refrigerators must be equipped with calibrated temperature-controlling equipment appropriate to the level of risk but preferably capable of continuous recording and with sensor(s) located at a point or points within the cabinet that most accurately represents the temperature profile of the equipment during normal operation. Finally, Refrigerators must be preferably equipped with alarms to indicate temperature excursions or refrigeration failure and fitted with lockable doors or lids, or an access control system, as necessary the reason for this is to keep labeled TTSPP storage temperatures during long-term storage (Ziehr, 2011).

2.1.2.2. Temperature Monitoring

Maintaining pharmaceuticals and vaccines at the recommended temperature is called maintaining the cold chain. The cold chain starts at the manufacturer, extends to the distributor, and continues in the provider site until it is administered (Anonymous, n.d.) Proper cold chain temperature must be kept during transit and at every link in the chain to ensure its viability. For instance, Vaccine cold chain failure occurs when there is a break in any link of the chain. Cold chain failure may happen due to a power failure, staff error, equipment failure, etc. Preventing cold chain failure requires: properly

functioning equipment, properly trained staff, clearly written procedures, and easily accessible emergency operating protocols (Anonymous, n.d.). Temperature Monitoring is a critical part of good storage and management practice and it is important to undergo periodic calibration testing. Testing must be performed every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline. CDC recommends that testing meets standards defined in the Vaccine Storage and management Toolkit. If calibration testing indicates that the temperature monitoring equipment is no longer accurate, it must be replaced (CDC, 2014).

2.1.2.3. Dispatch and Transportation of Cold Chain Pharmaceuticals

Materials and pharmaceutical products must be transported in such a way that their integrity is not impaired and that storage conditions are kept. Special care must be exercised when using dry ice in cold chains. In addition, observing safety precautions it should be ensured that the materials or product does not come in into contact with dry ice, as this may adversely affect the product quality, e.g. by freezing. Where appropriate, the use of devices to control conditions such as temperature during the transportation is recommended. Monitoring records must be available for review. The dispatch and transport of materials and pharmaceutical products must be carried out only after receipt of a delivery order. The receipt of the delivery order and the dispatch of the goods should be documented. Dispatch procedures must be established and documented, taking into account the nature of the materials and pharmaceutical products concerned and any special precautions that might be needed. The outside container must offer adequate protection from all external influences and must be indelibly and clearly labeled. Records for dispatch must be retained, stating at least: a) the date of dispatch; b) the customer's name and address; c) the product description, e.g. name, dosage form, and strength (if appropriate), batch number, and quantity; d) the transport and storage conditions. All records must be readily accessible and available on request (Rd and Lanka, 2019).

2.1.2.4. Packaging of Cold Chain Pharmaceuticals

To keep the given temperature, which is usually below room temperature, storage and packaging during distribution become crucial. As transport modes change, they should be designed to keep the temperature regardless of outside temperature and against its effects. Various materials and technologies are being used today to assure the optimal

shelf life of the products dry ice, gel packs, liquid nitrogen, reefer containers, etc., used according to temperature standards. Common standards would be "banana" (13 °C), "chill" (2 °C), "frozen" (-18 °C), and "deep frozen" (-29 °C) (Rodrigue,2013).Different products will be using different cooling materials and packaging accordingly; usually gel packs for cooling, liquid nitrogen for frozen, and reefer containers for longer distances. Usually, these cooling materials cannot be stacked up for long periods in warehouses. Therefore, information must be shared throughout the chain, to prepare ahead of cooling materials as well as boxes and containers for its seamless movements. After the pre-conditioned settings to adapt its cargo is done, and then the cargo may be set to depart to its destinations. One of the major issues with cold chain movements is that shipments using cooling materials can keep the temperature cool enough for a limited period which is usually not so long. And it does not yet contain the controlling ability to keep its setting temperature range by itself in general, which requires more developments in technology. In other words, it can go below the set temperature as well as above the temperature, which both are deviations of the temperature range. The other problem could occur during storage; storing cooling packages, in boxes and containers, in cool storage rooms. If the cooling materials are still in function, then the packages must not be kept in cooling storage rooms whereas if it is no longer functioning then must be kept in cooling storage rooms at setting temperature; different procedures are required under different circumstances as they cannot adapt to changing conditions. Also, as containers for air transport are rather thin, products can be easily affected by the outside temperature, therefore requires careful controlling regarding cooling materials and replacements whenever needed (Yuri, 2014).

Meanwhile, a cold chain needs close monitoring of its temperature change thus it is usually recorded either manually at each stage or automatically by a data logger throughout the chain. However, monitoring at this stage is not meaningful, since there is no integrated system covering the whole chain. And even if the temperature deviation is found, many of the standard procedures today cannot fix the problem on a real-time basis. In addition, consumers usually cannot detect interruptions. The key point of the cold chain would be maintaining its given temperature, and over the years this field has been showing a lot of changes, yet it is still fragile in some ways. More technology developments and important training for people to establish stable cold chains,

especially for high-value products such as pharmaceuticals, must be anticipated in near future (Yuri, 2014).

2.1.2.5. Training

One of the key supply chain elements as per GAVI's immunization supply chain management is the people and practice aspect. This includes establishing human resource policies, education programs, and training and supervision systems to ensure that leaders and professionals with strong supply chain management capabilities are in place to manage distribution and supply chain performance (GAVI, 2014).

All personnel who manage deliver or receive vaccine shipments and anyone who has access to the unit(s) where vaccines are stored need to have the proper knowledge on vaccines. Vaccine storage and management training must be given to all new personnel who manage or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and management guidelines for a particular vaccine. It is mandatory to familiarize the storage and management of vaccines for all institutions involved on immunization supply chain activities (GAVI, 2014).

2.1.2.6. Importance of Cold Chain Logistics of Pharmaceuticals

Temperature-controlled movement of pharmaceuticals and medical supplies is a modern transit option for the shipping of frozen food. Over the past fifty years logistical third-party companies, such as World Courier in 1969 and Cavalier in 1986 began to emerge and institute new methods for successfully transporting these global commodities. Before their arrival, cold chain processes were mostly managed in-house by the manufacturer (De Palma, 2007). FDA restrictions and accountability measures over the stability of the cold chain forced many of these companies to rely on specialty couriers rather than completely overhauling their supply chain facilities (De Palma and Angelo, 2007). The value of the cold chain in the preservation of expensive vaccines and medical supplies was only beginning to be recognized when these logistical providers started to appear.

