UNIVERSITY of RWANDA

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

ASSESSMENT OF FACTORS AFFECTING EFFECTIVE VACCINE COLD CHAIN MANAGEMENT IN PUBLIC HEALTH FACILITIES IN KISII COUNTY,KENYA

A Research Dissertation submitted to the University of Rwanda, in partial fulfilment of the requirements for the degree of Master's in Health Supply Chain Management (MSc HSCM)

By

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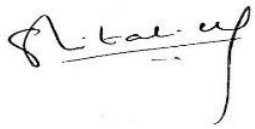
2.Signature  Date 18/01/2022

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DEDICATION

I dedicate this work to my family for their support throughout the process.

ACKNOWLEDGEMENT

I thank God for the grace and strength that he continuously gave me to enable to carry out and complete this research.

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ABSTRACT

Background To maintain a reliable vaccine cold chain, different key procedures need to be observed during storage, transportation, handling, and administration to the end user. Otherwise, there will be loss of vaccine potency leading to death due to vaccine preventable diseases.

Objective The objective was to assess the factors affecting effective vaccine cold chain management in public health facilities in Kisii County, Kenya

Methods

The study was carried out in public health facilities that offer immunization services in Kisii County. A descriptive cross-sectional design was adopted, and ninety-four health facilities selected. The respondents were vaccine handlers in the selected health facilities. Data collection was done using structured questionnaires. Data was analyzed by use of Microsoft Excel and Statistical Package for Social Sciences (SPSS)software(Ver 28,2021) and results presented in tables. Study approval was sought from the ethics committee, KNH/UON-ERC prior to commencing the study.

Results

The vaccine handlers in Kisii county have adequate knowledge , the right practices, and a positive attitude towards effective vaccine cold chain management. There was availability of functional refrigerators and thermometers, lack of backup generator and fuel and inadequate equipment maintenance .The most common barriers to effective vaccine cold chain management included insufficient funding, inadequate qualified human resource, lack of new technology and lack of equipment maintenance.

Conclusion and recommendations

The gaps identified include financial, technological, and human resource. There is therefore need for resource mobilization to curb the identified gaps.

Keywords: Vaccine cold chain management, Personnel knowledge, Attitude, Equipment maintenance.

ABBREVIATIONS AND ACRONYMS

BCG – Bacillus Calmette–Guerin

CHAI – Clinton Health Access Initiative

COVID-19-Corona Virus 2019

DPT -/HepB/ HIB/ – Diphtheria, Pertussis, Tetanus, Hepatitis b vaccine/Hemophilus influenza type B vaccine

EPI-Expanded Program on Immunization

ERC – Ethical Research Committee

FEFO – First Expiry First Out

LMIS-Logistics Management Information System

RTM-Remote Temperature Monitoring

SPSS-Statistical Package for Social Sciences

UK-United Kingdom

UNICEF- United Nations International Children's Emergency Fund

UoN - University of Nairobi

USA-United States of America

VVM – Vaccines Vial Monitor

WHO – World Health Organization

LIST OF TABLES

OPERATIONAL DEFINITION OF TERMS

Attitudes- Set of emotions or behaviors towards cold chain management**.**

Barriers-obstacles facing vaccine cold chain management.

Cold chain equipment maintenance- preserving the condition of the cold chain equipment.

Cold chain equipment-equipment for transporting and storing vaccines and their diluents within the required temperature ranges.

Cold chain Storage capacity-the total volume of functional temperature-controlled storage.

Knowledge-awareness of vaccine cold chain management**.**

Public health facilities-health facilities that are owned by the government**.**

Technology-adoption of scientific knowledge into the vaccine cold chain

Vaccine cold chain management – ensuring that the vaccines are kept within optimal temperature ranges and maintain the desired states from start to finish.

Vaccine Cold chain- temperature controlled system for storing vaccines in good condition.

Vaccine potency- the relationship between the immune response and the dose of a vaccine administered.

Vaccines – the antigenic proteins used for prevention of infectious diseases.

CHAPTER 1: INTRODUCTION

1.1 Background to the study

Vaccine quality needs to be assured from the point of manufacture to the time of administration to a client. Vaccine quality is maintained by a cold chain that meets specific temperature requirements set by the World Health Organization (WHO) and therefore maintaining the vaccine potency(1). To maintain a reliable vaccine cold chain different key procedures need to be observed during storage, transportation, handling and administration to the end user (1).Lost potency cannot be regained and this is evidenced when the immunized patients contract diseases of which the vaccines were meant to prevent against.

An assessment carried out in the Kenyan health sector revealed gaps in all the levels of the vaccine supply chain(2). Although vaccine transportation at the national and regional levels is well organized and efficient due to outsourcing, vaccine transportation to lower levels is challenging due to lack of the right equipment like refrigerated trucks and appropriate carriers. These factors compromise the quality of vaccines. The other challenges cited in the report that affects effective vaccine management included inadequate knowledge in vaccine management, cold chain equipment and funding for equipment maintenance. Lack of a replacement plan for cold chain equipment by the counties and also a low storage capacity at sub county stores necessitated frequent collection of vaccines from the regional stores and since a reliable transport is not guaranteed the vaccine quality is at risk. Fifty percent of the country has no access to electricity (3) hence a need for backups like solar and these are threatened by lack of resources both human and financial. All these factors affect vaccine potency and may cause increased infections and poor health outcomes. Therefore, there is a need to assess the factors affecting vaccine cold chain management for improvement of the vaccine supply chain and consequently improving its responsiveness and agility. In addition, the supply chain should comply to the WHO set standards that requires skilled health workers handling the supply chain and increased funding to curb the financial related challenges(4).

1.2 Problem statement

Vaccines play a critical role in prevention and control of infectious diseases leading to reduced morbidity and mortality (5) .The vaccine cold chain ensures maintenance of vaccine potency from the manufacturer to the end user. Once lost, vaccine potency cannot be restored properly and therefore a need to ensure potency by maintaining a functional cold chain at all levels.

Kisii County obtains vaccines from the regional warehouse in Kisumu County which are then distributed to health centers and dispensaries. Following an effective vaccine management assessment carried out by WHO and UNICEF, it was noted that weak cold chain systems and an overall poor management of the vaccine supply chain pose a threat to vaccine potency(4). Once vaccine potency diminishes, the vaccinated patient is not adequately protected, and this can lead to an increased risk of infections. In Kisii County, there is inadequate cold chain infrastructure especially in the health centers and dispensaries. The public health facilities have low storage capacity, and this necessitates frequent vaccine collection putting the vaccine quality at risk during transportation. Equipment maintenance in the county is also a challenge due to lack of the resources needed for maintenance. All these factors affect vaccine quality that may lead to increased vaccine preventable diseases.

1.3 Purpose of the study

The study sought to assess the factors affecting effective vaccine cold chain management in public health facilities in Kisii county, Kenya and provide data that can provide a basis for continuous improvement of the vaccine supply chain by strengthening human resource capacity, improvement of the cold chain infrastructure by resource mobilization and consequently improving health outcomes hence achieving high standards of health as per the Kenya Health policy (2014-2030).

1.4 Objectives

1.4.1 General objective

To assess the factors affecting effective vaccine cold chain management in public health facilities in Kisii County.

1.4.2 Specific objectives

1. To determine the personnel factors that affect effective vaccine cold chain management in public health facilities in Kisii County, Kenya.
2. To assess the institutional factors that affect effective vaccine cold chain management public health facilities in Kisii County ,Kenya.
3. To describe the challenges facing effective vaccine cold chain management in public health facilities in Kisii County, Kenya.

1.5 Research questions

1. What are the personnel factors that affect effective vaccine cold chain management in public health facilities in Kisii county, Kenya?

2. What are the institutional factors that affect effective vaccine cold chain management in public health facilities in Kisii county, Kenya?

3. What are the challenges facing effective vaccine cold chain management in public health facilities in Kisii County, Kenya ?

1.6. Significance of the study

A reliable vaccine cold chain ensures vaccine safety and efficacy and therefore assuring a reduced mortality and morbidity rates from vaccine preventable diseases (6).Understanding the factors that affect vaccine cold chain management will help the county government and the supporting partners to address the gaps identified. This will assure improvement in vaccine cold chain management practice ensuring vaccine quality is kept intact to the time of administration to patients reducing vaccine preventable diseases. The study will also inform the health professionals about measures to take at the facility level to improve vaccine management practice. If unchecked, there will be vaccine supply chain disruptions that may lead to a spike of otherwise preventable infections and eventually deaths.

1.7 Delimitations

The study was done in public health facilities in the 9 sub counties in Kisii County and it assessed the knowledge ,practices and attitudes of health professionals in vaccine cold chain management, status of the cold chain equipment and the barriers to effective vaccine cold chain management.

