Addis Ababa University School of Commerce
Department Of Logistics and Supply Chain Management
Graduate program

Factors Affecting Supply Chain Management of Vaccines: The Case of Pharmaceuticals Fund and Supply Agency, Ethiopia

A Thesis submitted

For Partial Fulfillment of the Requirements for Master of Arts

in Logistics and Supply Chain Management

By: Tesfamichael Bayeh

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ADDIS ABABA UNIVERSITY
SCHOOL OF COMMERCE

Graduate Program in Logistics and Supply Chain Management

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By: Tesfamichael Bayeh

Approved by a board of Examiners and Advisor:

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Examiner	**Signature**	**Date**

Declaration

I, Tesfamichael Bayeh declare that this thesis is a result of my independent research work on the topic entitled “Factors Affecting Supply Chain Management of Vaccine The Case Pharmaceuticals Fund and Supply Agency, Ethiopia.” in partial fulfillment of the requirements for the Degree of Masters of Art in Logistics and Supply Chain Management at Addis Ababa University School of commerce. This work is original in nature and has not been presented for a degree in any other University. All the references are also duly acknowledged.

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Date_____

Confirmation

This is to certify that Tesfamichael Bayeh has carried out this thesis on the topic Entitled "Factors affecting Supply Chain Management of Vaccines in the case of Pharmaceuticals Fund and Supply Agency ,Ethiopia." under my supervision. Accordingly, I here assure that his work is appropriate and standard to be submitted for the partial fulfillment of the requirements for the award of the degree of Masters of Art in Logistics and Supply Chain Management.

Berhanu Denu (PhD)

Signature_____

Date _____

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Acronyms & Abberviations

BCG	Bacille Calmette Guerin
DTP	Diphtheria Tetanus Pertussis
EPI	Expanded Program on Immunization
FMHACA	Food, Medicine and Healthcare Regulatory Authority
FMOH	Federal Ministry of Health
HepB	Hepatitis B
Hib	Haemophilus influenza
HPV	Human Papilloma Virus
GAVI	Global Alliance for Vaccine and Immunization
GIVS	Global Immunization and Vision Strategy
GMP	Good Manufacturing Practice
IRL	Ice Lined Refrigerator
MHPRA	Medicines and Healthcare Products Regulatory Agency
MOH	Ministry of Health
MSH	Management Science for Health
ODGD	Operational Deputy General Director
OPV	Oral Polio Vaccine
PCV	Pneumococcal Vaccine
PFSA	Pharmaceuticals Fund and Supply Agency
SCM	Supply Chain Management
SPSS	Statistical Package for Social Science
TT	Tetanus Toxoid
WHO	World Health Organization
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VPD	Vaccine Preventable Disease
VVM	Vaccine Vial Monitor

Abstract

This study identified how Pharmaceuticals Fund and supply Agency, Ethiopia has developed its cold chain supply systems of vaccines and how it is able to maintain cold chain for temperature sensitive vaccines, considering the challenges of; transport systems, storage facilities, packaging, technical capacity. The main objective of the study was to identify the factors affecting supply chain of vaccines in Pharmaceutical Fund and Supply Agency of Ethiopia. Descriptive survey design was considered. The data was collected by use of self administered questionnaires.

Major findings: The study has identified factors that affect supply chain management system of vaccine; these include inadequate vehicles for distribution of vaccines to public healthcare facilities. Lack of on job training with special emphasis on storage, handling and distribution of vaccines. Lack of storage space in PFSA and PFSA branches.

Conclusions: PFSA Need to strengthen the transport system of cold chain vaccines according to their optimum temperature ranges, because the temperature may affect their quality and Need to strengthen the storage practices of vaccines by providing on job training, so as store in-charge and immunization focal personnel they can know how to use refrigerator and good practice of storing vaccines.

Areas for Further Research: This study just focused on factors affecting supply chain management of vaccines in PFSA central and PFSA Addis Ababa branch No-1, further research can be carried out to cover the whole country health facilities to assess the magnitude of the problem.

Key words: Supply chain, vaccine, supply chain management

CHAPTER ONE: INTRODUCTION

1.1. Background of the study

Supply chain management (SCM) is the means, by which firms engaged in creating, Distributing, and selling products, can join forces to establish a supply network With an unbeatable competitive advantage-has emerged as one of the most Powerful business-improvement tools around (Deveshwar et al ,2010). Companies all over the world are Pursuing supply chain as the latest methodology to reduce costs; increase Customer satisfaction, better utilizes assets, and builds new revenues (Deveshwar et al,2010)

Supply chain management is becoming more crucial for the survival of a world-class enterprise. Nowadays many organizations become a part of at least one supply chain. They have to perform equally well, in order to achieve better performance. This also requires elimination of interface between many techniques across applications and individual departments (Premaratne, 2005).

A supply chain and logistics system provides excellent customer service: by fulfilling the six rights, ensuring that the right goods, in the right quantities, in the right condition, are delivered to the right place, at the right time, for the right cost (The Logistics Handbook, 2006). Each person who works in supply chain management systems (SCMS) must remember that s/he selects, procures, stores, or distributes products to meet customer needs.

The logistics system ensures customer service by fulfilling the six rights. Each activity in the logistics cycle, therefore, contributes to providing excellent customer service. The situation where customers and service provider can choose, obtain, and use medicines and other health commodities when and where they need them for prevention, diagnosis, treatment, and care is the one that SCM can provide. The whole supply chain activities in

pharmaceutical industries are for saving lives and/or improving the health status of the people (Desalegn, 2015).

A vaccine is biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease causing microorganism. The agents stimulates the body's immune system to recognize the agent as foreign, destroy it and ―remember it, so that the immune system can more easily recognize and destroy any of these micro-organisms that it later encounters (strive-4-five, 2005).

There are several type of vaccines sources although is often made from weakened or killed form of microbe or its toxins. Some form type of vaccines sources are as follows; killed, attenuated, toxoid, subunit, conjugated, and experimental vaccine sources. (strive-4-five 2005).

The distribution system of vaccines is concerning with maintaining of the cold chain. The cold chain is the system of transporting and storing of vaccine at the recommended temperature range which is (+2°C to+8°C for refrigerator vaccines) and (-15°C to -25°C for freezer vaccines). Cold chain begins from the time the vaccine is manufactured, stored, distributed and ends when it is administered to client (Desalegn, 2015). Vaccines are delicate biological substances that can become less effective or destroyed if they are:-

1) Frozen- this is the most common reason for vaccine damage

Freezing of vaccine- this refers to situation whereby vaccines stored at or below 0°C of temperature for type of vaccines which need to be stored in refrigerator temperature range of +2°C to + 8°C. Vaccine damage at temperature of 0°C is common although it may not appear frozen. (Strive for five, 2005).

2) Allowed to get too hot – when vaccines are exposed to repeated episodes of heat the loss of vaccine potency is cumulative and cannot be reversed. (Strive for five, 2005)

3) Exposed to direct sunlight or fluorescent light. (Strive for five, 2005).

Distribution is the delivery or giving out of an item or items to the intended recipient. Distribution system is a system of administrative procedures, transport facilities, storage facilities and user facilities through which supplies move from a central point to the user facilities.(MSH, Managing Drug Supply, 1997).Distributing vaccine from manufacturers to the final recipients is composed of a series of Procurement, storage, shipment and other related activities. One of the challenges is that vaccine demand and supply are variable. In many low and middle income countries, the demand for a vaccine is increasing exponentially because of the continued growth in the birth rate. Additionally, vaccines are also used for the purpose of immediate response to disease outbreak (Deveshwar et al, 2010)

World Health Organization (WHO) has noted that twenty five percent of all vaccine products reach their destination in a degraded state (Monicah, 2015). This is according to The Medicines and Health care Products Regulatory Agency (MHPRA) is due to temperature rises above desired parameters thereby contributing forty-three percent of reported non-compliant cases worldwide vaccine-preventable diseases are responsible for about twenty five percent of the ten million deaths occurring annually for children under five years of age (Monicah, 2010). Global warming makes temperature control issues a growing challenge in the cold chain supply (Bishara, 2007).

Vaccination is one of the most effective ways to prevent the outbreak of an infectious disease. This medical intervention also brings about many logistical challenges. Some of the challenges of vaccine supply chain are that Vaccines are biological products that can be damage by high temperatures, Freezing temperatures, and excessive light. They are generally effective for a limited period of time at room temperature (Evelot.et al, 2017). Inappropriate transportation and improper storage of vaccines might lead to a decrease in vaccine effectiveness. For example,

according to the product information sheets, inactivated polio vaccine diphtheria-tetanus-pertussis vaccine (DTP), diphtheria and tetanus toxoids vaccine, hepatitisB vaccine(HepB),and tetanus toxoid vaccine (TT) are seriously damaged at temperatures less than 0°C (Duijzer,2011). HepB vaccine freezes at temperatures less than-0.5°C (Path, 2011). Once potency has been lost through exposure to excessive heat or freezing temperatures, returning the vaccine to the correct storage temperature will not cause the vaccine to regain its potency. If potency is lost through heat exposure, the vaccine's appearance will not change (Duijzer et al, 2017).Without performing a laboratory test, it is not possible to know whether a vaccine has lost its potency or not. The supply chain of vaccines in Ethiopia now is performed by pharmaceuticals fund and supply agency (PFSA) in collaboration with UNICEF. So far this organization faces different challenges during the logistics of vaccines.

1.2. Statement of the problem

The role of vaccine 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 (Bishara, 2007).The importance of the cold chain is crystal clear to the government and key stakeholders within the industry based on their impact on health, very little effort is done 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 (Bishara, 2007).