In today's global market, reliance on the cold chain continues to gain importance; much as it has been over the past century. Within the pharmaceutical industry, for instance, the testing, production, and movement of drugs rely heavily on controlled and

uncompromised transfer of shipments. A large portion of the pharmaceutical products that move along the cold chain is in the experiment or developmental phase. Clinical research and trials are a major part of the industry that costs millions of dollars, but one that also experiences a failure rate of around 80% (Quinn, 2006). According to the Healthcare Distribution Management Association, of the close to 200 billion dollars in pharmaceutical distribution, about 10% are drugs that are temperature sensitive (Quinn, 2006).

This makes the cold chain responsible for transporting a nearly 20-billion-dollar investment. If these shipments should experience any unanticipated exposure to variant temperature levels, they run the risk of becoming ineffective or even harmful to patients. If we are going to spend all this money developing drugs, we want to get them to the customer so they are effective and safe”, is what package and product testing company DDL West’s technical director Karen Greene told Pharmaceutical Commerce (Heinze, 2007)

2.2. Empirical Literature Review

2.2.1. Cold Chain Pharmaceuticals Supply in Ethiopia

Cold chain pharmaceuticals supply in Ethiopia is performed by Ethiopian Pharmaceutical Services (EPSS) for program items. EPSS distributes cold chain pharmaceuticals from its central stores and branches to health facilities. Health facilities transport cold chain pharmaceuticals by their own vehicles for budget items when they procure from EPSS. Private pharmaceutical suppliers also supply cold chain pharmaceuticals from their warehouses to health facilities when these facilities procure pharmaceuticals from these suppliers.

The policy decision of Ethiopia in 2013 to transfer responsibility for a vaccine supply chain to Pharmaceuticals Supply Services (PSS) from the Ethiopian Federal Ministry of Health (TechNet conference, 2015), a Federal agency responsible for the distribution of essential medicines and most other health commodities. The Ethiopian Existing Country Context for Vaccine Distribution Cold Chain system for vaccines and other cold storage requiring health commodities consists of five levels, following the FMOH administrative structure.

2.2.2. Challenges in Cold Chain Logistics of Pharmaceuticals

There are 80 million shipments of life sciences Cold Chain products supplied on a global basis annually, broken into the following areas: Vaccines and injectables, high-value biologicals Blood products including whole, blood, plasma, and platelets, Diagnostic products including reagents and test kits, Veterinary products Medical devices

Statistical data related to Cold Chain, as a percentage of life sciences distribution, is difficult to find, as sometimes the product is Cold Chain sensitive at different periods in the lifecycle. For instance, the materials used in R&D and clinical trials are normally temperature sensitive, but the approved and manufactured products can differ in requirements based on the dispensing form. One thing that is clear however is that biologicals are becoming more widespread and the related percentage of Cold Chain needs is growing (Reed, 2005).

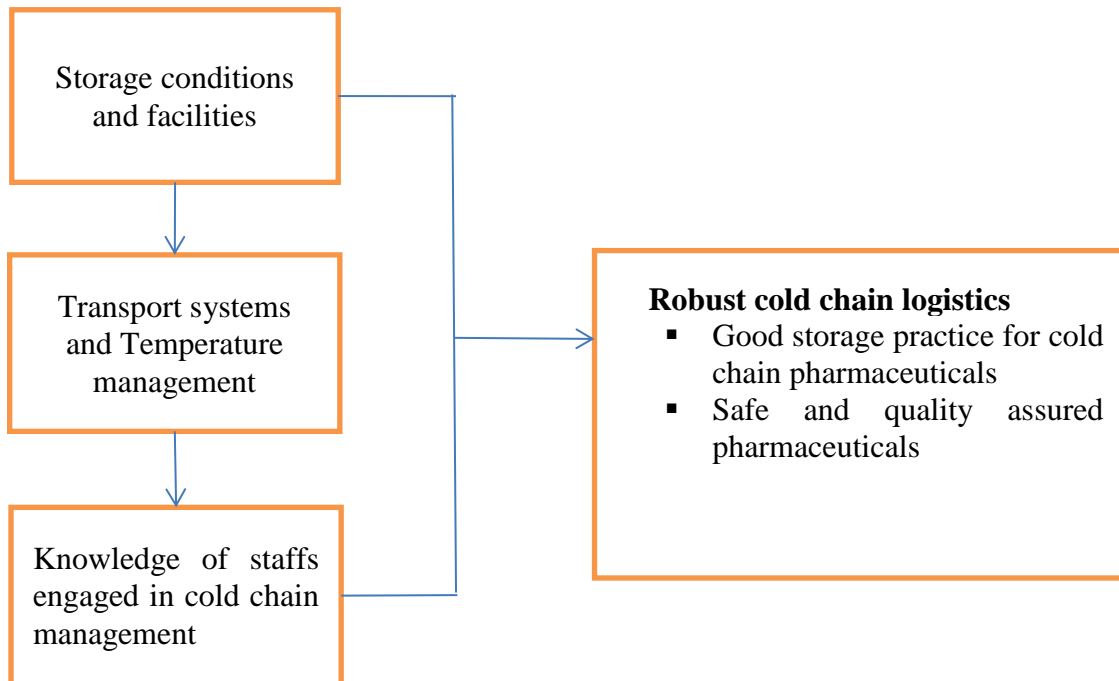
In the case of the pharmaceutical industry, every drug has stability data that dictates its required temperature storage range. The FDA requires that these products be stored under appropriate temperatures so that their identity, strength, quality, effectiveness, and purity are not affected. Though, many variables influence temperatures within a facility, including airflow, facility layout, traffic patterns, and seasonal extremes (Reed, 2005).

In the case of Ethiopia, pharmaceutical distributors like EPSS have the following challenges; insufficient storage area for storing temperature-sensitive pharmaceuticals, lack of cold chain equipment, few cold vans for transporting these pharmaceuticals, and lack of training for staff working on the cold chain at EPSS.(Tefamichael,2018).

2.3. Identified Literature Gap

From the above reviewed literature, EPSS has the following cold chain logistics gaps which are storage conditions and facilities are not up to standard, Lack of cold chain vehicles, insufficient storage area for temperature-sensitive pharmaceuticals, poor record keeping, and lack of knowledge among staffs working on the cold chain are identified. The above gaps were assessed and recommendations were given.

