

FEASIBILITY STUDY ON HANDLING PHARMACEUTICALS IN COLD CHAIN LOGISTICS WITH REFERENCE TO INTERNATIONAL SHIPPING CORPORATION

Submitted in partial fulfillment of the requirements for the award of

MASTER OF BUSINESS ADMINISTRATION

by

JOSHUA SAMUEL.A

Register No.41410148



SCHOOL OF MANAGEMENT STUDIES

SATHYABAMA

INSTITUTE OF SCIENCE AND TECHNOLOGY

(DEEMED TO BE UNIVERSITY)

Accredited with Grade "A" by NAAC | 12B Status by UGC | Approved by AICTE

JEPPIAAR NAGAR, RAJIV GANDHI SALAI, CHENNAI - 600 119

APRIL 2023



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SCHOOL OF MANAGEMENT STUDIES

BONAFIDE CERTIFICATE

This is to certify that this Project Report is the bonafide work of **JOSHUA SAMUEL.A 41410148** who carried out the project entitled "FEASIBILITY STUDY ON HANDLING PHARMACEUTICALS IN COLD CHAIN LOGISTICS WITH REFERENCE TO INTERNATIONAL SHIPPING CORPORATION" under my supervision from January 2023 to March 2023.

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Submitted for Viva voce Examination held on

06/05/2023

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TO WHOMSOEVER IT MAY CONCERN

SUB: COMPLETION OF MBA PROJECT

This is to certify that Mr. Joshua Samuel (REG.No. 41410148), pursuing final year MBA in Sathyabama Institute of Science and Technology, Chennai, has been completed the Logistics project in our concern from 09/01/2023 to 09/03/2023

We wish him all the success in his future endeavours.

For International Shipping Corporation


J. JOHNSON
Authorised Signatory

DECLARATION

I **JOSHUA SAMUEL.A (41410148)** hereby declare that the Project Report entitled **“FEASIBILITY STUDY ON HANDLING PHARMACEUTICALS IN COLD CHAIN LOGISTICS WITH REFERENCE TO INTERNATIONAL SHIPPING CORPORATION”** done by me under the guidance of **DR. JOHN BRITTO** is submitted in partial fulfillment of the requirements for the award of Master of Business Administration degree.

DATE: 05/05/2023

PLACE:Chennai

A small rectangular box containing a handwritten signature in blue ink, which appears to read "Joshua".

Joshua Samuel.A

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I wish to express my thanks to all Teaching and Non-teaching staff members of the **School of Management Studies** who were helpful in many ways for the completion of the project.

Joshua samuel.A

ABSTRACT

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate. Through this study, the researcher tries to identify the key areas to be enhanced to improve the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines. The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines in pharmaceutical distributors. The other objectives are to determine how storage conditions in pharmaceutical distributors influences safety of vaccines, evaluate the influence of packaging in pharmaceutical distributors on the safety of vaccines and to establish the extent to which technical capacity in pharmaceutical distributors influence safety of Vaccines.

Convenience sampling method has used in the research work. Multiple choice questions have been chosen to collect the responses from 118 members involved in cold chain logistics of pharmaceutical products. The data collected has been analyzed through various statistical tools like Karl Pearson's Correlation, Chi-square test and One-way Anova test. Numerous new findings has been derived from this research has helped to provide few suggestions to improve the efficiency of the cold chain logistics for pharmaceutical products like vaccines of International Shipping Corporation.

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CHAPTER 1:

1.1 INTRODUCTION

A cold chain is a monitored temperature-controlled supply chain. The goal of the cold chain is to keep a sample or material within a certain temperature range during all stages of delivery, processing and storage. Cold chains are widely used to ensure the viability of products in the pharmaceutical and agricultural sectors, and are critical components of vaccination programs and bio-medical surveillance activities.

Many biological samples deteriorate when exposed to heat, sunlight, or fluorescent light. When transporting and storing such biological substances, it is imperative that field and laboratory teams control environmental conditions, ensuring that exposure to potentially damaging environmental factors is minimized.

The cold storage, handling, and distribution of temperature-sensitive drugs represent an increasingly important component of the global pharmaceutical supply chain. Clinical trial material (CTM) or investigational medicinal products (IMP) are an important part of the earliest stages of the life science supply chain. Given the increased number of global regulatory and standards-based guidance documents issued over the past two years, members of the pharmaceutical supply chain are taking notice and making changes to ensure product quality and protect patient safety. The purpose of this paper is to review the various factors affecting Good Cold Chain Management Practices for Clinical Trial Materials/Investigational Medicinal Products.

Cold Chain is a system of storing and transporting vaccine at the recommended temperature range from the point of manufacture to point of use. In order to provide potent and effective vaccine to the beneficiaries a vast cold chain infrastructure is required, which should have a

network of Vaccine Stores, Walk-in-coolers (WIC), Walk-in-freezers (WIF), Deep Freezers (DF), Ice lined Refrigerators (ILR), Refrigerated trucks, Vaccine vans, Cold boxes, Vaccine carriers and icepacks from national level to states up to the out reach sessions. The cold chain system and vaccine flow in the country:- The vaccines are transported from the manufacturer

through air transport under the temperature range of 2-8°C to the primary vaccine stores (GMSDs/State head quarter).

COMPANY PROFILE

International shipping corporation is a pioneer in Logistics and Supply Chain Solutions in India. We, at International shipping corporation, offer comprehensive custom designed logistics projects and supply chain management services to our customers. Our highly experienced professionals at various locations in India ensure sustainable growth and development to enhance customer value and quality. We have set benchmarks in customer satisfaction and service.

Within International shipping corporation we take a consistent and systematic approach to Health and Safety management within our operations, thus giving customers the confidence to choose our services above all others.

International shipping corporation has an established Global Health and Safety Team comprising regional representation with direct accountability to the Regional and Global Leadership Teams. This affords timely and effective reporting and management support for HSE initiatives. The team is empowered to oversee and support company-wide compliance to a growing list of industry, customer and legislative requirements.

A primary Health and Safety function within International shipping corporation which sets us apart is that we listen to the client to ensure Health and Safety initiatives bring added value to both parties and further protect our mutual business interests. In achieving this we prioritize Health & Safety as a core pillar within our business and decision making processes.

At International shipping corporation we place a great emphasis towards safety of all persons working for or with us including our customers by using a Lost Time Incident (LTI) reporting structure augmented by a developing awareness to Near Miss reporting

INDUSTRY PROFILE

The 2015 Biopharma Cold Chain Landscape

Although dealing with rising cost pressures from payers around the world, the biopharma industry is enjoying strong growth, especially in the US. The long-sought promise of using genomic information to develop drugs and diagnostics is starting to come home. Monoclonal antibodies (mAbs) have been premier products in oncology (a strong growth area by itself) for several years; now, with new mAbs such as the so-called PCSK9s to treat cholesterol-related conditions, their application is broadening.

These high-value products put an added emphasis on proper storage, transportation and dispensing. Maintaining a secure “cold chain” through the storage, handling and transportation of temperature-sensitive drugs, vaccines and blood products assures product quality and integrity for the benefit of the patient, and keeps the manufacturer, hospital, pharmacist, physician and nurse in compliance with various laws, regulations, guidelines and codes.

In clinical trials, where following protocols is so essential to obtaining meaningful results, maintaining the cold chain also preserves the validity of the tests.

It costs more to keep products at 2–8 °C or at frozen temperatures than it does to keep them at uncontrolled ambient conditions, more to pack and transport them cold, and more to be able to demonstrate by process qualification or by measurement of each shipment that they stayed cold. But industry and society benefit enormously when temperature-sensitive drugs and biological products can be made in efficient large batches, shipped around the world, and delivered as needed to the point of purchase or use.

1.2 NEED FOR THE STUDY

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C. but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate.

Through this study, the researcher tries to identify the key areas to be enhanced to improve the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines with special reference to International Shipping Corporation

1.3 SCOPE OF THE STUDY

The major scope of the analysis on cold chain logistics in pharmaceuticals are

- a. To increase the longevity of the medical characteristics
- b. Maintain the temperature level for the vaccines
- c. Retain the nutritional value of vaccines
- d. Maintain the chemical substance of vaccines
- e. Reduce wastage and return of expired stock of vaccines

1.4 OBJECTIVES

PRIMARY OBJECTIVE

The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines with special reference to International Shipping Corporation

SECONDARY OBJECTIVES

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

1.5 LIMITATIONS OF THE STUDY:

For anything there should be some limitations like that my project also have certain limitations. The following are some limitations what I faced:

1. The information provided by majority of the respondents could also be biased or inaccurate. No independent verification of the data was possible.
2. Time is one major constraint, which limits the effective data collection.
3. Non-availability of data collection from all the people involved in cold chain logistics of pharmaceutical products
4. The sample size is only 118 so the sample may not be truly representative of the total population
5. Reliability and accuracy of the analysis depends on the respondents' openness and trueness towards each question in the questionnaire.

CHAPTER 2: REVIEW OF LITERATURE

Laboratory Cold Chains:

As medicine developed through the centuries the advances created the basis for diagnostic discoveries. In the latter part of the 19th century the clinical laboratory started to be established. By the turn of the century many specific chemical, haematological and bacteriological tests had been developed due to innovations in basic science **(Berger, 1999a)** enabling the clinical laboratory to be used for diagnostic purposes. Different types of laboratories started to emerge, including physiological, pharmaceutical, forensic, public health, clinical chemistry and microbiological **(Berger, 1999b)**.

Laboratories developed similarly in Britain and the United States of America (USA) due to the influences of medical faculties in Europe **(Petts, 2012; Race, Tillery, & Dysert, 2004)**. The number of laboratory tests available increased dramatically over the 20th century. The first half of the century was involved in developing individual biochemical methods for the variety of parameters that medical professionals were interested in such as ion concentration of elements in serum (Berger, 1999b). Because the refrigerator was not invented until the late 1910s to early 1920s these methods did not require refrigeration. Today the range of different analyses available is now well over 3000, and still increasing, although not all will be available at each laboratory **(Wians, 2009)**.

Requests for laboratory investigations increased as medical professionals found the data useful in establishing diagnoses. The desire to have this data prior to treatment led to the expectation of faster turnaround times for testing **(Seligson, 1966)**, so more efficient methodologies needed to be introduced. The first convenient and accurate kit-type diagnostic test, Clinitest®, was introduced in 1941 and measured reducing sugars in urine 3 (Chemical Heritage Foundation, 2010). This was followed by **Clinistix® in 1956**, the first dipstick which measured glucose in urine **(Chemical Heritage Foundation, 2010)**.

Samples of the patient's blood (**Seligson, 1966**). In the 1960's culture media became more sophisticated with antibiotics included as selective agents (**Smith, 2005**) necessitating storage at sub-ambient temperatures. The sixties also saw computers introduced into laboratories in Europe, Britain and the USA but they did not become mainstream until the **1970's-1980's** (**Keller, 1982**). Miniaturisation of laboratory techniques began in the 1970s with microbiology and immunoassays being the initial beneficiaries' and this has progressed through all disciplines (**Fung, 2002; Hansen, Hardesty, & Myers, 1974; McGlennen, 2001**).

The reagents for these kit/reagents needed to be stored at sub-ambient temperatures (**Ammann, 2011; Ramanujam, Koelbl, & Ting, 1993**). An example of this type of kit is the API® range manufactured by **bioMérieux Inc.** More recently these techniques have moved onto full automation especially in larger laboratories (**Wu, 2006**). The molecular era started in **1943** when **Oswald Avery (1877-1955)** demonstrated that deoxyribonucleic acid (DNA) played a significant role in the carriage of genetic information (Bersch, 2006). Research into DNA moved forward on multiple fronts with **James Watson (b. 1928)**, **Francis Crick (1916-2004)**, **Maurice Wilkins (1916-2004)** and **Rosalind Franklin (1920-1958)** all working on defining DNA's structure in the early **1950's** (**Bersch, 2006**).

In **1953** the peer reviewed academic journal Nature published this research and the findings were widely accepted. This along with further discoveries of critical enzymes and manipulation techniques led to the development of new laboratory procedures. However, it was not until the invention of the polymerase chain reaction (PCR) technique by **Kary Mullis (b. 1944)**, in **1983**, that molecular methodologies moved from the research laboratory into the clinical laboratory (**Tang, Procop, & Persing, 1997**) providing enhanced sensitivity and faster turnaround times. Kits that use this technique require sub-ambient temperatures. Kits such as the Hain Lifescience **Genotype® Mycobacterium CM/AS**, **Genotype® MDR TBplus** and **Genotype® SL** require a mix of temperatures for storage.

The primers and probes need to be kept at **4o C** and the master mix that contains the enzymes and dinucleotides at **-20o C** but are provided together in the same kit. Today, the diagnostic industry is starting to move towards "**black box**" type testing

methods (**Bersch, 2006**) that includes the three main phases of PCR, extraction, amplification and detection. This type of testing often does not require specialised staff or sub-ambient storage conditions for reagents. An example of this is the **Gene Expert®** range of cartridges manufactured by **Cepheid**. To complicate matters the supply chain's national and international regulations are moving towards "**controlled room temperature**" (CRT) requiring additional monitoring steps for ambient temperature packages, and adding complexity to the transportation process (**Healthcare Commerce Media Corporation, April 09, 2010**). Ultimately, even the ambient temperature "**black box**" products being developed by the diagnostic industry will come under the CRT auspices.

There is an abundance of literature and regulations on the development of drugs for human use including stability, experimental design and data analysis for the pharmaceutical industry but for the in vitro device (IVD) manufacturers, who manufacture kits for the clinical laboratory, there are guidance documents but few regulations. However, the need for regulation was reinforced by a study performed in **2011** that showed that devices that had been deemed low risk and were not covered by regulations had resulted in serious health problems or death for some patients (**Zuckerman, Brown, & Nissen, 2011**). A draft document was issued by the Food and Drug Administration (FDA) that covered companion diagnostic tests, with a deadline of **31 March 2013** but as late as **October 2013** the FDA were still talking about regulating but with no definitive action to date (**Novales-Li, 2013**). Currently, licenced laboratory developed tests (LDTs) and IVDs must be validated and any reagents used, including calibrators, controls, and sample diluents, must undergo stability testing so consumers know the temperature and storage limits of the product. In order to deliver an accurate and precise result each of these components must be functioning properly. Stability studies cover the following: expected shelf life or expiration date, temperature, humidity and photostability, stress testing and storage conditions (**Food and Drug Administration, 2003; International Conference on Harmonisation, 2003**). Environmental factors such as temperature, humidity and light can affect the quality and shelf life of a product. Stability testing using the climatic zones helps establish a shelf life and the recommended storage conditions for a product (**Markens, 2009**). The shelf life should be based on the long

term study at the recommended storage condition. The product should also be subjected to elevated temperatures for an appropriate time period to emulate the effect of short term excursions outside the recommended storage conditions which occurs during shipping (**World Health Organisation, 2009**). The time-stress or excursion hours are cumulative and includes all stages of the product's life from production to storage in the central warehouse, then from the supplier to the distributor, which may mean exporting overseas, customs or border processing, and lastly from the distributor to the customer. At signed acceptance of the delivery the stress period is ended for the distributor company as it has no control over what happens post-delivery.

