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Influence of Cold Chain Supply Logistics on the Safety of Vaccines. A Case of Pharmaceutical Distributors in Nairobi County

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Abstract
Supply of safe vaccines is very important and appropriate procedures, monitoring and logistics systems need to be put in place to ensure safety. The pharmaceutical supply chain have various global regulatory requirements to be met during transport ,storage, packaging and handling environmentally sensitive products like biologicals, vaccines and some medicines. This is to ensure that quality and efficacy of cold chain products is not compromised along the supply chain. Global players have regulations and guidelines that address product integrity and safety during the entire supply chain. It was therefore of importance to identify how Pharmaceutical distributors in Nairobi County have developed their cold chain supply systems and how it is able to maintain cold chain for temperature-sensitive pharmaceuticals considering the challenges of; Transport systems, storage facilities, packaging, technical capacity, unreliable electricity supply, weak validation systems, probable poor monitoring of cold chain supply systems. The main objective of the study was to establish the influence of supply chain logistics in supply of safe pharmaceutical cold chain products in Pharmaceutical distributor firms in Nairobi County while the specific objectives were to determine how storage conditions in pharmaceutical distributors in Nairobi influences safety of vaccines; to determine the influence of transport systems on the safety of vaccine; to evaluate the influence of Packaging on the safety of vaccines and finally establish the extent to which technical capacity influence safety of Vaccines in pharmaceutical distributors in Nairobi. Descriptive survey design was considered because it is non-experimental and studies the relationship between non-manipulated variables in a natural setting. The study was carried out in five major pharmaceutical firms out of 16 registered cold chain pharmaceutical distributors in Nairobi County. A sample size of 67 participants was selected out of a population of 211 staff from different firms consisting of the automatically included 5 supply chain managers and 62 employees from procurement and stores department. The data was collected by use of self-administered questionnaires to the sampled respondents by a drop and pick method. The questionnaires were coded and data analyzed using Statistical Package for Social Science (SPSS V-17).Correlation analysis was done to determine the relationship between the dependent and independent variables whereby it was found that technical capacity and storage conditions have the greatest relationship and influence to the safety of vaccines. The findings were presented through figures, tables, and graphs.
Keywords: Cold chain, logistics, Pharmaceuticals, Safety

1. INTRODUCTION

In as much as globalization has made the world a global village through phone calls, emails, social networking, e-conferencing and videos that are easily transmitted in seconds, this has not penetrated other areas such as pharmaceuticals where goods have to be physically moved. Ames, (2006) emphasizes that cold chain supply requires a lot of logistical coordination and this can only be made possible by cold chain technology which has various impacts on timely delivery and quality of the pharmaceutical cold chain products and hence their potency and safety for administration to patients.

At the global perspective, Estrada, (2008) defines procurement as the acquisition of goods, services or works from an outside external source at the best possible cost to meet the needs of the purchaser in terms of quality and quantity, time, and location. The cold chain is the process of maintaining medication such as insulin, vaccines; biologicals within recommended temperatures mostly between 2ºC to 8ºC throughout the supply chain (Bishara, 2006). In the health sector pharmaceutical cold chain is concerned with the transportation, storage, and handling of pharmaceutical products in a safe environment from the manufacturer to the end user. Temperatures outside recommended temperature ranges may reduce potency leading to lack of desired response e.g. reduced immunity. Control of storage and transportation temperature is essential in maintaining the quality of medicines and in helping to protect patients from sub-standard or ineffective medicines that may result from inadequate control (Blake, 2008). Lack of awareness by distributors in the control of storage and transportation temperatures can have a major impact on product quality.

World Health Organization (WHO) has noted that twenty five percent of all vaccine products reach their destination in a degraded state. This according to The Medicines and Healthcare Products Regulatory

Agency 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. Global warming makes temperature control issues a growing challenge in the cold chain supply (Bishara, 2007).

Bishara, (2007) states that according to Medicines and Healthcare Products Regulatory Authority (MHRA) of the United Kingdom, thirty two percent of all critical and major deficiencies recorded by MHRA's Good Distribution Practice (GDP) inspectors during 2005/2006 related to the control and monitoring of storage and transportation temperatures. Comparatively, forty three percent critical and major deficiencies were recorded in 2004/2005 respectively. In view of this, many countries such as Canada, Ireland, Australia, Singapore, South Korea, and European Union have issued regulations and specific guidelines that address product integrity during transportation of cold chain medicines and hence the significant reduction in deficiencies.

At the continental level, Forcinio and Wright, (2005) has noted that in lower-income countries in Africa, efforts to have an efficient cold chain supply process are often hampered by poor health delivery systems, low political commitment, low levels of investment, poorly maintained cold chains, lack of human resources, poor effective disease surveillance and reporting systems which are key components of the procurement and logistics process.

A survey by Agyekum (2012), conducted in Ghana, Kenya and Uganda indicates that an average of sixteen percent of the sampled facilities were not compliant to the guidelines laid out by regulatory authorities and fifty percent of these facilities had temperatures 4°c or more outside the recommended temperatures. For example only four per cent of facilities stored vaccines in cold boxes, while the remainder used refrigerators and storage outside the recommended range. Though significant variation was observed between the countries; twenty six percent, sixteen percent, and eight percent for Ghana, Kenya, and Uganda, respectively there remains significant room to improve cold chain supply in these countries among others in Africa (Burger, Kopf, Yoong, & Sood. 2012)

In a comparison of African countries based on their cold supply chains, it was found that Ghana had developed its cold chain supply systems and now it is able to maintain cold chain for temperature-sensitive items than Kenya and Uganda in spite of facing similar challenges. According to Agyekum (2012), this was because Ghana's regulatory Authorities have been able to develop validation methods and guidelines for the cold chain delivery system, with the goal of providing temperature assurance during the manufacturing, storage, shipping and delivery of cold chain items (Burger, Kopf, Yoong, & Sood. 2012)

The Kenyan government and several international donors that provide vaccines which are the main pharmaceutical cold chain products for the Kenya Expanded Programme for Immunisation (KEPI). These pharmaceutical cold chain products are managed and distributed through the KEPI vertical program and are stored at the central level in the KEPI cold store. KEPI has a strong information system that includes good stock control practices. This facilitates recording of vital information on vaccines on reception, during storage and when they are leaving the store for distribution.

However, it is not only KEPI that imports and distributes medical products and vaccines in Kenya as there are other players in the field. Kalunda, Nduku, and Kabiru (2012) reveal that a pharmaceutical company is a commercial business licensed to research, develop, market and/or distribute drugs, most commonly in the context of healthcare. The pharmaceutical industry consists of three segments namely the manufacturers, distributors and retailers (Export Processing Zones Authority– Kenya, 2005).. The key players in the industry in Kenya include multinational corporations (MNC's) like GlaxoSmithKline, Bayer, Sanofi Aventis, and Pfizer while key local establishments include Dawa Pharmaceuticals Ltd, Cosmos Pharmaceuticals. They deal in brand and/or generic medications. They support the country's health sector, which is estimated to have about 8,006 health institutions countrywide (Kenya National Bureau of Statistics (KNBS), 2012).

