



**ASSESSMENT OF VACCINE STORAGE AND STOCK MANAGEMENT
PRACTICES IN VIHIGA COUNTY, KENYA**

By

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DECLARATION

Declaration by the Student

This proposal is my original work and has not been submitted to any other university

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Signature 

Date 25/04/2023 .

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DEDICATION

To my family, I dedicate this thesis.

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I am indebted to my supervisors Dr. Evans L. Sagwa and Dr. Domina Asingizwe for their assistance and ensuring that I have done and completed this thesis. Their effort and continued unrelenting input through encouraging remarks and suggestions guided me through the entire procedure.

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ABSTRACT

Background: Immunization of children is crucial in reducing infant and child mortality. A number of elements need to be properly implemented for an effective vaccine management. This includes cold chain management, vaccine management, logistics and waste management. Failing to effectively implement these elements, can reduce the vaccines potency.

Objectives: This study was conducted to assess the vaccine storage and stock management practices in health facilities within Vihiga County. More specifically, it determined the status of the cold chain equipment; evaluated the stock management practices and assessed the knowledge level of the vaccine cold chain handlers involved in vaccines supply chain management in Vihiga County.

Methods: A descriptive cross-sectional research design was used. 103 public health facilities were selected and one staff involved in handling vaccines from each facility participated in the study. The study utilized survey questionnaires and observational checklist to collect quantitative data

Results: The findings indicated that 61 (70.9%) of the health facilities had functional refrigerators, the source of power being Electricity. 76(88.4%) had a vaccination micro plan, all facilities (100.0%) use standard vaccine requisition forms for ordering and receiving vaccine and physical stock counts are done in all facilities. Further, 49 (57.0%) had proper storage of vaccines in the refrigerator. The immunizing healthcare workers knew how to condition icepacks 76 (88.4%); prevent vaccine freezing during transport 76 (88.4%) and knew the antigens that were eligible for the four weeks' open vial policy 66 (76.7%). However, many did not know all the heat, cold and light sensitive vaccines 49(57.0%).

Conclusion: Majority of public health facilities storage conditions were in line with the WHO guidelines, some nevertheless fall short of the recommended storage conditions required due to sharing of refrigerators among the dispensaries. There is need for the County Government of Vihiga to invest more in purchasing of the WHO recommended refrigerators.

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ABBREVIATIONS AND ACRONYMS

AMC: Average Monthly Consumption

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

EPI – Expanded Program on Immunization

ERC – Ethical Research Committee

eVIN – electronic vaccine intelligence network

FEFO – First Expiry First Out

KDHS – Kenya Demographic and Health Survey

LMIS – Logistics Management Information System

OPV – Oral Poliovirus Vaccine

RTM – Remote Temperature Monitoring

SPSS – Statistical Package for Social Sciences

SVS – Stock Visibility Solution

UK – United Kingdom

UNICEF – United Nations International Children's Emergency Fund

USA – United States of America

VVM – Vaccines Vial Monitor

WHO – World Health Organization

DEFINITION OF TERMS

Cold chain equipment: this refers to equipment for transporting and storing vaccines and their diluents within the required temperature ranges. They include ultra-low temperature freezers, refrigerators, carriers, cold boxes among others.

Cold chain Vaccine Storage- This refers to the vaccine storage facilities available like ultra-low temperature freezers, refrigerators, carriers, cold boxes among others and the mechanisms of storage that include whether the vaccines are stored within the standard temperature

Knowledge-awareness about vaccine cold chain management and storage procedures and standards

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

Technology-adoption of scientific knowledge into the vaccine cold chain

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

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

Vaccine cold chain management – Ensuring that the vaccines are kept within optimal temperature ranges and maintains the desired states from the manufacturer to the end user.

CHAPTER ONE: INTRODUCTION

1.1 Background to the study

Immunization of children is crucial in reducing infant and child mortality. Child vaccination is among the most significant achievements in promoting child health and preventing infectious diseases. Immunization programs greatly depend on effective and efficient supply chain systems to transport, distribute, and store these vaccines and health commodities, which ensures that the right products are available at the right place, in the right condition and at the right time in order to provide efficient health services to the communities (1). To be effective, however, a number of elements need to be implemented properly in a vaccination program. This includes logistics management, cold chain management, vaccine management, and waste management. Failing to effectively implement these elements, can reduce the level of protection that is expected from vaccines. This calls for the need to ensure the availability of vaccine and logistics management systems and proper cold chain, from the manufacturer to the end user.

Global immunization coverage has dropped from 86% in 2019 to 83% in 2020 (2). An estimated 23 million children under the age of one year did not receive basic vaccines, this being the highest number since 2009 (2). The immunization coverage in Vihiga County for the children under the age of 5 years was 70.2 % according to KDHS 2019 (3). The County has a goal of increasing immunization coverage from 70.2% in 2019 to 80% by the year 2022 (4), however, this goal hasn't been achieved. The lack of sufficient cold chain equipment's, low storage capacities and vaccine stock outs in some sub-counties, might hinder the county goal of increasing the immunization coverage as envisaged. The Ministry of Health in 2021 (5) noted that Vihiga is one of the counties that have the lowest vaccine coverage in Kenya at 71% compared to the county with the highest coverage which is Nairobi at 86%. In terms of coverage, Vihiga only out ranks Busia in Western Kenya at 70.8% (5). This means that an examination of vaccine cold chain management in Vihiga is important.

Clearly, poor stock management within the global, regional and even local scanning of countries is a significant challenge for vaccine cold chain management. However, little is known about vaccine stock management in Kenya and especially in Vihiga County, hence the need for the

present study. Also, studies done in Kenya have been done in urban areas like Nairobi but not in the semi-urban and rural areas like Vihiga County, and thus the present study is both important and necessary (6).