1.8 Limitations

1. The study was carried in Kisii County a rural setting and therefore the results cannot be extrapolated to an urban setting

2. The study faced logistics challenges related to the infrastructure and terrain of Kisii.

3. The study was limited to health professionals and the effect of effective vaccine management on the patients cannot be conclusive.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter presents literature from scholarly circles discussing the factors affecting effective vaccine cold chain management in public hospitals. Specifically, it reviews global, regional and Kenyan literature that assesses the knowledge, practices and attitudes of health professionals on effective vaccine cold chain management; the status of the vaccine cold chain equipment in public health facilities; and evaluates the barriers to effective vaccine cold chain management**.**

2.2 Overview

Effective vaccine cold chain management is highly predicated on high standards of vaccine cold chain equipment, knowledge and practices of health professionals and leveraging on barriers that may impact on cold chain management (7,8). Further, vaccine wastage mostly because of poor vaccine cold chain management that does not consider proper temperatures, handling and storage, create significant cost-losing outcomes for health facilities (9). Vaccine quality needs to be assured from the manufacturing point to the time of administration to a client. There is a need to maintain an effective vaccine cold chain management to ensure maximum coverage. That is why it is vital to engage in a review of scholarly articles and works that discuss the factors affecting vaccine cold chain management in public hospitals. Specifically, it reviews global, regional, and Kenyan literature that assesses the knowledge, practices and attitudes of health professionals on effective vaccine cold chain management; the status of the vaccine cold chain equipment in public health facilities; and evaluates the barriers to effective vaccine cold chain management.

2.3 Personnel factors

Improper vaccine cold chain management has been noted as a key reason for the reduced vaccine potency (7). A cross-sectional study done in India found that health professionals' knowledge and skills are positively and significantly correlated to efficient vaccine cold chain management. Training opportunities in cold chain management of vaccines considerably led to efficient vaccine cold chain management (7). What is however missing in this study, and which is vital for the present study, is the assessment of attitudes of health professionals towards vaccine cold chain management; a factor that the present study hopes to fill.

Global studies show that knowledge and practices are particularly needed owing to the dynamic technological innovations that have been adopted to help improve cold chain management of vaccines (8). A study done in the USA shows that effective vaccine cold chain management requires technology that enhances its capacity, but also aligns decision making to the overall strategy and allows for the acquisition of useful data to help create better ways to handle and store vaccines (8). While technological innovation bears the strongest potential to increasing the quality of the process, knowledge and skills gaps are often the aspect that diminishes that potential (8). Nonetheless, from the review of this study, one aspect is not considered and that is the attitude of health professionals and how it affects vaccine cold chain management.

Studies done in the UK, China and Canada show that knowledge and practices of health professionals have a strong relationship with the effectiveness of vaccine cold chain management (9–11). The studies that are largely cross-sectional in nature, observe that health professionals who have higher training in vaccine cold chain management and who have more experience in handling and storing vaccines are more likely to engage in more efficient ways of storing the vaccines and improve its potency (9–11). These studies do not however look at attitude of health professionals which is an aspect that the present study considers important.

In Africa, the potency of vaccines has always been called into question mostly because of the challenges concerning storage and handling in tropical climates. This can be illustrated by a cross sectional study done in Cameroon (12). The standards of vaccine handling, storage and cold chain monitoring are significantly low (24.1%) mostly because of inadequate knowledge, skills and practices of the health professionals (12). Further, due to lack of commitment and ineffective resource mobilization, the health professionals do not engage in the relevant training activities (12). What is observed is that lack of training leads to insufficient knowledge and low skills which then affect the quality of vaccines due to poor handling and storage.

A study done in Nigeria shows that generally, poor handling and storage practice is as a result of lack of knowledge and skills by the immunization service providers (13). While many of the staff (63.0%) had received vaccine cold chain management training, fewer (38%) had translated it into practice which eventually showed low knowledge and skills about the whole process (13). Health professionals who had advanced vaccine cold chain management training were more likely to have better handling and storage competences (13). Training is positively correlated to improved knowledge and skills of health professionals in vaccine cold chain

management. It should be noted that this study does not consider the construct of health professional attitude and how it impacts on vaccine cold chain management. This research gap will be filled by the present study.

Maintaining vaccine quality has been noted as one of the central challenges affecting the immunization process in tropical countries like Ethiopia (14). The study observes that to a significant extent, 47.3% health professionals were without sufficient knowledge about the recommended temperature levels (2 °C – 8 °C) needed to keep vaccines in refrigerators while only 23% of the health professionals had satisfactory knowledge and skills in vaccine cold chain management (14). Further, fewer health professionals had adequate cold chain management practice in the hospitals surveyed (14). This study is supported by another study done in Bahir Dar city in Ethiopia which also observes that the knowledge, skills and practices of staff is significantly inadequate and affects the performance of vaccine cold chain management (15).Further, it was revealed by Mohammed et al. in a study done in Ethiopia that there were gaps identified in knowledge, practices and attitudes(16) this puts the immunization process in jeopardy and reduces the quality of vaccines.

In Kenya, the coverage rate for vaccination has remained at 75% for the last 5 years (17). However, to continue sustaining this coverage rate, there is need to maintain an effective vaccine cold chain management. One of the ways proposed by reviewed Kenyan-based studies is the use of Remote temperature monitoring (RTM) technology (17,18). The studies have noted that during the 7 months, the quality of vaccines improved markedly after using the RTM. Also, the storage process managed to maintain the WHO recommended temperatures following the adoption of the technology. Of note however is the observation from this study that the implementation was often hampered by lack of knowledge and skills of health professionals engaged in vaccine cold chain management (17,18). This shows that even in the Kenyan set-up, insufficient knowledge and skills have a negative effect on the vaccine cold chain management. However, a gap exists because, one, these Kenyan studies did not examine the aspect of health professional attitude towards vaccine cold chain management. Further, the studies have been done in Nairobi where it is estimated that technological innovation and its adoption is high and not in a semi-urban area like Kisii, hence the need for the present study**.**

2.4 Institutional factors

Global studies, especially those done in developed countries, show that effective vaccine cold chain management is highly predicated on the high quality of equipment(7,9). In countries like

India and the USA, studies show that almost all vaccine cold chain enabling equipment is mobilized then constantly maintained and subsequently improved using enabling technologies. This is the reason why vaccine potency in those countries is as high as 98% (7,9).

The case is different continentally, a study done in Kenya, Ghana and Uganda on the status of equipment used for vaccine cold chain management systems shows significant gaps (19). This study shows that 58% of the 300 health facilities had unmaintained vaccine cold chain enabling equipment which lowered the potency of vaccines by 16%. Further, many of these equipment were not compliant to most of the WHO recommended guidelines mostly because other compatible infrastructure like constant electrical supply, availability of backup generators and internet to enable technology based support were also not available (19). This shows that the absence of or the poor conditions of vaccine cold chain equipment led to significant inefficiencies in the vaccine cold chain management in some African countries.

A cross-sectional study done to examine vaccine cold chains of countries within the Clinton Health Access Initiative (CHAI) notes that three issues affecting vaccine cold chain management in these countries are lack of capacity in terms of resource mobilization and the proper and full identification of future capacity gaps, lack of technology upgrade for vaccine cold chain management equipment and problems in controlling temperatures and maintaining equipment after breaking down (20). Low status of vaccine cold chain management systems is common in many African countries which then lead to the low potency of vaccines which affects the immunization process in health care systems.

However, other countries in Africa post positive results. For instance, the study done in Bahir Dar city in Ethiopia showed that many facilities there had a functional electrical powered refrigerator, a working thermometer and a functional back-up generator (15). Having noted earlier that, health professionals in the same facilities lacked adequate knowledge, skills and practice in vaccine cold chain management, it becomes clear that on the other hand, they more or less, have acceptable standards of the vaccine cold chain management equipment. This is important to note because studies have observed problems in the status of the vaccine cold chain equipment especially in tropical countries, a situation that is further compounded by low knowledge, skills and practice in vaccine cold chain management (15).

The Kenyan vaccine cold chain management situation is no different from that of other countries. Low status of vaccine cold chain management systems is common in many parts of the country which then lead to the low potency of vaccines which affects the immunization

process in health care systems (17,18,21). This is exacerbated by the fact that influx of Pentavalent, Rotavirus and pneumococcal vaccines has increased antigen volumes by more than five times. This has also enhanced the value of vaccines needed for efficient immunization (17,18,21). Consequently, vaccine wastage mostly because of poor vaccine cold chain management that does not consider proper temperatures, handling and storage, create significant cost-losing outcomes for health facilities. This means that vaccine cold chain management is not only vital for improvement and maintenance of vaccine potency but also for stopping significant monetary loss (21). However, none of these studies have been done in Kisii County to look at the status of vaccine cold chain equipment where at present, vaccination of COVID-19 is about to begin and where other vaccination efforts for measles and Rotavirus have been ongoing.