Most of these players that are predominantly, privately owned firms in engaging in pharmaceutical products that require cold chain sometimes use equipment that are not compatible with WHO–UNICEF product information sheets (PIS) and cannot ensure the storage temperatures required for different types of pharmaceutical cold chain products. Ayaya, Liechty, Conway, Kamau, and Esamai, (2007) reasons that this may lead to poor maintenance and possible malfunction which may put vaccines at risk of exposure to unacceptable temperatures. The factors leading to this supply of not very safe pharmaceutical cold chain items has not been well identified and this research therefore seeks to establish these factors (Ministry of Health (MOH), 2004).

In Kenya the cold chain supply has generally been neglected in regard to the establishment, development, maintenance and control of the activities involved especially in the private sector which really supports the health sector mainly because the cold chain supply process involves multiple parties, high risks and high financial investments .When there is an equipment or management failure at the primary level, large quantities of cold chain products may be destroyed in a matter of a few hours (Kamau, & Mukui. 2005).

Most of these players require a cold chain logistic in order to ensure proper handling, temperature control and monitoring for safety and quality in each stage of the supply chain lest the very functions of the

medicinal products and vaccines as stated by Bishara, (2006) be rendered futile. According to PPB (2013) there are 1332 registered pharmaceutical companies and chemists in Kenya, with 50 percent of them in Nairobi and only 10 percent are involved in cold chain supply and only 10 percent of those involved in cold chain supply are involved in importation and distribution to the other pharmaceuticals, the hospitals and health facilities.

1.1 STATEMENT OF THE PROBLEM

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. This is confirmed by Bishara, (2007) 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.

Kamau and Mukui ,(2005), noted that 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 dire effects on the health of the users.

Storage conditions and facilities are not upto standard and there lacks a fleet of specialised transport systems to ensure no cold chain breaks during transport by doing proper monitoring of tempretures. Packaging materials used are questionable in maintain the correct tempretures and conditions to ensure safety of vaccines. Most firms also seem not to be technically capable to handle cold chain effectively to ensure their safety.

Proper packaging Regulatory and compliance issues relating to transportation, storage, packaging and technical compliance , influences the safety cold chain items to the user level are critical in this process to avoid degradation (Blake, 2008) This is why this study is timely in analysing the influence of cold chain supply logistics on supply of safe cold chain products.

1.2 OBJECTIVES

General Objective

The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines in pharmaceutical distributors in Nairobi.

Specific Objectives

1 To determine how storage conditions in pharmaceutical distributors in Nairobi influences safety of vaccines.
2 To determine the influence of transport systems on the safety of vaccines in pharmaceutical distributors in Nairobi
3 To evaluate the influence of Packaging in pharmaceutical distributors in Nairobi on the safety of vaccines.
4 To establish the extent to which technical capacity in pharmaceutical distributors in Nairobi influence safety of Vaccines

Research Questions

The research questions of this study were:

1. How does storage conditions in pharmaceutical distributors in Nairobi influence safety of vaccines?
2. How do transport systems of vaccines in pharmaceutical distributors in Nairobi influence their safety?
3. How does packaging of vaccines within pharmaceutical distributors in Nairobi influence their safety?
4. How does technical capability of pharmaceutical distributors in Nairobi influence safety of Vaccines

2. LITERATURE REVIEW

The study was grounded on three theories mainly;Agency theory,Flat earth theory and the 3-dimensional theory.

2.1 Agency Theory

Agency theory explains relationship between two parties, mainly an agent and a principal whereby the principal delegates to the agent his powers to act on behalf, represent, and carry out transactions with a third party. In such relationships, there is often a tendency of power abuse by agents and problems arise due to agency inefficiency. Agency theory helps understand the conditions under which a supply chain member is likely to attempt to exploit other members.

The theory also guides in an investigation of the effect of such opportunism on supply chain effectiveness and how it can be prevented or minimized. The agency theory was promoted with seminal works of Max Weber (Beckert, and Zafirovski, 2006), was mostly concerned with the conflict between political master

and state officials. This view was built on the foundation of the neoclassical view of organization-that views the organization as black boxes of operations, where the "relationship between performance and incentives "was over looked (Beckert, and Zafirovski, 2006).

New institutionalism view of organization opened the black box of organizational operations and paved way for contemporary view of the agency theory. In the old institutionalism view, opportunistic behavior based on the rational system view was dominant. However, the new institutionalism view of the organizations, promotes the delegation of responsibilities and operation, through an open system view towards the environment. The agency theory – from the classical or neoclassical perspectives provides contributions to the understanding of supply chain management. Agency theory has been applied to various activities associated with supply chain management including, outsourcing (Logan, 2000; Loebbecke & Huyskens, 2009,) sourcing (Shook, Adams, Ketchen & Craighead 2009), and supply chain collaboration (Kwon & Suh, 2004). Agency theory is useful in the study of cold supply chain in the pharmaceutical industry as it informs why firms opt to use distributors or agent to supply products

2.2 Flat Earth Theory

Friedman, (2007) explains that there are three eras of globalization and ten flatteners which made the world smaller, making it easier to communicate and share our knowledge. The first era, called between the years 1492, when Columbus set out to discover a new trade route to the New World, and 1800, made the world fall in size from large to medium. During this period, the strength of a country was based on the number of horsepower or the number of steam engines owned, compared with other countries. The second period between the years 1800 and 2000 decreased the size of the world, from medium to low. Multinational companies were the integration force, and the power was given to a company by the level of innovation in the field of machinery and equipment. The third globalisation era began around the year 2000. The first two eras led to globalization at the country level and, later, at the company level, this new era favorized reduction to a very small world, flattening the playing field and putting the individual in the centre Friedman, (2007). Globalization has been maintained by the action of some flattening factors that favoured the levelling of the World and the emergence of some opportunities that could increase welfare if successfully exploited.

One common misconception in cold chain supply is that product storage and distribution temperatures are the same. The idea that the products' long-term storage temperature is not the same as the distribution temperature is easily forgotten .Cold chain products was be exposed to warmer or colder conditions as it moves downstream the supply chain. Where the vaccines are taken out of the target refrigeration temperature range for a short period and later placed back to the proper conditions without compromising the product quality. In the pharmaceutical industries, we find that the stability studies are mandatory by health authorities and these studies are performed following a strict and standardized method outlined by the International Committee of Harmonization (ICH). The Quality Stability group performs these studies and the Regulatory group uses the results to establish storage temperature and product shelf life, to file the drug product registrations and to answer questions from regulatory bodies however, stability studies are lengthy and expensive and are specific to the primary container and the manufacturing site.

On the other hand, a standardized method to define the distribution temperature is not available and is common to find that many companies only perform long-term stability studies and established storage temperatures. Companies with only storage temperature have the flat-earth view because they assume that distribution temperature must be the same as the storage temperature. This flat-earth view creates many supply chain inefficiencies because of the need of extra protection due to the fear of the unknown outside the long term stability conditions.

2.3 Three-Dimensional Generic Theory Approach

Efficient intra and inter organizational information management in cold chain supply has different dimensions (Althoff, Ellebrecht, & Petersen, 2005). The technical dimension implies aspects of data distribution and storage, the possibilities of data exchange and in general the technology it incorporates. Craig (2007) describes the technical dimension as a group which includes mainly visible, tangible, measurable and easy-to-change components.