World Health Organization (WHO), created practice guidelines for different service levels, that include vaccine monitoring, immunization techniques, cold chain management and reporting systems (7). The guidelines are often quite difficult to practically implement in field situations due to various factors like workload pressures and infrastructure problems (8). This requires the primary health care providers to have adequate knowledge to effectively manage the cold chain (9). Coupled with the dynamic technological advancement, and adoption of the innovations thereof to improve on the vaccine cold chain management, knowledge and skills are highly needed. Studies have found that the knowledge and skills regarding vaccine management was lowest among health care workers in facilities within rural areas and in areas in the periphery of towns and cities. It would be instructive to examine if this is true for Vihiga Sub County which largely has health facilities in the town area and others in more rural areas.

Therefore, this study aims to assess the status of the cold chain equipment, in Vihiga County, the stock management practices in place as well as the knowledge level of the personnel involved in the vaccine cold chain management. This will help ascertain compliance with the global standards, as well as identify any gaps that need to be addressed to improve on the cold chain management and vaccine availability within the county.

1.2 Problem statement

Optimum practices of vaccine storage and stock management can be hindered by lack of cold chain equipment's, poor visibility regarding the current status of cold chain equipment and seldom regular inventory updates. Improper temperature monitoring and need for the latest equipment because the outdated refrigerators lack freeze protection and have poor temperature control capabilities, hinders the effective performance of the cold chain which endangers vaccines quality.

According to WHO report only 14% in low and lower-middle-income countries met the standard criteria for temperature control in the cold chain (10). The study done in Ghana on Effective Vaccine Management indicated that the average district score for stock management was only

32% (11). The study done in Kenya in Kacheliba Division observed problems in reference to vaccine storage practices, record keeping and temperature regulation (12).

In Vihiga County there appears to be cold chain management weakness observed due to lack of logistics for vaccine distribution from sub county Expanded Program of Immunization (EPI) stores to health facilities, improper use of refrigerators, equipment breakage, lack of knowledge on biomedical matters to help maintain the vaccine cold chain storage facilities and power interruption all this leading to vaccine wastage. According to the County Health Management Team (CHMT) supervision report done in April 2021, 47% of the health facilities lacked WHO recommended refrigerators making them to share the refrigerators of the nearby facilities. The report indicates also 42% of wastage rate due to Vaccine Vial Monitor (VVM) change to stage 3 and 4. Of note however is the lack of documented and empirical data to ascertain if this vaccine cold chain storage and management issues are verifiable and valid; hence the need for the present study.

The findings from this study will therefore help inform the stake holders on the various factors affecting the vaccine storage and stock management practices within Vihiga County, thereby providing a basis for the improvement of the same.

1.3 Justification of the study

In recent years, following the COVID-19 pandemic, the place of vaccination has taken Centre stage. Alongside vaccination issues is the matter of immunization. To ensure that immunization, that save lives and enable healthy growth in people, there is need to ascertain the efficacy of vaccines and most importantly, the storage capacity and effectiveness. Consequently, an examination of the vaccine storage and stock management practices in health facilities is critical. However, such vaccine storage practices are not usually carried out requiring an investigation into the status on storage equipment, stock management practices used and the knowledge of the health experts; hence the need for the present study.

1.4 Research questions

1. What is the status of cold chain equipment in Vihiga County, Kenya?
2. What are the stock management practices in Vihiga County, Kenya?
3. What is the knowledge level of the Vaccine cold chain handlers on effective vaccine management in Vihiga County, Kenya?

1.5 Study objectives

1.5.1 General Objective

To assess the vaccine storage and stock management practices in health facilities within Vihiga County, Kenya in line with the WHO immunization practice guidelines.

1.5.2 Specific Objective

1. To determine the status of the cold chain equipment in Vihiga County, Kenya.
2. To evaluate the vaccine stock management practices in Vihiga County, Kenya.
3. To assess the knowledge level of the Vaccine Cold Chain Handlers on effective vaccine management in Vihiga County, Kenya.

1.6 Significance and anticipated output

Vaccines are biological products which are sensitive to freezing and heat thus requires to be stored within recommended temperature ranges in a cold chain system. Effective vaccine supply chain makes sure that the vaccines reach recipients in their potent form. Full benefit of

immunization depends on the good practices of proper vaccine handling and storage. The study will help County government and partners to address the gaps identified and provide basis for improvement. It will also enlighten and help the health personnel to improve in vaccine storage and stock management thus improving the health status of the society. The study will also help health facilities with knowledge about their level of vaccine preparedness and practice in a bid to help them improve on the identified gaps. The study will also help immunization policy makers who will use the results from the study to create or modify policies that would advance vaccine storage effectiveness. The study will also help academicians in relevant fields with results that will help fill or advance the research pursuits.

1.7 Delimitations

The study was done in public health facilities in the 5 sub counties in Vihiga County. The study assessed the status of cold chain equipment, determined the stock management system practices and assessed the level of knowledge of health professionals in vaccine supply chain management. The study focused on health staff from the health facilities with immunization capacities.

1.8 Limitations

The study was limited to the extent that the results may not be generalized to other areas and counties outside Vihiga County as is common with surveys. Nonetheless, the study ensured reliability and validity of the results to improve generality.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter presents the reviewed literature related to the assessment of the vaccine storage and stock management practices in health facilities. More specifically, the chapter offers an overview of status of the cold chain equipment; the stock management practices, and the knowledge level of the cold chain handlers involved in vaccines supply chain management. It then offers the conceptual framework and the research gaps.

2.2. Overview of vaccine storage and stock management

Ineffective vaccine storage systems have been identified as one of the key reasons for vaccine stock-outs and loss of vaccine viability in many health facilities in the world (13). Consequently, part of effective vaccine storage and stock management requires that health facilities identify both the strengths and weaknesses of the whole system to eventually ascertain where gaps can be filled and where improvements can be made (14). There are significant procedures that have been laid down to help in vaccine storage and stock management. Some of the procedures are found in the WHO vaccine management procedures (15). These procedures when followed are bound to significantly improve the vaccine storage and stock management in health facilities (13, 14). Further, it has been estimated that vaccine storage and stock management mainly require adequate and appropriate cold chain equipment absent of which the vaccines lose their viability (16). Also, studies have shown that the knowledge and skills of the vaccine management staff is important to improve the cold chain management practices and so are the stock management practices (16, 17). Consequently, the subsequent sections looked at literature related to the study variables from a global, African, and Kenyan view.

