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ADDIS ABABA UNIVERSITY
SCHOOL OF COMMERCE
MASTERS OF ARTS IN LOGISTICS AND SUPPLY CHAIN
MANAGEMENT

ASSESSMENT OF COLD CHAIN QUALITY MANAGEMENT FOR PHAR-
MACEUTICALS IN
GOVERNMENT HOSPITALS IN ADDIS ABABA
EXPERIMENTAL/QUASI-EXPERIMENTAL APPROACH

A THESIS SUBMITTED TO THE OFFICE OF GRADUATE STUDIES
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MANAGEMENT

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Acronym and Abbreviations

| | |
|---------|---|
| °C | Degree Celsius |
| EFMHACA | Ethiopian Food Medicines and Health Care Activities Control Authority |
| EPI | Expanded Program on Immunization |
| GDP | Good Distribution Practice |
| GMP | Good Manufacturing Practice |
| GSP | Good Storage Practice |
| GOV.HO | Government Hospital |
| MOH | Ministry of Health |
| PFSA | Pharmaceuticals Fund and Supply Agency |
| WHO | World Health Organization |

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Abstract

Background: Cold chain management for pharmaceuticals is an extension of Good Manufacturing Practice. The entire supply chain system is expected to keep this practice throughout the chain starting from the moment the pharmaceuticals/ vaccines and other medicines released from the manufacturer until they reach to the beneficiaries. The safety of these medicines depends on the properly maintaining of the system.

Objective: To examine the cold chain management practice of government hospitals in Addis Ababa

Design: An Experimental/Quasi experimental research design was used to record the temperature of six government hospitals cold chain system cross-sectionally for one week by using Log-Tag® reader model TRIX 8 and Questionnaire which contains basic cold chain quality management principles.

Result: The practice of cold chain management in the Hospitals was described by analyzing the temperature record of the device. Reading of one hospital temperature record was not possible to extract from the device. The five hospital data had shown that 4/5 (80%) of them experience cold chain break during the study period. The result of the Questionnaire also revealed that there were gaps in the management of vaccines described in terms of lack of SOP in receiving and dispatching, absence of advisor during cold chain break and lack of decision matrix that indicated which types of cold chain breaks can be managed at the hospital level or higher regulatory body advice to accept or reject vaccines exposed to high/low temperature out off the standard +2°C to +8°C.

Conclusion: There is a real gap in maintaining the standard cold chain temperature for vaccines and other cold chain medicines in the hospitals. Therefore there is need for using monitoring devices that can track temperature fluctuations and duration of exposure, developing cold chain guideline, development of experts in the area and cold chain breach decision matrix.

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

The cold chain is the process of maintaining medication such as insulin, vaccines; biologicals within recommended temperatures mostly between +2°C to +8°C throughout the supply chain. (Bashara,2006).

The cold chain involves the transportation of temperature sensitive products along a supply chain through thermal and refrigerated packaging methods and to protect the integrity of these shipments. There are several means in which cold chain products can be transported, including refrigerated trucks and railcars, refrigerated cargo ships as well as by air cargo. The cold chain is thus **ascience, a technology and a process**. It is ascience since it requires the understanding of the chemical and biological processes linked with perishability of the items in the system. It is a technology since it relies on physical means to insure appropriate temperature conditions along the supply chain. It is a process since a series of tasks must be performed to prepare, store, transport and monitor temperature sensitive products (Jean-Paul, 2014).

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

EFMHACA (2005), The Ethiopian regulatory body for medicines and medical supplies advises during packing and transportation of medical items through a cold chain system there should not be direct contact of the medicines with the Ice-packs, which are used to generate cold in order to protect the vaccines from exposure for high temperature.

Cold chain management in pharmaceuticals covers wide range of sensitive items: all vaccines, serums, specific medicines, diagnostic tests, laboratory reagents, specific samples for further investigations...and so on. The cold chain supply system links the manufacturing plant to the last point where the products are administered to the patient or used to diagnose a patient, in the case of diagnostic tests. In all these supply chain the products have to be packed and transported using active cold chain systems i.e. using refrigerated containers or passive: using cold ice packs where the temperature is adjusted to be kept between 2 - 8 C° (degree Celsius). Variations from the recommended temperatures of 2-8 degree Celsius, affect the quality of the products and an expert advice is mandatory to use or not to use (WHO, 2006).

The research was designed to investigate the cold chain management of six Government Hospitals in Addis Ababa city, working under Addis Ababa Health Bureau. Those were: Yekatit 12, Menelik, Zewditu, Ghandi, Ras-Desta and Tirunesh-Beijing hospitals.

1.1.1 The inherent temperature sensitivity of vaccines:

Antigen instability is an inherent attribute of vaccines because of the complex nature of the three-dimensional structure of these biological polymers. Classically, there have been two general types of vaccines, live viral and bacterial vaccines, which do not require adjuvants to boost the immune responses but are more sensitive to potency loss during storage and distribution, especially at elevated temperatures, and non-replicating vaccines, such as inactivated viruses and bacteria, purified protein and carbohydrate antigens, which often require adjuvants to boost the immune responses. They are typically stable to moderate heat exposure, but mostly due to adjuvants, are sensitive to freezing. The current cold chain was developed for these two types of vaccines: those whose temperature sensitivity is intrinsic to the structure of the vaccine antigen and those whose temperature sensitivity is related to additives and adjuvants. The live vaccines contain weakened, attenuated versions of infectious viruses and bacteria that can replicate in vivo (and, therefore, mimic natural infection). Live vaccines require careful maintenance of the vaccine cold chain. For example, the varicella-containing vaccines may even require frozen storage to ensure long stability, even in the lyophilized state, and thus can rapidly lose potency under refrigerated storage. The second category, non-replicating vaccines (as they cannot replicate in vivo), usually require adjuvants in lieu of prohibitively high doses to provide sufficient levels of

protective immunity in humans. From stability viewpoint, inactivated and subunit vaccines are generally more stable and are typically available as liquid formulations (Umit.K.2014)

On the other hand diagnostic tests will be affected and may provide a false-positive result: In this case doctors consider that the patient needs treatment and prescribe medicine, practically the patient is fine and needs no treatment. On the contrary the diagnostic tests show false-negative results: by this result the doctor will be misled not to prescribe a medicine while the patient suffers from the disease. Then the patient conditions will be aggravated or more complicated and the patient will die without getting proper treatment. Therefore the importance of cold chain management has direct impact on the health conditions of the patients. The issue becomes more serious during epidemics like: Meningitis, cholera, Measles, the vaccines we stocked for emergency preparations will not help us, unless we keep them according to the standard. The situation will end up with deaths of thousands of population who could be protected with vaccines, by ensuring their quality with proper cold chain management system in the health facility (WHO, 2014).

1.2 Statement of the Problem

World Health Organization (WHO) has noted that twenty five percent of all vaccine products reach their destination in a degraded state (Bishara, 2007). The main reason was due to temperature rises above desired parameters thereby contributing forty three percent of reported non-compliant cases. Worldwide vaccine-preventable diseases are responsible for about twenty five percent of the ten million deaths occurring annually for children under five years of age. (MONICHAW, 2015)

To reduce these deaths there has to be a strong cold chain management system which ensures the safety and efficacy of the items subjected to cold chain. WHO has big concern on the management of cold chain in all African countries and believes that it needs high commitment of all professionals involved in the management system and even high government officials(WHO, 2017)

A research conducted in Ethiopia (Birhane, 2000) revealed that there had been a problem observed in the health centers to maintain the cold chain system to be in line with the international standard between +2°C to +8°C. In addition to that some facilities had not even the basic temperature monitoring thermometers.

(WHO press release: - 2017) WHO Calls the Highest Level of Government in African Countries to Ensure Strong Vaccine Safety systems. According to the organization press release on April 3, 2017 in Addis Ababa: A working dinner to discuss the Global Vaccine Safety Initiative (GVSI) policy was held on, 23 March, 2017 where about 80 participants including AU Member States and delegates, senior level officials from African Union Commission, partners, and distinguished invited guests met at The Multipurpose Hall of the African Union Commission in Addis Ababa, Ethiopia. This advocacy dinner meeting was organized by World Health Organization (WHO) in collaboration with the African Union Commission. The meeting aimed to enforce African countries to ensure strong vaccine safety systems. It also intended to provide the vision for a future where vaccine safety concerns are addressed in a rigorous and transparent fashion and share perspectives on 21st century approaches that are relevant to African countries

In the past, many studies have shown that health care providers accidentally expose vaccines to improper storage temperatures outside of the +2°C to +8°C range and do not monitor refrigerator temperatures regularly. There is a need to ensure that an effective product is being used, otherwise recipients may not be protected against vaccine-preventable diseases; this could result in the re-emergence or occurrence of those diseases. Loss of vaccine effectiveness may result in the cancellation of immunization clinics and thus lost opportunities to immunize, as well as increased costs to the program. Revaccination of people who have received an ineffective vaccine may cause a loss of public confidence in vaccines and/or the health care system. A shortage of vaccine supply could be created by increased demand in a mass revaccination scenario. (Canada MOH, 2015).

WHO, IPAC, (2014) has revealed that inclusion of new vaccines in the cold chain system from time to time created burden in the cold chain supply system, since a huge supply volume is moving in the system which needs big resource. As a result countries are experiencing inventory unpredictability, inadequate cold chain capacity and lack of funding. As an example in 2012 Ethiopia has average of 5 levels inventory holding points and experienced lack of maintenance leading to 30% of cold chain equipment being nonfunctional.

The EPI, (2015) had noted that the vaccine cold chain was plagued with a high rate of non-functional (32.6%) equipment as established by the national cold chain inventory of 2013. The cold chain maintenance system was not performing satisfactorily because it suffered from several issues: As an example:

- Lack of a management system to swiftly and effectively address all breakdown and repair requests, Poor organizational structure and staffing of the repair and maintenance functions: e.g., lack of a competent focal person at district level, unclear hierarchy and job description, inefficient coordination across actors; Lack of standard operating procedures for the different actors: e.g., how to trigger a repair request, how to conduct preventive maintenance;
- Inadequate resources and resource mobilization for maintenance operations, e.g., funds for transportation and per diem of cold chain technicians;
- Lack of proper reporting of cold chain equipment status to enable effective management and monitoring of cold chain assets (including lack of an updated cold chain equipment database);
- Miss management and mal-distribution of shortage of spare parts;
- Insufficient tools to carry out repair and maintenance; Inadequate planning, implementation and monitoring of preventive and curative maintenance.