All products of a temperature-sensitive nature should be labelled appropriately to alert the customer of the package's storage requirements. The expectation is that the customer would have procedures in place to manage the receipt of temperature-sensitive products. However, no products are sold with the cumulative stress hours available making it all the more essential that all parties involved in the transportation of goods monitor and ensure that cold chain products are kept at the recommended temperature.

Knowledge of the stress hours originally available and how many have been used would be useful to the purchaser. For most products the process of bringing a cold chain kit/reagent to ambient temperature is a requirement before the test can be performed. The speed of chemical reactions are altered at different temperatures therefore the prerequisite of bringing a kit to room temperature is necessary because the kit/reagent will have been designed to work in an ambient environment. These excursions should also be considered as time-stress hours outside the recommended storage conditions. Consideration should be given to how many times a kit/reagent is brought to, and left, at ambient temperature in the laboratory environment and if consumption of the kit is slow then it should be discarded prior to finishing or reaching its expiry date.

CHAPTER 3: RESEARCH METHODOLOGY

Fundamental to the success of any formal marketing research project is a sound research design. A good research design has the characteristics of problem definition, specific methods of data collection and analysis, time required for research project and estimate of expenses to be incurred. The function of a research design is to ensure that the required data are collected accurately and economically. A research design is purely and simply the framework or plan for an analysis of data. It is a blue print that is followed in completing a study. It resembles the architect's blue-print (map) for constructing a house. It may be worthwhile to mention here that a research design is nothing more than the framework for the study ensures that the study will be relevant to the problem and the study will employ economical procedures.

Claire seltizetal defines Research Design as "Research design is a catalogue of the phases and facts relating to the formulation of a research effort. It is the arrangement of collection and analysis of data in a manner that aims to combine relevant to the research purpose with economy in procedure".

Three important about research design are

1. The design of investigation should stem from the problem
2. Whether the designs are productive in a given problem setting depends on how imaginatively they are applied. An understanding of the basic design is needed so that they can be modified to suit specific purpose
3. The three basic design are as follows
 - i. Exploratory Research design
 - ii. Descriptive Research design
 - iii. Casual Research design

The Research design used in the study is descriptive research design

3.1 RESEARCH DESIGN

Descriptive research design is also called explanatory design. This is the one that simply describes something such as demographic characteristics. The descriptive study is typically concerned with determining frequency with which something occurs or how two variables vary together.

3.2 SAMPLE SIZE

It refers to the number of elements of the population to sample. The sample size chosen for the survey is **118**.

3.3 DATA SOURCES

After identifying and defining the research problem and determining specific information required to solve the problem, the researcher's task is to look the type and sources of data which may yield the desired results. Data sources are of two types through which data is collected.

Data sources may be classified as

1. Primary data
2. Secondary data

PRIMARY DATA

Primary data is the original data collected by the researcher first hand. It is collected for the first time through field survey. These are those that are gathered specifically, for the problem at hand. The various sources for collecting primary data are questionnaire, observation, interview etc. The primary source used for the study is questionnaire.

SECONDARY DATA

Secondary data is the information which is already available in published or unpublished form. When the needed information is collected from the census of population available in a library means then it is a secondary data. It is also used for collecting historical data. The various sources of secondary data are books,

periodicals, journals, directories, magazines, statistical data sources etc. The secondary source used for this study is company profile, scope, need, review of literature.

3.4 RESEARCH INSTRUMENTS

Research instrument are the instruments which is used for gathering or collecting information. The instruments used in the study are

1. Direct questions
2. Close end questions
3. Dichotomous questions
4. Multiple choice questions

DIRECT QUESTIONS

Direct questions are just what their names indicate. They explicitly ask for the desired data. However the directness of the question also relates to the way a response is interpreted.

CLOSE END QUESTIONS

Such questions are also called fixed alternative questions they refer to those questions in which the respondent is given a limited number of alternative response frame which he/she is to select one that most closely matches his/her opinion or attitude.

DICHOTOMOUS QUESTIONS

A dichotomous question refers to one which offers the respondent a choice between only two alternatives and reduces the issue to its simple terms. The fixed alternatives are of the type, yes/no, agree/disagree, true/false etc.

MULTIPLE CHOICE QUESTIONS

A multiple choice question refers to one which provides several set alternatives for its answers. Thus, it is a middle ground between free answers and dichotomous question.

3.5 SAMPLING

Collecting data about each and every unit of the population is called census method. The approach, where only a few units of population under study are considered for analysis is called sampling method. There are two main categories under which various sampling method can be put.

The two categories are

1. Probability sampling
2. Non-probability sampling

The sampling method adopted for the study is convenience sampling under non-probability sampling.

NON-PROBABILITY SAMPLING

In non-probability sampling, the chance of any particular unit in the population being selected is unknown, since randomness is not involved in the selection process. But this does not mean that the findings obtained from non-probability sampling are of questionable value. If properly conducted their findings can be accurate as those obtained from probability sampling. The three frequencies used non-probability designs are

1. Judgment sampling
2. Convenience sampling
3. Quota sampling

3.6 CONVENIENCE SAMPLING:

In this method, the sample units are chosen primarily on the basis of the convenience to the investigator. The units selected may be each person who comes across the investigator.

3.7 SAMPLE FRAME:

A Sample frame may be defined as the listing of the general components of the individual units that comprise the defined population.

3.8 SAMPLE DESIGN

Sample design is the theoretical basis and the practice means by generalizing from characteristics of relatively few of the comprising population. It is the method by which the sample is chosen.

3.9 ANALYTICAL TOOLS

ANALYSIS USING KARL PEARSON'S CORRELATION:

Correlation analysis is the statistical tool used to measure the degree to which two variables are linearly related to each other. Correlation measures the degree of association between two variables. The Pearson product-moment correlation coefficient is a measure of the strength and direction of association that exists between two variables measured on at least an interval scale. It is denoted by the symbol r .

$$r = \frac{N\sum XY - \sum X \sum Y}{\sqrt{N\sum X^2 - (\sum X)^2} \sqrt{N\sum Y^2 - (\sum Y)^2}}$$

CHI- SQUARE TEST I – (χ^2)

A chi-squared test, also referred to as chi-square test or χ^2 test, is any statistical hypothesis test in which the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true, or any in which this is asymptotically true, meaning that the sampling distribution (if the null hypothesis is true) can be made to approximate a chi-squared distribution as closely as desired by making the sample size large enough.

The χ^2 test was first used by Karl Pearson in the year 1980. The quantity χ^2 describes the magnitude of the discrepancy between theory and observation.

It is calculated using:

$$\chi^2 = \Sigma [(O_i - E_i)^2 / E_i] \text{ with } (n - 1) \text{ degrees of freedom.}$$

Where, O_i refers to the observed frequency & E_i to the expected frequencies. χ^2 was used as a test of independence and goodness of fit.

PERCENTAGES

Percentages refer to a special kind of ratio. Percentages are used in making comparison between two or more series of data. Percentages are used to describe relationships, it is expressed as.

$$\text{Percentage} = (\text{no of employees} / \text{total no of employees}) \times 100$$

CHARTS:

Charts are graphic displays of data for easy understanding of relative positions that is not always possible with descriptive words or numbers. Types of charts commonly used in business data presentation are: Bar and pie.

BAR CHARTS:

The bar chart is commonly used for presentation of qualitative data. The data can be continuous or discrete data, which are plotted against discrete data intervals. The vertical bar diagram, also called bar chart where the length or height of bars represent the numerical value of the event or measurement. Width or gap between the bars is of no significance to the bar chart data, but they are uniform in a diagram.

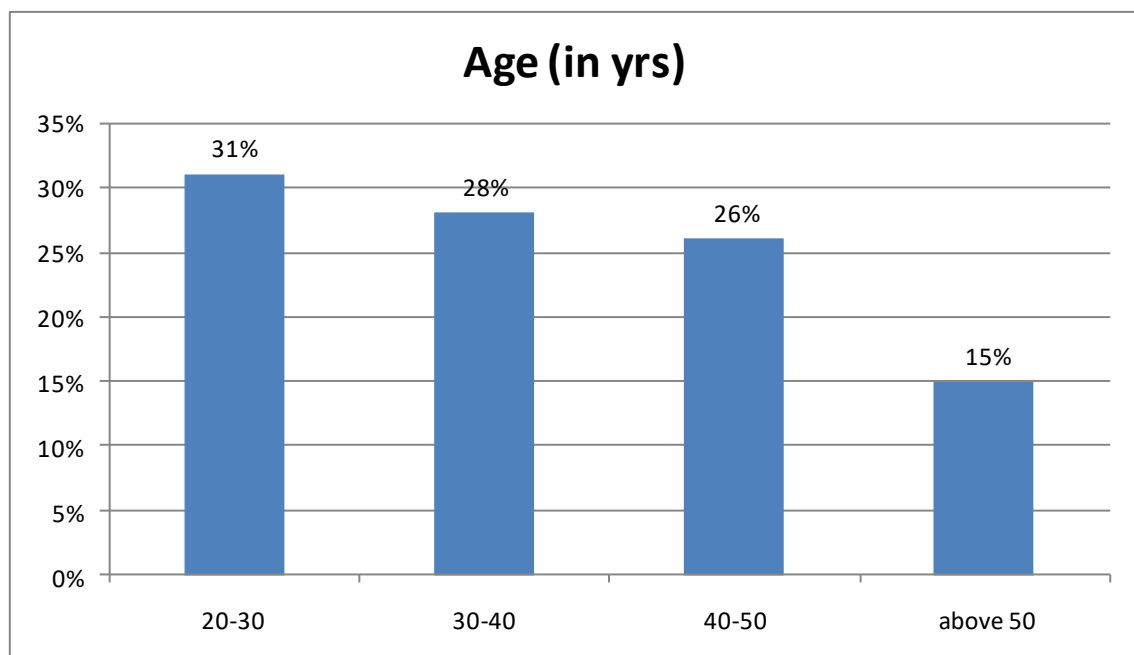
CHAPTER 4 DATA ANALYSIS AND INTERPRETATION

1. DEMOGRAPHIC

TABLE 1 AGE

Age (in yrs)	No. of Respondents	% of Respondents
20-30	36	31
30-40	33	28
40-50	31	26
above 50	18	15
Total	118	100

CHART 1



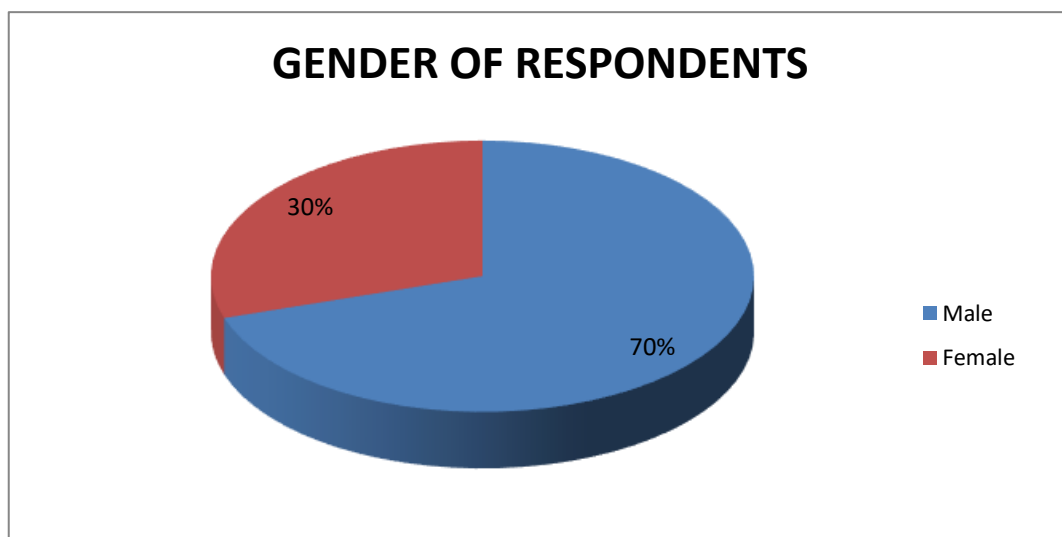
INFERENCE:

31% of the respondents belong to the age group between 20-30 , 28% of the respondents belongs to the age group between 30-40, 26 % of the respondents belongs to the age group between 40-50 and 15% of the respondents belongs to the age group above 50.

TABLE 2 GENDER

Gender	No. of Respondents	% of Respondents
Male	83	70
Female	35	30
Total	118	100

CHART 2



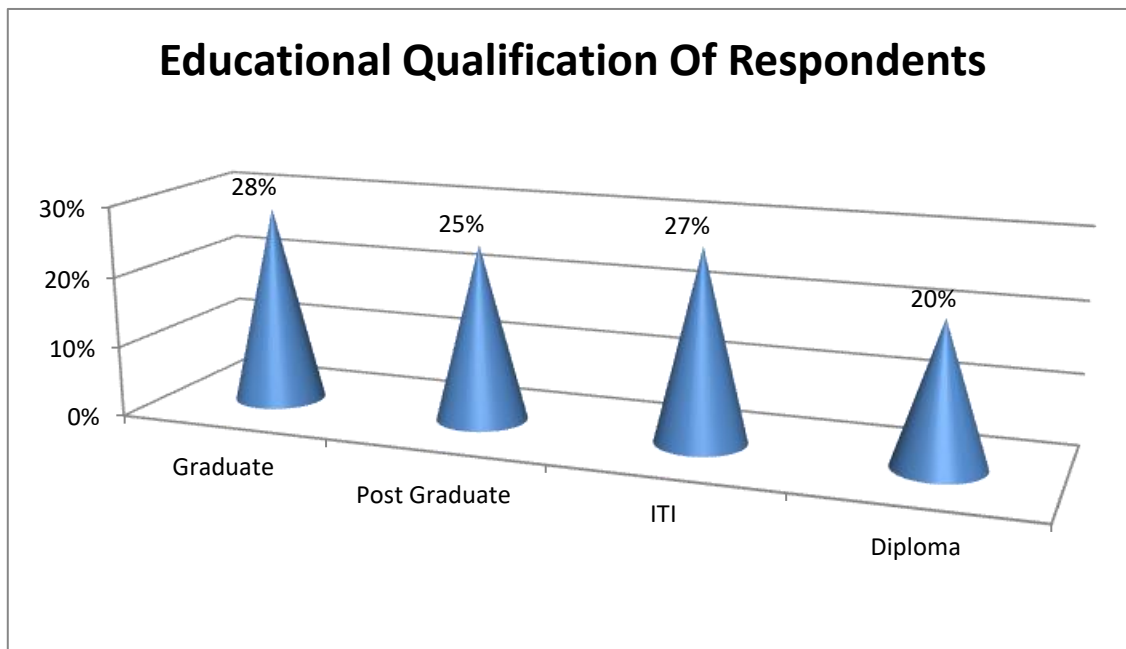
INFERENCE:

70% of the respondents are male and 30% of the respondents are female.