Organizational structure indicates the performance of different tasks as well as activities, for example in cross-functional teams. Van der Vorst, Da Silva, and Trienekens, (2007). understands under this aspect management methods, power and leadership structure, risk and reward structure and culture and attitude of the involved organizations describe in their techno-managerial approach a technical and an organizational or managerial perspective, respectively. Althoff, Ellebrecht and Petersen, (2005) define a third functional dimension of functional requirements which determine the information management in a quality and health management context. In relation to pharmaceutical cold chain management, mainly the proposed linkage of quality related data to other data sets at inspection and decision points may be categorized in this dimension.

Safety of cold chain products is influenced by the organisation structure in terms of information sharing, technical and functional undertaking of cold chain related processes.

2.4 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.

In Kenya very little cold chain medicine is manufactured and hence relies heavily on importation. Private suppliers receive their cold chain products from the airport cold room, transport them to wholesale storage facilities and distribute to retail pharmacies from their cold storage holding facilities. The Safety of cold chain pharmaceuticals/ 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 cold chain 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. Storage is a critical parameter in maintaining the quality, safety, stability and efficacy of cold chain products and must be stored in accordance with the requirements of its marketing authorization (Skuce, 2010).

The operation of the pharmaceutical 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.

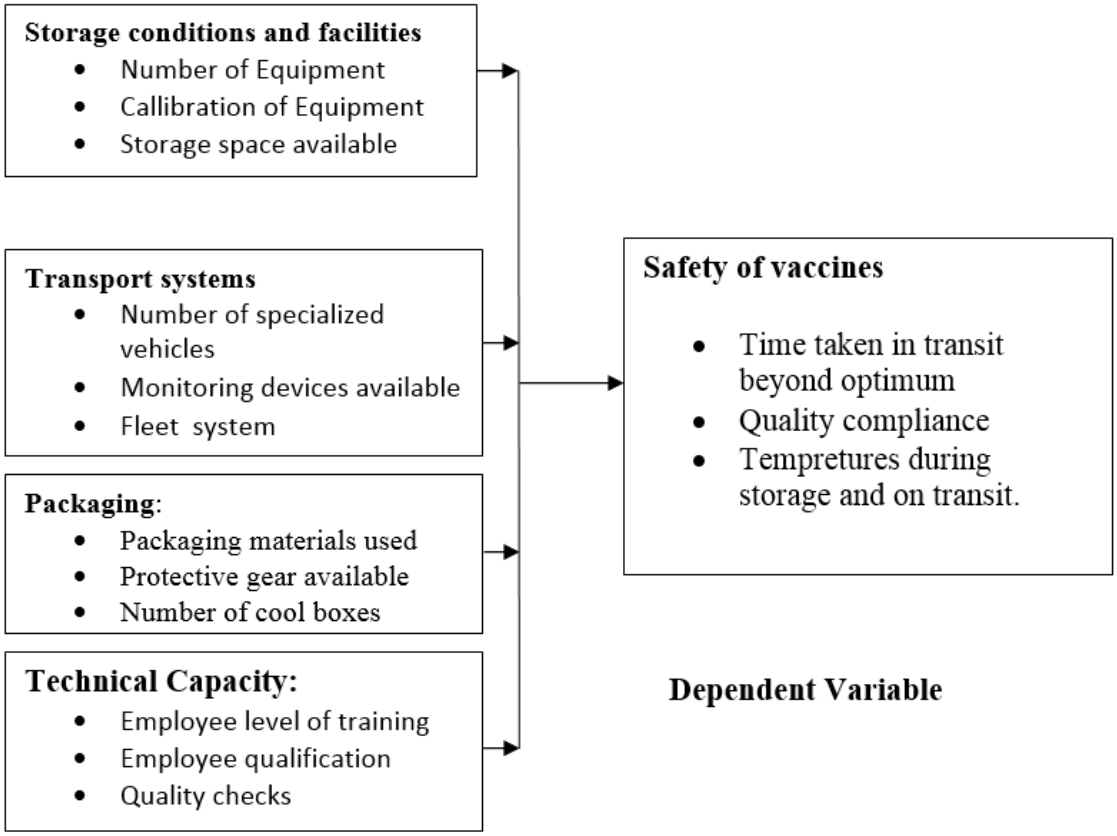

Figure 2.1: Conceptual Framework

3. RESEARCH METHODOLOGY

3.1 Research Design

This study adopted a Descriptive survey design to generate answers to the research questions (Orodho, 2003). Descriptive survey design was considered because it is non-experimental and it studies the relationship between non-manipulated variables in a natural setting, it also allows the collection of a large amount of data from a

sizable population in a highly economical way (Kumar. R. 2005). The data collected was descriptive in nature and was used to assess the influence of cold chain supply logistics on the safety of vaccines in Nairobi County. This design helps obtain information that describes existing phenomena by asking individuals about their perceptions, attitudes, behaviour or values (Mugenda, O. & Mugenda, and A. 2003).

3.2 Population

Mugenda and Mugenda, (2003) defines a population as the full set of cases from which a sample is taken. The population in this research study was drawn from Pharmacies and Poison Board registered cold chain pharmaceutical distributors in Nairobi County.

3.3 Sampling frame

The sampling frame for the study was drawn from the registered cold chain pharmaceutical distributors in Nairobi County . Mugenda, and Mugenda, (2003) states that a sampling frame is an index of cases from which a sample is selected. According to PPB (2013) there are 16 registered cold chain pharmaceutical distributors in Nairobi County.

Table 1: Sampling frame

Population Size(Firms)	Percent Sample %	Sample Size
16	30	5

The five firms are; Phillips Healthcare, GlaxoSmithKline Kenya, Novartis Limited, Laborex Kenya, and Sanofi Aventis.

3.4 Sampling and Sampling Technique

A sample is a representative of a population according to Mugenda, and Mugenda, (2003).Sampling facilitates the study of a relatively smaller number of units compared to the target population and therefore helps obtain data that is representative of the whole population. A non-probabilistic sampling technique, specifically purposive sampling, was used to select the study region (Nairobi county) .Purposive sampling was appropriate in the selection of the Nairobi county region in because it allows for the selection of unique cases that are especially informative. Nairobi County being the capital city of Kenya where most of the main distributors are located (PPB, 2013).

Mugenda, and Mugenda, (2003) suggests that a sample size of 384 is representative for a population greater than 10,000 when the Z statistic is 1.96 at 95% confidence level. However the target population in this case is much less and hence followed Orodho (2005) statement that a sample of thirty percent is representative enough for a descriptive study; therefore a representative sample of five organizations was selected being thirty percent of the sixteen registered cold chain pharmaceutical distributors in Nairobi county involved in distribution to the other pharmaceuticals, the hospitals and health facilities .The five firms were selected purposively as firms that influence eighty percent of the cold chain supply market in the pharmaceutical sector as they are directly involved in the importation of vaccines (PPB, 2013). The five firms are; Phillips Healthcare, GlaxoSmithKline Kenya, Novartis Limited, Laborex Kenya, and Sanofi Aventis.

The target population was stratified into, middle level managers and operational level personnel involved in the cold chain. For the middle level managers (departmental heads), there was automatic inclusion sampling while for the operational level personnel stratified simple random sampling was used to sample other categories of sample size to select 30 percent of the target population based on Orodho (2005) that a sample of 30 percent is representative enough for a descriptive study based on characteristics such as position and experience, among others.

