

**PUBLIC HEALTH CHALLENGES IN THE SUPPLY CHAIN MANAGEMENT
OF COLD CHAIN MEDICINES IN THE GREATER ACCRA REGION**

by

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DECLARATION

I, hereby declare that this submission is my own work towards the Executive Masters of Public Administration and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of the University, except where due acknowledgement has been made in the text.

KNUST

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DEDICATION

I dedicate this work to the almighty Jehovah God for seeing me through my Masters Degree in Commonwealth Executive Masters in Public Administration (CEMPA).

My next dedication goes to my family; sweet wife Gifty Agyekum (Mrs.), my daughter Nana Yaa Atwimaa Agyekum and son Kwabena Ohene Apau Agyekum for their sacrifice throughout the study.

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ABSTRACT

Members of the pharmaceutical supply chain have various global regulatory requirements to meet while handling, storing and distributing environmentally sensitive products. The focus of the regulatory requirements is to provide cold chain management for temperature sensitive pharmaceuticals to ensure that the quality and efficacy of the product are not compromised along the supply chain. Many countries such as Canada, United Kingdom, South Africa, etc, have issued regulations and specific guidelines that address product integrity during the entire supply chain. It will therefore be of importance to identify how Ghana has developed its cold chain supply systems and how it is able to maintain cold chain for temperature-sensitive medicines considering the challenges of; unreliable electricity supply, inadequate storage facilities, weak validation systems, perceived poor monitoring of cold chain supply management by regulatory authorities. The study was conducted to establish the challenges in the supply chain management of cold chain medicines in the Greater Accra Region and their impact on product quality and public health and safety. The methodology that was used in collecting the research data was descriptive survey where questionnaires were personally administered and visual observation made to corroborate practices, processes and procedures. Purposive sampling was used to identify cold storage facilities that stock cold chain medicines to meet the objectives of the research. The results indicated absence of quality management system, poor contingency for power outages, weak validation of cold storage facilities and qualification of cold chain vans and carriers for transport of cold chain medicines along the supply chain which obviously will impact negatively on product quality, efficacy and potency and finally putting public health and safety at risk.

The way forward is effective regulatory oversight responsibilities to ensure compliance to cold chain management standards to protect public health and safety.

TABLE OF CONTENTS

CONTENTS	PAGE
TITLE PAGE	i
DECLARATION	ii
DEDICATION	iii
ACKNOWLEDGEMENT	iv
ABSTRACT	v
TABLE OF CONTENTS	vi
LIST OF TABLES	vii
LIST OF FIGURES	ix
CHAPTER ONE	1
1.1 BACKGROUND	1
1.2 PROBLEMS IDENTIFICATION	2
1.3 MAIN OBJECTIVE	3
1.4 SPECIFIC OBJECTIVES	4
1.5 RESEARCH QUESTIONS	4
1.6 RELEVANCE OF THE STUDY	4
1.7 SCOPE OF THE STUDY	5

1.8 LIMITATION OF THE STUDY	6
1.9 ORGANIZATION OF THE STUDY	6
CHAPTER TWO	7
LITERATURE REVIEW	7
2.1 INTRODUCTION	7
2.2 GLOBAL PHARMACEUTICAL MARKET	7
2.3 COLD CHAIN MEDICINES	8
2.3.1 INSULIN	8
2.3.2 VACCINES	10
2.4 DIABETIC SITUATION IN GHANA	11
2.5 SUPPLY CHAIN MANAGEMENT OF COLD CHAIN MEDICINES	12
2.6 GLOBAL REGULATION OF COLD CHAIN MEDICINES	13
2.7 REGULATION OF COLD CHAIN MEDICINES IN GHANA	15
2.7.1 FOOD AND DRUGS BOARD	15
2.7.2 PHARMACY COUNCIL	16
2.7.3 GHANA STANDARD BOARD	17
2.8 COLD CHAINS DISTRIBUTION CHANNEL IN GHANA	18
2.9 STORAGE FACILITIES FOR DISTRIBUTION OF COLD CHAIN MEDICINES	19
2.9.1 COLD ROOM FOR WHOLESALE STORAGE	19

2.9.2 STANDARD DOMESTIC REFRIGERATOR	21
2.9.3 PURPOSE BUILT PHARMACEUTICAL REFRIGERATOR	21
2.10 QUALITY MANAGEMENT SYSTEMS AND DOCUMENTATION	22
2.11 VALIDATION OF COLD STORAGE EQUIPMENT OR ROOM	23
2.12 QUALIFICATION OF COLD EQUIPMENT OR STORES	24
CHAPTER THREE	26
RESEARCH METHODOLOGY	26
3.1 INTRODUCTION	26
3.2 RESEARCH DESIGN	26
3.3 STUDY POPULATION	27
3.4 SAMPLE AND SAMPLING PROCEDURES/TECHNIQUES	29
3.5 DATA COLLECTION TOOLS/PROCEDURES	30
3.5.1 QUESTIONNAIRE	30
3.6 DATA ANALYSIS/PRESENTATION PROCEDURE	30
3.7 ETHICAL CONSIDERATIONS	31
CHAPTER FOUR	32
DATA ANALYSIS AND DISCUSSION OF RESULTS	32
4.1 INTRODUCTION	32

4.2 RESULTS OF WHOLESALE PHARMACY/HEALTH FACILITY COLD STORAGE FACILITIES	33
4.3 DISCUSSION OF WHOLESALE COLD CHAIN STORAGE FACILITY RESULTS	40
4.4 RESULTS OF RETAIL PHARMACY/HEALTH COLD CHAIN FACILITIES	43
4.5 DISCUSSION OF RETAIL COLD CHAIN STORAGE FACILITIES RESULTS	49
4.6 RESULTS OF END USERS OF COLD CHAIN MEDICINES (INSULIN)	52
4.7 DISCUSSION OF END USERS OF COLD CHAIN MEDICINES RESULTS	55
CHAPTER FIVE	57
SUMMARY, CONCLUSION AND RECOMMENDATIONS	57
5.1 INTRODUCTION	57
5.2 KEY FINDINGS	57
5.3 CONCLUSION	59
5.4 RECOMMENDATIONS	60
REFERENCES	63
LIST OF ABBREVIATIONS	67
APPENDIX A: QUESTIONNAIRE	68
ATTACHMENTS	

LIST OF TABLES

Table 1	How do you maintain appropriate storage condition in the event of a power failure	36
Table 2	How often does food and drugs board visit your facility	47
Table 3	How often does Pharmacy Council visit your facility	48
Table 4	What information do you give to client	49

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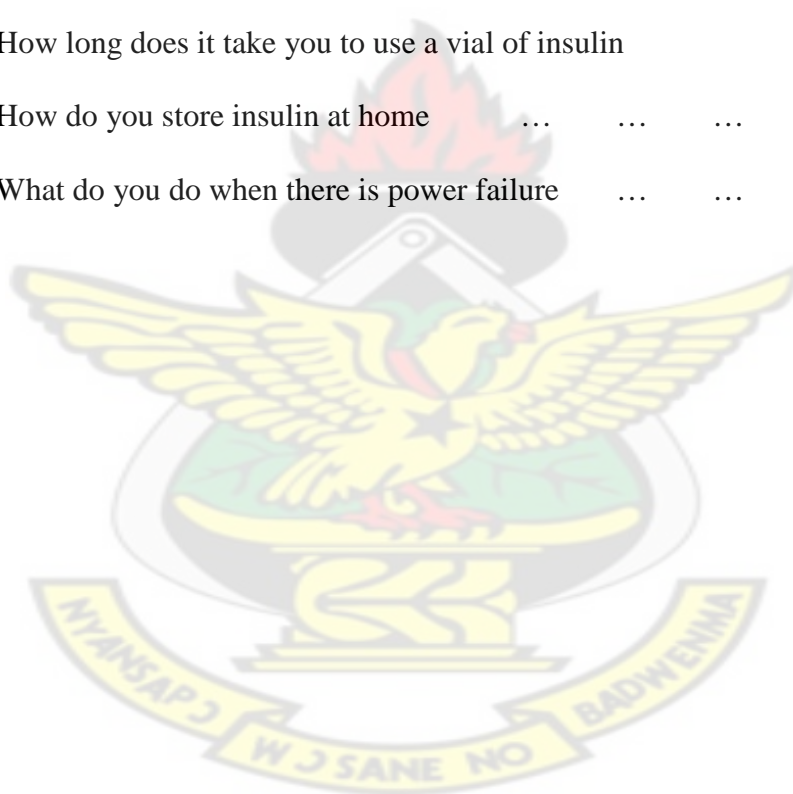


LIST OF FIGURES

Figure 1	A Cold Chain System	18
Figure 2	How long have you been doing this work	33
Figure 3	What type of system do you have in place to ensure quality of cold medicines	33
Figure 4	Name any guideline you use for managing the Quality Management System (QMS)	34
Figure 5	Which of the following WHO requirement do you use as part of QMS	34
Figure 6	Have all employees been trained on specific cold chain Regulations, Standard Operation Procedures (SOP's) and other related tasks	34
Figure 7	How often does Food and Drugs Board (FDB) visit your facility	35
Figure 8	Do they specifically inspect cold chain medicines storage facility	35
Figure 9	What specific guidelines or standards do they use as a benchmark	35
Figure 10	Do you have an automated generator system to cater for power failure after closing hours	36
Figure 11	Are all sensors and probes, including temperature monitoring devices calibrated at least once a year	36
Figure 12	Which institution did the calibration	37
Figure 13	How do you manage temperature excursion	37
Figure 14	Have controlled temperature areas been mapped to determine high and low temperature areas within during seasonal extremes	37
Figure 15	Do you check the temperature of the products before dispatching	38
Figure 16	Is the device calibrated	38
Figure 17	Where temperature control is needed, have the transportation cold van or carrier qualified	38

Figure 18	Do transportation vehicle have temperature monitoring device	39
Figure 19	Are the temperature monitoring devices on the vehicle calibrated	39
Figure 20	Have you ever refused to dispense cold chain medicine, including insulin to a retail pharmacy facility although the medicine is available	39
Figure 21	What was the reason	40
Figure 22	What is your job title	43
Figure 23	How do you receive and or transport cold chain product from wholesales	43
Figure 24	Do you check temperature of product before receiving supplies	44
Figure 25	List the type of cold chain medicines stored in the storage facility	44
Figure 26	List any other things which are stored in the storage facility	44
Figure 27	Are there written instructions describing storage procedures, materials handling and documentation	45
Figure 28	Is the storage device furnished with low and high temperature alarms	45
Figure 29	Is the storage device equipped with thermometers	45
Figure 30	Which institution did the calibration	46
Figure 31	Is temperature monitoring being recorded	46
Figure 32	What time do you switch off the storage facility	46
Figure 33	How do you maintain appropriate storage condition in the event of power failure	47
Figure 34	Do you have an automated generator system to cater for power failure	47
Figure 35	Do they specifically inspect cold chain medicine in the storage facility	48

Figure 36	What specific guideline or standard do they inspect the cold chain facility or the product against	48
Figure 37	How do you pack the insulin for patients	49
Figure 38	How long have you been using insulin?	52
Figure 39	Where have you been buying your insulin from?	52
Figure 40	Which of the following information on insulin do you receive from Dispensers	53
Figure 41	How do you carry your insulin home from where you buy it	53
Figure 42	How long does it take you to take your insulin home from where you purchased it	53
Figure 43	How long does it take you to use a vial of insulin	54
Figure 44	How do you store insulin at home	54
Figure 45	What do you do when there is power failure	54



CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

Interest in Supply Chain Management (SCM) has steadily increased since the 1980s when firms saw the benefit of collaborating relationships within and beyond their own organization. In view of this, firms are finding that they can no longer compete effectively in isolation of their suppliers or other entities in the supply chain. Members of the pharmaceutical supply chain have various global regulatory requirements to meet while handling, storing and distributing environmentally sensitive products (Maclean, 2009). Their focus is to provide cold chain management for temperature sensitive pharmaceuticals to ensure that the quality and efficacy of the product are not compromised along the supply chain. Supply chain is a strategic enabler for pharmaceutical business performance.

The cold chain is the process of maintaining medication such as insulin, vaccines, oxytocins, human immunoglobins, etc. between temperatures of 2°C to 8°C throughout the supply chain (Northamptonshire Service Provider, 2009). Temperatures outside this range 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. According to Cheryl Blake of Medicines and Healthcare Products Regulatory Authority (MHRA) of the United Kingdom, 32% 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, 42%, 52%, 36%, 43% critical and major deficiencies were recorded in 2001/2002, 2002/2003, 2003/2004, 2004/2005 respectively. In view of this, many countries such as Canada, Ireland, UK, South Africa, Austria, Australia, Czech Republic, China Brazil, Venezuela, Singapore, Spain Australia, South Korea, and European Union have issued regulations and specific guidelines that address product integrity during transportation of cold chain medicines (Bishara, 2007).

All cold chain medicines distributed in Ghana are imported because there are no cold chain medicines manufacturing company currently in Ghana. According to Food and Drugs Board (FDB), there are ninety one (91) registered cold chain medicines in use in the country being distributed by twenty four (24) pharmaceutical wholesalers. The distribution channels for cold chain medicines in Ghana include public health facilities (Expanded Programme for Immunization (EPI), Central Medical Stores (CMS) of the Ministry of Health (MOH), hospital pharmacies and private facilities (Wholesalers, Community Pharmacies).

This study seeks to identify and address the challenges in supply chain management of cold chain medicines and the impact on product quality and public health and safety.

1.2 PROBLEM IDENTIFICATION

The World Health Organization (WHO) has stated that as much as 25% of all vaccine products reach their destination in a degraded state (Oosterzee, 2007). The Medicines and Healthcare Products Regulatory Agency reports that temperature rises above desired parameters are the number one critical deficiency in pharmaceutical warehouses contributing to about 43% of reported non-compliant cases (Jet Environmental, 2009). It

is not the general conditions that affect product quality, but extremes of temperature within the operational space. As global warming is widely accepted as reality, temperature control issues are likely to become even more of a problem in warehouses that are not equipped with appropriate cooling systems.

Vaccines and pharmaceuticals are particularly sensitive materials which, if not manufactured and shipped under stringent controls, can become ineffective or even hazardous to the consumer (Kandal, et al, 1997). Eventually, validation methods and guidelines are developed for the cold chain delivery system as well, with the goal of providing temperature assurance during the manufacturing, storage, shipping and delivery of medicines. Since cold chain supply medicines are well managed, as evidence has shown in other countries such as USA, UK, Canada, etc., it will be of importance to know how Ghana has developed its cold chain supply systems and how it is able to maintain cold chain for temperature-sensitive medicines considering the following challenges; unreliable electricity supply, inadequate storage facilities, weak validation systems, perceived poor supervision and monitoring of cold chain supply management by regulatory authority, and traceability and management of product recall.

Insulin has been chosen among the many temperature-sensitive medicines to find out how end users handle cold chain medicines because it is the most widely circulated and cold chain medicine stored at home by patients managing diabetics' mellitus (type 1) which affect a significant proportion of Ghanaians.

1.3 MAIN OBJECTIVE

- To study the challenges in supply chain management of cold chain medicines and their impact on product quality and public health and safety.

1.4 SPECIFIC OBJECTIVES

- To examine the extent to which cold chain management systems (Storage/Transportation Distribution) comply with the WHO requirements.
- To verify the validated and monitoring systems in place to ensure product quality.
- To ascertain how end users handle cold chain medicines along the supply chain using insulin.
- To examine the role of regulatory authorities in enforcing regulatory standards to ensure compliance by public institutions, health facilities and or pharmaceutical industries engaged in cold chain medicines as a business.

1.5 RESEARCH QUESTIONS

- What is the level of compliance of Cold Chain Management systems to the WHO requirements?
- To what extent are cold chain storage facilities and monitoring devices validated to guarantee product quality?
- How does storage of cold chain medicines by end users contribute to product quality?
- To what extent has enforcement of regulatory standards assisted public institution(s), health facilities and or medicine distribution outlets (pharmacies) in compliance to cold chain standards?

1.6 RELEVANCE OF STUDY

This study identified some of the key challenges in the management of cold chain medicines supply in Ghana with focus on temperature control, validation of storage

systems, monitoring of cold chain facilities and oversight responsibilities by regulatory authority in Ghana.

The study has revealed how end users of cold chain medicines (insulin) contribute to product deterioration through inappropriate storage and handling practices. The findings and recommendations of the study are useful for policy makers and regulatory authorities' by way of designing guidelines and enforcement of cold chain standards for compliance. Insights from the study inform key stakeholders in cold chain management along the supply chain to effectively manage cold chain medicines in Ghana for improvement of health of the citizenry and finally, the research brings to the fore questions to expose gaps that would require further investigation.

1.7 SCOPE OF STUDY

The scope of this study was focused on cold chain medicines supply management and the effect of non-compliance to manufacturer's temperature storage conditions on product quality and public health and safety. The research was carried out in the Greater Accra Region concentrating on the following areas: Public: Government/Ghana Health Service/EPI (National cold storage facility, Regional cold storage facility, District cold storage facility, Hospital pharmacy / health facility cold storage facility); Private (Wholesalers of cold storage facilities, Retail Pharmacy (community and hospital) cold chain storage facilities); Diabetic patients attending clinic at National Diabetic Management and Research Centre (NDMRC) at the Korle-Bu Teaching Hospital (KBTH).

1.8 LIMITATION OF THE STUDY

Research on supply chain management of cold chain medicines is an extensive area of study, therefore the researcher concentrated on the wholesale and retail cold chain storage facilities in public and private pharmacies and health facilities in the Greater Accra Region of Ghana. Due to time constraint and lack of other resources the student researcher used a fairly limited sample size from the public and private cold chain storage facilities that stock cold chain medicines. There were challenges in the administration of questionnaire because some respondents were unwilling to open up their storage facilities for verification of processes and monitoring devices which was critical to this research.

1.9 ORGANIZATION OF THE STUDY

The study was organized under five main chapters. The chapter one, which is the introduction dealt with the background to the study, statement of the problem, objectives of the study, scope and limitations of the study, as well as the organization of the study.

Chapter two dealt with the review of relevant literature related to the study including but not limited to global pharmaceutical industry, cold chain medicines, supply chain management, regulation of cold chain medicines and distribution channels for cold chain medicines. The chapter three discussed methods adopted for the study which included the research design, population, sample and sampling procedures/technique, data collection tools/procedures, data analysis/presentation procedures. The fourth chapter dealt with analysis of data and discussion of results. The last but not the least is the chapter five which dealt with the summary of findings, recommendations and then the conclusion.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter reviews relevant literature on the key areas that the study covers. The literature review entails a critical perusal of literature sources which have a bearing on the topic and these set off the existence of a store of data and materials for consideration. This chapter presents the theoretical underpinnings of the study. With a focus on the objectives and theoretical thresholds of this study, the chapter reviews related and contemporary literature on the concept of global pharmaceutical markets, cold chain medicines, supply chain management of cold chain medicines, global regulation and regulation of cold chain medicines in Ghana. The chapter also looked at storage facilities for cold chain medicines, Quality Management Systems and documentation, validation and qualification of storage facilities, monitoring and cold chain vans and carrier boxes.

2.2 GLOBAL PHARMACEUTICAL MARKET

The rapid growth of biopharmaceuticals industry or business in addition to complex global sourcing and distribution chains with a variety of transportation modes has brought about the global interest in the supply chain management of cold medicines. Given that biopharmaceuticals tend to be temperature sensitive, the cold chain has become an increasingly important component of the overall pharmaceutical supply chain. According to Oosterzee (2007), the growth of biopharmaceutical products was greater than €50 billion of pharmaceutical product sold worldwide in 2005. Of this, 10% or €5 billion were biopharmaceuticals. Additionally, 40% of pharmaceutical products were temperature sensitive where as 100% biopharmaceuticals were also temperature sensitive. Between 2004 and 2005, the biopharmaceutical market grew 17.1%, much

faster than traditional pharmaceutical market which grew by about 7-10%. The expectations were that the market will grow exponentially.

2.3 COLD CHAIN MEDICINES

In health care delivery, there are many critical resources that need to be managed very well in order to save lives and prevent disabilities e.g. pharmaceuticals, vaccines, blood and other medical supplies (Thuermer 1997 as cited in Spens, 2001).

Cold chain is the process of maintaining medication between temperatures of 2 °C to 8 °C throughout the supply chain (Northamptonshire Service Provider, 2009). Cold chain medicines are temperature sensitive biopharmaceutical products that require controlled temperature storage conditions throughout their distribution in order to maintain product quality. Temperatures outside this range may reduce potency leading to lack of desired response e.g. reduced immunity. Examples of cold chain medicines are insulin, vaccines, blood products, etc.

2.3.1 INSULIN

Insulin according to Oxford dictionary (2000) is a pancreatic hormone which regulates glucose levels in the blood, a lack of which causes diabetes. Insulin is a hormone produced in the islets of Langerhans of the pancreas that regulates the metabolism of carbohydrates, fats, and starches in the body. Insulin enables the cells of the body to take up glucose, the simple sugar that cells burn for energy. If the pancreas does not produce sufficient insulin or if the cells become resistant to the effects of insulin, the body cannot use glucose effectively, and the disease diabetes mellitus results. This is a serious illness that can lead to kidney failure, blindness, and death if left untreated (Vimalavathini & Gitanjali, 2009).