TABLE 3 EDUCATION

Educational Qualification	No. of Respondents	% of Respondents
Graduate	33	28
Post Graduate	29	25
ITI	32	27
Diploma	24	20
Total	118	100

CHART 3



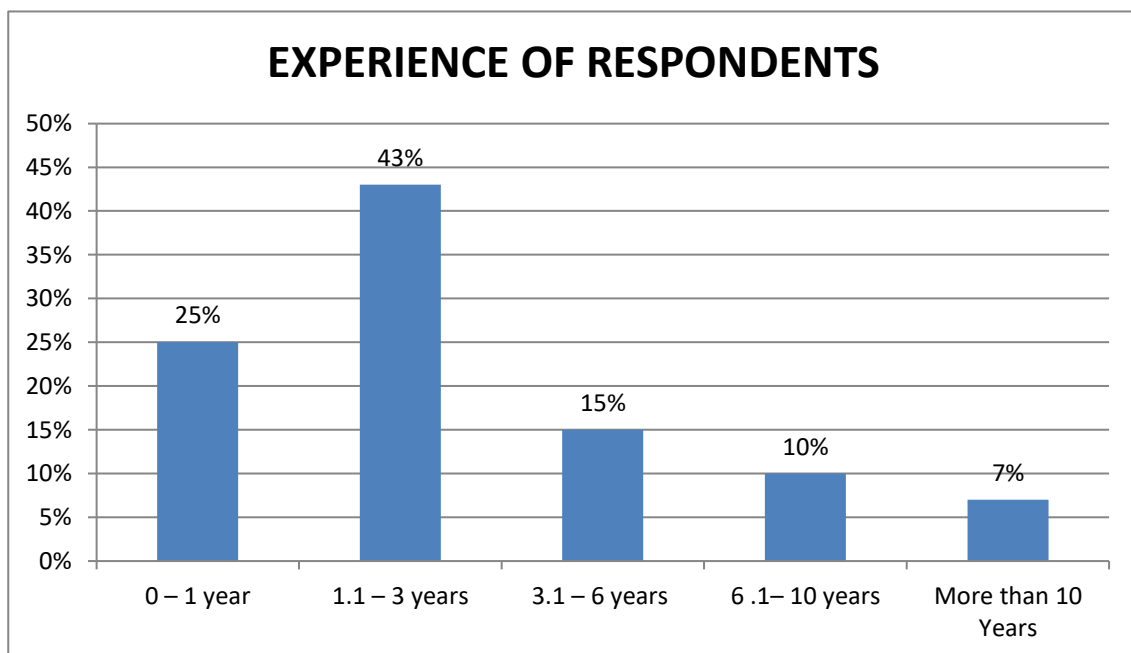
INFERENCE:

28 % of the respondents are graduate, 27 % of the respondents are ITI, 25 % of the respondents are post graduate, 20 % of the respondents are diploma.

TABLE 4 EXPERIENCE

Experience	No. of Respondents	% of Respondents
0 – 1 year	29	25
1.1 – 3 years	51	43
3.1 – 6 years	18	15
6 .1– 10 years	12	10
More than 10 Years	8	7
Total	118	100

CHART 4

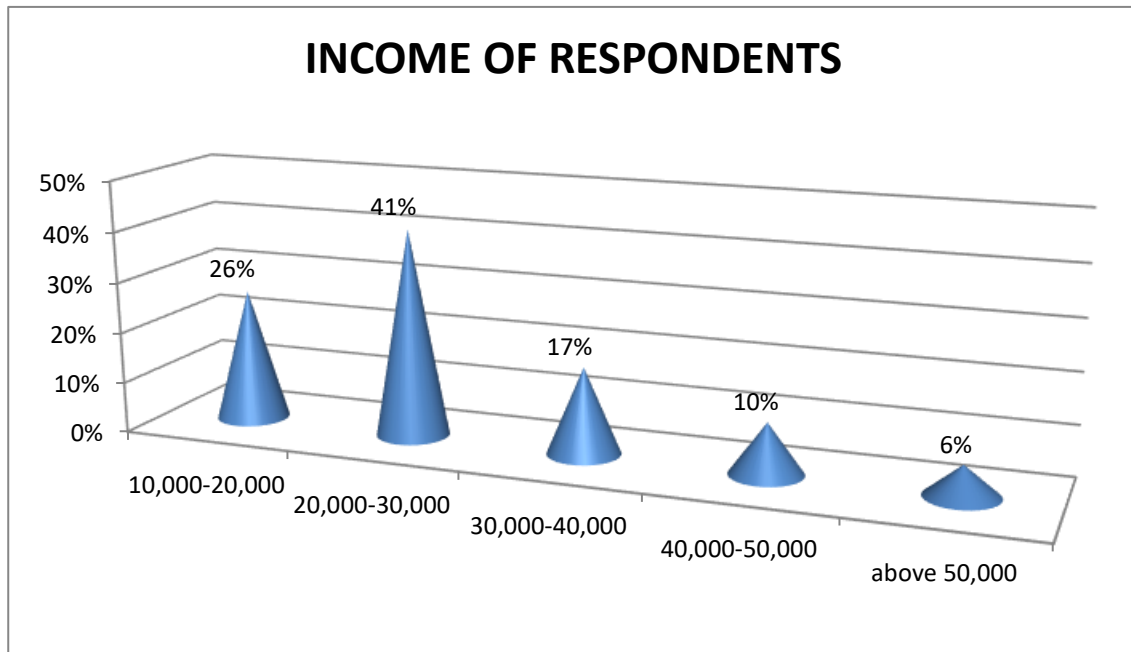


INFERENCE:

43% of the respondents have 1.1 – 3 years of experience, 25% of the respondents have 0 – 1 years of experience, 15% of the respondents have 3.1 – 6 years of experience, 10% of the respondents have 6 .1– 10 years of experience & 7% of the respondents have more than 10 Years of experience.

TABLE 5 INCOME

Income	No. of Respondents	% of Respondents
10,000-20,000	31	26
20,000-30,000	48	41
30,000-40,000	20	17
40,000-50,000	12	10
above 50,000	7	6
Total	118	100

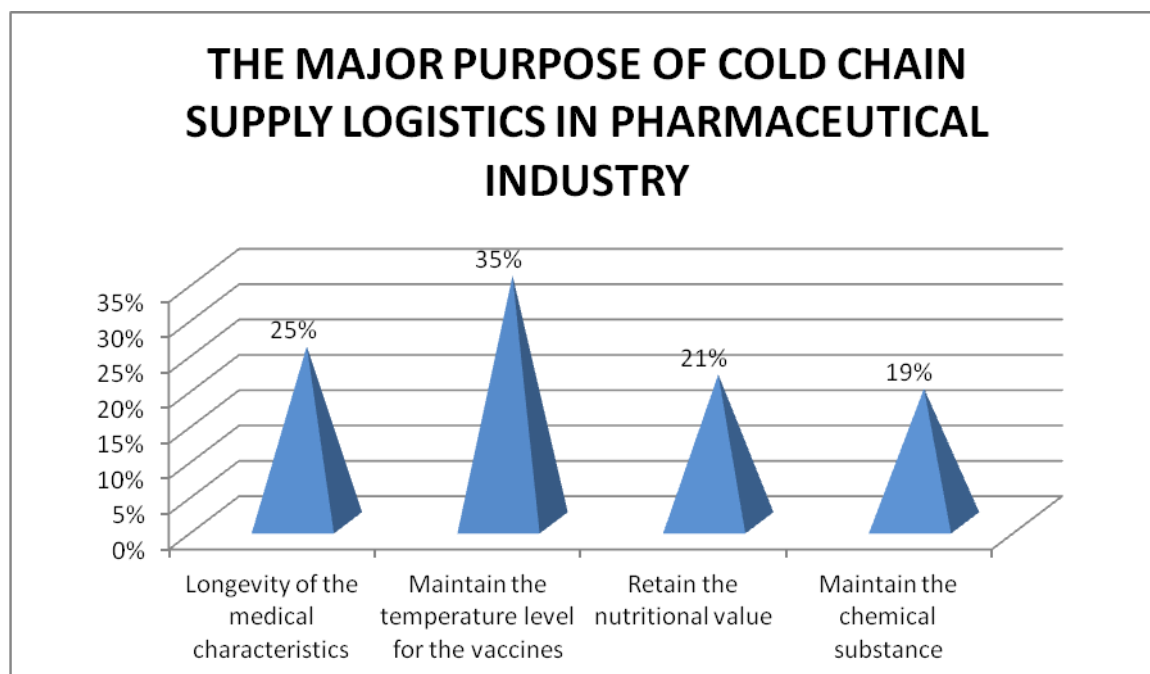
CHART 5**INFERENCE:**

41% of the respondents income range between Rs.20,000-30,000, 26% of the respondents are income range between Rs.10,000-20,000, 17% of the respondents income range between Rs.30,000-40,000, 10% of the respondents income range between Rs.40,000-50,000, 6% of the respondents income are above Rs.50,000.

TABLE 6 THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No. of Respondents	% of Respondents
Longevity of the medical characteristics	30	25
Maintain the temperature level for the vaccines	41	35
Retain the nutritional value	25	21
Maintain the chemical substance	22	19
Total	118	100

CHART 6



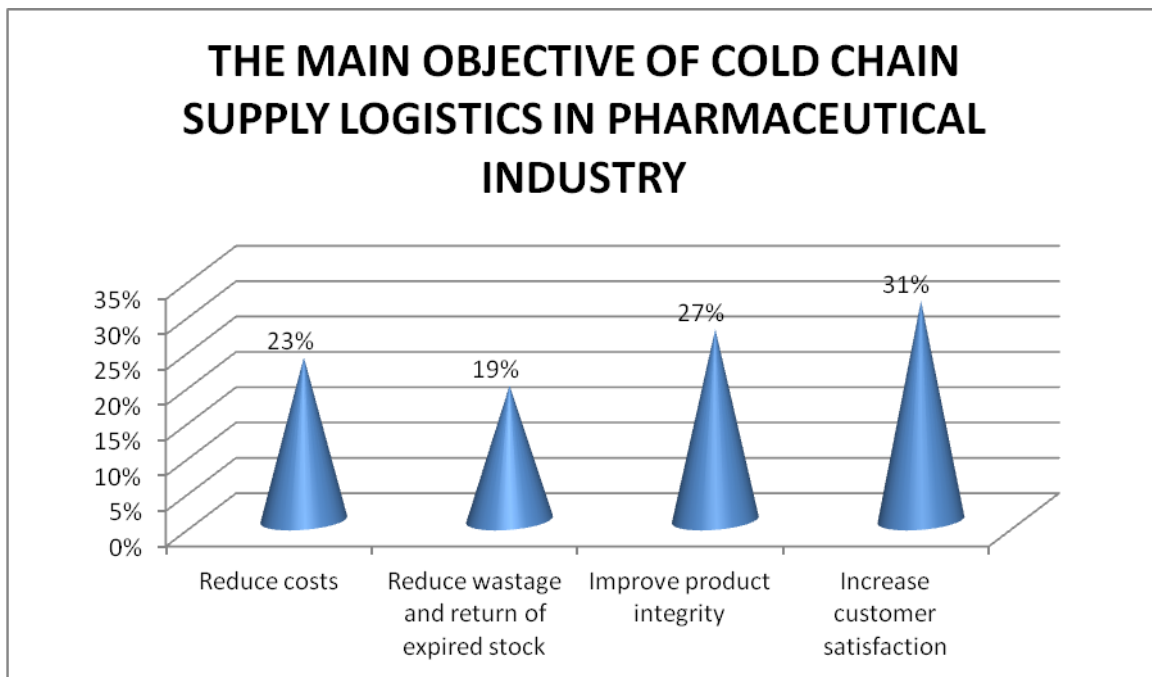
INFERENCE:

35% of the respondents mention that the major purpose of cold chain supply logistics in pharmaceutical industry happens by Maintaining the temperature level for the vaccines, 25% of the respondents mention that the major purpose of cold chain supply logistics in pharmaceutical industry happens by longevity of the medical characteristics., 21% of the respondents mention that the major purpose of cold chain supply logistics in pharmaceutical industry happens by retaining the nutritional value, 21% of the respondents mention that the major purpose of cold chain supply logistics in pharmaceutical industry happens by maintaining the chemical substance.

