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Emungat, G. A., & Nkirina, S.

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DETERMINANTS OF QUALITY STANDARDS ADHERANCE BY COLD CHAIN PHARMACEUTICAL DISTRIBUTORS IN KENYA

Emungat, G. A.,[*1] & Nkirina, S.[2]

[*1]Jomo Kenyatta University of Agriculture and Technology [JKUAT], Mombasa, Kenya
[2]PhD., Jomo Kenyatta University of Agriculture and Technology [JKUAT], Mombasa, Kenya

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ABSTRACT

Quality of medicine is critical to quality healthcare of citizens in a country like Kenya. Provision of healthcare through quality medicine faces many challenges. The purpose of this study was to investigate determinants of quality standards adherence in distribution of cold chain pharmaceutical products in Kenya. Specifically, the research investigated whether staff qualifications, storage, packaging of products and their transportation influenced the quality specifications in distribution of cold chain products in the pharmaceutical industry in Kenya. The study was undertaken in 16 selected pharmaceutical companies operating within Nairobi County. Data was obtained from employees of the pharmaceutical companies through purposeful sampling technique. The research design was descriptive research design in which quantitative data was collected using a structured questionnaire. The data was analyzed using descriptive statistics. Correlation and regression analysis were the inferential techniques used to determine relationships between study variables. Statistical Package for Social Science (SPSS V-20) was used to analyze data. The correlation procedure revealed that staff qualification, storage conditions, packaging and transportation were each positively correlated with quality of medicine in the Nairobi County. Through linear regression procedure, these four factors collectively accounted for 58% of the total variation in quality of medicine in the County. It was thus recommended that pharmaceutical companies should strictly embrace packaging technology with accurate clear labeling of medicine. They should also keep on recruiting and retaining high quality and skilled employees within the industry. Ensure that already existing storage facilities are fully functional through equipping the maintenance and repairs departments. Pharmaceutical firms should strategize to provide quality medicine by ensuring that adequate resources are channeled to transportation section. Based on the time limitation of the current study; it is sensible that another similar study be carried that covers more other firms in other towns in Kenya.

Key terms: *Cold chain, Distribution chain, Distribution, Good Distribution Practices (GDP), Good Warehousing Practice (GWP), Quality Management Systems, Temperature*

INTRODUCTION

Quality Management is the process of ensuring that a product (good or service) continuously meets and even exceeds customer expectations and can be generally looked at as a business management approach that attempts to maximize organizational competitiveness through continuous improvement of its products, services, work force, processes, and environment. It is an approach aimed at continuously improving the competitiveness, effectiveness and flexibility of the entire organization through total involvement of everyone in the organization led by the management (Kasongo & Moono, 2010).

According to ISO, quality is the totality of features, as well as, product characteristics, which bear on its capability to satisfy the implied or stated need (Terreri, 2009). Besides, it is conformance to the requirement and fitness for use, especially when it comes to edibles like drugs and other pharmaceutical products. Quality is not only checked on the properties alone, but also regarding the manner in which these properties have been attained (Peri, 2006). This means maintaining quality from the time a product is being processed, in its supply chain, up to the time it is consumed (continuous quality improvement). In this regard, quality in consumable products is attributed to appearance, feel, defects, odor, taste, texture, wholesomeness, nutritive value, and safety (Morris & Young, 2000).

The overall objective of QM is to ensure continuous improvement in the organization's people, systems, processes and environment so as to achieve improved customer service and increased profits through efficiency and effectiveness in the entire organization (Bahri *et al*., 2012). Since implementation of QM is associated with benefits to both the organization and its clients, it is regarded a double sided competitiveness tool. It is important to note that any organization can implement QM irrespective of the size or operations. However, the success of the implementation process depends on how well the organization understands the process and the strategies adopted. One guiding principle in implementation of QM is that the process must be organization wide; everyone and every function in the organization must be involved in the process with the management taking a leading role (Schuurman, 2011)

To ensure successful implementation of quality management, implementers of quality management should reward truly exceptional individual performance and increase capacity for proper cooperation and coordination of all channels involved in process improvement. A lean and efficient organization can easily perform better than a wide and bureaucratic system of an organization (Miller, 2012).

Implementation of QM is an elaborate process that takes time and resources. It is a process that must be initiated and managed by the top management. The top management must make available all critical resources required as well as the organizational structure and culture required. The process must focus on finding out, meeting and exceeding customer needs and expectations through total involvement of everyone in the organization and through continuous improvement. This process requires exceptional skills and team work that call for continuous employees training and development (Oluwatoyin, 2008)

Sebastianelli and Tamimi (2013), identified five barriers in the implementation of QM as poor planning, practice management and development of human resources insufficient and inadequate, lack of quality planning, lack of leadership in the

development of a quality culture and inadequate resources for TQM. These and other factors may render TQM ineffective hence affect the level of service delivery in the organization. Sebastianelli and Tamimi (2013) further noted that those involved in the implementation of TQM have the responsibility of ensuring that the process is fair to those subjected through it so that the organization can benefit from the process.

Globally, a number of organizations have adopted quality initiatives. Toyota company for instance developed the philosophies of 'customer first' and 'quality first'. They set up quality assurance systems across various divisions and departments (Omware, 2013). They introduced statistical quality control (SQC) in 1949 followed by Total Quality Management (TQM) initiatives based on the unchanging principles of 'customer first' and 'total participation'. Through their quality initiatives, they won the Deming Application Prize in 1965 and the Japan Quality Medal Award in 1970 (Union of Japanese Scientists and Engineers, 2006). Sony Company set out to respect their customers' viewpoints and remain committed to deliver quality products and customer service that exceed their customers' expectations. To achieve this, Sony implemented continuous, decisive efforts in enhancing product quality and continuously improve its quality management system (Sony Company, 2012). The Coca-Cola Company focused on developing consistency and reliability in their products. They for instance developed a new management system, Coca-cola Operating Requirements (KORE) in place of the initial Coca-Cola Management System (TCCMS) in January 2010. The company created an integrated quality management program which is used in all operations of the organization to ensure they deliver quality to customers (Coca-Cola Company, 2012).

In Kenya, many organizations, especially in the service industry have embraced quality management techniques such as ISO standards and TQM programs. For instance, all government parastatals and Public Universities in Kenya are currently ISO certified. It has been pointed out that some elements of TQM are not adhered to making it less effective to address the challenges to quality. Despite the existence of quality policy across organizations in Kenya, concerns have been raised over the lack of implementation of TQM across organizations (Kenya Bureau of Standards, 2014).

Members of the pharmaceutical supply chain have various global regulatory requirements to meet while handling, storing and distributing environmentally sensitive products (Maclean, 2009). 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).

Cold chain refers to the transportation of temperature sensitive products along a supply chain through thermal and refrigerated packaging methods and the logistical planning to protect the

integrity of these shipments (Simchi-Levi, Kaminksy, & Simchi-Levi, 2008). The goal of the cold chain management is to preserve the quality by maintaining the proper temperature (between 2ºC to 8ºC throughout the supply chain (Bishara, 2006) of the product throughout the cold chain handoffs till the time it reaches the customer (Burger, *et al*. 2009). In the health sector, the pharmaceutical cold chain is concerned with the transportation, storage, and handling of pharmaceutical products in a safe environment from the manufacturer to the end user. Temperatures outside the recommended ranges may reduce potency leading to the lack of desired response e.g. reduced immunity. Thus, the control of storage and transportation temperature is essential in maintaining the quality of medicines and protecting patients from sub-standard or ineffective medicines that may result from inadequate control (Kanji, 2012).