2.5 Challenges facing effective vaccine cold chain management

The main barriers to effective vaccine cold chain management include lack of capacity in terms of resource mobilization and the proper and full identification of future capacity gaps; lack of technology upgrade for vaccine cold chain management equipment and the problems in controlling temperatures and maintaining equipment after breaking down (20). As far as capacity is concerned, many cold chains across Africa and in Kenya face challenges in delayed new vaccine introduction, inability to devise copying strategies to deal with gaps in availability of vaccines or to deal with reduced cold storage space for more vaccines. Further, breaking down of vaccine cold chain equipment reduces the capacity of health facilities to effectively maintain the quality of vaccines.

The other barrier is the low adoption of technology to help improve vaccine cold chain management. This problem is compounded by the fact that in many health care facilities, the vaccine cold chain equipment used is mostly outdated. This outdated equipment is noted to lack the freeze protection components, low and ineffective temperature controls, and shorter periods for holdover of vaccines. This problems lead to massive vaccine potency loss and monetary problems (20). In fact, the CHAI program showed that in Ethiopia alone, just a 1% drop of temperature inevitably leads to a monetary value loss of US$8 million of vaccines per year (20). Further based on the report, many of the countries reviewed have outdated equipment with between 15-20% of them being 10 years older which is outside the WHO recommended lifespan of cold chain equipment. Many others use domestic fridges which unfortunately do not possess the optimal temperature capability needed to store vaccines (21,22). Moreover, absorption-based fridges are used by these countries at a significant 65% level, fridges that are

kerosene fueled or driven by liquid petroleum gas, which are now not WHO approved. Studies show that many health facilities in Africa, mostly, are unable to acquire newer technology largely due to the exorbitant costs of such technologies and lack of awareness among health professionals about the benefits of these technologies (22).

Another significant barrier is the insufficient knowledge and skills of health professionals regarding the effective vaccine cold chain management. Reviewed studies have shown that to a significant extent, health professionals are significantly without sufficient knowledge about the recommended temperature levels (2 °C – 8 °C) needed to keep vaccines in refrigerators. Two, generally, the studies have found that very few health professionals have satisfactory knowledge and skills in vaccine cold chain management (14). Further, fewer health professionals have adequate cold chain management practice in the hospitals surveyed (14). Further, studies have observed that health professionals who have higher training in vaccine cold chain management and who have more experience in handling and storing vaccines are more likely to engage in more efficient ways to store the vaccines and improve its potency than those who don't have the knowledge, skills and experience (9–11).

Having reviewed these barriers, it would be instructive to examine how they affect vaccine cold chain management in Kisii County, Kenya. This is because, despite the shortage of studies on barriers to vaccine cold chain management in Kisii, the county has been significantly engaged in vaccinations in line with government policy. This means that there is an urgent need to examine the factors that affect vaccine cold chain management to remedy the situation.

2.6 Research Gaps

Studies have been reviewed regarding the knowledge and practices of workers regarding vaccine cold chain management and status of equipment and barriers to vaccine cold equipment. However, what is missing in most studies, and which is vital for the present study, is the assessment of attitudes of health professionals towards vaccine cold chain management. The Kenyan studies reviewed, studies have been done in Nairobi where it is estimated that technological innovation and its adoption is high and not in a semi-urban area like Kisii, hence the need for the present study. On status and barriers, none of the reviewed studies have been done in Kisii County to look at the status of vaccine cold chain equipment where at present, vaccination of COVID-19 has begun and where other vaccination efforts for measles and Rotavirus have been ongoing.

2.7 Conceptual framework

Figure 2.1 illustrates how the study variables are interrelated. The dependent variable is the status vaccine cold management which is measured by the status of vaccine supply chain management. This will be determined by checking whether the standard operating procedures are implemented properly. This variable is assumed to be influenced by three independent variables: They include personnel and institutional factors as well as the existing challenges.

Personnel factors encompasses the quality and quantity of the workers. The health professionals should have the requisite knowledge, skills and attitudes in order to effectively run a vaccine cold chain process. Unskilled personnel coupled with inadequate number may lead to inefficient and ineffective cold chain management. The institutional factors which mainly embodies infrastructure is critical in maintaining the efficacy of vaccines. Poor storage leads to deterioration of vaccines. The requisite equipment should be available and in good working condition. Challenges exists in the management of vaccine cold chain. Scarcity of resources such as finances, equipment, as well as human resource poses a challenge.

Independent Variable-Factors

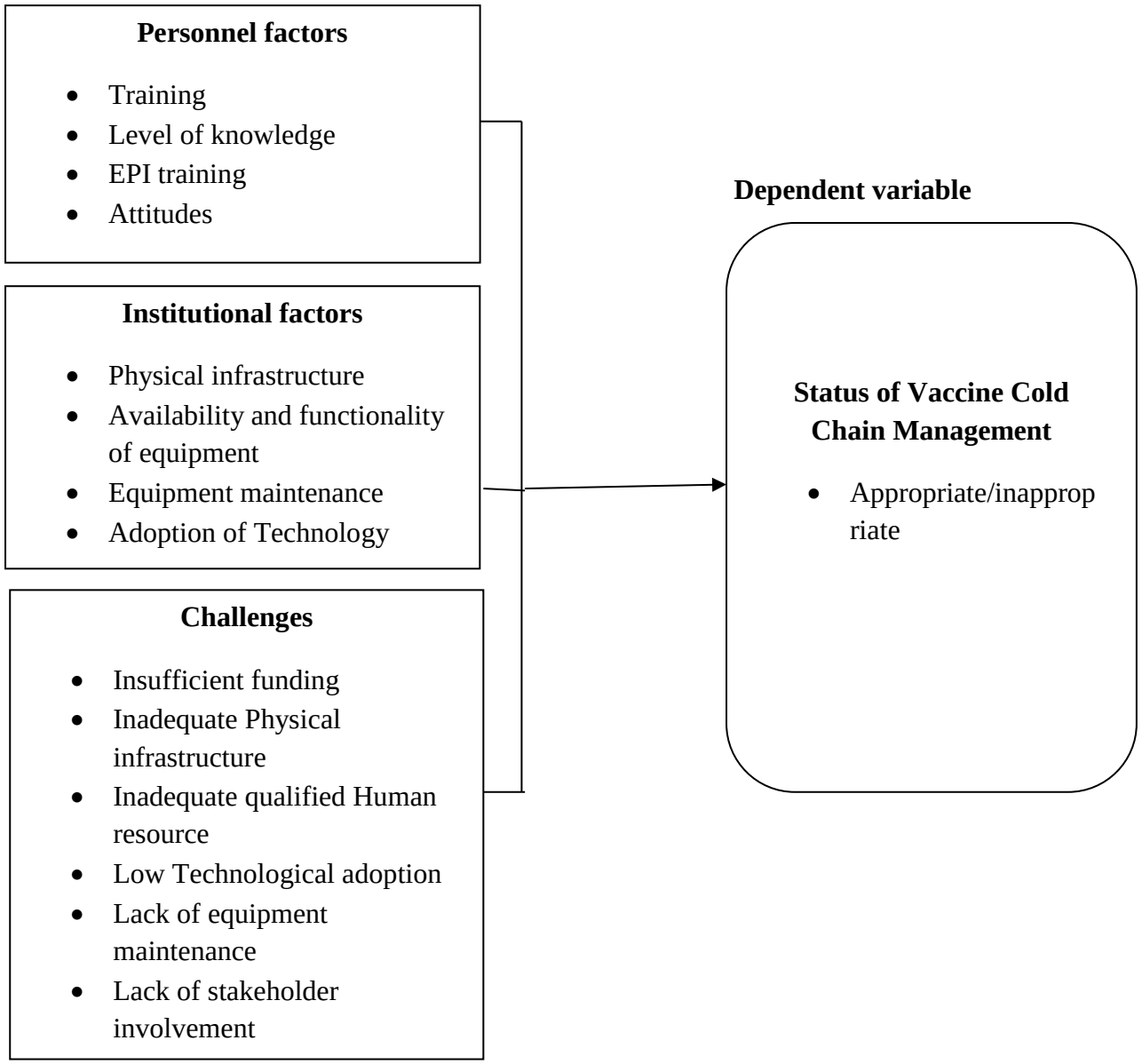

Figure 2.1 Conceptual framework **(Author 2021)**

CHAPTER THREE: METHODOLOGY

This chapter presents the research methodology applicable to the current study. It thus presents that research design, the target population, the sample size and sampling technique, the data collection instruments, validity and reliability tests of the instruments, data collection procedure, the data analysis procedures, and the ethical concerns.