The targeted population under study comprise of staffs that are involved directly or indirectly in the procurement and logistics process of cold chain pharmaceuticals from the selected pharmaceutical distributors. The sample size of 67 participants was selected from all the different firms consisting of the automatically included 5 supply chain managers and 62 employees from procurement and stores department.

Table 2: Distribution of sample size

Staff Category	Sampling technique	Population Size	Percent Sample %	Sample Size
Supply-chain manager	Automatic inclusion	5	100	5
Procurement team	Simple random	86	30	26
Stores-Support staff	Simple random	120	30	36
Total		**211**		**67**

3.5 Instruments

The main instrument for data collection used was a structured questionnaire.

According to Sushil (2010), 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. This study used a structured questionnaire with close ended questions standardized in order to allow for easy comparison (Mugenda, O. & Mugenda, A.2003). The questionnaires contained relevant questions which were designed with the objectives of the study in mind. The questionnaire was issued to all sampled respondents across various category spectrum, and explore perceptions and feelings, general experiences, as well as knowledge and general information on the subject under study (Mugenda,O. & Mugenda,A.2003).

3.6 Data Collection methods

The research data was collected from primary sources through questionnaires and secondary data reviewed from existing literature, the firms' records, published material, journals and internet sources. The questionnaires were self-administered to the sampled respondents by a drop and pick method. Permission to carry out the research and authorization letter was be received from the University prior to administering the questionnaires and the researcher also went the sampled organizations for introduction and also seek a written approval to carry out the research confidentially for academic purpose only.

3.7 Data analysis and presentation

The researcher used both descriptive and inferential statistics to analyze data to allow for meaningful description data collected using statistics and to compare variables numerically by Correlation analysis. The data collected through questionnaires was coded and entered into the Statistical Package for Social Science (SPSS V-17) for analysis of quantitative data . Correlation analysis was 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. The resulting correlation coefficient (R) gave the indication of the strength and direction of the relation between the independent and dependent variables where values closest to +1 indicate a strong relationship and vice versa. Inferential statistics were used to make inferences about the population and a comparison for qualitative data based on literature reviewed and industry standards already set.Analyzed data was presented using Tables, graphs and charts .

4. RESEARCH FINDINGS AND DISCUSSION

4.1Introduction

This chapter describes the analysis and methods that were used in order to answer the research questions generated from the general objective of the study which is to establish the influence of cold chain supply logistics on safety of vaccines in pharmaceutical distributors in Nairobi. Detailed descriptive statistics such as frequencies and graphs and inferential statistic such as exploratory factor analysis, Pearson's correlation coefficient the key research findings are presented.

Gay and Airasian (2006) states that data analysis is the separation of data and examining data separately. Data analysis refers to examination of information collected by ordering and restructuring data from the field in order to grasp the overall meaning in relation to the hypothesis, the purpose of which is to illustrate the issues by making inferences.

4.2 Response Rate

An analysis of the respondents who were responsive and non responsive was as illustrated in the table below.

Table 4.1 Response Rate

Rating	Frequency	Response rate %
Responded	58	87
Non-response	9	13
Total	67	100

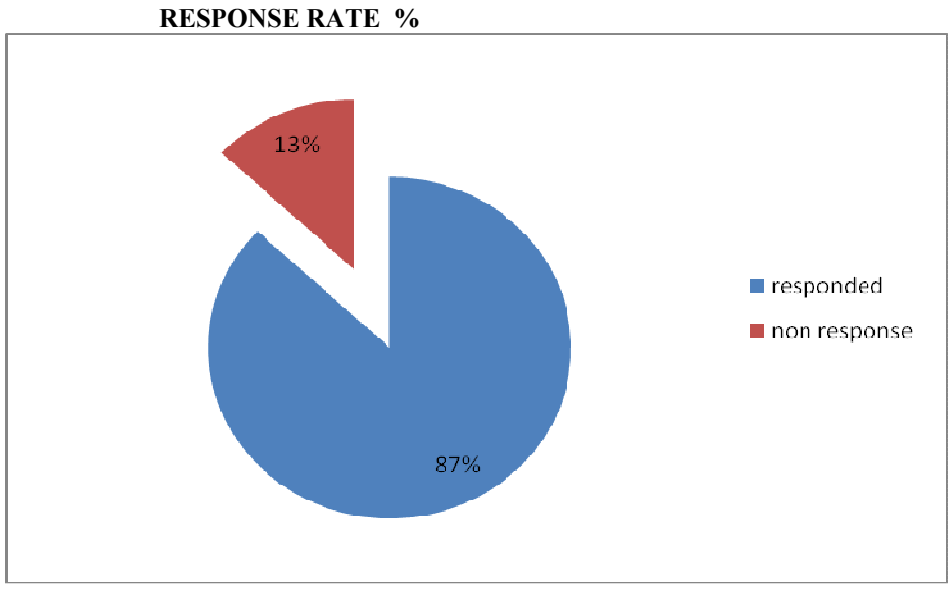

Figure 4.1 .Response Rate

This was to establish the response rate of the respondents from Table 4.1, the total number of that were administered were 67 and out of them 58 questionnaires representing 87% were fully answered and returned while 9 questionnaires representing 13% were not returned. The response rate was high and the findings were representative.

4.3 Back ground Information Analysis

The background information collected included the respondent's position, level of education and years of experience. A pie chart was used to illustrate the study findings as shown in Table 4.2 below.

Table 4.2 Background Analysis on respondent category

Respondent Characteristics	Characteristics Details	Number of Respondents	Response Rate%
Position	Supply chain Manager	4	6
	Procurement Personnel	23	34
	Stores personnel	31	46
Total		**58**	**87%**

Cold chain logistics mainly involve the stores and procurement personnel with 46 % and 34% respondents respectively and 6% are their managers who oversee the cold chain operation .Below is a pie chart illustration.

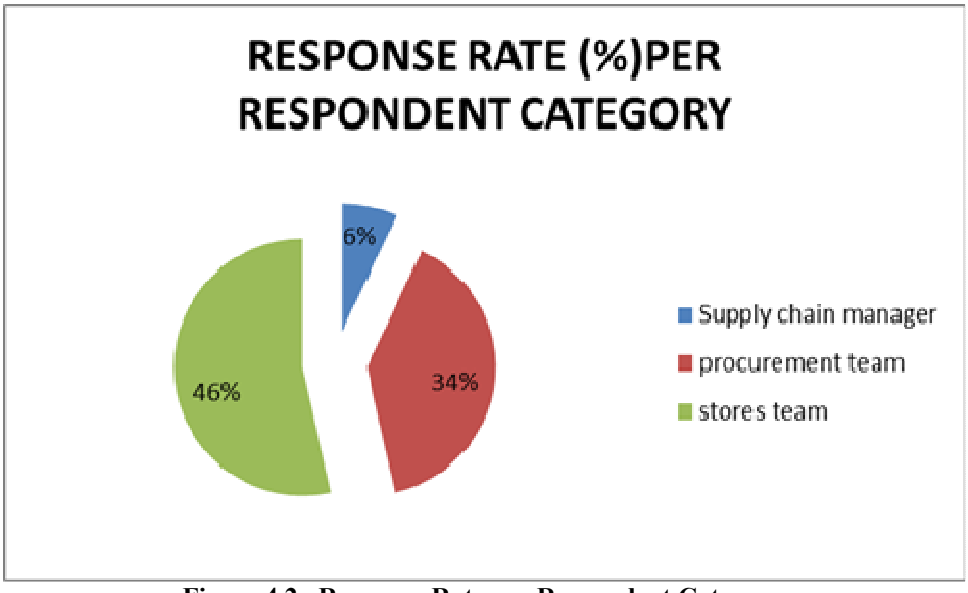

Figure 4.2 . Response Rate per Respondent Category

The researcher also sought to find out the highest level of education attained by the respondents and also if they had any special training on Cold chain.