World Health Organization (2010) has noted that 25% of all vaccine products reach their destination in a degraded state. This according to the Medicines and Healthcare Products Regulatory Agency is due to temperature rises above desired parameters, thereby contributing 43% of reported non-compliant cases. Worldwide vaccine-preventable diseases are responsible for about 25% of the 10 million deaths occurring annually for children under 5 years of age. Global warming makes temperature control issues a growing challenge in the cold chain supply (Bishara, 2007).

Bishara (2007) states that according to Medicines and Healthcare Products Regulatory Authority (MHRA) of the United Kingdom, 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, 43% critical and major deficiencies were recorded in 2004/2005 respectively. In view of this, many countries such as Canada, Ireland, Australia, Singapore, South Korea, and European Union have issued regulations and specific guidelines that address product integrity during transportation of cold chain medicines and hence the significant reduction in deficiencies. In Kenya, it is just recently (May 2016) that PPB issued proposed guideline for transportation of cold chain products. The product must be transported in a manner that ensures the products will be maintained within an acceptable temperature range as defined in the approved labeling and supported by stability data. Pharmaceuticals shall be transported in a manner that transportation temperatures meet the Pharmacy and Poisons Board's and WHO's temperature zoning requirements, and any temperature excursions above or below the manufacturer's labeled storage temperature range do not adversely affect product quality. It is the responsibility of the transporters to maintain load temperatures within the temperature defined for the product. Temperature-controlled road vehicles shall be used for transportation of pharmaceuticals, and these shall be calibrated by the Kenya Bureau of Standards (KEBS) to ensure they comply with temperature and humidity requirements in Kenya Pharmaceuticals otherwise, cold chain supply has generally been neglected in regard to the establishment, development, maintenance and control of the activities involved especially in the private sector which really supports the health sector mainly because the cold chain supply process involves multiple parties, high risks and high financial investments .When there is an equipment or management failure at the primary level, large quantities of cold chain products may be destroyed in a matter of a few hours (Kamau & Mukui, 2005).

The Pharmaceutical Companies in Kenya consists of three segments namely the manufacturers, distributors and retailers. All these play a major role

in supporting the country's health sector, which is estimated to have about 4,557 health facilities countrywide. Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50% of the regions' market. Out of the region's estimated of 50 recognised pharmaceutical manufacturers; approximately 30 are based in Kenya, with 50 percent of them in Nairobi and only 10 percent are involved in cold chain supply and only 10 percent of those involved in cold chain supply are involved in importation and distribution to the other pharmaceuticals, the hospitals, and health facilities (Kamau & Mukui, 2005).

According to the Global Cold Chain market of 2014 – 2019 report, the Cold chain market is expected to grow by 15% per year over this period. Global spending on healthcare is estimated to reach $1.3 trillion. According to UNICEF, the young population in Africa may reach 1 billion by 2050. Access to healthcare is pivotal to healthy population growth. Global healthcare industry is changing manufacture of more complex modern drugs e.g. biologics and specialty use drugs.

A study by Kamau and Mukui (2011), noted that lack of awareness by distributors in the control of storage and transportation temperatures can have a major impact on product quality by non-observance of the cold chain or inefficiency in its monitoring mechanisms. This may affect the products' therapeutic properties and consequently generate deficiency quality risks such as loss of therapeutic effects and intoxication with dire effects on the health of the users.

Objectives

- To investigate the effect of staff qualifications on adherence to quality standards in distribution of cold chain pharmaceutical products in Kenya.
- To assess the effect of packaging on adherence to quality standards in distribution of cold chain pharmaceutical products in Kenya.
- To determine the effect of storage on adherence to quality standards in distribution of cold chain pharmaceutical products in Kenya.
- To analyze the effect of transportation on adherence to quality standards in distribution of cold chain pharmaceutical products in Kenya.

RELATED LITERATURE REVIEW

Theoretical Framework

Crosby's Theory

Philip Crosby is a prominent figure as far as quality is concerned. He believed that spending money on improving and ensuring quality is proper spending (Bowen, 2013). This is because, during his time, the conventional wisdom was that all the quality levels have some price. He based this belief on the fact that improving quality requires some purchases such as buying better machines, improved materials, or spending on trainings. The same case applies to the cold chain distribution. The pharmaceutical distributors have to incur costs to train their personnel on how to handle the distribution chain. They must ensure they are updated with the state-of-art equipment required in maintaining the required temperatures of drugs in the chain so that they can adhere to the quality specifications. Crosby pinpoints that there are hidden costs in quality; for example, lost future sales such as when goods deteriorate when transporting them due to temperature monitoring.

Philip believed in management taking the key responsibility whereas the workers should follow their lead (Kanji, 2012). With his notions and concepts, he described the absolutes involved in

quality management. The first one is quality as conformance to the requirements. If cold chain distributors were to adhere to quality specifications, they would never have to worry about unqualified suppliers, mislabeling, and temperature issues among others. Here, quality means meeting the accurate requirements devoid of defects. Second is quality prevention being preferred over quality inspection. It is important to establish quality prior to performing a task, which comes with practicing. This means that a cold chain supplier must be qualified and experienced as required by the PPB. It is only analysis that should be performed after finishing a task. This calls for individuals to get accustomed to thinking about how to prevent defects rather than conducting appraisals to check for defects (Suganthi & Samuel, 2004).

Such practices save companies' time and money while satisfying customers beyond their expectations. Third is when Crosby likens quality performance standard to zero defects. By zero defects, it does not mean perfection. Instead, it implies meeting the accepted requirements without any gap between the client and supplier. In the cold chain, adherence to quality specifications is paramount if the drugs are to reach their destination safe. The designated personnel must be qualified for the job and adhere to the temperature requirements plus adjust them according to monitoring. Further, those in charge of labeling should ensure proper labeling with temperature storage conditions clearly and conspicuously visible. Thus, the objective should always be doing it right the first time. The fourth aspect is measuring quality in monetary terms. When a firm fails to meet the requirements of a client, it has to pay a price. In the business arena, this price is articulated in the form of money. Organizations should concentrate on the cost of non-conformance instead of depending on intricate indices while measuring quality.