EFMHACA, the Ethiopian regulatory body for the importation of Medicines and Medical supplies (Federal NegaritGazeta, 1999): Ethiopian Food Medicines and Health Care Activities and Control Authority (EFMHACA) have strong importation guideline. The authority has been implementing strict rules, regulations and procedures to protect the public from counterfeit/poor quality of medicines. The regulatory body is demanding different quality documentations indirectly to check the quality of products imported i.e. to understand how the manufacturing process is in line with international standard procedures. Or Check WHO pre-qualification certificate is given for the manufacturer. For certain sources the regulatory body made audits of the manufacturing plants to check for their compliance with GMP (Good Manufacturing practice). (FMHACA, 2012)

According to the regulatory body all medicines and medical supplies have green light for importation based on two procedures:

1. Products from SRA countries (Stringent Regulatory Authorities) e.g. Europe, USA, Canada, Japan, Switzerland.....EFMAHCA gives import permit by analysis of documentation without GMP inspection of the production site.
2. Products from non-SRA regions: Asia, Middle East and Africa, EFMHACA makes GMP auditing of manufactures to give importation permit for medicines.(EFMHACA,2013)

On top of that at the port of entrance the regulatory authority requests other quality documents and makes physical inspection of the products using random sampling to ensure good packaging and distribution procedure are maintained during transport (EFMHACA, 2015)

EFMHACA also makes quality analysis for selected medicines using its laboratory located in Addis Ababa head office at Bole Road,wollo-sefer to ensure the Medicines imported are produced by the manufacturers based on the specifications set on the Pharmacopeia: A book containing directions for the identification of compound medicines, and published by the authority of a government or a medical or pharmaceutical society.

All the above existing problems in the cold chain supply system are relevant issues. But there should be different approach which can measure the existing cold chain system provides the recommended temperature range without break or not. The main focus of the research is to examine the cold chain management of the government hospitals available in Addis Ababa, on their compliance in regards to global standards of cold chain management practice.

1.3 Research Questions

The following research questions were basic and designed to be answered by the responsible person who is managing the cold chain in each hospital on daily basis.

1. What is the status of cold chain management in the hospital in regards to its quality? I.e. does the cold chain system maintain the recommended temperature +2 to +8 degree Celsius?
2. What is the procedure used when the cold chain management fails?
3. How are decisions made to use or not to use the vaccines exposed for cold chain break?

1.4 Research Objectives

General objective

- The main objective of the study was to examine the practice of cold chain management in government hospitals in Addis Ababa, Ethiopia.

Specific objectives

- To examine the quality of cold chain management system in each hospital.
- To analyze the cold chain break management system.
- To analyze the decision procedure, when the cold chain temperature record is > 8 degree Celsius or lower than 2 degree Celsius.

1.5 Significance of the study

The cold chain supply management system is a synchronized team work which needs close follow up and understanding the nature of products under the system from the manufacturer to the final beneficiaries. In this regards Ministry of Health, EFMHACA, Pharmaceuticals Fund and Supply Agency, Regional Health Bureaus, Hospitals, Health Centers and clinics have responsibility on maintaining the system up to the standard.

The research tries to examine the problems in the system and recommends corrective measures to be taken; all the stakeholders mentioned above in the system are beneficiaries from the final output of the research. The research alerts them to pay strict attention in order to ensure the medicines which pass through this supply system are with guaranteed safety and efficacy.

EFMHACA has been implementing strict procedures by the virtue of mandate given to it by Proclamation no. 176/1999 (FEDERAL NEGARIT GAZETA, 1999), to control the quality of medicines and medical supplies imported and circulated in the country. But there is no proper guideline for the management of vaccines and other cold chain supplies by the regulatory body. Therefore, the study will initiate the regulatory body to design a procedure for the management of cold chain items and to develop a standard operation procedure when the items are exposed to temperature outside the recommended range.

In addition to that there is no post market analysis for the cold chain items by the regulatory body. Therefore, the study will alarm the authority to work on post market sample analysis of items subjected to be kept in the cold chain supply system.

The Safety of cold chain pharmaceuticals/ vaccines is greatly influenced by variations during transport, storage conditions and facilities, handling and packaging (Bishara, 2007). There is lack of adequate study performed in the area. Hence, there is a need for further exploration. Therefore the study will raise the questions in the minds of other Non-Governmental organizations, Importers, exporters and distributors that there is a simple mechanism to monitor perishable logistics temperature during transportation, storage and distribution.

It also avoids confusion among stakeholders during cold chain failure claims, since it exactly identifies where the problem is, who is responsible for themis-management of the cod chain items. It can serve as an evidence regarding items damaged by cold chain breaches. Hence, time and money will be saved during claims.

At the end with proper cold chain management the entire population of the country will receive safety and quality guaranteed vaccines and other cold chain products.

1.6 Scope of the study

The study scope is:

- To standardize and streamline the cold chain management equipment across the hospitals in order to ensure safety and efficacy of vaccines and other cold chain medicines managed in the system. By that the health facilities can provide the maximum care for the beneficiaries.
- To develop standard operation procedure (SOP) for vaccines storing, transporting receiving and dispatching using temperature monitoring devices which can track every minute's fluctuations on temperature of the cold chain system, So that the health professionals make proper decision on the items exposed for cold chain breach: either to be used, disposed or their shelf life to be reduced to avoid adverse effect of the vaccines (Claire, 2012) plus to avoid wrong result of diagnosis can be prevented.
- The study result will show directions for the regulatory bodies: EFMHACA and Ministry of Health to revise their cold chain management and good distribution practice of vaccines by introducing a simple tool which can avoid bias and human error to avoid difficulties in making proper decision. It will help the regulatory bodies to develop a quick reference

guideline during cold chain breach both for logistic and medical professionals who are managing the cold chain.

- Creates awareness for the cold chain system managers the correct procedure to be followed while they are managing sensitive products: Vaccines and other medicines and medical supplies.
- To initiate medical professionals for further study why we are facing recurrent epidemic emergencies? Like: Measles, polio... Does this have a link with the cold chain system failure in the government or private health facilities: retail pharmacies, drug stores, cold chain cargo terminals and soon.
- To help the responsible organizations to develop a decision making matrix which considers what type of cold chain failures can be managed bywhom at which level.

1.7 Limitation and Delimitation of the study

The study is a new approach in its kind using this device to assess cold chain management in the Hospitals. People may understand it as a kind of spying their cold chain quality system and may fear not to be responsible. Therefore they may not feel comfortable to let the analyzers being installed in their refrigerators.

Stakeholders' perception towards the check list and providing honest response is another area of concern. Individuals who have direct involvement in the packaging, storing, do the reception and distributing of these sensitive products may not be open. The reason is the device records the specific date, time and duration of the cold chain break; hence it revealed under whom responsibility the breach has happened. There is no way to escape from the reality and pushing the problem to other stakeholder/partner. Therefore they may refuse to let the device record their cold chain temperatures.

Time is also a constraint the longer we take records the more confidence in making decision.

The failure of quality of cold chain system has a cumulative effect. Slight deviation from the standard that will be compromised at one point, if it happens again it has an additive effect and the product might end up in total disposal. Therefore the tool needs to be analyzed having all the past trends of the cold chain system. Otherwise we may lose a critical data that can compromise

quality of the product itself. Hence the result can be considered as an indicator that revealed care should be taken in the cold chain management system but not as a clear cut point to make decision at the spot.

There has not been a study conducted earlier using the device or other similar devices in Ethiopia. Therefore, there was difficulty to have baseline information in this regards.

The delimitation of the study was its being confined geographically in Addis Ababa and even focusing on specific hospitals for one week follow-up of their cold chain system.

1.8 Operational Definitions of Terms:

Cold Chain: is a supply system which is used to store, transport and distribute vaccines in a controlled temperature of +2 to +8 degree Celsius Using refrigerators, cold stores, freezers and cold boxes from the factory to the point of use.

Cold chain breach/break: is a condition where the vaccines are exposed for temperatures $>+8$ or $<+2$ degree Celsius.

Cold chain items: are medicines and medical supplies which are intended to be kept in cold chain.

Cold chain management: is a system which manages cold chain items in the recommended temperature range.

Cold chain quality: is the ability of maintaining cold chain items in a temperature range of 2 to 8 degree Celsius without fluctuations.

1.9 Organization of the study

The study was organized in a way that can cover all the Hospitals in order to have representative result which will reflect the current situation of the cold chain management. The researcher used the monitoring device and questioners to identify exactly the cold chain gaps existing in the health facilities.

CHAPTER TWO

LITRATURE REVIEW

2.1 Cold chain management

The cold chain is the process of maintaining medication such as insulin, vaccines; biologicals within recommended temperatures mostly between 2°C to 8°C throughout the supply chain. In the health sector pharmaceutical cold chain is concerned with the transportation, storage, and handling of pharmaceutical products in a safe environment from the manufacturer to the end user. Temperatures outside recommended temperature ranges may reduce potency leading to lack of desired response e.g. reduced immunity.(WHO, 2006).

Control of storage and transportation temperature is essential in maintaining the quality of medicines and in helping to protect patients from sub-standard or ineffective medicines that may result from inadequate control (Blake, 2008).

2.2. Understanding the cold chain system

There must be clear understanding of the cold chain supply system by answering the basic definition of, what is a supply chain? According to (Lambert, Cooper, and Pagh 1998), the current definitions cover multiple functions or processes across multiple firms and call for an integrated approach that adds value for stakeholders. Therefore all the stakeholders' contribution on the proper management of cold chain in the system adds the value for the final result on providing better quality products. It's quite important to see the researches performed in the area by different authors to have clear view where the gaps are in regards to the cold chain management and propose a holistic approach to solve the problems.

Quality management of a system generally requires major changes in all three components of the organizational rules of the game, namely systems for allocating decision rights, performance measurement systems, and reward and punishment systems (Karen and Michael, 1994).

The same rule is applicable for cold chain management. There should be a rule which is applicable in the system with performance measurement procedures hence decision can be made using the result.