This is confirmed by who asserts that pharmaceutical cold chain items like vaccines are particularly sensitive materials which, if not manufactured and shipped under stringent controls, can become ineffective or even hazardous to the consumer due to reduced potency. Vaccines must be stored correctly from the time they are manufactured until the

time they are administered to children. The exposure of vaccines to heat or cold can reduce the vaccines potency, thus increasing the risk of children not being protected against vaccine-preventable diseases (Monicah, 2015)

There are three basic problems that affect supply chain of vaccines. The first problem is transportation of vaccines; the temperature will not maintain in the required level because of lack of cold chain transport mechanism. The second is the distribution of vaccines; ensuring that every health facility has an adequate supply of all vaccines in the routine and supplementary immunization schedules (Bishara, 2007). A 'stock out' is said to occur when a facility has insufficient vaccines on hand to perform scheduled services. Stock outs mean that immunization sessions must be cancelled or children who arrive not receive vaccinations.

There are multiple causes of stock outs including overall shortages of vaccines in the system (for example, if insufficient stock comes in to the national level), delays or mistakes in ordering at different levels, over allocation of stock to some facilities (which means there is not enough to get to other facilities), travel delays or lack of transport, and incorrect forecasts of demand (Richard ,2014).

The other factors that affect supply chain management of vaccine are maintaining the cold chain to keep vaccines in a safe temperature range. The safe range is generally considered to be 2℃ to 8℃ with the freezing of vaccines the biggest concern. Some exposure to temperature above 8℃ is acceptable, although this varies across vaccines. The WHO guidelines are that vaccines should not be exposed to temperatures of less than -0.5℃ for more than one hour, or temperatures of more than 8℃ for more than 10 hours. These conditions are referred to as alarm conditions (Richard, 2014).

The ultimate goal of Pharmaceuticals Fund and Supply Agency is to ensure the uninterrupted availability of quality vaccines from manufacturer to service delivery

levels, so that opportunities to vaccinate are not missed because vaccines are unavailable. To ensure an uninterrupted supply of quality vaccines to patients the regulatory environment needs to reflect the complexity of new vaccine and Good Manufacturing Practice (GMP).The overall full immunization coverage 23.4% in Ethiopia is considerably low as compared to the national target set 66 % (Yihunie, et.al, 2011). The study will assess the factors that affect supply chain management of vaccines in Pharmaceuticals Fund and Supply Agency (PFSA) of Ethiopia.

1.3. Research questions

1. What are the factors affecting vaccine supply chain in Pharmaceuticals Fund and Supply Agency, and PFSA Addis Ababa branch no-1?
2. How can determine vaccine availability and stock out level
3. How to manage the storage condition, transportation and distribution of vaccines to different branches and health facilities?
4. Are Pharmacy professionals involved in the vaccines (cold chain) management knowledgeable on storage condition of vaccines?

1. 4. Objective /Aim of the study

1. 4.1. General objective

The general objective of the research is to identify the factors affecting supply chain management of vaccines in Pharmaceuticals Fund and Supply Agency, and PFSA Addis Ababa branch no-1.

1.4.2. Specific objectives

1. To identify the factors affecting vaccine supply chain management in pharmaceuticals fund and supply agency, and PFSA Addis Ababa branch no-1
2. To identify how vaccines are stored, transported and distributed in pharmaceuticals fund and supply agency, and PFSA Addis Ababa branch no-1.
3. To determine the availability of vaccines for immunization
4. To determine the level of knowledge of the pharmacy personnel on storage and handling of vaccines.

1.5. Definition of terms

The terms listed below have multiple interpretations, but here they are defined as follow for the purpose of this thesis :

1. 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.
2. Vaccine: is a biological preparation that improves immunity to a particular disease.
3. Cold Chain: is the system of transporting and storing of vaccine at the recommended temperature range.
4. Immunization: is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine.

1. 6. Significance of the study

The study was identifying the factors that affect the supply chain management of vaccines in Pharmaceuticals Fund Supply Agency. The findings and recommendations of the study will be useful for pharmaceutical fund and supply agency to improve supply chain management of vaccines. The result of the study will benefit UNICEF, FMOH, PFSA, regional health bureaus and stakeholders to (1) understand the factors that affect

the vaccine supply chain (2) get information about the progress made so far and see the possible future direction of the vaccine supply chain, (3) identify areas that need more attentions and collaboration in the vaccine supply chain management system.

1.7. Scope for the study

The research was delimited on pharmaceuticals fund and supply agency of Ethiopia, and PFSA Addis Ababa branch no-1. The study was not included health facilities, i.e. hospitals and health centers. The study was addressed: storage, transportation, distribution and cold chain of vaccines. The study included those Pharmacists and Druggists working in pharmaceuticals fund and supply agency, and PFSA Addis Ababa branch no-1.

1.8. Limitations

The supply chain management of vaccines of the organization is peculiar to itself; it is difficult to generalize the findings of the study to other firms in the pharmaceutical supply chains in Ethiopia. Besides the factors affecting supply chain management of vaccines from the stand point of the focal organization (Pharmaceutical Fund and Supply agency) it did not involve the other members of the supply Chains (customers and suppliers) reaction or responses towards the organization; in addition the research limited on Pharmaceutical Fund and Supply Agency and PFSA Addis Ababa branch No-1, this is due to time and resource limitation. Finally, the factors that affect supply chain management presented in the study are only a proportion of the potentially relevant variables that might have been included the vaccine supply chain only serve as examples and special attention is rather paid for the vast majority of vaccine supply chain, And therefore it is important to note that the findings of this study can only be used for comparative purposes 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: LITRATURE REVIEW

This chapter focuses on reviewing previous research studies and evaluates the available literature to give a wider perspective on factors affecting and supply chain management of vaccine. How to manage the vaccine supply chain and how the cold chain for vaccines is maintained from the time of distribution until the time of administration to children.

2.1. Supply Chain Management: Concepts, key Issues, and Functions

2.1.1. Supply Chain Management concepts and key issues

Supply chain is a system of suppliers, manufactures, distributors, retailers and customers where material typically flows downstream from suppliers to customers and information flow in both directions. SCM involves managing a connected series of activities including planning, coordinating and controlling movement of goods from supplier to customer. Therefore there are decisions to be made strategic, tactical and operational. The decision making levels in supply chain are strategic (5 to 10 years), Tactical (3 months to 2 years) and operational (day to day) (Charu & Swatantra, 2004).The common key issues that face SCM activities are distribution network configuration, inventory control, supply contracts, distribution strategies, supply chain integration and strategic partnering, outsourcing and procurement strategies, information technology and decision support systems, and customer value (Encyclopedia, Charu & Swatantra, 2004).

2.1.2. Function of the Supply Chain

Supply chain management (SCM) is becoming more crucial for the survival of a world-class enterprise. Nowadays many organizations become a part of at least one supply chain. They have to perform equally well, in order to achieve better performance (Premaratne, 2005). As a result, organizations increasingly find that they must rely on

effective supply chains, or networks, to compete in the global market and networked economy.

The functions of the supply chain are to resolve the major business challenges of the organizations and for developing capabilities to manage value, volume, volatility, velocity, variety, variability, visibility and virtuality of the organizations. Visibility is a core capability for managing the total supply chain from source to customer. Visibility or transparency ensures that parties within the total supply chain know what the current pipelines look like (Hines, 2004).

Supply chain strategies require a total systems view of the links in the chain that work together efficiently to create customer satisfaction at the end point of delivery to the consumer. As a consequence, costs must be lowered throughout the chain by driving out unnecessary expenses, movements, and handling. The main focus is turned to efficiency and added value, or the end user's perception of value. Efficiency must be increased, and bottlenecks removed. The purpose of a logistics system is simple: to obtain and move goods, supplies and equipment in a timely fashion to the places where they are needed, at a reasonable cost. Matters are complicated by the fact that equipment and supplies usually cannot go directly from their source to the end user; they frequently must be held as inventory at one or more intermediate points along the way (Desalegn, 2015).

There are only four reasons for holding inventory: transportation efficiency, safety stocks, storage capacity and anticipation of a program that is growing or changing (USAID|DELIVER PROJECT, 2009). Hence, reducing cost of operations, improving inventory, lead times and customer satisfaction, increasing flexibility and cross-functional communication, and remaining competitive appear to be the most important objectives to implement SCM strategies (Tummala, Cheryl, & Melanie, 2006).

Therefore, the whole purposes of SCM are to reduce cost, speed market, and to provide better customer services/satisfaction, so that the organization will be visible, effective and efficient both internally and with its customers (supplier and consumer) (Dessalegn ,2015).

2.2. Elements of Supply Chain

The key elements of the supply chain for most organizations are upstream, internal and downstream, however the details vary by industry. These three elements should be interlinked with appropriate information systems. The first elements of supply chain is about the relationship with suppliers specifically supplier relationship management and procurement management that is upstream supply chain. The second element of the supply chain is basically about internal value chain including manufacturing, packing and inventory management. Whereas, the third element is the downstream supply chain which focus how best to reach the customers and distribution centers and hence include distributions, warehousing and transportation management (Desalegn, 2015).

2.3. Vaccine Preventable Disease

The first step to understanding a vaccination program is to understand the burden of vaccine preventable disease (VPD.) It is estimated that 17% of deaths of children under five years old is attributable to disease that could have been prevented by vaccination (Cakouros, 2009). Such diseases include diphtheria, measles, tetanus, rotavirus, and yellow fever, to name a few. Some diseases, such as maternal tetanus, polio, and measles, have specific goals of eradication.