3.1 Research Design

To effectively examine the factors affecting vaccine cold chain management in public hospitals, this study employed a descriptive cross-sectional and analytical research design. This design was appropriate for this study because it mainly answers the 'what' question as described by Kothari(23). This research design describes what is happening in a study sign in a reliable and credible way and applies to happenings that the research has no control over(23). Further, it is relevant to the present study because it allows for quantitative data that describes events in a research study area. Also, descriptive cross-sectional research design permits the description and analysis of multiple variables applicable to the study(23).

3.2 Location of the Study

The study was done in Kisii County which is one of the 47 Counties in Kenya, and which borders the counties of Nyamira to the North, Migori and Homabay to the West and Narok to the south. The County has 9 constituencies which are Bonchari, Bobasi, South Mugirango, Bomachoge Chache, Kitutu Chache North, Bomachoge Borabu, Nyaribari Chache, Kitutu Chache South and Nyaribari Masaba (24). Further, the County covers an area of 1,302km2, and a population of 2, 189,876 (24). As far as the health care system is concerned, Kisii County presently has several public health facilities. These are 79 dispensaries,29 health Centers, 17 hospitals and 1 referral hospital. Of these facilities, only 123 offer immunization to patients(25,26).

3.3 Target and Study Population

The study targetted the 123 public health facilities in Kisii County that offer immunization services. The study population were the vaccine handlers at the health facilities. One respondent per facility was recruited. The vaccines offered include DPT-HepB-Hib, BCG, Pneumococcal, Inactivated Polio Vaccines, Oral polio, Rotavirus, Measles Rubella together with Tetanus especially for pregnant women and COVID-19.

3.3.1 Inclusion Criteria

1. Public health facilities in Kisii County offering immunization services

2. Nurses involved in handling and administration of vaccines who will voluntarily consent to participate in the study.

3.3.2 Exclusion Criteria

1. Nurses not involved in handling and administration of vaccines in public health facilities offering immunization services.

2. Private facilities, faith-based organizations, and nongovernmental organizations offering health services.

3.4 Samples

3.4.1 Sampling Technique

The study used stratified sampling technique to select the health facilities that were included. Stratified sampling is useful because it gets the requisite data from the selected health facilities who do not share similar characteristics. Not all health facilities have the same levels of documentation and processes and therefore stratified sampling is appropriate. The categories of health facilities to be considered were hospitals, health centers and dispensaries. After determining the number of facilities required in each category, simple random sampling using computer generated numbers was applied to identify the specific facilities to be visited. In every facility one participant was selected using simple random sampling where lottery method was deployed. Simple randomization is useful as it reduces representational bias and gives everyone equal chance to participate in the study.

3.4.2 Sample Size determination

The Yamane, (1967), formula to get a credible sample size from the population was used:

$$n = \frac{N}{1 + Ne^2}$$

Where

n= sample size

N= population size

e=desired degree of precision

$$n = \frac{123}{1+123(0.05)^2}$$

$$n = \frac{123}{1.3075}$$

n=94

Additionally, proportionate stratified random sampling was applied to determine the number of sample participants according to the level of care in that stratum (Table 1)

Where;

$$X = \text{Sum of } \frac{Yi \times 94}{123}$$

X=sample size in the county(stratum)

Yi=number of health facilities per level of care in that stratum (dispensaries, health centers, hospitals)

Table 3. 1: the specific number of each type of facility

Type of facility	Number of facilities	Number sampled
Dispensaries	77	58
Health centers	28	22
Hospitals	17	13
Referral hospital	1	1
Total	123	94

3.5 Data Collection Methods

3.5.1 Data Collection Instruments

The study used structured questionnaires to get data from the vaccine handlers in the health facilities. Questionnaires are appropriate in accessing information from many respondents, in this case 94, and are the most applicable tool to get data underpinned by cross-sectional survey research design (20). (Appendix 1)

3.5.2 Pre-Testing

To check and enhance the reliability of the structured questionnaire to be used for data collection, a pretest was done in 13 health facilities in Kisii County (10% of the target population) before ethical approval and before commencing data collection. The structured questionnaires were administered to the target population. Data from the 13 was not included in the study but was used to review the instruments. Any ambiguity was corrected before data collection. Consequently, errors were eliminated from the instruments based on the pre-test. To ensure that the revised questionnaire was free from ambiguity, a different group of the target population was requested to fill it. Any additional corrections were also effected.

3.5.3 Validity of the Instruments

Validity is the "degree to which an instrument measures what it is supposed to measure as defined by Kothari(23). To ascertain the level to which the research instruments test the variables that is intended, the supervisor reviewed the content of the instruments. His feedback was used to review the instruments to make them more valid. A comparison between tools used in similar studies and the one proposed in this study was carried out and the necessary changes and improvements made.

3.6 Data Collection Techniques

Permission was sought from the Kisii County Health Department office to enable the researcher to access the health facilities. Secondly, permission was sought from the respondents to ensure that they were answering the questions voluntarily. The researcher then visited 3-4 health facilities each day to distribute the questionnaires for filling. The questionnaires had all specific objectives catered for in each section. Informed consent was sought from the respondents through signing or marking to show their understanding on the purpose of the study .

3.7 Data Analysis

Data generated from the questionnaires was checked for completeness, coded, and verified. Data was analyzed using descriptive statistical tools characterized by mean, standard deviation, frequency and percentages that will be achieved with the help of the Statistical Package for Social Sciences (SPSS) version 28,2021 and Microsoft Excel. The analyzed data was then presented in tables as per the objectives.

3.8 Logistical and Ethical considerations

Study permission and approval was obtained from Kenyatta National Hospital and University of Nairobi Ethical Research Committee. The respondents consented before taking part in the study.

CHAPTER 4 : RESULTS

4.1 .Socio-Demographic Characteristics

The Socio-demographic characteristics of the respondents are shown in Table 2. Majority of the participants were female (63.8%) . On the academic aspect 86.5% of them were diploma holders. Cumulatively82.0% had worked at the health facilities for more than 2 years. Of note is that 68.%)had received Expanded Program on Immunization (EPI) training. Majority (61.7%) of the respondents worked in dispensaries. It is clear from this result that the respondents were trained in EPI which means they had significant ability to deal with vaccine cold chain management.

Table 4. 1: Social demographic characteristics (n=94)

Variable	Frequency	Percentage
Gender		
Male	34	36.2
Female	60	63.8
Level of education		
Degree	9	9.6
Diploma	81	86.2
Certificate	4	4.3
Years of experience		
<2 years	17	18.1
2-5 years	26	27.7
6-10 years	29	30.9
>10 years	22	23.4
Trained on EPI		
Yes	64	68.1
No	30	31.9
Level of health institution		
Teaching and referral	1	1.1
Hospital	13	13.8
Health center	22	23.4
Dispensary	58	61.7

4.2 Personnel factors.

4.2.1 Cold Chain Management Practices in Facilities

The study sought to examine the cold chain management practices in public health facilities in Kisii County(Table 3)There were standard operating procedures in the facilities (91.5%) and that there were other commodities than the vaccine stored in refrigerator (14.9%) in a few

health facilities. Further, there was adequate capacity for storing vaccines (87.2%), and proper arrangement of vaccines in the refrigerator (95.7%). The vaccine management followed FEFO principle (92.5%) and . there was little presence of expired(1.06%)and frozen vaccines(5.32%) in the refrigerator. Moreover, in most facilities, there was maintenance of refrigerator temperature between 2-8^{0}C (98.4%), presence of a functional thermometer in the refrigerator (97.9%), recording of the temperature twice daily (97.9%) and protection of the packing area from direct sun light (96.8%). Other practices that were maintained included vaccine transactions recorded, VVM status of vaccine recorded for each vaccine and vaccine LMIS reporting, and requisition form done in the previous one month. There were satisfactory positive and effective vaccine cold chain management practices in the health facilities in Kisii County.

Table 4. 2: Cold chain management practices in facilities (n=94)

Variable	Frequency	percentage
Availability of standard operating procedures in the facility	86	91.49
Anything other than the vaccine stored in refrigerator	14	14.89
Availability of adequate capacity for storing vaccines	82	87.23
proper arrangement of vaccines in the refrigerator	90	95.74
Vaccine management follows FEFO principle	87	92.55
Presence of expired vaccine in the refrigerator	1	1.06
Presence of frozen vaccines in the refrigerator	5	5.32
Maintenance of refrigerator temperature between 2-8^{0}C	93	98.44
Presence of a functional thermometer in the refrigerator	92	97.87
Recording of the refrigerator T^{0}twice daily	92	97.87
Is the Packing area of vaccine protected from direct sun light	91	96.81
Vaccine transactions recorded	94	100
VVM status of vaccine recorded for each vaccine	93	98.94
Vaccine LMIS reporting, and requisition form done in the previous one month	89	94.68

4.2.2. Knowledge and Attitudes of Health Professionals towards the Vaccine Cold Chain

The respondents were asked questions regarding their knowledge and attitudes on effective vaccine cold chain management and the results are presented in Table 4 and 5. Based on Table 4, all respondents had knowledge on the correct placing practice of thermometer, temperature reading and vaccine storage. More than 80% of them had knowledge on the correct

interpretation of shake test and more than 90% on the correct interpretation of VVM and awareness that freezing is harmful for some vaccines and those vaccines are heat sensitive.

