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THE CHALLENGES TO STORAGE TEMPERATURE ADHERENCE AT DISTRICT VACCINE STORES IN MALAWI

Thesis submitted to the University of Rwanda, in partial fulfilment of the

requirements for the degree of Masters in Health Supply Chain Management (MHSCM)

By

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DECLARATION

I, Chimwemwe Chunga to the best of my knowledge, hereby declare that the thesis titled "**The challenges to storage temperature adherence at district vaccine stores in Malawi,"** is my own work and has never been presented in any institution of higher learning for any academic qualification.

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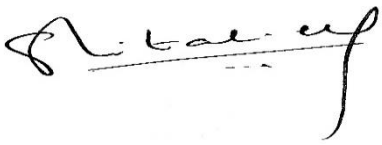

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DEDICATION

To my wife Roseline Chunga and two sons Chimwemwe Victor Chunga and Vitumbiko Kafamtenganji Chunga I dedicate this thesis.

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ABSTRACT

Background: Over the years new vaccines have been introduced in the EPI program since its initiation in 1979. The EPI program has been introducing new antigens since reception in 1979 from 4 to 13 in 2019. Vaccines are kept at national, regional and district vaccine stores apart from service delivery points. While these stores are known to have available human resource, standard operation procedures and connection to national power grid, adherence to temperature requirements is still one of major challenges. This research aimed at examining the factors that contribute to non-adherence to temperature ranges at district vaccine stores (DVS) in order to contribute towards a reduction in vaccine wastage due to temperature excursions.

Methods: This study was sequential mixed method design where qualitative and quantitative data were collected. The study sample size was 67 cold chain technicians and 101 refrigerators. Data Collection was done using three tools namely; structured questionnaires for cold chain technicians for quantitative. structured checklist for cold chain equipment and Fridge Tag2 temperature data was downloaded. On qualitative data, a question guide for an in-depth interview was used. Data analysis for correlation was done using Statistical Package for Social Scientists (SPSS) Version 23.0 while Microsoft Excel package was used for descriptive statistics. Thematic analysis was used for qualitative data.

Results: It was observed that, 13 (46%) districts were found to have at least one refrigerator operated at temperatures above $8^{o}C$ for a period of more than 10 hours and $-0.5^{o}C$ and below for an hour or more. Furthermore, it was found that there was a significant correlation [$p = 0.004$, $r(47) = 0.417$] between alarms and average temperature. Out of 28 districts, 22 (79%) districts had their temperature charts completed correctly and 82% recorded it twice a day. However, lack of power back up, fuel, maintenance tools and lack of refresher training were amongst the major challenges that were being reported.

Conclusion: There was a relationship between temperature and alarms recorded. Lack of power back up, maintenance tools and fuel were the major challenges which were revealed. There is need to provide power back up and maintenance tools to DVSs in order to improve cold chain management.

ABBREVIATIONS AND ACRONYMS

BCG	:	Bacillus Calmette Guerin
CCE	:	Cold Chain Equipment
CCT	:	Cold Chain Technicians
DVS	:	District Vaccine Store
EPI	:	Expanded Program on Immunization
FT2	:	Fridge Tag 2
HPV	:	Human Papilloma Virus
IPV	:	Inactivated Polio Vaccine
ISC	:	Immunization Supply Chain
MR	:	Measles Rubella
NVS	:	National Vaccine Store
PCV	:	Pneumococcal Conjugated Vaccine
RVS	:	Regional Vaccine Store
SOP	:	Standard Operation Procedure
Td	:	Tetanus depthelia
VVM	:	Vaccine Vial Monitor
WCR	:	Walk in Cold Room
WIFR	:	Walk in Freezer Room

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CHAPTER ONE:

1.1 Background information

This chapter provides an overview on temperature adherence and challenges in funnel way starting from global. Temperature adherence and challenges in this document are organized from global perspective, Africa and finally Malawi.

1.1.1 Global status of supply chains

Health institutions encounter numerous challenges accompanied with new requirements such as customer dissatisfaction and increasing cost of the health services. All of these aspects force the health organizations to adopt a system that can meet these requirements, dealing with the continuous changes, technology changes, rise in the health service costs, increase in competitive position and gaining customers' satisfaction[1]. There is an increasing need by private health institutions administrators to assume supply chain management in order to encourage the development of health care [2]. Due to cost control supply chain management has become an important phenomenon by health care organizations in order to achieve the organization's set goals. Supply chain management (SCM) deals with different categories of flows namely: flow of goods, cash and information within and among supply chain partners in order to satisfy consumer needs in the most efficient way [2]. Immunization supply chain consists of people, data, and assets such as refrigerators, processes that manage the data collection, forecast and ordering, distribution, cold chain and dry storage of vaccine and associated injection devices[3].

Vaccines have to maintain their quality from production, transportation, storage and time of administration[3]. The quality of supply chain management on health care have to do with excellence from an administrative point of view, and medical service quality can be measured either from a professionally medical perspective, or from the recipient of such services, the patient, or from an administrative perspective, which is the focus of this study. The quality of health care services rendered from an administrative perspective primarily makes use of the available resources and the ability to attract new ones to cover the required needs of exceptional service, at the right time and at a reasonable cost. Supply chain management (SCM) deals with the management processes of flow of goods, information and funds among supply chain partners in order to satisfy consumer needs in an efficient way [2].

Both freezing and heat may cause damage to vaccines during storage [4]. Exposure to freezing damage vaccines that are heat sensitive at -0.5^{O}C within a period of not less than 1 hour while heat damage vaccines at temperatures of above 8^{O}C within a period of not less than 10 hours [5]. Damaged vaccines due to heat exposure can be identified by checking vaccine viral monitor (VVM) colour change. Vaccine vial monitor has four stages namely stages 1, 2, 3 and 4. Stages 1 and 2 are recommended for use while 3 and 4 are not. Heat sensitive vaccines such as Measles Rubella and BCG can be frozen, while freeze sensitive such as Td and PCV vaccine lose potency [3]. Vaccine viral monitor are heat and not freezing indicators. In Malawi, vaccine freezing is monitored by Fridge Tag 2 during storage and Freeze Tag during transportation[4]. For one to know that vaccine was frozen, there is need to conduct shake test once freezing is suspected. Health workers handling vaccines need to have knowledge on how shake test is conducted in order to rule out vaccine freezing [4],since one cannot tell that a vaccine is damaged due to freezing by looking with eyes unless the vial is still in frozen state or shake test has been conducted. Some health workers may use vaccines that have lost potency. When vaccine freezing is suspected, shake test is recommended.

1.1.2 Health supply chain system in Malawi

The health system in Malawi has three tiers, namely tertiary, secondary and primary. The highest level of health system is tertiary followed by secondary and primary. Tertiary facilities are central hospitals, while secondary are district hospitals and primary are rural hospitals/health centers and health posts. Vaccines are administered at secondary and primary levels of the health system. The Malawi health system operates in zones but the geographical boundaries are in regions. There are three regions namely north, central and south which are further divided into five health zones. There are 2 health zones in the central and southern region while one in the north[6].

The structure of EPI program follows the pattern of health system from national to health post. In each region there is a regional vaccine store serving districts with immunization supplies on a monthly basis, while regional vaccine stores are served by national vaccine store every quarter[4].

The storage duration for vaccines at national vaccine store is six months while regional vaccine store is three months. District vaccine stores, community hospitals, rural hospitals,

health centers and health posts keep vaccines for a month only. Storage temperature for vaccines at NVS and RVSs is -25^{O}C to -15^{O}C for heat sensitive vaccines. While freeze sensitive are kept at +2 ^{O}C to +8^{O}C. In Malawi, DVS and service delivery points store all vaccines at +2 ^{O}C to +8^{O}C.

Across the country, there are 29 district health offices with a district vaccine store (DVS) individually. The district vaccine store is a facility at a district health office with a number of refrigerators for storing vaccines and dry store for keeping injection device. Each DVS has a minimum of 2 refrigerators and maximum of seven depending on population size.
Additional vaccines have been introduced in the immunization program since its initiation in 1979 from 5 to 13. Newly introduced vaccines include PCV in 2002, Rota in 2011, Measles rubella in 2015, IPV in 2016, PCV13 and Td in 2017[7], HPV and Malaria on implementation trial in 2019[8].

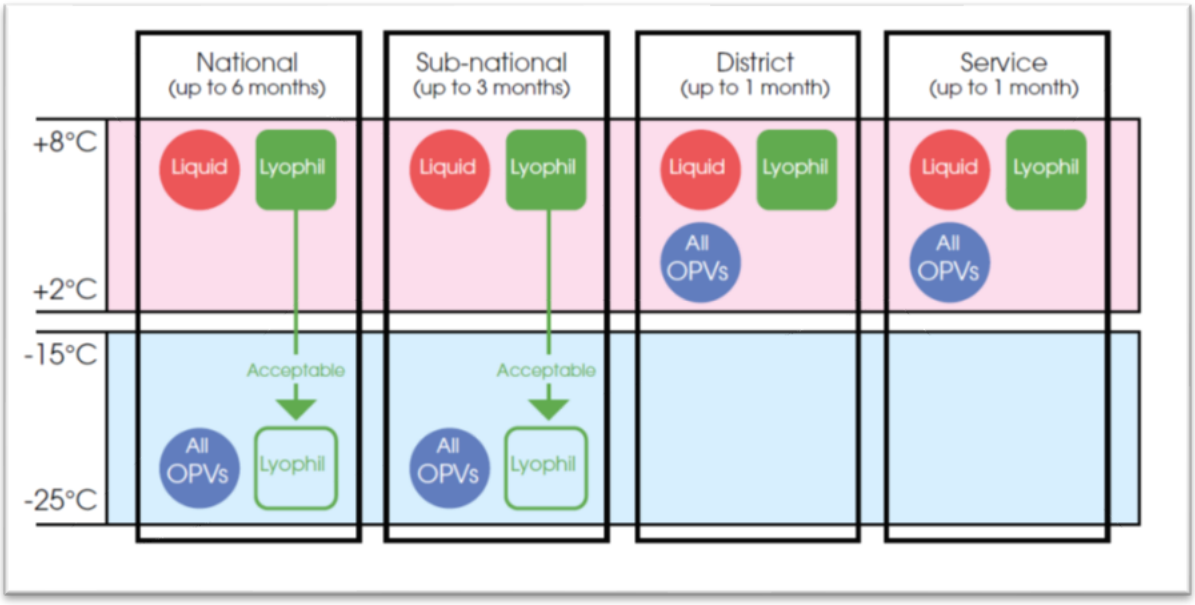


Figure 1: WHO recommended storage temperature and duration at different tiers[9]

This research was examining factors that contribute to non-adherence storage temperature at district vaccine stores in Malawi. The scope of this study included human resource knowledge, equipment performance and processes adhered to at DVS.