Sub-Saharan Africa accounts for a high percentage of the burden of disease attributable to VPD. 58% of pertussis deaths, 41% of tetanus deaths, 59% of measles deaths, and 80% of yellow fever deaths occur in this region of the world (WHO, 2012). Estimating such

numbers can be difficult, as countries all have different methods of disease reporting and surveillance; however, the pattern of high rates of these diseases remains consistent across the region. Strong immunization programs have the ability to help control such disease. Smallpox eradication is one of the strongest testaments to the need of strong immunization programs supplemented by substantial campaigns that catch "missed opportunities," those patients that miss vaccination opportunities offered by a clinic. Other efforts, such as measles and polio, are modeled after the success of smallpox eradication campaigns

2.4. The Expanded Program on Immunization

The Expanded Program on Immunization (EPI) was established in 1974 by the World Health Organization with the goal of providing all children access to life saving vaccines to prevent and control vaccine preventable diseases. It was modeled after the success of smallpox eradication campaigns (WHO, 2012).The EPI originally targeted diphtheria, tetanus, pertussis, measles, polio and tuberculosis. Other vaccines have since been added, including hepatitis B and Haemophilus influenza type b (Hib.) Although the EPI varies by country, the eight vaccines listed above are the basic requirements of most national policies. In addition, some countries have region specific vaccines, such as yellow fever and Japanese encephalitis. Over the years, advancements in research have combined many of these vaccines, such as the commonly used trivalent DTP (protecting against diphtheria, tetanus, and pertussis in a 3 dose vaccine.)

The coverage rate for three doses of DTP is also the most common measure of a vaccine program across the globe. The EPI supports each country to developing its own vaccination delivery system according to the ongoing health conditions of that country (WHO, 2012). The core EPI vaccines should all be administered in the first year of life.

While this can be expensive, UNICEF has been critical in the negotiation of acquiring vaccines at lower prices. The Global Immunization and Vision Strategy (GIVS) is a framework developed by the World Health Organization and UNICEF in order to help countries outline stronger immunization plans. This ten year strategy has four main goals:

- To immunize more people,
- To introduce new vaccines,
- To integrate immunization into other health interventions, and
- To help countries be able to manage vaccine programs independently.

In addition, GIVS can help develop regional vaccine programs within countries in order to better supply specific areas that need attention (Cakouros, 2009). Aside from creating vaccination schedules, the intent of the EPI is also to supply cold chain equipment (refrigerators, freezers, cold rooms, vaccine carriers, etc.) in order to ensure the safety of vaccines traveling through the system.

In developing countries this was a challenge. Issues such as fickle power sources, unreliable road conditions, and limited storage capacity existed in nearly every setting in every country. However, WHO and UNICEF developed ways to finance the purchase and allocation of such equipment (WHO, 2012). Just as UNICEF's purchasing power helped to obtain vaccines at reasonable prices, this was true with equipment. As the EPI continues to adapt to new technologies, emerging diseases, and shifting health trends, it is important to be able to make educated decisions affecting the supply chain in order to control health outbreaks and epidemics.

Vaccine supply chains include all of the people, equipment, and activities that must harmoniously work together in order to deliver vaccines from the producer to the patient (Kaufmann, 2011). People involved include everyone from the Ministry of Health to the

health worker delivering vaccines; equipment encompasses cold rooms and hand-held vaccine carriers; activities include both delivering vaccines to locations and administering doses to patients.

Temperature control is a critical step to ensuring proper vaccine delivery. Originally, the cold chain was created to keep vaccines between the recommended temperature of 2°-8°C.However, recent studies show that exposure to freezing temperatures along the supply chain is becoming just as much a problem as heat(Cakouros,2009). Predicting adjustments to the supply chain that would be needed in situations such as vaccine introduction, vial size change, additional space needed, and changes in supply routes, among others, is challenging.

2.5. Importance of the vaccine supply chain

Vaccination has been widely accepted as one of the most cost-effective public health interventions for disease prevention (David, 2016). Despite high immunization coverage rates and vaccine effectiveness there are still a number of reported outbreaks, some of which could be prevented by better vaccine management practices. For example, measles and polio outbreaks have been observed in several countries where measles and polio were previously under control, including In Italy, Japan, Laos, and Namibia (path, 2011). The continuing number of reports of vaccine-preventable disease outbreaks raises concerns about vaccine quality.

Vaccines are biological products that can be damaged by high temperatures, freezing temperatures, and excessive light (path, 2011). They are generally effective for a limited period of time at room temperature. Inappropriate transportation and improper storage of vaccines might lead to a decrease in vaccine effectiveness. For example, according to the product information sheets, inactivated polio vaccine, diphtheria-tetanus-pertussis

vaccine (DTP), diphtheria and Tetanus toxoids vaccine, hepatitis B vaccine (HepB), and tetanus toxoid vaccine (TT) are Seriously damaged at temperatures less than 0°C.HepB vaccine freezes at temperatures less than -0.5°C (Path, 2011).Once potency has been lost through exposure to excessive heat or freezing temperatures, returning the vaccine to the correct storage temperature will not cause the vaccine to regain its potency. If potency is lost through heat exposure, the vaccine's appearance will not change. Without performing a laboratory test, it is not possible to know whether a vaccine has lost its potency.

2.6. Association between vaccine quality and proper transport/storage

There have been a number of reports demonstrating an association between vaccine quality and appropriate vaccine transport and storage. In Nigeria, the potency of oral polio vaccine (OPV) as well as vaccines for measles and yellow fever was found to decrease below international standards when they were transported from the national warehouse to health facilities (Path: 2011) . The rate of the decrease in the potency of measles vaccine was greater than in OPV and yellow fever vaccine. The potency loss was most likely due to several factors, including repeated cycles of Vaccine freezing and thawing caused by deficiencies in cold storage equipment, inconsistent electrical distribution systems, a lack of backup electricity, and improper vaccine storage.

A study in Australia reported that improper vaccine storage may have been associated with an outbreak of diphtheria from 1993 to 1996.One localized measles outbreak in the United States in 1970 was associated with the storage of vaccine in the door shelf of a refrigerator rather than in its central core (path: 2011).There was also a report of poor vaccine effectiveness and an outbreak of 180 measles cases in one province of Thailand. Two villages of that province that had the highest Morbidity rates (9.57% and 6.99%) had

vaccine coverage rates of 71.7% and 50.9% and low Vaccine efficacy rates of 35.2% and 39.9%, respectively (WHO: 2011).

2.6.1. Temperature monitoring devices

Correct, reliable and consistent monitoring of temperature where-ever and when-ever vaccines are manufactured, stored, transported, and used is an important activity to insure potent and effective vaccines reach the beneficiary. From temperature monitoring devices some of them are listed below:

1. Thermometer

Thermometers need to be available storage equipments so that vaccines with in recommended temperatures, i.e. 2°-8°C.

2. Vaccine vial monitors (VVM)

A VVM is a label containing a heat sensitive- material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly. Before opening a vial check the status of VVM.

3. Freezer Tags

Freezer tags are generally used while transporting large quantities of freeze sensitive vaccines. The tags are to be placed in between the stocks of vaccines being transported/ stored.

4. Electronic data logger

The electronic data loggers are being introduced to monitor the temperature Ice Lined Refrigerator (ILR). It is an electronic device placed with the vaccine which records the vaccine temperature for 30 days. It has visual display alarm system. As the temperature of the equipment storing the vaccine crosses the safe range the visual alarm alerts the handler.

2.7. Problems in the vaccine supply chain and logistics

The transport and storage of vaccines at temperatures higher than 8°C (the optimum temperature range for vaccine storage is 2°C to 8°C) have been reported in the United States and Australia (WHO: 2011). Vaccine freezing has been reported in many countries. A study in Indonesia that monitored the temperature of HepB vaccine shipped from the manufacturer to the provider) found that 75% of vaccine shipments were being frozen. The highest rates of freezing Occurred during transport from provincial to district warehouses (WHO: 2011).

A study in Bolivia that monitored the temperature of DTP- HepB- Haemophilus influenza type b vaccine throughout its transportation from the national warehouse to 11 communities in 3 provinces reported that the proportion of time that the temperature fell to less than 0°C ranged from 2% to 50%. Vaccine freezing occurred at all levels of the cold chain, especially from the district warehouse to health centers. In addition, 7 of the 11 routes from provincial to district warehouses had a temperature higher than 8°C (PATH: 2011). A study in Papua New Guinea recorded vaccine temperatures during transportation from the national warehouse to health centers and detected frozen vaccine vials caused by insulation between the vaccines and the icepacks that was not sufficient to protect the Vaccines from direct contact with the ice packs (WHO:2011).

In the United States, a temperature study was conducted of refrigerators used to store vaccines in medical clinics. Thermometers were used to measure the minimum and maximum temperatures for a 24-hour period. The results indicated that only 2 of the 21 clinics studied had refrigerator temperatures that fell within the acceptable range. About 63% of the samples had temperatures that fell below the acceptable range, 59% reached temperatures higher than the acceptable range, and 93% were both higher and lower than the acceptable range. Since the study measured only the minimum and maximum

temperatures, it is impossible to know how long the temperatures remained outside the acceptable range (PATH: 2011). During a three-day monitoring period, a study in New South Wales used data loggers to measure the temperature of 53 vaccine refrigerators in pharmacies and found that only 19% of the refrigerators studied had temperatures that fell within the acceptable range, while 23% of the refrigerators had temperatures that fell to less than 0°C and 29% had temperatures higher than 8°C (WHO, 2010).