2.3 Status of the cold chain equipment

The WHO (18) vaccine storage guidelines demand that vaccines be stored within temperature ranges of between 2°C and 8°C for almost the entire spectrum of vaccines. To store vaccines below or above these ranges negatively affects the immunological properties that the vaccines have and eventually reduces vaccine potency. The WHO standard also notes that exposing

vaccines to above 8°C for more than 10 hours constitutes an adverse vaccine situation and dispensing of vaccines at that stage may lead to adverse health outcomes on the clients.

In Kenya, vaccine cold chain storage and management are monitored by the National Vaccine and Immunization Programme (NVIP). The NVIP adopts the WHO standards on temperature management of vaccines. Further, Cold Chain temperatures in sub counties and nationally are monitored using the Fridge-tag 2 (FT2) which is a temperature logger that checks if the temperature levels are adhered to. The Ministry of Health report (5) notes that the logger faces significant challenges especially regarding lack of knowledge that enables correct reading of the results from the Fridge-tag 2. Further, through the NVIP, there has been renewed focus for public health facilities with vaccine storage capability to invest in Remote Temperature Monitoring (RTM) in order to help monitor temperature levels with limited data available about the extent to which the public facilities have adopted the system. Further, according to the WHO (18) vaccine storage and its status refers to the vaccine storage facilities available like ultra-low temperature freezers, refrigerators, carriers, cold boxes among others and the mechanisms of storage that include whether the vaccines are stored within the standard temperature

There have been significant studies done to examine the status of cold chain equipment from across the global, regional, and Kenyan settings. However, these studies come with certain gaps which the present study hopes to fill to progress knowledge in that field. For example, a study was conducted in Malaysia to examine the vaccine cold chain practices and how it associates with adherence to practices, knowledge and skills and status of the equipment's (15) . The study found that while the health facilities were exceptionally well stocked with vaccines, their potency reduced by 12% due to low effective status of the storage equipment's. The low status was mainly as a result of lack of consistent and regular upgrade of the equipment's to help deal with the new vaccines coming into the market.

Another example is a study conducted in New Delhi to examine the vaccine cold chain equipment status (16). This study revealed that cold chain equipment's form an integral and essential part of the whole immunization process in any health facility. Of 29 health facilities, the study found that from the 56 electrical-based cold chain equipment's, 8.9% of these were not functional. Further, 5.7% of the equipment's were not free from chlorofluorocarbon, 9.7% of the equipment's lacked stabilizers and 4.7% lacked temperature monitoring devices. To a

significant extent, 47.6% of the cold chain equipment's were not compliant with the WHO cold chain standards. Further, the health facilities did not have any maintenance standards and this often left many cold chain equipment's unattended to. Clearly, from the results, the status of cold chain equipment was not up to date with significant gaps.

Studies done in the UK (17), the USA (19) and Australia (20) unlike the studies done in some parts of Asia (16) and Africa (13, 14); show a high level of cold chain equipment maintenance, resourcing and usage. The studies, cumulatively, all of which are cross-sectional, show that health facilities have innovatively set up cold chain equipment's in each facility that include the entire cold chain infrastructure from refrigerators, temperature controlling devices that are significantly automated, stabilizers, chlorofluorocarbon controlling gadgets, vaccine display technology that allows vaccine cold chain handlers to monitor the whole process remotely and thus reduces unwarranted human contact with the vaccine plus other technologies that are aligned with the future of vaccine management. Does the same case apply to the Kenyan setup? This is why the present study seeks to examine the status of cold chain equipment in Vihiga County in Kenya.

A cross-sectional study done by Iwu et al (13) examined vaccine stock and storage management practices in health facilities in South Africa. The study used multiple data triangulation method by engaging in surveys, observation and documentary analysis to assess vaccine management practices and stock outs in 64 health facilities in Tambo region of South Africa. The study's main finding was that many of the vaccine standard stock and storage procedures were not followed mostly owing to the lack of knowledge in cold chain management. Many of the health workers surveyed were trainees who were placed in the vaccine cold chain management offices. The study further noted that the health facilities were not committed to vaccine cold chain management due to the consistent use of outdated vaccine cold chain equipment. Some of the machines engaged some vaccines to freezing which is against WHO procedures (13). Nonetheless, majority of the health facilities used stock cards coupled with the stock visibility solution (SVS) gadgets. However, majority of the health facilities did not regularly fill the stock cards which led to stock outs and storage mismanagement. The supply process was often delayed due to stock mismanagement and the OPV and BCG vaccines were the most affected. From the study, it is clear that the health facilities in South Africa faced significant cold chain storage and

stock management challenges due to lack of knowledge but mostly due to lack of cold chain equipment. While the study offered valuable insights, it however did not look at other cold chain equipment's that are necessary and this gap will be filled by the present study.

Another cross-sectional study was done to examine the vaccine cold chain management practices, knowledge, and skills of health care workers and stock management in 41 health facilities in Ethiopia (14). The study found that each of the facilities had at least one functional deep freezer and one functional iced-lined refrigerator. This implied that the vaccine cold chain equipment was available but only at the basic level. The study further noted that the knowledge of the health care workers was fair. Overall, the study noted that as far as the equipment is concerned, the facilities have adequate and functional vaccine cold chain equipment. However, this study critiques this conclusion because a health facility cannot be said to have sufficient vaccine cold chain equipment just because they have two functional equipment's. What about stock visibility solution (SVS) gadgets, cold chain monitoring equipment's and all the new technologies in vaccine cold chain management, power supply equipment among others? This significant gap is what the present study hopes to fill.

De Timóteo et al. (21) examines vaccine cold chain management practices in health facilities within Mozambique. The study uses surveys to collect data and further examines records on vaccine cold chain management. The study finds that vaccine management requires a robust infrastructure that not only includes refrigerators but constant and adequate power supply, fluid transportation systems and skilled and knowledgeable human resource. The study finds that in Mozambique the inadequacy in functional vaccine cold chain equipment is the reason for poor vaccine cold chain storage that reduces the potency of vaccines at a rate of 23% every month. The study does not however identify what these equipment's are and their level of functionality or dysfunctionality as the present study will.