1.2 Problem statement

Vaccines are delicate biological products that are easily damaged by heat or freezing and must be kept at the correct temperature from manufacturer to the point of use. The system used to distribute vaccines in good condition is called cold chain. Cold chain consists of

storage and transportation vessels [10]. Despite the availability of WHO prequalified refrigerators, standard operational guidelines, cold chain technicians and cold chain trainings, countries adherence to WHO standards were established to be poor. Considering average scores from effective vaccines management by UNICEF at regional and district vaccine stores and service delivery points were less than 80% minimum required score: ability to monitor storage temperatures (24%), buildings and cold chain equipment, cold chain maintenance 16%, vaccines management 30%,infomation system 20% and pre-shipment & vaccine arrival 20% [10]. In additional to non-adherence to storage temperature, vaccine wastage may also occur through opened or unopened vials, expiry, breakage, exposure to freezing and heat [11]. In Africa immunization failure (antibody formulation failure) may be due to questionable vaccine potency resulting from cold chain problems, poor seroconversions and weakening immunity[12]. Further research reveals that there are other factors such as cold chain problems that lead to immunization failure [11].

Although Malawi has high coverage in most antigens, measles second dose was introduced to boost immunity in case first dose did not result in seroconversion due to vaccine damage during storage amongst other reasons. Cold chain problems still exist at different levels of the immunization system. In order to address such problems EPI Malawi has embarked on different strategies such as trainings, procuring of new cold chain equipment (refrigerators, cold boxes, vaccine carriers, voltage regulators) and intensifying supervisions to improve cold chain. The EPI Program also introduced standard operation procedures (SOP) on immunization supply chain in 2016. According to unpublished EPI programme report on temperature monitoring it was revealed that temperatures were within the normal range at national and regional vaccine stores. However, the report established that district vaccine stores and service delivery points adherence to storage temperature was a problem. So far there is limited study to explore the reasons for non-adherence to cold chain immunization procedures in Malawi. Only one study conducted in 2015 focused on exposure to freezing that tracked Penta valent vaccine from NVS to service delivery point. However, the study did not look at other issues such as human resource knowledge, equipment and processes except for temperature. Again, the sampled districts had at least one or both data loggers indicating temperature excursions. Out of 12 data loggers, it was established that 8 (67%) had at least one temperature excursion within 90 days of the study [13]. Current temperature data collected in the first week of June 2019 from 92 refrigerators at DVSs found that 12 (13%) had at least one temperature excursion in 60 days despite different strategies put in

place by EPI Program [14]. Therefore, this study explored other factors behind non-adherence to temperature for cold chain in DVS across all 29 district health offices.

1.3 Research significance

The purpose of this study was to contribute towards reduction of vaccine wastage due to non-adherence to temperature storage requirements and enhanced benefits from immunization services by vaccinating with potent antigens. Using potent vaccine does not only have economic benefits but also prevent adverse effects following immunization. Considering the high cost of vaccines [8], this study was intended to significantly contribute towards reduction of vaccine wastage as a results of temperature excursions during storage and ensure that potent vaccines are used for vaccination.

1.4 Broad research objective

The main objective of this study was to investigate the immunization cold chain temperature adherence and non-adherence of all 29 district vaccine stores in Malawi.

1.4.1 Specific research objectives

The specific objectives of this study were to:

a) Assess knowledge of cold chain technicians in management of cold chain systems.
b) Analyze the performance for vaccine storage refrigerators.
c) Determine cold chain processes that are adhered to at district vaccines stores
d) To assess challenges that affect some district vaccine stores not to adhere to storage temperatures for vaccines.

1.5 Research questions

a) Are the cold chain technicians knowledgeable in managing the district vaccine stores?
b) Do different vaccine storage refrigerators perform to the required standards?
c) Which cold chain processes are adhered to at district vaccine stores?
d) What are the most common reasons that prevent the cold chain technicians from taking corrective actions?

1.6 Research hypothesis

Based on-research questions, different hypotheses were pursued in order to assess the knowledge of cold chain technicians, performance of refrigerators, processes adhered and not adhered to at DVS in management of district vaccine stores. Below are the following hypotheses that were formulated:

i. Cold chain technicians across DVSs are knowledgeable in managing cold chain systems.

ii. All cold chain processes are adhered to at district vaccine stores.

iii. There is relationship between the management of cold chain system and associated factors.

CHAPTER TWO:

2.0 Literature Review

2.1 Introduction

Literature review section has related key information gathered from other studies. The section is assembled into four sub tittles namely: Human resource knowledge in managing temperatures, cold chain equipment, routine processes and cold chain management challenges.

2.2 Operational definitions

This section provides some technical operations definitions used in immunization programme. Below are operation definitions based on the EPI field manual for Malawi of November 2012[15].

Variable:	Operation definition
Walk in cold room:	A refrigerated enclosure with a door large enough to allow a person to walk into it. The enclosure is used for storing freeze sensitive vaccines such as pentavalent and PCV. It operates between +2^{o}C to 8^{o}C. The enclosure is usually used at national and regional vaccine stores. It can also be used in districts with large populations[15]
Walk in freezer room:	A refrigerated enclosure with a door large enough to allow a person to walk into it. The enclosure is used for storing heat sensitive vaccines such as BCG and Measles rubella. It operates between -25^{o}C to -15^{o}C. The enclosure is usually used at national and regional vaccine stores. It can also be used in districts with large populations[15]
Fridge Tag 2:	Temperature monitoring device used at district vaccine stores. It records temperature continuously and stores data for 60 days. Health workers check temperature from it twice daily and plot results on temperature charts. Fridge Tag 2 (FT2) triggers alarms when exposed to temperature of -0.5C for one hour or above 8^{o}C for 10 hours. Data from FT2 is ca be downloaded using USB into a computer or phone[16].

Freeze Tag:	Freeze tag is a temperature monitoring device that is used to monitor freezing temperature during transportation of vaccines. An "X" on freeze tag signaling exposure to freezing. This meaning that vaccines may have been damaged hence shake test to rule out vaccine freezing is mandatory. On the other hand, a tick "✓" indicating no exposure to freezing was experinced meaning that vaccines are safe.
Shake Test:	It is a test that is used to rule out if freeze sensitive vaccines that were suspected to have been frozen were really frozen. The test is not done to vaccines that are visibly frozen since the proof is already there. Examples of vaccines that qualify for shake test once freezing is suspected include PCV and Td[7][15].
VVM:	An acronym standing for Vaccine Vial Monitor. It is a thermal indicator on the top cover or side of vaccines vial. The VVM is used to monitor if vaccines vial was exposed to temperatures of above $8^{o}C$. VVM measure cumulative temperature and it is irreversible once the state migrates from used states to unused stages. There are 4 stages of VVM (I, II, III & IV). Stages I & II are suitable for use while III & IV are not[15].
Freeze Senstive vaccines:	These are vaccines that are easily damaged by freezing. By no any means these vaccines must be kept in freezing temperatures[15].
Heat Senstive vaccines:	These are vaccine that are easily damaged by heat and light.
Cold chain:	The term included all devices used to ensure right temperature for vaccines is maintained. This includes: cold boxes, vaccine carriers, cool packs and refrigerators amongst others[15].
Cold chain technicians:	Cold Chain technicians are trained personnel in cold chain management responsible to maintain cold chain equipment and manage vaccines stock. In Malawi the cadre is responsible for managing district vaccine stores[15].

Health Assistants:	**Surveillance**	**Community health worker cadre that is responsible for vaccinating children in Malawi in addition to other health workers.it is this cadre that is trained in cold chain management to become cold chain technicians.**

2.3 Theoretical framework on supply chain evolution.

A number of models on supply chain management are available. An example of these models is the 'health and immunization supply chain evolution' which is based on supply chain leadership and management. Apart from that, other models include supply chain organization, policies, procedures and supply chain strategy implementation [12]. Ministry of health has the overall responsible for ensuring that sufficient quantities of essential commodities are available at the correct locations in different health institutions. The quality of pharmaceuticals maybe addressed by establishing policies and monitoring mechanisms to ensure quality standards are maintained. Quantities and availability are addressed by policies related to who is authorized to distribute commodities and authorized distribution sites. It is further argued that the MoH may provide sufficient quantities of commodities in the correct locations by determining the supply chain management system to be used [12].

Usually, immunization and vaccine supply chains have been centralized, with the MoH playing a central role. Due to increasing complexity, health supply chains are now following the evolution of commercial supply chains. The idea of a network is now established as the new working model. Supply networks adapt, as organizations collectively attempt to fulfill demand through individual firm-level actions while responding to changes in both the environment and actions of other firms in the network. Based on this evolution theory, the MoH must play the role of a steward, providing guidance and vision in regard to, but not exercising direct control over, services and facilities. Common approaches of MoH include public sector implementation, outsourcing all functions, or individual functions, of the SCM system, and mixtures of public/private implementation mechanisms. All these activities should fall under a predominant supply chain strategy. It is unclear if the MoH defines a supply chain strategy in these terms, and if this strategy is connected to activities that aim to develop human resource capacity [12]. For this study since all the cold chains fall under the Malawi's Ministry of Health system, the 'health and immunization supply chain evolution' was applicable to this study.

2.4 Human resource knowledge on temperature management

Knowledge can be acquired through five stages and applied differently. These stages on knowledge acquisition include the novice stage (in which the learner needs to be instructed and they can acquire only simple facts and features that are context independent and then rules for determining action based on these facts and features); advanced beginner stage (in which the learner recognizes the first situational aspects); competent stage (in which the dominant feature is organization); proficient stage (where intuition first appears) and expert stage (which is characterized by complete indwelling-the expert does not become detached from the situation anymore, does not devise any plans, does not worry about the future, they don't see problems and solves them[12]

Over the past 60 years, many innovations have been introduced in the field of immunization, cold chain, temperature monitoring and vaccine handling. These new innovations call for capacity building for health workers taking care and handling vaccines. There is need for enhanced trainings on cold chain management in order to impart skill and knowledge [17]. While it is believed that knowledge is power, results of study on knowledge and adherence to cold chain in Malaysia showed that majority of health workers responsible for taking care of vaccines have78.7% knowledge, while their attitude is significantly poor (79.7%) towards cold chain. Due to poor attitude, it was established that there was only 5.6% adherence to cold chain practices [18]. The study did not say how much proportion of the facilities were targeted and covered as a country however it was indicated that all the facilities that are involved in the immunization services in the selected areas were considered for the study. In addition to that, results of the study revealed that the level of knowledge and level of negative attitude to cold chain is almost the same hence low 5.6% adherence towards cold chain practices. Knowledge of cold chain among vaccine handlers and monitors is limited.

Immunization supply chain requires dedicated leaders and entire supply chain staff in order to achieve its goals. Since human resource is considered as the backbone for the success of every health system. Recommendation made by Kasonde M and Steele P in 2017 on human resource policies, procedures recruitment, management, job description, working conditions, training opportunities, carrier path must be addressed in order to make impact on immunization supply chain[19].

A study conducted in western Cameroon on factors associated to temperature excursion in cold chain, was established to be not more than 28.3%. Based on the study it was suggested that there was need for training on health workers and regular supervision [20]. As also supported by [21]that many technicians in Malawi, Uganda and Tanzania are under skilled

due to lack of training and this has an implication on management of cold chain equipment and other processes apart from that, knowledge of health workers was also limited on the following areas: open vial policy 57%, keeping of vials within $+2^{O}C$ to $+8^{O}C$ was 62% and storage of vaccine for only one month at district vaccines store and lower was 30%[20]. However, the study had section bias of sites to conduct the study since only facilities from western Cameroon were selected. There were two main recommendations from the study, need for intensive health workers training on cold chain and regular supervision.