Crosby theory informs the study by emphasizing that investing in quality because it saves the cost of the supply chain and promotes customer satisfaction. Customer satisfaction is a major factor in cold chain distribution because neither the re-packagers, nor the distributors/wholesalers, nor the delivery points, who are the major customers of the manufacturers, can agree to take deteriorated or damaged pharmaceutical products. This is given the fact that the cold chain products are sensitive to temperature and hence requiring proper storage with adherence to the set regulations and industrial standards failure to which the products are damaged. The temperatures are affected by the monitoring in climate, which give no warnings at times, thereby making unprepared staff unable to control the situation. Thus, the factors that have been identified in influencing the quality of the cold chain management process include speed and timely delivery, safety, compliance, temperature, and storage

The Resource-Based View Theory

The Resource-Based View of the firm is an emerging strategic management theory that explains the disparities in firm prosperity that cannot be attributed to differences in industry conditions alone. It emerged in 1980s and 1990s after the major works published by Wernerfelt, B "The Resource-Based View of the Firm". It is a method of analyzing and identifying a firm's strategic advantages based on examining its distinct combination of assets, skills, capabilities and intangibles as an organization. The RBV"s underlying premise is that a firm differs in fundamental ways because each firm possesses a "unique" bundle of resources-tangible and intangible assets and organizational capabilities to make use of those assets. Each firm develops competencies from these resources, and when developed especially well, these become the source

of the firm's competitive advantage; (Pearce & Robinson, 2007).

In the context of this theory, it is evident that the resources that a firm has will play a big role in the strategic implementation process. This is because no matter how good the strategies are, without the necessary resources to enable the implementation, they remain in the planning phase. The resource-based approach sees firms with superior systems and structures being profitable not because they engage in strategic investments that may deter entry and raise prices above long run costs, but because they have markedly lower costs, or offer markedly higher quality or product performance. This approach focuses on the rents accruing to the owners of scarce firm-specific resources rather than the economic profits from product market positioning. Competitive advantage lies 'upstream' of product markets and rests on the firm's idiosyncratic and difficult-to imitate resources.'

Cool and Schendel (2008) have shown that there are systematic and significant performance differences among firms which belong to the same strategic group within the U.S. pharmaceutical industry. Rumelt (2011) has shown that intra industry differences in profits are greater than inter industry differences in profits, strongly suggesting the importance of firm-specific factors and the relative unimportance of industry effects. Wemerfelt (2009) made similar findings. The resource-based perspective puts both vertical integration and diversification into a new strategic light. Both can be viewed as ways of capturing rents on scarce, firm specific assets whose services are difficult to sell in intermediate markets.

Wemerfelt and Montgomery (2009) provide evidence for this proposition. It is evident that the resource-based perspective focuses on strategies for exploiting existing firm specific assets. However, the resource-based perspective also invites consideration of managerial strategies for developing new capabilities. Indeed, if control over scarce resources is the source of economic profits, then it follows that such issues as skill acquisition, the management of knowledge and know-how and learning become fundamental strategic issues.

Resource-Based View Theory in reference to the cold chain distribution, the theory is applicable because the cold chain has to rely on the resources at their disposal such as the technical capacity to provide competitive advantage. For example ensuring employee qualification or training them can add value as a resource to the firm and hence gain competitive advantage

Flat Earth Theory

Friedman, (2007) explains that there are three eras of globalization and ten flatteners which made the world smaller, making it easier to communicate and share our knowledge. The first era, called between the years 1492, when Columbus set out to discover a new trade route to the New World, and 1800, made the world fall in size from large to medium. During this period, the strength of a country was based on the number of horsepower or the number of steam engines owned, compared with other countries. The second period between the years 1800 and 2000 decreased the size of the world, from medium to low. Multinational companies were the integration force, and the power was given to a company by the level of innovation in the field of machinery and equipment.

The third globalization era began around the year 2000. The first two eras led to globalization at the country level and, later, at the company level, this new era favored reduction to a very small world, flattening the playing field and putting the individual in the center Friedman, (2007).

Globalization has been maintained by the action of some flattening factors that favored the levelling of the World and the emergence of some opportunities that could increase welfare if successfully exploited. One common misconception in cold chain supply is that product storage and distribution temperatures are the same. The idea that the products' long-term storage temperature is not the same as the distribution temperature is easily forgotten .Cold chain products are to be exposed to warmer or colder conditions as they move downstream the supply chain. Where the vaccines are taken out of the target refrigeration temperature range for a short period and later placed back to the proper conditions without compromising the product quality. In the pharmaceutical industries, we find that the stability studies are mandatory by health authorities and these studies are performed following a strict and standardized method outlined by the International Organization for Standardization.

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

Three-Dimensional Supply Theory

Efficient intra and inter organizational information management in cold chain supply has different dimensions (Althoff, Ellebrecht, & Petersen, 2005). The technical dimension implies aspects of distribution and storage, the possibilities of data exchange and in general the technology it incorporates. Craig (2007) describes the technical dimension as a group which includes mainly visible, tangible, measurable and easy-to-change components. Organizational structure indicates the performance of different tasks as well as activities, for example in cross-functional teams. Van der Vorst, Da Silva, and Trienekens, (2007) understands under this aspect management methods, power and leadership structure, risk and reward structure and culture and attitude of the involved organizations describe in their techno-managerial approach a technical and an organizational or managerial perspective, respectively.

Althoff, Ellebrecht and Petersen, (2005) define a third functional dimension of functional requirements which determine the information management in a quality and health management context. In relation to pharmaceutical cold chain management, mainly the proposed linkage of quality related data to other data sets at inspection and decision points may be categorized in this dimension. Safety of cold chain products is influenced by the organization structure in terms of information sharing, technical and functional undertaking of cold chain related processes.

Three-Dimensional Supply Theory guides in an investigation of the effect of such opportunism on supply chain effectiveness and how it can be prevented or minimized. Three-Dimensional Supply Theory view of organization opened the black box of organizational operations and paved way for contemporary view of the agency theory. In the old institutionalism view, opportunistic behavior based on the rational system view was dominant. However, the other theories view of the organizations, promotes the delegation of responsibilities and operation, through an open system view towards the environment. Three-Dimensional Supply Theory from the classical or

neoclassical perspectives provides contributions to the understanding of supply chain management, hence useful in the study of cold supply chain in the pharmaceutical industry as it informs why firms opt to use distributors or agent to supply products

Staff Qualifications

The distributing personnel must be adequately qualified. Each clinical setting where vaccines or temperature sensitive medicines are stored must have (a) one trained and designated individual (this may include administrative staff) and (b) one trained deputy to be responsible and accountable for receipt and storage of vaccines/temperature sensitive medicines, monitoring and recording of fridge temperatures, and audit and evaluation of training needs for staff using or involved in use of these products. The designated person and/or their deputy should be easily identifiable by recording the name on fridge monitoring records (Burger *et al*., 2012).