2.8. Vaccine supply chain in Ethiopia

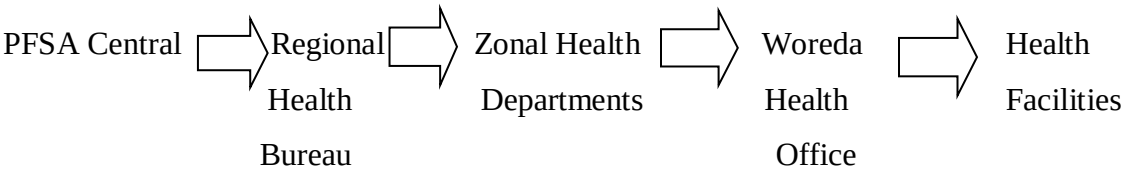
The Clinton Health Access Initiative operates in many countries including Ethiopia with an aim to save lives from preventable and treatable diseases. In Ethiopia the organization is working to advice the ministry of health in Ethiopia on an efficient logistics and supply chain management system for vaccine (Hajara, 2010).Currently the vaccine distribution capacity is five vaccines and will rise to seven with the introduction of a number of vaccines like the pneumococcal vaccine (pcv10) and Rota next year. The introduction of these vaccines will inevitable affects the organizations, i.e. Pharmaceuticals Fund and supply Agency's stock management and logistics in Ethiopia since the rate of hospital visits per health center will remain constant (Hajara,2010).

As for all national vaccine supply chains, the vaccine's sensitivity to heat poses a risk of waste, especially for the health facilities. The current systems is paper based and includes the use of stock cards which is predominant in most health centers, about 80% practice (Hajara, 2010).This system is very inefficient and prone to errors (including transcription errors), is not regular enough to be useful, and can't forecast demand of inventory and makes it tedious to extract use full information for decision making at any level of the supply chain.

Ethiopia has switched to a number of vaccines like the single dose pentavalent vaccine (a few years ago), the pneumococcal and plans to introduce the Rota vaccine (Hajara, 2010). These vaccines are bulky and more expensive both to purchase and store. Thus, it is essential that an improved and efficient logistics system is put in place to reduce waste, stock outs, over stocks, expired stock, and to improve on decision and information flow between the national cold storage, the regional health facilities, and every level of the vaccine supply chain (Hajara, 2010).

The current system is highly decentralized for a country with 80 million people with great regional differences, which also affects the distribution of the vaccine. The vaccine is meant to be given to every child under one year with an average of 4 to 5 visits to the health care facility. The need for better logistics, transportation innovations, and the increase in the distribution costs will have to be taken in to account.

Policy decision of Ethiopia in 2013 to transfer responsibility for vaccine supply chain to Pharmaceuticals Fund & Supply Agency (PFSA) from Ethiopian Federal Ministry of Health (TechNet conference, 2015), Federal agency responsible for 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 structures:



2.9. Empirical Literature Review

Supply chain management (SCM) is a rapidly evolving area of interest to academics and business management practitioners alike. As a result most of the industries innovations in improving efficiency and reduce cost targeted innovations on key functions including logistics (Charu & Swatantra, 2004). The aspects of marketing, economics, logistics and organizational behavior are all important for developing insights into how and why different SCM arrangements emerge and for understanding the consequences of these arrangements for industry efficiency and competitiveness (Jill & Hobbs, 1996).Like most other industries, SCM in vaccines is now slowly evolving in developing countries like Ethiopia.

Vaccine supply chain starting from the planning and acknowledge the specialization and importance in accomplishing immunization programs. Vaccine supply chain in most developing countries are designed and implemented to meet demands of specific program logistics. The different health programs have multiple parallel SCM but all basically perform similar functional activities i.e. primarily meeting the supply needs of their clients or customers. However, as the health programs mature and funding from donors decline, there are interests and efforts for integration to takeover (Jill & Hobbs, 1996) . The main anticipation for integrations is SCM knowhow improves and capacity developed.

Ethiopian government started moving to make the vaccine SCM more efficient and integrated. However, unlike other sectors such as discrete parts in manufacturing and fast-moving consumer goods where there has been a long history and experience with management of inventory, the healthcare sector is behind other industry sectors in

implementing effective supply chain management (SCM) practices (McKone et al., 2005;Baltacioglu et al., 2007).

The main reason for the sector's difficulties in implementing effective SCM practices is supply chains are much more complex compared to supply chains in other industries (Vikram, Prakash, & Amrik, 2012). However, several factors contribute to this complexity. There are also new vaccines continually adding to the SCM, demanding specific conditions like transportation, storage or cold chain and distribution that challenge the supply chain and inventory management.

The Ethiopia case is that Food, Medicine and Health Care Regulatory Authority (FMHACA) adapts and follows stringent registration and market authorization procedures. Food and health products need to undergo registration and licensing with detail product descriptions, manufacturer information Andover, there are regular import permit approval and licensing requirements. Third, pharmaceutical products are characterized by long developmental cycles that are distinctly different from medical devices. These long lead times have a significant impact on capacity planning and supply chain strategies, particularly inventory management.

As a result, in vaccine SCM, getting a child vaccinated, a mother an appropriate medicine and controlling any epidemic outbreak are all very critical while ensuring the proper management and use of medicines. That makes supply chain in vaccine more difficult while it requires the bulk of the health resources even if funded by UNICEF. Although, vertical and integrated systems each have advantages and disadvantages there are valid technical reasons, often reflecting changes in the environment, make integrating a logistics system more advantageous or feasible. Some of the advantages include improved transportation infrastructure, improved data management, improved

communications system coverage, new customer service requirements and increased storage and transportation efficiency (USAID | DELIVER PROJECT, 2009).

Adopting SCM initiatives primarily requires that companies take a long-term view and have an extensive focus, on all the channels that are employed in the total transformation process from the earth to the end-user to create a productive and reliable supply chain network system. Specially vaccine supply chain needs to consider the various administrative levels and wide that requires specific storage conditions, cold chain, regulated levels of usage, and seasonal and campaign effects and bulkiness of the products and storage capacity at all levels.

Proper execution of SCM requires commitment and champion from senior management too. In old days and currently even in some organizations, internal supply chain and inventory management were over emphasized. However, organizations and partners have to re-think how their SCM linked to others within and outside the organization, locally and internationally, and upwards and downwards supply chain. Hence by evaluating and mapping a specific supply chain, a company is able to find and reduce system redundancies while improving reliability and flexibility of a system. SCM needs to begin by investigating each function a department handles and breaking it down if necessary.

Despite the challenges that are created developing an effective and efficient supply chain become a core competency or even a distinctive competency. A core competency is any function, which a firm does well at performing. On the other hand, a distinctive competency is a function that is performed well and is unique. Literature has shown that the basis of competition in many industries in the future will revolve around supply chain development (Das & Narasimhan, 2000). Supply chain analysis advocates reducing non-core processes (waste) and streamlining the supplier and logistics network. Thus the supply chain network includes upstream, downstream and lateral suppliers producing

goods, services or other value adding activities. The information and communication technologies provide a backbone support to distribute and share information real-time for effective decision making by supply chain partners.

2.10. Conceptual framework

The conceptual framework illustrates the relationship between the independent variable, and dependent variable. The independent variables include; storage conditions, transport systems, packaging and technical capacity which was measured, the dependent variable is safe cold chain items, which in this study is vaccines. PFSA receive Vaccine products from the airport cold room, transport them to PFSA storage cold chains and distribute to health facilities from their cold storage holding facilities. The Safety of cold chain vaccines is greatly influenced by variations during transport, storage conditions and facilities, handling and packaging (Bishara, 2007).

Members of the pharmaceutical supply chain have various regulatory requirements to meet while distributing, storing and handling vaccine products to ensure that the quality and efficacy of the product are not compromised along the supply chain. The cold chain system consist of a series of transport and storage links which also involve a lot of handling, designed to Keep products within an accepted temperature range until it reaches the end user/children.

Storage is a critical parameter in maintaining the quality, safety, stability and efficacy of cold Chain vaccines and must be stored in accordance with the requirements of its manufacturers (Skuce, 2010). The operation of the vaccine cold chain management cycle is also affected by some intervening factors which are political, legal, and regulatory framework may cause delays reducing on the lead time and compromise on product quality and safety; however these intervening factors were not measured in this study.