2.4. Conceptual Framework



Independent variables

Dependent variable

Figure 1: Conceptual Framework (Monicah, 2015).

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

4.1. Study Area

The current Ethiopian Pharmaceuticals Supply Services previously EPHARMECOR, PHARMED, PFSA, and EPSA were first inaugurated in 1947 with a capital of 80 million birrs by the name “the main Pharmacy.” The military regime then reorganized “the main Pharmacy” in 1976.

EPSS’s Head Office located in Addis Ababa organizes the activities of the nineteen branches. It is the core center of pharmaceutical affairs in the country, EPSS CENTRAL procures and distributes pharmaceuticals, medical supplies, medical equipment, and laboratory reagents from local and international manufacturers to its nineteen hubs that in turn reach over 4,000 medical facilities located in all parts of the country. The Head Office also manages contracts with various local and international companies (EPSA, 2020).

The Central Cluster comprises Addis Ababa 1 and 2 branches. Addis Ababa 1 serves seven sub-cities in the capital: AkakiKaliti, Nifas Silk Lafto, Kirkos, Kolfe, Lideta, Addis Ketema, and Arada. It also serves Western Shoa, South Western Shoa, and some surrounding areas of Finfine from the Oromia region. From the Southern Nations, Nationalities, and Peoples’ region, the branch serves the Gurage zone entirely, Hosana town of Hadiya zone, and two woredas of the Silte zone: Mugo and Lera. Addis Ababa 2, on the other hand, serves Gulele, Bole, and Yeka sub-cities in Addis while it covers the Northern Shoa zone of Amhara region partially, the Northern Shoa of Oromia zone entirely and surrounding areas of Finfine partially. The cluster sustainably provides program pharmaceuticals (those for HIV, TB, Malaria, and family planning) and RDF pharmaceuticals (EPSA, 2020).

4.2. Study Design and Study Period

A cross-sectional study design, deploying cross-sectional data and using quantitative data collection techniques was used to collect the required data from Dec 31, 2021, to Feb 28, 2023.

4.3. Population and Sampling Techniques

The populations of the study were Ethiopian pharmaceutical supply service central, and EPSS Addis Ababa branch no-2 warehouse managers, officers, supervisors, and cold

van drivers of the organizations. A non-probabilistic sampling technique, specifically purposive or convenience sampling, was used to select the target population. Purposive sampling was preferred in the selection of samples in the Ethiopian Pharmaceutical Supply Service since it allows for the selection of unique cases which are staffs working on storage and distribution directorate that are particularly informative. According to the data obtained from Ethiopian Pharmaceutical Supply Service and EPSS Addis Ababa branch no-2 in 2013 E.C. There are a total of 247 employees in Storage (WIM) and Distribution Directorate of the organization out of this 95 are health professionals.

4.4. Data Collection Instrument

The main tool for data collection was close-ended questionnaires. A questionnaire is a method of study data collection with printed questions that are purposely designed and structured to gather information from respondents. The study used a structured questionnaire with close-ended questions standardized to allow comparison (Makuru, 2012). The questionnaires contained relevant questions which are designed with the objectives of the study in mind. The questionnaires were distributed to all sampled respondents across different categories, and investigated perceptions and feelings, general experiences, as well as knowledge and general information on the subject under study. The questionnaire was adapted from (Tesfamichael, 2018).

4.5. Data Collection Procedure

The research data was collected from primary sources through questionnaires which are adopted from (Tesfamichael, 2018) and secondary data was organizational records, and information collected from the organization's directorates. The questionnaires were self-administered to the sampled respondents. Permission to conduct the research and an authorization letter was received from the University before administering the questionnaires and the investigator sent it to the selected organization for introduction and also gave written approval to conduct the study confidentially for academic purpose only.

4.6. Data Analysis and Presentation

Both descriptive and inferential statistics were used to analyze the data. The data collected through questionnaires were coded and entered into the Statistical Package for Social Science (SPSS V-24) for analysis of quantitative data. Analyzed data was presented using Tables, graphs, and charts.

4.7. Inclusion and Exclusion Criteria

4.7.1. Inclusion Criteria

The inclusion criteria for this study are pharmacists, Druggists, and other health professionals working in the storage and distribution directorate of EPSS central and EPSS Addis Ababa no 2.

4.7.2. Exclusion Criteria

Health institutions and patient side cold storage is not included in this study

4.8. Ethical Considerations

Before conducting the study, ethical clearance was granted from the ethical committee of the School of Pharmacy Addis Ababa University College of health sciences. During data collection, the researcher told the respondents the purpose, scope, and expected outcome of the study. All data were anonymous; no individual or facility was identified in any reports or any publication based on this study

4.9. Validity Test

About 5% of the questioner were distributed to cold chain store managers and pretest was done prior to study and some of the questions on the questioner was amended as validity test.

CHAPTER FOUR: PRESENTATION, ANALYSIS, AND INTERPRETATION OF DATA

In this study of the selected 73 warehouse managers, storage and distribution officers, and supervisors 69 (94.5%) participated in this study. Four individuals had not returned the disseminated questionnaire. The majority (73.9%) of the respondents were males (39.1%) and between 25-30 years of age. About (36.2%) of the cold chain store supervisors had worked for 1-5 years (Table 1).

Table 1: Sociodemographic variables of respondents in EPSS December2022.