In Kenya, the coverage rate for vaccination has remained at 75% for the last 5 years (22-23). 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 (23,24). 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 sufficient and appropriate cold chain equipment and lack of knowledge and skills of health professionals engaged in vaccine cold chain management (24-23). These shows that even in the Kenyan set-up, insufficient knowledge and skills plus lack of enough and well-maintained cold chain equipment have a negative effect on the vaccine cold chain management practices.

2.4 The vaccine stock management practices

The WHO (24) offers a vaccine stock management procedure and guideline rule book. In the guideline, WHO promotes use of a vaccine stock management system that allocates and tracks the whole process of the vaccine from resourcing to final dispensing and evaluating. The procedures also highlight the need for effective record keeping using batch cards, inventory control card, transaction cards, loan reports plus summary and feedback reports. Further, the WHO (18) recommends a formula that helps in assessing the status of vaccine stock to ensure stock-outs are limited. They thus propose the following formula.

$$\text{Months of supply} = \frac{\text{Quantity in hand}}{\text{Average monthly consumption}}$$

The quantity in hand is retrieved from the inventory control cards while the average monthly consumption (AMC) is retrieved from the consumption ledger (24). Of course, the consumption rate can vary depending on various circumstances like the frequency of immunization, pandemic outbreak among many others. That said, it is important for the various vaccine officers to ensure that the records strictly reflect what is being stocked to ensure that the stock management process is up to date.

Significant empirical studies have been done to examine how some health facilities have engaged in vaccine stock management. A study done in India to examine stock management of vaccines using a cross-sectional survey (25) found that stock management practices that denied health facilities a clear, unambiguous and seamless control of stock led to massive stock-outs in India. The study thus proposed the use of the electronic vaccine intelligence network (eVIN) to help in stock management. The study found that the adoption of technology has become the key feature that enhances better vaccine stock management and health facilities that have not adopted these technologies will continue to face vaccine stock management challenges. Consequently, the question that is posed is; what is the extent to which Vihiga County has leveraged on technology to enhance its vaccine stock management practice?

A cross-sectional study done in Malaysia observed that effective vaccine stock management ensures that the vaccines are kept and maintained within acceptable standards and the vaccines are continuously and adequately available at the service delivery stage (26). The study after regressing the results to ascertain the extent to which the adherence to stock management affected vaccine cold chain management noted that in Malaysia, vaccine wastage prevalence rate was at 12.2% which is a significant figure. The study noted that vaccine wastage rates were enhanced as a result of low level of knowledge by healthcare workers about vaccine management, insufficient equipment to store vaccines and most importantly, non-adherence to the laid down vaccine stock management protocols (26). The study further added that the high vaccine wastage rates were witnessed in the stocking and maintaining of the lyophilized vaccines like BCG that involves freeze drying which eventually preserves the vaccines when water is removed and the vaccines controlled. The liquid types vaccines like DPT and OPV have lower wastage rates due to their less intensive stock and storage requirements (26). It would be important to ascertain in the current study, which between the lyophilized vaccines and liquid vaccines have better stocking and storage management in Vihiga County in Kenya.

Kartoglu et al. (27) on their part first observe that the Vaccine Vial Monitor (VVM) has remained, consistently, as the best tool that health facilities have used in Europe to monitor and maintain effective stock and vaccine potency management. The study engages in an experimental design study by having health facilities use the VVM while another uses more traditional and paper-based systems. The study found that the VVM has the highest success rate

in vaccine stock and storage management at 96% more than other traditional ways of vaccine monitoring. While this study offers insights into VVM, it does not examine a similar case within the Kenyan context hence the need for the present study.

Lyndon et al. (28) does an elaborate and extensive study that examines vaccine stock-outs across the globe. The scoping review looked at the countries who are members of the WHO and who have ratified the Global Vaccine Action Plan. The study from that scoping and systematic review of documents and literature found that one in just three countries within the WHO membership goes through stock out of at least a single vaccine per month. This represents a 33.3% stock out level for one vaccine each month in the WHO member states. The study observes that worse stock-out levels at 38% is witnessed in Sub Saharan Africa. BCG and DPT is the vaccines most affected in the stock-outs across the globe but mostly in Africa. The analysis shows that 39% of the stock outs was as a result of government delays in funding. Delays in the whole vaccine stock procurement process took 28% of the attribution while 18% was attributed to ineffective and poor stock management located at the country levels. Clearly, poor stock management within the global, regional and even local scanning of countries is a significant challenge for vaccine cold chain management. However, little is known about vaccine stock management in Kenya and especially in Vihiga County that forms part of the Western part of the country; hence the need for the present study.

Similar results, that poor stock management within the global, regional and even local scanning of countries is a significant challenge for vaccine cold chain management are seen in a study done in Iraq (29). The additional information from this study is that low level of knowledge and skills regarding vaccine stock and storage management and misalignment of the stock and storage procedures to best practices have led to massive vaccine stock mismanagement (29).

A study done in Ghana to examine the stock management practices of vaccines found that many health facilities did not have effective practices that conformed to WHO standards (18). Further, the ineffective vaccine stock practices led to long lead times in procuring vaccines, protracted payment and supply schedules and eventually loss of vaccine potency owing to poor vaccine inventory control. It would be instructive to determine if the same ineffective stock management practices done elsewhere in Africa also applies to Kenya and specifically Vihiga County.

Significant cross-sectional studies done in Africa (30-31) also attest to the fact that poor stock management is a significant challenge for vaccine cold chain management and that low level of knowledge and skills regarding vaccine stock and storage management and misalignment of the stock and storage procedures to best practices have led to massive vaccine stock mismanagement. In fact, these studies suggest that the stock management practices for vaccines is made worse by negative attitudes of staff who feel that their lack of knowledge is a hindrance and low level of government funding if not protracted delays in funding. The studies have generally suggested that a thorough and stricter adherence to best practices and standards like those by the WHO should be implemented and a significant integration and adoption of vaccine stock and storage management-based technologies (30-32).