It is necessary to invest in human skills and physical assets for an efficient medicine supply chain (Yadav, 2010). In a framework to improve procurement and supply chain management systems in African countries set up by WHO, eight necessary training for IM and T&D are suggested. These training cover technical support for establishing and adapting information systems; development of plans for drug distribution; effective management support & supervision for transportation, equipment, buildings, office space and supplies; maintenance and assistance; development of model guidelines/SOPs for effective and integrated distribution systems; as well as conducting regional training courses regarding medicine storage requirements (WHO, 2006). Transaid suggests training and technical assistance for establishing fleet management and transport policies (Transaid, 2008). Because of poor road conditions, long travel times and small budgets it is important to repair and maintain vehicle fleets and specify procedures and documentation requirements (Transaid, 2013). ciations such as i+solution, People that Deliver, International Association of Public Health Logisticians and Reproductive Health Supplies Coalition. Learning and Professional Training Opportunities (LAPTOP) is a shared web data base, which summarizes and lists around 215 available training courses in supply chain management aimed at governments and organizations (RH Supplies, 2013). Another reason for inefficient use of drugs is due to over-prescription or noncompliance by patients. Therefore, prescribers of medicine should be trained in STG and patients better informed about usage to avoid wastage of drugs (Foster, 1990)

Packaging

Packaging can be defined as the container which is necessary to convey a product to the ultimate consumer, as contrasted with packing (cartons, crates, etc.) that is required for bulk shipment. Also, packaging is the art of enclosing or protecting products for distribution, storage, sale which is bought by the consumer. Pilditch (2013) has defined packaging as the silent salesman in the store and it was the only communication between a product and the final consumer at the point of sales, most consumers are moved by the products package, that is by the color of the design used, barrier protection, the image used, information transmission that is how to use the product and mostly containing the expiry date for the product.

Packaging is the process by which the pharmaceuticals are suitably placed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. Members of the pharmaceutical supply chain have various regulatory requirements to meet while

distributing, packaging, storing and handling cold chain products to ensure that the quality and efficacy of the product are not compromised along the supply chain. The cold chain system consist of a series of transportation and storage links which also involve a lot of handling, designed to keep products within an accepted temperature range until it reaches the end user. Storage is a critical parameter in maintaining the quality, safety, stability and efficacy of cold chain products and must be stored in accordance with the requirements of its marketing authorization (Skuce, 2010).

The cold chain packaging must be able to retain the cold chain requirements throughout the supply chain. A lot of validation studies therefore go into this to be able to come able with cooler boxes that can maintain the required temperatures of between 2 to 8 degrees centigrade. These studies then inform the qualification process in order to determine the duration the boxes are able to retain the cold chain without breaking it for the various climatic conditions and routes.

Packaging affects the buying behavior of some individuals looking at the young people. Packaging provides the manufacturer with the final opportunity to persuade prospective buyers prior to brand selection, because shoppers are exposed to packages just as they are in other forms of promotion. Also, consumers can easily overcome the challenge of visually assessing volumes contained within a variety of shapes because most product labels provide the information via packaging (Ampuero and Vila 2006).

Storage

In Kenya very little cold chain medicine is manufactured and hence relies heavily on importation. Private suppliers receive their cold chain products from the airport cold room, transporting them to wholesale storage facilities and distribute them to retail pharmacies from their cold storage holding facilities. The Safety of cold chain pharmaceuticals/ vaccines is greatly influenced by monitoring during transportation, storage conditions and facilities, handling and packaging (Bishara, 2007).

The fact that cold chain products are sensitive means that they are affected by temperature monitoring in the distribution chain. Temperature is a major factor in cold chain distribution of pharmaceutical products. These temperature-sensitive products are transported from the manufacturer to the re-packagers then to the wholesaler/distributor then to the delivery points such as hospitals. This means that a delay in timing during any point in the cold chain may damage the pharmaceutical products thereby causing losses and further delay to the delivery points (Kamau & Mukui, 2005). The deterioration means affecting the quality of the products being supplied which may lead to the rejection upon deliverance and thus lack of customer satisfaction. In the cold chain, customers are the re-packagers, wholesalers and the delivery points meaning the stakeholders involved in that supply chain. Evidently, time and temperature are the main factors in quality degradation. This is because the chemical and physic of the pharmaceutical products, that is, the chemical stability is dependent on temperature (Burger *et al.*, 2012). Thus, the aim of the cold chain should be to incorporate product quality degradation in distribution planning.

The other factor is adherence to the set quality guidelines. Some good practices exist to guide the distribution of cold chain products. However, many distributors are yet to comply fully given the many stakeholders involved in the chain of supply. The totality aspect of quality lacks in the cold chain; hence, monitoring the distribution network

becomes problematic. This calls for the need to distribute these temperature-sensitive products according to the product requirements, industry standards, and regulations such as proper labeling (Montero, 2016). The storage temperatures should be monitored continuously in what is known as a continuous electronic temperature monitor helps to identify breaks in the cold chain through the process of distribution.

A study conducted in Bali province Indonesia regarding improving the animal health cold chain and vaccine management indicated that there were urgent needs for improvements in management of vaccine. Approximately half of the refrigerators were unsuitable for vaccine storage generally in poor condition, temperature was not monitored. As a result, healthcare workers did not know if the temperature of refrigerator was within the recommended range at 2-8^{o}C. In additional vaccines were arranged inappropriately in the refrigerators, and were mixed with other items including expired and partially used vaccine vials (Indonesia MOA, 2011).

In a cross sectional study that was conducted in Toronto Canada from August to December 1992, staff responsible for vaccine storage were interviewed about their knowledge and practices of vaccine handling and storage. Refrigerators were inspected, fewer than 7 (6%) practices staff answered all questions related to vaccines storage and handling correctly, and only 11 (10%) refrigerator had thermometer. One–third of refrigerators had temperatures outside the recommended range of 2-8^{o}C. Older refrigerators were more likely to had inappropriate temperature than newer ones. Knowledge and practice of vaccine storage and handling were often inadequate in primary care physicians' offices (Yuan *et al*., 1995). The study conducted in Secunderabad India concerning vaccine distribution found that the implementation of an Immunization program in the rural areas was affected by gap in the distribution system. The study also identified other problem areas such as a faulty cold chain and need for an improved monitoring and control system and for better supervision (Subramanyam, 1989).

Agyekum (2012) performed a survey in Kenya, Ghana, and Uganda. He found that 16% of the pharmaceutical facilities that were sampled did not comply with the regulatory guidelines. From the sample, 50% had temperature of 4^{o}C or above the recommended one. The noncompliance revealed a gap that these countries have to fulfill in order to ensure quality. However, a comparison between Africa nations revealed that Ghana unlike Kenya had managed to develop its cold chain supply processes such that it can comply with the industrial standards. Ghana has validation techniques and guidelines because they aim at improving temperature assurance throughout the cold supply chain (Burger *et al*., 2012).

Transportation

Some of the transportation and distribution challenges include limited funds for vehicle purchase, maintenance, repairs, fuel and driver salaries (USAID, 2011). In Ghana 13% of the stock value of the essential health commodities constitute for logistics costs. There are competing interests between low distribution costs and high service quality. If distribution frequency is high, transportation costs are high, but in a more reliable demand planning horizon with less stock-out situations (Yadav *et al*, 2011). Research shows that decentralized transportation systems in Guatemala results in a high performance (Bossert *et al,* 2007).

There may be opportunities to reduce the number of supply chains by combining different commodities with similar distribution

characteristics which may reduce overall costs for T&D. But, supply chain entities are fragmented and competing and thus, collaboration is difficult (WHO, 2006). Vertical supply chains have advantages for ad hoc and irregular drug deliveries and for a lack of capacity within the public supply chains. On the other side vertical approaches duplicate the need for specific services, which could increase total costs (USAID, 2008a). Another approach is to bundle consumer goods and medicine for last mile delivery (Village, 2013), but there are differences between consumer goods and medicine due to strong regulations in a small market and high necessity of traceability and security for health commodities (Yadav, 2010).