Table 4. 3: Knowledge on the vaccine cold chain (n=94)

Variable	Frequency	Percentage
Awareness that vaccines are heat sensitive	94	100
Awareness that freezing is harmful for some vaccines	92	97.87
Knowledge on the correct placing practice of thermometer	94	100
Knowledge on the correct temperature reading	94	100
Knowledge on the correct temperature for vaccine storage	94	100
Knowledge on the correct interpretation of VVM	93	98.94
Knowledge on the correct interpretation of shake test	84	89.36

As far as attitude is concerned (Table 5), majority (91.5%) of the respondents were aware that placing food, drinks, or other medicines with vaccines in the refrigerator affect vaccine potency. Majority (80.8%) agreed that an “open when needed label” should be placed on the door of every vaccine refrigerator and 92.5% agreed that Vaccine refrigerators should be opened at most 2 times a day. Further, 98.9%agreed that reconstituted vaccines should be used before 6 hours all of them those vaccines should be used before expiration. Finally, 98.9% of the respondents agreed that temperature execution should be reported as soon as they occur. This implies that the knowledge and attitude of health professionals about vaccine cold chain management was positive.

Table 4. 4: Attitudes towards the vaccine cold chain

Variable	Frequency	Percentage
Placing food, drinks, or other medicines with vaccines in the refrigerator affect vaccine potency		
Strongly agree	70	74.47
Agree	16	17.02
Undecided	0	0
Disagree	3	3.19
Strongly disagree	5	5.32
An "open when needed label" should be placed on the door of every vaccine refrigerator		
Strongly agree	46	48.94
Agree	30	31.91
Undecided	6	6.38
Disagree	6	6.38
Strongly disagree	6	6.38
Vaccine refrigerators should be opened < 2 times a day		
Strongly agree	57	60.64
Agree	30	31.91
Undecided	4	4.26
Disagree	2	2.13
Strongly disagree	1	1.06
Reconstituted vaccines should be used before 6 hours		
Strongly agree	73	77.66
Agree	20	21.28
Undecided	0	0
Disagree	0	0
Strongly disagree	1	1.06
Vaccines should be used before expiration		
Strongly agree	83	88.30
Agree	11	11.70
Undecided	0	0
Disagree	0	0
Strongly agree	0	0
Temperature execution should be reported as soon as they occur		
Strongly agree	68	72.34
Agree	25	26.60
Undecided	1	1.06

4.3 Institutional factors

4.3.1 Availability and functionality of cold chain equipment

The study further investigated the status of cold chain equipment in health facilities in Kisii County. To do this effectively, both the availability of cold chain equipment and the maintenance levels of that equipment was examined as seen in Tables 6 and 7. As far as the availability of cold chain equipment was concerned, there was a functional refrigerator (88.3%), functional temperature monitoring device (92.5%) and enough storage capacity (89.4%) for the vaccines and their consumables. However, some of the essentials were lacking such as functional backup generator (25.5%), fuel for generator (20.2%), separate vaccine cold room (25.5%) and cold chain equipment coupled with new technology (i.e., Nexleaf) (14.9%).

Table 4. 5: Availability and functionality of cold chain equipment (n=94)

Variable	Frequency	Percentage
Availability of functional refrigerator/freezer	83	88.3
Availability of functional temperature monitoring device	87	92.55
Availability of functional backup generator	24	25.53
Availability of fuel for generator	19	20.21
Availability of enough storage capacity for the vaccines and their consumables	84	89.36
Availability of separate vaccine cold room	24	25.53
Availability of cold chain equipment coupled with new technology (i.e., Nexleaf)	14	14.89

4.3.2 Maintenance of equipment

On maintenance, there was plan for equipment (54.2%), presence of trained person for minor maintenance (52.1%), clean cold room free of dust (95.7%) and maintained windows and external room security (91.5%). However, there were no spare part for minor maintenance (14.9%) and no permanently assigned personnel for cold chain equipment maintenance (40.43%). This implies that while the cold chain equipment was maintained there were no adequate spare parts and expert personnel for major maintenance.

Table 4. 6: Maintenance of cold chain equipment (n=94)

Variable	Frequency	Percentage
Presence of maintenance plan for equipment	51	54.26
Presence of trained person for minor maintenance	49	52.13
Availability of spare part for minor maintenance	14	14.89
Presence of permanently assigned personnel for cold chain equipment maintenance	38	40.43
Cold room clean, free of dirt and floor dry to acceptable levels	90	95.74
Windows and external room security maintained for the cold room	86	91.49

4.4 Challenges facing Effective Vaccine Cold Chain Management

The study sought to examine the key challenges facing effective vaccine cold chain management and the results are summarized in Table 8. The main challenges were insufficient funding for effective vaccine management (40.4%), inadequate qualified human resource as per the human resource for health norms in Kenya (35.1%), lack of new technological adoption into the vaccine supply chain (47.9%) and lack of maintenance in the facility leading to cold chain equipment being rendered nonfunctional (75.6%). However, there was sufficient physical infrastructure in the facility for effective vaccine management (54.3%), and relevant stakeholders are always involved in decisions pertaining vaccine management (75.6%).

Table 4. 7: Challenges facing effective vaccine cold chain management

Variable	Frequency	Percentage
There is sufficient funding for effective vaccine management		
Strongly agree	11	11.70
Agree	27	28.72
Undecided	15	15.96
Disagree	38	40.43
Strongly disagree	3	3.19
There is adequate qualified human resource as per the human resource for health norms in Kenya		
Strongly agree	14	14.89
Agree	19	20.21
Undecided	15	15.96
Disagree	38	40.43
Strongly disagree	8	8.51
There is sufficient physical infrastructure in the facility for effective vaccine management		
Strongly agree	14	14.89
Agree	37	39.36
Undecided	9	9.57

Disagree	31	32.98
Strongly disagree	3	3.19
There is new technological adoption into the vaccine supply chain		
Strongly agree	16	17.02
Agree	29	30.85
Undecided	16	17.02
Disagree	29	30.85
Strongly disagree	4	4.26
The relevant stakeholders are always involved in decisions pertaining vaccine management		
Strongly agree	23	24.47
Agree	48	51.06
Undecided	17	18.09
Disagree	4	4.26
Strongly disagree	2	2.13
Lack of maintenance in the facility leads to cold chain equipment being rendered non-functional		
Strongly agree	26	27.66
Agree	45	47.87
Undecided	11	11.70
Disagree	8	8.51
Strongly disagree	4	4.26

4.5 Association between variables

Association between variables was done using Fischer's exact and the results were summarized in Table 9 and Table 10. Based on the results from Table 9, a functional backup generator in the facility, fuel for generator, separate vaccine cold room and cold chain equipment coupled with new

Technology had a statistically significant association with type of health facility (p-value<0.01).

Table 4. 8: Association between types of health facility and availability of equipment

*Key *- statistically significant relationship*

L1- Teaching and Referral hospital, L2- Hospital, L3-Health center, L4- Dispensary

Variable	Availability status	L1	L2	L3	L4	p- value
Functional refrigerator/freezer	Available	1	12	21	49	0.557
	Not available	0	1	1	9	
Functional temperature monitoring device	Available	1	13	21	52	0.644
	Not available	0	0	1	6	
Functional backup generator in the facility	Available	1	4	18	48	**0.001***
	Not available	0	9	4	10	
Fuel for generator	Available	1	8	4	6	**0.001***
	Not available	0	5	18	52	
Enough storage capacity for the vaccines and their consumables	Available	1	12	21	50	0.669
	Not available	0	1	1	8	
Separate vaccine cold room	Available	1	10	6	7	**0.001***
	Not available	0	3	16	51	
Cold chain equipment coupled with new technology (i.e., Nexleaf)	Available	1	12	1	0	**0.001***
	Not available	0	1	21	58	

On the other hand, a functional refrigerator/freezer, functional temperature monitoring device and enough storage capacity for the vaccines and their consumables did not have a statistically significant association with type of health facility (p-value>0.01). Based on the association between type of health facility and maintenance of equipment (Table 10), maintenance plan, presence of a trained person for minor maintenance, availability of spare part and permanently assigned personnel had a statistically significant association with type of health facility (p-value<0.01). On the other hand, clean cold room and security enacted by windows and external rooms did not have a statistically significant association with type of health facility (p-value>0.01).