Literature reviewed from another study on assessing quality of storage of vaccines at central Manchester and Bradford revealed that only 40% of health workers have adequate knowledge on appropriate storage of vaccines. The study established that power to run cooling machines was a problem, performance of refrigerators was also noted to have gaps. One of the challenges was respondents self-completing questionnaires were sent to respondents and sent back to the researcher after completion [22] hence this may have positive or negative effects. Advantages of respondents self-completing questionnaire include no influence bias due to the presence of researcher and anonymity. On a negative side of the respondents self-administered questionnaire include misinterpretation of some questions, no way of knowing if researcher is dealing with the right respondent and also high level of none respondent rate amongst others. The study also indicated that out of 8 facilities selected, 4 were selected due to proximity to the researcher therefore selection bias was not eliminated. Considering 4 out of 8 facilities selected based on proximity, it means that 50% of the facilities were affected by selection bias.

While other studies are encouraging on training of health workers as part of solution to cold chain problems, this has to be reinforced by regular supportive supervision which has been recommended to significantly improve cold chain, vaccine, and equipment management. It was suggested that there is also need to strengthen on interventions such as micro-planning and cold chain monitoring in order to improve on temperature management [23]. Health workers knowledge is key to adherence to cold chain temperatures, the study by Tan et al in 2018, established that there is no significant relationship between level of knowledge on health workers and taking care of vaccines with P= 0.159(23).

Cold chain management is limited among different cadres despite being that it is a prerequisite for vaccine safety. Data from research on origin of cold chain and glimpse of the future by Pasteur A and Francis T revealed that only 16% of physicians had adequate knowledge on cold chain. Some of the recommendations made were sourcing of reliable

equipment, such as prequalified refrigerators, cold boxes and vaccine carriers. The study also recommended to opt for solar power as an alternative or national grid power [23]. In many countries there is limited compliance on cold chain. Some of the factors contributing to unsatisfactory compliance is lack of designated personnel to take care and maintain refrigerators for vaccines at each site. It was established that there is significant relationship between lack of designated personnel for cold chain and less chance of achieving safe storage [24].

In conclusion, level of knowledge on vaccine storage temperature was found to be lower in health workers as revealed from different studies. Yakumu MN in 2015 established health worker's knowledge as low as 62 % while Thankker Y and Wood S in 1992 discovered that level of knowledge in health worker was around 40%. On the other hand, level of knowledge was also relatively moderate 78% as revealed by a study conducted by Azira B.in 2016 in Malysia. Based on a 2016 study conducted in France it was established that level of knowledge was as low as 16%.

2.5 Cold chain equipment

Cold chain system is a process used to maintain optimal temperatures for storage of vaccines from manufacturer, transportation, storage and handling up to the time of service point. There are different equipments used in cold chain such as cool packs, refrigerators, cold boxes, vaccine carriers, temperature monitoring charts and temperature monitoring devices amongst others [25]. According to WHO African region Mild level Management Manual on logistics and cold chain, vaccine refrigerators become none economical to repair after 10 years of commissioning hence they are supposed to be disposed off[26]. Research has revealed that most vaccine wastage is due to cold chain gaps as the highest cause seconded by vaccine expiration. In America, these two causes leadto wastage of at least 6 to 31 million United States Dollars. The study suggested that there is need for mailing out data logger to document ongoing compliance vaccine standard during storage [27].

A cross-sectional study in western Cameroon indicated that equipment breakdown is one of the major causes of temperature excursion in cold chain system. About 23% of health facilities involved in the study happened to have refrigerator breakdowns within 2 months. Within the same period, a total of 10% of BCG vaccines in two facilities were found to have altered vaccine vial monitor (VVM) which had reached discard point. Vaccine vial monitor changes to discard point once the antigen has been exposed to temperatures of above 8 ^{O}C

for a longer period while exposure to freezing is detected by fridge tag 2 and other temperature recording devices[20]. Since the study was a cross sectional and only one section of the country was considered, it would be difficult to generalize the results of the study for the whole Cameroon. Cross sectional study collects data at one point in time hence all seasons of the year are not considered. Study conducted by Vangroenwegh Porcine Health Management in 2017 revealed that refrigerator temperature is affected by season of the year. During cold season, refrigerator readings were found to be skewing towards lower temperatures while during the hot season they were skewing towards higher temperatures[28]. However, it has been argued that model of the refrigerator plays a role in temperature. The VLS 400 and MK304 have been recognized as among the best models as they have volume capacity of 90 to 120+ liters with a holdover day of 1.1[29].

There is a difference between domestic refrigerators and vaccine prequalified refrigerators. Vaccines are therefore supposed to be stored in prequalified equipment only since domestic refrigerators are designed to operate within the required $2^{O}C$ to $8^{O}C$ and maintain temperature within a reasonable period during power supply cut [24]. Having equipment is important but it is of no use to have equipment without reliable power. Power cuts and interruption is one of the major problems that cause losses in vaccines, damage equipment and alters temperatures of cold chain. In five facilities under the study in Cameroon, it was revealed that 17% of the facilities had power interruptions for longer hours [24].

Despite having grid power line as power source for cold chain equipment, there is still a wide gap for some facilities to access generator backup. It was noted that 90% of cold chain equipment did not have access to power backup. In addition to that, only 9% of refrigerators had voltage stabilizer. The study used structured questionnaire adopted from concepts of previous similar study[30]. Adoption of tool from a previous similar study may lead to repeated errors that were in that study. It was also established that health facilities lacked emergency plan in case there is refrigerator breakdown. Refrigerators are supposed to be kept 10 cm or above away from the wall, kept out of reach of direct sunlight and placed on wooden block. About 83% of facilities were established to have Fridge Tag 2 (Temperature monitoring device) cross Africa [31]. The study considered a wide range of the countries. Data from different set up gives a broader picture of a situation. The period for the study was five years, which was good enough to collect comprehensive data.

Use of same cold chain equipment for vaccines and other non-vaccines commodities increase the frequency of refrigerator opening. Cold chain is one of the most vulnerable point for immunization program. Some of the factors that lead to vulnerability of cold chain is increased frequency of opening of refrigerators. Increased frequency of opening of refrigerators is a risk for vaccines due to rise in temperatures[31]. Cold chain equipment maintenance does not only save vaccines from damage and economical losses but also prevent adverse effects following immunization (AEFI) that may occur follow using damaged vaccines due to malfunctioning cold chain system[32]. Data from study by Millik S. in India established that cold chain can be improved with proper rearranging of cold chain equipment and conducting cold chain training for vaccines handlers. Some of the activities that were done to improve cold chain performance were: Correct cold chain equipment placement, stock security maintenance, and orderly placement of cool packs, rotating of old stock when new stock is received and temperature reading and recordings [32].

2.6 Operation and processes

Worldwide, about 20 million children estimated to be under immunized and remain at risk of vaccine preventable diseases due to loss of vaccine potency during storage [33]. Introduction of many vaccines in developing countries has contributed to storage challenges. African countries need to cope up with the increased quantities and types of vaccines. Many challenges of immunization system affect supply chain, logistic and cold chain. These challenges affect almost all levels of immunization system namely national, subnational, districts and lower facilities. Countries need to adopt optimized supply chain to endure the upcoming workload of new and expensive vaccines[33]. Effectiveness of vaccines depends on proper management at all levels of tiers from manufacture to the point of service delivery as concluded in the study conducted in Dakshana Kannada district in India[34].

Vaccine packaging materials are specialized to withstand developing countries conditions. It is advisable to store vaccines in their original packaging material till the vaccine is administered to the beneficially. Since vaccines are expensive and fragile products adherence to general practices is highly advised to protect them from direct sunlight apart from temperature excursions[25]. Number of facilities with functioning refrigerator with properly organized stock were only 42% (11).

Data from several studies have indicated unsatisfactory monitoring of cold chain temperatures. Temperature charts are one of the key temperature monitoring activities that

are supposed to be done twice daily. However, it was established that 50% of health facilities did not adequately complete temperature charts in Cameroon. Furthermore, 63% did not attempt to complete temperature charts despite the task being a one of the routine process or activity [20]. Facilities with temperature charts were satisfactory 96% while with stock ledgers was very low 57% (20).

Some studies have revealed that good practices regarding cold chain management are still very low. Good practices were rated at 38% while knowledge was very high 86% on cold chain. Some of the areas that looked at good practices were cool packs storage which was found to be not satisfactory [31]. Efficient practices of cold chain and temperature monitoring are key to ensure optimal benefits from vaccines administration. It was revealed that good practices on cold chain was not very high 73.9%. Determinants of good practices were found to be cold chain training, presence of functioning refrigerators, supervision and level of education. Vaccines are supposed to be kept in separate refrigerators with other pharmaceutical and non pharmaceutical products. However, it was claimed that still 21% of facilities had vaccines mixed with other non vaccine products [31]. Good practices are still an issue in many countries based on different research such as that of Vangroenwegh F. The study revealed that good vaccine handling practices and storage were less than 10%. In addition to that, temperature was not satisfactory with 71% within accepted range of $2^{O}C$ to $8^{O}C$ due to unsatisfactory practices. It was also indicated that during the hot season average temperatures were $9.2^{O}C$ in 43% of the facilities (27).

In another cold chain study conducted in southern Nigeria claimed that only 73.9% of health workers taking care of vaccines had good practices on cold chain and temperature management. The study considered the determinants on cold chain management, functionality of refrigerators, supervision and level of education[35]. In a study conducted in Bradford and Manchester on assessment to quality of storage of vaccines, it was indicated that only 12.5% of facilities monitored and recorded temperature data twice daily [35]. Data from a study on awareness, practices and management evaluation of cold chain established that improper vaccine storage was less than 10%. However, in South India majority of health workers taking care of vaccines had adequate knowledge [33]. This means that having knowledge is not equal to adherence to good practices. Problems of vaccine storage are common and related to inadequate cold chain storage. In addition to that, lack of job description for personnel taking care of vaccines is another factor that contribute to non-

adherence to good practices. Some of the good practices that are not adhered to included not rotating of vaccines when new stock arrives and recording of temperature on monitoring charts twice daily[36].

2.7 Temperature adherence

Monitoring of vaccines storage temperatures is a corner stone of immunization services [37]. This is one of the best practices that need to be enhanced at all times. Vaccines lose potency very swiftly when exposed to temperatures of -0.5^{o}C for 1 hour or above 8^{o}C for 10 hours [20]..On average 26% of temperature excursions occurred within a period of two months in western Cameroon [38].

It has conclusively been shown in a number of studies including a study conducted in Lao People's Democratic republic in 2018 that temperature challenges are more visible at district vaccine stores and lower facilities [39]. Furthermore, the study by Kitamula et al, suggested that there was need for more effort to improve vaccine storage challenges. Temperatures were above 8^{O}C during the hot season and lower than 2^{O}C in the cold season also taking into consideration different regions [39]. It was revealed in a study conducted in Bradford and Manchester that 74% of facilities with temperature devices included in the study, exposed vaccine to temperatures above 16^{O}C [22]. The study further recommended that it was required to have adequate cold chain equipment, training of staff on cold chain on maintenance and care in order to achieve objectives on immunization services. One of the major factors associated with temperature excursion was established to be lack of `alternative power source rated at odds ratio of 6.5 and P= 0.03[22].