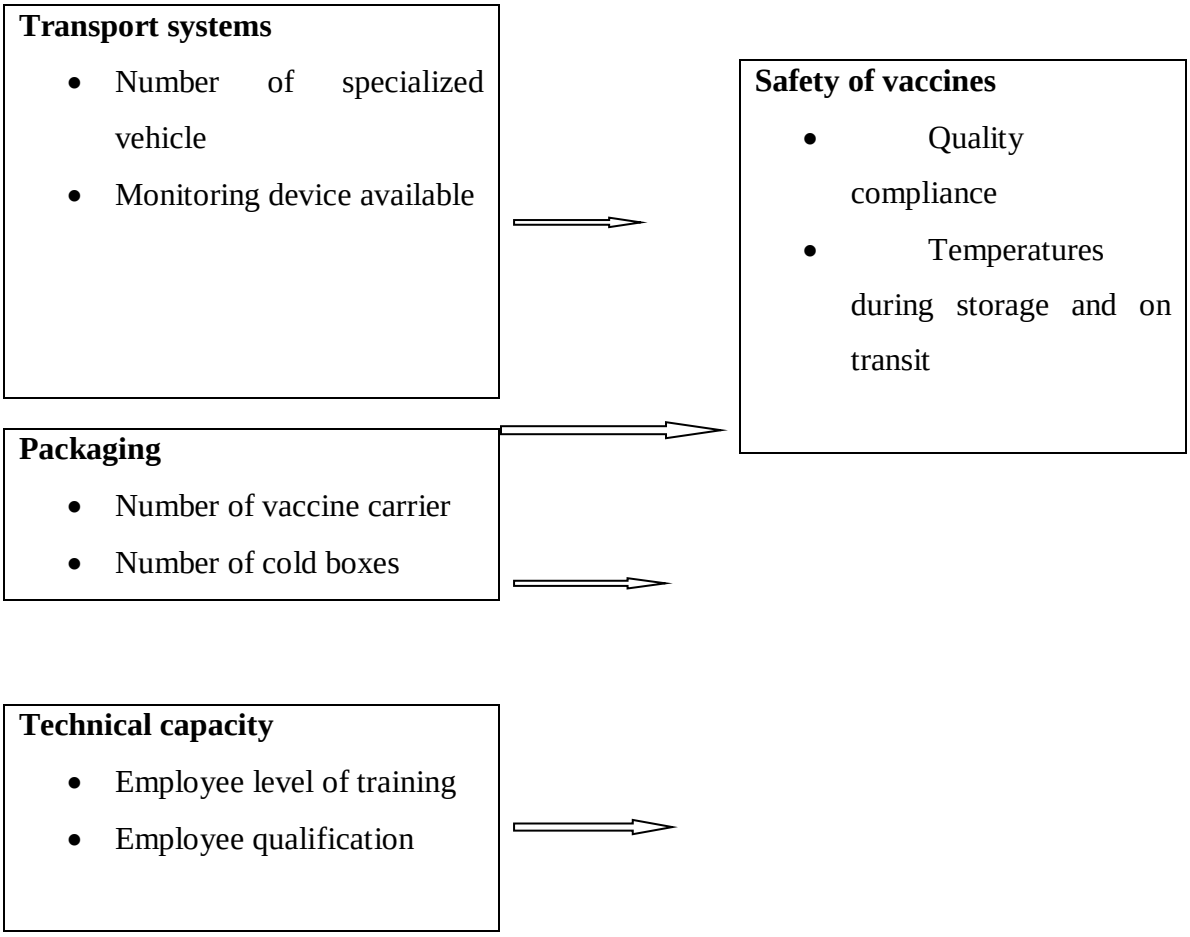


Figure 1: conceptual frame work (Monicah, 2015)

2.11. Background of the Organization

PHARMID was established by law to regulate price of pharmaceuticals in the country by supplying the same from both local and foreign suppliers at a competitive price. In fact PHARMID was not duty bound to make sure uninterrupted supply of quality pharmaceuticals to neither public nor private health facilities, rather PHARMID used to bridge market gap and involve more in business oriented activities.

In general the existing pharmaceuticals supply system is push system, where by pharmaceuticals are supplied in anticipation for customer demand. In practice the forecasting and procurement activity is performed mainly based on sales data marketability and revenue generation principles. Customers are obliged to buy what is available in stock at the time of arrival to PHARMID hubs. The distribution system is more or less first come first served. Customers are expected to physically collect pharmaceuticals of their interest from PHARMID branch warehouses based on list of products available in stock. There is poor or no transport service to deliver products to customers.

In few PHARMID branches where there is transportation service; it is only for bulk purchasers. Even if many customers are interested to get their pharmaceuticals supply from PHARMID; for many reasons (including competitive price), stock rupture has turned out stumbling block. Because of the very nature of the business PHARMID was involved in and its bargaining power it has possessed through economy of scale and 60 years of experience, the attention endowed to customers was not as required.

In order to avoid the historical problems in the public pharmaceuticals supply system, establishment of central procurement agency was mandatory. Hence PFSA is the established to overcome the problems & ensure an interrupted supply of pharmaceuticals to the public at an affordable price. Nevertheless to effectively carry out the duties & responsibilities given to PFSA, reengineering the existing pharmaceuticals distribution system based on supply chain network reengineering principles is considered to be worthy. The Pharmaceuticals Fund and Supply Agency was established in September 2007 by Proclamation No. 553/2007 as part of logistic master plan implementation. The objectives of PFSA are to:

1. Enable public health institutions supply quality assured essential pharmaceuticals at affordable price in sustainable manner to the public;

2. Play a complementary role in developmental efforts for health service expansion and strengthening by ensuring enhanced and sustainable supply of pharmaceuticals;

3. Create enabling conditions for enhancing the accumulation of fund in its revolving and Cost recovery process and thereby ensure the realization of the objectives referred above 1 and 2

The following mission and vision have been considered for the selection of critical path, which is the centerpiece process for the success of PFSA.

- PFSA Vision

—To see the public access quality pharmaceuticals with honorable service

- PFSA Mission

"Avail affordable and quality pharmaceuticals sustainably to all public health facilities by using revolving drug fund".

- Strategic goals

The overall strategic goal of PFSA is to ensure availability of pharmaceuticals at all levels of the public sector health care delivery system thorough an integrated supply chain. The organization structure of PHARMID has been transformed in to PFSA. This structure is designed by giving mandates to each function. There are nine directorate directed by the Director General. The structure is very suitable if all operations are integrated and coordinated with information and technology. The main directorates which have a major responsibility for the organization are Forecasting and Capacity Building Directorate, Procurement Directorate, and Storage & Distribution Directorate. But this does not mean that the roles of other directorate are less. A good supply chain is the one that fills the gap in the weak chain. Roles and responsibilities of each directorate is explained below

1. Forecasting and Capacity Building Directorate: This directorate has roles to forecast the pharmaceutical need of the country and to give training to public health facilities as well as to the employee within the agency.

2. Procurement Directorate: This directorate has a role to procure all pharmaceutical Products from the local manufacturers and from the international suppliers based on the forecasted result from the above directorate.

3. Storage and Distribution Directorate: This directorate has responsibility to store and distribute all the pharmaceutical products to the branch hubs and to public health facilities.

4. Quality and Compliance Directorate: The main duty of this directorate is to assure the quality of pharmaceutical products by setting standards for the facilities. This directorate works together with FMHACA. In addition to these, it also handles the compliance from the customers.

5. Fund Management Directorate: This directorate has a responsibility to raise the fund and to manage the finance used to procure the pharmaceutical products. This directorate works together with MoH.

6. Human Resource and General Service Directorate: This directorate has mainly two broad roles. One is to recruit employee, to manage employee etc. The other is to manage the general service within the agency, like fleet management, cleaning, maintenance, outsourcing etc.

7. Operations Deputy General Director: The ODGD leads the forecasting and capacity building directorate, procurement directorate and storage and distribution directorate.

8. Fund and Human Resource Management Deputy Director General: This manager is responsible to fund management directorate and human resource and general service directorate.

9. Director General: The general director has responsibility of the entire directorate within the agency in the country. The director is under MOH.

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

3.1. Research design

The study adopted empirical investigation with descriptive research design since the major focus of the research was the factors affecting supply chain management of vaccines in Pharmaceuticals Fund and supply agency of Ethiopia (PFSA). Descriptive research studies are those studies which are concerned with describing the characteristics of a particular individual, or of a group. Studies concerned with specific predictions, with narration of facts and characteristics concerning individual, group or situation are all examples of descriptive research studies (Kothari, 2004, p37).The independent variable refers to the antecedent phenomenon, while the dependent variable relates to the consequent phenomenon. Therefore, in order to accurately describe the effect & relationships between the independent variables and the dependent variable descriptive research studies were employed. Quantitative method of design was the preferred method that the study allow for analysis of the problem statement.

3.2 Population and Sampling Techniques

The populations for this study were approximately 70 employees. The study was included pharmaceutical fund and supply agency central, and PFSA Addis Ababa branch no-1 warehouse managers, officers and supervisors of the organizations. Sampling facilitates the study of a relatively smaller number of units compared to the target population and therefore helps to obtain data that is representative of the whole population. A non-probabilistic sampling technique, specifically purposive sampling, was used to select the study population. Purposive sampling was appropriate in the selection of samples in the Pharmaceutical Fund and Supply Agency, because it allows for the selection of unique cases that are especially informative. According to the statistics obtained from Pharmaceutical Fund and Supply Agency central and PFSA Addis Ababa branch no-1 in

2010 E.C. There are a total of 136 employees in Storage and Distribution Directorate of the organization, of which 39 warehouse managers, 93 officers, and 4 supervisors.

3.2.1. Types of Data and tools / Instrument of data collection

The main instrument for data collection was close ended questionnaires. A questionnaire is a method of survey data collection with a group of printed questions which are deliberately designed and structured to gather information from respondents. The study was used a structured questionnaire with close ended questions standardized in order to allow for easy comparison (Makuru, 2012). The questionnaires were contained relevant questions which are designed with the objectives of the study in mind. The questionnaires were issued to all sampled respondents across various category spectrums, and explore perceptions and feelings, general experiences, as well as knowledge and general information on the subject under study.

3.2.2. Procedure of data collection

The research data were collected from primary sources through questionnaires and secondary data are organizational records, information collected by organization departments. The questionnaires were self-administered to the sampled respondents. Permission to carry out the research and authorization letter were received from the University prior to administering the questionnaires and the researcher also sent to the selected organization for introduction and also give a written approval to carry out the research confidentially for academic purpose only.