In view of this, patients with severe diabetes must take insulin to control their disease. But insulin is a protein, and like other proteins, it is partially digested if administered orally. Hence patients who require insulin have traditionally needed to inject the hormone into a muscle. It is an established fact that labile drugs and vaccines show decrease in potency if not stored under controlled temperatures (Brown, et al, 2004; 2008 and Camacho-Amor, et. al, 1990). Insulin is one such labile drug, sensitive to extreme temperatures and sunlight and hence needs to be stored under refrigeration between 2-8°C (Grajower, et. al, 2003). Previous studies have shown that during storage and use, insulin is degraded by hydrolytic reactions or transformed to higher molecular weight components (Oliva, et. al, 2000 and Gregory, et. al, 1991). Hence it is recommended that insulin vials should be stored under refrigeration between 2-8°C when the vials are unopened and be protected from light (Grajower, et. al, 2003 and Kumar, Bhat, 2003).

Despite the recommendation, discrepancies exist in the storage recommendation shelf-life for opened insulin vials, manufactured and marketed by the different drug companies. For example, Novo Nordisk, Bangalore, in its package insert for human insulin, recommends storage at room temperature up to 25°C for 4 weeks but should not be kept in a refrigerator. Likewise, Eli Lilly, Gurgaon insert package, recommends that the vials can be refrigerated or stored below 30°C for up to 4 weeks, and according to Biocon, Bangalore, opened vials can be stored at room temperature up to 25°C for 6 weeks. However, this storage condition is not universally accepted as observed in a research conducted by Vimalavathini and Gitanjali (2009) that storing insulin at 32°C (room temperature) and 37°C (room temperature in summer) showed a decreased in potency of insulin in both formulations for all the three brands (Novo Nordisk, Lilly Elli and Boicon) by 14% to 18% compared to a cut-off recommended by the Indian Pharmacopoeia which is 10%. This extreme room temperature is the ideal situation in India, where temperature remains

well above 25°C in many parts of the country, including Tamil Nadu and Puducherry for most of the year just as most tropical countries including Ghana.

2.3.2 VACCINES

Vaccines are biological products that contain antigens capable of inducing a specific and active acquired immune response in the body and have been used for centuries to immunize individuals against pathogenic organisms with the goal of preventing the associated disease (United State Pharmacopeia, 2012). They are produced from the same micro-organism or toxins that cause disease but in either case are modified so as to be harmless to humans. Three main substances are used for the production of vaccines, which are;

- Live micro-organism e.g. weakened measles and polio viruses or tuberculosis
- Killed micro-organism e.g. pertussis micro-organism used in DPT production, Toxoid e.g. inactivated toxins such as tetanus toxoids and diphtheria toxoid
- In addition, some vaccines are produced using genetic engineering technologies e.g. recombinant DNA hepatitis B vaccine.

Vaccines for human use are preparations containing antigens capable of inducing a specific and active immunity in man against an infecting agent or the toxin or antigen elaborated by it (British Pharmacopeia, 2012). Vaccines by its nature are sensitive biological substances that progressively lose their potency. The loss of potency is much faster when the vaccines are exposed to temperatures outside the recommended storage range. Any loss of potency is permanent and irreversible. Thus, storage of vaccines at the correct recommended temperature conditions is important in order that full vaccine potency is retained up to the moment of administration. Some other vaccines also lose their potency entirely if frozen, although others can sustain freezing without any damage

whatsoever. Vaccines are cold chain medicines used mainly in the immunization programme in Ghana.

It has been estimated that without immunization, 3% of all children will die from measles, 2% will die from whooping cough, 1% will die from tetanus and 0.5% will be crippled by polio for the rest of their lives. Neonatal tetanus, which is prevented by immunizing mothers with tetanus toxoid (TT), could in addition be responsible for up to 20% of all infant deaths in the country (GHS, 2003). The targeted childhood illnesses for EPI programme in Ghana are poliomyelitis, measles, diphtheria, pertussis (whooping cough), neonatal tetanus, tuberculosis, hepatitis B, haemophilus influenza type b and yellow fever. These diseases have one thing in common; they are vaccine preventable diseases i.e. they can be prevented by immunisation. Immunisation is achieved by the administration of a vaccine, produced from either an attenuated, inactivated or killed form of virus or bacteria that cause the disease. It is normally injected or in some cases may be given orally as in the case of Polio vaccine. The vaccine then provokes the development of antibodies in the infant, who thus acquires immunity without suffering the disease (WHO, 1998). A child who is fully immunized is thus protected from the disease of which a vaccine is given.

2.4 DIABETIC SITUATION IN GHANA

According to Centre for Health Information Management (CHIM) of Ghana Health Service, between 2002 and 2011 there was a total of seven hundred and ninety one thousand, one hundred and twenty three (791, 123) diabetes mellitus outpatient morbidity was recorded nationwide. Out of this, Greater Accra Region had a total of one hundred and seventy four thousand, nine hundred and seventy eight (174, 978), representing

22.12% of the national diabetic population. For the six days (11-15th and 18th June, 2012) that this research administered questionnaire to patients managing diabetics at the National Diabetic Research Centre, Korle-Bu, a total of five hundred and fifteen patients attended clinic according to the daily attendance records, with an average daily attendance of one hundred and three (103) patients.

2.5 SUPPLY CHAIN MANAGEMENT OF COLD CHAIN MEDICINES

Interest in Supply Chain Management (SCM) has steadily increased since the 1980s when firms saw the benefit of collaborating relationships within and beyond their own organization. In view of this firms are finding that they can no longer compete effectively in isolation of their suppliers or other entities in the supply chain. Members of the pharmaceutical supply chain have various global regulatory requirements to meet while handling, storing and distributing environmentally sensitive products (Maclean, 2009). Their focus is to provide cold chain management for temperature sensitive pharmaceuticals to ensure that the quality and efficacy of the product are not compromised along the supply chain. Supply chain is a strategic enabler for pharmaceutical business performance.

Supply chain management encompasses all those activities that are associated with the flow and transformation of goods from the raw materials stage through to the end user as well as the associated information flows (Handfield and Nichols, 1999). It thus focuses on the transport, warehousing and the related information technology. The Institute of logistics (1998) defined supply chain as the sequence of events intended to satisfy a customer. It can include procurement, manufacture, distribution and waste disposal together with associated transport, storage and information technology.

Logistics management is essentially an integrative process that seeks to optimize the flow of materials and supplies through the organization and its operations to the customers or clients. It is a planning process and an information-based activity (Christopher, 2003). For the real benefit of logistics concept to be realized, there is the need to extend the logic of logistics upstream to suppliers and downstream to final customers or consumers. This is the concept of supply chain management. Supply chain management as explained by Christopher is a fundamentally different philosophy of business organization and is based upon the idea of partnership in the marketing channel and a high degree of linkage between entities in that channel. Under the supply chain management model the goal is to maximize profit through enhanced competitiveness which is achieved by lower cost to serve in the shortest time frame possible. Such goals are only attainable if the supply chain as a whole is closely coordinated in order that total channel inventory is minimized, bottlenecks eliminated, time frames compressed and quality problems eliminated.

2.6 GLOBAL REGULATION OF COLD CHAIN MEDICINES

The World Health Organization (WHO) declares that as much as 25% of all vaccine products reach their destination in a degraded state (Oosterzee, 2007). In view of this the WHO has put in place guidelines and Good Distribution Practices (GDP) requirements for the storage and distribution of cold chain medicines (WHO, 2005). According to the WHO, although the target end users includes regulators, logisticians, and pharmaceutical professionals industry, government and the international agencies, it also accepts the fact that local legislation and regulations will continue to take precedence. Medicines requiring controlled-temperature storage conditions must be distributed in a manner that ensures that their quality will not be adversely affected (Bishara, 2006). This applies to low risk product as well as high risk product such as vaccines and blood products which

normally require storage between 2 °C to 8 °C. All distributors of drug products are required to record storage and transportation temperatures as well as being licensed by the appropriate authorities. Temperature monitoring devices should be used to demonstrate compliance with the records that are kept (ABB, 2009). The responsibility for the cold chain ultimately resides with the manufacturer but accountability is shared across the supply chain. This requires increased oversight, management, and control of environmental conditions across the entire supply chain. There should be mandatory increased importance of temperature control and monitoring with heightened priority of patient safety and focus on product quality.

Many countries such as Canada, Ireland, UK, South Africa, Austria, Australia, Czech Republic, China Brazil, Venezuela, Singapore, Spain Australia, South Korea, and European Union have issued regulations and specific guidelines that address product integrity during transportation (Bishara, 2007). The regulations include temperature-controlled products which have specific storage temperature requirements.

Cold chain products and starting materials used in the manufacture of temperature sensitive products should be stored and transported under conditions which ensure that their quality is maintained (WHO, 2003). Good warehousing and distribution practices require that storage areas for medicines should be maintained within acceptable temperature limits and that, where special storage conditions are specified by the manufacturer; these should be provided, checked and monitored (WHO, 2010, Health Canada, 2011). Measuring and monitoring equipment should be calibrated and checked at defined intervals. Temperature sensitive products should be transported in such a way that they are not subjected to unacceptable degree of heat and cold, and specialized means of transportation should be used where necessary to ensure that the quality of the products are maintained throughout all distribution networks (WHO, 2009).

2.7 REGULATION OF COLD CHAIN MEDICINES IN GHANA

Patients and other healthcare professionals are entitled to expect that medicines sold or supplied from a pharmacy are fit for their intended purpose. To ensure that medicines distributed to retail pharmacies and other persons entitled to sell products to the general public are of the appropriate quality, they must be manufactured in licensed facilities that comply with the principles and guidelines of good manufacturing practices. They must also be distributed through a network of licensed pharmaceutical wholesalers, who in turn, must comply with GDP (Todd, 2008).

2.7.1 FOOD AND DRUGS BOARD

The competent authority mandated by law to regulate all medicines in Ghana including cold chain medicines is Food & Drugs Board (FDB) as established by Food and Drugs Law, 1992, 305B. Article 11 of the FDB law prohibits sale of drugs and other chemical substances and states that “A person commits an offence if that person sells a drug, cosmetic, device or chemical substance

- a) which has in or on it a substance that may cause injury to the health of the user when the article is used”, according to the directions on the label accompanying the article, or for a purpose and by a method of use that is customary or usual
- b) Consists in whole or in part of a filthy, rotten, decomposed or diseased substance or of a foreign matter likely to cause injury
- c) Is adulterated, or
- d) Is prepared, preserved, packed or stored under unsanitary conditions.

Article 17 put restriction on importation, and manufacture of drugs which makes the Minister of health by legislative instrument; prohibit the importation, manufacture, exportation, advertisement or sale of a drug, cosmetic, device or chemical substance

specified in the instrument. Article 18 of the law makes registration mandatory and states that “A person shall not manufacture, prepare, sell, supply, export or import a drug, cosmetic, device or chemical substance unless the article has been registered with the Board”.

All cold chain medicines distributed in Ghana are imported because there are no cold chain medicines manufacturing companies/industries currently in Ghana. According to FDB, there are ninety one (91) registered cold chain medicines in use in the country. These cold chain medicines are classified into vaccines (45), insulin (26) and human immunoglobulin (20) and are imported by twenty four (24) wholesale pharmaceutical companies.

2.7.2 PHARMACY COUNCIL

The Ghana Pharmacy Council is a statutory regulatory body established by an Act of Parliament, The Pharmacy Act, 1994 (Act 489). The Minister for Health has ministerial responsibility for the Pharmacy Council; it thus falls under the statutory bodies in the Ministry of Health.

The major function of the Council is to secure in the Public interest the highest standards in the practice of Pharmacy. In addition the Council also undertakes the following functions

- Prescribe standards of professional conduct
- Exercise disciplinary power over pharmacists
- Uphold and enforce professional standards through its disciplinary powers conferred on it
- Regulate the distribution of Pharmacies in the Country

According to Pharmacy Council, there are one hundred and fourteen (114) wholesale pharmacies and four hundred and ninety seven retail pharmacies in the Greater Region.

2.7.3 GHANA STANDARD AUTHORITY

The Ghana Standards Authority (GSA) which is the national Standards body was established by the Standards Decree, 1967 (NLCD 199) which has been superseded by the Standards Decree, 1973 (NRCD 173). The Authority is also the custodian of the Weights and Measures Decree (NRCD 326, 1975). These legislations together mandate the Authority to undertake:

1. National Standards development and dissemination;
2. Testing Services;
3. Inspection Activities
4. Product certification scheme
5. Calibration, Verification and Inspection of Weights, Measures and Weighing and Measuring Instruments
6. Pattern approval of new weighing and measuring instruments
7. Destination Inspection of imported High Risk goods
8. Promoting Quality Management Systems in Industry
9. Advice the Ministry of Trade, Industry, on standards and related issues

The above information show that Food and Drugs Board, Pharmacy Council and Ghana Standard Authority play a critical role in cold chain management systems in the area of market authorization/regulation of standards, enforcement of pharmacist practice/facilities and validation of storage facilities/monitoring devices respectively which are critical in maintaining product potency and quality along the distribution channel and to guarantee end users health and safety.

2.8 COLD CHAIN DISTRIBUTION CHANNEL IN GHANA

The system used for keeping and distributing temperature sensitive medicines in good condition is called the Cold Chain (WHO, 2004). The cold chain system consist of a series of storage and transport links, all designed to keep products within an accepted temperature range until it reaches the end user.

Maintenance of the cold chain requires products to be:

- Collected from the manufacturer or an airport as soon as they are available
- Transported between $2^{\circ} - 8^{\circ}\text{C}$ from the airport to wholesale facilities
- Stored at the correct temperature at wholesale facilities
- Transported between $2^{\circ} - 8^{\circ}\text{C}$ to pharmacy facilities and outreach sites during mobile sessions
- Kept between $2^{\circ} - 8^{\circ}\text{C}$ range during immunization sessions and
- Kept between $2^{\circ} - 8^{\circ}\text{C}$ during return to health facilities from outreach sites.

FIGURE 1: A COLD CHAIN SYSTEM



Source: Presentation by Kone, 2007

The illustration of maintenance of cold chain system through the distribution channel is as shown in figure. 1 by Kone. The two distribution channels for cold chain medicines supply in Ghana are: public facilities (Expanded Programme for Immunization-EPI, Central Medical Stores and hospital pharmacies) and private facilities (Wholesalers, community pharmacies and hospital pharmacies).

For example EPI is responsible for distribution and management of all vaccines procured by government. The EPI receives all cold chain medicines in the national cold chain room. Distribution is done from the national cold room to regional cold chain facilities. From regional cold storage facilities distribution is done to Districts and from the District to the health facilities. Likewise and like stated earlier since no cold chain medicine is manufactured in the country private suppliers also 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.

2.9 STORAGE FACILITIES FOR DISTRIBUTION OF COLD CHAIN MEDICINES

Storage is a critical parameter in maintaining the quality, safety, and efficacy of a medical product. Storage condition is an important parameter to maintaining the stability of the product. Product must therefore be stored in accordance with the requirements of its marketing authorization (Skuce, 2010).

2.9.1 COLD ROOM FOR WHOLESALE STORAGE

A simple cold room is commonly used to store material between 2 to 8 °C. Such cold rooms are now available commercially as walk-in chambers and are used for the storage of critical pharmaceutical products, samples, and raw materials by wholesalers where excursions in temperature conditions may affect the quality of stored material(s) in terms

of their appearance (color), consistency, potency, and impurity levels. Some cold chain items such as vaccines, insulin, biotech products and products derived from blood and plasma can be classified as high risk because they are at risk from freezing as well as elevated temperatures (Todd, 2008). Hence it is essential to qualify cold storage chambers under the worst-case scenarios. Some pharmaceutical manufacturers perform only Installation Qualification and Operational Qualification of cold rooms, but the Performance Qualification is also essential because data-based conclusions should be arrived at by challenging the system for all the attributes that may have bearing on the performance of the chamber for maintaining the desired temperature conditions. Following manufacturing, some medicinal products need to be stored and shipped at lower than ambient temperatures to assure their quality and efficacy. These are often referred to as “cold chain products” or “fridge lines” and wholesale dealers are expected to store and distribute them in strict accordance with the product labeling requirements. Wholesalers cannot rely on stability data in the event of temperature deviations (Todd, 2008).

After dispatch from a manufacturing facility, the distribution chain for medicinal products can be complex, potentially involving a number of storage locations, wholesalers and modes of transport, before the delivery finally reaches the pharmacy. The transportation arrangements from one location to another should be regarded as an extension of the storage activities and distributors are expected to treat each journey as unique with the length and complexity, as well as any seasonal variations, being considered when choosing the packing method and mode of distribution. In view of this, cold chain products should be packed in such a way as to ensure that the required temperatures are maintained throughout the journey.

When cold chain products are received at a pharmacy, it is important that they are promptly checked in and placed in a refrigerator. The person responsible for receiving the delivery must also satisfy themselves that the goods have been transported under appropriate conditions (e.g. there has been no direct contact between the products and gel or ice blocks). If it cannot be confirmed that the products have been transported under appropriate conditions and there is concern that their quality may have been compromised, the delivery should be quarantined in a suitable refrigerator whilst enquiries of the supplier are made. Until the issue has been clarified to the pharmacist's satisfaction the products in question should be considered as unsuitable and should not be supplied or sold to patients. If, following enquiries, there is still doubt as to the quality of the medicines received, the delivery should not be accepted and should be returned to the supplier.

2.9.2 STANDARD DOMESTIC REFRIGERATOR

Standard domestic refrigerators are not ideal for storing cold chain products for a number of reasons, including an uneven temperature distribution (as a result of minimal air circulation) and a normal operating range of between 0 °C and 10 °C. Opening and closing the fridge door can cause significant temperature fluctuations, making monitoring of the internal temperature difficult. There is also a risk that products could freeze if they come into contact with the chiller plate or coil at the back of the fridge (Taylor, MHRA).

2.9.3 PURPOSE BUILT PHARMACEUTICAL REFRIGERATOR

A purpose-built pharmaceutical refrigerator is recommended for the storage of cold chain products, especially those identified as high risk. The air within this type of refrigerator is circulated by a fan, which provides a uniform temperature profile and a rapid temperature pull down after the door has been opened. Temperature monitoring is usually by a

calibrated electronic min/max thermometer, with an accuracy of ± 0.5 °C, which can be read without opening the refrigerator door. Additional benefits are that these refrigerators can be locked and some have the option of either an audio or visual alarm system to alert staff in the event of temperature deviations. Many also have glass fronted doors giving greater visibility to stock levels, aiding stock management and also deterring the storage of non-medicinal products, as mentioned above.

When purchasing a new refrigerator therefore, factors to consider might include how long the unit can maintain the recommended temperatures if the power is turned off and to what extent the cabinet temperature is affected by ambient temperature variation, for example, in hot spells.

2.10 QUALITY MANAGEMENT SYSTEMS AND DOCUMENTATION

A quality management system (QMS) is the organisational structure, responsibilities, procedures, processes, documentation and resources for implementing quality management (Commonwealth of Australia, 2000). A QMS for cold chain distribution should ensure that:

- There is a programme of calibration of measuring devices
- Storage facilities are monitored, qualified/re-qualified
- Transport arrangements are validated and monitored
- There is a comprehensive staffing training programme
- There is a periodic review of activities
- There is a process for implementing corrective and preventive actions and assessing their effectiveness.

2.11 VALIDATION OF COLD STORAGE EQUIPMENT OR ROOM

Validation is a documented testing, performed under highly controlled conditions, which demonstrates a process consistently produces a result meeting predetermined acceptance criteria (Bishara, 2005). According to Scott Mills (2012), cold chain relies on validation to maintain high standards. In a general sense, to "validate" means to give official sanction to, approve or confirm. Accordingly, "validation" can be applied to a very wide range of procedures, products or circumstances. In the area of cold chain distribution - where it is critical to maintain a stable environment during the transport of temperature-sensitive medicines, validation is a vital part of the quality control process (Krause, 2012). This assures that active or passive insulate storage holding facilities (cold vans, cold boxes, carrier containers, etc.) are thoroughly tested and able to meet specific hold time requirements.

Vaccines and biological pharmaceuticals are particularly sensitive materials which, if not manufactured and transported under stringent controls, can become ineffective or even hazardous to the consumer. To that effect, regulatory institutions like the Food and Drug Administration (FDA) of the United States of America (USA) have since 1970s developed specific guidelines to test and evaluate biologic and pharmaceutical products before they could be released to the public.

Validation procedures have since taken shape and have been applied to the pharmaceutical and vaccine approval process. Eventually, validation methods and guidelines have been developed for the cold chain delivery system as well, with the goal of providing temperature assurance during the manufacturing, storage, transportation and delivery of medicines. With some exceptions, the temperature standard during the manufacturing, storage and shipping of pharmaceuticals and vaccines is between 2 to 8 °C.