TABLE 7 THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No. of Respondents	% of Respondents
Reduce costs	27	23
Reduce wastage and return of expired stock	22	19
Improve product integrity	32	27
Increase customer satisfaction	37	31
Total	118	100

CHART 7



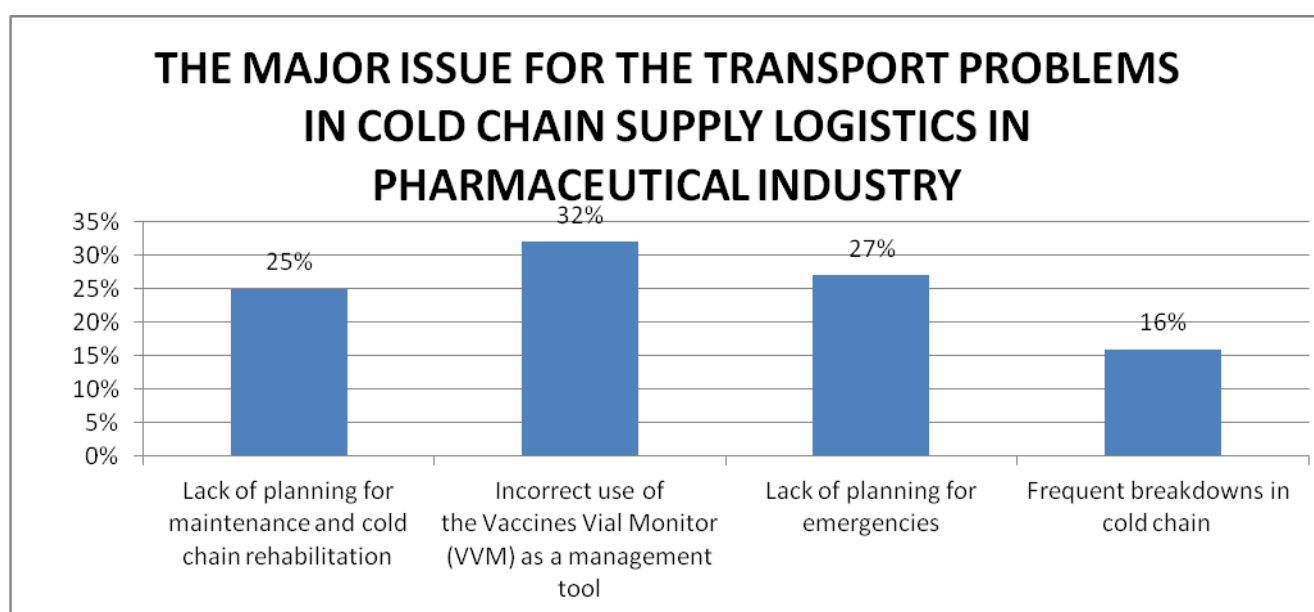
INFERENCE:

31% of the respondents say that the main objective of cold chain supply logistics in pharmaceutical industry is to increase the customer satisfaction, 27% of the respondents say that the main objective of cold chain supply logistics in pharmaceutical industry is to improve the product integrity, 23% of the respondents say that the main objective of cold chain supply logistics in pharmaceutical industry is to reduce the costs, 19% of the respondents say that the main objective of cold chain supply logistics in pharmaceutical industry is to reduce the wastage and return of expired stock.

TABLE 8 THE MAJOR ISSUE FOR THE TRANSPORT PROBLEMS IN COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No. of Respondents	% of Respondents
Lack of planning for maintenance and cold chain rehabilitation	30	25
Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool	38	32
Lack of planning for emergencies	32	27
Frequent breakdowns in cold chain	18	16
Total	118	100

CHART 8



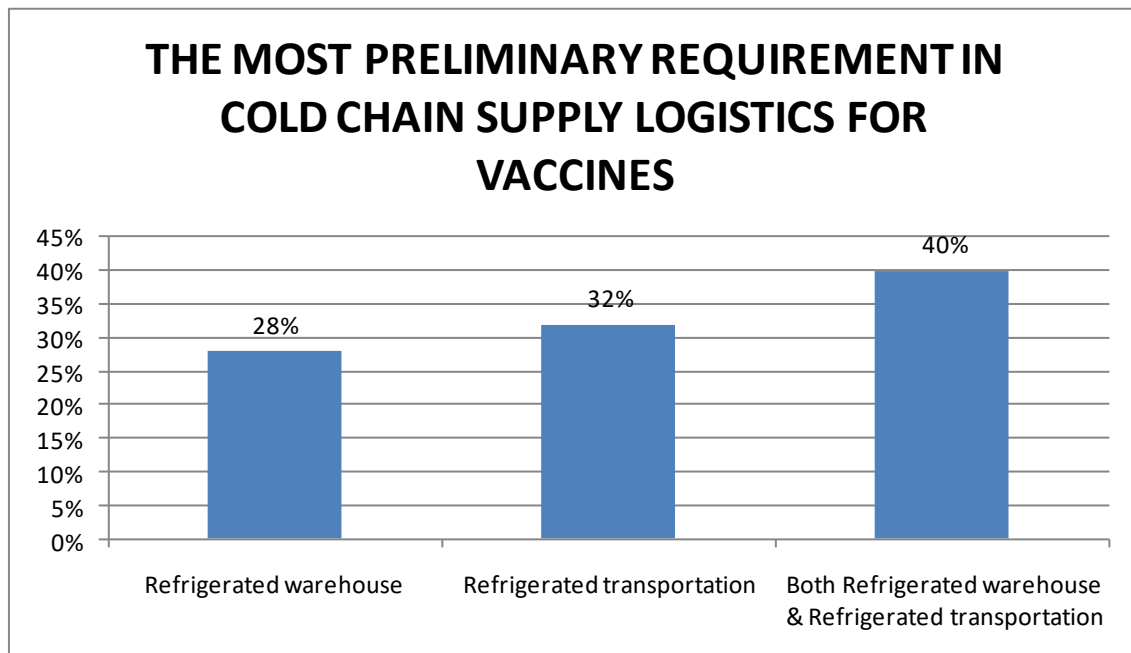
INFERENCE:

32% of the respondents mention that the incorrect use of the Vaccines Vial Monitor (VVM) as a management tool causes the major issue for the transport problems in cold chain supply logistics in pharmaceutical industry , 27% of the respondents mention that the lack of planning for emergencies causes the major issue for the transport problems in cold chain supply logistics in pharmaceutical industry, 25% of the respondents mention that the lack of planning for maintenance and cold chain rehabilitation causes the major issue for the transport problems in cold chain supply logistics in pharmaceutical industry, 16% of the respondents mention that the frequent breakdowns in cold chain causes the major issue for the transport problems in cold chain supply logistics in pharmaceutical industry.

TABLE 9 THE MOST PRELIMINARY REQUIREMENT IN COLD CHAIN SUPPLY LOGISTICS FOR VACCINES

Particulars	No. of Respondents	% of Respondents
Refrigerated warehouse	33	28
Refrigerated transportation	38	32
Both Refrigerated warehouse & Refrigerated transportation	47	40
Total	118	100

CHART 9



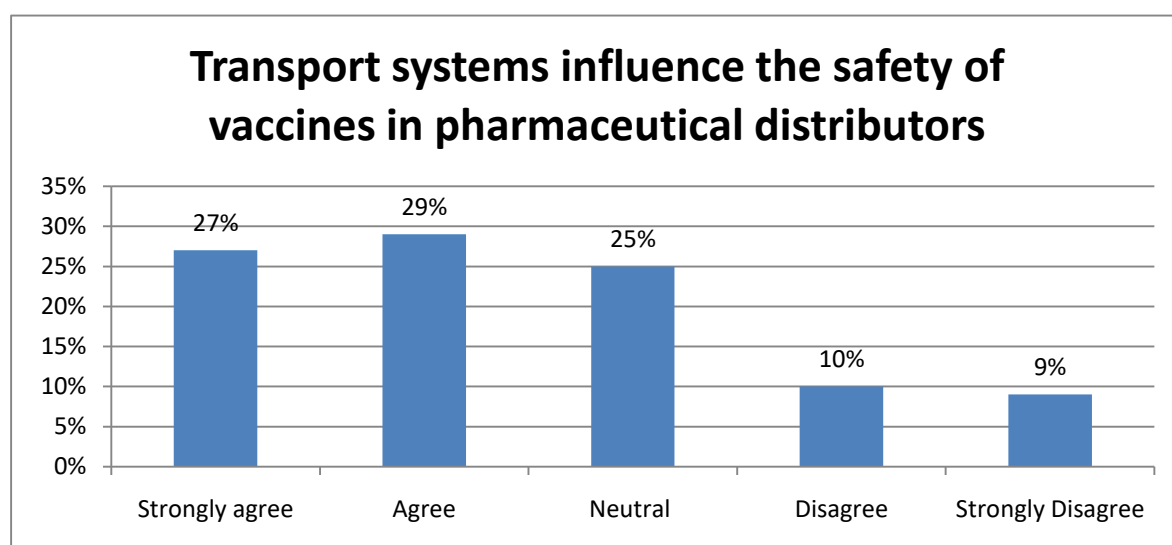
INFERENCE:

40% of the respondents preferred both the refrigerated warehouse & refrigerated transportation for the most preliminary requirement in cold chain supply logistics for vaccines, 32% of the respondents preferred the refrigerated transportation for the most preliminary requirement in cold chain supply logistics for vaccines, 28% of the respondents preferred the refrigerated warehouse for the most preliminary requirement in cold chain supply logistics for vaccines.

TABLE 10 TRANSPORT SYSTEMS INFLUENCE THE SAFETY OF VACCINES IN PHARMACEUTICAL DISTRIBUTORS

Particulars	No. of Respondents	% of Respondents
Strongly agree	32	27
Agree	34	29
Neutral	29	25
Disagree	12	10
Strongly Disagree	11	9
Total	118	100

CHART 10



INFERENCE:

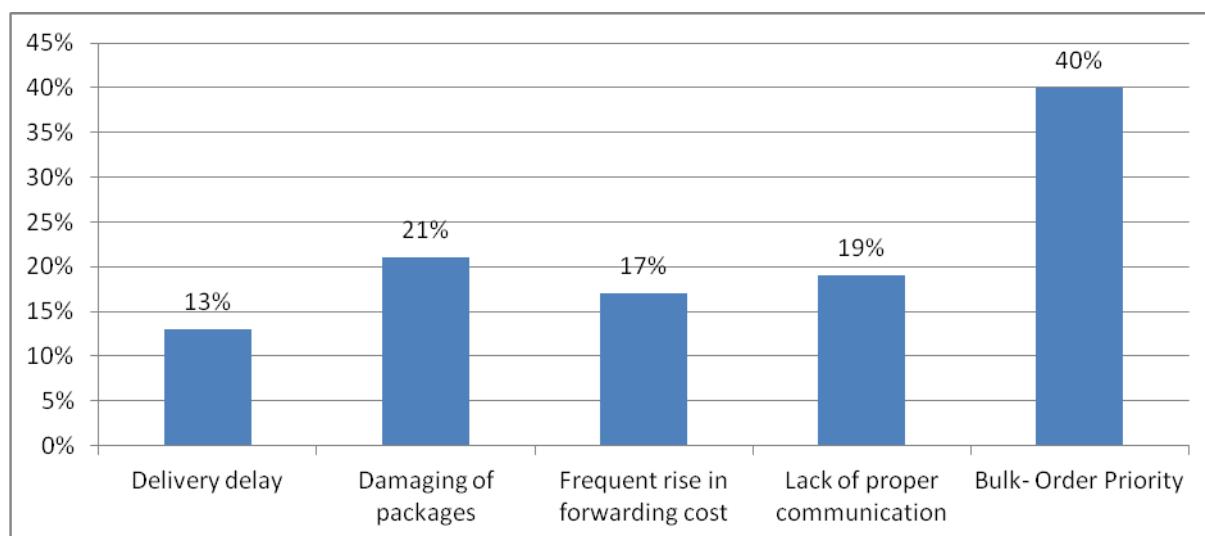
29% of the respondents agreed with the transport systems which influence the safety of vaccines in pharmaceutical distributors, 27% of the respondents strongly agree with the transport systems which influence the safety of vaccines in pharmaceutical distributors, 25% of the respondents neutrally agreed with the transport systems which influence the safety of vaccines in pharmaceutical distributors, 10% of the respondents Disagreed with the transport systems which influence the safety of vaccines in pharmaceutical distributors, 9% of the

respondents Strongly Disagreed with the transport systems which influence the safety of vaccines in pharmaceutical distributors.

TABLE 11 RANKS THE PROBLEMS FACED FROM CARRIERS DURING COLD CHAIN SUPPLY LOGISTICS IN MAINTAINING THE SAFETY OF VACCINES

Particulars	No. of Respondents	% of Respondents
Delivery delay	15	13
Damaging of packages	24	21
Frequent rise in forwarding cost	20	17
Lack of proper communication	22	19
Bulk- Order Priority	47	40
Total	118	100

CHART 11



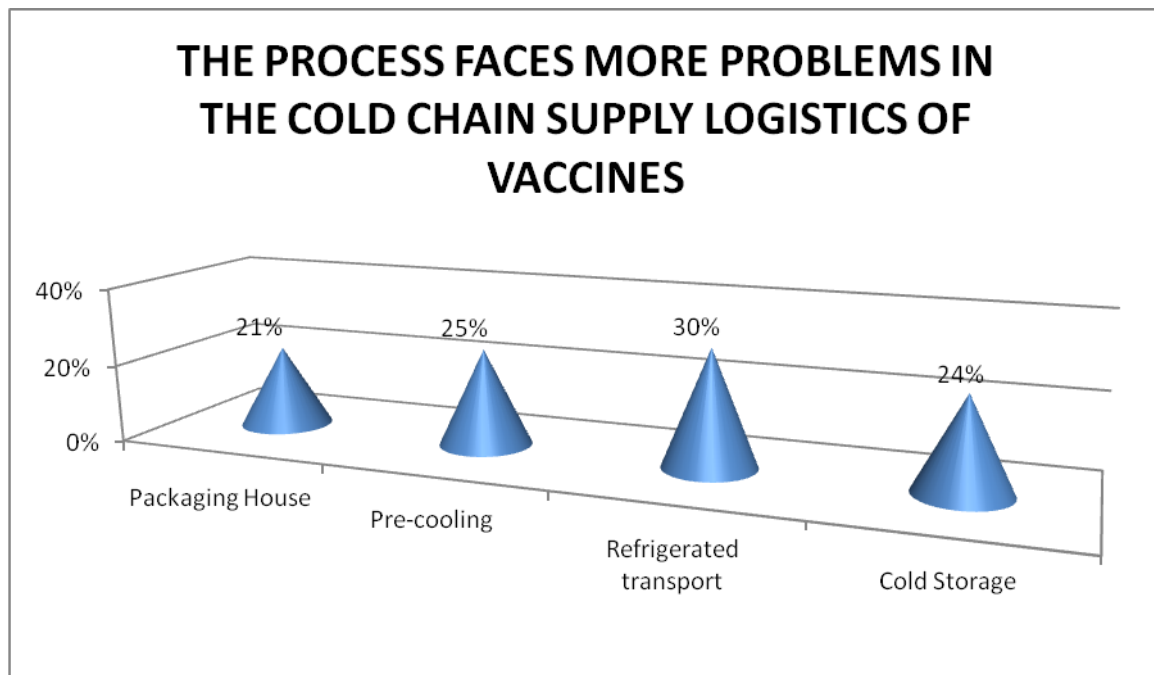
INFERENCE:

40% of the respondents rank no 1 for Bulk- Order Priority which causes the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines, 21% of the respondents rank no 2 for damaging of packages which causes the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines, 19% of the respondents rank no 3 for lack of proper communication which causes the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines, 17% of the respondents rank no 4 for frequent rise in forwarding cost which causes the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines, 13% of the respondents rank no 5 for delivery delay which causes the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines.