S no	Variable		Frequency	Percentage
1	Gender	Male	51	73.9
		Female	18	26.1
2	Age	18-24	7	10.1
		25-30	27	39.1
		31-36	23	33.3
		Above 36	12	17.4
3	Experience	Less than 1	23	33.3
		1 to 5	25	36.3
		6 to 10	13	18.8
		11 to 15	8	11.6
4	Professional in charge	Pharmacist	60	87.0
		Pharmacy technician	6	8.7
		Clinical officer	1	1.4
		Others	2	2.9

4.1. Factors that Lead to a Fault in Storage Condition at Your Facility

Respondents were asked questions about the factors that lead to fault for storage conditions at the center and branch. Respondents pointed out several factors which are shown in figure 5 below, majority about (30.43%) pointed all factors are the cause for fault in storage condition at facility about(21.74%)mentioned lack of space as the fault for storage conditions, and lack of knowledge was mentioned by only (8.70%) of the respondents as results are summarized in figure 2 below

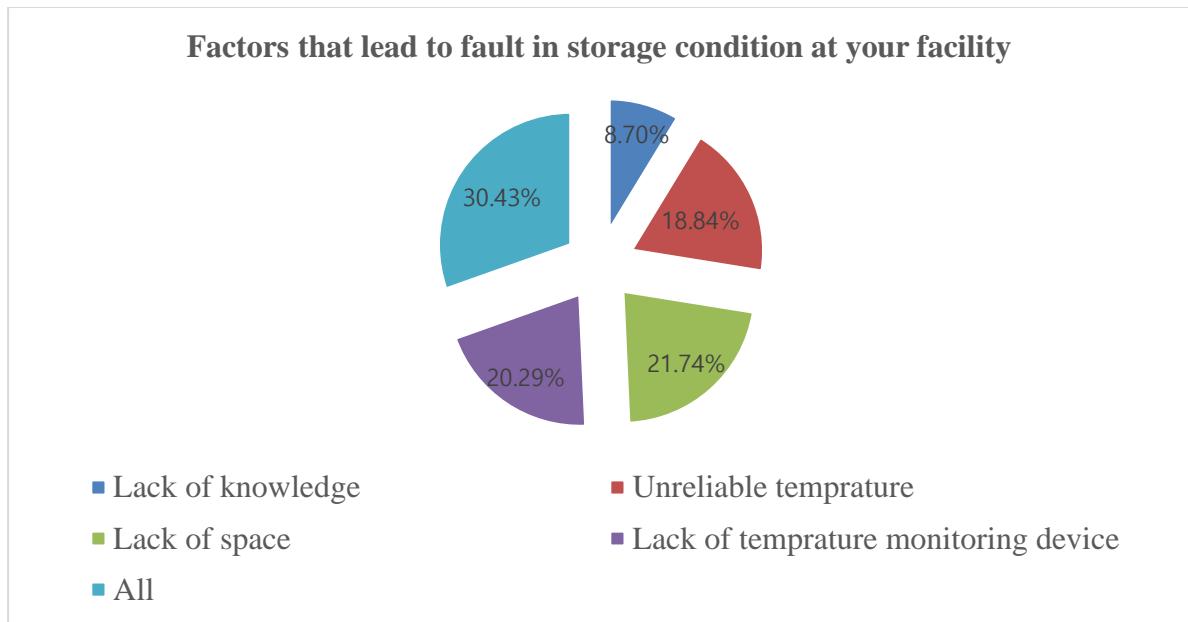


Figure 2: Respondent's response for factors that lead to a fault in storage condition in EPSS December 2021

4.2. Availability of EPI Guidelines for Vaccine Management

The respondents were assessed on the presence of EPI Guidelines for vaccine management which is a very important tool for health professionals engaged in daily vaccine store management transactions and immunization sessions, the results of which are summarized in figure 3 below.

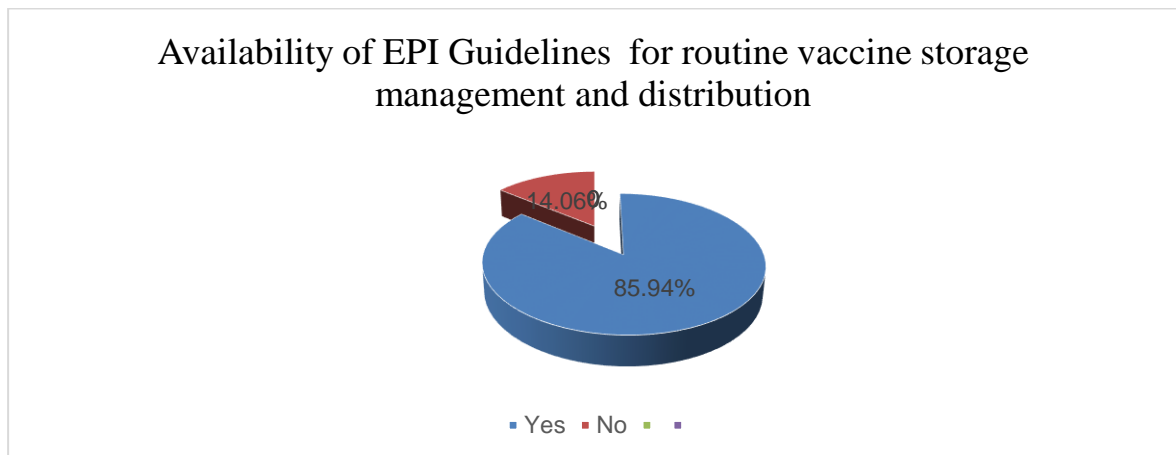


Figure 3: Above depicts that a higher proportion (85.94%) of contacted respondents had EPI Guidelines for vaccine management.

4.3. Methods Regularly Used to Transport Cold Chain Pharmaceuticals at EPSS

A greater proportion (94.3%) of respondents used cold chain vehicle and cold box to transport cold chain pharmaceuticals and few (5.7%) used cold box and vaccine carriers to transport cold chain pharmaceuticals to their branches and facilities (Figure 4).