Table 4. 9: Association between type of health facility and maintenance of equipment

Variable	Status	Type of health facility				p-value
		L1	L2	L3	L4	
Maintenance plan for equipment present	Yes	1	12	15	23	**0.001***
	No	0	1	7	35	
Trained person for minor maintenance present	Yes	1	13	13	22	**0.000***
	No	0	0	9	36	
Spare part for minor maintenance present	Yes	1	8	1	4	**0.000***
	No	0	5	21	54	
Permanently assigned personnel for cold chain equipment maintenance follow up present	Yes	1	11	8	18	**0.001***
	No	0	2	14	40	
The cold room is clean, free of dirt and floor dry to acceptable levels	Yes	1	13	21	55	1.00
	No	0	0	1	3	
The windows and external room security maintained for the cold room	Yes	1	13	21	51	0.409
	No	0	0	1	7	

Key ***-** *Statistically significant relationship*

L1- Referral hospital, L2- Hospital L3- Health centre, L4- Dispensary

CHAPTER FIVE: DISCUSSION , SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1: Introduction

This chapter presents the discussion of findings of the study. It then presents the summary and conclusions of the findings and the recommendations based on the conclusions. It finally offers recommendations for further research.

5.2: Discussion

The findings from the study significantly agree with literature especially those done in developed countries that show that effective vaccine cold chain management is highly dependent on adequate vaccine cold chain equipment, knowledge and practices of health professionals and leveraging on barriers that may impact vaccine cold chain management(7,8).The study found that the health professional at the health facilities had adequate knowledge, good practices and positive attitudes towards effective vaccine cold chain management. This is a markedly significant positive finding as compared to a study done in east Gojam zone of Amhara Region, Ethiopia where only 38% of the respondents had sufficient knowledge on effective vaccine cold chain management(14). A potential factor associated to this could be training in EPI that was received by 68.1% of the health professionals. In a study done in Ibadan, Oyo State Nigeria,Dairo and Osizimete showed that health professionals who had received good training were more likely to exhibit good practices(13).In a later study carried out in Ethiopia (16),it emerged that half the vaccine handlers had satisfactory knowledge while below average had positive attitudes and good practices .Further, knowledge and practices on vaccine cold chain management have been noted to play a key role in enhancing the effectiveness and quality of vaccines as shown in global studies(8).Providing continuous technical support at both pre service and in service trainings on effective vaccine cold chain management is likely to improve the knowledge ,practices and attitudes of health professionals.

Cold chain equipment was adequately available and functional at Kisii County unlike in Ethiopia where it emerged that the availability of cold chain equipment was unacceptable(14). The health facilities did not have backup generators and the equipment were not aligned to new technology. In addition, while the cold chain equipment was maintained there were no spare parts and expert personnel for major maintenance. In general agreement with reviewed literature, the study compares with global studies that show that effective vaccine cold chain

management is highly predicated on high standards of vaccine cold chain equipment (7,9). In countries like India and the USA, studies show that almost all vaccine cold chain enabling equipment is mobilized, then constantly maintained, and subsequently improved using enabling technologies. This is the reason why vaccine potency in the countries reviewed are as high as 98% (7,9). The study also agrees that the case is different continentally. A study done in Kenya, Ghana and Uganda on the status of equipment used for vaccine cold chain management systems shows significant gaps (19). This study shows that 58% of the 300 health facilities had unmaintained vaccine cold chain equipment which lowered the potency of vaccines by 16%(19). Further, many of these equipment were not compliant to most of the WHO recommended guidelines mostly because other compatible infrastructure like constant electrical supply, availability of backup generators and internet to enable technology based support were also not available (16) and this is in line with studies carried out in Ethiopia where equipment were predominantly dependent on electricity and alternative power sources were low(14,15).Only about a quarter of public health facilities in Kisii county had a functional generator and of those only a fifth had fuel for the generator. Due to irregular availability of electricity ,presence of backup generator is a prerequisite in maintenance of vaccine potency and continuous immunization delivery services.

Insufficient funding, inadequate qualified human resource, lack of new technology in vaccine chain management and lack of equipment maintenance were the key barriers to effective vaccine cold chain management at the public health facilities in Kisii County. The availability of physical infrastructure and stakeholder involvement were not significant barriers. Previous studies show that the main barriers to effective vaccine cold chain management include lack of capacity in terms of resource mobilization and the proper and full identification of future capacity gaps; lack of technology upgrade for vaccine cold chain management equipment and the problems in controlling temperatures and maintaining equipment after breaking down (20). The other barrier is the low adoption of technology to help improve vaccine cold chain management. This problem is compounded by the fact that in many health care facilities, the vaccine cold chain equipment used is mostly outdated (20).

In this study, a functional backup generator in the facility, fuel for generator, separate vaccine cold room and cold chain equipment coupled with new technology had a statistically significant association with type of health facility . The county teaching and referral hospital and the subcounty hospitals were well equipped as compared to the health centres and dispensaries. Further, the presence of a maintenance plan, presence of a trained person for minor

maintenance, availability of spare part and permanently assigned personnel for maintenance had a statistically significant association with the type of health facility. This can be attributed to the more allocation of resources i.e. human resources, financial and technological in the higher levels of healthcare(27).

5.3: Conclusion

From the study,there was significantly positive and effective vaccines cold chain management practices in the health facilities in Kisii County, adequate knowledge, and positive attitude of health professionals. It can be concluded that while cold chain equipment was adequately available and functional, the health facilities did not have backup generators and the equipment were not aligned to new technology. In addition, while the cold chain equipment was maintained there were no spare parts and expert personnel for major maintenance. Further, on challenges facing effective cold chain management, insufficient funding, inadequate qualified human resource, lack of new technology in vaccine chain management and lack of equipment maintenance were the key barriers to effective vaccine cold chain management at the health facilities in Kisii County while availability of physical infrastructure and stakeholder involvement were not significant barriers.

5.4: Recommendations

5.4.1: Recommendations for Policy and Practice

1. The facility managers in conjunction with the Sub county EPI managers should create a policy guideline that streamline vaccine cold chain management to ensure all necessary management gaps are dealt with.
2. Ensure that the health professionals in the facilities should have periodic, at least twice a year; training on EPI and vaccine cold chain management and this can be done in conjunction with the County government.
3. The health facilities should embark on robust resource mobilization to ensure vaccine cold chain management has sufficient funds, new equipment, new technology and adequately trained personnel.
4. Install functional backup generators at the health facilities to ensure that the potency of the vaccines is safeguarded.

5.4.2: Recommendations for Future Research

1. Conduct a study to examine the factors affecting new technology integration in vaccine cold chain management in Kisii County
2. Engage in research which in this case adds qualitative analysis and observation schedule into the study to get in depth perspectives of the health professionals.

REFERENCES

1. WHO. The Vaccine Cold chain. Med J Aust. 2015;160(5):312.

2. Ministry of Health G of K. Kenya Comprehensive Multi-Year Plan for Immunization 2015 - 2019. 2015;(July 2015). Available from: http://www.nationalplanningcycles.org/sites/default/files/planning_cycle_repository/kenya/kenya_cmyp_2015-2019.pdf

3. Kenya Energy Situation - energypedia.info [Internet]. [cited 2021 Mar 4]. Available from: https://energypedia.info/wiki/Kenya_Energy_Situation

4. UNICEF, WHO. Achieving immunization targets with the comprehensive effective vaccine management (EVM) framework. WHO/UNICEF Jt statement [Internet]. 2016;2014:1–5. Available from: http://www.who.int/immunization/programmes_systems/supply_chain/EVM-JS_final.pdf

5. World health organization. Vaccines and immunization: What is vaccination? [Internet]. 2020 [cited 2021 Feb 19]. p. 2019–21. Available from: https://www.who.int/news-room/q-a-detail/vaccines-and-immunization-what-is-vaccination?adgroupsurvey=%7Badgroupsurvey%7D&gclid=Cj0KCQiA3smABhCjARIsAKtrg6JZjZvcR2NLeQOBiMxh1eVZG_bs5kKdbKDJOa7W_IESbezP-dSADfYaArsfEALw_wcB%0Ahttps://www.who.int/news-room/q-a

6. World Health Organisation. State of the world ' s vaccines and immunization. 2009;

7. Shah J, Agarwal M, Patel J, Trivedi A. Quality Assessment of Immunization Services: A Cross Sectional Study at UHCs of Ahmedabad Municipal Corporation. undefined. 2015;

8. Comes T, Bergtora Sandvik K, Van de Walle B. Cold chains, interrupted: The use of technology and information for decisions that keep humanitarian vaccines cool. J Humanit Logist Supply Chain Manag. 2018;8(1):49–69.