In view of the critical nature of cold chain medicines, rigorous testing is performed on the equipment and materials responsible for its effective delivery to ensure that it meets established standards. Some examples of validated procedures within a cold chain distribution channels are:

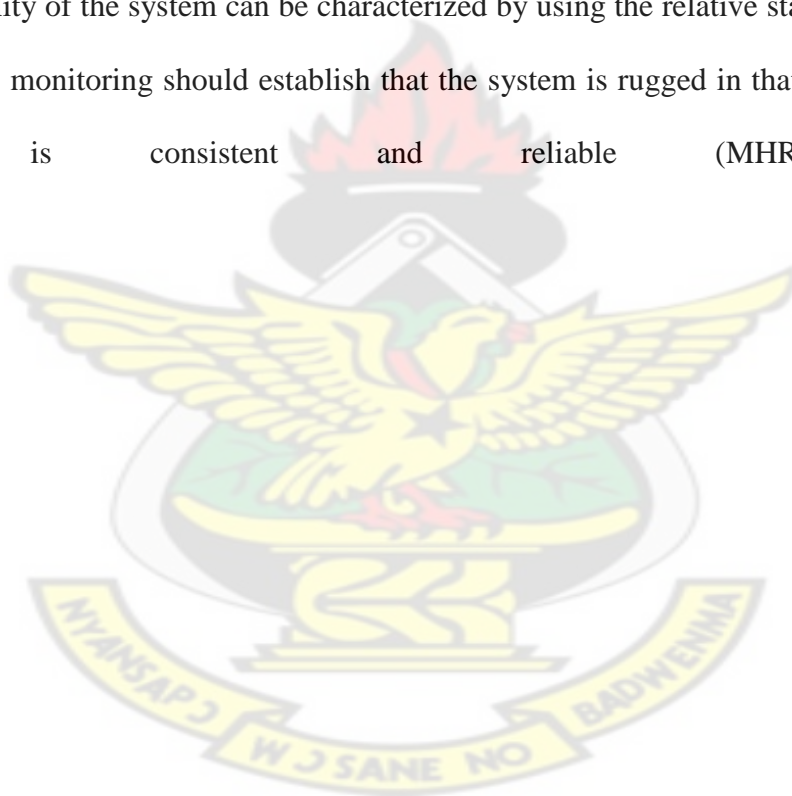
- All storage devices and or transportation equipment (fridges, cold vans, cold boxes, carrier containers, etc.), are subjected to a full validation process. This ensures that equipment is installed properly and functions as intended.
- Temperature monitoring devices (probes, thermometers, alarms) are calibrated at least annually against a traceable reference device and ensure that record is accurately documented.
- All elements of the cold chain packaging system to be validated are inspected to ensure that they meet specification. This ranges from insulated shipping containers and refrigerant packs to active heating and cooling systems.

It must also be understood that cold chain validation does not stop upon successful testing of storage and transportation facilities. The monitoring, analysis and documentation of the system must continue even after initial validation testing is done. The importance of consistent and reliable temperature control in situations where life-saving products are involved cannot be emphasized enough. And to those who manage cold chain distribution operations, the validation process offers insurance.

2.12 QUALIFICATION OF COLD EQUIPMENT OR STORES

Qualification is a documented testing that demonstrates with a high degree of assurance that a specific process will meet its pre-determined acceptance criteria (Bishara, 2005). On a regular basis, qualification procedures should be independently conducted on equipment in cold stores to guarantee their suitability and proper functioning.

The procedure should demonstrate the temperature profile for both air and product temperatures when chambers are empty as well as when loaded. The procedure should also demonstrate the time taken for temperatures to exceed the maximum temperature in the event of a power failure. Qualification should consider thermal fluctuations that occur during stock replenishment and order removal. The results of the qualification should demonstrate the ability of the equipment to maintain the required temperature range in all areas, defining any zones which should not be used for storage such as those areas in close proximity to cooling coils, doors, or cold air streams from equipment ventilation. The variability of the system can be characterized by using the relative standard deviation and thermal monitoring should establish that the system is rugged in that its temperature profile is consistent and reliable (MHRA, 2007)



CHAPTER THREE

RESEARCH METHODOLOGY

3.1 INTRODUCTION

The study identified the public health challenges in the supply chain management of cold chain medicines in the Greater Accra Region. The findings would help pharmaceutical institutions, managers of cold chain systems and regulatory authorities to improve efficiency and effectiveness of cold chain management in Ghana. This chapter consist of the research design, population, sampling procedures/techniques, data collection tools/procedure and data analysis/presentation procedure. Main issues of consideration are the source of the data; study approach and purpose; sampling techniques; data collection method; and data preparation and analysis. The chapter provided an overview of the methodological approach and the research design selected for the study. The methodology used in this study included the data and their sources and how the analyses are outlined.

3.2 RESEARCH DESIGN

Research design refers to how a researcher puts a research study together to answer a set of research questions. Research design works as a systematic plan outlining the study, the researchers' methods of compilation, details on how the study will arrive at its logical conclusions and the limitations of the research (Wills, 2003). A descriptive survey was employed to explore cold chain supply management in the Greater Accra Region. A descriptive survey 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. The choice of a survey design depended on the relatively large scale of the sample-a

total of 150 respondents. The data collected was primarily qualitative in nature. Additionally, the survey was also analytical because it was meant to assess the effect of non-compliance to cold chain standards on the quality of cold chain medicines and its impact on public health and safety. The research design covers sampling and choice of data collection method and concludes with a consideration of problems encountered in the data collection.

In order to find the factors that affect cold chain supply management and also the relationship between these factors, there was questionnaire administration. Visual observation was also utilised to verify processes, storage facilities, monitoring devices and performance of activities to corroborate the information provided by the respondent on the questionnaire which was personally administered.

3.3 STUDY POPULATION

The full set of cases from which a sample is taken is called the population (Saunders et al., 2007). The population in this research consist of FDB registered cold chain pharmaceutical distributors/wholesale cold chain storage facilities, PC registered retail community pharmacy, hospital pharmacy (public and private) cold chain storage facilities, EPI (National, Regional, District and Health/Outreach facilities) and diabetic patients who attend clinic at NDMR at KBTH in the Greater Accra Region. It was out of this population that a sample of respondents was drawn for the study as illustrated below;

- Public: Government/Ghana Health Service/EPI (National cold storage facility, Regional cold storage facility, District cold storage facilities, Hospital pharmacies / health facilities cold storage facilities)
- Private (Wholesalers of cold storage facilities, Retail Pharmacies (community and hospital) cold chain storage facilities)

➤ Diabetic patients attending clinic at NDMRC at KBTH

The one hundred and fifty (150) respondents was selected at random in the greater Accra region and purposive sampling was later used to solicit responses from wholesale and retail storage facilities who stock cold chain medicines and diabetic patients who attend clinic at NDMRC at KBTH who use insulin. The one hundred and fifty (150) respondents comprised of nine (9) wholesale cold chain storage facilities, fifty nine (59) retail pharmacies/health facilities cold chain storage facilities and eighty two (82) end users of cold chain medicines (insulin) was selected from their respective populations in the greater Accra region. For reasons of efficiency and easy access, Greater Accra Region was chosen for the study. The region was chosen as the study area because of the central role it plays in the socio-economic and political development of the country. The region according to the 2010 Population and Housing Census is the second most populous (4, 010,054) in the country after Ashanti Region, representing 16.3% of the total national population (Ghana Statistical Service, 2012). It is the administrative, communications, and economic center of the country and houses all the major FDB registered wholesale pharmaceutical cold storage facilities, most of the Pharmacy Council registered retail pharmacies, the national cold room for vaccines and National Diabetic Management and Research Center for people living on insulin, the region with the largest diabetic mellitus population in the country. Additionally, the region represents the various geographical settings of the country i.e. cosmopolitan, metropolis, districts and rural; where electricity supply critical to cold chain management could be reflected upon. The study covered seven (7) out of the ten districts including Accra and Tema Metropolis, Ashaiman, Ga South, Adenta, Dangbe East and Ledzokuku/Krowor Municipal Assemblies.

3.4 SAMPLING TECHNIQUE

Sampling technique provides a range of methods that enables you to reduce the amount of data you need to collect by considering only data from a sub group (known as a sample), rather than all possible cases or elements (Saunders et al, 2007). The purpose of taking a sample is to obtain a result that is representative of the whole population being sampled without going to the trouble of asking everyone. A purposive non-probability sampling technique was used to select the study region because it seeks to get all possible cases that fit particular criteria (Lind, et al, 2005). Purposive sampling was appropriate in this situation because;

- i. It enabled the selection of unique cases that were especially informative.
- ii. It also allowed in-depth investigations into the entire cold chain management systems along the supply chain among facilities that stock cold chain medicines and end users of insulin; the most widely distributed cold chain medicines in the country.

The sample size has the same chance of selection. This means that each member in the one hundred and fifty (150) was chosen with a purpose because the researcher approached the sampling problem with a specific plan in mind. Purposive sampling can be very useful for situations where one needs to reach a targeted sample quickly and where sampling for proportionality is not the primary concern. With a purposive sample, one is likely to get the opinions of a target population. The advantage of using non-probability sampling is it saves time and cost. The sample of 150 for the study consisted of 9 (6%) wholesale cold chain storage facilities, 59 (39%) retail pharmacies/health facilities cold chain storage facilities and 82 (55%) end users of cold chain medicines (insulin) from National Diabetic Management and Research Centre at the Korle-Bu Teaching Hospital.

3.5 DATA COLLECTION TOOLS / PROCEDURES

The aim of this study was mainly to ascertain the challenges in the supply chain management of cold chain medicines and impact on product quality and public health and safety. In line with the recommendations of Eisenhardt (1989), different methods were used to collect data including a survey, visual observations of processes, examination of records and interaction with respondents. The main primary data gathering instrument for the survey was a structured questionnaire.

3.5.1 QUESTIONNAIRE

The questions were standardized in order to allow easy comparison (Saunders et al 2007). The questionnaires contain the relevant questions which were designed with the objectives of the study in mind, i.e. profession and length of experience of people managing cold chain systems or using cold chain medicines, cold chain management systems compliance to WHO requirements, validated storage/monitoring devices, end users handling of cold chain medicines and regulatory oversights in enforcing compliance of cold chain regulation(s). There were both close-ended and open-ended questions. This was used to collect information from respondents. Three (3) different questionnaires were developed for wholesale cold chain storage facilities, retail pharmacies cold chain storage facilities and end users of cold chain medicines (insulin) to gather information from cold chain management systems in the Greater Accra Region.

3.6 DATA ANALYSIS

The primary data collected was initially edited to detect and correct any omissions and errors to ensure consistency and completeness. Again the edited data was coded and analysed by the use of IBM Statistical Package for the Social Sciences (SPSS), version

19. The analysed data was presented in the form of descriptive statistics in frequency distribution, mainly tables, bar and pie charts.

3.7 ETHICAL CONSIDERATIONS

This research required mandatory ethical clearance from Ghana Health Service Ethical Review Committee (GHS-ERC) before I could use any of its facilities (government hospital pharmacies, EPI-cold chain storage facilities, health data from CHIM, staff, patients, etc.) for the research. Ethical clearance was sought from the ethical review committee and permission was granted on the 9th May, 2012 with Ethical Clearance – ID NO: GHS-ERC: 09/03/12, before I could start the research. The ethics of the research required that, participants be given written information about the research, a written consent form be given to every respondent to read and sign and finally, participants given assurance through debriefing information that all information shared will be used purely for the research purposes, they will be kept confidential and the participants' anonymity will be maintained as only pseudonyms will be used and participant's names withheld. All collected information will be destroyed after 5 years. In all, each of the 150 questionnaires administered contained participants information form, informed consent sheet and debriefing form for each of the respondents in line with ethical requirement.

CHAPTER FOUR

DATA ANALYSIS AND DISCUSSION OF RESULTS

4.1 INTRODUCTION

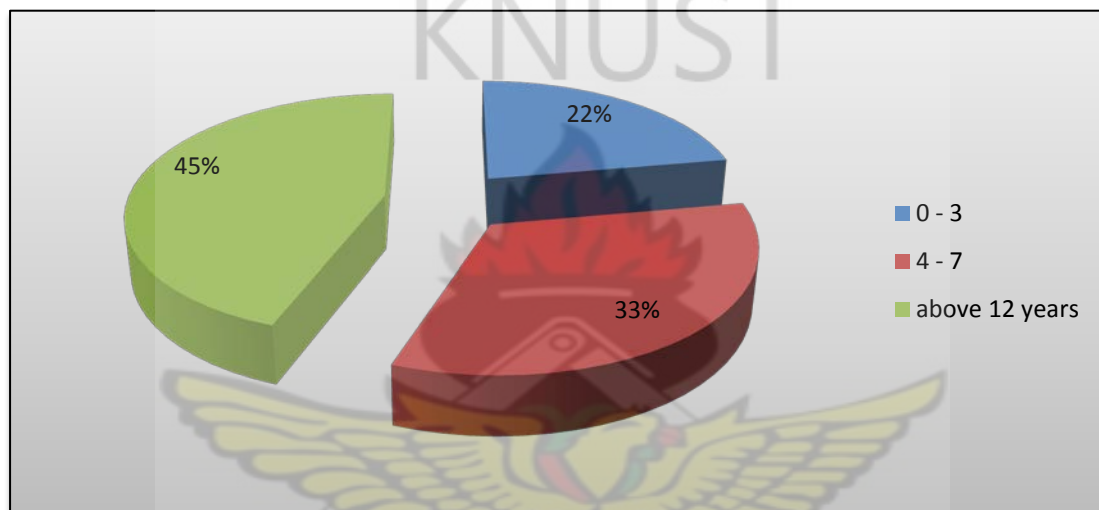
This chapter examines and analyses the data gathered from the questionnaire administered and personal visual observations made at wholesale and retail pharmacy cold chain storage facilities and National Diabetic Research Centre at Korle-Bu Teaching Hospital. Analysis of data are presented and discussed in the remainder of this chapter. The research generated a lot of data through responses and therefore in order to keep the discussion focused and findings in the right context, the chapter has been arranged in three parts. The first part presents the results and discussion on wholesale cold chain storage facilities. The second part presents the results and discussion on retail pharmacies cold chain storage facilities and the third and final part presents the results and discussion on end users of cold chain medicines (insulin). In all instances, results are arranged first, with all figures and tables well labeled before discussions are placed beneath. The discussion placed emphasis on questions that addressed the research objectives and issues are placed in the right perspective by making references to the various figures or tables. The study achieved a 100% response because the questionnaire was personally administered and a total of 150 responses were obtained. The high response rate could be attributed to the fact that the respondents were personally interested in the research because of the direct benefit they stand to gain especially those managing diabetics using insulin and Expanded Programme for Immunisation for both public health and safety and cost management reasons.

It could also be attributed to the fact that, the questionnaire designed was very informative and questions relevant to the respondents and well structured which

according to them was easy and convenient to respond to and because there was interaction during the administration of the questionnaire which was done personally; it offered them an opportunity to ask questions which was well explained to their satisfactions.

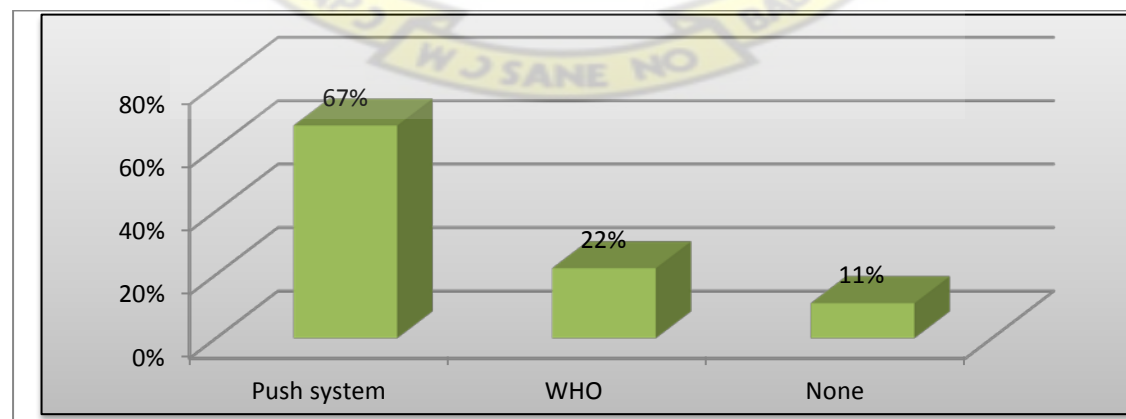
4.2 RESULTS OF WHOLESALE PHARMACY/HEALTH FACILITY COLD CHAIN STORAGE FACILITIES

Figure 2: How long have you been doing this work



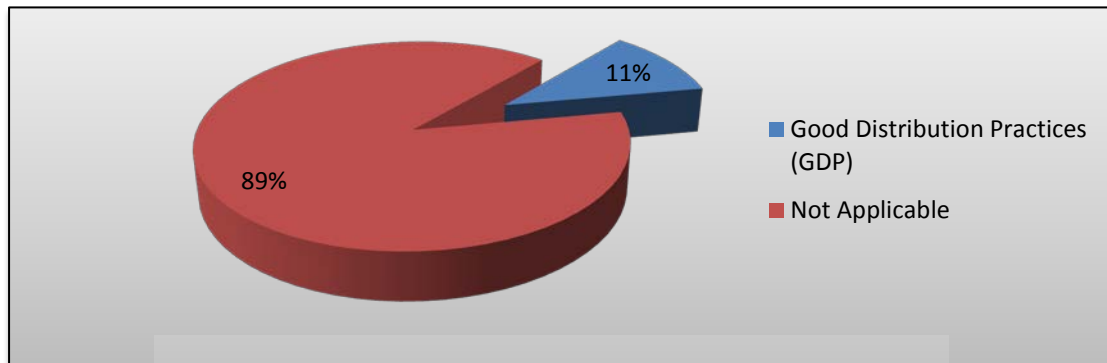
Source: Field Survey May, 2012

Figure 3: What type of system do you have in place to ensure quality of cold medicines



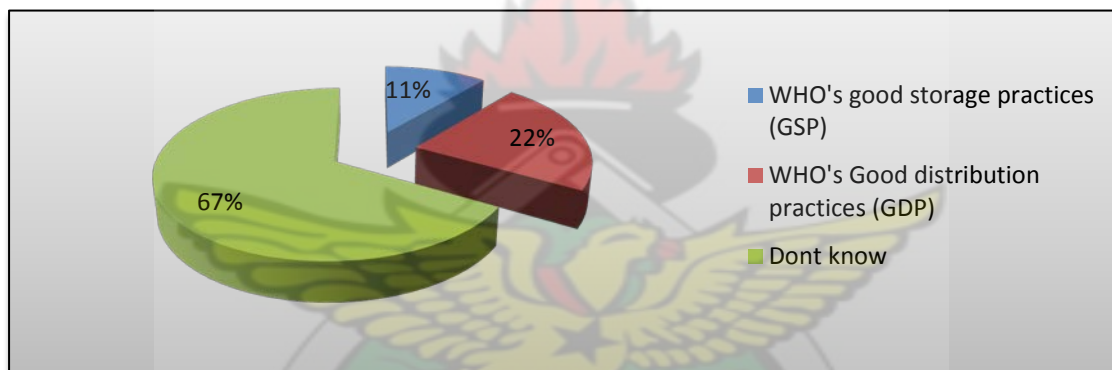
Source: Field Survey May, 2012

Figure 4: Name any guideline you use for managing the Quality Management System



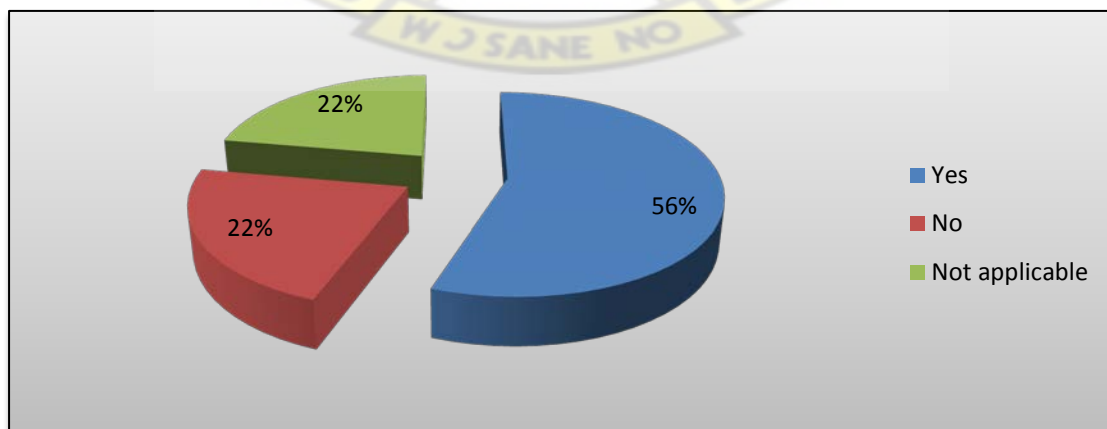
Source: Field Survey May, 2012

Figure 5: Which of the following WHO requirements do you use as part of the QMS



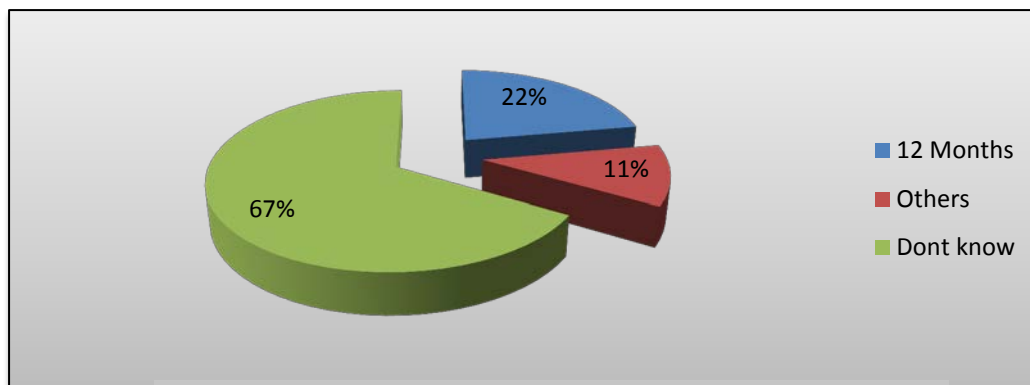
Source: Field Survey May, 2012

Figure 6: Have all employees been trained on specific cold chain regulations, Standard Operating Procedures (SOP's) and other related tasks