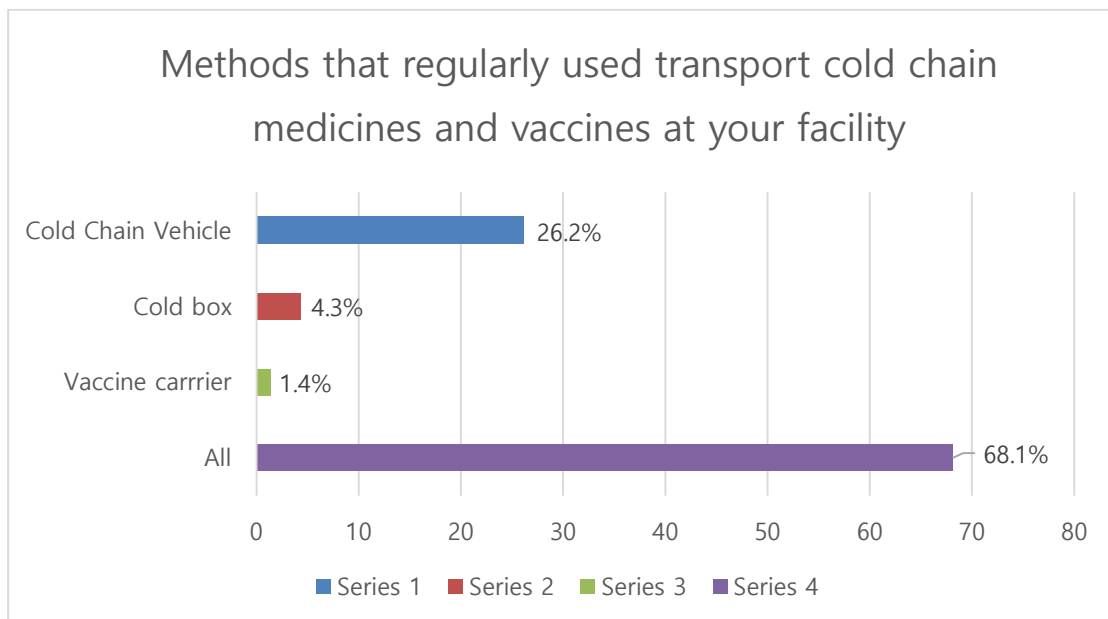


Figure 4: Means of transport used to transport cold chain pharmaceuticals and vaccines December 2021.

4.4. Barriers to Efficient Distribution System of Cold Chain Pharmaceuticals

A majority (44.90%) of respondents mentioned the shortage of cold chain transport vehicles as a barrier to an efficient distribution of cold chain pharmaceuticals and (20.29%) of respondents mentioned stock out of cold chain pharmaceuticals, absence of refill report,, lack of contingency distribution plan and shortage of cold chain vehicle are a barrier to efficient distribution (Figure 5).

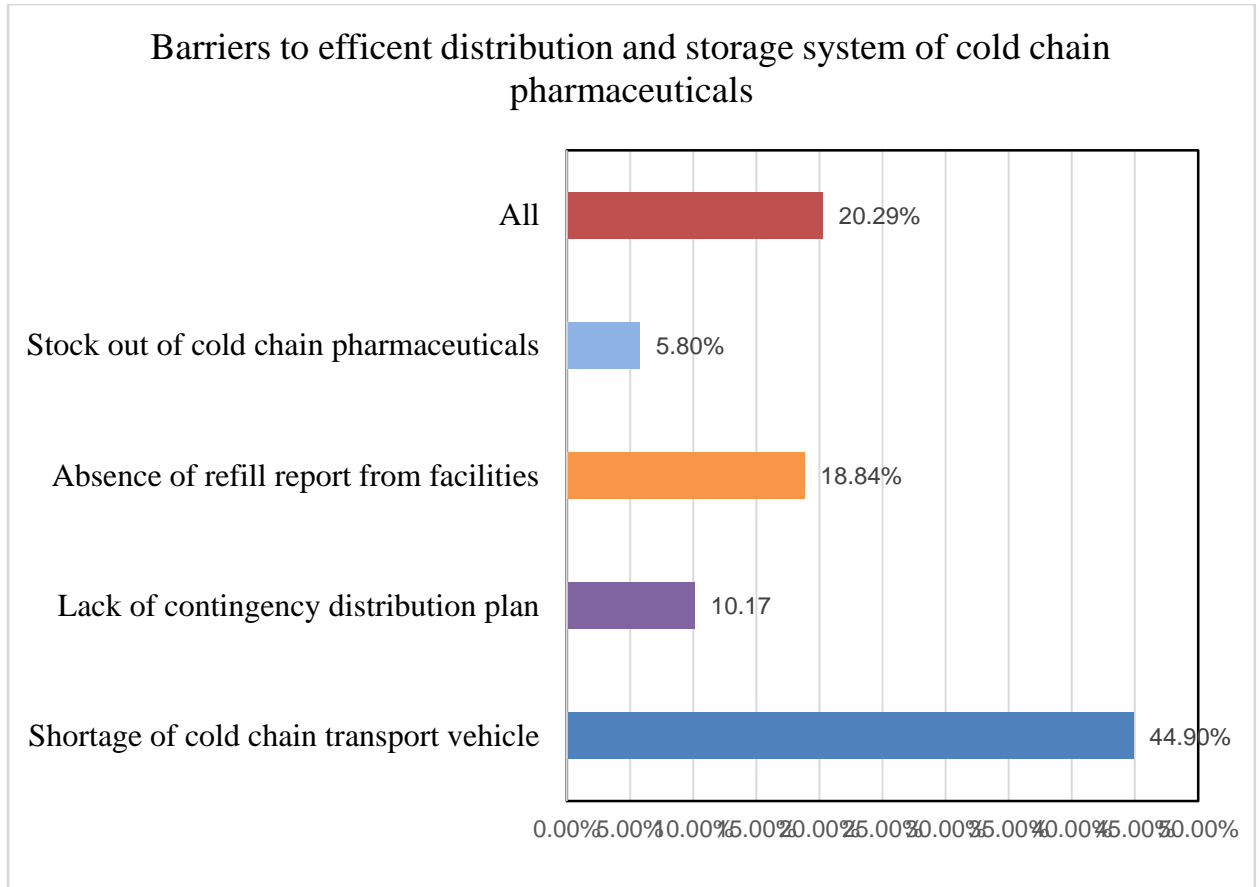


Figure 5: Barriers to an efficient distribution system of cold chain pharmaceuticals
December 2021

4.5. Knowledge Levels of Respondents on Recommended Temperature Range for Cold Chain Pharmaceuticals Stored in Refrigerators

The majority (94.2%) of respondents had the knowledge and some (5.8%) of respondents did not know the recommended temperature range of cold chain pharmaceuticals and vaccines stored in the refrigerator (figure 6).