The Kenyan case regarding vaccine stock management is not any different from that of Africa. A study done at the Kenyan Ministry of health to look at inventory control of vaccines found significant stock-outs created by poor stock management, corruption in the procurement process and low government funding (33). Another study done to examine vaccine stock management and challenges in Nairobi County found that stock-out prevalence rates were at 35% especially for BCG and DPT due to lack of knowledge regarding vaccine stock management and inadequate physical, financial, human and technological resources related to vaccine storage management (30). Nonetheless, these studies have been done in urban areas like Nairobi but not in the semi-urban and rural areas like Vihiga County, and thus the present study is both important and necessary.

2.5 Knowledge level of healthcare workers involved in vaccines supply 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 (34-35). 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 (34-35). These studies do not however look at knowledge of health professionals working in rural and semi-urban areas like Vihiga County of Kenya which is an aspect that the present study considered important.

Azira et al. (15) who examine the vaccine cold chain practices and how it associates with adherence to practices, knowledge and skills and status of the equipment's in Malaysia using descriptive analysis and chi-square test of association found certain key results as far as knowledge is concerned. The study found that there was good knowledge of vaccine cold chain management and stock processes among the health care workers. In fact, all the health care workers had received advanced certification from the in-service training that was mandatory after every two years. The good knowledge was positively correlated to improved vaccine storage and stock management and is partly the reason why the vaccine process was significantly effective. Again, the difference in the socio-economic status between Malaysia and Kenya is wide and it is thus important to examine if the same level of knowledge by health care workers applies to Kenya; hence the need for the present study.

The cross-sectional study done by de Timóteo et al. (21) to examine knowledge and skills and practices in vaccine management in Mozambique found that the knowledge and skills regarding vaccine management was lowest among health care workers in facilities in rural areas and in areas in the periphery of towns and cities. It was however, highest among health care workers in health facilities in urban centers. The study thus concluded that health facilities in rural areas had lower financial resources and innovativeness in terms of equipment and thus attracted the less educated health care workers while the urban based health facilities attracted better educated ones due to their superior financial resourcing. It would be instructive to examine if this is true for Vihiga Sub County which largely has health facilities in the town area and others in more rural areas.

Basically, knowledge of the vaccine cold chain process that includes storage and stocking has been found to significantly correlate with improved vaccine storage and stock management (17-19). Further, whether you look at studies done in the global realm (34-35) or in Africa (15-21), almost by consensus, the find that health facilities that have healthcare workers with high or medium level knowledge regarding vaccine supply chains and management also have better vaccine storage and stocking management practices. However, health facilities that have healthcare workers with low level knowledge regarding vaccine supply chains and management have negative to worse vaccine storage and stocking management practices and outcomes. It would be useful to see if this is also the case in Vihiga County in Kenya.

2.6 Research Gaps

From the studies reviewed, it is clear that the health facilities in Africa face significant cold chain storage and stock management challenges due to lack of knowledge but mostly due to lack of cold chain equipment. While the studies offer valuable insights, they however do not look at other cold chain equipment's that are necessary for vaccine storage and this gap will be filled by the present study. Further, studies show that having a deep freezer and iced-lined functional refrigerator is a testament to adequate vaccine cold chain equipment. This study critiques this conclusion because a health facility cannot be said to have sufficient vaccine cold chain equipment just because they have two functional equipment's. What about stock visibility solution (SVS) gadgets, cold chain monitoring equipment's and all the new technologies in vaccine cold chain management? This significant gap is what the present study hopes to fill.

On vaccine stock management, reviewed studies have shown that the ineffective vaccine stock practices led to long lead times in procuring vaccines, protracted payment and supply schedules and eventually loss of vaccine potency owing to poor vaccine inventory control. It would be instructive to determine if the same ineffective stock management practices done elsewhere in Africa also applies to Kenya and specifically Vihiga County. Also, studies have found that the adoption of technology has become the key feature that enhances better vaccine stock management and health facilities that have not adopted these technologies will continue to face vaccine stock management challenges. Poor stock management within the global, regional and even local scanning of countries is a significant challenge for vaccine cold chain management. However, little is known about vaccine stock management in Kenya and especially in Vihiga County that forms part of the Western part of the country; hence the need for the present study. Also, studies done in Kenya have been done in urban areas like Nairobi but not in the semi-urban and rural areas like Vihiga County, and thus the present study is both important and necessary.

On knowledge of the health care workers regarding vaccine management, some studies have found that the knowledge and skills regarding vaccine management was lowest among health care workers in facilities within rural areas and in areas in the periphery of towns and cities. It was however, highest among health care workers in health facilities within urban centers. It would be instructive to examine if this is true for Vihiga Sub County which largely has health facilities in the town area and others in more rural areas.

2.7 Conceptual Framework

The following figure offers a diagrammatic representation of the link between the study variables.