3.3 Methods of Data analysis

The researcher used descriptive statistics to analyze data to allow for meaningful description. Data collection were using statistics and to compare variables numerically by

Correlation analysis. The data collection were through questionnaires coded and entered into the Statistical Package for Social Science (SPSS) for analysis of quantitative data Correlation analysis were used to establish the relationship between the independent variables which are storage conditions, transport systems, packaging and technical capacity with the dependent variable which is safety of cold chain items.

CHAPTER FOUR: PRESENTATION, ANALYSIS, AND INTERPRETATION OF DATA

4.1 Response Rate

In this study of the selected 70 warehouse managers, storage and distribution officers, and supervisors (i.e. PFSA central and PFSA Addis Ababa branch No-1), All PFSA central and PFSA Addis Ababa branch No-1 respondents agreed and participated in the study. Of the selected 70 people for interviewees all 70 (100%) participated in the study.

4.2. Distribution of Demographic Variables

Gender, sex and experience at work of the interviewees were the demographic variables that were examined and their distribution is summarized in the table 1 below.

Table1: Distribution of sex of respondents

Demographic variables		frequency	Percentage (%)
Sex	Male	54	77.1
	Female	16	22.9

From table 1 above, the results show that majority (77.1%) of the contacted respondents were males.

Table 2: Distribution of ages of respondents

Demographic variables		frequency	Percentage (%)
Age	18-24	5	7.1
	25-30	28	40
	31-36	25	35.7
	Above 36	12	17.1

From the above figure 2 shown that regarding age distribution, majority (40%) of the contacted respondents were 25-30 years of age.

Table 3: Distribution of experiences of respondents

Demographic variables		frequency	Percentage (%)
Experience	Less than 1	20	28.5
	1 to 5	26	37.1
	6 to 10	18	25.7
	11 to 15	6	8.6
	More than 15	0	0

From the table 3 above In case of experience at work many (37.1) of the vaccines store supervisors/immunization focal person had worked for 1-5 years and no one (0%) had worked for more than 15year of experience as vaccines store supervisor or immunization focal person.

4.3. Knowledge levels of respondents on recommended temperature range for vaccine stored in refrigerators.

Respondents were asked question with regard to the recommended temperature range for vaccines stored in refrigerators such as Pentavalent, TT, BCG, Ant rabies and diluents and results are summarized in figure 2 below.

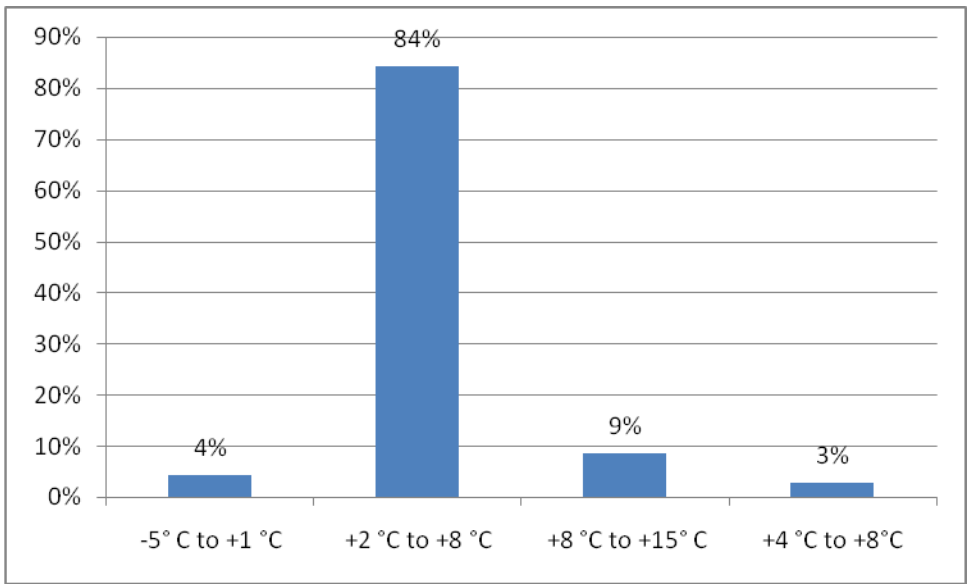


Figure2: Knowledge level of respondents on recommended temperature range for vaccines stored in refrigerator.

Majority (84%) of respondents had knowledge on recommended temperature range of vaccines stored in refrigerator.

4.4. Knowledge levels of respondents on recommended temperature range for vaccine stored in freezers.

Respondents were asked question for the recommended temperature range for vaccines stored in freezer such as Measles vaccines and OPV and results are summarized in figure 3 below.

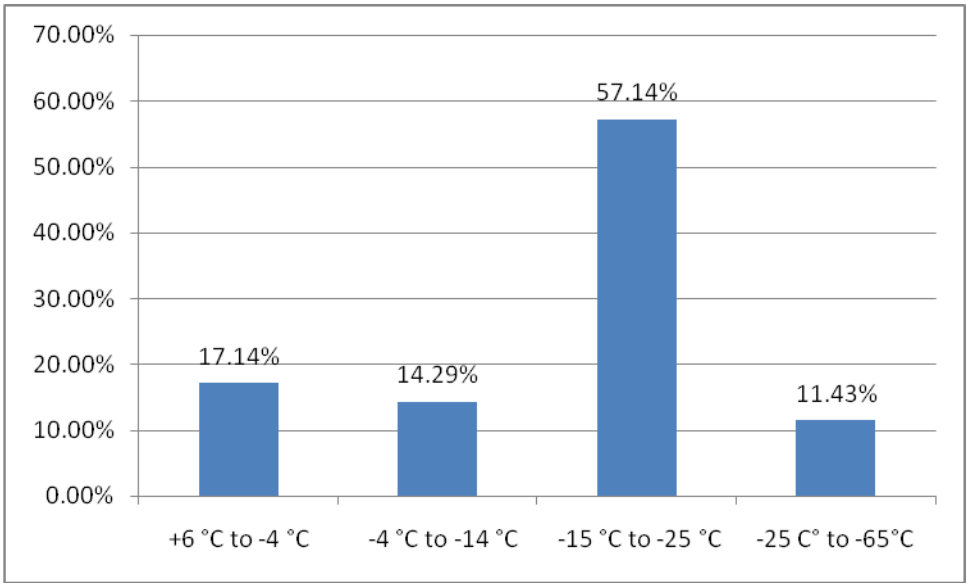


Figure 3: Knowledge level of respondents on recommended temperature range for vaccines stored in freezers.

Majority (57.1%) of respondents had knowledge on recommended temperature range of vaccines stored in freezer and (42.9%) of the respondents had no knowledge on recommended temperature range for vaccines stored in freezers.

4.5. Factors that lead to fault in storage condition at your facility

Respondents were asked question for the factors lead to fault storage conditions at the center and branch. Respondents mentioned a number of factors which are shown in figure 5 below, was mentioned by about (44.3) lack of space and lack of temperature monitoring

device was mentioned by only (7.1%) and the respondents results are summarized in figure 4 below

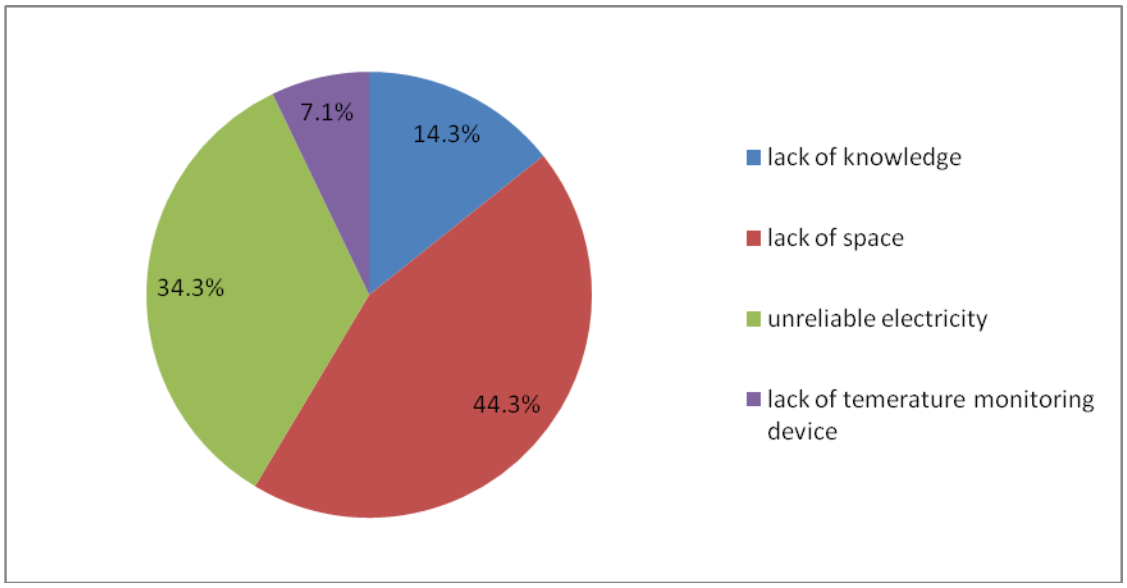


Figure 4: Responses of respondents on the factors that lead to improper storage condition.

4.6. Availability of vaccines at PFSA and PFSA Addis Ababa branch No-1

The availability of six key vaccines used in routine Immunization was used as tracer vaccines. The distribution of availability of vaccines from 70 contacted respondents in PFSA central were summarized in the tables below

Table 4: Availability of vaccines at PFSA central

Tracer vaccines	PFSA vaccine availability in Percentage (%).
BCG vaccine	98
Pentavalent vaccine	97
Oral Polio vaccine (OPV)	96
Measles vaccine	99
Tetanus Toxoid vaccines	97.5
Rabbies vaccine	56
Mean (average)	90.5

From the table 4 above the least available vaccine at PFSA central was Rabies vaccine (56%). Mean availability of vaccines is 90.5%.