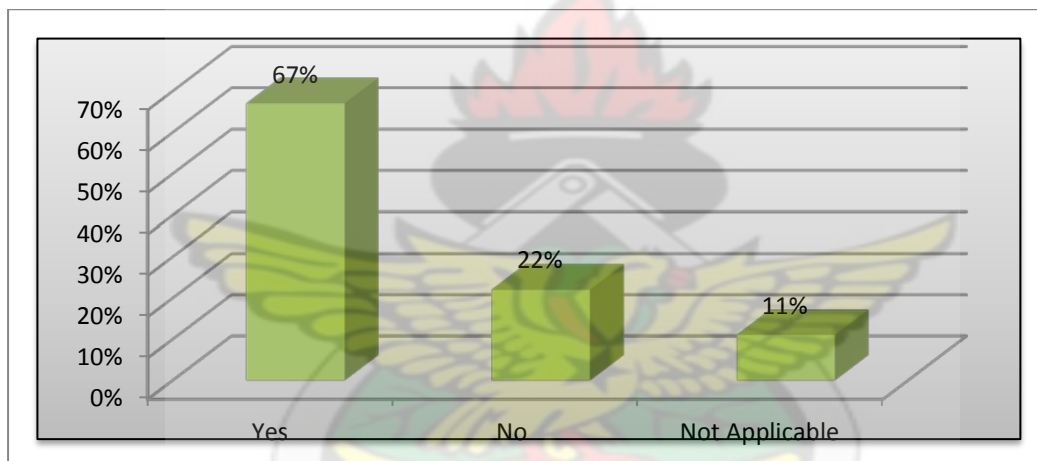
Source: Field Survey May, 2012

Figure 7: How often does Food and Drugs Board (FDB) visit your facility



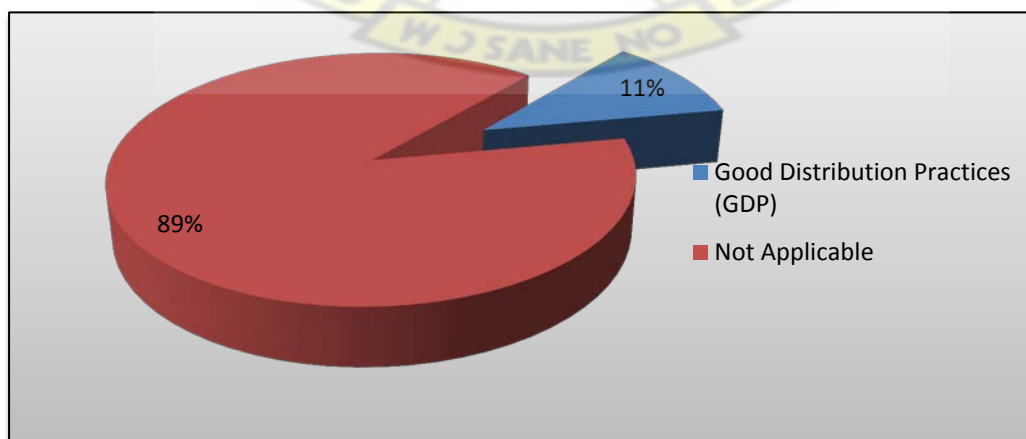
Source: Field Survey May, 2012

Figure 8: Do they specifically inspect cold chain medicines storage facility



Source: Field Survey May, 2012

Figure 9: What specific guidelines or standards do they use as a benchmark



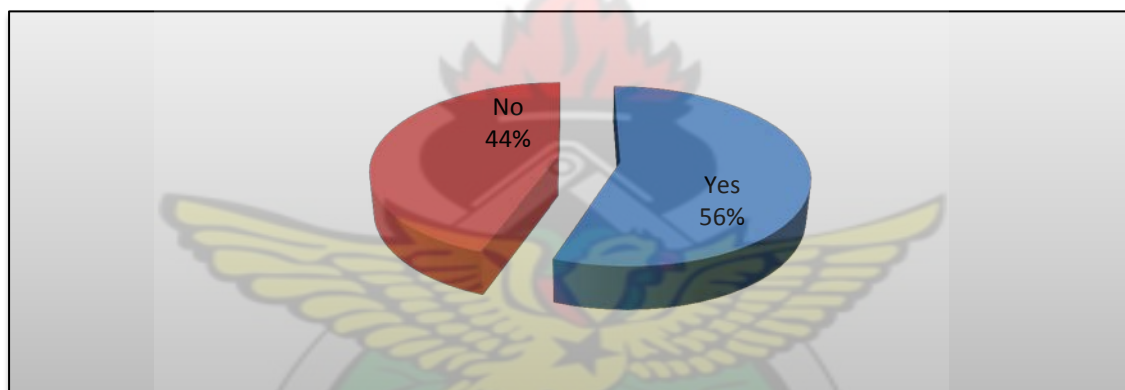
Source: Field Survey May, 2012

Table 1 How do you maintain appropriate storage condition in the event of a power failure

	Frequency	Percent	Cumulative Percent
Do not know	2	22.2	22.2
Generator	5	55.6	77.8
Ice Pack with Cubes	1	11.1	88.9
Transport the product to the nearest cold chain facility	1	11.1	100
Total	9	100	

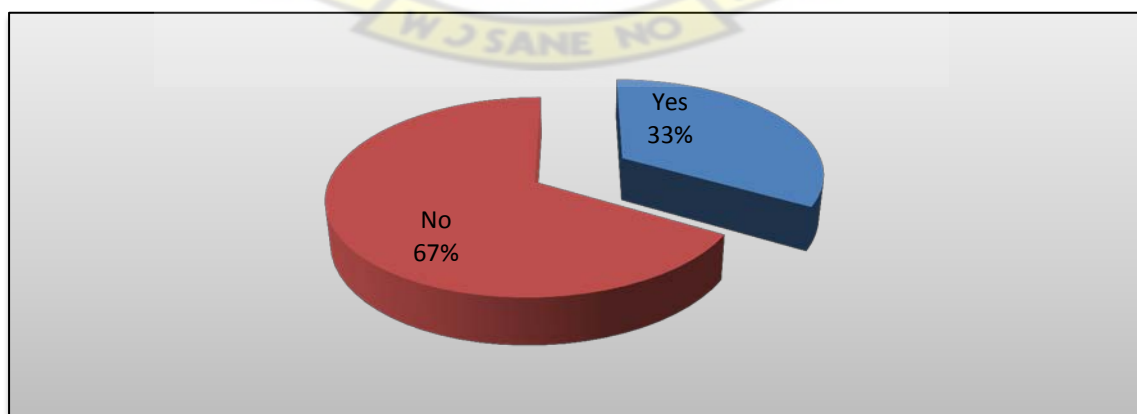
Source: Field Survey May, 2012

Figure 10: Do you have an automated generator system to cater for power failure after closing hours



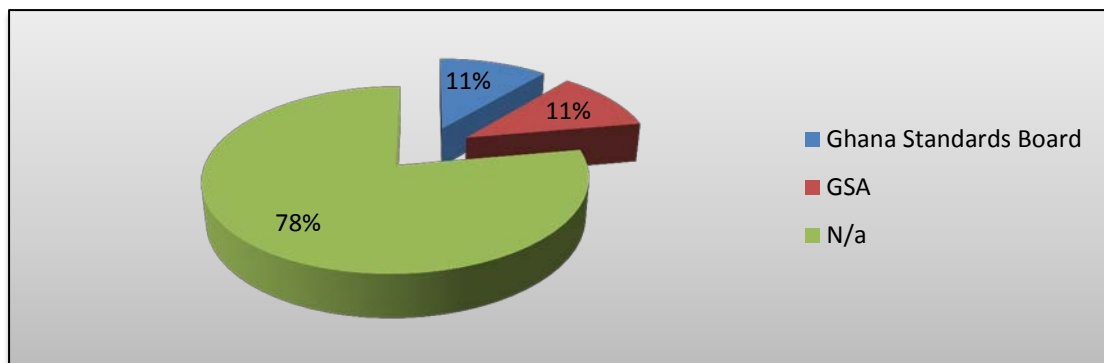
Source: Field Survey May, 2012

Figure 11: Are all sensors and probes, including temperature monitoring devices calibrated at least once every year



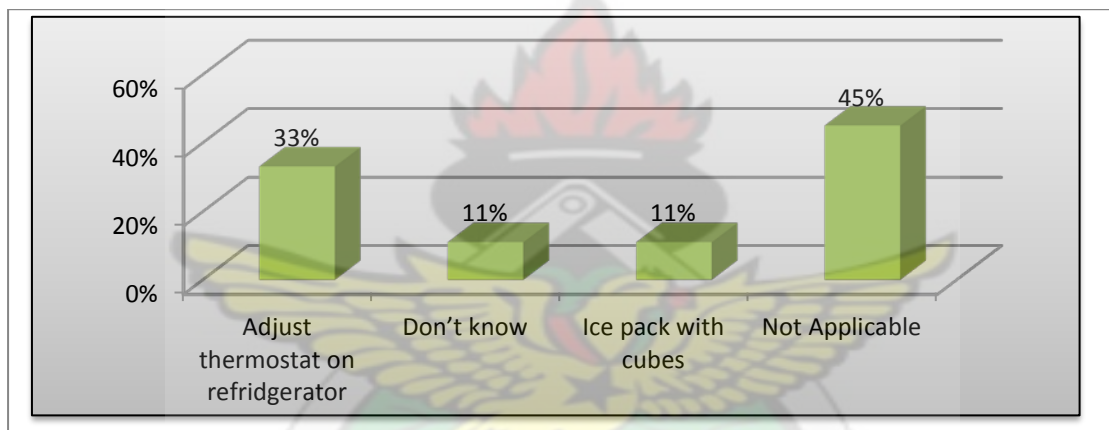
Source: Field Survey May, 2012

Figure 12: Which institution did the calibration



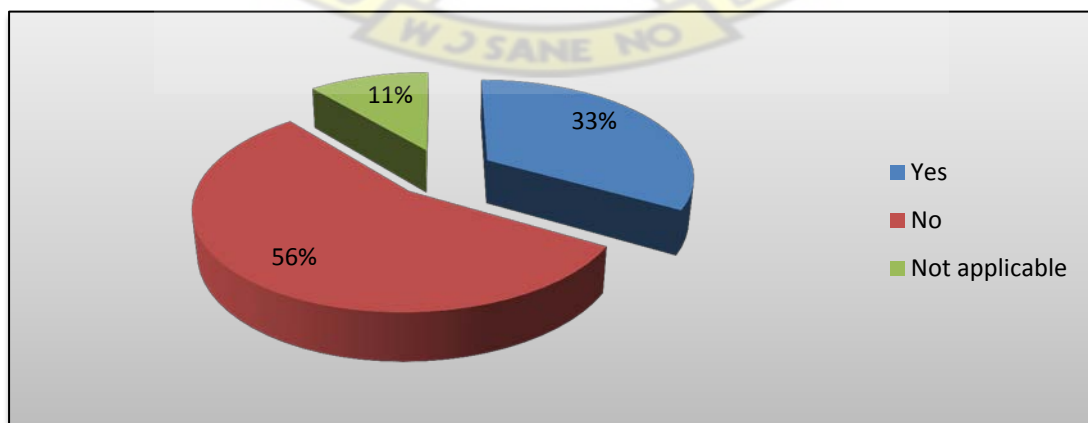
Source: Field Survey May, 2012

Figure 13: How do you manage temperature excursion



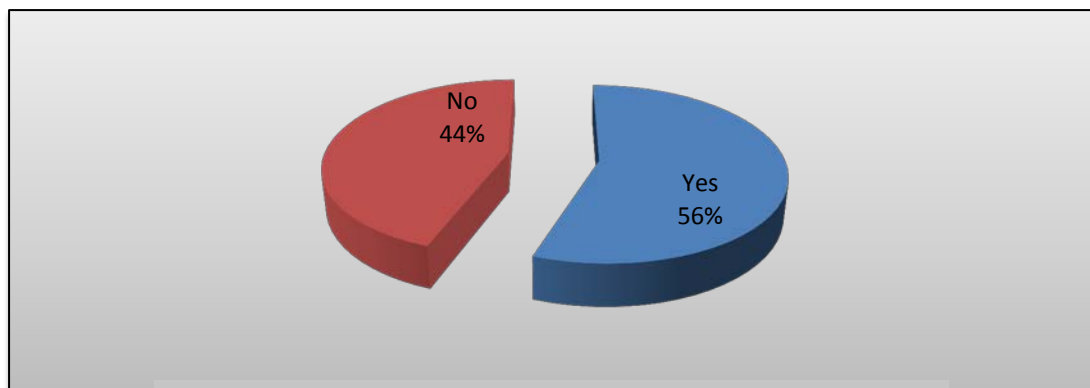
Source: Field Survey May, 2012

Figure 14: Have controlled temperature areas been mapped to determine high and low temperature areas within the storage during seasonal extremes



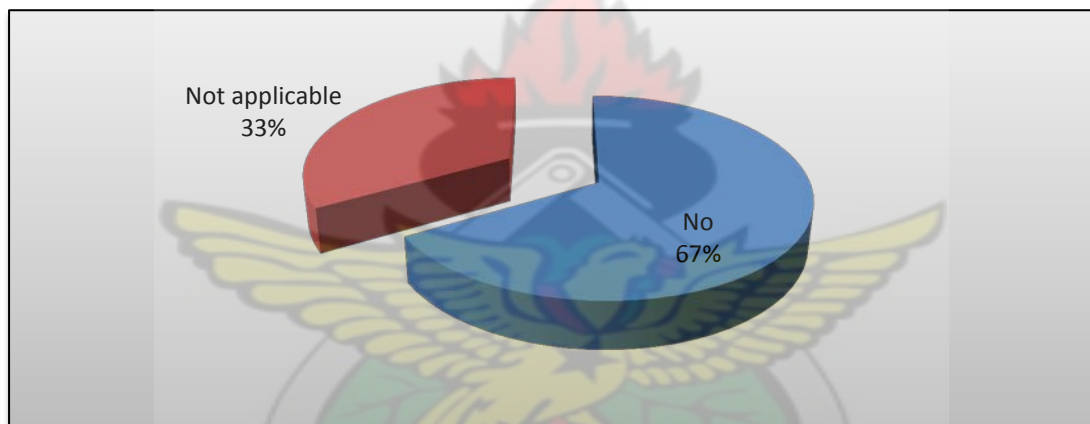
Source: Field Survey May, 2012

Figure 15: Do you check the temperature of the products before dispatching



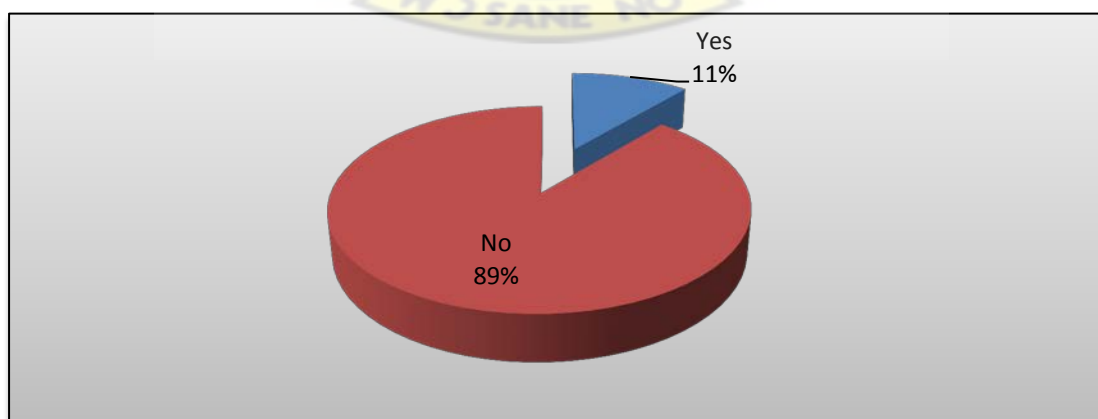
Source: Field Survey May, 2012

Figure 16: Is the device calibrated



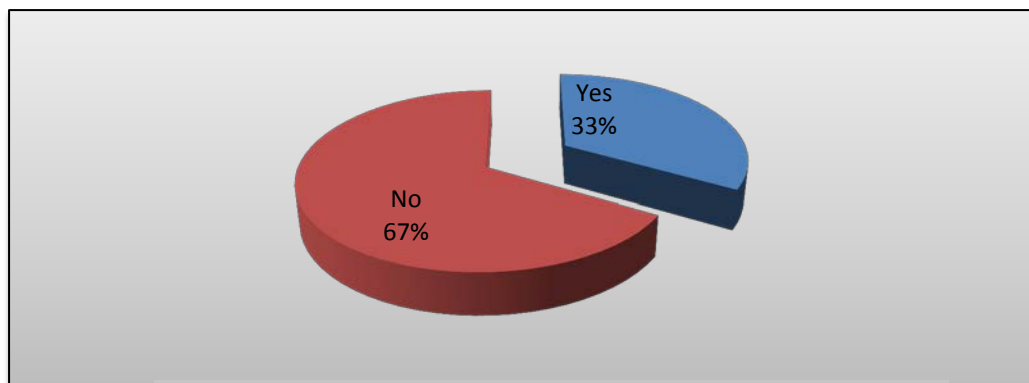
Source: Field Survey May, 2012

Figure 17: Where temperature control is needed, has the transportation cold van or carrier qualified



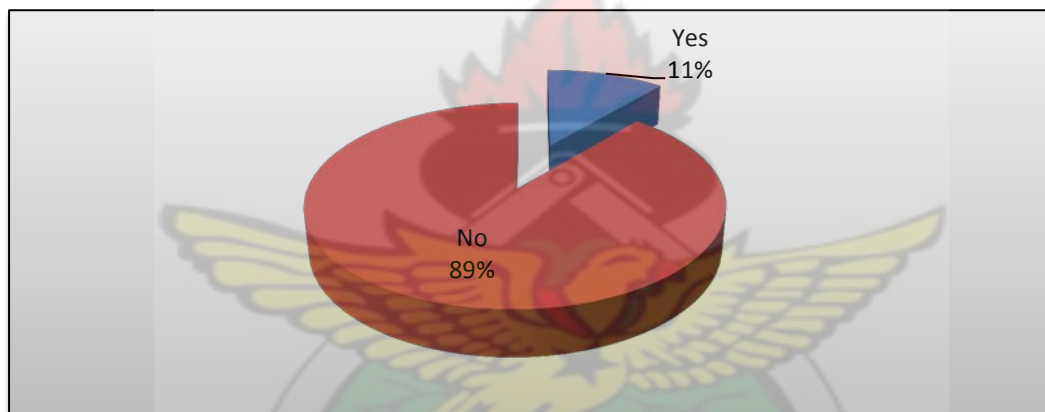
Source: Field Survey May, 2012

Figure 18: Do transportation vehicle have temperature monitoring device



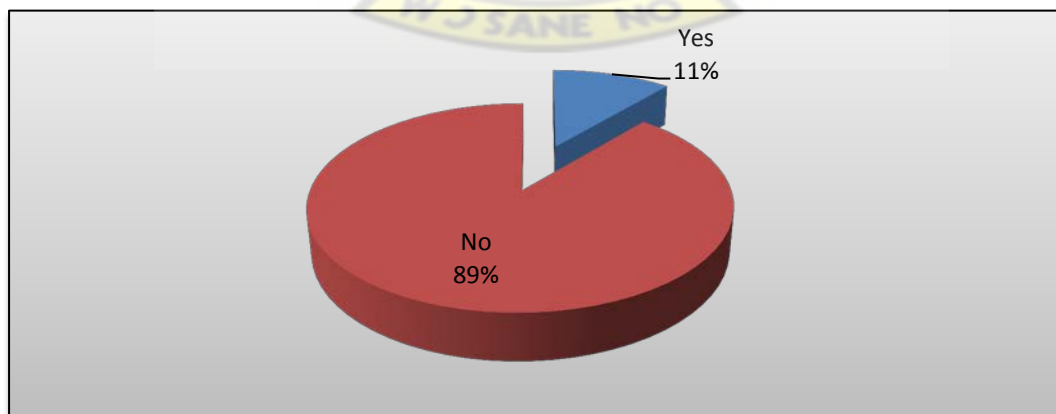
Source: Field Survey May, 2012

Figure 19: Are the temperature monitoring devices on the vehicle calibrated



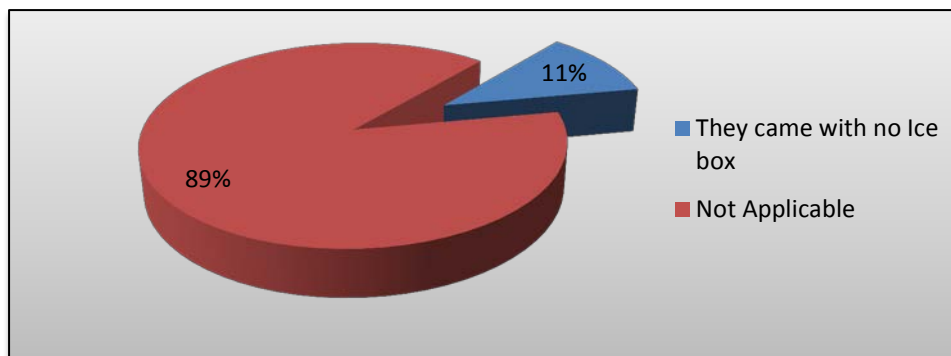
Source: Field Survey May, 2012

Figure 20: Have you ever refused to dispense cold chain medicine, including insulin to a retail pharmacy facility although the medicine is available



Source: Field Survey May, 2012

Figure 21: What was the reason



Source: Field Survey May, 2012

4.3 DISCUSSION OF WHOLESALE COLD CHAIN STORAGE FACILITIES RESULTS

There was a good indication according to fig. 2 that, those managing cold chain have experience as 78% have done the job over 4 years while 22% have worked up to 3 years therefore there is expectation that they will do the right thing. There was no evidence that any of the wholesale facilities operate a Quality Management System this is because the constituents of QMS i.e. Quality Policy, procedures or process, documentation, clear reporting structure as observed by Commonwealth of Australia (2000) are largely missing in their operations. What they termed as QMS are basically operational activities, like the Push System (fig. 3) which obviously is used for medicines quantity request management along the supply chain but not systems to protect product potency and quality which are critical to public health and safety Blake, (2008).