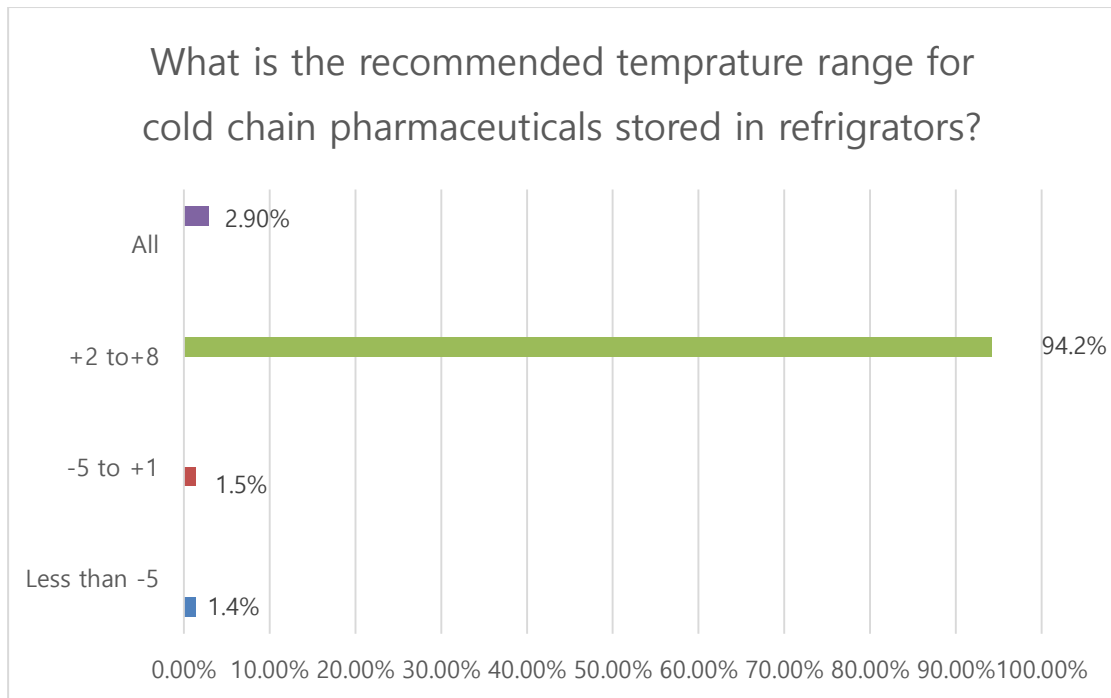


Figure 6: Respondent response for the recommended temperature range for cold chain pharmaceuticals stored in refrigerators in December 2021.

4.6. Knowledge Levels of Respondents on Recommended Temperature Range for Cold Chain Pharmaceuticals Stored in Freezers

Majority (50.72%) of the respondents knew recommended temperature range of cold chain pharmaceuticals stored in the freezer and almost half (49.28%) of the respondents had no knowledge of recommended temperature range for cold chain pharmaceuticals and vaccines stored in freezers.

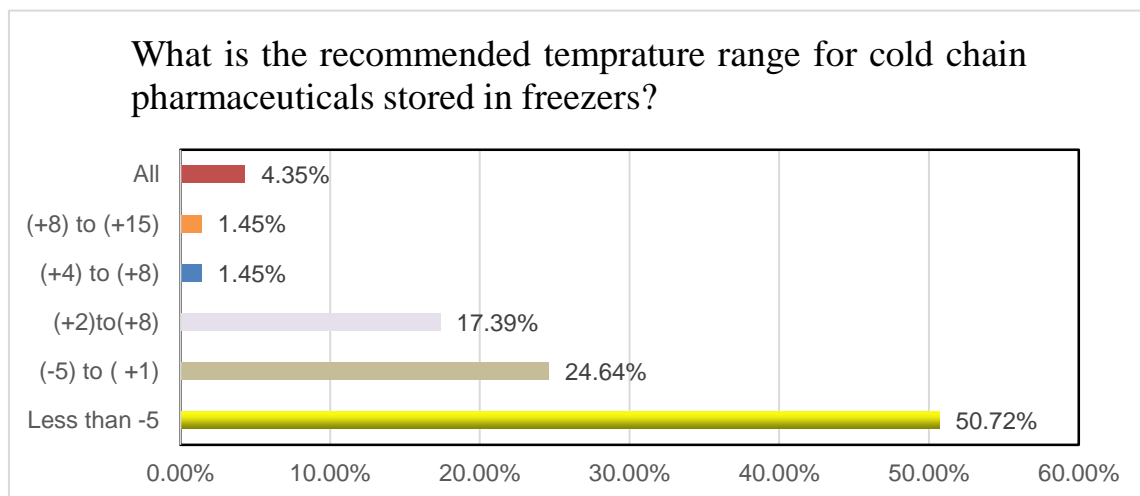


Figure 7: Respondent's response for the recommended temperature range for cold chain pharmaceuticals stored in freezers respondents in December 2021.

4.7. Records of Discarded Cold Chain Pharmaceuticals

From the respondents with regards to records of cold chain pharmaceuticals discarded due to incorrect storage temperature, the higher proportion of respondents (57.97%) said that there were no records and (42.03%) of the respondents said they kept records.

4.8. Response of Respondents to the Action Taken When Cold Chain Pharmaceuticals are Found out of Recommended Temperature Range

The action taken when cold chain pharmaceuticals are found out of recommended temperature range are summarized in table 2 below.

Table 2: Action is taken when cold chain pharmaceuticals are found out of recommended temperature range.

Action/Measure	Frequency	Percent
Continue stored in the cold chain for future use	7	10.1
Stop using and record in the book for all pharmaceuticals discarded due to incorrect storage temperature	18	26.1
Others (Transfer to the nearest facility or adjust the refrigerator)	7	10.1

From table 2 above a greater proportion (26.1%) of contacted respondents responded by saying stop using and record in the book for all pharmaceuticals discarded. About (10.1%) of respondents said continue storing in the cold chain for future use and 10.1 % of respondents responded using other mechanisms (transfer to the nearest facility or adjust refrigerator)

CHAPTER FIVE: SUMMARY OF MAJOR FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1. SUMMARY OF MAJOR FINDINGS

From this study, it is identified that storage conditions and facilities to store cold chain pharmaceuticals is one of the problem to ensure the safety of cold chain pharmaceuticals, this gap was also mentioned in the study done by Tesfamichael (2018). Proper storage is crucial to keep purity, potency, safety and effectiveness of cold chain pharmaceuticals.

There was lack of cold chain vehicles for the efficient transportation and distribution of cold chain pharmaceuticals at EPSS this problem was also mentioned by a study done by other researchers in 2018 and 2020. Due to the lack of cold chain vehicles most health facilities transport pharmaceuticals by their own vehicles which doesn't fulfill the temperature requirement for transportation of cold chain pharmaceuticals.