The cold chain management is a unidirectional supply system. It needs to maintain the supply system up to the standard from the beginning to the end. It's not a supply system where reverse logistic is applied to modify defective items back to normal since the loss of potency of vaccines is an irreversible process (WHO, 2014)

A Cross sectional study conducted in Cameron by (Martin, 2015) had revealed that there is a limitation on proper usage of cold chain management tools by the responsible personnel's in the health facility. At the moment of their data collection, temperature out of the recommended vaccine storage temperature range of +2°C to +8°C was recorded in 32.7% of health facilities that had a functional thermometer. In total, 36.9% health facilities had 239 abnormal temperatures during two previous months. Up to 43.8% did not know the recommended vaccine temperature storage range.

Practically, it's not enough to provide the tools for the monitoring of the temperatures but easily analysis of the result has great impact on the safety and efficacy of the vaccines under the system. The authors explained that in 36.9% of health facilities 239 abnormal temperatures had been recorded during earlier two months of the study conducted. It's clear that recurrent breach has an additive effect on the deterioration of safety and efficacy of the vaccines in the cold chain system. Therefore there should be a mechanism to track these deviations and analyze the status of the vaccines. That is the reason why in this research the researcher used a device which records and shows the trend of the temperature fluctuations retrospectively to make decision. In the case of the study in Cameron the health facilities might be using/keep in their stock the vaccines that already experienced compromised quality.

A research conducted by (Birhane, 2000) under the title '*Cold chain status at immunization centers in Ethiopia*' had revealed that the cold chain management situation in Ethiopia in the year 2000, with 88.3% of the vaccine refrigerator recorded temperatures within the recommended range during the data collection. The apparent higher proportion of health facilities with cold chain in recommended range in Ethiopia could be explained by the fact that the recommended temperature range in the study in Ethiopia was 0°C to +8°C.

But, only mentioning the percentage of the facilities in the range is not sufficient. There should be an indicator how far those remaining 11.7% were beyond the standard. It's also necessary to know exactly how often breach had been occurring in the system. As the cumulative effect of

The cold chain management process is an extension of Good manufacturing Practice (GMP) environment that all drugs and all pharmaceutical products are required and adhere to, requirements enforced by different regulatory authorities. The vaccines should be kept in the specified temperature range during manufacturing, in transit storage facilities, cold rooms, refrigerators, vaccine carriers during transporting until it reaches to the final destinations. The GMP requires that all processes that might impact the safety, efficacy or quality of the drug product must be validated; including the storage and distribution of the drug substance (WHO, 2004).

According to a study conducted by (Prakash.G, 2012) under a title "*RFID based Mobile cold chain management system for Warehouses*" they have noted that, Temperature data loggers and RFID tags help monitor the temperature history of the truck, warehouse, etc. and the history of the product being transported. That is a fact which provides clear information regarding the temperature conditions the way the supplies had been stored or transported. But that is not the only information needed to be on the safest side from cold chain items being damaged. There should be also an assessment of knowledge and practice of the stockholders in the supply chain as routine practice is difficult to change. That is the reason why in this research, the researcher try to assess the knowledge and practice of the individuals participating in the day to day activity of cold chain management using simple check list.

Vaccines are sensitive biological substances that gradually lose their potency with time (WHO, 1998) and this loss of potency can be accelerated when stored out of the recommended range of temperature being exposed to excessive heat, freeze or light (WHO, 2014). Any loss of potency in a vaccine is permanent and irreversible. Consequently, a proper storage of vaccines at the recommended temperature conditions is vital so that vaccine's potency is retained up to the moment of administration (Martin, 2015)

The exposure of vaccines to adverse temperature conditions does not only nullify the immunization effect, but also induces adverse events following immunization. Therefore, vaccines must be handled with care and a lot of attentions to ensure their quality and consequently full immunization benefit (Silva ML. and Camina RC., 2007)

A cross sectional study conducted in Cameron (Martin N. *etal* 2015) had revealed that Among the 50 health facilities that had a functioning thermometer in a vaccine fridge, 10 of them had a thermometer reading out of the optimal vaccine storage temperature of +2°C to +8°C at the moment of data collection. Exposure to temperature higher than 8°C was more frequent 6 than the exposure to temperature less than 2°C 4. Furthermore, from the records of the 2 months preceding data collection, 12 health facilities had recorded at least one temperature out of the optimal vaccine storage temperature of +2°C to +8°C. Similarly, exposure to overheat was more frequent. A total of 12 vaccine fridges were exposed to overheating (temperature higher than 8°C) and 6 exposed to cold (temperature lower than +2°C) in the two previous months to data collection. It is worth noting that all the vaccine refrigerators that were exposed to cold during the two months were equally exposed to overheating. The research had shown clearly the problem of cold chain failure in the health facilities both above and below the recommended range for the management of vaccines. Off course all vaccines needs to be kept in the standard range. When the temperature is not maintained accordingly the decision understands the nature of the vaccines and the duration it exposed for the temperature outside the range. The research doesn't clearly show that. Meaning we don't know exactly for how long at what temperature the vaccines were exposed. Therefore, it's not possible to make proper decision to reject the vaccines or to be used in the facilities.

There is a need for another approach for monitoring the refrigerators of the health facilities using a device which clearly records the time and duration of exposure of the vaccines for unwanted temperature. That is the reason why the researcher designed to have another approach for the use of LogTag® tag recorder. The device will record every minute fluctuation and enables to make proper decision. So that use of quality compromised vaccines will be prevented. The public will receive safe and effective vaccines.

A study conducted in Papua New Guinea using temperature loggers (THEO.W, *etal*, 2016) had revealed that five of the 12 loggers experienced a freezing episode after leaving the health center under the study, either in transport or during the outreach session. All other loggers experienced a rise in temperature after they left the refrigerated cold chain on the way to outreach clinics. Most rapidly reached ambient temperature, but it was not possible to tell whether the vaccines themselves had already been administered prior to the loggers warming up, or whether the vaccine vials heated up before administration. One health center dispatched the vaccines to the outreach clinic but kept the logger at the health center! To measure ambient temperatures along the distribution route, one data logger was shipped with the vaccines to one of the study health centers, but at ambient, rather than cold chain, temperatures. It was shipped and stored in the same room or vehicle as the vaccines and according to the same schedule as the vaccines, but out of direct sunlight and away from heat sources. The temperature logger recording ambient temperature was not put in the cold boxes or refrigerators used for the vaccines. The research approach is good. But the loggers don't show the duration of the exposure of the vaccines to unwanted temperature. It is not possible to make proper decision only by seeing a rise or fall of the temperature unless the duration is measured quantitatively. That is the reason why here, the researcher is using a device which monitors the exposure of vaccines for unwanted temperature and the duration they are exposed for, which makes the decision easier for the experts.

2.3 Conceptual Framework

The conceptual framework illustrates the relationship between the independent variable, and dependent variable. In this research:

Independent variables: In this research, functional refrigerators, storage volume of refrigerator, type of refrigerator, room space volume, trained personnel, guidelines, backup system, Ice packs and cool box.

Dependent variable: safe vaccines are dependent variables in this study.

CHAPTER THREE

METHODOLOGY

3.1 Study area

The study included all government hospitals in Addis Ababa City, working under Addis Ababa Regional Health Bureau supervision, for their compliance with the international standards. The hospitals were selected based on their activity in the management and supply of vaccines for the beneficiaries either in routine activity of vaccination or their involvement in the management of epidemics when needed. Therefore the investigation of their cold chain system was to have a clear view how they manage their cold chain system, what procedures are followed by them when there a break in the system and to understand how decision is made to use or not to use vaccines exposed for cold chain break. In general to what extent the vaccines provided by the facilities are of proven safety?

3.2 Research Approach, Design and Sample size

An experimental/quasi experimental design was used. In this design the researcher attempted to select groups that are as similar as possible (Jeoffery, David and David, 2015). All the six Hospitals working under the Addis Ababa Regional Health Bureau were included in the study. This makes 100 % coverage of the sample size.

The research approach is to examine the quality of the cold chain system of the hospitals by measuring its compliance with the standard limitation range of temperature convenient / an ideal range of 2 to 8 degree Celsius. Therefore, the reading of the cold chain were collected and analyzed for its perfection.

Institutional based Cross-sectional quantitative-qualitative mixed research design was used in all government hospitals of Addis Ababa working under the Health Bureau, in May, 2017 using:

1. LogTag® temperature recorder: an electronic device approved by WHO, (Registered in EU, CE marked).

The LogTag® temperature recorder software had been installed in a computer online from the manufacturer web page. The logger had been configured to take the temperature records of the refrigerator in 15minute interval for seven consecutive days. The normal temperature reading was adjusted to be between 2-8 degree Celsius, as standard so that within this range LogTag® blinks

green light that means the refrigerator has maintaining the temperature in the normal range. When Readings below 2 and above 8°C are detected, after 4 consecutive alert readings (1hr) the logger blinks red light showing that cold chain breach has been detected. The reader was activated by pressing the start button for 2 seconds until both red and green lamps blink simultaneously, and then the device starts recording (MSF, 2016). Using the LogTag® interface connected with a computer the data had been extracted to Microsoft excel file and analyzed against the international standard. The readers were marked with the name of the hospitals.