Table 4.3 Background Analysis on Education Level

Respondent Characteristics	Characteristics Details	Number Respondents	Response Rate%
Education level	1.Primary School	0	0
	2.Secondary school	9	13
	3.Certificate	15	22
	4.Diploma	16	24
	5.Graduate Degree	10	15
	6 Post graduate degree	8	12
	7.Others (special training on cold chain)	6	9
Total		**58**	**87%**

Results of the study indicated that 24% had a diploma, 22% a certificate, 15% had a degree and 12% had post graduate degrees. Out of all respondents only 9% had a special training on cold chain. Education plays a very crucial role in the social-economic development and understanding and hence a high level of education depicts a higher and better understanding. In this case, majority of the respondents have diplomas and certificates and were able to respond accurately with understanding however the very low percentage of respondents specially trained in cold chain makes their competence in cold chain operations questionable.

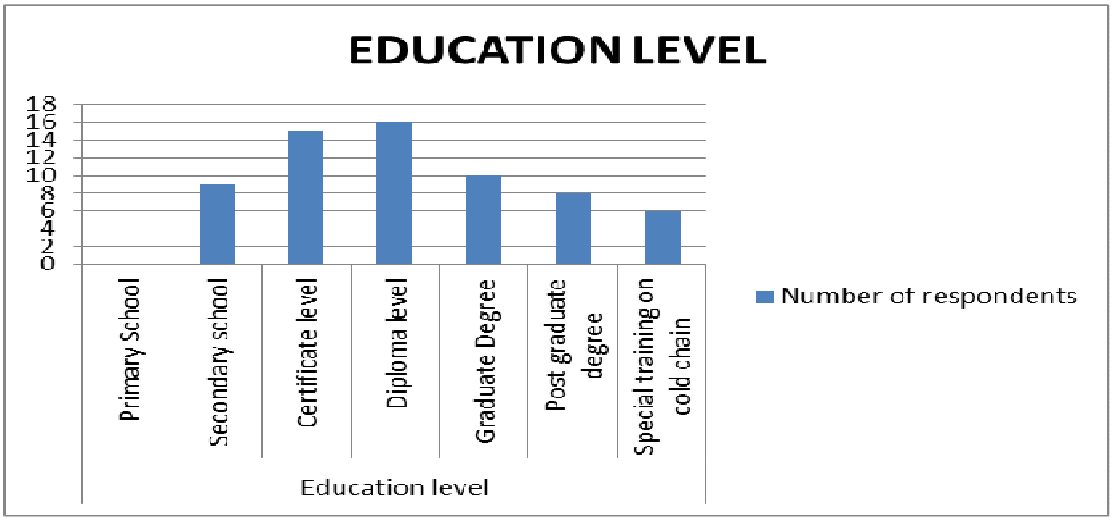

Figure 4.3 . Response per Educational level

The researcher also sought the years of experience by respondents in cold chain process

Table 4. 4 Background Analysis on Years of Experience

Respondent Characteristics	Characteristics Details	Number of Respondents	Response Rate%
Years of experience	1	11	16
	1-3	14	20
	3-5	23	34
	5-10	7	10
	above 10	3	4
Total		**58**	**87%**

The results revealed 54% 16% and 10%, had worked at the organizations between, 1-5 years, less than 1 year and 5-10 years respectively with only 4% with over 10 years experience . This indicates that majority of the employees have stayed in the organizations long enough to understand the routine and cold chain operations though not specially trained

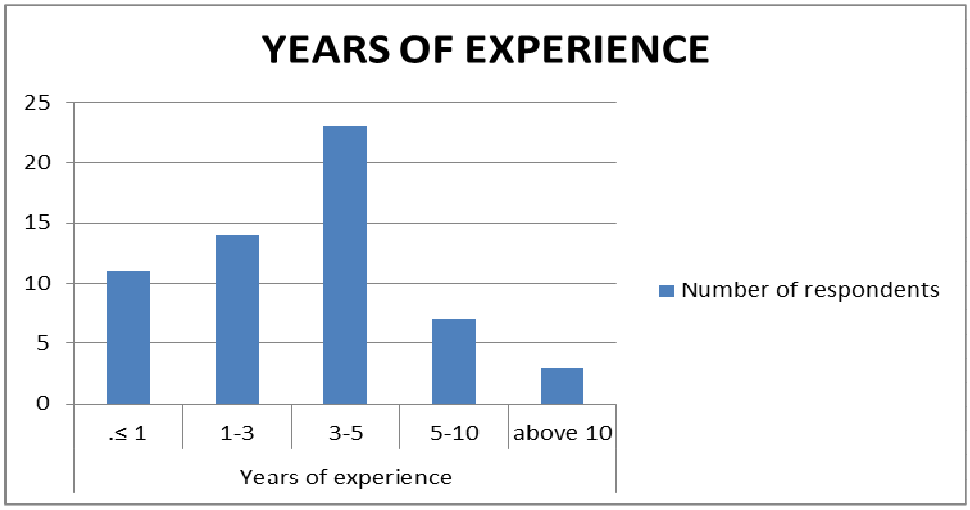

Figure 4.4 . Response per years of experience

4.4 Discussion of findings

The findings which were presented in tables and percentage frequencies were discussed as follows.

4. 4 .1 Storage conditions and facilities and Safety of vaccines.

The responses were generated 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 f=Frequency*

Table 4.5 Storage conditions

storage conditions and facilities		SD	D	S	A	SA
Available special storage area	F	0	9	12	31	6
	%	0	16	21	53	10
Enough storage space available	F	4	6	24	18	6
	%	7	10	41	31	10
Fully functional storage equipment	F	4	24	18	6	6
	%	7	41	31	10	10
Different storage equipment for different kinds of vaccines	F	24	18	6	10	0
	%	41	31	10	17	0
Storage equipment are regularly checked for compliance	F	30	18	10	0	0
	%	52	31	17	0	0
Existing SOPs that are followed to ensure proper storage	F	24	18	6	6	4
	%	41	31	10	10	7
Measures in place to ensure vaccines don't go bad	F	0	0	20	24	14
	%	0	0	34	41	24
Storage practices are satisfactory	F	10	18	20	3	7
	%	17	31	34	5	12
Average %		**21**	**24**	**25**	**21**	**9**

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 4.5. Craig, (2007) points that maintaining correct temperatures during storage are a very important task for cold chain items. A frequency of 53% of respondents agree that there exists special storage areas, 52% of respondents strongly disagree to regular checking of equipment for compliance.41% are satisfied with the storage space available and disagree on the functionality of equipments and availability of different for different kinds of vaccines. and 41% strongly disagree to the use of SOPs in storage of cold chain vaccines.However,34% are satisfied with the storage conditions and practices in their organisations.