Generally, there is no guideline for managing cold chain as expressed by 89% of the facilities and only 11% do have guideline (fig. 4) and the implication is that people do things without recourse to any control and therefore it was not surprise that 67% of the facilities have no knowledge about any of the WHO requirements for managing cold chain as against 33 who have working knowledge with GDP and GSP (fig. 5).

According to fig.6, 56% of the people working on cold chain have been trained on cold chain procedures while 44% of the people have no training on cold chain procedures. Most of the facilities (67%) have no knowledge about FDB visit; 22% said at least they do visit once every 12 months and the remaining 11% chose others and said it is MOH/GHS health directorate that visits their facilities to inspect their cold systems (fig. 7). Likewise, 78% of the respondents admitted that FDB do not specifically inspect cold chain facilities during their visits while 22% said they do (fig. 8). Additionally, 89% of respondents (fig. 9) said FDB do not have any guideline as bench mark for cold chain enforcement while 11% said they use GDP as a reference standard for their inspections. The implication for figures, 7, 8 and 9 is that there are weak regulatory oversight responsibilities in the monitoring and control over cold chain activities to ensure compliance to quality standards as required by regulation WHO, (2009).

There was evidence that 56% (table 1) of the facilities use generator to maintain appropriate storage condition during power failure while 22% do nothing in the event of power failure and 11.1% each either use ice packs or transfer the medicines to a nearby storage facility in order to maintain the appropriate storage condition. Likewise, 56% (fig. 10) of the facilities have automated generator to maintain storage condition in the event of power failure after close of work but the remaining 44% do not have automated generator. Lack of contingency for power outages means that storage condition cannot be met leading to temperature excursions and could cause product deterioration leading to lost in potency and quality of medicines.

It was observed that 33% of the storage facilities temperature probes, sensors and temperature monitoring devices were calibrated but majority (67%) were not calibrated (fig. 11). Likewise, only 22% calibrated monitoring devices are traceable to GSA; the remaining 78% have no idea about the existence of such institution (fig. 12). There was

general indication that majority of the respondents (56%) do not have any idea as how to manage temperature excursion, while 33% and 11% (fig. 13) said, they adjust thermostats and or use ice pack respectively to manage temperature excursion. Majority of the facilities (67%) had not mapped their storage facilities to determine high and low temperature areas within the storage area and also during seasonal extremes while the remaining 33% have storage areas mapped (fig. 14).

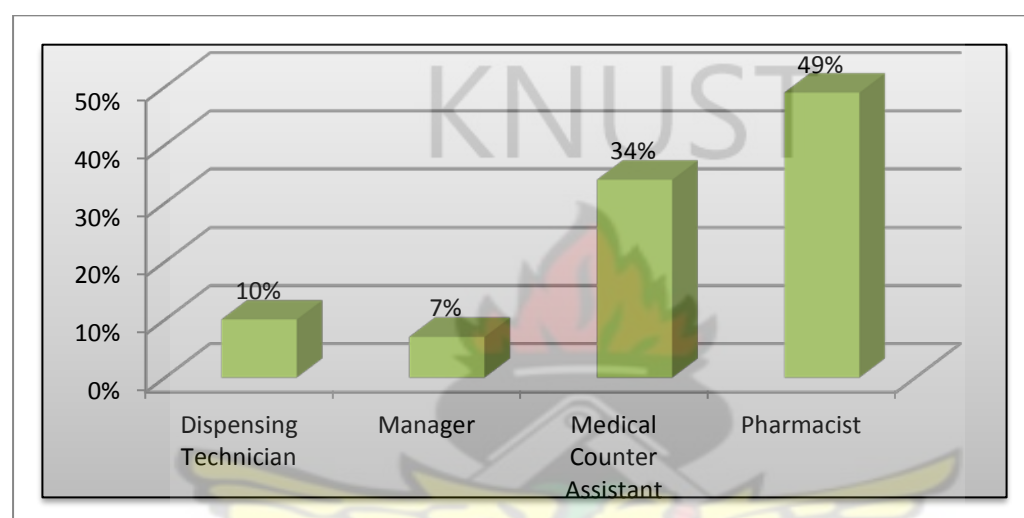
There was admission that 56% of the facilities check temperature of the medicines before dispensing to retailers while 44% do not (fig. 15). In all instances, there was 100% indication that none of the thermometers used for temperature readings are calibrated as observed in (fig. 16) because 67% responded not applicable while the remaining 33% said no. There was strong indication that majority (89%) of distribution containers or cold chain vans are not prequalified, except few (11%), (fig. 17). Generally, vehicles for distribution of cold chain medicines do not have temperature monitoring devices (67%); only 33% do have (fig. 18). Likewise 89% of the thermometers are not calibrated (fig. 19).

The absence of calibration of storage probes, sensors, thermometers and qualification of cold chain vans and carriers means that there is no validated system to protect product quality, efficacy and potency Bishara, (2005) and lack of qualification implies there cannot be assurance that cold chain vans and carriers have the temperature storage capacity to transport medicines within a stipulated time as observed by MHRA, (2007) and WHO, (2010). The effect of validation was observed on the field when some fridges thermostats though was set at 4 °C; the actual temperature recordings was 14 °C and in another instance, monitoring thermometer was observed reading -4 °C contrary to expected temperature ranges of 2 to 8 °C On a whole, cold chain medicines have always been sold to retail facilities (89%) (fig. 20) and on the occasion where sales have been

refused (11%), the justification was that the person making the purchase was not having ice cold box to maintain the cold chain during transportation (fig. 21).

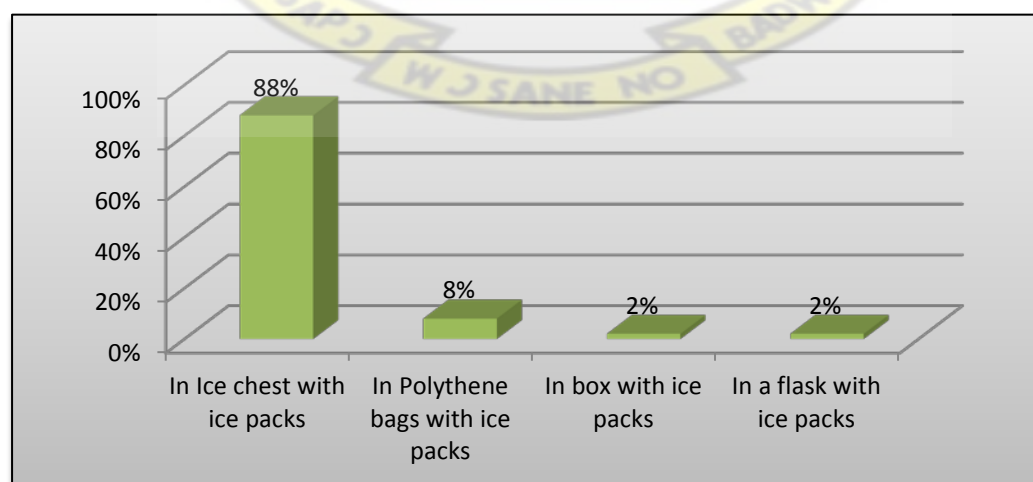
4.4 RESULTS OF RETAIL PHARMACY / HEALTH FACILITY COLD CHAIN TORAGE FACILITIES

Figure 22: What is your job title



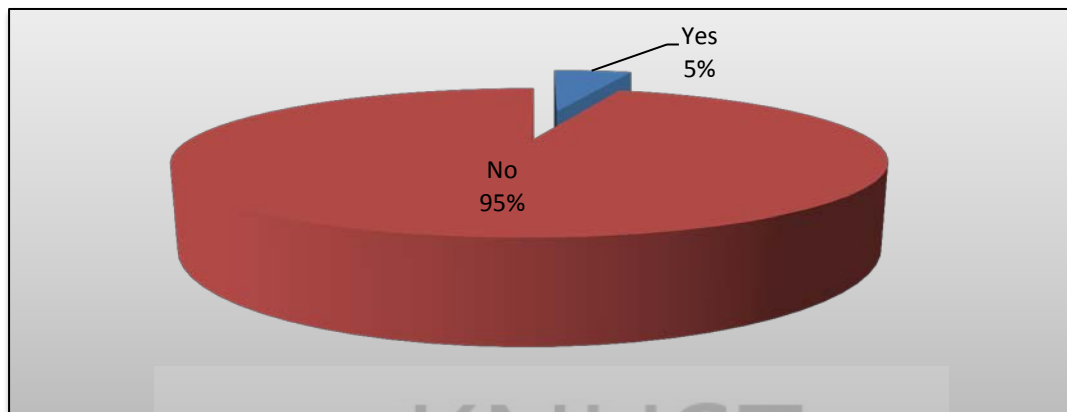
Source: Field Survey May, 2012

Figure 23: How do you receive and or transport cold chain product from wholesalers



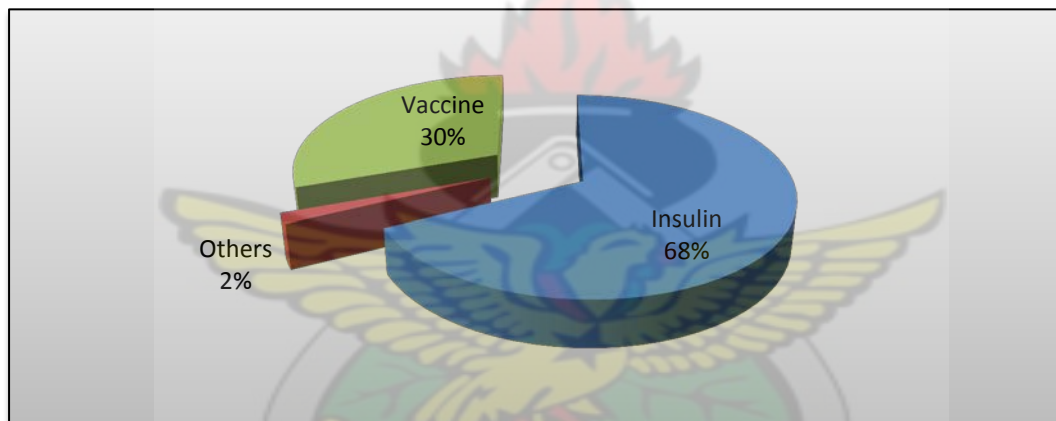
Source: Field Survey May, 2012

Figure 24: Do you check temperature of the product before receiving supplies



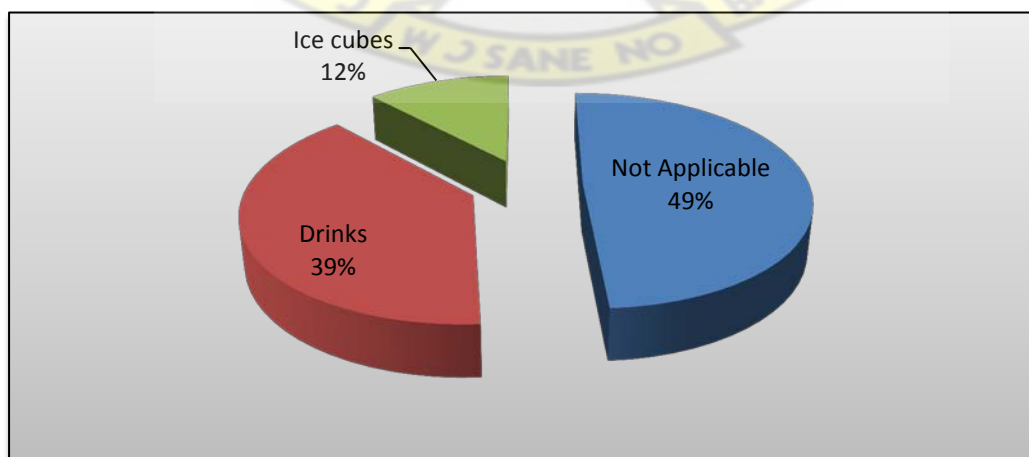
Source: Field Survey May, 2012

Figure 25: List the type of cold chain medicines stored in the storage facility



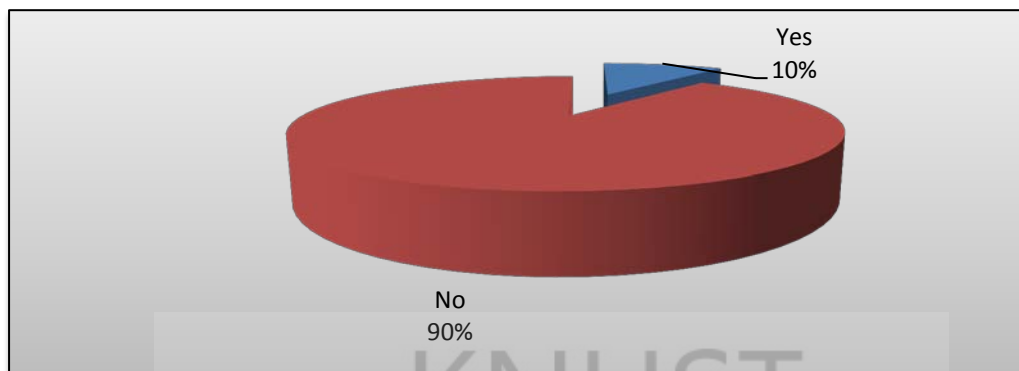
Source: Field Survey May, 2012

Figure 26: List any others which are stored in the storage facility



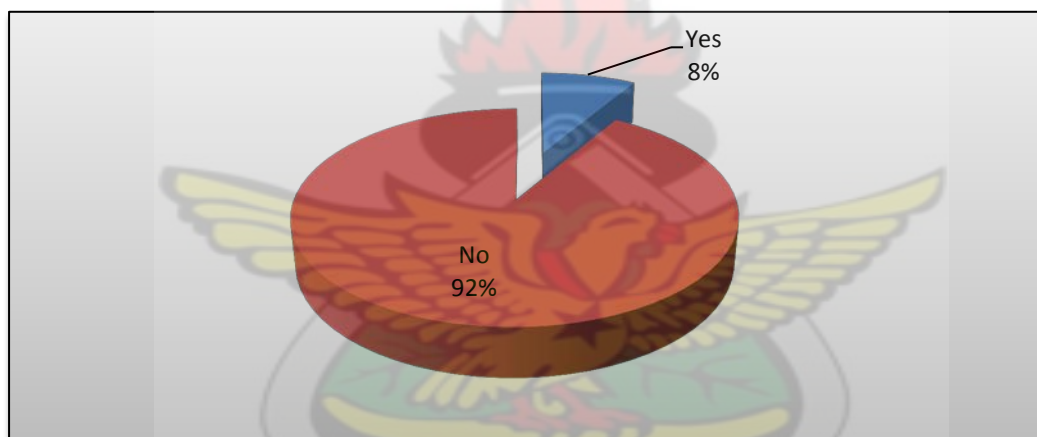
Source: Field Survey May, 2012

Figure 27: Are there written instructions describing storage procedures, materials handling and documentation