Vaccines are exposed to freezing during transportation, more than any other times. This is due to packing of vaccines too close to icepacks [40]. Another study in Indonesia revealed that most vaccines 75%, are exposed to freezing during transportation from subnational to district vaccine stores and health facilities[41]. About 48% of the 54% refrigerators included in study by Mc Collos P. and Vallbona C., operated within +2 ^{O}C to +8 ^{O}C. The same study revealed that about 24% of refrigerators protracted at less than 0^{O}C. Correlation of r=0.76 was recognized in relation to vaccine freezing and cases of pertussis [42]. About 14% of vaccines were found to have been exposed to temperatures below 0^{O}C and was about 10.5% in India in 2013. Vigorous effort to improve cold chain system monitoring during transport and storage was recommended [42]. In baseline survey by Nelson in 2004 in Indonesia, it

was established that about 75 % of freezing of vaccines occurred during transportation from regional vaccine stores to district vaccine stores and from district vaccine stores to health facilities. This was attributed. A policy change to regulate storage of freeze sensitive vaccine was recommended [42]. In addition to that, 14% to 35% of vaccines were found to have been exposed to freezing temperatures during storage and transportation by Matthias D.et al in 2007 conducted in many countries [43]. It has been further noted that this is not rarely exception but presents a chronic gap in management of the cold chain equipment which requires consistent monitoring of the excursions[44].

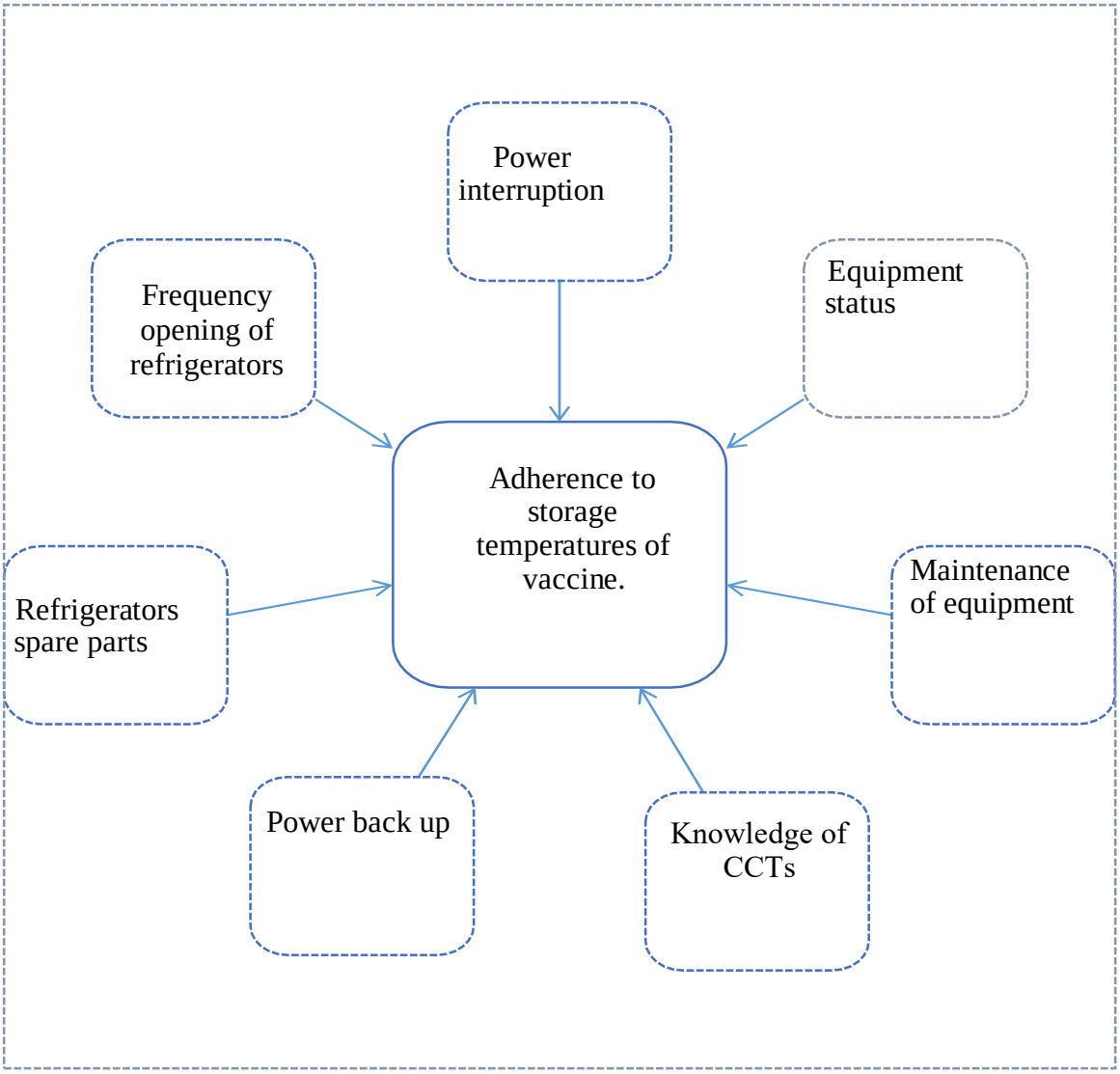
2.8 Challenges affecting vaccine stores

With the introduction of new vaccines, many countries face challenges in cold chain management to meet the demand[44]. A Study that was conducted in six countries established that main challenges of immunization cold chain include poor refrigerator performance of 58% that lead to freezing. The second problem revealed was improper ice pack conditioning 28%[45]. The study conducted in Uganda established that power access and roads were some of the challenges cold chain encountered. The challenge affected 75% of Health facilities in UG. Lack of performance management systems was also a challenge indicated to be affecting cold chain. it was also established that lack of latest or optimal technologies , inadequate temperature monitoring and lack of maintenance were some of the challenges encountered by immunization cold chain in Uganda [44]. Another study established that some of the challenges faced by cold chain include extreme temperature, humidity, interrupted power supply, insufficient maintenance of cold chain system, lack of spare parts and high failure rate of cold chain equipment. The study recommends tracking and evaluation of cold chain equipment for proper informed decisions[46]. Another study discovered that challenges to immunization cold chain include structural, funding and poor planning[47].Also another on transforming cold chain performance and management in lower income countries stressed that lack of technology to improve cold chain capacity, information, decision making and infrastructure were some of challenges for cold chain management[48]. Apart from that, less education, experience and knowledge were established to be some of the challenges for cold chain management[49]. Finally additional study stressed that challenges to storage temperature and transport for vaccines differ based on region[36].

2.9 Conceptual framework

This section on conceptual framework illustrates interaction of different independent variables with respect to storage temperature adherence at district vaccine stores.

Figure 2: Conceptual Framework



CHAPTER THREE:

3.0 Methodology

3.1 Introduction

This section of the study discusses the study design, location, target population, sample size, data collection technique, pre-test, validity, reliability, data analysis, logistics and ethical considerations that were considered.

3.2 Research design

This study was sequential mixed method design where qualitative and quantitative data were collected. Quantitative data was collected at initial stage followed by qualitative data gathered two weeks after quantitative. The quantitative data was analyzed first to identify areas that needed qualitative data support and completeness of information needed.

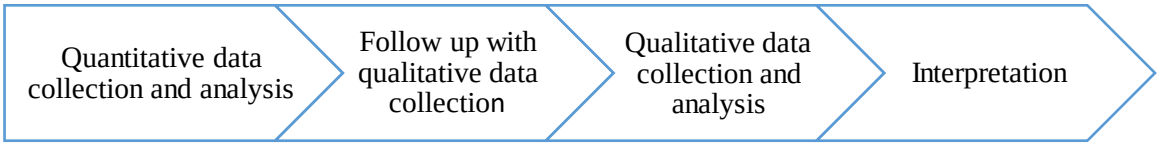


Figure 3: Sequential explanation mixed method design [50]

3.3 Location of the study

All twenty-nine (29) district vaccine stores were the study areas. Each district vaccine store was situated at district health office across the country. District vaccine stores were taken care by at least 2 cold chain technicians. Every district vaccine store had 2 to 7 refrigerators depending of the population size of the district.

3.4 Target and study population

This study had two categories of study population. The first category of study population was cold chain technicians. During this time of study cold chain technicians were health workers employed as health surveillance assistant (HSAs) who were trained in cold chain management. Cold chain technicians were usually deployed at district vaccine stores. Each Vaccine store had at least two cold chain technicians. In total there were 67 cold chain technicians who were situated at district vaccine stores across the country. The second target population was vaccine refrigerators in all district vaccine stores. Each district vaccine store had at least two refrigerators. In total there were 101 vaccine storing refrigerators (including 2 walk-in cold room) at district vaccine stores in Malawi.

3.5 Sample size

Sample size was not calculated since all 67 cold chain technicians and 101 refrigerators were targeted for quantitative data collection. As for qualitative data, purposively 15 cold chain technicians who were missed during quantitative data collection were selected.

3.6 Data collection

For quantitative data, three types of data collection tools were used in this study and these were: structured questionnaire for cold chain technicians and structured checklist for cold chain equipment. Data was also downloaded from Fridge Tag2 which is an instrument used to monitor temperature and it keeps sixty-day data. Data was collected using self-administered structured questionnaire to collect information from cold chain technicians at district vaccine stores. Checklist was used to observe information on equipment such as refrigerators, fridge tag 2 and temperatures monitoring charts. Thirdly, temperature data was downloaded from fridge tag 2 for every refrigerator. Each FT2 pdf data was saved in a laptop and saved by name of DVS and refrigerator model the FT2 was collected from. Fridge Tag 2 is an electronic device used to monitor vaccine Refrirators storage temperature. Temperature data for sixty days is stored in FT2. The data could be downloaded on visual display to check records for the past sixty days.

In this study, sixty-day temperature data was downloaded from FT2 of each refrigerator included in the study. Similar data that was beyond sixty days was collected from temperature monitoring charts. Temperature chart is a hard booklet with graphs that are used to document temperature data from FT2 recorded twice daily. In this study six-month temperature data was captured using checklist. Alternatively using USB, data could be downloaded as PDF into a computer or phone. Enumerators were employed to collect quantitative data from 67 CCTs at DVSs. Quantitative data was collected first followed by qualitative. For qualitative data, a follow up data collection exercise was done through phone calls until saturation point was reached. A saturation point was reached after three consecutive respondents gave no new information. The main purpose of qualitative data was to explain why the challenges identified by the quantitative data occurred.

3.6.1 Pre-test

Tools for data collection were pre-tested a week before data collection begun. Correction on the tools were made after pretesting and before actual data collection. One health facility from Salima and one from Ntchisi districts were used for pretesting.

3.7 Validity of data collection tools

Data collection tools were read thoroughly by personnel who is an expert in immunization to validate if key issues of the topic are captured. Questions were checked for common problems such as double barreled, confusing and leading question. The third method to validate the data collection tool was pretesting.

3.8 Data analysis

Data was analyzed by international business machine (IBM) statistical package for social scientists (SPSS) version 23.0 and Excel packages for descriptive statistics.