Different countries face and try to solve these problems with different approaches and models. One approach is to use integrated community case management (iCCM) for rural areas, which is a strategy to train, support, and supply HWs to provide diagnostics and treatments to people with limited access to HCs (Marsh, 2012). The difficulty for this approach is to balance incentives for services and transportation of HWs, training and supervision of HWs and collection of consumption data. The Living Goods project in Uganda is a door-to-door health education approach, where HWs provide health services to patients for childhood diarrhea, malnutrition, and malaria and earn a living by selling drugs to patients (Yadav, 2013).

In some rural areas the road quality is poor and the travel distance to the nearest HC is long, which makes travel expenses high. For example in Ghana over 20% cover over 48 kilometers to travel to the nearest hospital, which could hinder rural people from going to HCs and thus, encourages them to use traditional medicine or self-medication (Buor, 2003). Remote communities also face problems with accessing health care services due to limited and irregular supplies of vaccines and medical equipment to HCs, which results in lower confidence and use of the health care system (Nakagawa and Beale, 2009).

The cost of proper vehicles fitted with the equipment used to maintain the cold chain throughout the supply chain is very high. The maintenance and fuel cost is a well is very expensive. Most of the firms therefore have challenges to purchase these kind of vehicles for fear of the costs.

Conceptual Framework

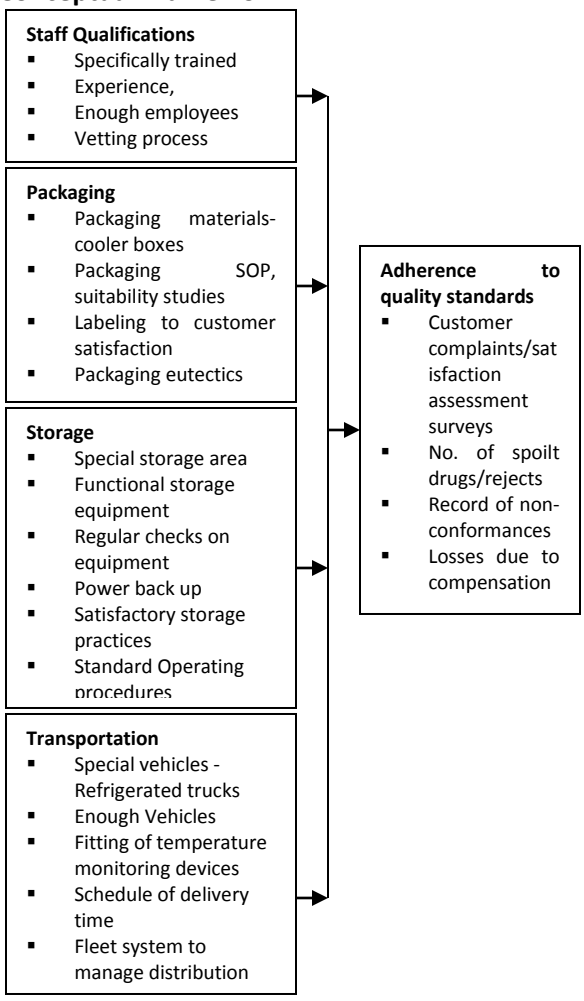

Figure 1: Conceptual Framework

METHODOLOGY

This study adopted a Descriptive survey design to answer the research questions. The researcher analyzed the responses in terms of percentages. Therefore, it was a reliable test to adopt for the study. Hence, the regression model for this was;

$$\mathbf{Y} = \boldsymbol{\beta_0} + \boldsymbol{\beta_1}[\mathbf{qualification}] + \boldsymbol{\beta_2}\mathbf{Storage} + \boldsymbol{\beta_3}\mathbf{Packaging} + \boldsymbol{\beta_4}\mathbf{Transport} + \boldsymbol{\varepsilon}$$

Where By

$\mathbf{Y}$ Quality Management (value of dependent variable)

$\boldsymbol{\beta_0}$ Regression constant (The value of dependent valuable when all the independent variables are Zero)

$\boldsymbol{\beta_1}$ Regression coefficient of the respective independent variables

$\boldsymbol{\varepsilon}$ An error term

RESEARCH FINDINGS

Staff qualification and quality standards adherence in pharmaceutical companies in Nairobi County

Respondents rated the statements on staff qualification on a scale of 1=strongly disagree, 2=disagree, 3= moderate, 4=agree and 5=strongly agree. The mean (m) of the responses and the corresponding standard deviation (SD) of each item were used for analysis. Table 1 shows that all the items had a mean close to four or more than four (=agree). Thus it meant that the employees who handled cold chain items were specifically trained (m=4.75, SD=.648) and have necessary experience (m=4.02, SD=.521). Also it shown that the employees were enough in handling the demand (m=4.22, SD=.662) and vetting process for cold chain personnel was in place (m=3.91, SD=.981). This implied that there were experienced and skilled employees in these organizations. Therefore according to the RBV of the firm these organizations had the accumulated knowledge and experience to develop competitive advantage. And according to the Crosby theory, in such organizations there is reduced costs of supply chain and improved customer satisfaction.

Table 1: mean and standard deviation of staff qualification in quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Statement	Mean	SD
Staff who handle cold chain items are specifically trained	4.75	.648
Staff who handle cold chain have necessary experience	4.32	.521
Enough employees to handle the demand	4.22	.662
Existence of vetting process for cold chain personnel	3.91	.981

Majority of the respondents that is 62.3% strongly agreed that staffs who handle cold chain are specifically trained. This implied that pharmaceutical staffs who handle cold chain items are trained. To adhere to the quality standards pharmaceutical firms need to ensure that the employees improve on the level of skills. The pharmaceutical staffs could be trained through on job training whether they train when performing their daily routine jobs and this has a positive effect on quality standards. Also the staffs who handle cold chain items can be trained through off job training and this can also have a positive influence on adherence to quality standards.

From the findings majority of the respondents 51.76% strongly agreed that the staffs who handle cold chain have necessary experienced. This implied

that staff who handled cold chain items in pharmaceutical firms was experienced. Pharmaceuticals firm with experienced staff will have less customer complains as compared to pharmaceutical firms with less experienced staff this is because when staff have experience they have more knowledge and also they will be more effective with less errors and this will improve on the quality of standards.

Storage conditions and quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Findings on storage conditions presented in table 2 indicated that there is existing sops that are followed to ensure proper storage (m=4.4 SD=.690), there is enough storage space available (m=4.2, SD=1.22) and there is different storage equipment for different kinds of vaccines (m=3.9 SD=.873). However, it noted that storage equipment are not regularly checked for compliance (m=2.0, SD=1.20) and they are not fully functional (m=2.3, SD=.99).

The result revealed that the storage conditions were not generally fully compliant in some aspects of cold supply chain requirements and standards. Therefore there is storage conditions gap that could compromise quality of the medicine. The lack of regular check for compliance in most organizations meant that were no regular records which should be kept for at least the self-life of the stored materials or product. This implied that the records available did not adequately describe the storage and therefore some of the organizations incurred cost associated with improper storage. As such there is needed in these organizations to relook at their storage policies with a view to improve it. Storage conditions should be adequate to maintain the quality of the medicines and free from factors that can cause the deterioration of drug products.