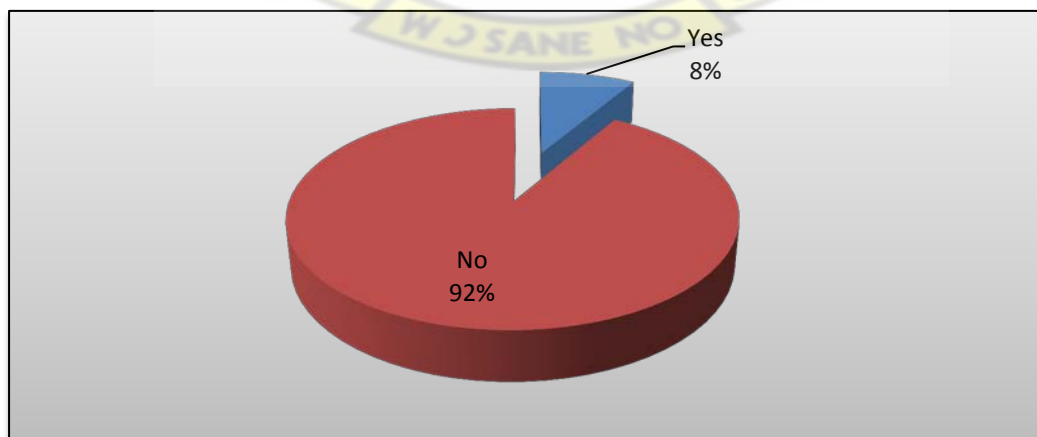
Source: Field Survey May, 2012

Figure 28: Is the storage device furnished with low and high temperature alarms



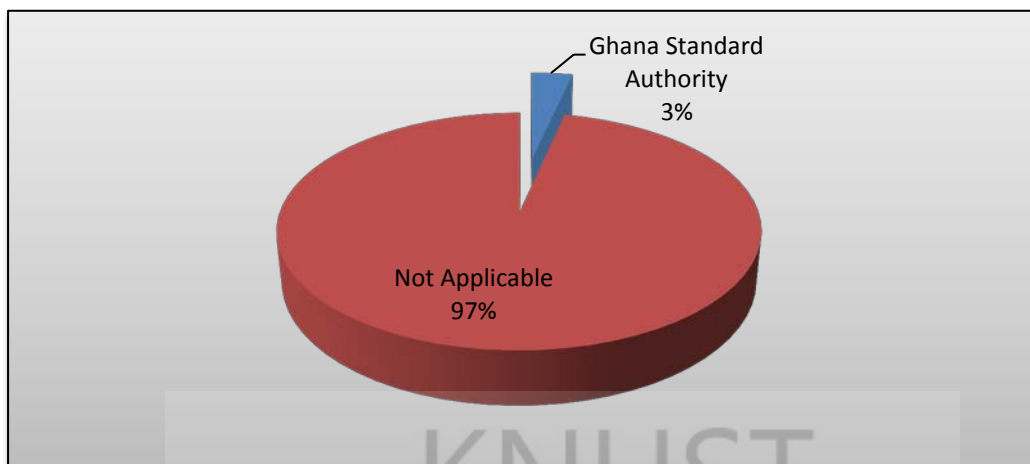
Source: Field Survey May, 2012

Figure 29: Is the storage device equipped with thermometers



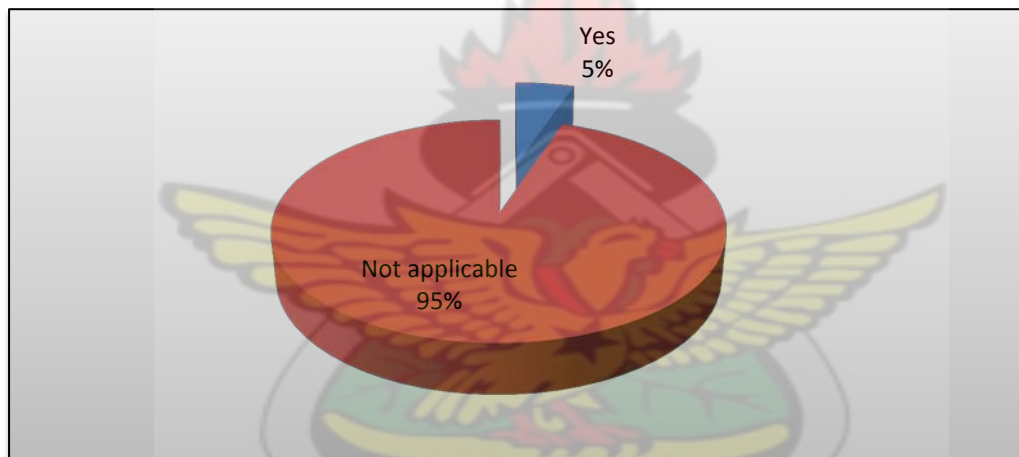
Source: Field Survey May, 2012

Figure 30: Which institution did the calibration



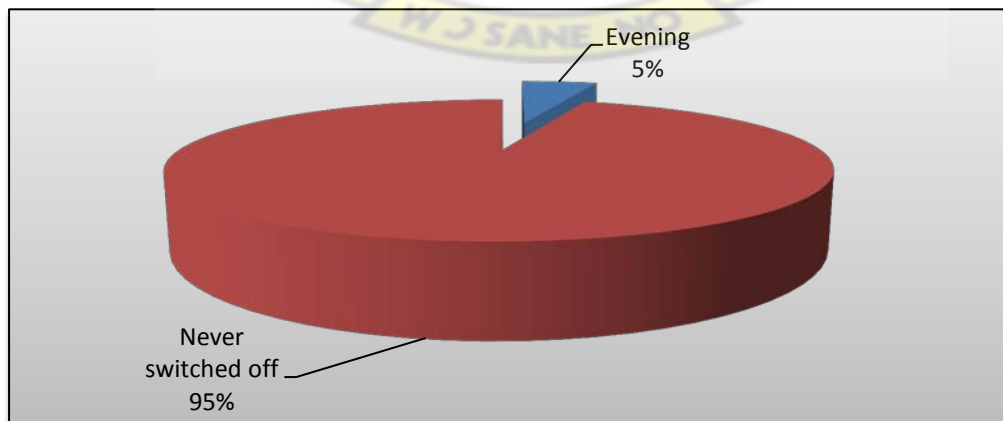
Source: Field Survey May, 2012

Figure 31: Is temperature monitoring being recorded



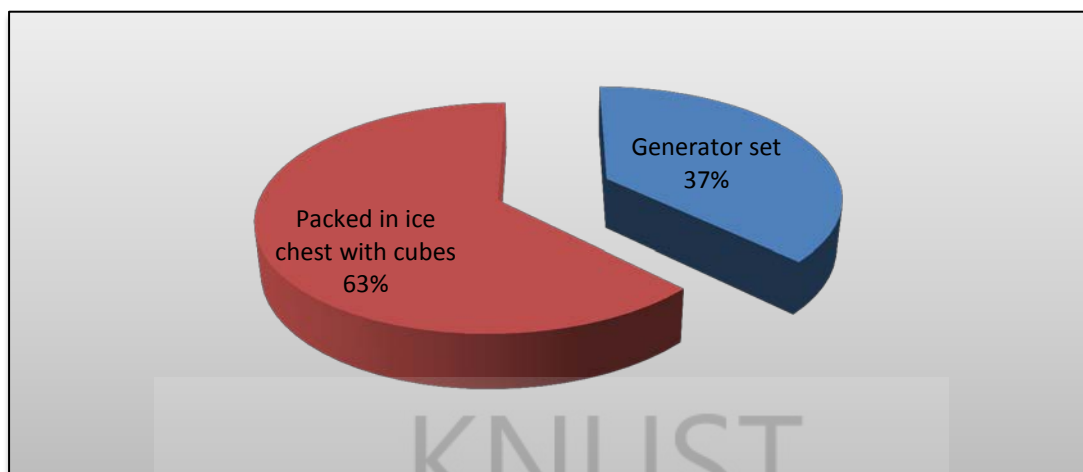
Source: Field Survey May, 2012

Figure 32: What time do you switch off the storage facility



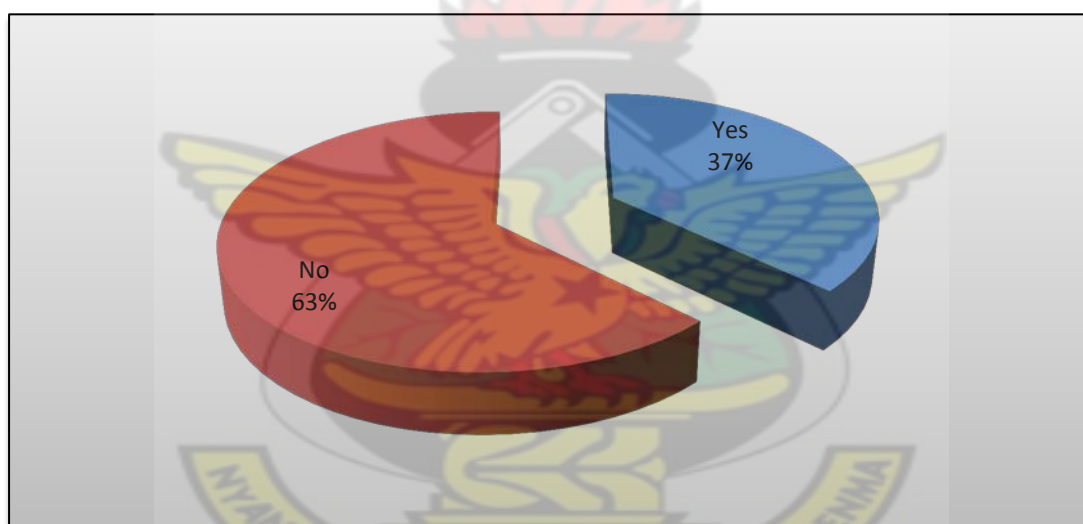
Source: Field Survey May, 2012

Figure 33: How do you maintain appropriate storage condition in the event of power failure



Source: Field Survey May, 2012

Figure 34: Do you have an automated generator system to cater for power failure



Source: Field Survey May, 2012

Table 2: How often does food and drugs board visit your facility

	Frequency	Percent	Cumulative Percent
3 Months	4	7	6.8
6 Months	6	10	16.9
12 Months	14	24	40.7
Others (specify)	29	49	89.8
Never	6	10	100
Total	59	100	

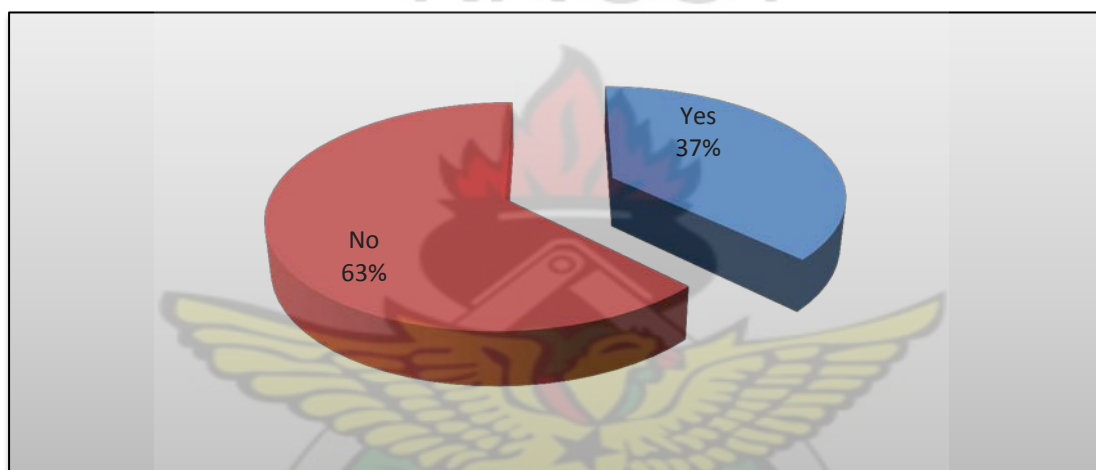
Source: Field Survey May, 2012

Table 3: How often does pharmacy council visit your facility

	Frequency	Percent	Cumulative Percent
3 Months	9	15	15.3
6 Months	17	29	44.1
12 Months	14	24	67.8
Others (specify)	16	27	94.9
Never	3	5	100
Total	59	100	

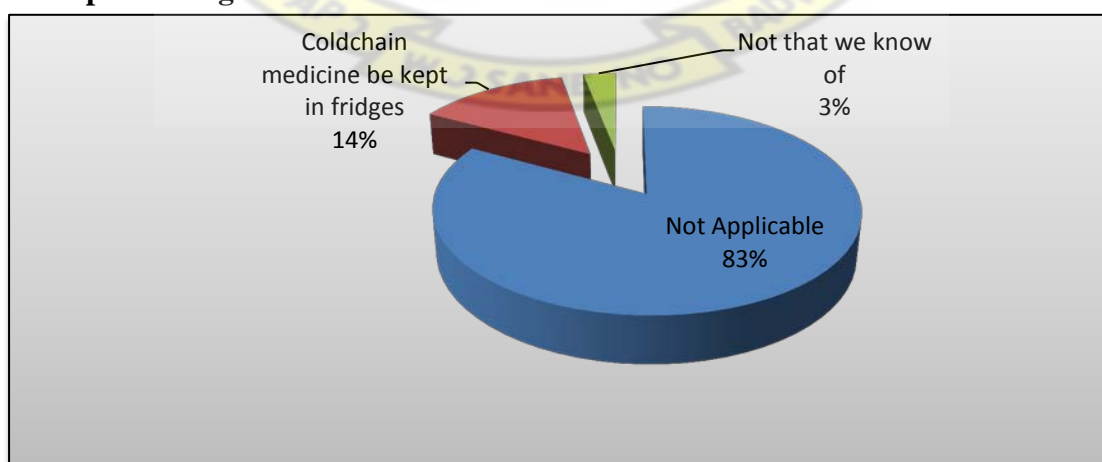
Source: Field Survey May, 2012

Figure 35: Do they specifically inspect cold chain medicine in the storage facility



Source: Field Survey May, 2012

Figure 36: What specific guideline or standard do they inspect the cold chain facility or the product against



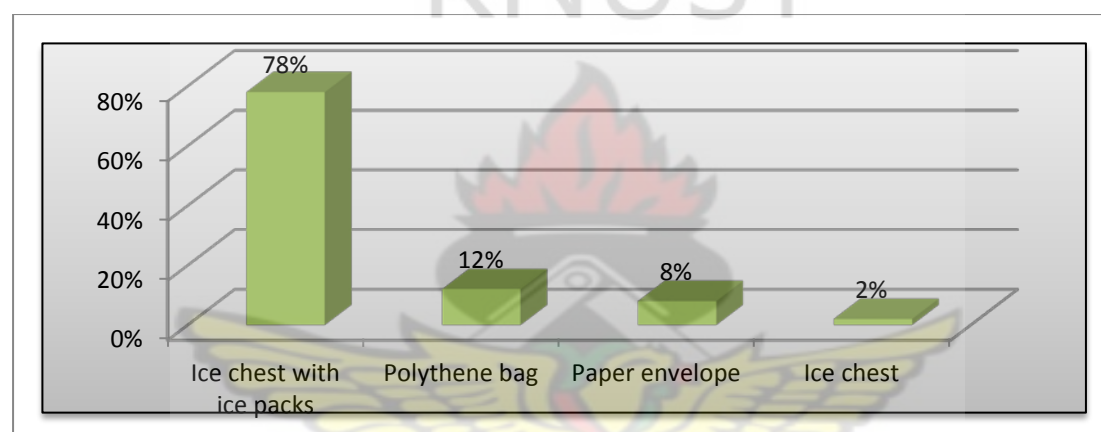
Source: Field Survey May, 2012

Table 4: What information do you give to client

	Frequency	Percent	Cumulative Percent
Dosage	11	19	19
Administration	14	24	43
Side effect	15	25	68
Storage	19	32	100
Total	59	100	

Source: Field Survey May, 2012

Figure 37: How do you pack the insulin for patients



Source: Field Survey May, 2012

4.5 DISCUSSION OF RETAIL COLD CHAIN STORAGE FACILITIES RESULTS

Figure 22 above shows that majority of the people at the retail pharmacy facilities are professionals representing pharmacist (49%), medical counter assistants (34%) and dispensing technicians (10%) and that irrespective of the carrier used (fig. 23); all the retailers receive or transport cold chain products from wholesalers to their facility over ice packs which is a positive development. According to fig. 24, majority of the retailers (95%) do not check the temperature of their product before receiving supplies and therefore are not in position to use calibrated thermometer, only 5% do verify temperature with thermometers before taking delivery.

In an instance, one respondent indicated that she used her hands to check temperature of the cold chain medicines before taking delivery. Figure 25 indicates that the type of cold chain medicines stored in the storage facility were Insulin, Vaccines and others (oxytocin, ergometrine, eye drops, suppositories) representing 68%, 30% and 2% respectively. In addition to the cold chain medicines, some respondents also indicated that they stock drinks (energy drinks) and drinking water in the fridges representing 49% (fig. 26), this will affect the frequency at which fridges are going to be opened and because fridges are not purpose built (92%) with warning alarms to signal temperature excursions this will lead to rampant temperature excursions, hence deteriorate medicines potency and quality Blake, (2008). Figure 27 shows that majority of the retail shops do not have written instructions describing storage procedures, material handling and documentation which represents 90%, meaning there is no traceability in place to track down monitoring storage conditions along the supply chain. Although most of the products stored in the fridges are physically segregated to prevent mixing, it can be deduced that, the storage devices are not furnished with low/high temperature alarm representing 92% (fig. 28). Likewise, most of the storage devices were not equipped with thermometers representing 92% (fig. 29), while most of the retail facilities said they had no idea of the institution that calibrates thermometer representing 97% (fig. 30). This implied there is no validation of storage facilities and monitoring devices through calibration of probes, sensors and thermometers therefore there cannot be guarantee that they could function properly to provide the desire storage condition to maintain product efficacy and potency MHRA, (2007). There was a strong indication (95%) that, temperature of storage facilities are not been monitored and therefore records not available (fig. 31).

According to fig. 32, most retail shops do not switch off their storage fridges representing 95% and maintain appropriate storage condition in the event of power failure by packing

the insulin in ice chest over ice packs (63%) while few of the retailers use generator set (36%) fig. 33

Most retail pharmacy facilities (63%) do not have an automated generator system to cater for power failure after closing hours, however, few of the retailers responded yes (positively) representing 37% (fig. 34). Lack of contingency for power outages to maintain storage condition is well established fact for contributing to about 25% of all vaccines before getting to the final end user Oosterzee, (2007).

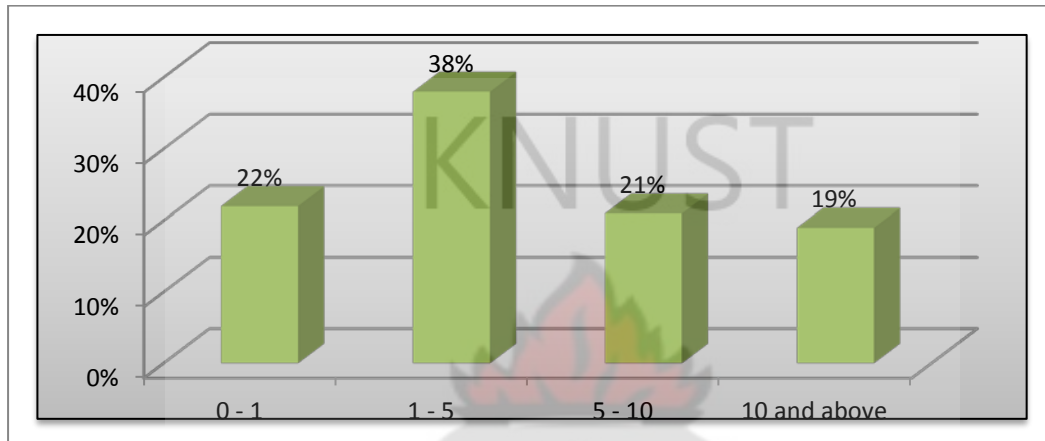
Table 2 indicates that majority of the retailers said they cannot tell how often Food and Drugs Board visited their facility, while 10% said they have never visited their facilities. However, there is an indication that pharmacy council visit retail pharmacy facility once in every six months (29%), likewise, some of the retailers said they cannot tell how often pharmacy council visited their shop (27%). Few of the respondents (5%) said pharmacy council has never visited their facility (Table 3). According to fig. 35, both Pharmacy Council and Food and Drugs Board do not specifically inspect cold chain medicine storage facilities representing 63% and there was a strong indication (100%) that none of the respondents are aware of any guideline for managing cold chain in Ghana (fig. 36). The regulatory presence of Pharmacy Council at retail pharmacy facilities as to be expected is encouraging compared to FDB, however and as observed under the wholesale facilities, there is no guideline for regulating cold chain.

It can also be seen from table 4 that, majority of the retail pharmacy dispensers inform clients on the storage of insulin after dispensing representing 32%. Few of the dispensers also inform clients on the dosage (19%) of the drug. Also, information given to patients on insulin side effect and administration was found to be fairly balanced at 25% and 24% respectively.

Figure 37 show that most of the retailers pack insulin for patients in an ice chest over ice cubes, indicating that they maintain cold chain.

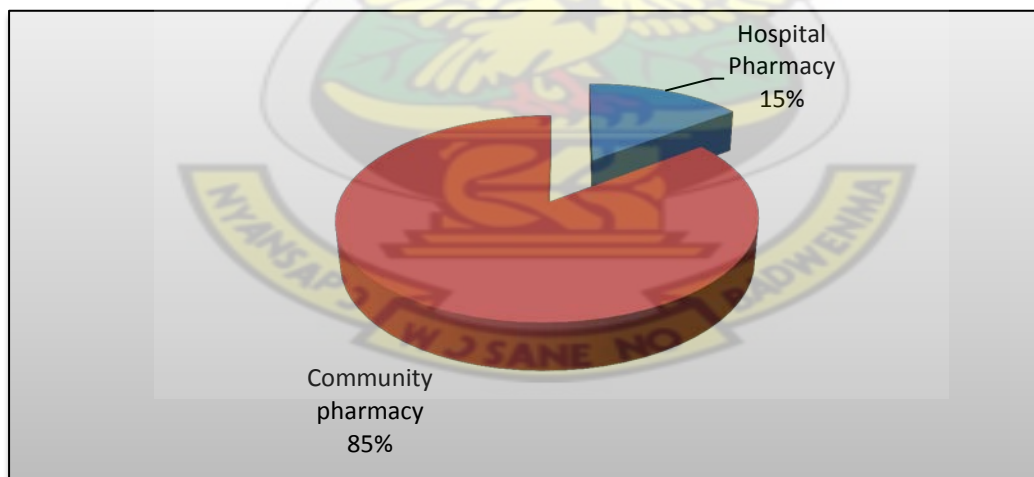
4.6 RESULTS OF END USERS OF COLD CHAIN MEDICINES (INSULIN)

Figure 38: How long have you been using insulin



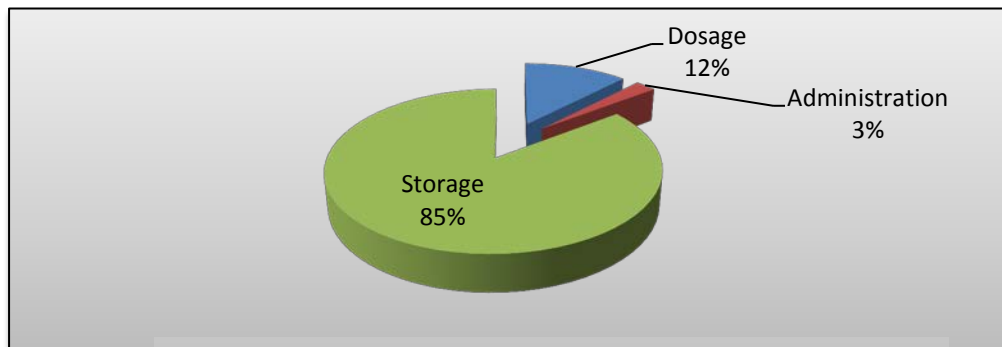
Source: Field Survey May, 2012

Figure 39: Where have you been buying your insulin from



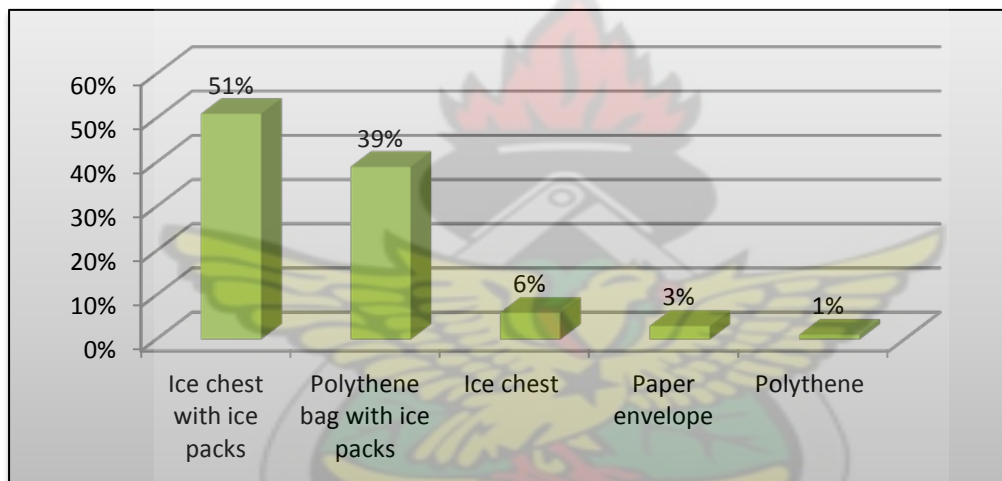
Source: Field Survey May, 2012

Figure 40: Which of the following information on insulin do you receive from Dispensers