On average 25% of the respondents are satisfied with the storage conditions in their organisations while 24% disagree to having proper storage conditions for cold chain vaccines and only 9% strongly agree to having 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 (Blake, 2008).

4. 4 .2 Transport Systems and Safety of vaccines.

The second objective of the study was to determine the influence of transport systems on the safety of vaccines in pharmaceutical distributor in Nairobi County.

Table 4. 6 Transport Systems and Safety of vaccines

Transport systems		SD	D	S	A	SA
Special Vehicles for transportation of cold chain items	F	30	18	10	0	0
	%	52	31	17	0	0
Enough vehicles to meet demand for distribution	F	0	6	30	18	4
	%	0	10	52	31	7
Transport vehicles are fitted with functional temperature and humidity monitoring devices	F	32	16	5	3	2
	%	55	28	9	5	3
Fleet system to manage distribution	F	44	6	8	0	0
	%	76	10	14	0	0
Delivery is done within recommended timelines	F	30	18	10	0	0
	%	52	31	17	0	0
SOPs are followed to ensure proper transport conditions	F	24	18	6	6	4
	%	41	31	10	10	7
Transport and distribution practices are satisfactory	F	10	18	20	3	7
	%	17	31	34	5	12
Average %		**42**	**25**	**22**	**7**	**4**

*SD=strongly disagree D=Disagree S=Satisfactory A=Agree SA=Strongly Agree f=Frequency.

The results on Table 4. 6 indicate that a frequency of 76% strongly disagree to having a fleet system that manages cold chain distribution, another 55% strongly disagree to the vehicles being fitted with functional temperature and humidity measuring devices and 52% of the respondents strongly disagree on the availability of special vehicles to transport cold chain items but are satisfied with the vehicles available to meet the demand .However, only 17% are satisfied with the deliveries being done within the recommended timelines and only 7% strongly agree to following transport SOPs while 5% of the respondents agree to having satisfactory cold chain transport systems.

On average a majority of 42 % strongly disagree to having proper transport systems to ensure safety of cold chain items. This means that the safety of cold chain items is greatly compromised during transportation within the county because specialized vehicles should be used to transport cold chain products and be fitted with monitoring devices, temperature monitors depending on the size of the load (John, 2007). Refrigerated transport is also recommended for deliveries taking longer than three hours in transit provide assurance that temperatures in all parts of the load remain acceptable and hence vaccine potency maintained (Craig, 2007).

4. 4 .3 Packaging and Safety of vaccines.

The third objective was to evaluate the influence of Packaging on the safety of vaccines in pharmaceutical distributor in Nairobi County.

Table 4. 7 Packaging

Packaging		SD	D	S	A	SA
Packaging SOPs exist for different cold items	F	24	13	15	6	0
	%	41	22	26	10	0
Different packaging materials for different cold chain items	F	0	11	20	22	5
	%	0	19	34	38	9
Protective gears to use during packaging	F	0	12	31	9	6
	%	0	21	53	16	10
Customers are satisfied about the packaging	F	0	15	13	18	12
	%	0	26	22	31	21
There are enough packaging equipment to meet demand	F	4	6	24	15	9
	%	7	10	41	26	16
The packaging practices are satisfactory	F	0	10	28	20	0
	%	0	17	48	34	0
Average %		**8**	**19**	**38**	**26**	**9**

*SD=strongly disagree D=Disagree S=Satisfactory A=Agree SA=Strongly Agree f=Frequency.

Descriptive statistics in form of frequencies and percentages were used to summarize the findings as shown in Table 4.7 above.

A frequency of 53% of respondents is satisfied with the protective gears provided for use during packaging and 48% of the respondents are satisfied with the packaging practises in their organisations. However, 41% of the respondents strongly disagree to existence of packaging SOPs for cold chain items but are satisfied

with the packaging equipments available and 34% of the respondents are satisfied with the availability of different packaging materials for different vaccines and 31% of the respondents agree that their customers are satisfied with their packaging practises.

On average 38% of the respondents are satisfied with packaging practices for cold chain items and 26% agree that packaging practises in their organisations ensure safe cold chain vaccines. However 8% of them disagree to having proper packaging practises mainly because they do not follow any SOPs for packaging of cold chain items.

This means that proper packaging is key to ensuring delivery of safe cold chain vaccines according to Blanchard (2007), use of proper and recommended packaging material protects the cold chain items and ensures their safe delivery while use of correct protective gear protects the personnel doing the packaging of cold chain items. The study reveals that packaging procedures practised are satisfactory and delivery of safe vaccines is ensured.

4. 4 .4 Technical Capacity and Safety of vaccines.

The final objective of the study was to establish the extent to which technical capacity of pharmaceutical distributor companies in Nairobi County influences safety of vaccines.

Table 4. 8 Technical Capacity

Technical capacity		**SD**	**D**	**S**	**A**	**SA**
Staff who handle cold chain items are specifically trained	F	24	15	10	6	3
	%	41	26	17	10	5
Enough employees to handle the demand	F	4	6	24	15	9
	%	7	10	41	26	16
Equipment are regularly checked and serviced to avoid breakdown and ensure compliance	F	30	18	10	0	0
	%	52	31	17	0	0
There are enough equipment to handle demand	F	4	6	24	18	6
	%	7	10	41	31	10
There is a power backup to ensure constant power supply for equipment	F	0	0	10	18	30
	%	0	0	17	31	52
Quality checks to ensure compliance with cold chain supply regulations	F	36	18	4	0	0
	%	62	31	7	0	0
Average %		**28**	**18**	**24**	**16**	**14**

*SD=strongly disagree D=Disagree S=Satisfactory A=Agree SA=Strongly Agree f=Frequency.

The results on table 4. 8 above reveal that 62% of respondents strongly disagree to having the technical capacity to perform quality checks on cold chain items in order to ensure compliance to supply chain regulations however, 52% of respondents strongly agree to availability of constant power to avoid any outages that may compromise tempreture conditions in freezers but strongly disagree to having their cold chain equipment checked and serviced to avoid breakdown . 41% of respondents have absolutely no special training in cold chain while only 15% agree to some form of training in cold chain supplies process.

On average 28% of respondents strongly disagree to having adequate technical capacity to ensure safety of cold chain items in pharmaceutical distributor in Nairobi County while Only 14% strongly agree to having the technical capacity to handle cold chain items and ensure their safety.

This means that most organizations are not technically capable to handle cold chain items and ensure their safety .Techinical capacity in terms of employee competence in monitoring storage and transport conditions as well as handling of equipment and cold chain items during packaging is very important in ensuring vaccine safety (Estrada, F.2008) .Other technical issues like quality checks ,calibration of equipment, handling of the systems, correct documentation of the data, the correction of adverse events and the integration within standard operating procedures is a key issue which should not be underestimated for the safety of the cold chain supply products such as vaccines (Bishara, R.H. 2006)

4. 5 Safety of vaccines

The safety of vaccines was the dependent variable being measured. The researcher wanted to find out the general opinion of the respondents in regards to ensuring delivery of safe vaccines by their organisations. A frequency of 62% a strongly disagree to having any quality laboratory tests being performed on the cold chain items to confirm their potency, another 59% of the respondents also strongly disagree to delivery of safe vaccines because the vaccines take longer than recommended time on transit and the recommended temperatures are neither monitored nor maintained as revealed by 34% of the respondents. Safety of cold chain vaccines seemed

to be compromised because 41% of the respondents strongly disagree to being specifically trained on cold chain and they do not use any S0Ps when handling cold chain vaccines.