Table 5: Availability of vaccines at PFSA Addis Ababa branch No-1

Tracer vaccines	PFSA Addis Ababa branch No-1 vaccine availability in Percentage (%).
BCG vaccine	98
Pentavalent vaccine	98.5
Oral Polio vaccine (OPV)	89
Measles vaccine	99
Tetanus Toxoid vaccines	100
Rabbies vaccine	86
Mean (average)	95

From the table 5 above the least available vaccines at Addis Ababa branch No-1was Rabies vaccines (86%). Mean availability at vaccine stores level is 95%.

4.7. Frequency of distribution of vaccines to the lower facilities

Responses of respondents with regard to the frequency of distribution of vaccines to the lower health facilities, question aimed at determined the effectiveness of vaccine distribution from stores to lower healthcare facilities were summarized in the table 5 below;

Table 6: Frequency of distribution of vaccines to the lower facilities

Frequency distribution of vaccines	Respondents	Percent
Once monthly	30	42.9
Twice a year	4	5.7
Quarterly a year	14	20.0
When necessary (no specified time period)	22	31.4

Table 6 above shows that 42.9% of the contacted respondents were distributing vaccine to the facilities monthly.

4.8. Methods regularly used to transport vaccines at PFSA

With regards to question that list all the method regularly used to transport the vaccines at PFSA, the respondents were required to list the method they regularly used to transport vaccines. This question was aimed in determining means of vaccines transport.

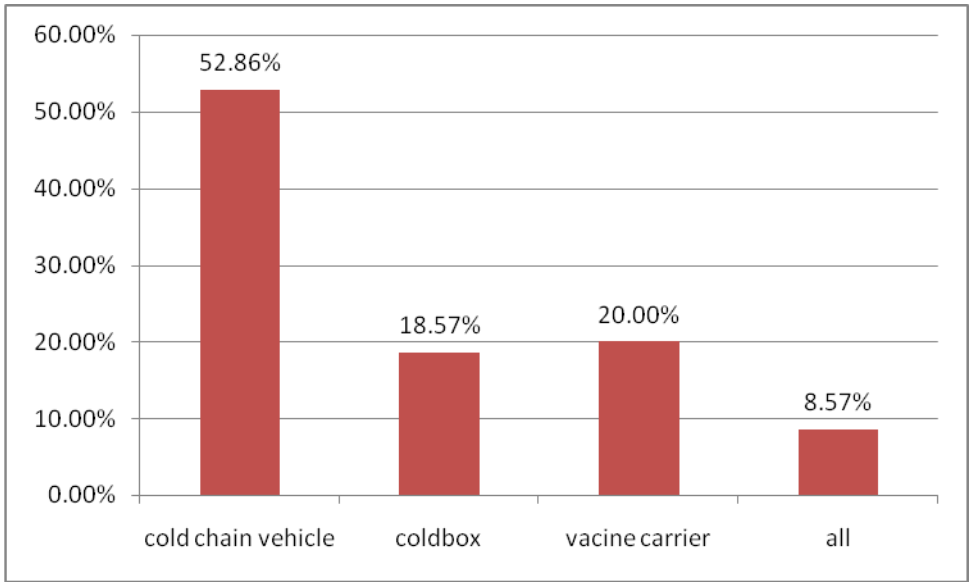


Figure5: Means of transport used to transport vaccine

From the figure 5 above (52.86%) of respondents used cold chain vehicles to transport vaccine, and (8.6%) used the listed here: cold chain cars, cold box, and vaccine carriers to transport vaccines to their branches and facilities.

4.9. Records of discarded vaccines

From the respondents With regards to records of vaccines discarded due to incorrect storage temperature majority of respondents (92.9%) said that there were no records and (7.1 %) of the respondents said they kept records.

4.10. Barriers to efficient distribution system of vaccines

The research looked into barriers to efficient distribution system that health facilities face whenever they plan to distribute vaccines. With regards to this question respondents

interviewed were asked to respond by mentioned some of the barriers she/he knows and results of which have been summarized below

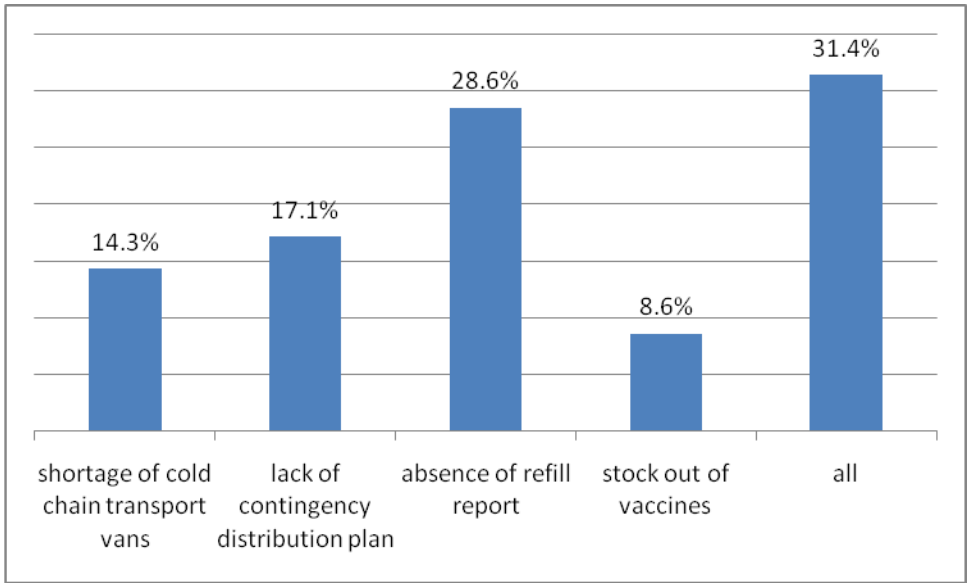


Figure 6: Barriers to efficient distribution system of vaccines.

From figure 5 above many (31.4%) of respondents mentioned that all of the above seated factors are a barrier to efficient distribution

4.11. Availability of EPI Guidelines for vaccine management

The respondents were assessed on presence of EPI Guidelines for vaccine management which is a very important tool for health professionals engaged in daily vaccines store management transactions and in immunization session, results of which are summarized in the figure 6 below.

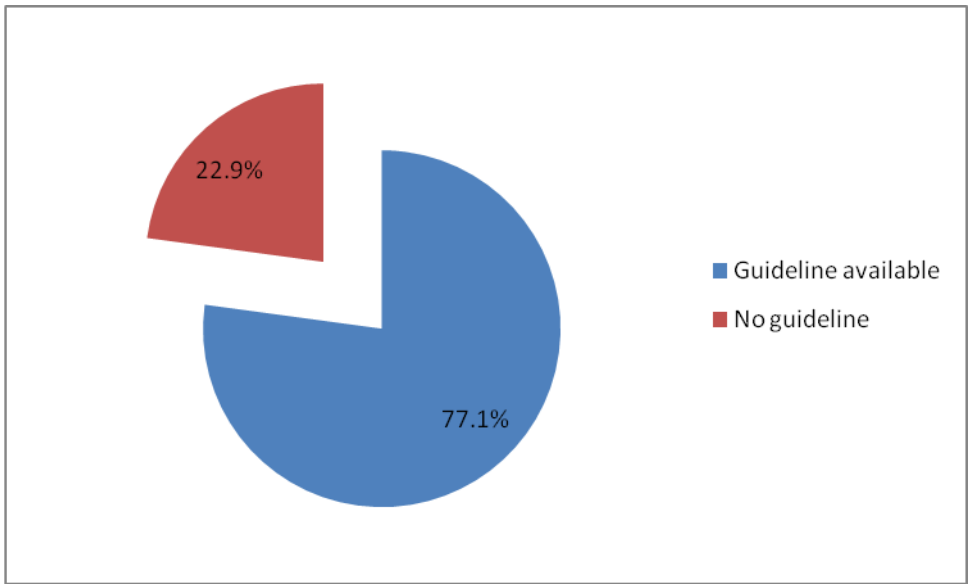


Figure 7: Availability of EPI Guidelines for vaccine management

Figure 7 above entails that for (77.1%) of contacted respondents had EPI Guidelines for vaccine management

4.12. Response of respondents to the action taken when vaccines are found out of recommended temperature range

The action taken when vaccines are found out of recommended temperature range are summarized in table below

Table7: Action/measure taken by respondents when vaccines were found out of recommended temperature range.

Action/Measure	percentages
Continue stored in cold chain for future use	34.3
Stop using and recorded in book for all vaccine discarded	64.3
Others(Transfer to nearest facility or adjust refrigerator)	1.4

From the table 7 above 64.3% of contacted respondents responded by saying stop storing using and recorded in book for all vaccine discarded. Only 1.4% of respondents said using other mechanisms (transfer to nearest facility or adjust refrigerator).

4.13. Storage Conditions and facilities and Safety of vaccines

The results were generated on a five point Likert scale; whereby the respondents were required to state their level of agreement. The responses were discussed in the table 6 below.