Table 2: Mean and standard deviation of storage conditions in quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Statement	Mean	SD
Existing sops that are followed to ensure proper storage	**4.4**	**.690**
Enough storage space available	4.2	1.22
Different storage equipment for different kinds of products	**3.9**	**.873**
Available special storage area	3.6	1.02
There is a functional power backup to ensure constant supply	**2.4**	**1.49**
Fully functional storage equipment	2.3	.99
Storage equipment are regularly checked for compliance	**2.0**	**1.20**

Majority of the respondents 45.8% strongly agreed that existing sops that are followed to ensure proper storage. This implied that pharmaceutical firms followed existing sops to ensure proper storage. To ensure that the pharmaceutical firms adhered to quality they ensured that the existing sop was stored properly.

Results indicate that 40% of the respondents agreed that there was enough storage space available. This implied that the pharmaceutical firms had enough storage. Enough space is important for vaccines as it make sure that there is minimal spoilage of the drugs.

Packaging and quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

The study investigated the packing practices of vaccines in cold supply chain in Nairobi. According to the findings in table 3; there is high standards and quality packing of vaccines (m=4.5/SD=.88), different packing protocols for cold and hot season are in place (m=4.3,SD=.97), there are appropriate packaging materials for different items (m=4.2, SD=1.02) and generally the packing practices at most of cold supply chain are satisfactory (m=3.9, SD=.83). This implied that the vaccines, which are one of the cold chain items, were packaged and well labeled. Thus organizations were keen on having proper packaging and informative labeling of medicine. This enabled consumers to determine the quality of medicine in terms of the active ingredients in the medicine and expiry dates. So the organizations were proactive on complaints about packing and labeling from healthcare professionals and other pharmaceutical companies. It worthy to note that utilizing sustainable packaging can be a challenge for everyday packaging needs, but even more so in the pharmaceutical industry where government safety regulations and patient usability take precedence. While consumers and retailers are shifting to a more environmentally conscious mindset, they still expect pharmaceutical companies to adhere to safety regulations and manufacture high-quality packaging for their products.

Table 3: mean and standard deviation of packaging practices in quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Statement	Mean	SD
There is high standard and quality packing of vaccines	4.5	.88
There are different packaging protocols for cold and hot seasons	4.3	.97
There are appropriate packaging materials for different items	4.2	1.02
There are enough packaging eutectics to meet demand	4.0	.67
The packaging and labeling of medicines are satisfactory	3.9	.83

Majority of the respondents 49.41% agreed that there is high standard and quality packaging of vaccines. This implied that pharmaceutical firms ensured that the packaging process of vaccines was quality and met the required standards. To ensure that the vaccination are not destroyed during the distribution period it is important that pharmaceutical firms to ensure that the vaccines are properly packaged. Majority of the respondents 57.6% agreed that there are different packaging protocols for cold and hot seasons. This implied that the packaging used for cold seasons was different packaging used for hot seasons. To ensure that there is conformance to quality it is important for the pharmaceutical firms to have packaging protocols for cold seasons and packaging protocols for hot seasons.

Transportation strategy and quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Findings in table 4 reveal that there were transportation logistics challenges of health products or vaccines based on the low mean scores obtained (disagreeing to the statements). Example, the transportation vehicles are not fitted with functional temperature and humidity monitoring devices (m=2.3, SD=1.22), it wasn't apparent that there were no good road network in some parts of the region (m=2.7, SD=1.32). However there were

noticeable number of special vehicles for transportation of cold supply chains items (m=3.9, SD=1.08).

This implied that, in some parts especially in the outskirts of major towns, where the road quality was poor, transporting drugs was a challenge. And as such, there was limited supply of quality of the vaccines especially in remote areas with poor infrastructure and with lack of basic amenities like power. The effectiveness of transport and distribution of drugs some areas was key determinant on the quality of drugs. Thus implying that the pharmaceutical firms encountered high maintenance and fuel cost to overcome the transportation challenges which impacts on the frequency of distribution of medicines and thus access to quality healthcare.

Table4: Mean and standard deviation of transportation in quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Statement	Mean	SD
Special vehicles for transportation of cold chain items	3.9	1.08
Distribution practices do not compromise vaccine quality	3.8	.98
Delivery is done within recommended timelines	3.3	1.00
There is good road network in all distribution jurisdiction	2.7	1.32
Transportation are fitted with functional temperature, humidity monitoring devices	2.3	1.11

Majority of the respondents 43.5% agreed that pharmaceutical firms had special vehicles for transportation of cold chain items. This implied that cold chain items had special vehicles for transportation. Special vehicles will ensure that cold chain items are transported safely and ensuring that the cold chain items are not destroyed this will enable that when the pharmaceutical are selling the medicines they will be of quality standards and there will be minimal customer complains. Pharmaceutical firms in Kenya should have special vehicles for transportation of cold chain items. Results indicate that the 38.8% of the respondents agreed that distribution practices do not comprise vaccine quality. This implied that when the pharmaceutical firms are distributing the vaccines there was no compromise in the transportation process. During the transportation if the vaccines are comprised there will be more drugs that will be spoilt. Pharmaceutical firms in Kenya should ensure that there is no compromise of drugs during the distribution process.

Quality standards in quality standards adherence in distribution of cold chain pharmaceutical products in Kenya

Quality standard of the cold supply chain was the dependent variable. Quality standards were measured in terms of number of customer complaints, number of spoilt drugs/rejects, number of record of non-conformances and losses due to compensation. The findings presented in table 5 show that there were minimum number of non-conforming drugs (m=4.2, SD=1.4), with few number of customer complaints (m=3.9, SD=.89), and in some areas, there were few cases of drug-related compensation (m=3.9, SD=.64). On overall, the consumer of cold supply chain in the county got not so good quality. This is majorly due to lack of stringent adherence to quality specifications in the cold chain distribution. The distribution chain involves storage packaging and transportation.

Table 5: Mean and standard deviation of quality of medicine in distribution of cold chain pharmaceutical products in Kenya

Statement	Mean	SD
There are minimum number of non-conforming drugs	4.2	1.4
There are few number of customer complaints related to the product quality	3.9	.89
There are few cases of drug-related compensation	3.9	.64
There are quite few cases of spoilt /rejected drugs	2.8	.91

Correlation result between independent variables and the dependent variable

A correlation analysis was undertaken to investigate the relationship between variables. The Pearson correlation coefficient was used to determine the nature and strength of the relationship. This is a real number ranging from -1 to +1. Values close to zero imply weak correlation and close to 1 imply strong correlation. The level of significant used for this study is 0.05. This is the probability of an error of identifying a significant relationship when indeed it doesn't exist.

Staff qualification and quality standards

It is noted that staff qualification and quality standards are significantly and positively correlated (r=.424, p=.000). The correlation is moderate. Thus those firms that engage higher qualified employees have higher quality supply vaccines than firms with less qualified employees. This implies that to ensure high quality standards of medicines, it is necessary to invest in human skills and physical assets for an efficient as noted by Yadav (2010). Skills and experience of firm employee are key resources that firm use to create competitive advantage by providing and supplying quality medicine in the region. Thus To have high quality vaccines in the Nairobi County, firms should invest in the development of its human resource.