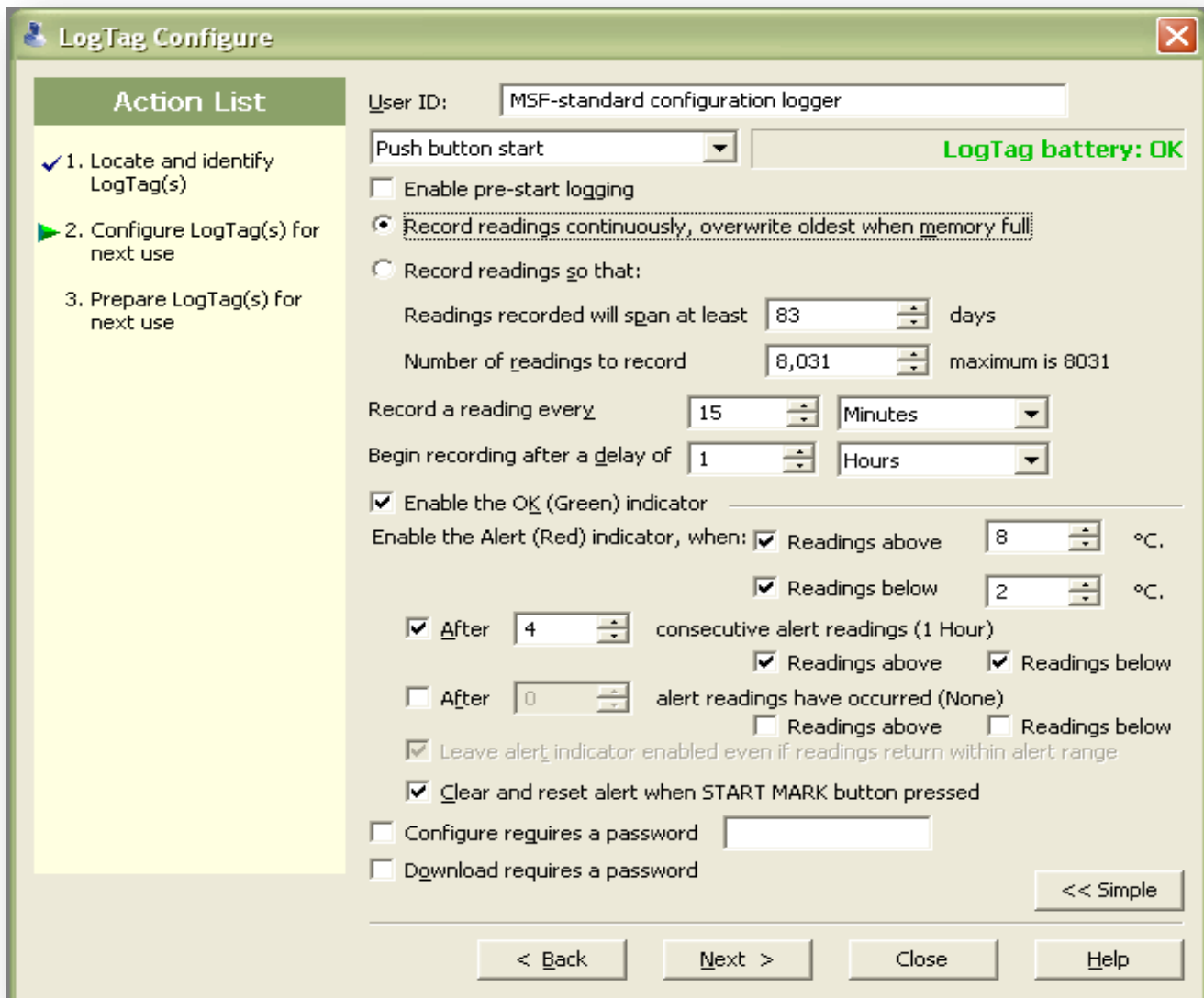


Fig. 2 Configuration of the LogTag® reader (MSF, 2016)

- Standard questioners adopted from (Birhane, 2000) modified by the researcher considering the ideal knowledge and practice of proper cold chain management was used. The response from the responsible people had been analyzed (Annex: 2)

3.3 Data Source, Type and collection procedures

Six government Hospitals working under Addis Ababa Health Bureau were included in the study: Yekatit 12, Menelik, Zewditu, Ras-Desta, Gandhi and Tirunesh-Beijing hospitals.

The first point in the data collection was to identify the validity of the collecting tool.

Validity and reliability of the LogTag®.

The LogTag® TRIX-8 is a versatile, wide range, multi-trip Temperature Recorder, featuring high resolution temperature readings over a measurement range of -40°C to +85°C (-40°F to +185°F)

LogTag® TRIX-8 is equipped with a unique external temperature sensor arrangement providing fast reaction time to temperature change.

Using the LogTag® Interface Cradle and the freely available companion software LogTag® Analyzer, the LogTag® TRIX-8 is easily set-up for recording including delayed start, sampling interval, number of readings and configuration of conditions to activate the 'ALERT' indicator.

LogTag® Analyzer also provides facilities for charting, zooming, listing data statistics and allows exporting the data to other applications such as MS Excel once the data has been downloaded

Specification

| | |
|-------------------|--------------------------------|
| Model | Trix-8 |
| Measurement Range | -40°C ~ +85°C (-40°F ~ +185°F) |
| Resolution | < 0.1°C for -40°C ~ +40°C, |

| | |
|-----------------------|---|
| | < 0.2°C for +40°C ~+80°C |
| Accuracy | Better than ±0.5°C for -20°C~ +40°C. Better than ±0.7°C for -20°C~ -30°C & +40°C~+60°C Better than ±0.8°C for -30°C~ -40°C & +60°C~+80°C |
| Sensor Reaction Time | Typically less than 5 minutes (<i>T90</i>) in moving air (1m/s). |
| Capacity | 8032 readings (16K bytes memory) |
| Sampling Frequency | Adjustable, 30 sec to several hours |
| Logging Start Options | Push button start or specific date & time. Optional start delay of up to 18hours. |
| Recording Indication | Flashing 'OK' indicator / flashing 'ALERT' indicator. |
| Download Time | Typically with full memory (8000 readings) in less than 5 secs depending on computer or readout device used. |
| Environmental | IP65 (roughly equivalent to NEMA 4) |
| Power Source | 3V LiMg battery |
| Battery Life | 2 ~ 3 years of normal use (based on 15 minute logging, download data monthly). |
| Size | 86mm(H) x54.5mm(W) x8.6mm(T) |
| Weight | 35g |
| Case Material | Polycarbonate |
| Other Features | <ul style="list-style-type: none"> • Logging start by push button or specific date/time start • Optional clearing of alert indication by push button (places inspection make at same time). |

- Download inspection mark recorded in LogTag memory every time Log-Tag is downloaded.
- 'Prestart' fail-safe logging (records temperature data even if not started)
- Low Battery indication in software.
- Comprehensive *Alert* indicator configuration.
- Calibration to achieve higher accuracy possible.

The data sources for the research were:

1. The temperature readings taken from each hospital cold chain using, the LogTag® temperature recorder the readings from the device had been extracted in to Microsoft excel by the help of software installed in a computer, the temperature was monitored 24 hrs at an interval of 15 minutes. The break in the cold chain was tracked and the vaccines sensitivity for high temperature or low temperature was checked, the deviations from the adjusted temperature had been calculated and analyzed.
2. The questioners' replies from the responsible people who are managing the cold chain system in the health facilities on daily basis were the other data source for the research. The questioner had been distributed after explain the objective of the study. Consent was obtained from the respondents. After collecting the data, the responsible people had an explanation regarding the status of their cold chain system in order to take corrective measures.

The data collectors were trained on how to use the temperature monitoring device and extraction of data's from the device. The Standard check list designed by the researcher was provided to the responsible people during the beginning of the temperature reading of the cold chain. After the explanation on the purpose of the research and confidentiality of the outcome the check list was provided for the responsible people and their reply were collected for analysis.

3.4 Measurements and instruments

The researcher used two instruments for the study. The first one is the device for measuring the temperature of the cold chain in degree Celsius quantitatively. The second one is the questioner for the qualitative measurement of the system in the hospitals.

3.5 Ethical considerations

The data collection was started after getting consent from the Medical directors, Pharmacy case team leaders and warehouse managers of the Hospitals under the study. They were informed at any time to withdraw from the study process if they don't feel comfortable plus and the researcher had confirmed their name will be kept secret at any time, not to be against their privacy.

CHAPTER FOUR

DATA ANALYSIS AND DISCUSSION

(Jeoffery, David and David, 2015) explains that in most types of research studies, the process of data analysis involves three steps: preparing the data for analysis, analyzing the data, and interpreting the data. The researcher analyzed the quantitative and qualitative research output as follows:

4.1 Data collected from the refrigerators of vaccines

The data was collected from the hospitals refrigerators for the vaccines, using computerized Log-Tag® Analyzer software program and extracted into Microsoft Excel program for analysis.

The information extracted from the tool explained: How long the reading has been run? The highest and lowest readings recorded, whether cold chain break was observed or not? How long the break stayed? (Summary of the LogTag® reading: Annex: 3, 4 and 5) it showed the detail of the record.

Based on the information recorded by the tool, the Standard Deviation is σ (the Greek letter sigma) has been calculated using the formula:

$$\sigma = \sqrt{\frac{1}{N} \sum_{i=1}^N (x_i - \mu)^2}$$

Where: square root of [(1/N) times Sigma i=1 to N of (xi - mu) ^2], with the following steps.

1. Working out the Mean (the simple average of the numbers)
2. Then for each number: subtracting the Mean and square the result
3. Then working out the mean of those squared differences.
4. Finally taking the square root of the result

LogTag ID 1000373644
 User ID GOV.HO 002
 First reading 12/05/2017 16:08:29
 Last reading 23/05/2017 11:38:29
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 File location D:\Users\lethiopl-pharmacy\Desktop\Logtag Reading GOV.HO\