Qualitative data was analyzed by coding and thematic analysis. After coding and thematic analysis texts with similar themes were put together. Integration of qualitative and quantitative data was conducted during analysis stage. Standardized measures of respondents' knowledge were crafted in from 16 questions. The questions were in two sets, in first set of questions (Annex 2) respondents were asked to indicate their level of agreement or disagreement with each question. The second set of questions respondents were asked to indicate yes or no with each question. In terms of analysis a Likert-type scale running from ―strongly agree‖ (=1), through ―neutral‖ (=3) to ―strongly disagree‖ (=5) was used. For most of the questions in the first set ―strongly agree and ―agree responses were used to indicate that the respondent 's knowledge is consistent with the topic. On the other hand, for the second set of questions, correct responses for at least 80% of the questions asked were used to indicate that the respondent 's knowledge is consistent with the topic [10]

3.9 Ethical considerations

Permission was sought from the ministry of health services (protocol number 19/04/2314) and the respective district health offices across the country to conduct the study. All respondents were informed in advance about their participation. Roughly information about the study was provided to all respondents on the consent form and verbally where it was necessary. Only if the respondent was willing to participate in the study it was when he or she was involved. Rights to privacy and freedom of expression to all participants was

observed. To ensure privacy, no name of respondent was indicated on the consent form. The following ethical aspects were adhered to in this research:

i) A letter of introduction was obtained from the University of Rwanda signaling approval to conduct the research. This letter was presented to the respondents together with the data collection instruments to encourage their participation in the research. Additional information was also provided to the participants concerning the nature of the study, participation requirements, confidentiality and contact information of the researcher. One of the health management team members signed approval to collect data in each district before enumerator visited.
ii) Informed consent form was made available to CCTs to read and tick where applicable to if they were to take part or not in the study. Respondents were advised to take a copy of informed consent for their record.
iii) Informed consent was also obtained from respondents verbally.
iv) The researcher tried to ensure that the study respondents remain anonymous by not writing name of respondents against questionnaire.

CHAPTER FOUR

4.0 Results

4.1 Introduction

This chapter outlines study results with respect to demographic data, cold chain technician's knowledge in DVS management, refrigerator performance and processes adhered to at DVSs.

4.2 Response rate

All (29) district vaccine stores across Malawi were targeted for the study. However, 28 (97%) district vaccine stores were visited for study. A total of 67 respondents was targeted. Out of 67 CCT targeted, 52(78%) participated in answering general questions while 15(22%) purposively selected for follow up for in-depth interview (table 1). Out of 15, purposively selected for in-depth only 12 were included because saturation point had been reached. The remaining three were those from the district that was not visited due to ethical limitations.

Table 1: Demographic characteristics of respondents

Characteristic	Category	Frequency	Percent (%)
Gender	Male	50	96
	Female	2	4
Age	21 to 30 years	7	13
	31 to 40 years	14	27
	41 to 50 Years	29	56
	>50 years	2	4
Region	North	13	25
	South	16	31
	Central	23	44
Zone	North	13	25
	Central East	10	19
	Central West	6	12
	South East	12	23
	South West	11	21

Of the 52 respondents who participated in the survey, 13 (25%) were from the northern region, 16(31%) were from the central region, and 23 (44%) were from the southern region. Majority (n= 29, 56%) of the CCTs were aged between 41 and 50 years whereas only 2 (4%) were at least more than 50 years (Table 1).

4.2.1: Educational level of the respondents

In terms of training of CCTs, 42 (81%) CCTs reported to have been trained in cold chain and vaccine management. Amongst those who were trained, 20 were from southern, 10 from central region and 12 from the northern region. On the other hand, central region reported a higher number (6) of untrained CCTs. Of the 52 CCTs, 25 (48%) were holders of Malawi

School Certificate of Education, 18 (35%) had junior certificate of education, and 9 (17%) had primary school leaving certificate. Southern region reported a highest number (11) of MSCE holders whereas central region reported a highest number (5) of PSLC holders (Table 2). In terms of CCTs experience, 21 (40%) have worked for 11 to 15 years and 2 (3%) have worked more than 20 years. Among those (21) CCTs who have worked for 11 to 15 years, majority are from central (8) and southern (8) regions. On the other hand, northern region had no CCT who had worked more than 20 years.

Table 2: Education level of the respondents and years of experience as CCT

Qualification						**Frequency**	**Percent (%)**
PSLC						9	17.3
JCE						18	34.6
MSCE						25	48.1
Total						**52**	**100**
Region	**Years**						**Total**
	<=5Years	6 to 10 Years	11 to 15 Years	16 to 20 Years	>20 Years		
North	2	5	5	1	0		13
Centre	3	3	8	1	1		16
South	2	8	8	4	1		23
Total	7	16	21	6	2		52

4.3 Knowledge of cold chain technicians on cold chain management

In order to define knowledge levels in cold chain management sixteen questions were asked with respect to cold chain management. Questions ranged from knowledge on VVM stages, VVM type, and heat and freeze sensitivity of vaccines, job description and other routine activities. Out of 16 questions related to the cold chain management, 10 (63%) were correctly answered.

A frequency table indicated that 42 CCTs had problems to recognize vials with VVM stage III while 10 managed (table 3). The difference is also supported from one of CCTs in depth interview who said: "…*for cold chain management, I have never done training before but I just remember the last one which was about vaccine management and it was about 2 years ago since then we have not received any refresher training. As of now I can say that I just get knowledge from my friend who helps me on what to do*." IDIs, CCTs, Chikwawa DVS.

Again, a frequency table on knowledge of VVM types, indicates that atleast 80% of the CCTs were able to know VVM type 2, 7, 14 and 30 (Table 3).

In terms of knowledge on heat sensitivity, at least 41(79%) correctly mentioned BCG and MR as heat sensitive vaccines. However, 34(65%) wrongly mentioned OPV as heat sensitive vaccine. Similarly, more than 80% of the CCTs were able to know that other

vaccines are freeze sensitive apart from BCG and MR (table 4). In terms of knowledge on cold chain management and availability of job description, it was indicated that majority (45) did not have knowledge of job description (Table 4).

On assessing knowledge on various aspects, more than 75% (39) were able to know that water packs are kept with vaccines in refrigerator. Whereas more than 80% (42) were able to know that user maintenance for refrigerator is supposed to be done weekly, duration of vaccine storage at DVS is one month and storage temperature of vaccine is at +2 to +8^{o}C (Table 5).

Table 3: Frequency table on knowledge for VVM stages recognition and types

Key: (Yes = Knowledgeable, No = Not knowledgeable)

Knowledge on VVM Stages	**Response**	**Frequency**	**Percent (%)**
VVM Stage I Recognition	Yes	46	88
	No	6	12
	Total	52	100
VVM Stage II Recognition	Yes	42	81
	No	10	19
	Total	52	100
VVM Stage III Recognition	Yes	10	19
	No	42	81
	Total	52	100
VVM Stage IV Recognition	Yes	45	86
	No	7	14
	Total	52	100
Knowledge on VVM types			
Type 2	yes	44	85
	No	8	15
	Total	52	100
Type 7	Yes	46	88
	No	6	12
	Total	52	100
Type 14	Yes	45	86
	No	7	14
	Total	52	100
Type 30	yes	42	81
	No	10	19
	Total		100

Table 4: Frequency table for knowledge on heat and freeze sensitivity and job description

Key: (Yes = Knowledgeable, No = Not knowledgeable)

Knowledge on Heat and freeze sensitivity	Response	Frequency	Percent
BCG Heat Sensitivity	Yes	41	79
	No	11	21
	Total	52	100
OPV VVM Heat Sensitivity	Yes	34	65
	No	18	35
	Total	52	
IPV freeze sensitivity	Yes	7	14
	No	45	86
	Total	52	
PCV freeze sensitivity	Yes	50	96
	No	2	4
	Total	52	100
ROTA freeze sensitivity	Yes	50	96
	No	2	4
	Total	52	100
PENTA Valent freeze sensitivity	Yes	46	88
	No	6	12
	Total	52	100
MR Heat Sensitivity	Yes	46	88
	No	6	12
	Total	52	100
Td freeze sensitivity	Yes	48	92
	No	4	8
	Total	52	100
Shake Test	Yes	38	73
	No	14	27
	Total	52	100
Knowledge on availability of job description	Yes	7	14
	No	45	86
	Total		100

Table 5: Frequency table on CCTs Knowledge on various aspects

Issue	Duration	Frequency	Percent
Routine Maintenance	Weekly	6	11.5
	Bi-monthly	4	7.7
	Monthly	5	9.6
	Quarterly	37	71.2
	Total	52	100
	Duration	**Frequency**	**Percent**
User Maintenance	Weekly	42	80.8
	Bimonthly	9	17.3
	Quarterly	1	1.9
	Total	52	100
	Duration	Frequency	Percent
Duration of Storage of Vaccines	one month	44	84.6
	1 to 2 months	8	15.4
	Total	**52**	**100**
	Temperature Range	**Frequency**	**Percent**
Storage Temperature of Vaccines	-25 ^{o}C to -15 oC	9	17
	+2^{o}C to + 8^{o}C	43	83
	Total	**52**	**100**
	Response	**Frequency**	**Percent**
Water Pack Stored in refrigerator with vaccines	Yes	39	75
	No	13	25
	Total	52	100

However, during in-depth interview most cold chain technicians were knowledgeable about their job description as one of the technicians said: *"...we are supposed to look into cold chain system which goes like if there is any problem with the fridges, if there is any we need to maintain them, and we also look if they are working properly that is to say they are maintaining temperatures between 2 and +8. Then again, some task and looking to other things, we are also distributing vaccines to health facilities, looking at the potency of vaccines....."* IDI CCT Kasungu DVS.

4.4 Performance for vaccine storage refrigerators.

Data was collected on refrigerator model, problems of non-functionality and alarms for heat and freezing. In terms of models of refrigerators at DVS, it was shown that there were two models (VLS400 and MK304) of refrigerators, of these two VLS400 model (n=47, 47%) was found to be commonly used. There were also two districts which had walk in cold rooms of different models, Foster and MGM32064F. More than half (n=55, 57%) of the refrigerators visited were in the age range of 2 to 4 years of operation and only 16 (16%) were above 10 years from time of commissioning (Table 6).

Assessing the functionality and availability of spare parts at DVS, 2 (7.2 %) DVS indicated that some of its refrigerators were not functioning due to socket problems and obsolete. 2 (7.2%) districts indicated that some of their equipment are not functioning because of other reasons. 3 (11%) district vaccine stores indicated that some of their refrigerators were not functioning because there are no spare parts available locally (Table 8). Similarly, during in depth interview it was revealed that lack of spare part tools was the common challenge in terms of maintenance of equipment as one of CCTs said: *"I think it would be better if well-wishers or the government give enough materials or cold chain equipment for repairing such as cold chain repairing tools. We do have repairing tools but they are not enough, they are basic ones such hammers, but we want materials such as compressors"* IDIs, CCTs Mulanje DVS. It was observed that out of 28 district vaccine stores, 12 (43%) were connected to power generator backup.