TABLE 12 THE PROCESS FACES MORE PROBLEMS IN THE COLD CHAIN SUPPLY LOGISTICS OF VACCINES

Particulars	No. of Respondents	% of Respondents
Packaging House	25	21
Pre-cooling	30	25
Refrigerated transport	35	30
Cold Storage	28	24
Total	118	100

CHART 12



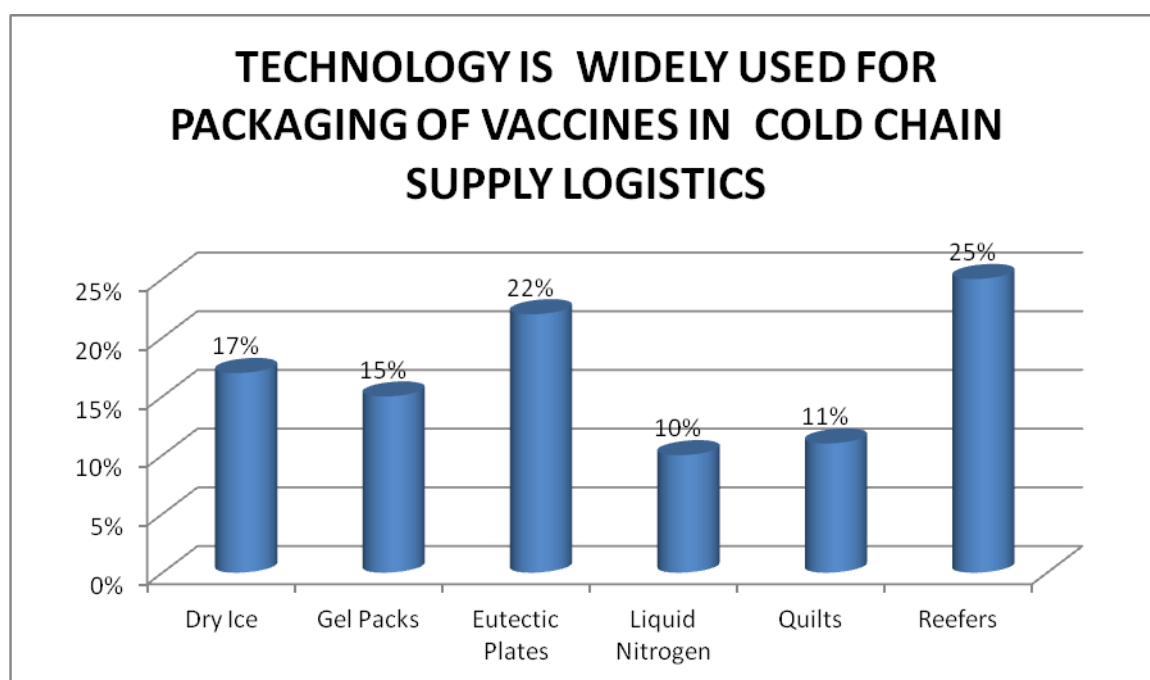
INFERENCE:

30% of the respondents say that the refrigerated transport process faces more problems in the cold chain supply logistics of vaccines, 25% of the respondents say that the pre-cooling transport process faces more problems in the cold chain supply logistics of vaccines, 24% of the respondents say that the cold storage transport process faces more problems in the cold chain supply logistics of vaccines, 21% of the respondents say that the packaging house transport process faces more problems in the cold chain supply logistics of vaccines.

**TABLE 13 TECHNOLOGIES IS WIDELY USED FOR PACKAGING OF VACCINES
IN COLD CHAIN SUPPLY LOGISTICS**

Particulars	No. of Respondents	% of Respondents
Dry Ice	20	17
Gel Packs	18	15
Eutectic Plates	26	22
Liquid Nitrogen	12	10
Quilts	13	11
Reefers	29	25
Total	118	100

CHART 13



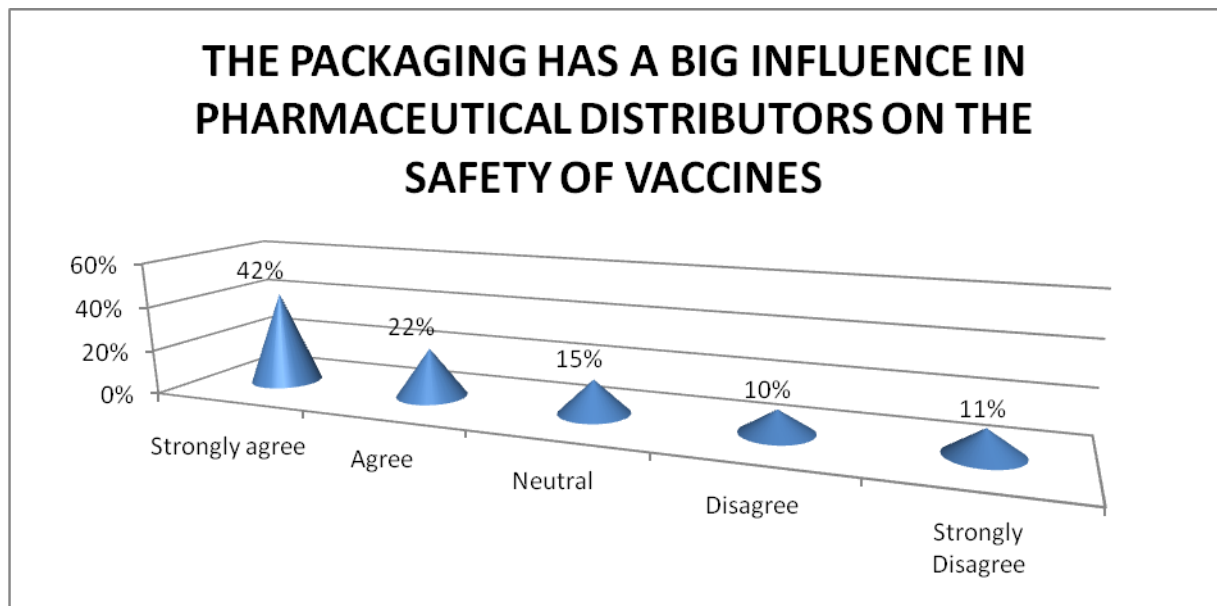
INFERENCE:

25% of the respondents say that Reefers is widely used for packaging of vaccines in cold chain supply logistics , 22% of the respondents say that Eutectic Plates is widely used for packaging of vaccines in cold chain supply logistics ,17% of the respondents say that Dry Ice is widely used for packaging of vaccines in cold chain supply logistics, 15% of the respondents say that Gel Packs is widely used for packaging of vaccines in cold chain supply logistics, 11% of the respondents say that Quilts is widely used for packaging of vaccines in cold chain supply logistics, 10% of the respondents say that Liquid Nitrogen is widely used for packaging of vaccines in cold chain supply logistics.

TABLE 14 THE PACKAGING HAS A BIG INFLUENCE IN PHARMACEUTICAL DISTRIBUTORS ON THE SAFETY OF VACCINES

Particulars	No. of Respondents	% of Respondents
Strongly agree	49	42
Agree	26	22
Neutral	18	15
Disagree	12	10
Strongly Disagree	13	11
Total	118	100

CHART 14



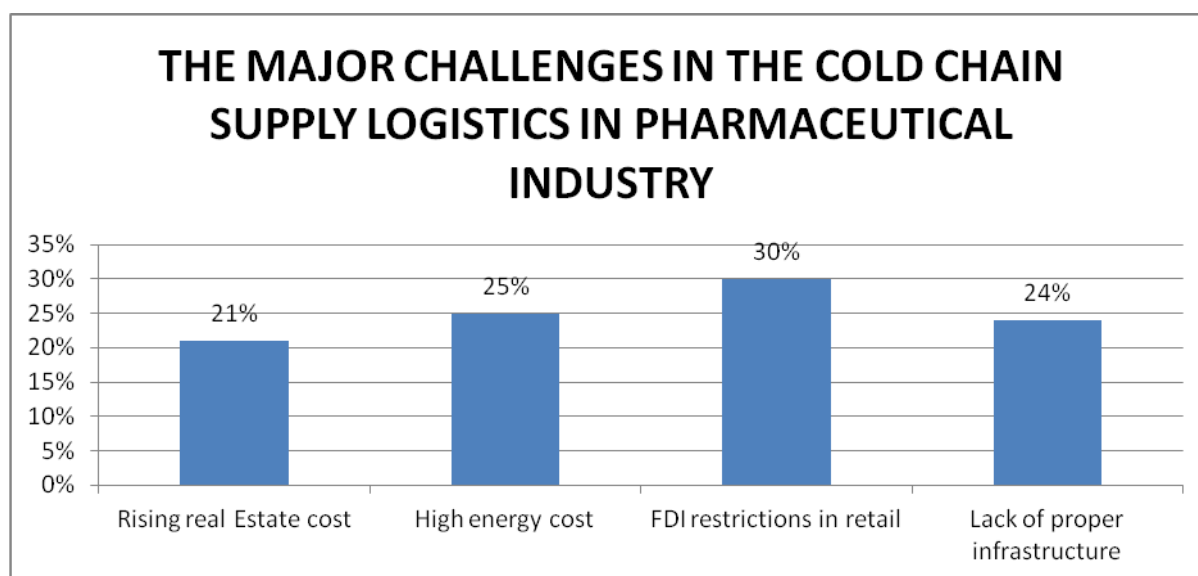
INFERENCE:

42% of the respondents strongly agreed that the packaging has a big influence in pharmaceutical distributors on the safety of vaccines, 22% of the respondents agreed that the packaging has a big influence in pharmaceutical distributors on the safety of vaccines, 15% of the respondents neutrally agreed that the packaging has a big influence in pharmaceutical distributors on the safety of vaccines, 11% of the respondents strongly disagreed that the packaging has a big influence in pharmaceutical distributors on the safety of vaccines, 10% of the respondents disagreed that the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.

TABLE 15 THE MAJOR CHALLENGES IN THE COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No. of Respondents	% of Respondents
Rising real Estate cost	25	21
High energy cost	30	25
FDI restrictions in retail	35	30
Lack of proper infrastructure	28	24
Total	118	100

CHART 15



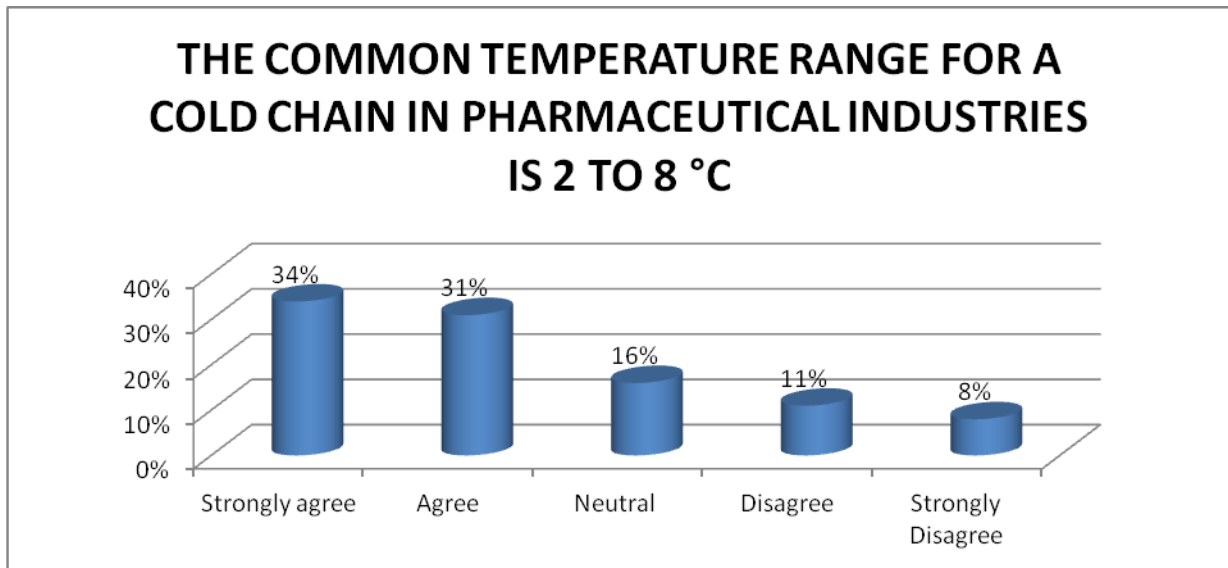
INFERENCE:

30% of the respondents say that FDI restrictions in retail is the major challenges in the cold chain supply logistics in pharmaceutical industry, 25% of the respondents say that high energy cost is the major challenges in the cold chain supply logistics in pharmaceutical industry, 24% of the respondents say that lack of proper infrastructure is the major challenges in the cold chain supply logistics in pharmaceutical industry, 21% of the respondents say that rising real estate cost is the major challenges in the cold chain supply logistics in pharmaceutical industry.

TABLE 16 THE COMMON TEMPERATURE RANGE FOR A COLD CHAIN IN PHARMACEUTICAL INDUSTRIES IS 2 TO 8 °C

Particulars	No. of Respondents	% of Respondents
Strongly agree	40	34
Agree	36	31
Neutral	19	16
Disagree	13	11
Strongly Disagree	10	8
Total	118	100

CHART 16



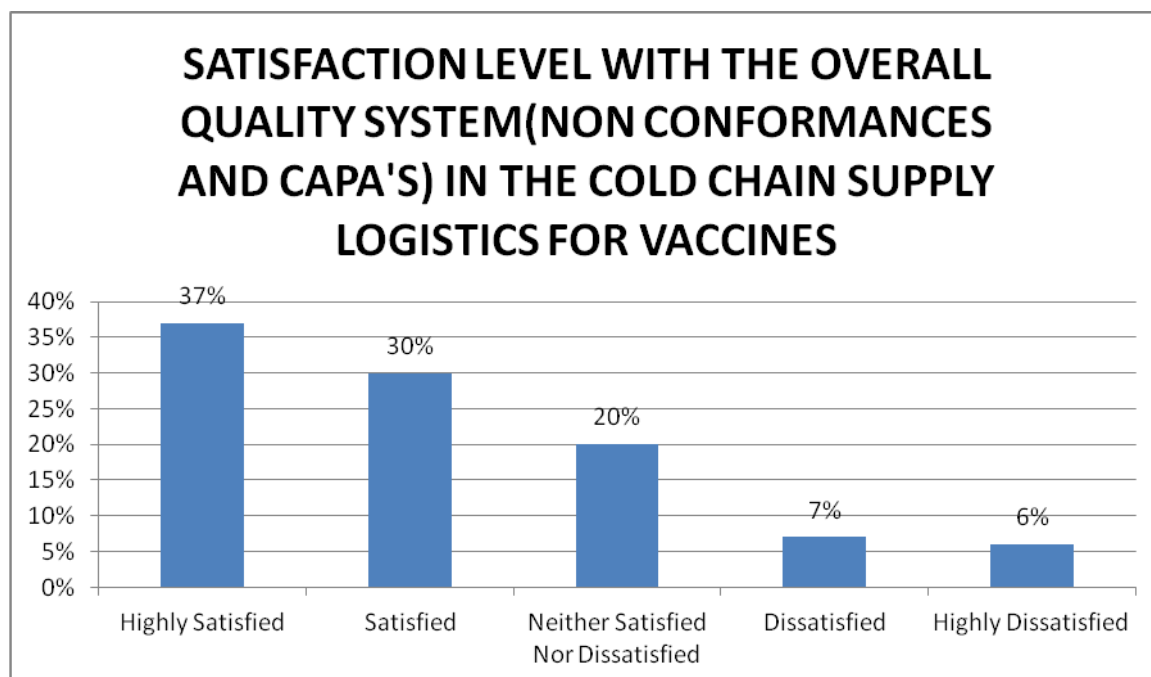
INFERENCE:

34% of the respondents strongly agree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °c, 31% of the respondents agree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °c, 16% of the respondents neutrally agree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °c, 11% of the respondents disagree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °c, 8% of the respondents strongly disagree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °c.