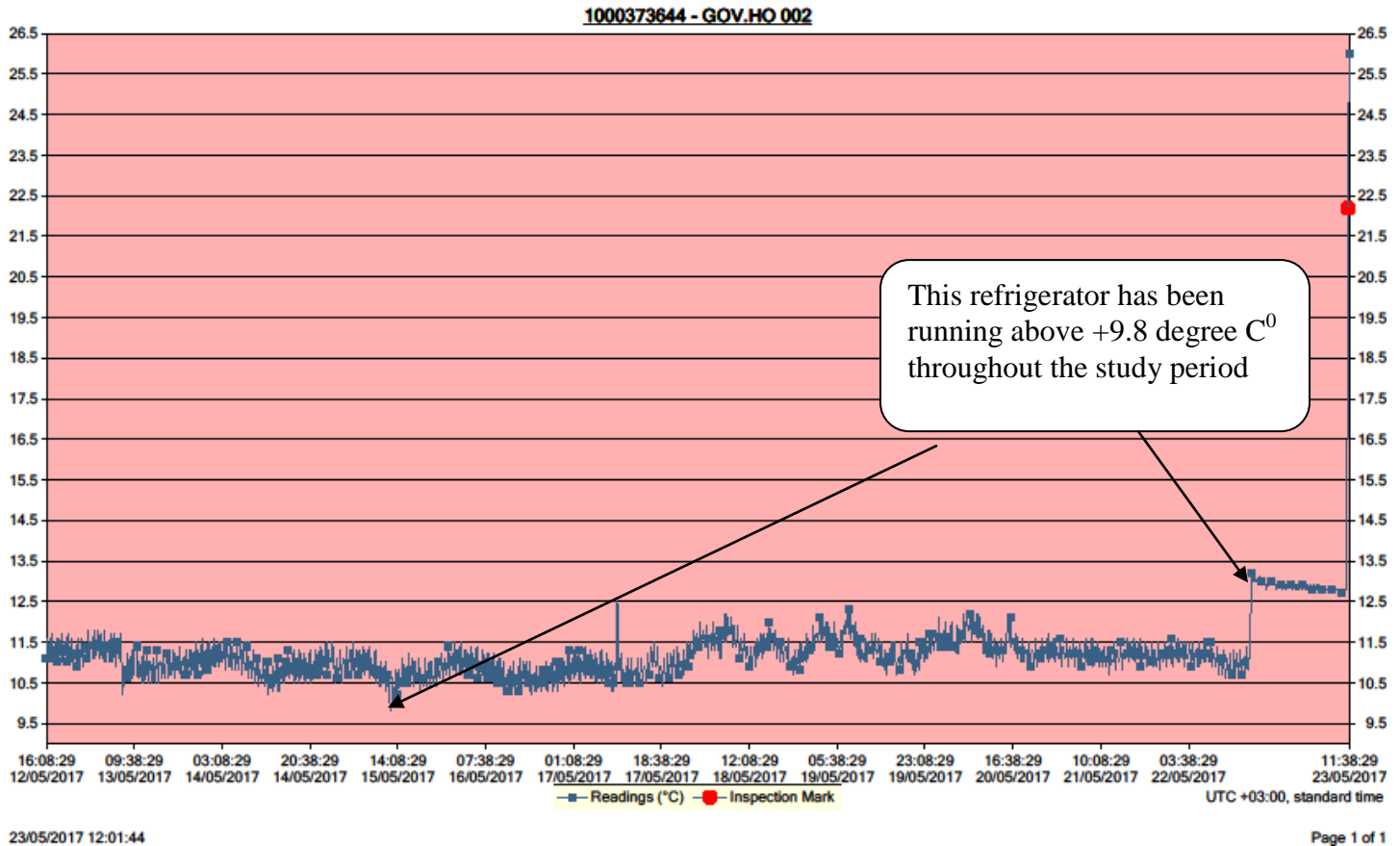


Figure.3. LogTag® reading of cold chain graphical representation (Menelik Hospital)

Data Analysis and discussion: The above graph represents vaccine refrigerator temperature reading of Menilik hospital. The reading of the refrigerator had showed that the refrigerator had been running above the recommended 8 degree Celsius throughout the study period. In the beginning of the study the record for the temperature was + 9.8 degree and it continues above this temperature during the study period. At the end of the study the reading increased to even +12.7 degree. Therefore the vaccines and other cold chain items were exposed to high temperature. This will affect the quality of heat sensitive vaccines and other medical supplies.

LogTag ID 1000700524
User ID GOV.HO 001
First reading 12/05/2017 16:08:26
Last reading 23/05/2017 11:38:26
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File location D:\Users\ethiopia-pharmacy\Desktop\Logtag Reading GOV.HO\

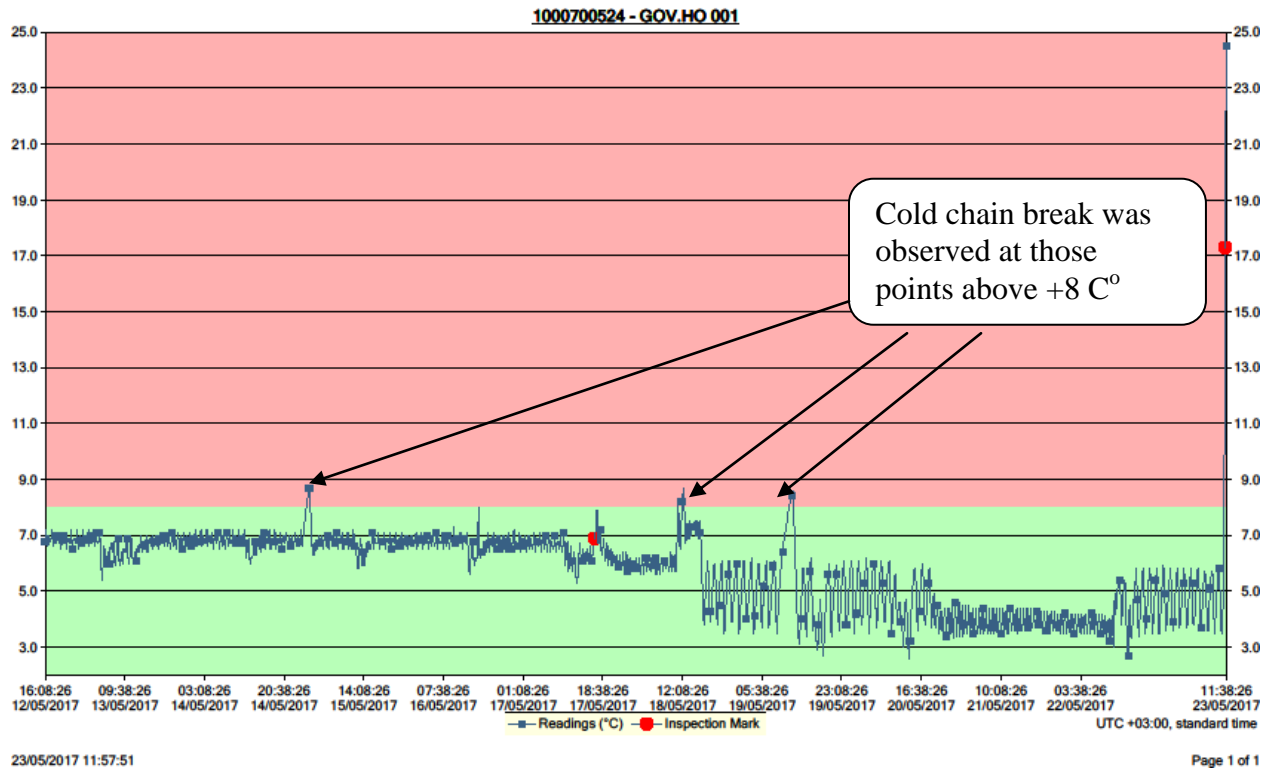


Fig.4. LogTag® reading of cold chain graphical representation (Ras-Desta Hospital)

Data Analysis and discussion: The above graph represents the vaccine refrigerator of Ras Desta Hospital. The graph for this refrigerator had shown that there was cold chain break at three points above +8 degree Celsius. The duration was for short period of time. But it's a reminder that there was difficulty in maintaining the recommended temperature range by the Hospital cold chain system.

LogTag ID 1000488593
 User ID GOV.HO 003
 First reading 12/05/2017 16:08:49
 Last reading 23/05/2017 11:38:49
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 File location D:\Users\ethiopia-pharmacy\Desktop\Logtag Reading GOV.HO\

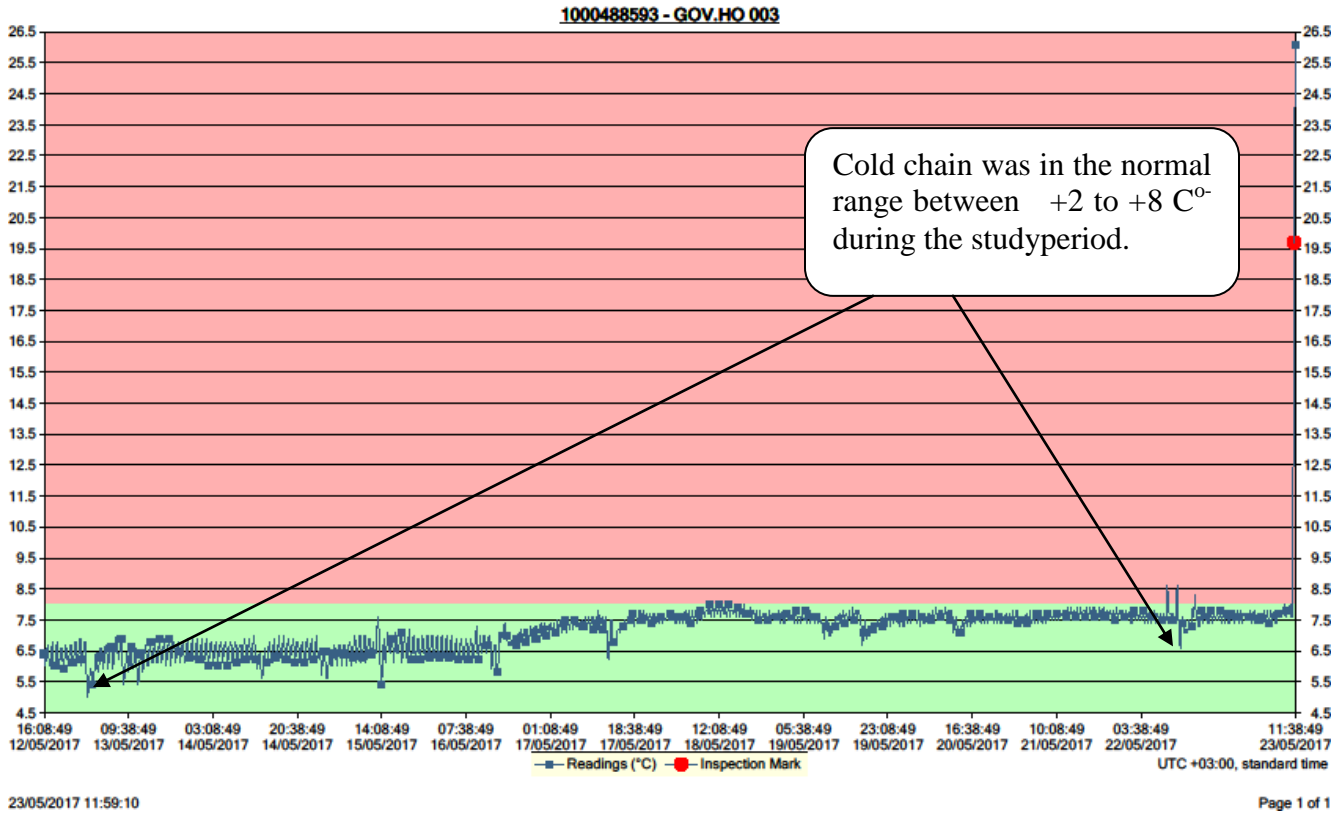
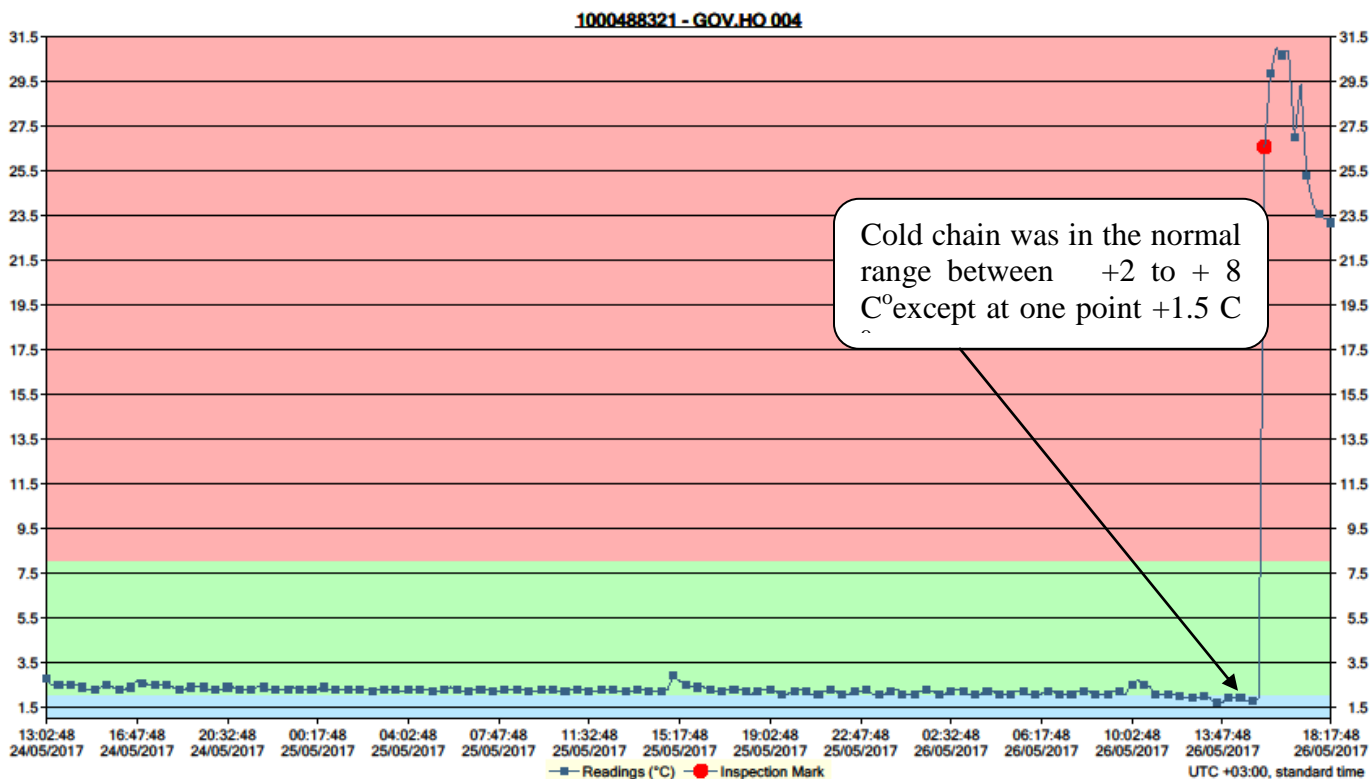