Table 6: Proportions of models of refrigerators/walk in cold rooms at DVSs

Refrigerator/Walk in cold room model	**Frequency**	**Percentage (%)**
MK304	27	28
VLS400	46	47
VLS350	7	7
TCW3000	5	5
VLS300	4	4
VLS200	2	2
TCW2000	3	3
TCW400	1	1
MK204	2	2
FOSTER WICR	1	1
MGM32064F WICR	1	1
Total	**97**	**100**
Age range	**Frequency**	**Percentage**
<2years	1	1
2 to 4 years	55	57
5 to 7 years	17	18
8 to 10 year	8	8
>10 year	16	16
Total	97	

Table 7: Problems of non-functionality of refrigerators

Key: (Yes = it is a problem at the DVS, No = it is not a problem at the DVS)

Lack of spare parts	**Frequency**	**Percent**	**Key**
Yes	3	10.7	**Yes** = Lack of spare parts was a problem. **No** =lack of spares parts is not a problem
No	25	89.3	
Total	28	100	
Socket problem	**Frequency**	**Percent**	**Yes**=sockets problem is an issue. **No=**Socket problem is not an issue.
Yes	1	3.6	
No	27	96.4	
Total	28	100	
Obsolete	**Frequency**	**Percent**	
Yes	1	3.6	**Yes**= Obsolete Refrigerators is problem. **No=**Obsolete refrigerators is not problem.
No	27	96.4	
Total	28	100	
Power back up	**Frequency**	**Percent**	
Yes	12	43	**Yes**= lack of power back up is problem. **No=** lack of power back up is not a problem.
No	16	57	
Total	28	100	

It was also observed that 13 (46%) districts were found to have at least one refrigerator operated at temperatures above 8^{o}C for a period of more than 10 hours and -0.5^{o}C and below for an hour or more. Based on data recorded in the temperature charts at DVSs, it was established that there were 20 alarms recorded in the past six months from the day of data collection. These alarms were for both freezing and high temperatures. Out of 20, 9 (45%) were due to freezing temperatures while 11(55%) were due to higher temperatures. Out of 9 alarms, 2 were recorded in the northern region, 2 in the central and 5 in the southern region (Table 8). In terms of alarms (11) triggered by higher temperatures of above recorded in the temperature monitoring charts at DVS, 7 alarms were recorded in the southern region, 3 in the northern region and 1 in the central region (Table 8).

A Pearson correlation showed that there was a significant positive correlation between alarms and average temperature [$p = 0.004$, $r(47) = 0.417$] (Table 9).

Table 8: Alarms triggered by freezing and high temperature for the past six months

Key: (Yes = there were alarms, No =there were no alarms)

Alarms below zero			
Region	**Yes**	**No**	**Total**
North	2	5	7
Centre	2	7	9
South	5	7	12
Total	9	19	28
Alarms above 8			
Region	**Yes**	**No**	**Total**
North	3	4	7
Centre	1	8	9
South	7	5	12
Total	11	17	28

Table 9: Correlation of average temperature and alarms

		Average Temperature
	Pearson Correlation	**0.417****
Alarms	Sig. (2-tailed)	**0.004**
	N	**47**

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

4. 5 Cold chain processes that are adhered to at district vaccine stores

This section provides information for processes that are adhered to and not adhered to at cold district vaccine stores. Data was collected using checklist by making observations and asking questions where necessary. Figure 4 present the information that was checked. All 28 (100%) districts vaccines stores had their refrigerators with Fridge Tag 2 and temperature monitoring charts. Out of 28 DVSs visited, 24 (86%) adhered to the practice of checking VVM stage, and routine check of expiry dates of vaccine and related supplies. 18(64%) DVSs adhered to confirming quantities on delivery, 10 (36%) adhered to checking for vaccine damages on consignments and 3 (28%) do write report after receiving vaccines. Only 1 (4%) DVS stated that it records time of vaccine arrival (Figure 4). Recording time of vaccine arrival is an important exercise because it helps to determine transit time taken for vaccines. According to WHO vaccines are supposed to be in transit for not more than 48

hours while in well packed prequalified passive container or refrigerated vehicle.. This help in determining why vaccines have changed VVM stage or not changed.

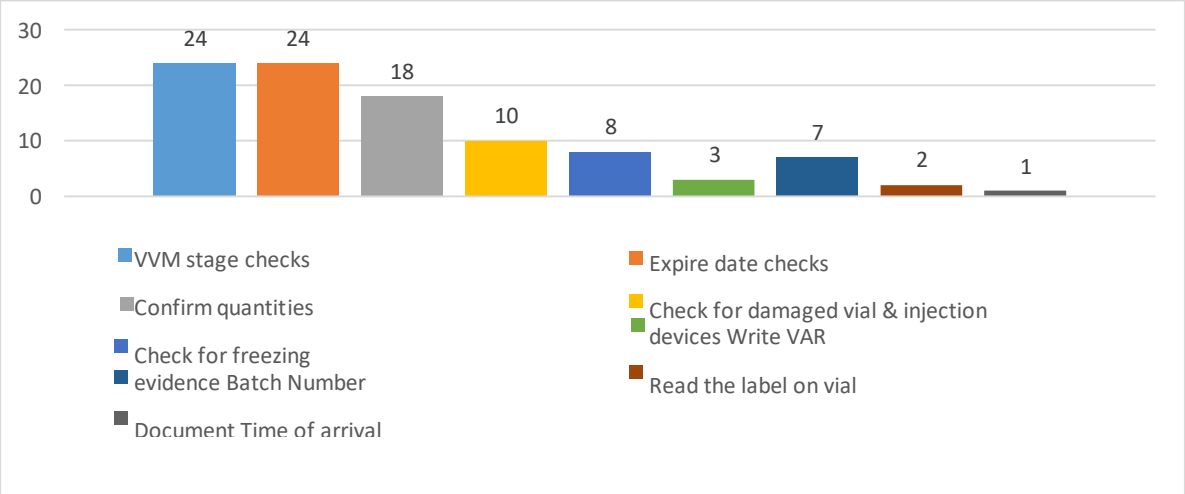


Figure 4: Number of district vaccine stores adhering to various processes

Table 10: Processes adhered and not adhered to at DVSs

Key: (Yes = process adhered to, No = process not adhered to)

DVS Temp. Charts Completed in the past 60 days	**Frequency**	**Percent**
Yes	26	92.9
No	2	7.1
Total	28	100
DVS with correct temp. charts completion	**Frequency**	**Percent**
Yes	22	78.6
No	6	21.4
Total	28	100
DVS with Temp. charts recorded twice daily	**Frequency**	**Percent**
Yes	23	82.1
No	5	17.9
Total	28	100
Only Vaccine kept in refrigerator	**Frequency**	**Percent**
Yes	26	92.9
No	2	7.1
Total	28	100

In terms of processes that were adhered to, 26 (92.9%) DVSs had their temperature completed in the past 60 days and had only vaccines kept in refrigerator, on the day of data collection. 22 (78.9%) DVSs had their temperature charts completed correctly and 23 (82.1%) had their temperature charts recorded twice in the past sixty days on the day of data collection (Table 11). The high proportion of temperature monitoring is in line with the results from in-depth interview where most districted were reported to record temperature

in the morning and afternoon as one of the CCTs said: *"I can say so far our cold chain is running smoothly. In terms of recording temperature, we do record daily morning and afternoon. For the weekend, because we are two then we have a roster, the other one comes this weekend then the other one next weekend"* IDI, CCTs Mulanje DVS.

4.6 Challenges of cold chain management

A frequency table showed that 77% (40) CCTs reported lack of power back up, 21% (11) reported lacked spare parts and 29% (15) reported the use of old refrigerator in management of cold chain as the main challenges (Table 16). However, from in-depth interview, it was revealed that most CCTs reported lack of fuel, transport and tools and refresher training as the major challenges regarding cold chain management: "*The problem we have is that in the meantime, even though we are cold chain technicians, we do not have tools to do the maintenance. Another problem is transport, but we can say we have transport, when we say transport, we are talking about fuel so that we can be going around to monitor facilities because they have very little knowledge about cold chain system"* IDI, Mzimba North DVS.

Table 11: Frequency table on challenges faced by CCTs at DVSs and cold chain management

Challenges	Response	Frequency	Percent
Lack of power back up	Yes	40	77%
	No	12	23%
	Total	52	100%
Spare parts	Yes	11	21%
	No	41	79%
	Total	52	100%
Inadequate room space	Yes	13	25%
	No	39	75%
	Total	52	100%
Old refrigerators	Yes	15	29%
	No	37	71%
	Total	52	100%

CHAPTER FIVE

5.1 Discussion

The study findings are about challenges of cold chain technicians in management of cold chain system, refrigerators performance and processes adhered to and not adhered to at district vaccine stores. These results are from 28 districts where 97 refrigerators were inspected and 52 cold chain technicians were interviewed.

In terms of assessing knowledge level of cold chain technicians in management of cold chain system, out of 16 questions related to management of cold chain system, 10 (63%) were answered correctly. This was lower than what was found in a similar study conducted in Malaysia. The study found that majority of health workers responsible for taking care of vaccines have 78.7% knowledge, while their attitude is significantly poor (79.7%) towards cold chain (18). However, the previous study did not clearly indicate the number of health facilities sampled across the country or number of health workers interviewed as well as areas of interview. Therefore, the current study only compares with the study done in Malaysia on proportion of knowledge of CCTs on vaccines management. The current study further revealed that there was a high proportion of the CCTs who were unable to recognize some stages of VVM as well as VVM types despite having larger number (n=42) attended training on cold chain management. However, this can be attributed to lack of refresher training on cold chain management as most CCTs were reported to have attended training three years ago.

Furthermore, this study found that 85% (n=44) of cold chain technicians were able to know that duration of vaccine storage at DVS is one month and 83% (n=43) indicated that storage temperature of vaccines should be at +2 to 8 ^{O}C. 71% (n=39) indicated that water packs should be kept with vaccines in refrigerator. This study found that CCTs demonstrated level of knowledge on vaccine storage compared with the findings of Thakker and Woods [22]on assessing quality of storage of vaccines at central Manchester and Bradford. The study found that only 40% of health workers had adequate knowledge on appropriate storage of vaccines. However, high prevalence of knowledge level in the current study maybe due to the methods of data collection. Unlike Thakker and Woods study where they used a self-administered questionnaire, the current study used face to face interview which create an opportunity for respondent to ask where the question is not clear.

The current study also found that 87% (n=45) of CCTs had no knowledge of cold chain management and availability of job description. Although there was a high prevalence (n=45, 87%) of those that attended training on cold chain management, the results showed that it may not attribute to the knowledge of job description. However, the current findings are contrary to Ashok, Brison, and LeTallec [21] who found that many technicians in Malawi, Uganda and Tanzania are under skilled due to lack of training and this has an implication on management of cold chain equipment and understanding their roles as CCTs. On performance of vaccine storage refrigerators, the study found that out of 97 refrigerators visited across the country VLS400 and MK304 were commonly used models (Table 7). The VLS 400 and MK304 have been recognized as among the best models as they have volume capacity of 90 to 120+ liters with a holdover day of 1.1 [29]. However, holdover day may be affected by the weather of the year hence affects the performance of the refrigerators [28]. The current study has also found that most refrigerators have been in operation for the past 2 to 4 years during the time of this study and 16% (16) have been operating for more than 10 years without major non-functionality or breakdown being reported (Table 7). In contrast to the results of [29]study which found that old and obsolete technologies (cold chain equipment) in Uganda, Malawi and Tanzania are between 15% and 50% older than the recommended 10 years, after which they are more susceptible to major breakdown and poor temperature control. This is also in support of the cross-sectional study happened in Cameroon which reported that 23% of health facilities had their refrigerators breakdown every 2 months [20]. In addition to that, WHO recommends that after 10 years Refrigerators for vaccines need to be disposed of since maintaining it becomes non- economical[26]. On the other hand, the current study found that lack of non-functionality or major breakdown in DVSs across the country can be due to the point that at least 95% of DVSs reported that lack of spare parts, socket problems, and obsolete were some of the challenges.