**TABLE 17 SATISFACTION LEVEL WITH THE OVERALL QUALITY SYSTEM
(NON CONFORMANCES AND CAPA'S) IN THE COLD CHAIN SUPPLY
LOGISTICS FOR VACCINES**

Particulars	No. of Respondents	% of Respondents
Highly Satisfied	44	37
Satisfied	35	30
Neither Satisfied Nor Dissatisfied	24	20
Dissatisfied	8	7
Highly Dissatisfied	7	6
Total	118	100

CHART 17

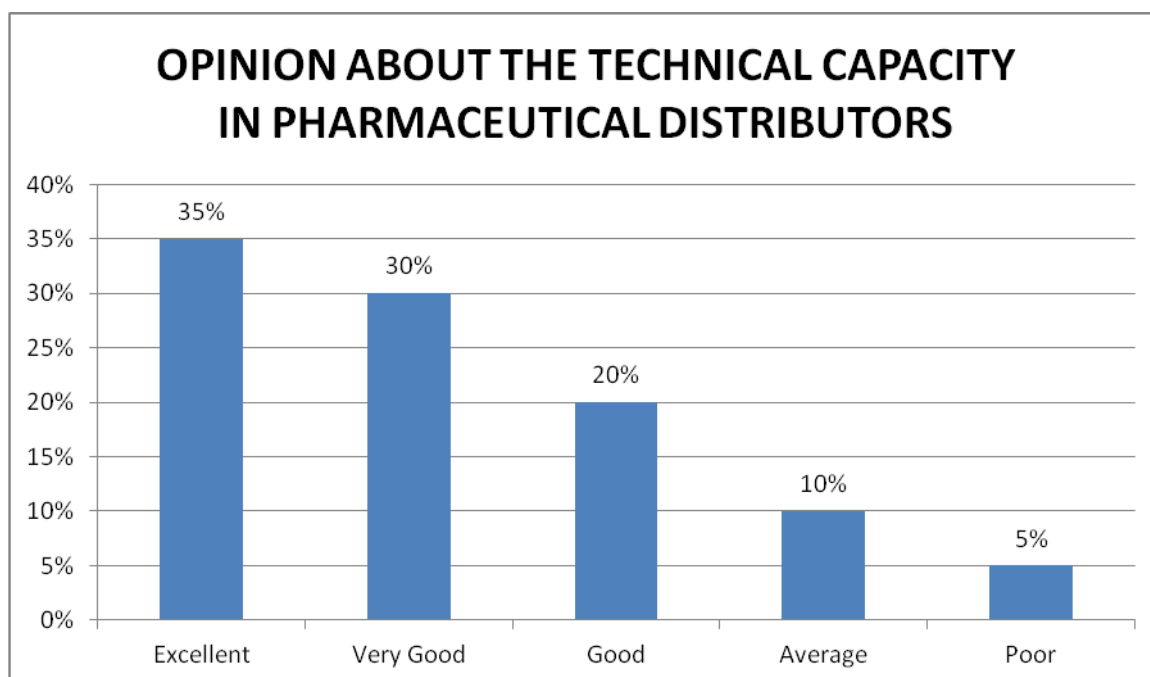


INFERENCE:

37% of the respondents are Highly Satisfied with the overall quality system(non conformances and capa's) in the cold chain supply logistics for vaccines, 30% of the respondents are Satisfied with the overall quality system(non conformances and capa's) in the cold chain supply logistics for vaccines, 20% of the respondents are Neither Satisfied Nor Dissatisfied with the overall quality system(non conformances and capa's) in the cold chain supply logistics for vaccines, 7% of the respondents are Dissatisfied with the overall quality system(non conformances and capa's) in the cold chain supply logistics for vaccines, 6% of the respondents are Highly Dissatisfied with the overall quality system(non conformances and capa's) in the cold chain supply logistics for vaccines.

TABLE 18 OPINION ABOUT THE TECHNICAL CAPACITY IN PHARMACEUTICAL DISTRIBUTORS

Particulars	No. of Respondents	% of Respondents
Excellent	41	35
Very Good	35	30
Good	24	20
Average	12	10
Poor	6	5
Total	118	100

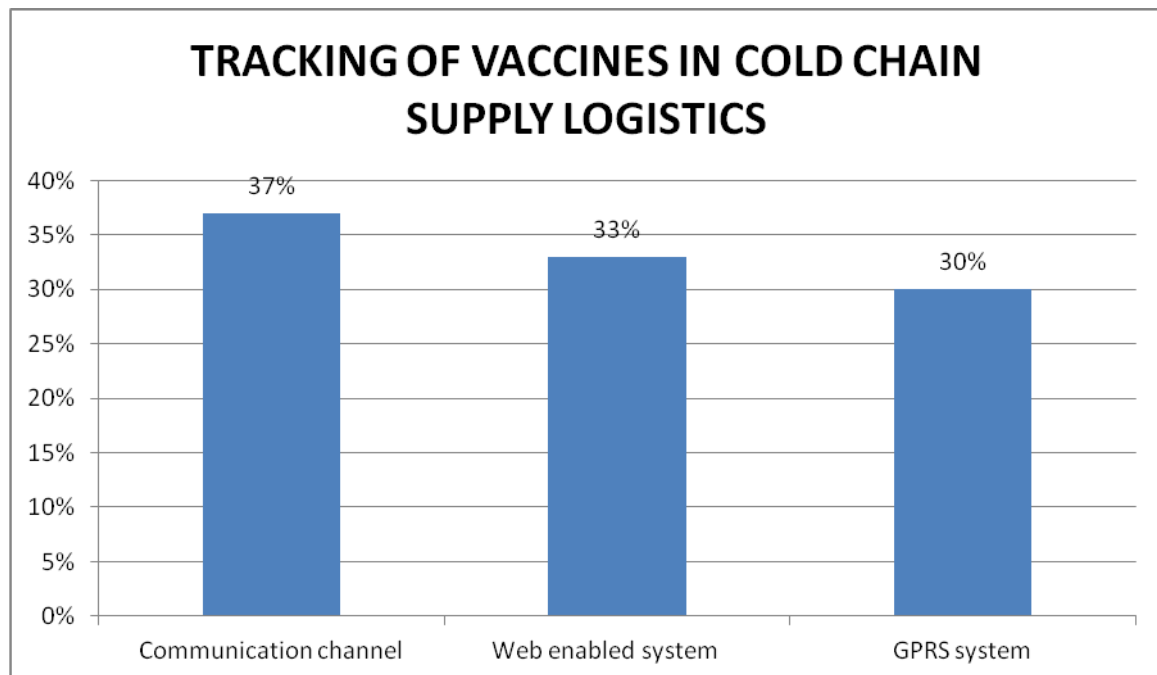
CHART 18**INFERENCE:**

35% of the respondents have an excellent opinion about the technical capacity in pharmaceutical distributors, 30% of the respondents have a very good opinion about the technical capacity in pharmaceutical distributors, 20% of the respondents have a good opinion about the technical capacity in pharmaceutical distributors, 10% of the respondents have an average opinion about the technical capacity in pharmaceutical distributors, 5% of the respondents have a poor opinion about the technical capacity in pharmaceutical distributors.

TABLE 19 TRACKING OF VACCINES IN COLD CHAIN SUPPLY LOGISTICS

Particulars	No. of Respondents	% of Respondents
Communication channel	44	37
Web enabled system	39	33
GPRS system	35	30
Total	118	100

CHART 19



INFERENCE:

37% of the respondents prefer the communication channel for tracking of vaccines in cold chain supply logistics, 33% of the respondents prefer the web enabled system for tracking of vaccines in cold chain supply logistics, 30% of the respondents prefer the GPRS system for tracking of vaccines in cold chain supply logistics.

STATISTICAL TOOLS AND ANALYSIS

CHI- SQUARE TEST I – (ψ^2)

Chi-square is the sum of the squared difference observed (o) and the expected (e) data (or the deviation, d), divided by the expected data in all possible categories.

Null hypothesis (Ho):

There is a relationship between the Experience and Income.

Alternate hypothesis (H1):

There is no relationship between the Experience and Income.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
EXPERIENCE * INCOME	118	100.0%	0	0.0%	118	100.0%

EXPERIENCE * INCOME Crosstabulation

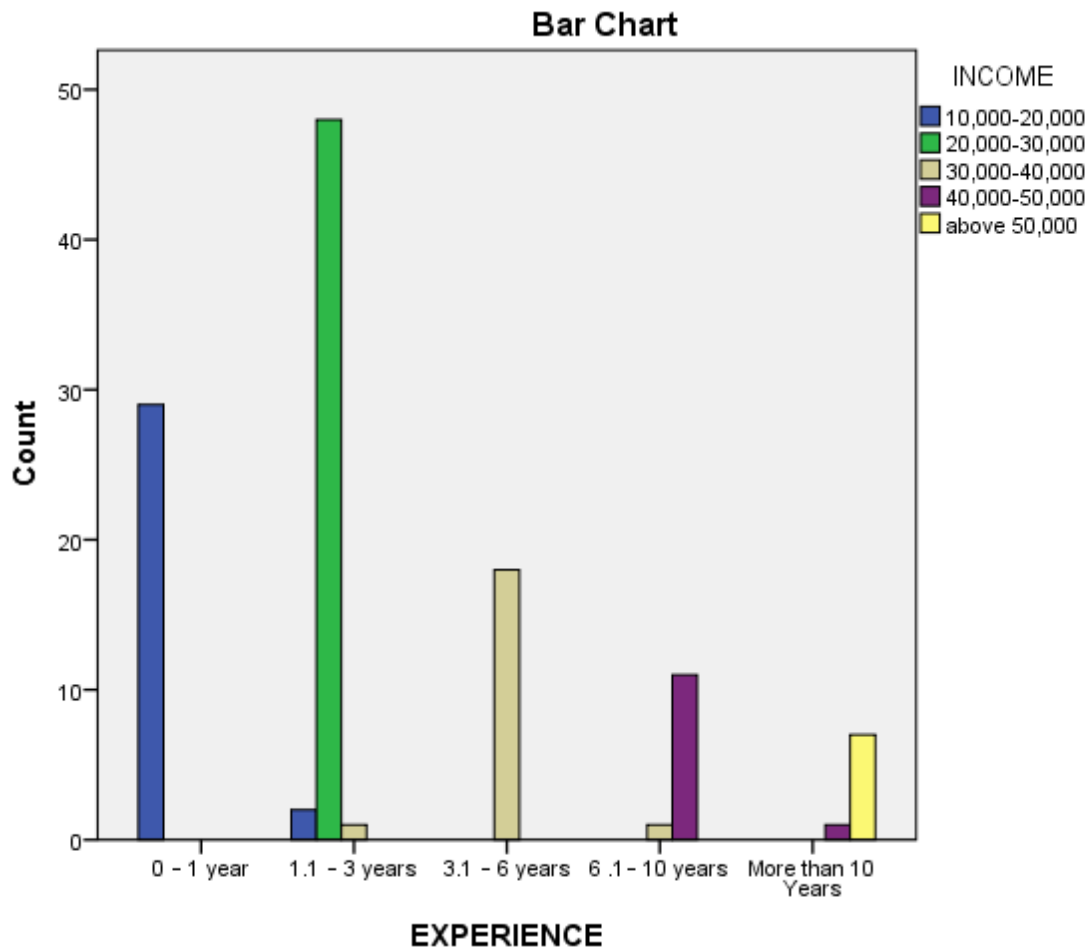
			INCOME					Total
			10,000-20,000	20,000-30,000	30,000-40,000	40,000-50,000	above 50,000	
EXPERIENCE	0 – 1 year	Count	29	0	0	0	0	29
		% within EXPERIENCE	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
		% within INCOME	93.5%	0.0%	0.0%	0.0%	0.0%	24.6%
	1.1 – 3 years	% of Total	24.6%	0.0%	0.0%	0.0%	0.0%	24.6%
		Count	2	48	1	0	0	51
		% within EXPERIENCE	3.9%	94.1%	2.0%	0.0%	0.0%	100.0%
		% within INCOME	6.5%	100.0%	5.0%	0.0%	0.0%	43.2%
	3.1 – 6 years	% of Total	1.7%	40.7%	0.8%	0.0%	0.0%	43.2%
		Count	0	0	18	0	0	18
		% within EXPERIENCE	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%
	6.1 – 10 years	% within INCOME	0.0%	0.0%	90.0%	0.0%	0.0%	15.3%
		% of Total	0.0%	0.0%	15.3%	0.0%	0.0%	15.3%
		Count	0	0	1	11	0	12

Total	More than 10 Years	% within EXPERIENCE	0.0%	0.0%	8.3%	91.7%	0.0%	100.0 %
		% within INCOME	0.0%	0.0%	5.0%	91.7%	0.0%	10.2%
		% of Total	0.0%	0.0%	0.8%	9.3%	0.0%	10.2%
		Count	0	0	0	1	7	8
		% within EXPERIENCE	0.0%	0.0%	0.0%	12.5%	87.5%	100.0 %
		% within INCOME	0.0%	0.0%	0.0%	8.3%	100.0%	6.8%
		% of Total	0.0%	0.0%	0.0%	0.8%	5.9%	6.8%
		Count	31	48	20	12	7	118
		% within EXPERIENCE	26.3%	40.7%	16.9%	10.2%	5.9%	100.0 %
		% within INCOME	100.0%	100.0%	100.0%	100.0%	100.0%	100.0 %
		% of Total	26.3%	40.7%	16.9%	10.2%	5.9%	100.0 %

Chi-Square Tests

	Value	df	Asymp. Sig. (2- sided)
Pearson Chi-Square	414.184 ^a	16	.000
Likelihood Ratio	295.079	16	.000
Linear-by-Linear Association	113.297	1	.000
N of Valid Cases	118		

a. 18 cells (72.0%) have expected count less than 5. The minimum expected count is .47.