Figure 5. LogTag® reading of cold chain graphical representation (Yekatit 12 Hospital).

Data Analysis and discussion: The above graph represents the vaccines refrigerator reading of Yekatit 12 Hospital. This refrigerator had stable temperature records throughout the study period which were in between the standard set. At the study period the lower reading was +5.4 and the higher + 8 degree Celsius.

LogTag ID 1000488321
 User ID GOV.HO 004
 First reading 24/05/2017 13:02:48
 Last reading 26/05/2017 18:17:48
 Name of file 1000488321 Started 24-05-2017, Finished 26-05-2017 gov 004.ltd
 File location E:\Logtag Reading GOV.HO\



26/05/2017 18:25:23

Page 1 of 1

Figure 6. LogTag® reading of cold chain graphical representation (Zewditu Hospital).

Data Analysis and discussion: The above graph represents the temperature readings of vaccines refrigerator for Zewditu hospital. This refrigerator had been working well except for the recording of a lower temperature than the recommended +2 degree Celsius at one point, which lasts only for 15 minutes. Overall, it had good performance in maintaining the recommended temperature and kept the vaccines safe.

LogTag ID 1000488592
 User ID GOV.HO 005
 First reading 24/05/2017 12:56:01
 Last reading 26/05/2017 18:11:01
 Name of file 1000488592 Started 24-05-2017, Finished 26-05-2017.ltd
 File location E:\Logtag Reading GOV.HO\

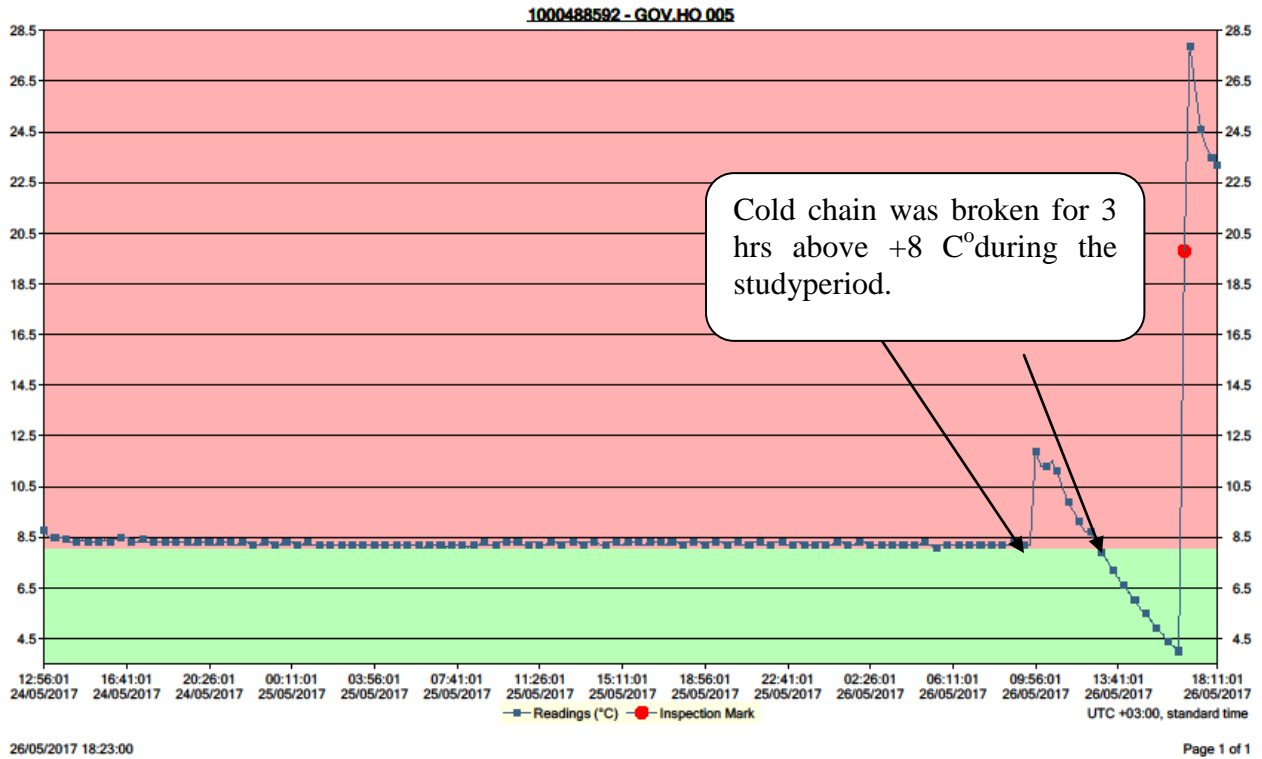


Figure 7. LogTag® reading of cold chain graphical representation for (Gandhi).

Data Analysis and discussion: The above graph represents the temperature records of Gandhi Hospital. This refrigerator had record of higher temperature above +8 degree Celsius at one point which stayed for almost 3hrs on 26/05/2017 starting from 09:56:01 up to 13:56:01. The period of the cold chain break was short.

One Logtag® reader device with code: GOV.HO.06 for Tirunesh – Beijing Hospital was damaged and retrieving the data was not possible. The recording of the other 5 hospitals cold chain temperature had shown that there was a cold chain breach observed in 4 Hospitals refrigerators out of 5 i.e. in (80%) of the facilities. It means that there is a problem in maintaining a stable temperature of the system between +2 to +8 C°. It doesn't mean necessarily all the vaccines in the refri-

generators were damaged, but it needs to analyze the previous history plus clearly understanding the intrinsic nature of the vaccines kept in these cold chain systems as the nature of vaccines vary to be damaged by excessive heat or cold.

In general, according to (WHO, 1998) and manufacturer guidelines clearly state that adjuvant vaccines (hepatitis B vaccine, DTP, tetanus toxoid (TT) and Haemophilus Influenzae type B (Hib)) must not be exposed to freezing temperatures and should be stored at temperatures between 2 and 8 °C. Freezing of vaccines containing diphtheria, tetanus, pertussis or hepatitis B antigens can compromise their immunological potency. Therefore, the degree of exposure is not affecting all items in the cold chain systems similarly. In order to reach to the final decision to discard, accept for use or to lower the shelf life of the vaccines exposed to cold chain break, it needs to measure for how long the cold chain break was existed.

As we have seen in the above tables the LogTag® reader has recorded the duration of the break in Hrs, Minutes and seconds. The device exactly tells the responsible person where? , how? and to what extent? The items were exposed for unwanted temperature without bias.

Therefore, it enables the experts (health professionals) to make proper decision knowing the nature of the vaccine. Hence, the health care system will provide medicines and supplies with proven safety and efficacy.

Regarding the response from the checklist, major indicators for the quality of cold chain management are summarized in Table 4. We can understand from the reply that there are gaps in maintaining proper cold chain system in the facilities.