Table 8: Storage Conditions and facilities and Safety of vaccines

Storage condition and facilities	Strongly disagree		Disagree		Satisfactory		Agree		Strongly Agree	
	frequency	Percent (%)	frequency	Percent (%)	frequency	Percent (%)	frequency	Percent (%)	frequency	Percent (%)
Available special storage area	7	10.0	15	21.4	12	17.1	18	25.7	18	25.7
Enough storage space available	9	12.9	21	30.0	15	21.4	13	18.6	12	17.1
Fully functional storage equipment	6	8.6	21	30.0	18	25.7	14	20.0	11	15.7
Different storage equipment for different kinds of vaccines	4	5.7	17	24.3	18	25.7	18	25.7	13	18.6
Storage equipment are regularly checked for compliance	5	7.1	13	18.6	18	25.7	26	37.1	8	11.4
Existing SOPs that are followed to ensure proper storage	1	1.4	10	14.3	28	40	19	27.1	12	17.1
Measures in place to ensure vaccines don't go bad while in distribution	1	1.4	15	21.4	24	34.3	22	31.4	8	11.4
Good Storage practices are satisfactory	2	2.9	9	12.9	25	35.7	21	30.0	13	18.6

Source: SPSS output, 2018

The first objective of the study sought to determine how storage conditions influences safety of vaccines. Descriptive statistics in form of frequencies and percentages were used to summarize the findings as shown in Table 6 points that maintaining correct temperatures during storage are a very important task for cold chain items. A frequency of 25.7% of respondents strongly agree that there exists special storage areas, 25.7% of respondents satisfied to regular checking of equipment for compliance.30% are disagree with the storage space available and disagree on the functionality of equipments and availability of different for different kinds of vaccines. 40% of the respondents answered satisfactory to the use of SOPs in storage of cold chain vaccines. However, 35.7% are satisfied with the storage conditions and practices in their organizations.

On average 25% of the respondents are satisfied with the storage conditions in their organizations while 24% disagree to having proper storage conditions for cold chain vaccines and only 9% strongly agree to have proper storage conditions that ensure safety of vaccines.

This means that the storage conditions are not excellent to ensure safety of cold chain items. Control of storage conditions and temperature is essential in maintaining the quality of cold chain items and in helping to protect patients from sub-standard or ineffective medicines that may result from inadequate storage control (Monicah,2015).

CHAPTER FIVE: SUMMARY OF MAJOR FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1. Conclusions

Supply chain management of vaccine is highly associated with many challenges that can not be sorted out by just one player but rather all players involved in the vaccines distribution system such as Manufacturers, UNICEF, PFSA, PFSA branches, Regional Vaccine Store, District Vaccine Store, district councils authorities.

5.2. Summary of major findings

The study has identified about 4 main factors that affect supply chain management system of vaccine; these include inadequate vehicles for distribution of vaccines to public healthcare facilities, Stock out condition the study reveals average stock out days was low at PFSA as compared to the branch and the comparison confirm that there is no statistical significance difference between stock out in PFSA and PFSA branch vaccine stores. Lack of on job training with special emphasis on storage, handling and distribution of vaccines. Lack of storage space in PFSA and PFSA branches. In order for a vaccine to maintain its efficacy it required good storage condition (cold chain) from point of manufacture up to point of administration. Last but not least non-adherence to good storage practices, arrangement was not proper within refrigerator, there were temperature monitoring devices, but there were no recording chart in few PFSA and its branches vaccine cold chains. All these may contribute to facilities not being able to maintain the required storage condition which may lead to deterioration of the vaccine.

5.3. Recommendations

The following are recommendation in response to the above that affect vaccine supply chain management revealed by study

- PFSA– Pharmacists are custodian in medicines once involved in the program it's our hope the problems of poor storage practices, lack of space and storing vaccines out of recommended temperature range can be reduced and controlled under his/ her supervision.
- PFSA- Need to strengthen the transport system of cold chain vaccines according to their optimum temperature ranges,because the temperature may affect their quality.
- PFSA – Need to strengthen supportive supervision at PFSA central and PFSA Addis Ababa branch No-1 so as to improve their performance in chart monitoring and recording for recommended temperature range.
- PFSA – Need to supply freezer tags to all cold chain warehouses which can help in monitoring and recording temperature even when the store managers in charge were absent.
- PFSA/EPI –Need to strengthen the storage practices of vaccines by providing on job training, so as store in-charge and immunization focal personnel they can know how to use refrigerator and good practice of storing vaccines.
- PFSA and Branch Authorities (PFSA central officers & PFSA branch Cold Chain Officers) should abide to the vaccines distribution scheduled plan.

5.4. Areas for Further Research

This study just focused on factors affecting supply chain management of vaccines in PFSA central and PFSA Addis Ababa branch No-1, further research can be carried out to cover the whole country health facilities to assess the magnitude of the problem.

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ANNEX-1

ADDIS ABABA UNIVERSITY
SCHOOL OF COMMERCE

DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGENMENT GRADUATE PROGRAM

Questionnaire

Dear respondents, my name is Tesfamichael Bayeh Muluneh, the purpose of this questionnaire is to gather data on the factors affecting supply chain management of vaccine in order to fulfill the University's (Addis Ababa University) requirement set for awarding of a Masters Degree in Logistics and supply chain Management. The study is purely for academic purpose and thus not affects you in any case. So, your genuine, frank and timely response is vital for successfulness of the study. Therefore, I kindly request you to respond to each items 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 part I and please tick (√) the answer in part II.

Contact Address

If you have any query, please do not hesitate to contact me and I am available as per your Convenience at (Mobile: 09-11-80-29-46 or e-mail: *tesfamic64@gmail.com*)

Thank you for scarifying your precious time in advance!

Questionnaires are used to assess the factors that affect logistics and supply chain management of vaccines in Pharmaceutical Fund and Supply Agency Ethiopia, and PFSA Addis Ababa branch no-1

Code No……

Name of the organization……

1. Professional of in-charge/coordinator/ immunization 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 of the vaccine 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 vaccines do you stock at PFSA?

a) Bacillus Calmette Guerin (BCG)

b) DTP-HepB-Hib or Pentavalent (Diphtheria, Tetanus, Pertussis , Hepatitis B, Heamophilus influenzae B)

c) OPV (Oral polio vaccine)

d) Measles virus vaccine

e) Rabies vaccine

f) TT (Tetanus toxoid vaccine)

g) 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 last three years?

a) Once

b) Twice

c) Thrice

d) Not attended

8. What is the recommended temperature range for most vaccine stored in refrigerators?

a) -5° C to +1 °C

b) +2 °C to +8 °C

c) +8 °C to +15° C

d) +4 °C to +8°C

9. What is recommended temperature range for most vaccine stored in freezers?

a) +6 °C to -4 °C

b) -4 °C to -14 °C

c) -15 °C to -25 °C

d) -25 C° to -65°C

10. Does it happen that vaccines in refrigerator or freezer 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 vaccine in stock storage were found out of recommended temperature range?

a) Continue stored in cold chain for future use

b) Stop using and recorded in book for all vaccine discarded due to incorrect storage temperature.

c) Others…….

12) Is there any record for all vaccine discarded due to incorrect storage temperature?

a) Yes (if yes ask to see)

b) No

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

a) Lack of knowledge c) Lack of space

b) Unreliable temperature d) Lack of temperature monitoring device

14. Explain in short how you handle vaccine medicines from the point of arrival up to the Point of administration

a) Cold chain vehicles c) Cold box

b) Ice pack d) Vaccine carrier

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

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

b) Martindale d) others (mention)

16. If you have the Expanded Program of Immunization (EPI) Guidelines for Safe vaccine management, have ever gone through it to find out proper ways of storage 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 vaccines 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 vaccines to branches?

a) Once monthly

b) Twice a year

c) Quarterly a year

d) When necessary (no specified time period)

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

a) Cold chain vehicle c) vaccine carrier

b) Cold box d) all

20. How do you determine your vaccines stock position at your facility?

a) By determining only safety stock

b) By determining only maximum stock level

c) By determining only minimum stock level

d) By determining 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 vaccine 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 over stock

22. When do you say the vaccines stock is at minimum stock level?

a) When stock is at 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 vaccines stock is at safety stock level?

a) When you have vaccines maximum stock

b) When you have vaccines minimum stock

c) When you have vaccines stock on hand to prevent stock out

d) When you have vaccines emergency stock

24. What do you put in consideration when you need to prepare the vaccines order at your facility?

a) Quantity used since last delivery

b) Storage volume within the refrigerator

c) Vaccines currently in the refrigerator

d) Disease outbreak

e) Seasonal variation f) OTHERS……

25. In your own opinion, what do you think are the barriers to efficient distribution and storage system of vaccine are?

a) Shortage of cold chain transport vehicles c) Absence of refill report from facilities

b) Lack of contingency distribution plan d)Stock out of vaccine

26. Do you think you need more professional training on vaccine distribution and its management in order to strengthening your pharmaceutical management skills on cold chain at your facility?

a) Yes

b) No

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

27. What do you finally recommend to the PFSA/ EPI on storage and distribution?

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

b) Enough cold chain vehicles d) All

Part II: Storage Conditions and facilities and Safety of vaccines.

The responses will generate on a five point Likert scale; whereby the respondents were required to state their level of agreement where: *SD=strongly disagree D=Disagree S=Satisfactory A=Agree SA=Strongly Agree

Storage conditions and facilities	Level of agreement				
	SD	D	S	A	SA
Available special storage area					
Enough storage space available					
Fully functional storage equipment					
Different storage equipment for different kinds of vaccines					
Storage equipment are regularly checked for compliance					
Existing SOPs that are followed to ensure proper storage					
Measures in place to ensure vaccines don't go bad while in distribution					
Good Storage practices are satisfactory					

Thank you for your participation!