Degree of Freedom= $(r-1) * (c-1)$

$$= 4 * 4 = 16$$

Calculated value = 414.184

Tabulated value = 26.296

$Z = Z_{cal} > Z_{tab}$

$$Z = 414.184 > 26.296$$

Hence, the Alternate hypothesis $[H_1]$ is accepted

INFERENCE:

Since the calculated value is greater than the tabulated value, we accept the alternate hypothesis and hence there is a relationship between the Experience and Income.

ONE-WAY ANOVA CLASSIFICATION

Null hypothesis (Ho):

There is a significance difference between the Transport systems influence the safety of vaccines in pharmaceutical distributors and the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.

Alternate hypothesis (H1):

There is no significance difference between the Transport systems influence the safety of vaccines in pharmaceutical distributors and the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.

Descriptives

TRANSPORT SYSTEMS INFLUENCE THE SAFETY OF VACCINES IN PHARMACEUTICAL DISTRIBUTORS

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Strongly agree	49	1.35	.481	.069	1.21	1.49	1	2
Agree	26	2.35	.485	.095	2.15	2.54	2	3
Neutral	18	3.00	.000	.000	3.00	3.00	3	3
Disagree	12	3.83	.389	.112	3.59	4.08	3	4
Strongly Disagree	13	4.85	.376	.104	4.62	5.07	4	5
Total	118	2.46	1.252	.115	2.23	2.69	1	5

Test of Homogeneity of Variances

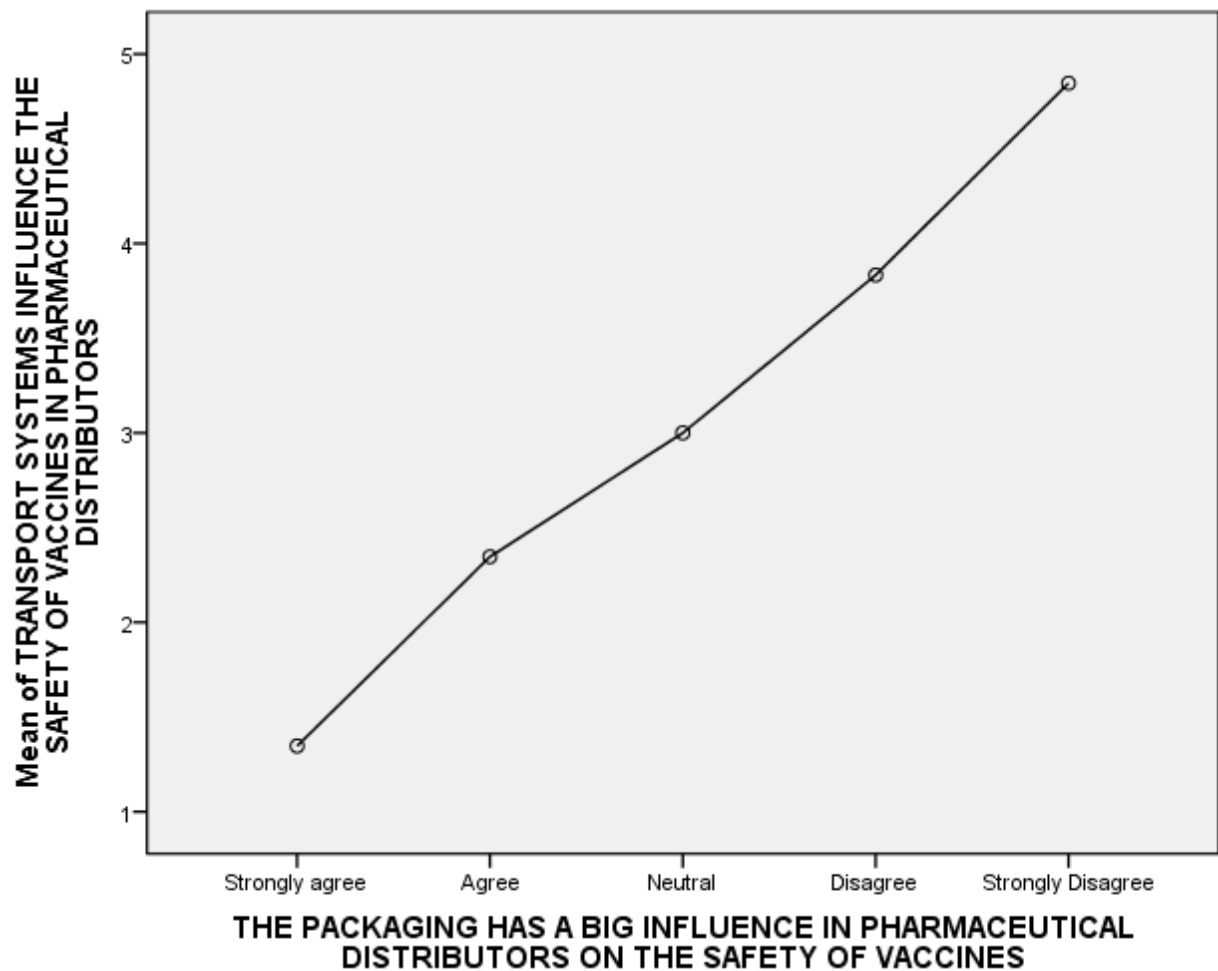
TRANSPORT SYSTEMS INFLUENCE THE SAFETY OF VACCINES IN PHARMACEUTICAL DISTRIBUTORS

Levene Statistic	df1	df2	Sig.
28.384	4	113	.000

ANOVA

TRANSPORT SYSTEMS INFLUENCE THE SAFETY OF VACCINES IN
PHARMACEUTICAL DISTRIBUTORS

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	162.943	4	40.736	226.246	.000
Within Groups	20.346	113	.180		
Total	183.288	117			



Calculated value = 226.246

Tabulated value = 2.47

$F = F_{cal} > F_{tab}$ $F = 226.246 > 2.47$

Hence, the Alternate hypothesis [H1] is accepted.

INFERENCE:

The calculated value of F is greater than the tabulated value. Hence, we reject the null hypothesis and conclude that there is no significance difference between the Transport systems influence the safety of vaccines in pharmaceutical distributors and the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.

ANALYSIS USING KARL PEARSON'S CORRELATION

Correlation analysis is the statistical tool used to measure the degree to which two variables are linearly related to each other. Correlation measures the degree of association between two variables.

Null hypothesis (H0):

There is positive relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

Alternate hypothesis (H1):

There is negative relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

		THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY
THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	Pearson Correlation Sig. (2-tailed) N	1 118	.910** .000 118
THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	Pearson Correlation Sig. (2-tailed) N	.910** .000 118	1 118

** . Correlation is significant at the 0.01 level (2-tailed).

$$r = \frac{N\sum XY - \sum X \sum Y}{\sqrt{N\sum X^2 - (\sum X)^2} \sqrt{N\sum Y^2 - (\sum Y)^2}}$$

r= .910

INFERENCE:

Since r is positive, there is positive relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

CHAPTER 5

5.1 FINDINGS:

- 31% of the respondents belong to the age group between 20-30.
- 70% of the respondents are male.
- 28 % of the respondents are graduate.
- 43% of the respondents have 1.1 – 3 years of experience.
- 41% of the respondents income range between Rs.20,000-30,000.
- 35% of the respondents say that maintain the temperature level for the vaccines.
- 31% of the respondents are Increase customer satisfaction.
- 32% of the respondents are incorrect use of the Vaccines Vial Monitor (VVM) as a management tool.
- 40% of the respondents are Both Refrigerated warehouse & Refrigerated transportation.
- 29% of the respondents are Agree with Transport systems influence the safety of vaccines in pharmaceutical distributors.
- 40% of the respondents are Bulk- Order Priority.
- 30% of the respondents are Refrigerated transport.
- 25% of the respondents are Reefers.
- 42% of the respondents are Strongly agree with the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.
- 30% of the respondents are FDI restrictions in retail.
- 34% of the respondents are Strongly agree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °c.
- 37% of the respondents are Highly Satisfied with the overall quality system(non conformances and capa's) in the cold chain supply logistics for vaccines.
- 35% of the respondents having Excellent opinion about the technical capacity in pharmaceutical distributors.
- 37% of the respondents are Communication channel.

5.2 SUGGESTIONS

1. International Shipping Corporation has to improve their planning for emergencies
2. Necessary measures need to be taken for maintenance and cold chain rehabilitation
3. Frequent breakdowns in cold chain has be avoided to improve the overall efficiency of cold chain logistics in handling pharmaceutical products
4. Frequent rise in forwarding cost can be avoided by owning the cold chain transportation and the cold storage.
5. Government can take suitable actions to reduce the high energy cost. This will help International Shipping Corporation involved in cold chain logistics to reduce their cost. When both the cost reductions happen, the end customers can avail the pharmaceutical products for a lesser price
6. Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool has be avoided. Proper process has to be followed during the overall cold chain logistics for vaccines.

5.3 CONCLUSION

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. There have been numerous events where vaccines have been shipped to third world countries with little to no cold chain infrastructure (Sub-Sahara Africa) where the vaccines were inactivated due to excess exposure to heat. This study has been undertaken to assess the feasibility in handling the pharmaceutical products like vaccines in cold chain logistics with special reference to International Shipping Corporation. For this purpose, responses from the members involved in cold chain logistics have been collected and analyzed. Based upon the findings out of the research, few valuable suggestions like proper use of Vaccines

Vial Monitor (VVM) as a management tool, improve the planning for emergencies etc have been suggested to International Shipping Corporation. These suggestions will pave way for improving the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines.

ANNEXURE

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- [1.] **Cooper, M. C., and L. M. Ellram. 1993.** Characteristics of Supply Chain Management and the Implications for Purchasing and Logistics Strategy. *The International Journal of Logistics Management*, 4, 2, 13-24.
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QUESTIONNAIRE

DEMOGRAPHIC:

1. Age: a) 20-30 b) 30-40 c) 40-50 d) above 50

2. Gender A) Male B) Female

3. Educational Qualification: a) Graduate b) Post Graduate c) ITI d) Diploma

4. Experience

a) 0 – 1 year b) 1.1 – 3 years c) 3.1 – 6 years d) 6 .1– 10 years e) More than 10 Years

5. Income:

a) 10,000-20,000 b) 20,000-30,000 c) 30,000-40,000 d) 40,000-50,000 e) above 50,000

6. What is the major purpose of cold chain supply logistics in pharmaceutical industry?

f. Longevity of the medical characteristics

g. Maintain the temperature level for the vaccines

h. Retain the nutritional value

i. Maintain the chemical substance

7. What is the main objective of cold chain supply logistics in pharmaceutical industry?

- a. Reduce costs
- b. Reduce wastage and return of expired stock
- c. Improve product integrity
- d. Increase customer satisfaction

8. What is the major issue for the transport problems in cold chain supply logistics in pharmaceutical industry?

- a. Lack of planning for maintenance and cold chain rehabilitation
- b. Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool
- c. Lack of planning for emergencies
- d. Frequent breakdowns in cold chain

9. Which is the most preliminary requirement in cold chain supply logistics for vaccines?

- a. Refrigerated warehouse
- b. Refrigerated transportation
- c. Both Refrigerated warehouse & Refrigerated transportation

10. Transport systems influence the safety of vaccines in pharmaceutical distributors?

- i. Strongly agree
- ii. Agree
- iii. Neutral
- iv. Disagree
- v. Strongly Disagree

11. Rank the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines?

S.No	Variables	Rank
1	Delivery delay	
2	Damaging of packages	
3	Frequent rise in forwarding cost	
4	Lack of proper communication	
5	Bulk- Order Priority	

12. Which process faces more problems in the cold chain supply logistics of vaccines?

- a. Packaging House
- b. Pre-cooling
- c. Refrigerated transport
- d. Cold Storage

13. Which technology is most widely used for packaging of vaccines in cold chain supply logistics?

- a. Dry Ice
- b. Gel Packs
- c. Eutectic Plates
- d. Liquid Nitrogen
- e. Quilts
- f. Reefers

14. Packaging has a big influence in pharmaceutical distributors on the safety of vaccines?

- i. Strongly agree
- ii. Agree
- iii. Neutral
- iv. Disagree
- v. Strongly Disagree

15. What are the major challenges in the cold chain supply logistics in pharmaceutical industry?

- a. Rising real Estate cost
- b. High energy cost
- c. FDI restrictions in retail
- d. Lack of proper infrastructure

16. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C

- i. Strongly agree
- ii. Agree
- iii. Neutral
- iv. Disagree
- v. Strongly Disagree

17. What is overall satisfaction level with the overall Quality System(Non Conformances and CAPA's) in the cold chain supply logistics for vaccines?

Highly Satisfied	Satisfied	Neither Satisfied Nor	Dissatisfied	Highly Dissatisfied
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		Dissatisfied		
1	2	3	4	5

18. What is your opinion about the technical capacity in pharmaceutical distributors influence safety of Vaccines?

- a. Excellent
- b. Very Good
- c. Good
- d. Average
- e. Poor

19. Tracking of vaccines in cold chain supply logistics is done by

- a) Communication channel
- b) Web enabled system
- c) GPRS system

20. Any suggestions to improve the overall effectiveness of cold chain supply logistics on safety of vaccines in pharmaceutical distributors?

THANK YOU

ANNEXURE II – RESEARCH ARTICLE

FEASIBILITY STUDY ON HANDLING PHARMACEUTICALS IN COLD CHAIN LOGISTICS WITH REFERENCE TO INTERNATIONAL SHIPPING CORPORATION

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DR. JOHN BRITTO, Associate professor, MBA department, Sathyabama University

ABSTRACT

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate. Through this study, the researcher tries to identify the key areas to be enhanced to improve the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines. The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines in pharmaceutical distributors. The other objectives are to determine how storage conditions in pharmaceutical distributors influences safety of vaccines, evaluate the influence of packaging in pharmaceutical distributors on the safety of vaccines and to establish the extent to which technical capacity in pharmaceutical distributors influence safety of Vaccines.