9. Santori G, Santamaria S, Sapienza A, Brandani S, Freni A. A stand-alone solar adsorption refrigerator for humanitarian aid. Sol Energy. 2014;100(February):172–8.

10. Sandvik KB. Now is the time to deliver: looking for humanitarian innovation's theory of change. J Int Humanit Action. 2017;2(1).

11. Tatham P, Stadler F, Murray A, Shaban RZ. Flying maggots: a smart logistic solution to an enduring medical challenge. J Humanit Logist Supply Chain Manag. 2017;7(2):172–93.

12. Yakum MN, Ateudjieu J, Walter EA, Watcho P. Vaccine storage and cold chain monitoring in the North West region of Cameroon: A cross sectional study. BMC Res Notes [Internet]. 2015;8(1):1–7. Available from: ???

13. Dairo DM, Osizimete OE. Factors affecting vaccine handling and storage practices among immunization service providers in Ibadan, Oyo State, Nigeria. Afr Health Sci. 2016;16(2):576–83.

14. Bogale HA, Amhare AF, Bogale AA. Assessment of factors affecting vaccine cold chain management practice in public health institutions in east Gojam zone of Amhara region. BMC Public Health. 2019;19(1):1–6.

15. Mulatu S, Tesfa G, Dinku H. Assessment of Factors Affecting Vaccine Cold Chain Management Practice in Bahir Dar City Health Institutions, 2019. Am J Life Sci. 2020;8(5):107.

16. Mohammed SA, Workneh BD, Kahissay MH. Knowledge, attitude and practice of vaccinators and vaccine handlers on vaccine cold chain management in public health facilities, Ethiopia: Cross-sectional study. PLoS One [Internet]. 2021;16(2 February):1–12. Available from: http://dx.doi.org/10.1371/journal.pone.0247459

17. Njuguna MW, Mairura CJ, Ombui K. Influence of Cold Chain Supply Logistics on the Safety of Vaccines . A Case of Pharmaceutical Distributors in. Int J Sci Res Publ. 2015;5(6):1–19.

18. Lutukai M, Bunde EA, Hatch B, Mohamed Z, Yavari S, Some E, et al. Using Data to Keep Vaccines Cold in Kenya: Remote Temperature Monitoring with Data Review Teams for Vaccine Management. Glob Heal Sci Pract. 2019;7(4):585–97.

19. Burchett HED, Mounier-Jack S, Torres-Rueda S, Griffiths UK, Ongolo-Zogo P, Rulisa S, et al. The impact of introducing new vaccines on the health system: Case studies from six low- and middle-income countries. Vaccine [Internet]. 2014;32(48):6505–12. Available from: http://dx.doi.org/10.1016/j.vaccine.2014.09.031

20. Ashok A, Brison M, LeTallec Y. Improving cold chain systems: Challenges and solutions. Vaccine [Internet]. 2017;35(17):2217–23. Available from: http://dx.doi.org/10.1016/j.vaccine.2016.08.045

21. Zaffran M, Vandelaer J, Kristensen D, Melgaard B, Yadav P, Antwi-Agyei KO, et al. The imperative for stronger vaccine supply and logistics systems. Vaccine. 2013;31(SUPPL2).

22. Osei E, Ibrahim M, Kofi Amenuvegbe G. Effective Vaccine Management: The Case of a Rural District in Ghana. Adv Prev Med. 2019;2019(October):1–8.

23. Vinet L, Zhedanov A. A “missing” family of classical orthogonal polynomials

[Internet]. Vol. 44, Journal of Physics A: Mathematical and Theoretical. 2011. 1–8 p. Available from: https://ejournal.poltektegal.ac.id/index.php/siklus/article/view/298%0Ahttp://repositorio.unan.edu.ni/2986/1/5624.pdf%0Ahttp://dx.doi.org/10.1016/j.jana.2015.10.005%0Ahttp://www.biomedcentral.com/1471-2458/12/58%0Ahttp://ovidsp.ovid.com/ovidweb.cgi?T=JS&P

24. Welcome to Kisii County Government [Internet]. Available from: https://www.kisii.go.ke/

25. Kisii County Government Health Services [Internet]. Available from: https://www.kisii.go.ke/index.php/departments/health-services

26. KHIS [Internet]. Available from: https://hiskenya.org/

27. Health M of. Kenya Health Policy 2014-2030.

APPENDICES

Appendix 1 Questionnaire

Please answer the questions asked as provided in the spaces given by ticking.

1. Socio-demographic characteristics of the respondents

No	Characteristics	
1.1	Gender	1. Male [ ]
		2. Female [ ]
1.2	Level of education	1.Undergraduate degree [ ]
		2.Diploma [ ]
		3.Certificate [ ]
		4.Others(specify) [ ]
1.3	Number of years in the vaccine department	1. <2 years [ ]
		2. 2-5 years [ ]
		3. 6-10 years [ ]
		4. >10 years [ ]
1.4	Have you ever taken EPI training?	1. Yes [ ]
		2. No [ ]
1.5	Level of health institution	1. Teaching and referral [ ]
		2. Hospital [ ]
		3. Health center [ ]

		4. Dispensary [ ]
		5. Others(specify) [ ]

2. Personnel factors

2.1 Cold chain management practice

No	Parameters	Yes	No
2.1	Availability of standard operating procedures in the facility		
2.2	Anything other than the vaccine stored in refrigerator?		
2.3	Has the vaccine room sufficient storage capacity?		
2.4	Are vaccines properly arranged in refrigerator?		
2.5	Is the vaccine management following FEFO principle?		
2.6	Are there expired vaccines present in refrigerator?		
2.7	Are there frozen vaccines present in refrigerator?		
2.8	Is refrigerator temperature maintained between 2-8^0C?		
2.9	Is there functional thermometer for refrigerator?		
2.10	Is the refrigerator T^0 recorded twice daily?		
2.11	Is the vaccine packing area protected from direct sun light?		
2.12	Are all vaccine transactions recorded?		
2.13	Is VVM status of vaccine recorded for each vaccine?		
2.14	Is there vaccine LMIS reporting and requisition form done in the last month?		

2.2. Knowledge on the vaccine cold chain

No	Characteristics	Know	Don't know
3.1	Do you know that vaccines are heat sensitive?		
3.2	Do you know that freezing is harmful for some vaccines?		
3.3	Do you know the correct placing practice of thermometer?		
3.4	Do you know the correct demonstration of temperature reading?		
3.5	Do you know the correct temperature for vaccine storage (2-8^{0}C)?		
3.6	Do you know the correct interpretation of VVM?		
3.7	Do you know the correctly interpreted shake test?		

2.3. Attitudes towards the vaccine cold chain

Key: SA-Strongly Agree A-Agree U-undecided D-Disagree SD-Strongly Disagree

No	Characteristics	**SA**	**A**	**U**	**D**	**SD**
3.8	Placing food, drinks, or other medicines with vaccines in the refrigerator affect vaccine potency					
3.9	An "open when needed label" should be placed on the door of every vaccine refrigerator					
3.10	Vaccine refrigerators should be opened < 2 times a day					
3.11	Reconstituted vaccines should be used before 6 hours					
3.12	Vaccines should be used before expiration					
3.13	Temperature exercusions should be reported as soon as they occur					

3. Institutional factors

3.1 Availability and functionality of equipment

No	Parameters	Available	Not available
4.1	Functional refrigerator/freezer		
4.2	Functional temperature monitoring device		
4.3	Functional backup generator in the facility		
4.4	Fuel for generator		
4.5	Enough storage capacity for the vaccines and their consumables		
4.6	Separate vaccine cold room		
4.7	Cold chain equipment coupled with new technology(i.e. Nexleaf)		

3.2 Maintenance of equipment

No	Parameters	Yes	No
4.8	Presence of maintenance plan for equipment		
4.9	Trained person for minor maintenance		
4.10	Spare part for minor maintenance		
4.11	Permanently assigned personnel for cold chain equipment maintenance follow up		
4.12	Is the cold room clean, free of dirt and floor dry to acceptable levels?		
4.13	Are the windows and external room security maintained for the cold room?		