It was also observed that 43% (12) of the DVSs had their refrigerators connected to generator back up. This is one of the contributing factors of non-functionality of refrigerators as most of DVSs are connected to power grid. Power cuts and interruption is one of the major problems that cause losses in vaccines, damage equipment and alters temperatures of cold chain [20].

Furthermore, it was observed that 54% (13) districts were found to have at least one refrigerator operated at temperatures above 8^{O}C for a period of more than 10 hours and -0.5^{O}C and below for an hour or more for the past six months. This is line with the findings done in Nigeria in 2014. The study found that 12–13% of cold chain equipment in study facilities maintain greater than 8 ^{O}C conditions for longer than five days. This is not rarely an exception but presents a chronic gap in management of the cold chain equipment which requires consistent monitoring of the excursions[44]. The findings of this study are only similar in the current study on excursions above 8 ^{O}C and not those excursions below +2 ^{O}C. Additionally, from recorded temperature database, it was observed that there were 20 alarms of alert for both high temperature and freezing below zero degrees for the past six months from the day the data was collected. However, increase in freezing alarms or high temperature alarms can be attributed to other factors and not refrigerator performance. For example, increased frequency of opening of refrigerators may increase temperature which may lead to alarms and pose a risk for vaccines [20].

Again, after running a Pearson correlation, it was found that there was a significant correlation [$p = 0.004$, $r(47) = 0.417$] between alarms and average temperature. This indicates that as the deviation of temperature from +2-8^{O}C increases there is an increase of alarms. However, this deviation may not be completely attributed to management of cold chain equipment but rather some external factors may have an effect. As it has been observed that during cold season, refrigerator readings are found to be skewing towards lower temperatures while the hot season skewed towards higher temperatures [28].

On cold chain processes that are adhered to at DVSs, the study found that all the districts visited had the fridge tag two and VVM monitoring charts. It was further observed that 86% (n=24) of the DVSs followed the practice of checking VVM stage and the expiry dates of vaccine and supplies. However, for record keeping in case of tracing the affected batches, it was observed that only three districts that do write a report upon receiving a vaccine.

This may bring some challenges to determine the number or volume of vaccines that can be used at a district. It was further revealed that 93% (n=26) of the districts had their temperature charts completed in the past sixty days. Out of these 26 districts, 22 (79%) districts had their temperature charts completed correctly and 82% recorded it twice a day. One of the reasons of high prevalence of this process adherence can be attributed to seriousness of monitoring of the activities put in place by the EPI at DVS. However, as this is one of the major activities for monitoring temperature and need to be done twice a day, a study conducted in Cameroon presented a different view. The study found that 50% of health facilities did not adequately

complete temperature charts[20]. Additionally, it was observed that ninety two percent of the districts visited followed good practices such as ensuring that only vaccine is kept in the refrigerator. As it is indicated that mixing vaccines with other products may affect vaccines which is delicate [34].

Amongst the challenges that were reported, lack of power back up was the mostly reported by the CCTs. This was so because most DVSs which were visited had their refrigerators connected to power grid that may interrupt operation refrigerators during power outage. Similarly, the study done in Uganda on the challenges of immunization cold chain management found that extreme temperature, humidity, interrupted power supply, insufficient maintenance of cold chain system, lack of spare parts and high failure rate of cold chain equipment were amongst the common challenges being reported (40). Furthermore, it was observed that the use of old refrigerators was not a common challenge as majority of the respondents did not mention it. One of the reasons that can be attributed to this is that only 16% (n=16) of refrigerators visited have been operated for more than 10 years which may affect the performance. The findings on present study contradict the study done in six countries which established that amongst the challenges reported, poor refrigerator performance (58%) was the main challenge that lead to freezing (41). However, the previous study did not specifically indicate as to whether old refrigerator is amongst the issues that lead to poor performance. Therefore, the comparison for the current study to the previous study is only based on the performance of the refrigerators which may be due to obsolete.

5.2 Study limitations

One of the limitations of this study was that data was collected at one point in time, it would have been better if the study was able to collect data for all four seasons of the year. Due to time factor, data for temperature was not collected for all four seasons of Malawi.

Temperature reading may vary with seasons, in cold season refrigerators tend to operate below $2^{O}C$ while in hot season it is above $8^{O}C$ [39]. Data for this study was collected towards the end of cold season (July). Results of the study has a limitation of not revealing higher temperature excursions that would have been exposed if it were in hot season. However, problem was solved by collecting temperature data on number of temperature excursions beyond cold season (past six- month data). The temperature data for the past six months included season outside cold season.

CHAPTER SIX:

6.1 Conclusion and Recommendations

6.1.1 Conclusion

This study found that less than half of the total refrigerators visited had a power back up. It was also observed that more than half VDS had at least one of the refrigerators operating above 8 ^{O}C for a period of more than ten hours and -0.5^{O}C and below for an hour or more. It was further found that there was a positive correlation between alarms and average temperature. All the districts visited had the fridge tag two and VVM monitoring charts. There was a high prevalence of adherence to the processes with one exception of only three districts writing report after receiving vaccines. About 80% of the districts had their temperature charts completed correctly and recorded twice a day. The study further found that there was relationship between the challenges faced and at DVS and adherence to cold chain processes. Lack of power back up, fuel, maintenance tools and lack of refresher training were amongst the major challenges being reported. There was a limitation of this study as data for temperature was collected at one point in time other than in all four seasons of the year. Therefore, further research should focus on gap.

6.1.2 Recommendations

There is need to capacity building of CCTs through refresher course training in cold chain management in order to understand their job description. There is also need for provision of power back up in DVS where refrigerators only rely on national power grid. There is need for extensive monitoring on DVS performance in order to improve adherence to cold chain management processes. Furthermore, there is need of a similar study on cold chain temperature adherence at service delivery point, during transportation of vaccines as well as assessing vaccine potency when exposed to temperature excursion without alarms at -0.5^{O}C for less than one hour and above 8^{O}C less than 10 hours.

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ANNEXES

Annex 1: Consent form for cold chain technicians

CONSENT FORM

You are invited to participate in a survey on **exploring the challenges to temperature adherence at district vaccine stores in Malawi**. This is a research project being conducted by **Chimwemwe Chunga**, a student at University of Rwanda College of Medicine and Health Sciences. It should take approximately 20 minutes to complete.

PARTICIPATION: Your participation in this survey is voluntary. You may refuse to take part in the research or exit the survey at any time without penalty. You are free to decline to answer any particular question you do not wish to answer for any reason.

BENEFITS: You will receive no direct benefits from participating in this research study. However, your responses may help us learn more about Vaccine storage and safety that would contribute towards wastage of vaccine due to storage temperature damage.

RISKS: There are no foreseeable risks involved in participating in this study other than those encountered in day-to-day life.

CONFIDENTIALITY: Your survey answers will be stored in a password protected electronic format after analysis. Survey identifying information such as your name will not be collected or documented in this study. Therefore, your responses will remain anonymous. No one will be able to identify you or your answers, and no one will know whether or not you participated in the study.

CONTACT: If you have questions at any time about the study or the procedures, you may contact the Principal Investigator Chimwemwe Chunga via phone at 0888599149 or via email at chimwemwechunga@yahoo.com or chimwemwechunga20@gmail.com

If you feel you have not been treated according to the descriptions in this form, or that your rights as a participant in research have not been honored during the course of this project, or you have any questions, concerns, or complaints that you wish to address to someone other than the investigator, you may contact Dr. Regis Hitimana email regis.hitimana@gmail.com

CONSENT: Please select your choice below. You may take one copy of this consent form for your records. Tick "Agree" if

- You have read the above information
- You voluntarily agree to participate
- You are 18 years of age or older

☐ Agree
☐ Disagree

Annex 2: Survey questionnaire for cold chain technicians

District Vaccine Store Name: ……

Zone: ……

Region: …… ……

Date of Data Collection: ……

Checklist Number: ……

SECTION A: RESPONDENT DEMOGRAPHIC INFORMATION

1. Indicate cold chain technician's number (1st to be interviewed is CCT 1)

1	2	3

2. Gender

Female	Male

3. How old are you?

<20 years	21 to 30 years	31 to 40 years	41 to 50 years	>50 years

4. How long have you worked as CCT? (Years of experience)

=< 5 Years	6 to 10 Years	11 to 15 Years	16 to 20 Years	> 20 Years

5. What is your level of education?

PSLC	JCE	MSCE	Tertiary

6. Have you ever attended cold chain training?

Yes	No

7. Name the institution that trained you is yes in question 6?

MoHP	Works training center	Technical college	Other

8. Have you ever attended courses on vaccine and cold chain management?

Yes	No

SECTION B: LEVEL OF KNOWLEDGE

9. Vaccine vial monitor is a thermochromic label put on vial containing vaccines which gives a visual indication of whether the vaccine has been kept at temperatures above 8^{O}C.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree

10. The significance of VVM is to monitor vaccines if they were exposed to freezing?

□ Strongly agree	□ Agree	□ Neutral	□ Disagree	□ Strongly disagree

11. The following stages of VVM are recommended for use?

a. Sage I	**b. Sage II**	**c. Stage III**	**d. Stage IV**
□ Strongly agree	□ Strongly agree	□ Strongly agree	□ Strongly agree
□ Agree	□ Agree	□ Agree	□ Agree
□ Neutral	□ Neutral	□ Neutral	□ Neutral
□ Disagree	□ Disagree	□ Disagree	□ Disagree
□ Strongly disagree	□ Strongly disagree	□ Strongly disagree	□ Strongly disagree

12. Are you conversant with each of the following VVM stages?

a.	**Stage I**	**b.**	**Stage II**	**c.**	**Stage III**	**d.**	**Stage IV**
□	Yes	□	Yes	□	Yes	□	Yes
□	No	□	No	□	No	□	No

13. Would you recognize VVM stages on the vaccines displayed?

a.	**Stage I**	**b.**	**Stage II**	**c.**	**Stage III**	**d.**	**Stage IV**
□	Yes	□	Yes	□	Yes	□	Yes
□	No	□	No	□	No	□	No

14. Do you thing each of the following are types of VVM?

a.VVM 2	**b.VVM 7**	**c.VVM 14**	**d.VVM 30**
□ Yes	□ Yes	□ Yes	□ Yes
□ No	□ No	□ No	□ No

15. Do you think each of the following vaccines are heat sensitive?

a. BCG	b. OPV	c. IPV	d. PCV	e. ROTA	f. PENTA-Valent	g. MR	h. Td
□ Yes	□ Yes	□ Yes	□ Yes	□ Yes	□ Yes	□ Yes	□ Yes
□ No	□ No	□ No	□ No	□ No	□ No	□ No	□ No

16. Do you agree that shake test must not be conducted for MR and BCG?

□ Strongly agree	□ Agree	□ Neutral	□ Disagree	□ Strongly disagree

17. Rate your agreement with the fact that shake test must be conducted when freeze sensitive vaccines are visibly seen to be frozen?