INTRODUCTION

A cold chain is a monitored temperature-controlled supply chain. The goal of the cold chain is to keep a sample or material within a certain temperature range during all stages of delivery, processing and storage .Cold chains are widely used to ensure the viability of products in the pharmaceutical and agricultural sectors, and are critical components of vaccination programs and bio-medical surveillance activities. Many biological samples deteriorate when exposed to heat, sunlight, or fluorescent light. When transporting and storing such biological

substances, it is imperative that field and laboratory teams control environmental conditions, ensuring that exposure to potentially damaging environmental factors is minimized.

The cold storage, handling, and distribution of temperature-sensitive drugs represent an increasingly important component of the global pharmaceutical supply chain. Clinical trial material (CTM) or investigational medicinal products (IMP) are an important part of the earliest stages of the life science supply chain. Given the increased number of global regulatory and standards-based guidance documents issued over the past two years, members of the pharmaceutical supply chain are taking notice and making changes to ensure product quality and protect patient safety. The purpose of this paper is to review the various factors affecting Good Cold Chain Management Practices for Clinical Trial Materials/Investigational Medicinal Products.

OBJECTIVES OF THE STUDY

PRIMARY OBJECTIVE

The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines with special reference to International Shipping Corporation

SECONDARY OBJECTIVES

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

NEED FOR THE STUDY

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C. but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate.

Through this study, the researcher tries to identify the key areas to be enhanced to improve the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines with special reference to International Shipping Corporation

SCOPE OF THE STUDY

The major scope of the analysis on cold chain logistics in pharmaceuticals are

- a. To increase the longevity of the medical characteristics
- b. Maintain the temperature level for the vaccines
- c. Retain the nutritional value of vaccines
- d. Maintain the chemical substance of vaccines

Reduce wastage and return of expired stock of vaccines

REVIEW OF LITERATURE

Laboratory Cold Chains:

As medicine developed through the centuries the advances created the basis for diagnostic discoveries. In the latter part of the 19th century the clinical laboratory started to be established. By the turn of the century many specific chemical, haematological and bacteriological tests had been developed due to innovations in basic science (**Berger, 1999a**) enabling the clinical laboratory to be used for diagnostic purposes. Different types of laboratories started to emerge, including physiological, pharmaceutical, forensic, public health, clinical chemistry and microbiological (**Berger, 1999b**).

Laboratories developed similarly in Britain and the United States of America (USA) due to the influences of medical faculties in Europe (**Petts, 2012; Race, Tillery, & Dysert, 2004**). The number of laboratory tests available increased dramatically over the 20th century. The first half of the century was involved in developing individual biochemical methods for the variety of parameters that medical professionals were interested in such as ion concentration of elements in serum (Berger, 1999b). Because the refrigerator was not invented until the late 1910s to early 1920s these methods did not require refrigeration. Today the range of different analyses available is now well over 3000, and still increasing, although not all will be available at each laboratory (**Wians, 2009**).

Requests for laboratory investigations increased as medical professionals found the data useful in establishing diagnoses. The desire to have this data prior to treatment led to the expectation of faster turnaround times for testing (**Seligson, 1966**), so more efficient methodologies needed to be introduced. The first convenient and accurate kit-type diagnostic test, Clinitest®, was introduced in 1941 and measured reducing sugars in urine 3 (Chemical Heritage Foundation, 2010). This was followed by **Clinistix® in 1956**, the first dipstick which measured glucose in urine (**Chemical Heritage Foundation, 2010**).

RESEARCH METHODOLOGY

Research Design: The research design was based on descriptive study.

Sampling Design: Sample design is the theoretical basis and the practice means by generalizing from characteristics of relatively few of the comprising population.

Data Collection:

Primary Data: It is collected by Questionnaire and Personal Interview.

Secondary Data: It is collected from journals, organization records, Organization website.

Structure of Questionnaire: Multiple choice questions and Likert Scale question.

Sample size: Sample size of 118 employees

Period of study: The period of study is carried out from January 2023 to March 2023.

Analytical Tools: In this study Percentage Analysis, Chi-Square Analysis, Correlation, is used as analytical tools for analysis.

DATA ANALYSIS

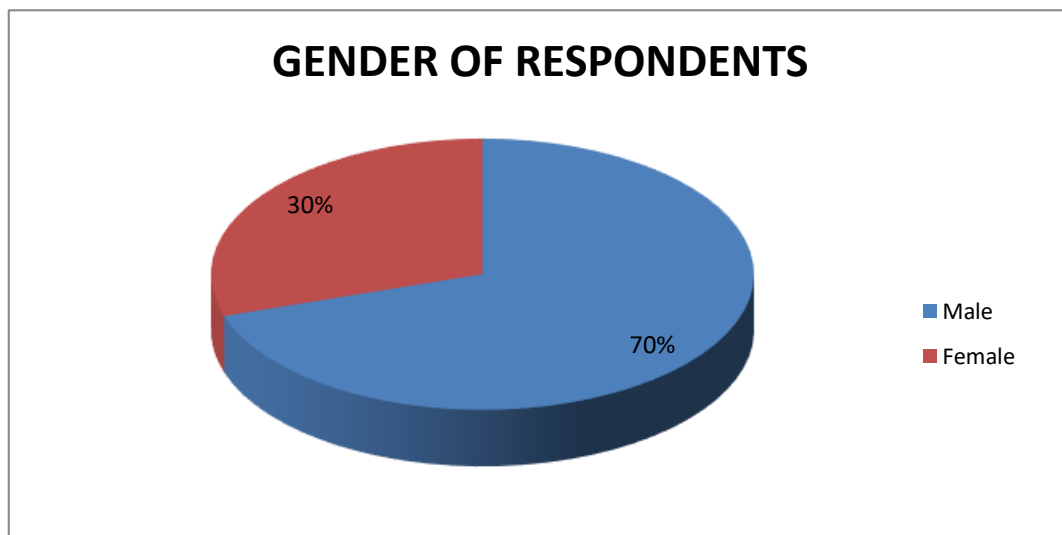
PERCENTAGE ANALYSIS:

Gender of the Respondents:

The following table shows the gender of the respondents and their frequencies in percentage

TABLE : GENDER

Gender	No. of Respondents	% of Respondents
Male	83	70%
Female	35	30%
Total	118	100%



INFERENCE:

70% of the respondents are male and 30% of the respondents are female.

CHI- SQUARE TEST I – (χ^2)

Chi-square is the sum of the squared difference observed (o) and the expected (e) data (or the deviation, d), divided by the expected data in all possible categories.

Null hypothesis (H_0):

There is a relationship between the Experience and Income.

Alternate hypothesis (H_1):

There is no relationship between the Experience and Income.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
EXPERIENCE * INCOME	118	100.0%	0	0.0%	118	100.0%

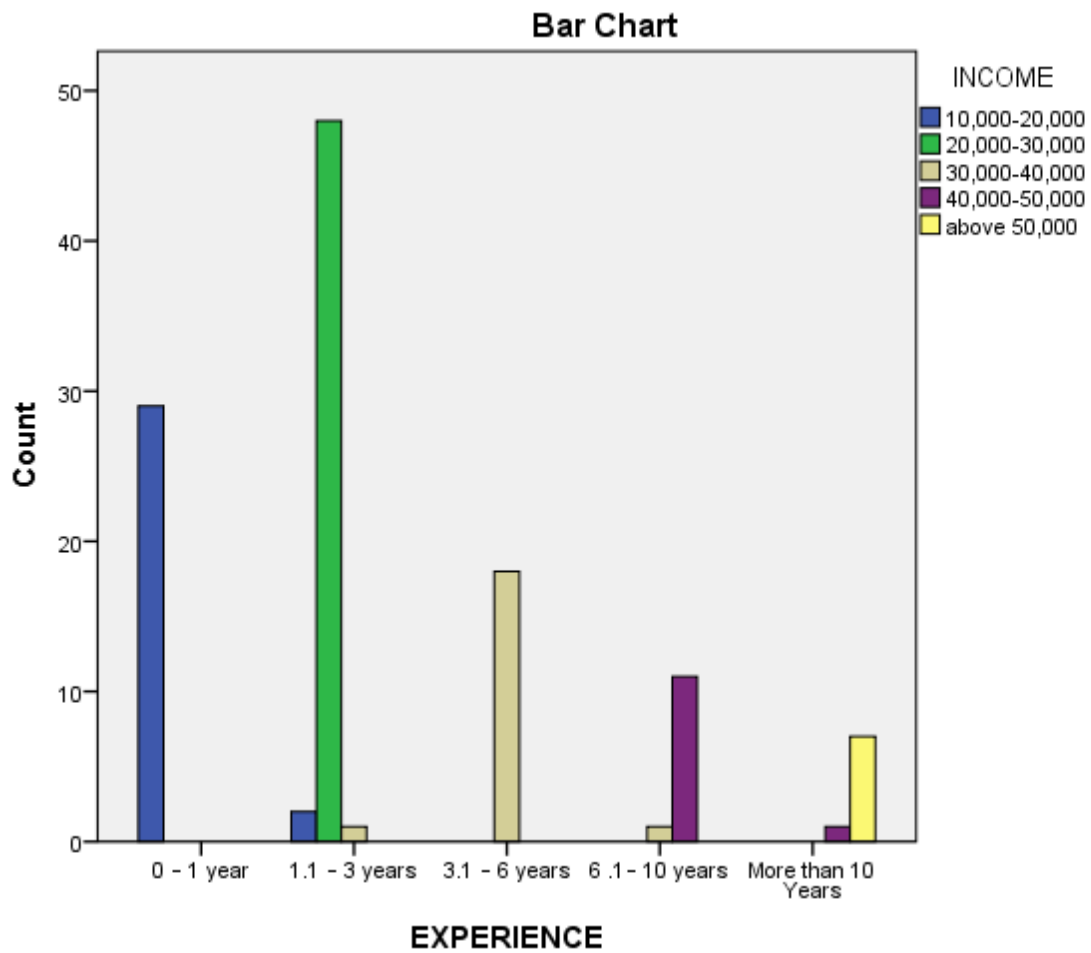
EXPERIENCE * INCOME Crosstabulation

			INCOME					Total
			10,000-20,000	20,000-30,000	30,000-40,000	40,000-50,000	above 50,000	
EXPERIENCE	0 – 1 year	Count	29	0	0	0	0	29
		% within EXPERIENCE	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
		% within INCOME	93.5%	0.0%	0.0%	0.0%	0.0%	24.6%
		% of Total	24.6%	0.0%	0.0%	0.0%	0.0%	24.6%
	1.1 – 3 years	Count	2	48	1	0	0	51
		% within EXPERIENCE	3.9%	94.1%	2.0%	0.0%	0.0%	100.0%
		% within INCOME	6.5%	100.0%	5.0%	0.0%	0.0%	43.2%
		% of Total	1.7%	40.7%	0.8%	0.0%	0.0%	43.2%
	3.1 – 6 years	Count	0	0	18	0	0	18
		% within EXPERIENCE	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%
		% within INCOME	0.0%	0.0%	90.0%	0.0%	0.0%	15.3%
		% of Total	0.0%	0.0%	15.3%	0.0%	0.0%	15.3%
	6 .1– 10 years	Count	0	0	1	11	0	12
		% within EXPERIENCE	0.0%	0.0%	8.3%	91.7%	0.0%	100.0%
		% within INCOME	0.0%	0.0%	5.0%	91.7%	0.0%	10.2%
		% of Total	0.0%	0.0%	0.8%	9.3%	0.0%	10.2%
	More than 10 Years	Count	0	0	0	1	7	8
		% within EXPERIENCE	0.0%	0.0%	0.0%	12.5%	87.5%	100.0%
		% within INCOME	0.0%	0.0%	0.0%	8.3%	100.0%	6.8%
		% of Total	0.0%	0.0%	0.0%	0.8%	5.9%	6.8%
	Total	Count	31	48	20	12	7	118
		% within EXPERIENCE	26.3%	40.7%	16.9%	10.2%	5.9%	100.0%
		% within INCOME	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
		% of Total	26.3%	40.7%	16.9%	10.2%	5.9%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	414.184 ^a	16	.000
Likelihood Ratio	295.079	16	.000
Linear-by-Linear Association	113.297	1	.000
N of Valid Cases	118		

a. 18 cells (72.0%) have expected count less than 5. The minimum expected count is .47.



Degree of Freedom= (r-1) *(c-1)

$$= 4*4= 16$$

Calculated value = 414.184

Tabulated value = 26.296

Z = Z cal > Z tab

$$Z= 414.184 > 26.296$$

Hence, the Alternate hypothesis [H1] is accepted

INFERENCE:

Since the calculated value is greater than the tabulated value, we accept the alternate hypothesis and hence there is a relationship between the Experience and Income.

ANALYSIS USING KARL PEARSON'S CORRELATION

Correlation analysis is the statistical tool used to measure the degree to which two variables are linearly related to each other. Correlation measures the degree of association between two variables.

Null hypothesis (H0):

There is positive relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

Alternate hypothesis (H1):

There is negative relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

Correlations			
		THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY
THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	Pearson Correlation	1	.910**
	Sig. (2-tailed)		.000
	N	118	118
THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	Pearson Correlation	.910**	1
	Sig. (2-tailed)	.000	
	N	118	118

**. Correlation is significant at the 0.01 level (2-tailed).

$$r = \frac{N\sum XY - \sum X \sum Y}{\sqrt{N\sum X^2 - (\sum X)^2} \sqrt{N\sum Y^2 - (\sum Y)^2}}$$

r= .910

INFERENCE:

Since r is positive, there is positive relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

SUGGESTIONS

1. International Shipping Corporation has to improve their planning for emergencies
2. Necessary measures need to be taken for maintenance and cold chain rehabilitation
3. Frequent breakdowns in cold chain has be avoided to improve the overall efficiency of cold chain logistics in handling pharmaceutical products
4. Frequent rise in forwarding cost can be avoided by owning the cold chain transportation and the cold storage.
5. Government can take suitable actions to reduce the high energy cost. This will help International Shipping Corporation involved in cold chain logistics to reduce their cost. When both the cost reductions happen, the end customers can avail the pharmaceutical products for a lesser price
6. Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool has be avoided. Proper process has to be followed during the overall cold chain logistics for vaccines.

CONCLUSION

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. There have been numerous events where vaccines have been shipped to third world countries with little to no cold chain infrastructure (Sub-Sahara Africa) where the vaccines were inactivated due to excess exposure to heat.

This study has been undertaken to assess the feasibility in handling the pharmaceutical products like vaccines in cold chain logistics with special reference to International Shipping Corporation. For this purpose, responses from the members involved in cold chain logistics have been collected and analyzed. Based upon the findings out of the research, few valuable suggestions like proper use of Vaccines Vial Monitor (VVM) as a management tool, improve the planning for emergencies etc have been suggested to International Shipping Corporation. These suggestions will pave way for improving the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines.

REFERENCE

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