Regarding infrastructure and storage facilities lack of storage space or area was another challenge observed for the storage of cold chain pharmaceuticals at EPSS this problem was also mentioned in a study conducted by Temesgen (2020) and Tesfamichael (2018). Though some progress was seen in this area as EPSS built three cold chain warehouses at central in 2020 but still needs intervention since EPSS is a major supplier of pharmaceuticals to all health facilities in Ethiopia.

Regarding the availability of EPI Guidelines for vaccines, EPSS was very good in this area and this should be encouraged since guidelines are important for good storage and distribution practice.

Concerning warehouse equipment like cold boxes, freeze tags, data loggers and ice bags, EPSS was good in availing this equipment and should be encouraged. Warehouse equipment are important for temperature monitoring and management. Moreover, in this study, it was observed that cold chain management of vaccines and availability of EPI guidelines was good but had a gap in the cold chain management of other pharmaceuticals. This finding is in contrast with a study conducted in

Nigeria(Ogboghodo *et al.*, 2017) and consistent with study done in Cameroon (Jerome *et al.*,2013).

Even though most of EPSS staffs working on cold chain storage had a good knowledge on storage of cold chain pharmaceuticals there was knowledge gap among some of health professionals working in the storage and distribution directorate of EPSS regarding standard recommended storage temperature for cold chain pharmaceuticals. This gap should be filled by providing continuous training and capacity building to staffs working in this area this is also supported by study done in Rwanda in 2023(Tumwine *et al.*, 2023) .The ideal knowledge regarding cold chain storage of pharmaceuticals should be 100% because pharmaceuticals are lifesaving if not stored at appropriate temperature and condition they degrade and become ineffective and even hazardous.

Registration or data management for expired and disposed cold chain pharmaceuticals at EPSS central is poor this is also a problem since registration of expired and disposed pharmaceuticals is an indicator of good storage practice and is important to handle environmentally hazardous pharmaceutical products. Proper inventory record keeping is important for proper inventory management at all levels of EPSS. Inaccurate recording increases the risk of stock-outs, leaks, and expiry (H. Talafha, 2006). In this study it is found that there is improper stock recordkeeping, this result is congruent with findings from healthcare facilities of Dares Salaam and Jordan (H. Talafha, 2006) where stock out and inventory management problems were reflected by stock records' accuracy. Despite this numerical difference, the issue of inaccurate stock records is critical. Though the ideal target for this indicator is 100%, EPSS central and Addis Ababa hub no 2.were not performing well from the target perspective. Qualitative findings highlighted that increased workload was the primary cause for delay and subsequent forget in recording issues and receipts transactions as they become due.

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As discussed above cold chain logistics of pharmaceuticals comprises different logistic issues so due attention should be given to this area by authorities as pharmaceuticals are lifesaving and important to the public. All the above mentioned factors like; lack of storage space, lack of cold chain vehicles, lack of knowledge are the reasons for health facilities not being able to get quality assured cold chain pharmaceuticals.

5.2. CONCLUSIONS

Lack of storage space was the challenge observed at EPSS for storage cold chain pharmaceuticals. Record keeping for discarded cold chain pharmaceuticals at EPSS was poor. EPI Guidelines for vaccines were not 100% available at EPSS. Storage conditions and facilities are not satisfactory or best to ensure safety of cold chain pharmaceuticals. Knowledge gap was another challenge observed among some health professionals working in storage and storage and distribution directorate of EPSS regarding standard recommended storage temperature of cold chain pharmaceuticals. Lack of cold chain vehicles or vans for efficient distribution of cold chain pharmaceuticals at EPSS was observed. Cold chain logistics of pharmaceuticals is related with different factors which involve different stakeholders in cold chain pharmaceuticals supply like EPSS central, EPSS branches, Regional health bureaus, Ministry of health and Authorities.

5.3. RECOMMENDATIONS

The following are recommendations in response to the above problems that affect the cold chain management of pharmaceuticals depicted by the study.

Health professionals like Pharmacists and Pharmacy technicians engaged in cold chain pharmacists are experts in medicines once involved in pharmacy practice problems of

poor storage practices and storing pharmaceuticals out of recommended temperature can be monitored under his/her supervision so should perform responsibly for this job.

EPSS has to properly manage and expand the available warehouses and also build additional cold chain warehouses to avoid lack of storage space. EPSS has to improve its cold chain storage conditions and facilities by availing equipment like freeze tags and data loggers and ensuring their functionality for proper management of cold chain pharmaceuticals.

EPSS has to improve the record keeping of discarded cold chain pharmaceuticals for the safety of the public and to avoid the reuse of these pharmaceuticals.

EPSS has to increase the number of cold chain vehicles for efficient distribution and to keep the safety of cold chain pharmaceuticals.

EPSS has to train its staff in cold chain management of pharmaceuticals, especially staff working on storage and distribution directorate.

MOH of Ethiopia or stakeholders needs to support the storage practices of cold chain pharmaceuticals by providing on job training for the store man in charge and cold chain focal personnel to enhance their knowledge in the use of refrigerators and good storage practices of cold chain pharmaceuticals.

MOH of Ethiopia or Stakeholders should avail of EPI Guidelines at all levels of EPSS for effective management of vaccines.

Areas for Further Research

This study focused on cold chain pharmaceuticals logistics at EPSS central and EPSS Addis Ababa branch no 2. Further study should be conducted in health facilities of the country and patient-side cold chain storage to assess the degree of the problem.

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ANNEXES

**ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PHARMACY
DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY
HEALTH SUPPLY CHAIN MANAGEMENT (MSc)**

Questionnaire

Dear respondents, my name is Thewodros Lemessa, the purpose of this questionnaire is to gather data on the assessment of cold chain logistics of Pharmaceuticals: to fulfill the University's (Addis Ababa University) requirement set for awarding of a Master's Degree in Health supply chain Management. The study is purely for academic purposes and thus not affects you in any case. So, your genuine, frank, and timely response is vital for the success of the study. Therefore, I kindly request you to respond to each item of the question very carefully.

General Instructions

There is no need of writing your name

Where answer options are available please circle the appropriate answer for the part I and please tick (✓) the answer in part II.