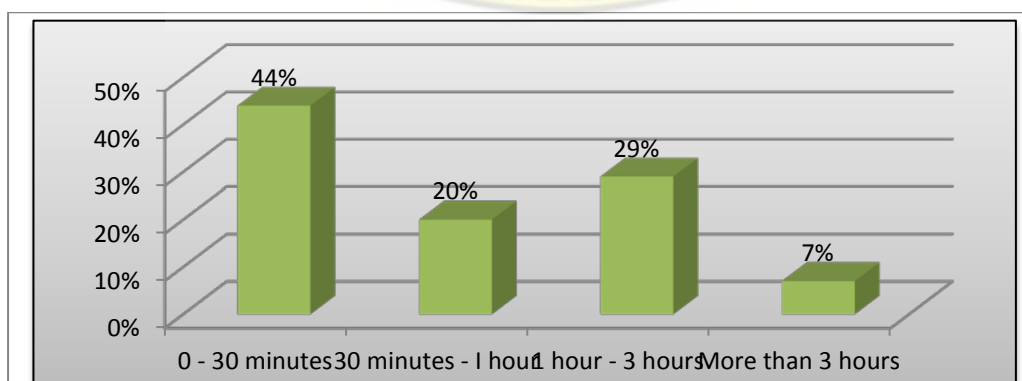
Source: Field Survey May, 2012

Figure 41: How do you carry your insulin home from where you buy it



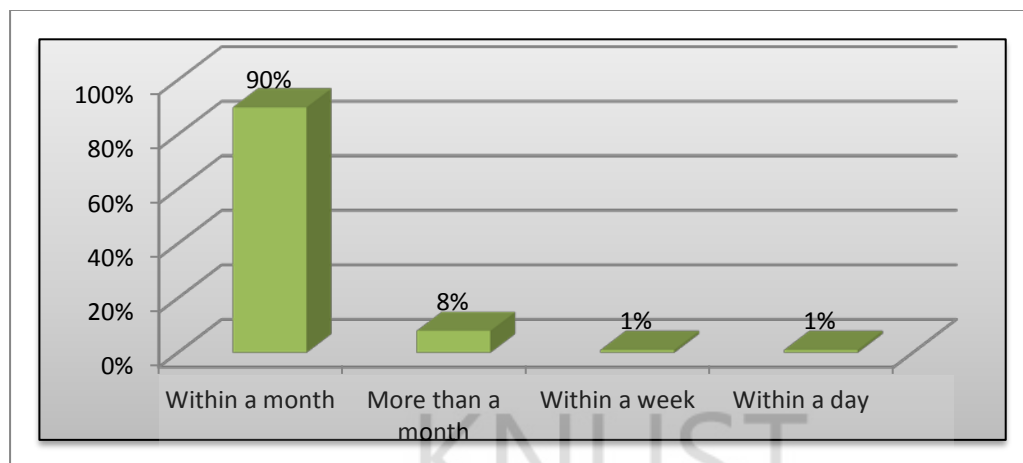
Source: Field Survey May, 2012

Figure 42: How long does it take you to take your insulin home from where you purchased



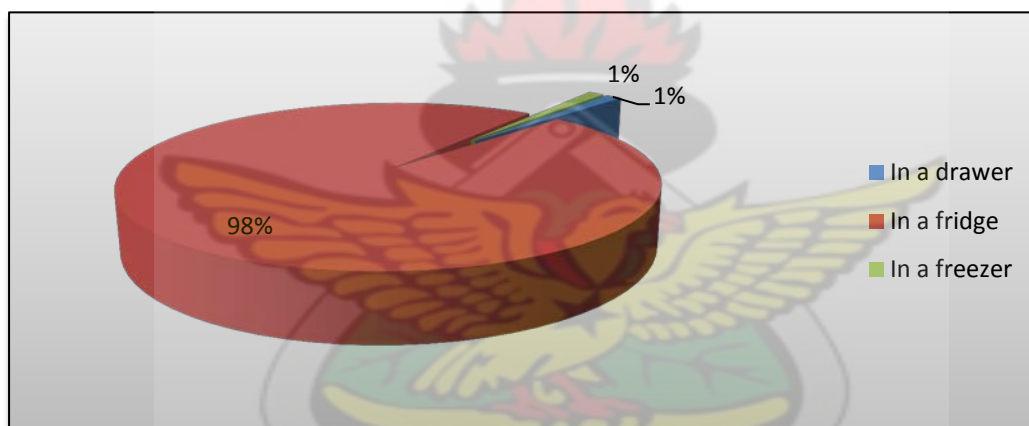
Source: Field Survey May, 2012

Figure 43 How long does it take you to use a vial of insulin



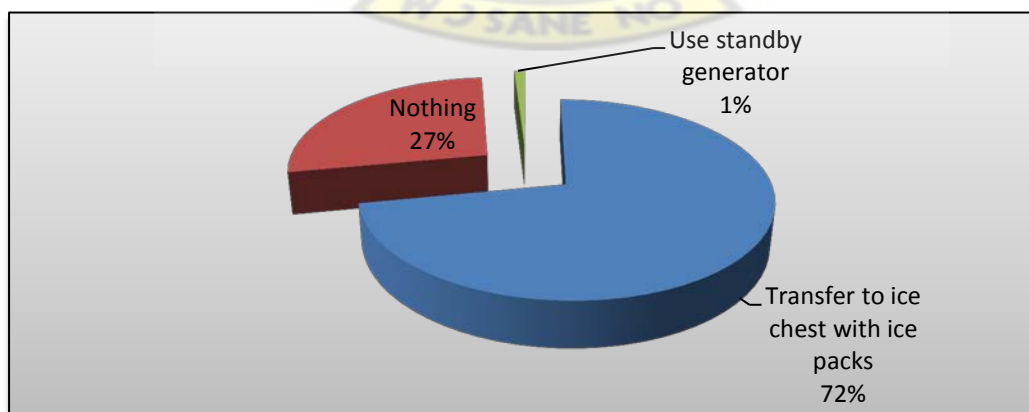
Source: Field Survey May, 2012

Figure 44: How do you store insulin at home



Source: Field Survey May, 2012

Figure 45: What do you do when there is power failure



Source: Field Survey May, 2012

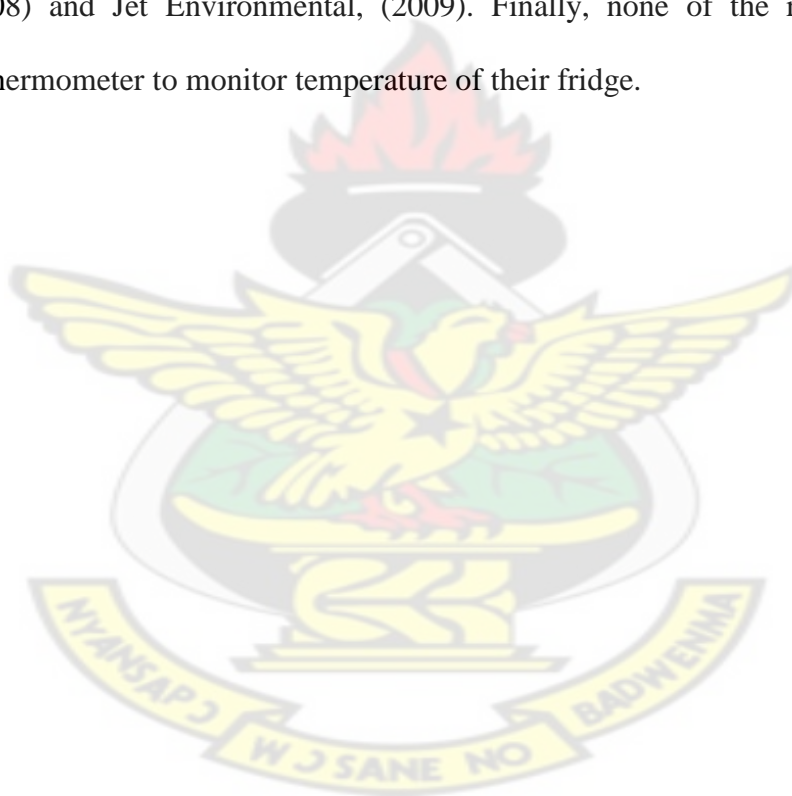
4.7 DISCUSSION OF END USERS OF COLD CHAIN MEDICINES (INSULIN) RESULTS

The research concentrated its effort on diabetic patients who use insulin in managing their diabetic conditions. In view of this, all the respondents to the end user questionnaire were insulin users representing 100%. Out of this, 22%, 38%, 21% and 19% have been using insulin for the past 0-1, 1-5, 5-10 and 10 and above years respectively (fig. 38).

It could be observed from fig. 39 above that, all the respondents buy insulin from pharmacy facility (community and hospital), representing 100%. None of the respondents indicated that they buy their insulin from license chemical shop. This is positive development because insulin is not over the counter medicine and therefore by law licensed chemical shops cannot sell them. According to fig. 40, there was strong indication that respondents were educated on how to handle insulin by dispensers at retail pharmacy facility outlet representing 85%, 12% and 3% on storage, dosage and administration respectively. On storage, 100% of the respondents admitted that they had already been informed to store their insulin under refrigeration condition and not frozen at the National Diabetics Management and Research Centre and most of them carry their insulin from where they purchase it in mini ice chest with ice cubes and polythene bag with ice cubes representing 51% and 39% respectively (fig. 41). A few of the respondents use ice chest (6%), paper envelope (3%) and polythene bag (1%) to carry their insulin home, meaning they are breaking the cold chain with its health implication as observed by Brown, et al, (2004); (2008) and Camacho-Amor, et. al, (1990). Labeling discrepancies as observed by Vimalavathini and Gitanjali (2009), became evident during interaction with two respondents during the questionnaire administration where it was revealed that, though they both have fridges at home, they have however chosen to store their insulin at room temperature because that is what the label of the product indicate, even though they admitted the insulin was sold to them over ice at the retail pharmacy

facilities. On a whole, it takes between 0-3 hours for 93% of the respondents to get their insulin home from point of purchase while the remaining 7% takes over 3 hours to get their insulin home (fig. 42). Majority of the respondents (98%) indicated that, they store their insulin in fridge (fig. 43) and 90% said they are given insulin which on the average last them a month (fig. 44) before their next visit to the clinic.

In the event of a light off, 72% of respondents transfer their insulin into ice chest with ice cubes while 27% of the respondents do nothing to the insulin and this could lead to temperature excursion and hence product deterioration as observed by, Oosterzee, (2007), Blake, (2008) and Jet Environmental, (2009). Finally, none of the respondents had calibrated thermometer to monitor temperature of their fridge.



CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 INTRODUCTION

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 field notes taken; visual observations made and relate it to previous studies done on cold chain medicines management and relevant literature from both research within the industry and from global and local regulatory standards.

It is well established fact that, all critical and major cold chain medicines deficiencies are attributed to the control and monitoring of storage and transportation temperatures (Blake, 2008). 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. In view of this, effort is made to provide cold chain management for temperature sensitive pharmaceuticals to ensure that the quality and efficacy of the product are not compromised along the supply chain. The main objective of the research therefore was to study the challenges in the supply chain management of cold chain medicines and their impact on product quality and public health and safety.

5.2 KEY FINDINGS

In this study, a number of objectives were set to be achieved. The first objective was to examine the extent to which cold chain management systems (Storage/Transportation/Distribution) comply with the WHO requirements. Regarding this, it was established that there were no Quality Management Systems in place, poor validation and qualification of storage facilities, monitoring devices and transportation

carriers, poor documentation for traceability and weak oversight responsibilities by regulatory authority(s) in ensuring compliance to cold chain management standards as per WHO requirements and best industrial practices along the supply chain. The second objective was to verify the validated and monitoring systems in place to ensure product quality. The research confirmed that validated systems with respect to calibration of storage facilities temperature probes and sensors and thermometers and qualification of transportation of cold vans and carrier boxes are generally poor along the supply chain, especially at the retail pharmacy/health facility level. Likewise, there was no procedures in place to verify actual temperature of cold chain medicines before taking delivery or dispatch to retail facilities, storage temperatures are generally not monitored and contingencies to deal with power outages especially after close of work hours especially at the retail pharmacy facilities are not in existence. The third objective was to ascertain how end users handle cold chain medicines along the supply chain using insulin as an indicator. This research can confirm that, end users of cold chain medicines using diabetic patients on insulin as indicator generally understand the reason why they should maintain cold chain and handle it well, except few who are misinformed by misleading room temperature storage labeling. This good understanding of storage condition could be attributed to education both at the National Diabetic Management and Research Centre at Korle-Teaching Hospital and dispensers of insulin at retail pharmacy outlet. The challenge for them also is how to deal with erratic nature of power supply and temperature excursions. Finally, the research seeks to examine the role of regulatory authorities in enforcing regulatory standards to ensure compliance by public institutions, health facilities and or pharmaceutical industries engaged in cold chain medicines as a business. The findings indicated lack of oversight responsibilities by legally mandated institutions in ensuring compliance to appropriate cold chain standards. This was

observed in lack of guideline to manage cold chain systems and erratic nature of inspections at cold chain facilities generally along the supply chain.

5.3 CONCLUSION

Supply chain management of cold chain medicines requires a quality management system, validation of storage facilities, qualification of cold chain vans and carriers for transport, competent personnel, a well-informed consumer, a constant power supply, an independent oversight regulatory authority and efficient management of information on the product along the supply chain through documentation for traceability in order to ensure product quality, efficacy and potency; to assure public health and safety.

The study has established that there are genuine public health challenges in the supply chain management of cold chain medicines and therefore all stakeholders involved in cold chain management either as businesses or as professionals must recognise the challenges and work towards reducing the impact of these challenges in maintenance of quality of medicines to protect public health and safety.

The four objectives which were set for the study was achieved and with regard to the main objective of the study it can be concluded that the key challenges i.e. quality management system, validation, qualification, power outages, documentation and regulatory oversights will affect effective management of cold chain supply and may risk public health and safety. The given recommendations if well taken and implemented could bring about improved supply chain management of cold chain medicines.

5.4 RECOMMENDATIONS

The findings revealed in the study requires the following measures for consideration to ensure efficient and effective cold chain management along the supply chain in order to ensure product quality, potency and efficacy and to guarantee public health and safety.

Development of specific Guidelines for managing cold chain system in Ghana

One of the challenges identified was the lack of specific guidelines for regulating cold chain systems in Ghana. It will be of great importance if the Ministry of Health (MOH) through its regulatory agencies FDB and Pharmacy Council could develop policy guideline on cold chain systems as pertaining in other countries globally or Ghana as a signatory member of WHO could adopt any of the WHO cold chain management systems (GDP, GSP, etc) for implementation.

Provision of contingency plan for 24 hour power supply at all cold chain storage facilities

One of the major challenges identified was erratic power supply through the Electricity Company of Ghana. It is recommended that regulatory agencies as part registration of premises and authorization for sale of cold chain medicines should ensure that all cold chain medicine suppliers, whether wholesale or retail should have adequate contingencies for light offs which must be commensurate to the size of the facility as wholesale or retail to cater for power outages especially during closed of work hours with strict documentation of temperature excursion for traceability.

Validation of storage facilities/monitoring devices and Qualification of cold vans/carrier boxes for transportation of cold chain medicines

Validation is critical to maintaining a stable temperature storage condition and during transportation of temperature-sensitive medicines. In view of this, a purpose-built

pharmaceutical refrigerator is recommended for the storage of cold chain products. This is because the air within this type of refrigerator 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. All temperature probes (for cold room mapping), sensors and thermometers must be calibrated and additionally, cold chain vans and carrier boxes must be qualified by Ghana Standard Authority (national institution mandated by law for calibrations) to demonstrate that the fridges consistently produces a result meeting predetermined acceptance temperature criteria of 2 °C to 8 °C and carrier boxes have the capacity to maintain the required temperature within the travel range respectively.

Regulatory agencies must enforce cold chain standards to ensure compliance

The mission statement of Food and Drugs Board states “Our mission is to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all food, drugs, cosmetics, chemical substances, and medical devices locally manufactured, imported, distributed, sold, or used to ensure the protection of the consumer as envisaged by the laws regulating food and drugs in force in Ghana”.

Likewise, the vision and mission statement of Pharmacy Council is as follows

“To guarantee the highest levels of pharmaceutical care” and its mission is “ To secure the highest level of pharmaceutical care by ensuring competent pharmaceutical care providers who practice within agreed standards and are accessible to the whole population. In addition we shall collaborate with related local agencies and international pharmaceutical organizations to enhance our effectiveness and our contribution to rational

drug use in the nation. This mission shall be carried out with dedication, integrity, and professionalism.”

The two statements above indicate that why FDB is responsible for the safety, efficacy and potency of cold chain medicines through registration and distribution along the supply chain, Pharmacy Council is responsible for registration of pharmacy premises and enforcement of professional pharmacist standards; therefore they must live up to their legal mandates.

Future studies

Future studies should concentrate on establishing the extent to which the identified challenges affect medicines potency, efficacy and quality in Ghanaian context as observed in India by Vimalavathini and Gitanjali (2009). This could be achieved by sampling a known batch of insulin 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.

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KNUST



LIST OF ABBREVIATIONS

Central Medical Stores	---	---	---	---	---	CMS
Centre for Health Information Management	---	---	---	---	---	CHIM
Commonwealth Executive Masters in Business/Public Administration	-----					CEMBA/PA
Expanded Programme on Immunization	---	---	---	---	---	EPI
Food & Drugs Board	---	---	---	---	---	FDB
Food and Drugs Administration	---	---	---	---	---	FDA
Ghana Health Service	---	---	---	---	---	GHS
Ghana Standards Authority	---	---	---	---	---	GSA
Good Distribution Practices	---	---	---	---	---	GDP
Good Storage Practices	---	---	---	---	---	GSP
Institute of Distance Learning	---	---	---	---	---	IDL
Korle' Bu Teaching Hospital	---	---	---	---	---	KBTH
Kwame Nkrumah University of Science and Technology	---	---	---	---	---	KNUST
Medicines and Healthcare Products Regulatory Agency	---	---	---	---	---	MHRA
Ministry of Health	---	---	---	---	---	MOH
National Diabetics Management and Research Centre	---	---	---	---	---	NDMRC
Non applicable	---	---	---	---	---	N/A
Pharmacy Council	---	---	---	---	---	PC
Quality Management System	---	---	---	---	---	QMS
Standard Operating Procedure	---	---	---	---	---	SOP
United States Pharmacopoeia	---	---	---	---	---	USP
World Health Organization	---	---	---	---	---	WHO

APPENDICES

QUESTIONNAIRE

QUESTIONNAIRE FOR WHOLESALE STORAGE FACILITIES

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

This study is meant to gather current information on the public health challenges in the supply chain management of cold chain medicine in the Greater Accra Region. You will be contributing immensely to this research by way of objectively answering the following questions. Your facility has been selected for this study because the researcher values your responses to the questions and would take your views, ideas, attitude, perceptions, expertise, professionalism and practices expressed as confidential. Hence your participation is entirely voluntary but your cooperation and assistance will definitely make a difference in this exercise.