4.2 Collecting the respondents' answers from the check list

The reply for the questioner's (Annex: 2) from all hospitals under the study had been collected, for analysis and summarized in the Microsoft excel file as shown in Table: 1

Table 1: Distribution of key indicators of the existing cold chain system in the health facilities

| Indicator | Total (%) |
|--|------------|
| Cold chain protocol available / EPI protocol availability | 1/6 (17%) |
| Availability of cold chain monitoring devices | 6/6 (100%) |
| Check list availability for reception and dispatching cold chain items | 0/6 (0%) |
| Regular follow up from the regulatory body | 0/6 (0%) |
| Decision matrix availability during cold chain breaks | 0/6 (0%) |
| Holdover time of the refrigerator is known | 2/6 (33%) |
| Backup system in the place if refrigerator breaks | 1/6 (17%) |
| Backup system in the place for electricity interruption | 6/6 (100%) |
| Availability of expert/institute for advice during cold chain break | 0/6 (0%) |
| Follow up on cold chain quality from the regulatory body | 0/6(0%) |
| Cold chain break reporting system | 0/6(0%) |
| Conditioning of the ice-packs | 1/6(17%) |

The above table shows the basic indicators that have to be fulfilled in the establishment of proper cold chain system in the place.

- Availability of cold chain protocols: According to the study there is no cold chain protocol almost in all hospitals. That means there is no clear information what to do? What measures should be taken during cold chain break? Where to report? Who is making decision on accepting or rejecting items exposed for cold chain break? is not known.
- Availability of cold chain monitoring devices: All hospitals have cold chain monitoring devices like: thermometer. Only the availability doesn't guaranty the safety of the vaccines managed under the cold chain system. It needs also analyzing the records of the

temperature and understanding the impact is the key point. In the hospitals temperature above 8 degree was monitored in the temperature recording sheet. But it's not clear what corrective measures had been taken by the responsible people because there is no a means of reporting the problem to higher level to make proper decision.

- Check list availability for reception and dispatching: There is no a check list available in all hospitals. Therefore, in what type of containers the vaccines should be packed? What types of temperature monitoring tools should be available? during sending and receiving cold chain vaccines and other supplies is not defined. Proper packaging is the key in ensuring delivery of safe cold chain vaccines. According to Blanchard (2007), use of proper and recommended packaging material protects the cold chain items and ensures their safe delivery while use of correct protective gear protects the personnel doing the packaging of cold chain items. The research revealed that packaging procedures are not well identified therefore there is no guaranty in maintaining of safety of the vaccines during transporting, receiving and dispatching of those items in the hospitals.
- Regular follow up from regulatory body: according to the response for the questionnaire by the responsible people managing the cold chain system, there is no follow-up of the cold chain management from the regulatory body. Setting up the cold chain system and putting the monitoring devices is not the end point in proper cold chain management. There should be regular follow up from the regulatory bodies to ensure that the system is working perfectly. Otherwise checking the thermometer record can't tell us the fluctuations of the system above and below the recommended temperature and its impact on the quality of the vaccine managed in the system. There should be a checking mechanism from the regulatory bodies for the existence of properly managed cold chain system in the hospitals.

Decision matrix availability during cold chain breaks: Cold chain breaks can be for short or long period and their impact varies accordingly. Therefore it's quite important to have a decision matrix which clearly put what type of breaks can be managed at the facility level and what type of cold chain break can be referred for further investigation, advice and decision to higher experts' level.

- Holdover time of the refrigerator: the study showed that only two hospitals (33%) know the holdover time of their refrigerators. i.e. the duration where the refrigerator keeps the vaccines in the refrigerator within the range of 2 to 8 degree Celsius after an electric supply system interruption. The cold chain managers have to know the holdover time of the refrigerators so that they can decide when to start the backup system of electrical supply. Therefore, the vaccines will not be affected due to an electric supply interruption.
- Backup system in the place if refrigerator breaks: Cold chain materials will provide services for longer period. But it hard to predict when they will be damaged and become useless. Therefore there should be a backup system in the place as contingency. Otherwise to replace a broken refrigerator will not be an easy task when it happens.
- Availability of expert/institute for advice during cold chain break: There is no expert to give an advice for cold chain break in all hospitals. Therefore there is no rational decision which is supported by justification to accept or reject vaccines exposed for cold chain break. It's mandatory to have a well-trained advisor at the hospital or higher level to make decision using his /her expertise during cold chain break.
- All the hospitals have an electric backup system in the place. That is a very good experience to be appreciated.
- Conditioning of the Ice-pack: it's a procedure where vaccines are transporting using Ice-Packs. Conditioning refers preparation of the ice-packs to release an optimum temperature of 2 to 8 degrees. For the vaccines as passive-cold chain energy source. In normal condition Ice packs are frozen to -20 degree Celsius. They have to be conditioned: i.e. bring them to a temperature of 0 degree Celsius by letting them to stand at room temperature (20 degree) for thirty minutes .Vaccines should not be packed unless they form water droplets on their surfaces. This concept is not known in the 5 hospitals, except at one hospital. Therefore, if the vaccines packed without conditioning the ice-packs, they will be exposed for freezing so they will be damaged.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Cold chain logistics is growing from time to time. New medicines and supplies are included to the cold chain logistics every time. The researcher has identified that there are gaps in the cold chain supply system of the hospitals examined. There will be also a problem when we go into the downstream of the supply chain: i.e. regional, district and Wereda level health institutions. Of course in order to be quite sure, there has to be an extensive study in these facilities as well. Its critical area where clear guideline or SOP to be developed by the regulatory bodies.

Data analysis of the two approaches for examination of the cold chain system in the hospitals had revealed that there is clear gap in the cold chain management of the hospitals in regards to protocol or procedure, regular maintenance, decision matrix availability.

5. 2.Recommendation:

The cold chain is a shared responsibility that begins from the time the vaccine is manufactured, and ends when the vaccine is administered to the recipient. A cold chain breach occurs when the temperature falls outside of the recommended +2° to +8°C temperature range at any point during the cold chain supply process. Common breaks in the cold chain occur through refrigeration failure, power outage, overheating of vaccines during transportation, and freezing of vaccines. Temperature variations outside the +2° to +8°C temperature range can result in loss of efficacy to the vaccine.

The care to be taken to ensure their safety and efficacy needs close follow up and well organized procedures. The availability of cold chain experts at different level is also mandatory. The regulatory bodies in the importation of medicines and implementation of programs like EFMHACA and MOH have double responsibility in maintaining all the cold chain products management system at health facility is in line with the international standards. In order to see the implementation to be in the place, the following issues have to be addressed in prior:

- Standardization of the equipments used for the management of vaccines in the facilities: These include refrigerators, cold boxes, thermometers and other monitoring devices.
- Developing standard operation procedures for storing, transporting, packing, receiving and dispatching of cold chain items.
- Developing a cold chain breach decision matrix which explains what kind of breaches can be managed at the facility level and what kind of deviations should be approved at higher level: EFMHACA/MOH
- Extensively trained experts' availability at Region, Federal or at the regulatory level for provision of training in the downstream of the supply chain and to make decision when cold chain excursion is reported.
- Strengthening and capacity building of the EFMHACA pharmaceuticals quality control department to extend its activity on the survey of the cold chain management quality of Government health facilities, Non-Governmental health facilities, importers, whole sellers, pharmaceutical manufacturing and the private drug outlets: Retail pharmacies, Drug stores, Clinics and so on to be quite sure the pharmaceuticals in all health facilities of the country are with guaranteed quality, safety and efficacy.

The research is specific and it may not show the whole picture, but can be considered as tip of the iceberg. Therefore there is a real need for further study and investigation in the area, in order to have the big picture at country level.

Whenever we think good storage temperature we have to consider the following points:

Vaccine Storage Requirements

Vaccine storage units must be selected carefully and used properly. A combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate door. However, vaccines should not be stored near the cold air outlet from the freezer to the refrigerator. Many combination units cool the refrigerator compartment by using air from the freezer compartment. In these units, the freezer thermostat controls freezer temperature while the refrigerator thermostat controls the volume of freezer temperature air entering the refrigerator. This can result in different temperature zones within the refrigerator.

Refrigerators without freezers and stand-alone freezers usually perform better at maintaining the precise temperatures required for vaccine storage, and such single-purpose units sold for home use are less expensive alternatives to medical specialty equipment. Any refrigerator or freezer used for vaccine storage must maintain the required temperature range year-round, be large enough to hold the year's largest inventory, and be dedicated to storage of biologics (i.e., food or beverages should not be stored in vaccine storage units). In addition, vaccines should be stored centrally in the refrigerator or freezer, not in the door or on the bottom of the storage unit, and sufficiently away from walls to allow air to circulate.

Temperature Monitoring

Proper temperature monitoring is a key to proper cold chain management. Thermometers should be placed in a central location in the storage unit, adjacent to the vaccine. Temperatures should be read and documented twice each day, once when the office or clinic opens and once at the end of the day. Temperature records should be kept on file for >3 years, unless state statutes or rules require a longer period. Immediate action must be taken to correct storage temperatures that are outside the recommended ranges. Mishandled vaccines should not be administered.

One person should be assigned primary responsibility for maintaining temperature logs, along with one backup person. Temperature logs should be reviewed by the backup person at least weekly. All staff members working with vaccines should be familiar with proper temperature monitoring.

Different types of thermometers can be used, including standard fluid-filled, min-max, and continuous chart recorder thermometers. Standard fluid-filled thermometers are the simplest and least expensive products, but some models might perform poorly. Product temperature thermometers (i.e., those encased in biosafe liquids) might reflect vaccine temperature more accurately. Min-max thermometers monitor the temperature range. Continuous chart recorder thermometers monitor temperature range and duration and can be recalibrated at specified intervals. In addition, temperature indicators WHO approved indicators can be considered as a backup monitoring system; however, such indicators should not be used as a substitute for twice daily temperature readings and documentation.

All medical care providers who administer vaccines should evaluate their cold chain maintenance and management to ensure that:

- 1) Designated personnel and backup personnel have written duties and are trained in vaccine storage and handling;
- 2) Accurate thermometers are placed properly in all vaccine storage units and any limitations of the storage system are fully known;
- 3) Vaccines are placed properly within the refrigerator or freezer in which proper temperatures are maintained;
- 4) Temperature logs are reviewed for completeness and any deviations from recommended temperature ranges;
- 5) Any out-of-range temperatures prompt immediate action to fix the problem, with results of these actions documented;
- 6) Any vaccines exposed to out-of-range temperatures are marked "do not use" and isolated physically;
- 7) When a problem is discovered, the exposed vaccine is maintained at proper temperatures while state or local health departments, or the vaccine manufacturers, are contacted for guidance;

8) Written emergency retrieval and storage procedures are in place in case of equipment failures or power outages. Around-the-clock monitoring systems might be considered to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.

On top of that, professionals and as a citizen we have to ask ourselves why we face recurrent outbreaks of Measles, Polio ... While our Expanded Program on Immunization (EPI) has been run for decades with sound good coverage. But, do these emergencies have a link with mismanagement of our vaccines? Is the question to be answered.