Storage Conditions and quality of medicines in Nairobi County

The study established that storage was positively correlated with quality medicine supplied storage (r=.374, p=.000) the correlation was significant at 0.05 significant level. Adherence to storage conditions of the medicine will result in having quality supply of medicine in Nairobi region. Therefore firms that have compliant storage facilities are in a position to provide quality medicine in the region. The firms can ensure this quality by having qualified and skilled personnel to manage the storage facilities. These personnel understand the importance of keeping accurate and updated store records of medicine with clear labels. Personnel that are skilled and experienced on storage issues of medicine are capable to effectively coordinate with other departments, especially procurement, to reduce storage costs by not only ordering the right quantities at the right time, but also ensuring that the procured consignment adheres to quality standards. Thus the clients of such a company are more likely to receive affordable quality medicine.

Packaging and quality of medicine supplied in Nairobi County

A correlation procedure conducted found that packaging standards and quality of medicine supplied by firms in Nairobi are positively and moderately correlated (r=.446, p=.000). Thus firms that supply quality medicines are firms that adhere to required packaging standards. They ensure that required standard packing procedures of vaccines

are in place, there are different packaging protocols for cold and hot seasons and that packaged products are attractive and satisfactory. Proper labeling of the packages with storage requirements provides information that is fundamental in handling of cold chain products within the supply chain.

Transportation and quality of medicine supplied in Nairobi County

Correlation procedure revealed that efficiency in transportation was positively correlated with quality of the medicine in the cold supply chain in Nairobi county (r=.410, p==.000) as seen in the correlation

Table. The correlation was moderate and significant. As the transportation of medicine becomes efficient and reliable; the quality of medicine supplied tended to be better than in inefficient and unreliable transport. As such, customers benefited by getting quality medicines from firms that are efficient and reliable in their transport in the county. These benefits led to customer satisfaction. Thus, pharmaceutical firms strategized to achieve customer satisfaction through overcoming transportation and distribution challenges of medicine. Therefore adequate funding for vehicle purchase, maintenance, repairs, fuel and salaries was necessary in removing transportation barriers of medicine thus ensuring quality of medicine and access to quality healthcare.

Table 6: Correlation coefficient between IVs (qualification, storage, packaging, transport) and DV (medicine quality)

Independent Variable	Correlation coefficient with quality	Sign (2-tail)
Staff qualification	.424**	.000
Storage	.374**	.000
Packaging	.446**	.000
Transportation	.410**	.000

Dependent variable: Quality adherence

Regression Result

The study conducted regression analysis to examine the relationship between the independent variables (staff qualifications, packaging, storage, and transportation) and the adherence to quality standards. Many problems in engineering, business and science involve exploring the relationships between two or more variables. Regression analysis is a statistical technique that is very useful for these types of problems. The most commonly used form of regression is linear regression, and the most common type of linear regression is called ordinary least squares regression. Multiple linear regression uses the values from an existing data set consisting of measurements of the values of more than one independent variables; x_1, x_2, x_3 … and dependent variable Y, to develop a model that is useful for predicting the value of the dependent variable, Y for given values of x_1, x_2, x_3 …thus in this study, the multiple linear regression model used is therefore of the form;

$$\text{Medicine Quality} = \beta_0 + \beta_1 \text{qualification} + \beta_2 \text{Storage} + \beta_3 \text{Packaging} + \beta_4 \text{Transportation} + \varepsilon$$

The SPSS output of a regression model gave results in three output tables, namely; model summary, Analysis of variance (ANOVA) and regression coefficient table of the estimated model parameters.

Model summary

The model summary

Table 7 have the value of the multiple correlation coefficients R. It shows the relationship between the four independent variables and the dependent variable. It therefore means that staff qualification, storage conditions, packaging and transportation correlated with quality of pharmaceutical products operating in Nairobi County.

The correlation and the coefficient of determination of the dependent variables when all independent variables are combined can also be measured and tested as in Table 4.9 below. From the findings 58.4% (adjusted r square = 0.584) of adherence to quality standards is attributed to combination of the independent factors that relate to (staff qualification, packaging, storage and transportation) investigated in this study. A further 41.6% of adherence to quality standards is attributed to other factors not investigated in this study.

Table 7: Model summary

Model	R	R square	Adjusted R square	Std. Error of the estimate
1	.774[a]	.598	.584	.599

A. Predictors: (constant), staff quality, storage, packaging, transportation

Analysis of variance (ANOVA)

The ANOVA

Table shows the Sum of Squares of the regression (SSR) model, the Residuals Sum of Squares (RSS) also known as the Sum of Squared Errors (SSE) and the Total Sum of Squares (TSS). The sum SSR is also known as the explained sum of squares (ESS) is a measure of the deviations between the predicted value and the mean.

The SSE is the sum of squared deviations (errors/residuals) between the regression function and the empirical data. A small RSS value indicates a tight fit of the model to the data. Total Sum of Squares (TSS) is total of SSE and SSR. The ratio of SSR (explained variance) and TSS gives the coefficient of determination given in the model summary table. The RSS divided by its degrees of freedom gives the mean square due to regression (MS_R). SSE divided by its degrees of freedom gives the mean square due to Error (MS_E). The ratio of MS_R and MS_E give the F ratio. The F-ratio is a test

statistic that used to decide whether a model as whole is statistically significant. From the ANOVA result below, this model is significant (F=41.238, p=000) and it accounted for about 58% (R square=.584)) of variations in quality regulatory guidelines of cold supply chain products within Nairobi region. Thus the model is appropriate in predicting the level of quality of cold supply chain at given levels of the independent variables.

Table 8: ANOVA

Model		Sum of squares	Df	Mean square	F	Sig.
1	Regression	44.452	3	14.817	41.238	.000[b]
	Residual	29.824	83	.359		
	Total	74.276	86			

Regression coefficients

The predicted regression model of this study was;

$$\mathbf{Y = \beta_0 + \beta_1[qualification] + \beta_2 Storage + \beta_3 Packaging + \beta_4 Transport + \varepsilon}$$

The beta coefficient values $\beta_0, \beta_1, \beta_2, \beta_3$ *and* β_4 and their significant values are presented in the regression coefficient for fitting the prediction model. The regression constant; = .260, and it is was not significant. Other regression coefficients; $\beta_1 =$ .133 1, $\beta_2 = .234$, $\beta_3 = .561$ and $\beta_{4=}.134$ -they were all significant and the therefore the resulting regression model is;

$$\text{Quality} = .260 + .133[\text{qualification}] + .234\text{Storage} + .561\text{Packaging} + .134\text{Transport}$$

The Constant which is 0.260 explains that if qualification, storage, packaging and transport are all rated as zero, adherence to quality standards would be 0.260. This implied that when factors related qualification, storage, packaging and transport are held constant quality of standards would be there in the pharmaceutical distribution firms.