4.Challenges facing effective vaccine cold chain management

Key: SA-Strongly Agree A-Agree U-undecided D-Disagree SD-Strongly Disagree

No	Parameters	SA	A	U	D	SD
5.1	There is sufficient funding for effective vaccine management					
5.2	There is adequate qualified human resource as per the human resource for health norms in Kenya					
5.3	There is sufficient physical infrastructure in the facility for effective vaccine management					
5.4	There is new technological adoption into the vaccine supply chain					
5.5	The relevant stakeholders are always involved in decisions pertaining vaccine management					
5.6	Lack of maintenance in the facility leads to cold chain equipment being rendered nonfunctional					

Appendix 2. Informed consent

(To be administered in English or any other language e.g., Kiswahili translation**)**

Title of study

Assessment of factors affecting effective vaccine cold chain management in public health facilities in Kisii County, Kenya

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Introduction

The above listed principal investigator is intending to conduct research on "Assessment of factors affecting effective vaccine cold chain management in public health facilities in Kisii county,Kenya".This consent form serves the purpose of giving you information that will help you decide whether to be a participant in the study or not. Feel free to ask any questions about the research. When we have answered all your questions to your satisfaction ,you may decide to be in the study or not. This process is called 'informed consent'**.**

Once you understand and agree to be in the study, I will request you to sign your name on this form based on the following principles.

I. You decision to participate is entirely voluntary
II. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
III. Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES/NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.(**P742/09/2021**)

What is this study about?

The researcher listed above is interviewing vaccine handlers and vaccinators. The purpose of the research is to assess the factors affecting effective cold chain effective vaccine cold chain management in public health facilities in Kisii County. The participants in this study will be asked questions about personnel factors, institutional factors and the challenges facing effective vaccine cold chain management. Participants will not undergo any tests. There will be approximately 94 participants in the study randomly chosen. We are asking for your consent to consider participating in the study.

What will happen if you decide to be in this research study?

If you agree to participate in this study, the following things will happen:

A structured questionnaire will be administered to you in a private area where you feel comfortable. The process will last approximately 15minutes and it will cover areas like the personnel factors and institutional factors affecting effective vaccine cold chain management and the challenges facing effective vaccine cold chain management.

Are there any risks, harm, discomforts associated with this study?

One potential risk of being in the study is loss of privacy. I will keep everything you tell me as confidential as possible. I will use a code number to identify you in a password-protected computer database and will keep all my paper records in a locked file cabinet**.**

You may decline to answer any or all questions and you may terminate your involvement at any time.

Are there any benefits being in this study?

There are no direct benefits to you for your participation in the study.However,we hope that the information obtained from this study will help identify gaps in the vaccine supply chain and how to improve them hence ensuring effective vaccine management for better outcomes.

Will being in this study cost you anything?

This study will only cost you time while responding to the questions.

Will you get refund for any money spent as part of this study?

This study does not have any monetary incentives.

What if you have questions in the future?

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

What are your other choices?

Your decision to participate in this study is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits

CONSENT FORM (STATEMENT OF CONSENT)

Participants statement

I have read, and I understand the provided information and have had the opportunity to ask questions. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this study Yes No

I agree to provide contact information for follow up Yes No

Participant printed name: _____

Participant's signature/Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned ,have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent

Researcher's name_____ Date _____

Signature _____

Role in the study; Data collection

For more information contact Daphine Kerubo at 0720169945 from 8.am -5.00p.m

Witness

Name _____ Contact information

_____

Signature/Thumb stamp _____ Date

_____

Appendix 3:Ethical Approval

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel (254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonerb.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/47

10th February, 2022

Daphine Kerubo Nyandondi
Reg. No. 220014821
School of Public Health-
EAC Regional Centre of Excellence for Vaccines,
Immunization and Health Supply Chain Management
College of Medicine and Health Sciences
University of Rwanda

APPROVED
10 FEB 2022

Dear Daphine,

RESEARCH PROPOSAL: ASSESSMENT OF FACTORS AFFECTING EFFECTIVE VACCINE COLD CHAIN MANAGEMENT IN PUBLIC HEALTH FACILITIES IN KISII COUNTY, KENYA (P742/09/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P742/09/2021**.The approval period is 10th February 2022 – 9th February 2023

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
Supervisors: Dr. Peter N. Karimi, Pharmaceutics and Pharmacy Practice Unit, UoN
Dr. Shital M. Maru, Pharmaceutics and Pharmacy Practice Unit, UoN

Appendix 4: Support Letter Kisii County Department of Health

KISII COUNTY GOVERNMENT
DEPARTMENT OF HEALTH
OFFICE OF THE COUNTY DIRECTOR OF HEALTH

Telegramme "Medical"
Telephone: 0721422400/0753122723
E-Mail: kisiicountyhealthcoordinator@gmail.com
When replying quote:
REF: KS/C/HS/42 VOL.III/ (42)

Kisii County
P.O Box 92 – 40200,
KISII
Date: 17th, August 2021

TO WHOM IT MAY CONCERN

RE: SUPPORT LETTER FOR DAPHINE NYANDONDI'S STUDY TITLED 'ASSESSMENT OF FACTORS AFFECTING EFFECTIVE VACCINE COLD CHAIN MANAGEMENT IN PUBLIC HEALTH FACILITIES IN KISII COUNTY, KENYA'

The above subject matter refers.

The above named study has undergone a feasibility assessment evaluation and is deemed feasible to be conducted under the tutelage of the County Pharmacist Kisii County subject to fulfilling all the requisite ethical approval requirements.

Upon meeting all the requirements, ***Daphine Nyandondi***, from ***The University of Rwanda*** will be required to report back to this office for Study registration and authorization prior to commencement of the study.

Kindly accord ***Daphine or her proxy bearing this letter*** any support that she requires to help to gain the requisite approvals in order to conduct this study.

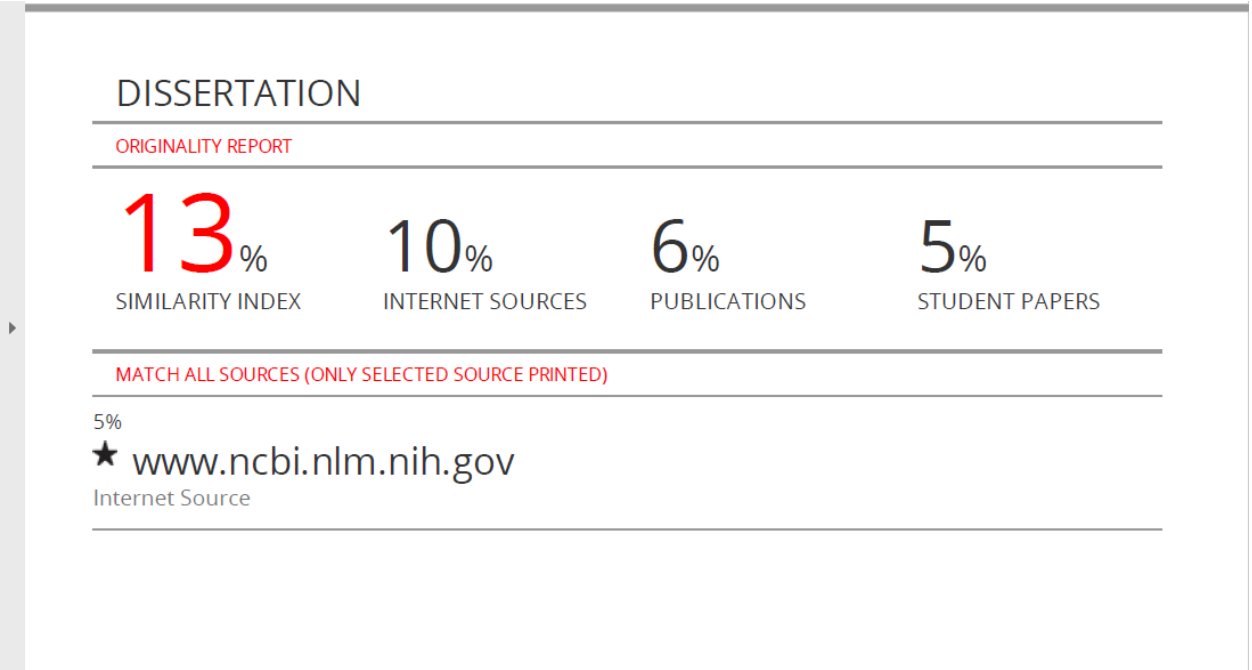
KISII COUNTY GOVERNMENT
COUNTY HEALTH DIRECTOR
P. O. Box 92 - 40200
KISII.

DR. STANLEY RATEMO
COUNTY RESEARCH COORDINATOR
FOR: COUNTY DIRECTOR OF HEALTH

Copy to:-

- All Heads of Departments
  KISII TEACHING AND REFERRAL HOSPITAL

Appendix 5: Similarity Index



DISSERTATION

ORIGINALITY REPORT

13%	10%	6%	5%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

MATCH ALL SOURCES (ONLY SELECTED SOURCE PRINTED)

5%

★ www.ncbi.nlm.nih.gov

Internet Source

Appendix 6: Geographical map of Kisii County indicating sub counties distribution