Independent Variables

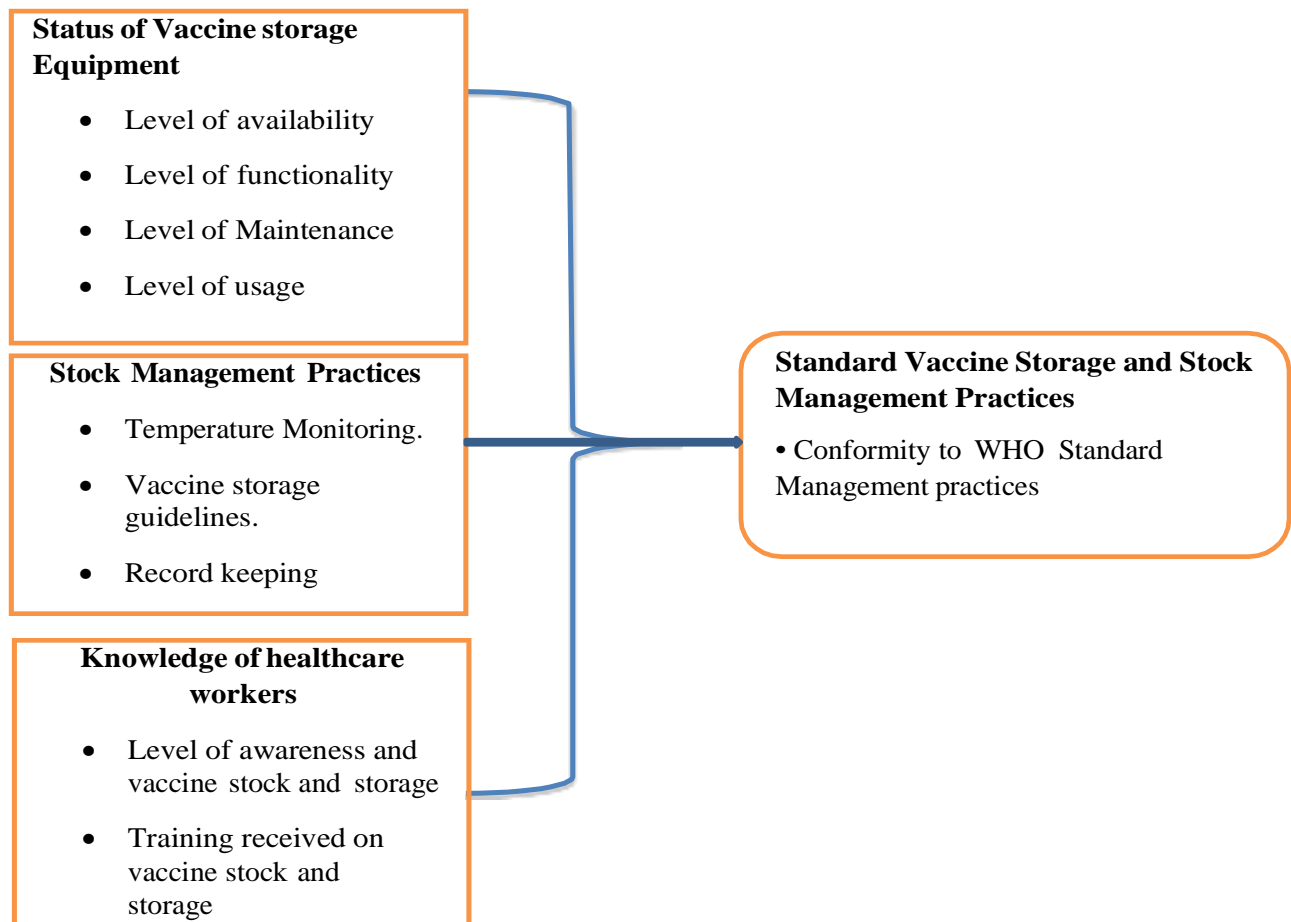


Fig 2.1 Conceptual framework Source: Author (2022)

2.7.1 How the variables relate to the conceptual framework

The study's variables are standard vaccine stock and storage management practices in public health facilities which is measured by examining the vaccine stock and storage procedures and guidelines, the use of appropriate technology and whether the practice conforms to the set standards (WHO). Specifically:

2.7.1.1 Status of vaccine cold chain equipment

This speaks to the level of availability, functionality, maintenance and usage of vaccine cold chain equipment.

2.7.1.2 Vaccine stock management practices

This deals with the temperature monitoring, proper record keeping and vaccine storage guidelines.

2.7.1.3 Vaccine stock management practices

This is the level to which the health professionals have the requisite knowledge and skills regarding vaccine stock and storage management practices in the public health facilities they operate in.

CHAPTER THREE: METHODOLOGY

This chapter describes the research methodology to be used in the present study. It consequently puts the chapter into the following segments: the research design, the location of the study, the target population, the sampling technique and sample size, the data collection instruments, reliability and validity tests related to the instruments, then data collection procedure, the data analysis procedures and then the notable ethical issues.

3.1 Research Design

A cross-sectional research design was used to assess the vaccine stock and storage management practices in Vihiga County, Kenya. Cross-sectional research design is an appropriate approach because it offers unambiguous, objective and clear answers on the ‘why’ and ‘what’ questions that constitute the main focus of this study (36). Further, the design presents and explains the happenings in a study situation and offers reliable, credible, repeatable and consistent descriptive findings in an objective fashion (36). Furthermore, cross-sectional research design is especially relevant in this study because it allows for the generation, analysis and subsequent interpretation of quantitative data which describes vaccine stock and storage practices in public hospitals in Vihiga County both descriptively and inferentially (37).

3.2 Location of the Study

The study was done in Vihiga County, which is one of the forty-seven counties in Kenya. The county has a population of 591,000 with a fertility rate of 3.6%. Within the county are 103 health facilities. Among many health services, the health facilities offer immunization services. At least one nurse in each health facility provides the immunization services. The Ministry of Health in 2021 (5) noted that Vihiga is one of the counties that have the lowest vaccine coverage in Kenya at 71% compared to the county with the highest coverage which is Nairobi at 86%. In terms of coverage, Vihiga only out ranks Busia in Western Kenya. This means that an examination of vaccine cold chain management in Vihiga is important.

3.3 Target Population

The study targeted the 103 public health facilities in Vihiga County all of which have immunization capability and thus need to stock and store vaccines. There is at least one health

care provider (immunizing nurse) in each facility. See Table 1 on the general categorization of the public hospitals.

Table 1: Population in Vihiga County public hospitals

Categorization (Levels of facilities)	Number of health facilities	Number of immunizing health providers
Dispensaries	45	45
Health centers	54	54
Sub County Hospitals	3	3
County Referral hospital	1	1
Total	103	103

Source: Vihiga County Health Staff Records

3.3.1 Inclusion Criteria

1. All Public health facilities in Vihiga County offering immunization services
2. Health care workers involved in handling and administration of vaccines who will voluntarily consent to participate in the study.

3.3.2 Exclusion Criteria

1. Health care workers involved in handling and administration of vaccines who will not voluntarily consent to participate in the study.

3.4 Sample size and sampling

3.4.1 Sampling technique

The census sampling design was adopted where by all the 103 public health facilities were included in the study. According to Collis & Hussey, regard a census is a systematic process of obtaining information from every member of the population to establish the problem under investigation. This study enumerated all 103 public health facilities in Vihiga County. All health care providers offering immunization services were considered.