□ Strongly agree	□ Agree	□ Neutral	□ Disagree	□ Strongly disagree

18. How often are you supposed to do refrigerator routine maintenance?

□ Weekly	□ Twice a moth	□ Once a month	□ Quarterly	□ Every six months

19. How often are you supposed to do user maintenance of refrigerators?

□ Weekly	□ Twice a moth	□ Once a month	□ Quarterly	□ Every six months

20. What is the duration of keeping vaccines at DVS?

□ One month	□ More than 1 month to less than 2 months	□ More than 2 months to less than 3 months	□ More than 3 Months

What is the storage temperature of vaccines at DVS?

□ < 2oC	□ -2oC to -15oC	□ +2oC to +8oC	□ -2oC to -8oC

21. Where are water packs supposed to be kept?

□ In shelves in stores	□ In freezer	□ In refrigerator with vaccines	□ In cartons placed in shelves

22. What is the recommended minimum distance of the refrigerators from the wall?

□ 5 cm and above	□ Less than 10 cm	□ Above 10 cm to 20 cm	□ Above 20 cm t 30 cm	□ Above 30 cm

23. What is the significance of distance indicated in question 23 above to the refrigerator?

□ For orderly looking of the environment	□ For safety of health workers	□ For air circulation refrigerator	□ Not significance	□ Not sure

24. Do you a copy of your job description?

□ Yes	□ No

SECTION C: EXPLORATION ON OTHER CHALLENGES FACED BY COLD CHAIN AT DISTRICT VACCINE STORE

25. Do you think that the following factors affect cold chain management at DVS?

Transport	□ Yes	□ No

Lack of power back up

□ Yes	□ No
□ Yes	□ No

Power interruption Spare parts

Lack of adequate maintenance tool Use of old refrigerators

Lack of power backup

□ Yes	□ No
□ Yes	□ No

End of questionnaire

Annex 3: Checklist on immunization cold chain processes and procedures at district vaccine stores

District Vaccine Store Name: ……
Zone: ……
Region: …… ……

Date of Data Collection: ……

Checklist Number: …….

1. Does every refrigerator have temperature monitoring charts?
2. Temperature charts completed twice daily for the past 60 days?
3. Temperature charts completed correctly for the past 60 days?
4. Frequency of reports submitted for the past 6 months (Jan to Dec 2019)
5. Do you routinely check each of the following on vaccines?
6. Are vaccines the only supplies being kept in the refrigerators?
7. Check if the following:

a. Vaccine & diluent orderly packed
b. Internal space well aerated

8. Does the facility have the following models of refrigerators?
   How old is each refrigerator since commissioning?

#	Model	Years since commissioning	
		10 Years and less	
		Yes	**No**
1			
2			
3			
4			
5			
6			
7			

9. Do all refrigerators function?
10. If no in question 10 above, do you think each of the following are reasons for refrigerator(s) not functioning?
11. Does every refrigerator have Fridge Tag 2 (check)?
12. Was temperature recorded daily for every refrigerator for the past 60 days?
13. Are all refrigerators connected to electricity generators?
14. If yes in question 14 above, does the generator have automated system?
15. Are all refrigerators connected to power surge protector?
16. Are all refrigerators connected to national power grid?
17. Does the DVS experience power blackout daily?
18. Does DVS have a maintenance schedule for refrigerators?
19. Does the DVS have maintenance record for refrigerators at DVS for the past six months?
20. Are the refrigerators clean externally?
21. Are the refrigerators clean internally?

22. Do have maintenance reports for any if any maintenance done for past six months?
23. Do you have maintenance equipment for cold chain?
24. If yes in question 24 above are the maintenance equipment adequate?
25. Do the refrigerators' FT2 displayed temperature alarms below 2^{o} C in the past 6 months.
26. Do the refrigerators' FT2 displayed temperature alarms below above 8^{o} C in the past 6 months
27. Do the refrigerators have bare wire connections?
28. Are the refrigerators reached by the sun?
29. are the refrigerators kept in well aerated rooms?
30. Are the refrigerators paced within a distance of not less than 10 cm from the wall?

End of checklist

Annex 4: In-depth interviews for cold chain technicians in district vaccine stores

Questions

1. What is your job title and description at DVS?
2. From your experience what are some of the challenges encountered at DVS in terms of cold chain management?
3. What was the last time you attended training related to cold chain management?
4. Is there any refresher training in DVS related to cold chain management? If yes, what areas are being focused on?
5. So far how has been your DVS performance in terms of adherence to cold chain management? (probe for good/bad performance)
6. In your opinion what do you think should be done in order to improve/maintain the performance of DVS? (give the examples that need to be improved such as temperature monitoring, good house practices such as avoidance of opening refrigerator frequently)
7. Any further opinion that a participant may have which is a great concern.

End of in-depth interview

Annex 5: Ethical Approval amendment letter

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail doccentre@malawi.net
All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. MED/4/36c
MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

23rd August, 2019

Chimwemwe Chunga
Rwanda University

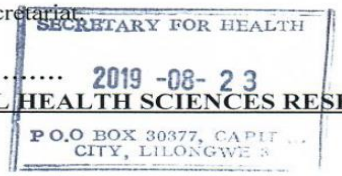
Dear Sir/Madam,

RE: Protocol # 19/04/2314: Exploring the challenges to temperature adhered at district vaccine stores in Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review.

The Committee **reviewed** and **approved** the rephrase of the title Exploring the changes to temperature adhered at district vaccine stores in Malawi and the scope increased to health workers knowledge, processes adhered to and not adhered to at district vaccine store.

Kind regards from the NHSRC Secretariat



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FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

PROMOTING THE ETHICAL CONDUCT OF RESEARCH
Executive Committee: *Dr.B. Chilima (Chairman), Dr B. Ngwira (Vice Chairperson)*
Registered with the USA Office for Human Research Protections (OHRP) as an International IRB
(IRB Number IRB00003905 FWA00005976)

Annex 6: Ethical approval initial

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail doccentre@malawi.net
All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. MED/4/36c

MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

18th April, 2019

Chimwemwe Chunga
University of Rwanda

Dear Sir/Madam,

Re: Protocol 19/04/2314: Vaccine Supply Chain Temperature Evaluation for District Vaccine Stores in Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review.

Please be advised that the NHSRC has **reviewed** your submission and recommended that you should address the following concerns before approval is given.

- Provide itemized budget
- The broad objective must be specific and to correspond with study title
- Separate ethical considerations section from logistical issues
- Attach support letter from Ministry of Health – Department of Preventive Health Services and ethical approval from Rwanda University
- Confirm if specific objective no. 2 can be achieved using secondary data available

Kind regards from the NHSRC Secretariat.

SECRETARY FOR HEALTH
2019 -04- 18
P.O BOX 30377, CAPITAL CITY, LILONGWE 3

.....

FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

Annex 7: Acceptance Letter to use temperature data

Telegrams: MINMED, LILONGWE

Telephone: Lilongwe 01 789 400
01 757 205

All communications should be addressed to: The Secretary for Health

In rely please quote no...

MINISTRY OF HEALTH
P.O.BOX 30377
LILONGWE 3
MALAWI

Ref. No. MED/4/51

27th April, 2019

Chimwemwe Chunga
EPI Program
Ministry of Health
P.O Box 30377
Lilongwe 3

Dear Sir

ACCEPTANCE LETTER TO USE EPI COLD CHAIN DATA FROM ALL 29 DISTRICT VACCINE STORES IN MALAWI BY CHIMWEMWE CHUNGA FOR ACADEMIC PURPOSES

The Ministry of Health and Population (MoHP) is here by allowing Mr. Chimwemwe Chunga to use EPI cold chain temperature data for all 29 District Vaccine store for academic purposes titled," ***Vaccine Supply Chain temperature evaluation for District Vaccine Stores in Malawi"***

The proposed study is critical because it will help the program implementors with relevant cold chain data for decisions making to ensure continual vaccine quality.

Yours faithfully

SECRETARY FOR HEALTH
AND POPULATION
2019 -04- 27
Dr. Bo Kalanzi
CAPITAL CITY, LILONGWE 3

Director of Preventive Health Services

For: SECRETARY FOR HEALTH AND POPULATION

Annex 8: Turnitin receipt (a)

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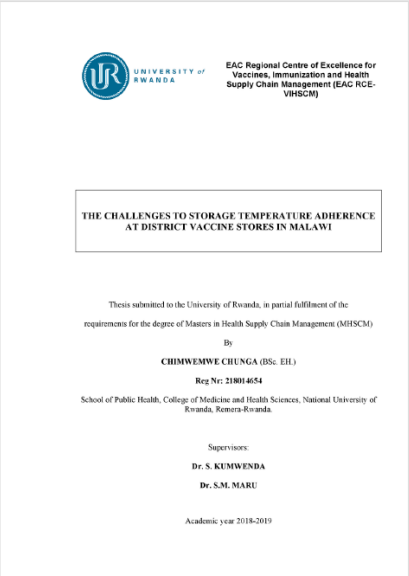
Assignment title:	Thesis HSCM
Submission title:	THE CHALLENGES TO STORAGE …
File name:	CHUNGA_VERSION_24_-23102019..
File size:	287.45K
Page count:	40
Word count:	12,324
Character count:	64,161
Submission date:	23-Oct-2019 02:23PM (UTC+0300)
Submission ID:	1181422043



UNIVERSITY of RWANDA

EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management (EAC RCE-VIHSCM)

THE CHALLENGES TO STORAGE TEMPERATURE ADHERENCE AT DISTRICT VACCINE STORES IN MALAWI

Thesis submitted to the University of Rwanda, in partial fulfilment of the requirements for the degree of Masters in Health Supply Chain Management (MHSCM)

By

CHIMWEMWE CHUNGA (BSc. EH.)

Reg Nr: 218014654

School of Public Health, College of Medicine and Health Sciences, National University of Rwanda, Remera-Rwanda.

Supervisors:

Dr. S. KUMWENDA

Dr. S.M. MARU

Academic year 2018-2019

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Annex 9: Turnitin receipt (b)

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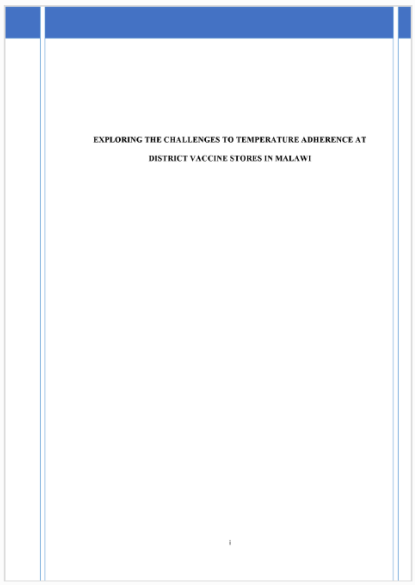
Submission title:	EXPLORING THE CHALLENGES TO.
File name:	turn_it_on_10092019.docx
File size:	175K
Page count:	43
Word count:	12,317
Character count:	64,566
Submission date:	10-Sep-2019 11:39AM (UTC+0300)
Submission ID:	1170108165


EXPLORING THE CHALLENGES TO TEMPERATURE ADHERENCE AT DISTRICT VACCINE STORES IN MALAWI

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Annex 10: Turnitin scores