The coefficient for qualification (X_1) is 0.133; this means that one unit change in qualification results to 0.133 units increase in adherence to quality standards. This implied that when employees are trained in the pharmaceutical distribution firms the quality of standard would be increased. Also the same applies to having more experienced staff in the pharmaceutical distribution firms. The adherence of quality of standard can improve with experienced staff.

0.234 is the coefficient for storage (X_2); it shows that one unit change in storage results to 0.234 units increase inherence to quality of standards. This implied that when the pharmaceutical distribution firms improved on having enough storage for the vaccines the less the drugs would spoil and this would increase the quality and standards.

The coefficient for packaging (X_3) is 0.561; this shows that one unit change in packaging results in

0.561 units increase in adherence to quality standards. This implied that when the pharmaceutical distribution firms improved on the packaging of the vaccines they improved on the quality and standards. Also when packaging of vaccines was different from cold seasons and hot seasons this would lead to less spoilage of the vaccines and thus improve on quality standards

Lastly, the coefficient for transport (X_4) is 0.134; this means that one unit change in transport results in 0.134 units increase in adherence to quality standards. This implied that when the pharmaceutical distribution firms improved on the distribution channel of the vaccines this would result to minimal damage of the drugs during transportation and thus improving on the quality and standards.

Table 9: Regression coefficients

Model		β	Unstandardized coefficients	Standardized coefficients	t	Sig
1	(constant)	.260	.210		1.241	.218
	Staff qualifications	.133	.056	.179	2.390	.019
	Storage	.234	.084	.228	2.794	.008
	Packaging	.561	.077	.626	7.260	.000
	Transportation	.134	.057	.180	2.305	.020

Dependent variable: Quality of pharmaceutical products

Discussion of findings

The purpose of the study was to investigate the determinants of quality standards adherence in distribution of cold chain pharmaceutical products in Kenya. The study was necessitated There are many challenges experience when managing the cold chain for biopharmaceuticals. Many of the cold chain pharmaceutical distributors in Nairobi are unable to offer appropriate training for all staff involved in the handling, receipt, storage, and packing and delivery operations for cold chain products. Storage conditions and facilities in majority of the firms are not up to standard and there lacks fleets of specialized transportation systems to ensure no cold chain breaks during transportation by doing proper monitoring of temperatures.

The study found that that qualification of employee in the pharmaceutical companies in Nairobi was positively correlated with quality of pharmaceutical products distributed. The employees handling pharmaceutical products were generally qualified. Trained personnel are the resource a company needs to create a competitive advantage than similar companies within the same strategic group. Qualified and skilled personnel enable companies achieve high levels of productivity and high capacity utilization. Market for Pharmaceutical products are competitive, therefore companies dealing with the products preferred building on internal capabilities to compete in the industry.

Storage conditions and packaging of pharmaceutical products were positively correlated with quality of the products. It was found that companies were not fully compliant in storage practices. Thus issues of proper labeling, inspection and non-functional storage facilities are common. The result is wastage of products and hence increased costs associated with poor storage.

Distribution efficiency was found to significantly correlate with quality of the products. In most parts of Nairobi, especially in town centers, traffic jam was a challenge and thus compromised distribution regulations which are ensure drug quality. This will implicate on the quality of treatment and health of rural majority.

From the foregoing findings, the net effect of employee qualification, storage, packaging and distribution of the drugs is on quality of treatment of Kenyans. WHO estimates that about 25% of the drugs sold in developing countries, including Kenya, are in most cases found not to have the required efficacy. In some countries rates up to 40% and higher have been reported including life-saving medicines against diseases such as malaria and bacterial infections (Hogerzeil, H. V, & Policy, A. 2002).

As a consequence, thousands of people die every year because the drugs they take do not have the anticipated therapeutic effect. This human tragedy together with the significant economic impact makes it obvious that drug quality assurance throughout the entire supply chain must be a priority for every national drug regulatory authority.

CONCLUSIONS

Based on the study findings, the following are the key conclusions;

Employees in the pharmaceutical industry had required formal education necessary to learn other professional skills required in the industry. They also had necessary skills to ensure and implement quality standards and guidelines in the handling and distribution of pharmaceutical products in Kenya.

Storage conditions had a positive significant effect on the quality of the pharmaceutical products. Therefore the lack of stringent storage conditions noted in the pharmaceutical companies compromised the quality of the products. In the long run there are increased costs of the drugs through spoilage, compensation, reduced customer satisfaction and stock outs.

Quality of packaging of pharmaceutical products had a positive significant effect on quality of the products. The standards of packaging of pharmaceutical products adhered to guidelines and therefore there was no quality defects due to packing of the products. Keeping the packing standards ensured availability of quality drugs at normal costs of the drugs to the final consumer. Thus affordable quality drugs will be available to majority of Kenyan citizen.

Distribution of cold supply chain of pharmaceutical products compromised quality of the products mostly due to traffic congestion network and as such any efforts by both the county and national government that will address the conditions of road network will realize the increased quality of pharmaceutical products of its citizens.

Almost of quality of medicine consumed in the county is accounted for the four factors; staff qualification, storage, packaging and transportation efficiency and reliability. The overall effectiveness of these factors is achieved when stakeholders strategies addresses the four factors collectively in a view to improve their positive contribution to the quality of medicine in the County.

RECOMMENDATIONS

Staff qualification had a positive significant correlation with quality of medicine. Therefore Pharmaceutical companies should keep on recruiting and retaining high quality and skilled employees within the industry. They should create enabling conditions to attract unique qualities and skilled personnel in the pharmaceutical sector. As

such, the companies therefore should work in collaboration with training institutions the content and requirements for trainees in the sector. The trainees should undertake a course on ethical issues and its consequences in the medical field.

Correct packaging of pharmaceutical products affects the quality of products in the cold chain distribution. Firms that supplied quality medicines were found to have adhered to required packaging standards. It is imperative to ensure that required standard packing procedures of vaccines are in place, packaging protocols for cold and hot seasons should be strictly followed in the distribution and storage of pharmaceutical products. Proper labeling of the packages with storage requirements providing information that is fundamental in handling of cold chain products within the supply chain should also be followed.

Storage had a positive significant relationship with quality of medicine found in the county. Therefore Pharmaceutical companies should invest in storage equipment. They should also ensure that already existing storage facilities are fully functional through equipping the maintenance and repairs departments. This will ensure quality of pharmaceutical products and at reduced cost for a healthy nation.

Reliability and efficiency in transportation correlated significantly with quality of medicine. Pharmaceutical firms should strategize to provide quality medicine by ensuring adequate resources are channeled to transportation. The national government and the county governments should also improve the road conditions to passable state such that they do not compromise the distribution of pharmaceutical products in the country. Through good road network, there is improved access of quality products even to the rural communities in Kenya, and as such improve their health status.

Recommendation for further studies

The current study was limited to pharmaceutical companies based in Nairobi. This study recommends that another similar study be carried that covers more companies in other towns in Kenya. The findings will therefore be more accurate reflection of the situation in Kenya.

The current study was limited to only four factors; employee qualification, storage, packaging and transportation of pharmaceutical products. These factors accounted for only 58%. Other factors, like leadership, customer awareness, and so on should be incorporated in a comprehensive study.

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