3.4.2 Sample Size

All the 103 immunizing health facilities were included in the study. One immunizing healthcare provider from each of the 103 health facilities working in the immunization section was selected to assess knowledge because in Vihiga County, currently there's at least one healthcare worker assigned to handle Immunization services.

3.5 Data Collection

3.5.1 Data Collection Instruments

3.5.1.1 Questionnaire

The study utilized researcher administered survey questionnaires to gain quantitative data about status of cold chain equipment, vaccine stock management practices, and knowledge of vaccine cold chain handlers on effective vaccine management working in the public health facilities in Vihiga County, Kenya. Questionnaires are tools used to access quantitative data from a large sample and align with the requirements of a cross-sectional survey design (36). In this study, the questionnaire was designed using the WHO-UNICEF Effective Vaccine Management Tool (38) that the NVIP has used to determine vaccine cold chain management. Besides, different studies that used this tool were explored (39). The questionnaire will contain three sections; socio-demographic characteristics of immunization service providers, status of cold chain equipment such as availability, functionality and maintenance, and assessment of knowledge on the vaccine cold chain. The questionnaire is customized form of validated form of WHO-UNICEF Effective Vaccine Management tool with the following sections; vaccine storage, stock management, knowledge of vaccine handlers.

3.5.1.2 Observation checklist.

The observational checklist was used to collect data on the status of the cold chain equipment and the vaccine management practices in the public health facilities. The checklist was developed based on WHO-UNICEF Effective Vaccine Management Tool (38) and previous published literature (39)

3.5.2 Pre-Testing of data collection instruments

The data collection instruments were not pretested because they are based on validated WHO-UNICEF Effective Vaccine Management Tool.

3.5.3 Data collection method

The questionnaires were administered to the respondents through face-to-face interviews. The investigator also fills the observational checklist.

3.6 Data Analysis

Quantitative data from the questionnaires and the checklist was analyzed using key statistical tools like the mean, standard deviation, counts and percentages. The data outcomes is presented using the Statistical Package for Social Sciences (SPSS) version 25 that helps to input and resent data outcomes. To assess the extent to which status of equipment and knowledge of Vaccine cold chain handlers influence vaccine stock and storage practices at the public health facilities in Vihiga County, the mean scores of the independent variables and the dependent variable were computed in the regression analysis. Through calculation of odds ratios with 95% confidence intervals and factors with p-value <0.05 will be considered.

3.7 Ethical Considerations

This study commenced after being ethically approved by Maseno University Ethical Review Committee (MUERC) and the National Commission for Science, Technology & Innovation (NACOSTI) and was conducted according to Helsinki's declaration. The permission to conduct this study was sought from the Vihiga County Director of Health (CDH), while the heads of each participating health facilities were formally informed about the study. Written informed consent was obtained from all the research participants. The consent states that participating in the study

is voluntary, it would not yield any financial benefits and those who opt out during the study can do so without any condition. To ensure participants' confidentiality, their names did not appear on data collection tools, instead, every participant was assigned a unique code to ensure anonymity. To ensure safety of researchers, the study was conducted alongside other routine facility activities while observing infection prevention and control protocols.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter presents the results about vaccine storage and stock management practices in public health facilities within Vihiga County, Kenya in line with the WHO immunization practice guidelines. The chapter analyzes the data using descriptive and inferential statistic.

4.2 Response Rate

The study targeted 103 public health facilities from Vihiga Count. Out of the 103 facilities only 86 respondents from 86 functional facilities answered all the questions asked bringing the response rate to 83.5% which is an acceptable rate that enhances the reliability of the responses.

4.3 Socio-Demographic Characteristics of the Respondents

Results that highlight the socio-demographic characteristics of the respondents are shown in Table 1. The results show that majority of the immunizing healthcare staff working in public health facilities in Vihiga County were female (84.9%). Further, the minimum age of the immunizing healthcare staff was 24 years, the maximum was 57 years and the mean age was 35 years with standard deviation of 10.0. Further, majority had worked for the vaccine service for between 2 and 10 years (63.9%). Also, majority of the immunizing healthcare workers had diploma certificates (93.0%) Majority of the results were drawn from dispensaries (73.3%) then from health centers (20.9%) and sub county hospitals (4.7%) with only one county referral hospital. Further, majority had received training in vaccine cold chain management (65.2%) with the same people receiving cold chain management and vaccine management or immunization in practice.

Table 2: Socio-demographic characteristics

Variable	Frequency	Percentage
Gender		
Male	13	15.1
Female	73	84.9
Age		
Minimum age (24 years)		
Maximum age (57 years)		

Mean age (35 years) Standard Deviation 10.0		
Experience in the Vaccine Service		
<2 years	16	19.8
2-5 years	29	33.7
6-10 years	26	30.2
>10 years	15	16.3
Level of Education		
Certificate	2	2.3
Diploma	80	93.0
Bachelors Degree	4	4.7
Training in vaccine cold chain management		
Yes	56	65.2
No	30	34.8
Type of Training		
Cold chain management	56	65.2
Vaccine management	0	0.00
Immunization in practice	0	0.00
Not applicable	30	34.8
Time of last training		
2021 (year)	19	22.1
2022 (year)	21	24.5
2023 (year)	16	18.6
Level of health Institution		
County referral hospital	1	1.2
Sub county Hospital	4	4.7
Health Centre	18	20.9
Dispensary	63	73.3

4.4 Status of Cold Chain Equipment in Vihiga County

The study looked at the status of cold chain equipment in Vihiga County. Table 2 and 3 give the descriptive results. Table 3 shows that at least one functional refrigerator in health facilities was available (70.9%). However, slightly more than half of refrigerators were not placed in a wooden platform (52.3%) but were 10cm away from the wall (70.9%). Further, the fridge power supply was mainly sourced via electricity power (70.9%) and there was a functional temperature

monitoring device in refrigerator (70.9%) of the fridge tag type (70.9%).