5.3 Directions for Future Researches.

The study was conducted by monitoring the cold chain system of the selected Hospitals only for one week. The quality of the cold chain system is not a onetime procedure which declares that the system is good or bad, it need observation for longer period to give a rational judgment on the quality. Therefore, the future study has to be conducted by monitoring the system for longer period may be for months in order to reach in conclusion , that certain system is whether in line with the standards or not.

The study was conducted taking in to consideration the hospitals working under Addis Ababa Health Bureau. There are also hospitals in Addis Ababa working under the supervision of Federal Ministry of Health, which are dealing with wide range of vaccines and other cold chain diagnostic tests, laboratory reagents... and so on. These Hospitals are: Black Lion, St. Petros, St. Pawlos, ALERT Hospital, and St. Amanuel are those working under the Federal MOH. In the other hand there are also more than 25 Health centers in Addis Ababa, where routine vaccination program is provided on daily basis .Therefore the future study shall consider those hospitals and Health centers which were not included in this study to have a clear view of the cold chain management system of all government health facilities in Addis Ababa.

The study was conducted in Addis Ababa. All hospitals have relatively a 24 hrs electrical supply system. One of the reasons for the cold chain break is an electric interruption. Even at this condition the study result showed there is a cold chain break. If we consider the other Health facilities outside Addis Ababa in other Regional Hospitals, Health Centers, clinics of different regional states, Zones and Weredas we may found quite interesting results which need an urgent corrective

measures to be taken. Therefore in the future conducting a study at a country level will show clearly the status of the cold chain at national level.

The private health sector has been increasing from time to time. These facilities are also involved in the management and provision of vaccines for the population in need. This sector also has to be studied for its compliance in regards to quality of cold chain.

The study conducted in the hospitals was from the supply chain point of view. There should be also a study to be conducted from the medical point of view in the future. The medical point of view will explain the impact of cold chain break on the health of beneficiaries. Lack in the protection of the individual from diseases, improper diagnosis and improper treatments due to failure of cold chain can be best explained when the medical side of the study is conducted.

There is also a need for the study in the future in cold chain warehouses for vaccines and cold chain medical supplies at Bole Airport cargo terminal and PFSA. Especially in the PFSA warehouse a longer period study has to be conducted since the cold chain items are kept in the system for years. It helps to see the fluctuations cumulative effect on those cold chain items.

Most frequently, problem in the cold chain management are observed during packing and transporting. The future study shall also focus on how vaccines are packed and transported from central level to regions by tracking them with a device used in this study. It clearly will show the other side of problem in this regards.

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Annexes

Annex: 1Data collecting instruments

1. LogTag® temperature recorder and reading interface.

**LogTag®
Recorders**



LogTag® Analyzer

Annex 2: Questioner

ADDIS ABABA UNIVERSITY SCHOOL OF COMMERCE

Questions: To be answered by the cold chain responsible person of the Hospital.

Dear Respondent,

First I want to explain my gratitude for your time in order to respond on the following questions, regarding the cold chain management system in the Hospital. The questions are prepared as a checklist. I am a post graduate student at Addis Ababa University School of commerce from the department of Logistics and Supply Chain Management, currently working on a thesis project” Quality of Cold Chain Management in Government Hospitals in Addis Ababa”

You are identified as a respondent person since you are dealing with cold chain items on daily basis. Your response on the questions will provide me concrete information in regards to the management of cold chain items in the hospital.

Purpose of the study is to examine the cold chain system of the hospital in order to understand the existing practice. All the information will be kept confidential and has no any risk in conjunction with it. But if you don't feel comfortable you can withdraw from the study at any time.

Best regards,

EndaleMenberuTessema

Post Graduate student, in Logistics and Supply Chain Management (LSCM)

Tel: 251 911 66 9314

E-mail: endaleebsr@gmail.com

Skype: escons17

Addis Ababa, Ethiopia

SECTION A:

DEMOGRAPHIC CHARACTERISTICS

Gender:

- a. Male b. Female

Department:

- a. Medical: b. Logistics

Qualification:

Certificate Dipl st Degree Mast

Experience:

Less than 1 year 1-5 years 6-10 years More than 10 years

SECTION B:

Checklist for an assessment of Cold Chain Management System in Government Hospitals in Addis Ababa, City.

| Basic principles/procedures | | Yes | No |
|-----------------------------|---|-----|----|
| 1. | The cold chain room is separated from the main store | | |
| 2. | The responsible person knows the storage temperature range for vaccines in the refrigerator | | |
| 3. | The refrigerator is large enough to keep all cold chain items | | |
| 4. | The responsible person knows what does holdover time means | | |
| 5. | The responsible person knows holdover time of the refrigerator/s | | |
| 6. | There is no any food item in the vaccine refrigerator | | |
| 7. | All vaccines are stored in the correct compartment | | |
| 8. | A national cold chain protocol or EPI guideline available in the Hospital | | |
| 9. | Perfectly working refrigerator is available in the health facility | | |
| 10. | Does the health facility have sufficient deep freezers? | | |
| 11. | Are refrigerators located away from any surrounding objects (approximately ½ meter)? | | |

| | | | |
|--|--|-----|----|
| 12. | A temperature monitoring device/s are available in all refrigerators | | |
| 13. | Temperature recording sheet is available | | |
| 14. | The temperature is recorded in the sheet twice per day | | |
| 15. | The arrangement of the vaccines in the refrigerator considers their intrinsic nature | | |
| 16. | There is a backup system in the place for electricity interruption | | |
| 17. | There is backup system in the place in case the refrigerator breaks | | |
| 18. | Sufficient cool boxes and Ice packs are available to keep the vaccines/cold chain items until the cold chain breach resolved | | |
| 19. | Experts /institute availability to advice/ make decision during the cold chain breaks | | |
| 20. | Regular follow-up on the quality of the cold chain management from the regulatory bodies. MOH? Or FMHACA? | | |
| 21. | Have you encounter cold chain breach? | | |
| 22. | How often you encounter cold chain breach? More than once in the last 3 months? | | |
| 23. | If the answer for Q 21 is Yes, do you inform for experts for technical decision? | | |
| 24. | Does the stock manager know what does conditioning of ice packs mean? | | |
| 25. | Does the stock manager know what does room temperature means? | | |
| 26. | Do you have a check list for reception of cold chain items from suppliers to your facility? | | |
| 27. | Do you have checklist for transporting of cold chain items from warehouse to the departments? | | |
| 28. | Does the cold chain system have a regular maintenance schedule? | | |
| 29. | Is there a stock rotation system for cold chain items to reduce the quantity of expiry at hand? | | |
| 30. | Is the temperature chart up-to-date? | | |
| Dispatching of cold chain items | | Yes | No |
| 1. | Is there a check list to dispatch cold chain items from the health facility? | | |
| 2. | Do you use vaccine carriers/cool box to transport cold chain items in the Health institution? | | |
| Reception of Cold chain items | | Yes | No |
| 1. | Is there a check list for reception of cold chain items from suppliers? | | |

Annex 3:LogTag® readings

for the GOV.HO. 001(Menelik) and
GOV.HO.002(Ras Desta)

| Hospital Code | Log Tag® Model | Evaluated Time | Reading Interval | Adjusted Temperature(C°) | Evaluated Readings | Lowest Reading | Highest reading | Cold chain break Recorded | Time of Break Above > 8 or < 2 C° | Standard deviation(S) | Remark |
|---------------|----------------|---------------------|------------------|--------------------------|--------------------|----------------|-----------------|---------------------------|--|-----------------------|---|
| GOV.HO 001 | TRIX 8 | 10 Days 19 Hours | 15 min. | 2-8 C° | 1039 | 2.6 C° | 8.9 C° | Yes | above : 8 C° @ 15/05/2017 02:23:26 2 Hours, 52 Minutes, 30 Seconds | 1.5 C° | There was a cold chain break for 2hr 52 min. expert advice is needed. |
| GOV.HO 002 | TRIX 8 | 10 Days 18 Hours | 15 min. | 2-8 C° | 1035 | 8.9 C° | 12.9 C° | Yes | above : 8 C° @ 12/05/2017 16:53:29 10 Days, 19 Hours, 30 Minutes | 0.8 C° | The cold chain has been above 8 degree throughout the study period. |

Annex 4: LogTag® readings
for GOV.HO.03(Yekatit) and
GOV.HO.04(Zewditu)

| Hospital Code | Log-Tag® Model | Evaluated Time | Reading Interval | Adjusted Temperature(C°) | Evaluated Readings | Lowest Reading | Highest reading | Cold chain break Recorded | Time of Break Above > 8 or < 2 C° | Standard deviation(S) | Remark |
|---------------|----------------|---------------------|------------------|--------------------------|--------------------|----------------|-----------------|---------------------------|--|-----------------------|--|
| GOV. HO 003 | TRIX 8 | 10 Days 19 Hours | 15 min. | 2-8 C° | 1039 | 5.0 C° | 7.8 C° | No | No | 0.9 | Perfectly working cold chain |
| GOV. HO 004 | TRIX 8 | 2 Days 5 Hours | 15 min. | 2-8 C° | 214 | 1.5 C° | 3.6 C° | Yes | Below: 2 C° @ 26/05/17 12:47:48 for 3 hrs. | 0.6 C° | All cold sensitive vaccines are exposed for low temperature. |

Annex 5: LogTag® readings

for GOV.HO.05(Gandhi) and
GOV.HO.06(Tirunesh)

| Hospital Code | Log-Tag® Model | Evaluated Time | Reading Interval | Adjusted Temperature(C°) | Evaluated Readings | Lowest Reading | Highest reading | Cold chain break Recorded | Time of Break Above > 8 or < 2 C° | Standard deviation(S) | Remark |
|---------------|----------------|---------------------|------------------|--------------------------|--------------------|----------------|-----------------|---------------------------|--|-----------------------|---|
| GOV. HO 005 | TRIX 8 | 10 Days 19 Hours | 15 min. | 2-8 C° | 214 | 3.5 C° | 12 C° | Yes | Above: 8 C° @ 24/05/17 1:41:01 for 3 hrs. | | The vaccines were exposed for high temperature |
| GOV. HO 006 | TRIX 8 | Error | 15 min. | 2-8 C° | Error | Error | Error | Error | Error | Error | The reader was damaged and data extraction failed |