Please tick [✓] as appropriate

1. Gender (a) Male [] (b) Female []
2. Age of respondent
a) 20 - 30 years [] b) 31 - 40 years [] c) 41 and above []
3. Highest level of education
(a) No Education [] (b) Primary [] (c) Secondary [] (d) Tertiary []
4. What is your job title/position? _____
5. For how long have you been doing this work?
(a) 0-3yrs [] (b) 4-7yrs [] (c) 8-12yrs [] (d) above 12yrs []

Quality Management System

1. What type of system do you have in place to ensure the quality of cold chain products?
(a) None [] (b) Specify _____
2. Is there a designated person in charge of the QMS? (a) Yes [] (b) No []
3. If yes to question 2, who does the person report to? _____
4. Do you have Quality Policy? a) Yes [] (b) No []

5. Name any guideline you use for managing the QMS _____
6. Which of the following WHO requirements do you use as part of the QMS? **Tick as many;** (a) WHO Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products (b) WHO's Good Storage Practices (GSP) [] (c) WHO's Good Distribution Practices (GDP) [] (d) WHO's Regulatory oversight on the management of time and temperature-sensitive pharmaceutical products []
7. If yes to question 6 above, how did you get to know of it? (a) WHO document [] (b) internet [] (c) MOH Agencies [] (d) Others (specify) _____
8. Are documentary evidence available? (a) Yes [] (b) No []

Staff Members

1. What is the background qualification of employees? Tick as many (Purchasing & Supply, Supply Chain, Procurement, Biomedical Engineer, Pharmacist, Nurse, Doctor, etc.....)
2. Do you have a training manager? (a) Yes [] (b) No []
3. Do you have a training policy for staff? (a) Yes [] (b) No []
4. Do you have programme to execute the training policy? (a) Yes [] (b) No []
5. Who does the training programme cover? Tick as many
(a) Managers (b) Continues staff (c) New recruits (d) Cold chain staff only
6. Have all employees been trained on specific cold chain regulations, SOPs and other related tasks? a) Yes [] (b) No []
8. Are trainee assessed after training? a) Yes [] (b) No []
9. Is documented evidence available on the training? a) Yes [] (b) No []
10. Please, indicate the source of the training _____

Documentation Management

1. Do you currently have a Quality agreement with all your suppliers?
(a) Yes [] (b) No []
2. Are there systems in place to ensure that cold chain products are received, transported, and stored under the appropriate temperature conditions? (a) Yes [] (b) No []

3. Are the records of each delivery retained? (a) Yes [] (b) No []
4. Which of the following institutions visit your facility as part of regulation? Tick as many; (a) FDB (b) GSA (c) PC (d) EPA (e) Fire service (f) Others (specify).....
5. How often does Food and Drugs Board visit your facility? Once every;
(a) 3 months [] (b) 6 months [] (c) 12 months [] (d) others (specify).....
6. How often does Pharmacy Council visit your facility? Once every;
(a) 3 months [] (b) 6 months [] (c) 12 months [] (d) others (specify).....
7. Do they specifically inspect cold chain medicines storage facilities?
(a) Yes [] (b) No []
8. If yes to question 7 above, what specific guideline or standard do they use as a bench mark?
9. Are calibration records available for each temperature-recording device?
(a) Yes [] (b) No []
10. Are storage conditions well documented? (a) Yes [] (b) No []
11. Are you currently documenting all out-of-specifications? (a) Yes [] (b) No []
12. Do you have written Standard Operating Procedures (SOPs) to cover the following activities? Tick as many (a) Cold Chain activities [] (b) Regulatory compliance []
(c) Environmental monitoring [] (d) Storage conditions [] (e) Materials handling []
(f) Documentation requirements [] (g) Monitoring daily temperature excursion []
(h) Action(s) to be taken when there is a temperature excursion []
(i) Dispatch and preparation of transportation orders []
9. Are all SOPs signed and approved? a) Yes [] (b) No []
10. Is there a regular preventative maintenance schedule in place to maintain equipment?
(a) Yes [] (b) No []
11. Have all employees been thoroughly trained on storage related SOPs?
(a) Yes [] (b) No []

Facilities and Storage Area

1. Are premises maintained in accordance with applicable procedures?

(a) Yes [] (b) No []

2. Are doors designed to provide security for the product and restrict entry of unauthorised persons? (a) Yes [] (b) No []

3. Do you regularly perform mapping of all your storage areas? a) Yes [] (b) No []

4. Is access to the storage areas limited to only authorized personnel?

a) Yes [] (b) No []

5. Are there segregated areas for the holding and storage of products including returned / rejected / recalled goods? (a) Yes [] (b) No []

6. How do you maintain appropriate storage condition in the event of a power failure? ...

7. Do you have an automated generator system to cater for power failure after closing hours? (a) Yes [] (b) No []

Storage Equipment and Environmental Monitoring

1. Are all equipment accurately identified? a) Yes [] (b) No []

2. Are equipment furnished with monitoring devices? a) Yes [] (b) No []

3. Are all sensors and probes, including temperature monitoring devices calibrated at least once every year? a) Yes [] (b) No []

4. Do calibrated devices have stickers indicating next due date for calibration?

a) Yes [] (b) No []

5. Which institution did the calibration?.....

6. Is the calibration traceable to national standards? (a) Yes [] (b) No []

7. How do you manage temperature excursion?.....

8. Have controlled temperature areas been temperature mapped to determine high and low

temperature areas within the storage area during seasonal extremes?

(a) Yes [] (b) No []

9. Is there a program in place to repeat temperature mapping as part of your validation plan? (a) Yes [] (b) No []

Product Distribution

1. Under what condition do you supply cold chain products to retail pharmacy or health facility?.....

2. Do you check the temperature of the products before dispatching supplies?

a) Yes [] (b) No []

3. If yes to question 2 above, what device do you use.....

4. Is the device calibrated? a) Yes [] (b) No []

1. Which transportation methods do you usually use? Tick as many

(a) Air (b) shipment (c) vehicle (d) others (specify).....

2. Where temperature control is needed, have the transportation containers/cold vans been qualified? (a) Yes [] (b) No []

3. Do you tackle, in general, the topic of transport qualification? (a) Yes [] (b) No []

4. Do transportation vehicles have temperature monitoring devices?

(a) Yes [] (b) No []

5. Are the temperature monitoring devices on vehicles calibrated?

(a) Yes [] (b) No []

6. Are vehicles secured? (a) Yes [] (b) No []

7. Is there a maintenance plan for vehicles? (a) Yes [] (b) No []

8. What contingency plan do you have in place if you encounter breakdown of vehicles?

.....

9. Have you ever refused to dispense cold chain medicines, including insulin, to a retail pharmacy facility/healthcare provider although the medicine is available?

(a) Yes [☐] (b) No [☐]

10. If yes to question 9 above, what was the reason?

Thank you for your time

KNUST



QUESTIONNAIRE FOR RETAIL PHARMACY FACILITIES

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

This study is meant to gather current information on the public health challenges in the supply chain management of cold chain medicine in the Greater Accra Region. You will be contributing immensely to this research by way of objectively answering the following questions. Your facility have been selected for this study because the researcher values your responses to the questions and would take your views, ideas, attitude, perceptions, expertise, professionalism and practices expressed as confidential. Hence your participation is entirely voluntary but your cooperation and assistance will definitely make a difference in this exercise.

Please tick [✓] as appropriate

6. Gender (a) Male [] (b) Female []
7. Age of respondent
 - a) 20 - 30 years [] b) 31 - 40 years [] c) 41 and above []
8. Highest level of education
 - (a) No Education [] (b) Primary [] (c) Secondary [] (d) Tertiary []
9. What is your job title/position? _____
10. For how long have you being doing this work?
 - (a) 0-3yrs [] (b) 4-7yrs [] (c) 8-12yrs [] (d) above 12yrs []

Management of Cold Chain Medicines

1. How do you receive and or transport cold chain products from wholesalers/distributors to your facility?.....
2. Do you check the temperature of the products before receiving suppliers?
 - a) Yes [] (b) No []
3. If yes to question 2 above, what device do you use.....
4. Is the device calibrated?
 - a) Yes [] (b) No []
5. What type of storage facility do you use?
6. List the type of cold chain medicines stored in the storage facility.....

7. List any other things which are stored in the storage facility.....
8. Is access to the storage facility limited to only authorized personnel? a) Yes [] (b) No []
9. Are there written instructions describing storage procedures, materials handling and documentation requirements? a) Yes [] (b) No []
10. Are products physically segregated to prevent mixing of separate products and/or batch numbers? a) Yes [] (b) No []
11. Is the storage device furnished with low/high temperature alarms? (a) Yes [] (b) No []
12. Is the storage device equipped with thermometers? (a) Yes [] (b) No []
13. If you responded yes to question 12 above, is the thermometer calibrated?
(a) Yes [] (b) No []
14. Which institution did the calibration?
15. Are calibration records available for each temperature-recording device?
(a) Yes [] (b) No []
16. Is the calibration traceable to national standards? (a) Yes [] (b) No []
17. Is temperature monitoring being recorded? (a) Yes [] (b) No []
18. If your response is yes to question 17 above, are records available? (a) Yes [] (b) No []
19. Is there a regular preventative maintenance schedule in place to maintain storage facility?
(a) Yes [] (b) No []
20. What time do you switch on the storage facility? (a) Morning [] (b) Afternoon [] (c) Evening [] (d) Always switched on []
21. What time do you switch off the storage facility? (a) Morning [] (b) Afternoon [] (c) Evening [] (d) Never switched off []
22. How do you maintain appropriate storage condition in the event of a power failure?
.....
23. Do you have an automated generator system to cater for power failure after closing hours (a) Yes [] (b) No []
24. Which of the following institutions visit your facility? Tick as many
(a) Food & Drugs Board [] (b) Ghana Standard Authority [] (c) Pharmacy Council [] (d) Others (Specify).....

25. How often does Food and Drugs Board visit your facility? Once every
(a) 3 months [] (b) 6 months [] (c) 12 months [] (d) others (specify).....
26. How often does Pharmacy Council visit your facility? Once every
(a) 3 months [] (b) 6 months [] (c) 12 months [] (d) others (specify).....
27. Do they specifically inspect cold chain medicines storage facilities? (a) Yes [] (b) No []
28. If yes to question 27 above, what specific guideline or standard do they inspect the cold chain storage facility and or the products against?.....

Answer Questions 29 to 35 if you Stock Insulin

29. Where do you stock or keep the insulin in your facility?
(a) Shelf [] (b) Fridge [] (c) Freezer []
30. Who dispense insulin to patient? (a) Pharmacist [] (b) Dispensing Technologist [] (c) Medicine counter assistants [] (d) Sales persons []
31. What information do you give to clients when you dispense insulin to them? Tick as many (a) Dosage [] (b) Administration [] (c) side effect [] (d) Storage []
32. What information on storage do you give patients?.....
33. How do you pack the insulin for patients? (a) Polythene bag [] (b) Paper envelope [] (c) Ice chest [] (d) Ice chest with cubes []
34. Have you ever refused to dispense insulin to a patient although they have valid prescription and also the insulin is available? (a) Yes [] (b) No []
35. If yes to question 34 above, what was the reason?

Thank you for your time.

QUESTIONNAIRE FOR END USERS OF COLD CHAIN MEDICINES

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

This study is meant to gather current information on the public health challenges in the supply chain management of cold chain medicines in the Greater Accra Region. You will be contributing immensely to this research by way of objectively answering the following questions. Insulin has been chosen because it is the most widely circulated and most directly handled and stored cold chain medicines at home by users. Your response will enable the researcher know and understand the challenges that users of such medicines go through with storage and its effect on public health and safety. You have been selected for this study because the researcher values your responses to the questions and would take your views, ideas, attitude, perceptions, expertise, professionalism and practices expressed as confidential. Hence your participation is entirely voluntary but your cooperation and assistance will definitely make a difference in this exercise.

Please tick [✓] as appropriate

11. Gender (a) Male [] (b) Female []
12. Age of respondent
(a) 0-19years [] (b) 20 - 30 years [] (c) 31 - 40 years [] (d) 41 and above []
13. Highest level of education
(a) No Education [] (b) Primary [] (c) Secondary [] (d) Tertiary []
14. What is your occupational status?
(a) Student [] (b) Self employed [] (c) Unemployed [] (d) Employee []
15. Are you on insulin? (a) Yes [] (b) No []
16. If your response to question 5 above is **NO**, please don't respond to the remaining questions and thank you.
17. If your response to question 5 above is **YES**, then for how long have you being using insulin? (a) 0-1year [] (b) 1 - 5 years [] (c) 5 - 10 years [] (d) 10 and above []
18. Where have you been buying your insulin from? Please, tick as many: (a) Hospital Pharmacy [] (b) Community Pharmacy [] (c) Licence Chemical facility [] (d) Other (specify) _____
19. What information did the dispenser give you? **Tick as many.**
(a) Dosage [] (b) Administration [] (c) side effect [] (d) Storage []
20. Did the dispenser advice you on how to store the insulin?

- (a) Yes [] (b) No []
21. If yes to question 10 above, what kind of advice did he/she give you on storage?
- (a) Under your bed [] (b) In a drawer [] (c) In a fridge [] (d) In a freezer []
22. How do you carry your insulin from where you buy it? **Tick as many.**
- (a) Polythene bag [] (b) Polythene bag with ice cubes [] (c) Paper envelope []
- (c) Ice chest [] (d) Ice chest with cubes []
23. How long does it take you to take your insulin home after purchase?
- (a) 0-30 minutes [] (b) 30-1hrs [] (c) 1-3hrs [] (d) More than 3hrs []
24. Have you ever been turned away from buying insulin although you have a valid prescription and also the insulin was available at the facility? (a) Yes [] (b) No []
25. If yes to question 14 above, what was the reason given?
.....
26. How long does it take you to use one vial of insulin injection?
- (a) Within a day [] (b) Within a week [] (c) Within a month [] (d) More than a month []
17. How do you store the insulin at home?
- (a) Under your bed [] (b) In a drawer [] (c) In a fridge [] (d) In a freezer []
18. If you store it in a fridge what do you do when there is power outage?
- (a) Nothing [] (b) transfer to Ice chest with cubes [] (c) Use standby generator []
19. Does the storage device (fridge) have temperature reader or monitoring device?
- (a) Yes [] (b) No []
20. If your answer is yes to question 19 above, have your device been calibrated?
- (a) Yes [] (b) No []

PARTICIPANTS INFORMATION SHEET

PARTICIPANTS INFORMATION SHEET FOR WHOLESALE AND RETAIL STORAGE FACILITIES

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region.

I am pursuing Commonwealth Executive Masters Degree in Public Administration at the Kwame Nkrumah University of Science and Technology (KNUST), Institute of Distance Learning (IDL). As part of this degree I am undertaking a research thesis leading to the award of my Degree. The thesis I am undertaking is to identify the public health challenges in the supply chain management of cold chain medicines in the Greater Accra Region. The main objective of my research is to study the challenges in supply chain management of cold chain medicines and the impact on product quality and public health and safety of end users.

It is my desire that the research outcome will provide an insight into the key challenges in the supply chain management of cold chain medicines in Ghana with focus on temperature control, validation of storage and monitoring devices, monitoring of cold chain facilities, documentation and oversight responsibilities by regulatory authority(s). The University and GHS require that ethics approval be obtained for research involving human participants.

Participants will be made to complete a questionnaire at their facilities or institutions (EPI, Wholesale Pharmacy facilities, Community and Hospital Pharmacy) where visual observation will also be made. The questionnaire administration will last for about ten minutes (10mins).

You will be contributing immensely to this research by way of objectively answering the following questions. Your facility have been selected for this study because the researcher values your responses to the questions and would take your views, ideas, attitude, perceptions, expertise, professionalism and practices expressed as confidential. Hence your participation is entirely voluntary but your cooperation and assistance will definitely make a difference in this exercise.

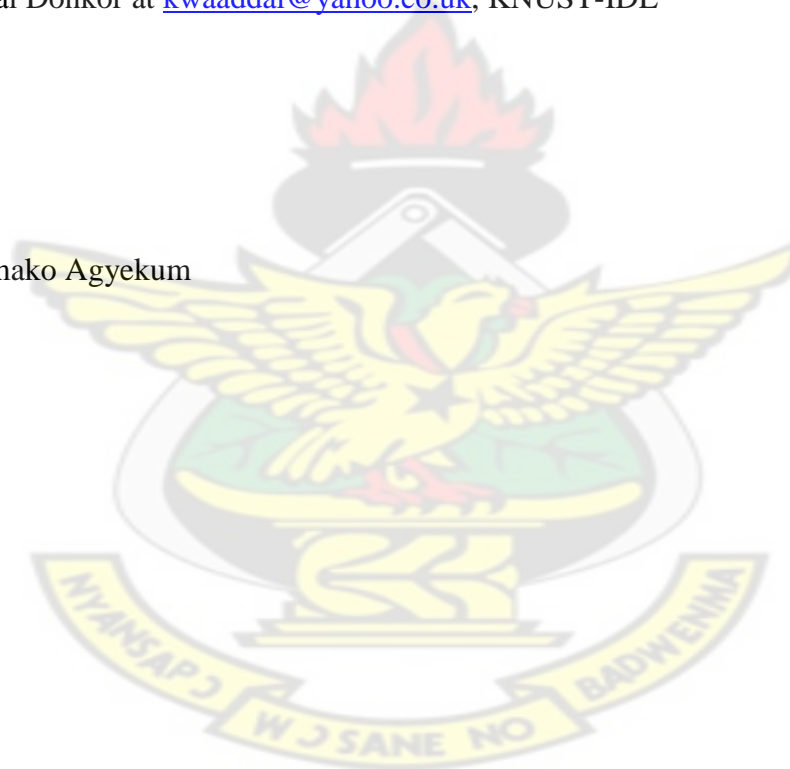
With your permission, notes will also be taken during the visual observation and will form the basis of my research thesis. The information will be put into a written report but none of your personal information such as your name and where you live will be shared. It will not be possible for your facility to be identified personally in any way. All material collected will be kept confidential. With the exception of my Thesis Supervisor, Dr. Kwasi Addai-Donkoh, no other person will see the notes that I write. The thesis will be submitted for marking to KNUST-IDL.

All collected data will be destroyed five years after the end of the thesis.

For any questions, enquiries or would you like to receive further information about the research thesis, please contact me at adopee@yahoo.com or my Thesis Supervisor Dr. Kwasi Addai Donkor at kwaaddai@yahoo.co.uk, KNUST-IDL

Signed:

Percy Adomako Agyekum



PARTICIPANTS INFORMATION SHEET (END USERS OF INSULIN)

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

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It is my desire that the research outcome will provide an insight into the key challenges in the supply chain management of cold chain medicines in Ghana with focus on temperature control, validation of storage systems, monitoring of cold chain facilities, documentation and oversight responsibilities by regulatory authority(s). The University and GHS require that ethics approval be obtained for research involving human participants. Participants will be made to complete a questionnaire at the Diabetics Clinic at the Korle' Bu Teaching Hospital (KBTH) which will take about five minutes (5mins).

You will be contributing immensely to this research by way of objectively answering questions. You have been selected for this study because the researcher values your responses to the questions and would take your views, ideas, attitude, perceptions, expertise, professionalism and practices expressed as confidential. Hence your participation is entirely voluntary but your cooperation and assistance will definitely make a difference in this exercise.

The information gathered will be put into a written report but none of your personal information such as your name and where you live will be shared. It will not be possible for you to be identified personally in any way. All material collected will be kept confidential. The thesis will be submitted for marking to KNUST-IDL. All collected data will be destroyed five years after the end of the thesis.

For any questions, enquiries or would you like to receive further information about the research thesis, please contact me at adopee@yahoo.com or my Thesis Supervisor Dr. Kwasi Addai Donkor at kwaaddai@yahoo.co.uk, KNUST-IDL

Signed:

Percy Adomako Agyekum



INFORMED CONSENT FORM

INFORMED CONSENT FORM FOR RESEARCH STUDIES (WHOLESALE & RETAIL STORAGE FACILITIES)

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

Title of Research Project: Public health challenges in the supply chain management of cold chain medicines in the Greater Accra Region.

Researcher(s): Percy Adomako Agyekum

Certificate of Consent

I confirm that I have thoroughly read and have understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have satisfactorily been answered.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected.

Participant Name

Date

Signature

Name of Person taking consent

Date

Signature

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has the opportunity to ask questions, I confirm that the individual has given consent freely.

Print Name of the researcher

Signature of Researcher

Date

The contact details of lead Researcher (Principal Investigator) are:

Percy Adomako Agyekum, Tel: 0208169407, Email: adopee@yahoo.com

INFORMED CONSENT FORM FOR RESEARCH STUDIES (END USERS OF INSULIN)

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

Title of Research Project: Public health challenges in the supply chain management of cold chain medicines in the Greater Accra Region.

Researcher(s): Percy Adomako Agyekum

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DEBRIEFING FORM

DEBRIEFING FORM FOR WHOLESALE AND RETAIL STORAGE FACILITIES

Survey on the Public Health Challenges in the Supply Chain Management of Cold Chain Medicines in the Greater Accra Region

Purpose: The purpose of the questionnaire administration is to identify the Public health challenges in the supply chain management of cold chain medicines in the Greater Accra Region, in order to prevent product quality deterioration along the supply chain and its effect on safety of end users of cold chain medicines.

Confidentiality: You are reminded that your original consent document included the following information: that “You are at liberty not to speak to me if you do not want to. If you feel the need to withdraw from the project, you may do so without question at any time before the data is analysed. You only have to inform me when that decision is made.”

If your concerns are such that you would now like to have your data withdrawn, and the data is identifiable, we will do so.

Contact: If you have questions about your participation in the study, please contact me at adopee@yahoo.com or my research thesis supervisor, Dr. Addai-Donkor at kwaaddai@yahoo.co.uk

Please again accept our appreciation for your participation in this study.

Thank you.

Name Percy Adomako Agyekum

Date

DEBRIEFING FORM FOR END USERS

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Name: Percy Adomako Agyekum

Date

LIST OF ATTACHMENTS

Letter from GHS-Ethical Review Committee (ETHICAL CLEARANCE – ID NO: GHS-ERC: 09/03/12)

Letter from Expanded Programme for Immunisation (EPI), GHS/KBTH

Letter from National Diabetes Management and Research Centre, KBTH

Letter from Centre for Health and Information Management, GHS/KBTH

KNUST