Table 4. 9 Safety of cold chain items

Safe cold chain items		SD	D	S	A	SA
Cold chain items do not take longer than recommended time while on transit	F	34	20	4	0	0
	%	59	34	7	0	0
Recommended temperatures are monitored and maintained while cold chain items are on transit	F	19	20	13	6	0
	%	33	34	22	10	0
Only specifically recommended packaging materials are used for specific items.	F	4	6	24	18	6
	%	7	10	41	31	10
SOPs are followed to the latter in ensuring that cold chain items maintain their integrity	F	24	13	15	6	0
	%	41	22	26	10	0
Staff who handle cold chain items are specifically trained	F	24	15	10	6	3
	%	41	26	17	10	5
Quality laboratory checks are performed to confirm potency of cold chain items.	F	36	18	4	0	0
	%	62	31	7	0	0
Average %		**41**	**26**	**20**	**10**	**3**

**SD=strongly disagree D=Disagree S=Satisfactory A=Agree SA=Strongly Agree f=Frequency.*

On average 41% strongly disagree to ensuring compliance and safety of vaccines while only 20% of the respondents are satisfied with the cold chain practices in their organizations to ensure safety of vaccines .3% of the respondents strongly agree to ensuring compliance and safety of cold chain vaccines in their organizations. This means that overall the safety of cold chain vaccines is compromised in most of our organizations and as Kamau and Mukui ,(2005), noted there is a lack of awareness by distributors on the sensitivity of cold chain items which affects the products' therapeutic properties and consequently generate deficiency quality risks such as loss of therapeutic effects and intoxication with dire effects on the health of the users. Regulatory and compliance issues relating to transportation, storage, packaging and technical compliance , influences the safety cold chain items to the user level and are critical in this process to avoid degradation (Blake, 2008).

4.6 Correlation Analysis

Correlation analysis was applied to determine the relationship between independent variables; Storage conditions, transport systems, packaging and technical capacity and dependent variable; Safety of vaccines. A range of +1 to -1 was used to determine the significance of the relationship between the independent and the dependent variables as either positive or negative in the cold chain pharmaceutical distributors in Nairobi County. The table below indicates the overall correlation between the variables.

Table 4.10 Correlation analysis

	Pearson Correlation	Safety of vaccines	Storage conditions	Transport systems	Packaging	Technical capacity
Safety of vaccines	Rho	1				
	Sig. (2-tailed)					
	N	58				
Storage conditions	Rho	0.463	1			
	Sig. (2-tailed)	.000				
	N	58	58			
Transport systems	Rho	0.136	0.022	1		
	Sig. (2-tailed)	0.04	0.876			
	N	58	58	58		
Packaging	Rho	0.043	.331	-0.170	1	
	Sig. (2-tailed)	0.003	0.013	0.215		
	N	58	58	58	58	
technical capability	Rho	.0505	.0420	-.074	0.056	1
	Sig. (2-tailed)	.000	.774	.613	.361	
	N	58	58	58	58	58

Table 4.11 Correlation analysis on Storage conditions

		Safety of vaccines	Storage conditions
Safety of Vaccines	Pearson Correlation	1	0. 463
	Sig. (2-tailed)		0 .000
	N	58	58

Correlation is significant at the 0.05 level (2-tailed).

The results in Table 4.11 reveals a significant positive relationship of (r = 0. 463) between safety of vaccines and storage conditions in pharmaceutical distributors in Nairobi County. The study established that most pharmaceutical distributors have special storage facilities but are not upto the recommended standards by regulatory bodies to ensure that cold chain items and vaccines stored are safe for consumption (PPB,2013).

Table 4.12 Correlation analysis on Transport systems

		Safety of vaccines	Transport systems
Safety of Vaccines	Pearson Correlation	1	0.136
	Sig. (2-tailed)		0.000
	N	58	58

Correlation is significant at the 0.05 level (2-tailed).

Table 4.12 shows a positive relationship of (r = 0. 136) between safety of vaccines and transport systems in pharmaceutical distributors in Nairobi County. This shows that safety of vaccines is not ensured in most pharmaceutical distributors and hence the weak relationship mostly because most transport systems are not specialised for cold chain items and do not have the temperature monitoring devices.

Table 4.13 Correlation analysis on Packaging

		Safety of vaccines	Packaging
Safety of Vaccines	Pearson Correlation	1	0.043
	Sig. (2-tailed)		0.003
	N	58	58

Correlation is significant at the 0.05 level (2-tailed).

A positive relationship of (r = 0. 043) is shown between Packaging and safety of vaccines in pharmaceutical distributors in Nairobi County. This shows that packaging of cold chain items is not upto standard to ensure that safety of vaccines is ensured .This is mainly attributed to the fact that SOP'S are not followed during packaging.

Table 4.14 Correlation analysis on Technical capacity

		Safety of vaccines	Technical Capacity
Safety of Vaccines	Pearson Correlation	1	0.505
	Sig. (2-tailed)		0.000
	N	58	58

Correlation is significant at the 0.05 level (2-tailed).

A significant positive relationship of (r = 0. 505) exists between safety of vaccines and technical capacity of most in pharmaceutical distributors in Nairobi County. The study established that most pharmaceutical distributors do not have the technical capacity to handle cold chain items since most of them do not have the special training in cold chain and neither are equipments checked for compliance nor quality checks done to ensure safety of vaccines.

4.7 Correlations summary

Table 4.15 Correlations summary

	R	R^2(Coefficient of determination	% coefficient of determination
Storage Conditions	0.463	0.214	21.0
Transport Systems	0.136	0.018	1.8
Packaging	0.043	0.002	0.2
Technical Capacity	0.505	0.255	25.5
TOTAL			48.5

The results of Table 4.11 above show that safety of vaccines in pharmaceutical distributors in Nairobi County is attributed to 21% proper storage conditions,1.8% to Transport Systems which is very low as well as 0.2% to packaging and a larger percent of 25% of safety of vaccines is attributed to technical capacity .However, all these variables contribute to only 48.5% of the safety of vaccines while 51.5% of vaccine safety is influenced by other factors. The other factors that influence safety of vaccines are prevailing conditions during custom clearance which could be exposure to extreme temperatures, poor handling and storage (Kamau & Mukui ,2005).

Safety of cold chain items is very critical and a 48.5% safety is not safe enough as it compromises the effects they could have on the consumers. Bishara, (2007) asserts that pharmaceutical cold chain items like vaccines are particularly sensitive materials which, if not manufactured, shipped, stored, packaged and handled under stringent controls, can become ineffective or even hazardous to the consumer due to reduced potency.

5. SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the summary of the research findings on the Influence of cold chain supply logistics on supply of safe cold chain pharmaceuticals. The chapter details the summary of the findings, conclusion, recommendation and suggestion for further studies. This chapter presents the summary of findings, conclusion and recommendations of the study. In order to rationalize the findings of the study, the chapter also discusses the findings in the light of secondary literature review from the organisations records and relate it to previous studies done on cold chain and from the current research.