Contact Address

If you have any queries, please do not hesitate to contact me and I am available at your Convenience at (Mobile: 09-11-33-74-17/0912675437 or e-mail: thewodros.lemessa@yahoo.com)

Thank you for sacrificing your precious time in advance!

Questionnaires are used to assess the Cold Chain logistics of Pharmaceuticals in Ethiopian Pharmaceutical Supply Agency Ethiopia, and EPSA Addis Ababa branch no- 2.

Code No.....

Name of the organization.....

1. Professional in-charge/coordinator/ focal person of the facility cold Chain or vaccine medicines store

- a) Pharmacist
- b) Pharmacy technician
- c) Medical doctor
- d) Clinical officer
- e) Environmental health officer
- f) Nursing officer/Nurse midwife
- g) Nurse Assistant
- h) Others (mention).....

2. Sex

- a) Male
- b) Female

3. Age (in years)

- a) 18-24
- b) 25-30
- c) 31- 36
- d) Above 36

4. Experience at work as the cold chain medicine store supervisor (in years)

- a) Less than 1
- b) 1 to 5
- c) 6 to 10
- d) 11 to 15 e) more than 15

5. What type of cold chain pharmaceuticals do you stock at EPSA?

- a) Vaccines
- b) Biologics
- c) Oncology treatments
- d)Some types of insulin and other medicines
- e) All

6. Have you ever attended training on storage, distribution, and handling procedures of Vaccines and cold chain medicines?

a) Yes (go to next Question)

b) No

7. How many times have you attended such a course within the last three years?

a) Once

b) Twice

c) Thrice

d) Not attended

8. What is the recommended temperature range for cold chain pharmaceuticals stored in refrigerators?

a) Less than -5°

b) -5° C to $+1^{\circ}$ C

c) $+2^{\circ}$ C to $+8^{\circ}$ C

d) $+8^{\circ}$ C to $+15^{\circ}$ C

f) $+4^{\circ}$ C to $+8^{\circ}$ C

g) All

9. What is recommended temperature range for most cold-chain pharmaceuticals stored in freezers?

a) Less than -5°

b) -5° C to $+1^{\circ}$ C

c) $+2^{\circ}$ C to $+8^{\circ}$ C

d) $+8^{\circ}$ C to $+15^{\circ}$ C

f) $+4^{\circ}$ C to $+8^{\circ}$ C

g) All

10. Does it happen that cold chain pharmaceuticals in refrigerators or freezers are not in recommended temperature range during storage?

a) Yes (if yes go to question 11)

b) No

11. If yes what measure or action you have taken when cold chain pharmaceuticals in stock storage were found out of recommended temperature range?

a) Continue storing in the cold chain for future use

b) Stop using and record in the book all pharmaceuticals discarded due to incorrect storage temperature.

c) Others.....

12) Is there any record of all pharmaceuticals discarded due to incorrect storage temperature?

a) Yes (if yes ask to see)

b) No

13. What do you think are the underlying factors that lead to a fault in storage conditions at your facility?

a) Lack of knowledge c) Lack of space

b) Unreliable temperature d) Lack of temperature monitoring device e) All

14. Explain in short how you handle cold chain medicines or vaccines from the point of arrival up to the Point of administration

a) Cold chain vehicles c) Cold box e) All

b) Ice pack d) Vaccine carrier

15. What reference material(s) is (are) available in your pharmacy store used as a reference during your practice?

a) EPI Guidelines for vaccine management c) Good Dispensing Manual

b) Martindale d) Good storage and distribution practice e) all f) others (mention)

16. If you have the Expanded Program of Immunization (EPI) Guidelines for Safe vaccine management, have you ever gone through it to find out proper ways of storing and handling vaccine medicines at your facility up to the point of administration?

a) Yes (if yes go to next question) b) No

17. Did you find the EPI Guidelines fit for routine vaccine storage management and distribution?

a) Yes

b) No (if No) state/mention any deficiencies that you think should be rectified to smoothen the distribution system and handling procedures:

18. How often do you distribute cold chain pharmaceuticals to branches?

a) Once monthly

b) Twice a year

c) Quarterly a year

d) When necessary (no specified period)

19. List all the methods that you regularly use to transport cold chain medicines and vaccines at your facility

a) Cold chain vehicle c) vaccine carrier

b) Cold box d) all

20. How do you determine your cold chain stock position at your facility?
- a) By determining only safety stock
 - b) By determining only maximum stock level e)b&c
 - c) By determining only, the minimum stock level
 - d) By determining the sum of stock on hand (working & safety stock) and stock on order, minus any stock-back ordered to clients.
21. When do you say the cold chain pharmaceutical stock is at a maximum stock level?
- a) When stock is at re-order level c) When you have safety stock
 - b) When the stock is sufficient to satisfy demand until the next order d) when there is overstock
22. When do you say the cold chain pharmaceutical stock is at the minimum stock level?
- a) When stock is at the Re-order level
 - b) When the stock is sufficient to satisfy demand until the next order
 - c) When you have safety stock
 - d) When there is stock out
23. When do you say the cold chain pharmaceutical stock is at the safety stock level?
- a) When you have cold chain pharmaceutical maximum stock
 - b) When you have cold chain pharmaceutical minimum stock
 - c) When you have cold chain pharmaceutical stock on hand to prevent stock out cold chain pharmaceutical
 - d) When you have cold chain pharmaceutical emergency stock
24. What do you put into consideration when you need to prepare the order at your facility?
- a) Quantity used since the last delivery
 - b) Storage volume within the refrigerator
 - c) Cold chain pharmaceuticals currently in the refrigerator
 - d) Disease outbreak f)All
 - e) Seasonal variation g) OTHERS.....
25. In your own opinion, what do you think are the barriers to efficient distribution and storage systems of cold chain pharmaceuticals?
- a) Shortage of cold chain transport vehicles c) Absence of refill report from facilities
 - b) Lack of contingency distribution plan d) Stock out of cold chain pharmaceutical e)All

26. Do you think you need more professional training on cold chain pharmaceutical distribution and its management to strengthen your pharmaceutical management skills on the cold chain at your facility?

a) Yes

b) No

If yes, mention a few areas that you need more exposure through job training

27. What do you finally recommend to the EPSA on storage and distribution?

a) Appropriate and enough cold chain storage space c) Trained pharmacy professionals on cold chain pharmaceuticals management

b) Enough cold chain vehicles d) All