5.2 Summary of the Research Findings

The main objective of the research therefore was to study the influence of cold chain supply logistics on the safety of vaccines. A sample of 67 respondents was selected from the target population with similar characteristics; out of the 67 issued questionnaires 58 were filled and returned. A combination of descriptive statistics and inferential statistics were used to analyze the data.

5.2.1 Storage conditions

In this study, a number of objectives were set to be achieved. The first objective was to establish the influence of storage conditions of cold chain items on delivery of safe vaccines. Regarding this, it was established that upto 52% of respondents conformed there is poor validation and qualification of storage facilities and monitoring devices. There are no different storage equipment for different vaccines in upto 41% of the organizations and hence run a risk of cross contamination and temperature excursions during storage which compromises the quality of vaccine. The research confirmed that validated systems with respect to calibration of storage facilities temperature probes and sensors and thermometers are generally poor along the supply chain with only 34% having satisfactory practices.

5.2.2 Transport systems

The second objective was to establish the influence of transport systems on safety of vaccines. The research confirmed that upto 76% of the firms do not have a fleet system that helps manage the distribution of cold chain vaccines .Calibration and qualification of transportation vans and carrier boxes are generally poor along the supply chain, and specialized vehicles for transport of cold chain items do not even exist in 52% of the firms and this compromise the safety of cold chain items. There are no procedures in place to verify actual temperature of cold chain medicines before taking delivery or dispatch to retail facilities and transport of vaccines does not always happen within the recommended timelines which exposes them to tempreture excursions and their safety compromised.

5.2.3 Packaging

Evaluation of the influence of Packaging in pharmaceutical distributors in Nairobi on the safety of vaccines was the third objective of the study and the research findings reveal that in as much as upto 41% of organisations do not follow packaging SOPs .The organisations packaging practices are satisfactory according to 48% of respondents. However, packaging practices still have to be improved and different packaging materials used for different vaccines and SOPs followed in order to avoid any compromise on the safety of cold chain items and raise the percentage of satisfactory practice to upto 75% and above to increase the confidence in delivery of safe cold chain vaccines.

5.2.4 Technical Capacity

The final objective of the study was to establish the extent to which technical capacity in pharmaceutical distributors in Nairobi influence safety of Vaccines. The findings of the study reveal that no quality checks are performed on the vaccines to confirm viability in 62% of the firms which means that the viability of the vaccines delivered is not confirmed . The firms technical capacity does not guarantee delivery of safe cold chain pharmaceuticals mainly because most equipment used in handling cold chain items are not regularly checked and serviced according to 52% of the respondents, hence not technically compliant.. Most employees handling cold chain items are not specifically trained with only 15% agreeing to some form of training or coaching and this greatly compromises the safety of the vaccines in as much as there are sufficient equipment and there is power back up to avoid power outages to ensure that vaccines don't go bad due to tempreture excursion during storage.

5.3 Conclusion

The overall finding of this study is that control of storage and transportation temperature, having proper storage

conditions, packaging materials and technical competence is essential in maintaining the quality of cold chain pharmaceuticals and hence delivery of safe cold chain pharmaceuticals. The study findings reveal that cold chain supply logistics are poorly coordinated and not fully adhered to and hence have a negative influence on the safety of vaccines among other cold chain pharmaceutical items .This means that end users are exposed to sub-standard or ineffective vaccines and pharmaceuticals that may result from poorly coordinated cold chain supply logistics. In view of this, more effort should be made to provide proper cold chain logistics management for temperature sensitive pharmaceuticals to ensure that the quality and efficacy of the product are not compromised along the supply chain.

5.4 Recommendations

Relevant recommendations were made considering the findings of the study which if adopted would lead to efficient and effective cold chain supply logistics in order to ensure product safety in terms of quality, potency and efficacy and hence guarantee public health and safety.

5.4.1 Storage Conditions

Storage conditions for cold chain items need to be closely monitored and improved so that the safety of cold chain items is guaranteed in having fully functional and enough storage facilities for different cold chain items because the research findings indicate that safety of cold chain items is greatly compromised in the current situation. Validation of storage facilities need to be done on a regular basis and storage temperatures checked (Bishara R.H, 2006). More storage freezers of varying temperature ranges need be purchased since all the cold chain items are not stored at the same temperatures. In view of this, proper pharmaceutical refrigerators are recommended for the storage of cold chain products. Additionally, cold rooms, refrigerators and carrier boxes should be qualified by Kenya Bureau of Standards to ensure capacity to maintain the required temperature during storage.

5.4.2 Transport Systems

The transport systems for cold chain items need to be improved put and have a fleet management system for the same so that the safety of cold chain items is guaranteed in having fully functional and enough vehicles for transport of cold chain items. Temperature validation should be ensured by having special vehicles bought and fitted with the correct temperature controlling and monitoring gadgets for cold chain transport.

This is because the air within this special cold chain transport and storage equipment is circulated by a fan, which provides a uniform temperature profile and a rapid temperature pull down after the door has been opened with alarm systems to draw attention when there is temperature excursion (Blanchard, D. 2007).

All temperature probes (for cold chain mapping), sensors and thermometers must be calibrated and regularly maintained to the required standards within the travel range respectively.

5.4.3 Packaging

Packaging SOP'S need to be updated and followed strictly and this therefore means that different packaging materials for different cold chain items need to be purchased. The exposure time during break bulk in packaging should be reduced by having proper equipment and protective gears for handling (Cleland,A.C,2005). It is recommended that the organization use refrigerated packaging systems such as use of dry ice, gel pack, kryotrans, kodiak, styrofoam and envirotainers to keep the cold chain products safe and in good condition when packed.

5.4.4 Technical capacity

The firm's technical capacity does not guarantee delivery of safe cold chain pharmaceuticals. This is because equipments are not technically compliant and also no quality checks are performed on the vaccines to confirm viability. This therefore suggests that special training is required for all personnel involved in cold chain sensitivity of cold chain items and hence improve their understanding and competency in handling cold chain pharmaceuticals to ensure their safety.

All equipment also need to be properly calibrated and up to standard as recommended by regulatory bodies. SOPs in place should be updated and strictly followed since; one of the challenges identified was the poor adherence and implementation. WHO cold chain management systems (GDP, GSP, etc) could also be adopted in order to adhere to some standard as recommended by regulatory bodies.

5.5 Suggestions for Future Study

Future studies could research on establishing the extent to which the identified logistics challenges affect cold chain pharmaceuticals potency, efficacy and quality by performing quality laboratory checks in Nairobi County .This can be achieved by sampling from known batches of cold chain pharmaceuticals with evidence and documentation that it has been distributed along the supply chain (whole, retail and end user) for traceability and be subjected to laboratory analysis.

Following the analysis of secondary data from the forms records , it was noted that there are other factors that influence delivery of safe cold chain pharmaceuticals like Coordinated customs clearance and

information technology which is an area of study that could reveal a lot in Cold chain studies.

Finally the role of regulatory authorities in enforcing regulatory standards to ensure compliance by cold chain pharmaceutical distributors engaged in cold chain medicines as a business is an area that needs to be explored further given that the research findings indicate very poor compliance to SOPs .

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