Table 3: Status of Cold Chain Equipment (n=86)

Variable	Frequency	Percentage
Availability of at least one functional refrigerator in health facilities		
Yes	61	70.9
No	25	29.1
Refrigerator placed over wooden platform		
Yes	41	47.7
No	45	52.3
Refrigerator 10 cm away from wall		
Yes	61	70.9
No	25	29.1
Type of power supply for fridge		
Electricity as main source	61	70.9
Solar as Main Source	0	0.00
Kerosene as main Source	0	0.00
N/A	25	29.1
Availability of functional Temperature monitoring device in refrigerator		
Yes	61	70.9
No	25	29.1
Type of Thermometer		
Thermometer (Not Applicable)	25	29.1
Fridge Tag	61	70.9

The results from Table 3 shows that the temperature for the cold chain equipment was recorded properly twice daily and complete (70.9%) and the temperatures recorded were within the recommended range (2-8°C) for more than half (68.6%) of the visited facilities. Also, more than half (61.6%) of the facilities, the refrigerator was used exclusively for vaccine stock (free from other products than vaccine, diluents and ice packs. 57.0%) of the facilities had discarded vaccines due to incorrect stock temperatures in the last six months preceding data collection and the discarded vaccines were duly recorded. On maintenance, only 6% of the facilities indicated that there a responsible person for cold chain equipment preventive maintenance and a plan for

preventive maintenance for vaccine cold chain equipment was only available in 6% of the facilities.

Table 4: Status of Cold Chain Equipment (n=86)

Variable	Frequency	Percentage
Temperature recorded properly (twice daily and complete)?		
Yes	61	70.9
No	25	29.1
Refrigerators with temperature within their commended range (2-8°C) at the moment data collection?		
Yes	58	68.6
No	2	2.3
Refrigerator used exclusively for vaccine stock (free from other products than vaccine, diluents and ice packs)?		
Yes	53	61.6
No	8	9.3
Discarded vaccines due to Incorrect stock temperatures in the last six months?		
Yes	49	57.0
No	11	12.8
Record of all vaccine discarded due to incorrect stock temperatures?		
Yes	49	57.0
No	11	12.8
Available person responsible for cold chain equipment preventive maintenance?		
Yes	6	7.0
No	80	93.0
Plan preventive maintenance to cold chain equipment?		
Yes	6	7.0
No	80	93.0

The availability of vaccine cold chain equipment was compared between different levels of institutions. The results show that the County referral hospital and the sub county hospitals have full status of vaccine cold chain equipment. However, dispensaries have up to 58.8% availability of vaccine cold chain equipment. Table 4 provides the details.

Table 5: Availability of Vaccine cold chain equipment per Level of health institution

		Level of health institution				Total
		Dispensary	Health centre	Sub county Hospital	Vihiga County Referral Hospital	
Availability of Vaccine cold chain equipment						
NO	Count	26	1	0	0	27
	% of Total	41.2	5.6	0.0	0.0	31
yes	Count	37	17	4	1	59
	% of Total	58.8	94.4	100	100	68.6
Total						
	Count	63	18	4	1	86
	% of Total	100	100	100	100	100.0

As far as the maintenance of the vaccine cold chain equipment is concerned, dispensaries (72.1%) and health centres (20.9%) are the two with no vaccine maintenance personnel and measures while the county referral hospital and the sub county hospitals have full maintenance measures and personnel.

Table 6: Available person responsible for cold chain equipment preventive maintenance? * Level of health institution Crosstabulation

			Level of health institution				Total
			Dispensary	Health centre	Sub county Hospital	Vihiga County Referral Hospital	
Available person responsible for cold chain equipment preventive maintenance?	No	Count	62	18	0	0	80
		% of Total	72.1	20.9	0.0	0.0	93.0
	Yes	Count	1	0	4	1	6
		% of Total	1.5	0.0	100	100	7.0
Total		Count	63	18	4	1	86
		% of Total	73.6	20.9	100	100	100.0

The results above also align with the observational checklist that was done to determine if status of vaccine cold chain equipment was aligned to the WHO recommended guidelines. Table 6 shows that the WHO recommended functional refrigerator was available in 70.9% of the facilities visited and its fridge tag in 70.9% of the facilities. What was not available was a functional backup generator or solar. Thus, the observational schedule agrees with the results from the immunizing healthcare workers.

Table 7: Observation Checklist results on status of equipment

Variable	Frequency	Percentage
Availability of WHO recommended functional refrigerator in the health facility		
Yes	61	70.9
No	25	29.1
Availability of Functional fridge tag		
Yes	61	70.9
No	25	29.1
Availability of functional generator/solar for electricity backup.		
Yes	4	4.7
No	82	95.3

4.5 Stock Management Practices in Vihiga County

Under the stock management practices, the study presents results based on these practices and a cross tabulation of some of the practices with the level of hospital (Table 7 and 8). The public health facilities have a vaccination micro plan (88.4%) and all facilities (100.0%) use standard vaccine requisition forms for ordering and receiving vaccine. Also, the facilities have minimum and maximum stock levels recorded (90.7%) and physical stock checks are completed in all facilities each time a monthly or before ordering the next request (100.0%). Further, there is not quite a serious and proper stock of vaccines in the refrigerator (57.0%). There is EPI SOP guideline in place (94.2%). Further, there is no vaccine which reaches the VVM discarding stage in fridge during the visit (97.7%). Moreover, most facilities record vaccine and diluents quantities, batch no and expiry date and VVM status and also calculate vaccine wastage rate (70.9%).

Table 8: Stock Management Practices

Variable	Frequency	Percentage
A Vaccination micro plan		
Yes	76	88.4
No	10	11.6
Standard vaccine requisition forms used for ordering and receiving vaccine		
Yes	86	100.0
No	0	0.0
Health facility have recorded minimum - maximum stock levels		
Yes	78	90.7
No	8	9.3
Physical stock checks are completed each time a monthly or before ordering the next request		
Yes	61	70.9
No	25	29.1
Proper storage of vaccines in the refrigerator		
Yes	49	57.0
No	37	43.0
EPI SOP guideline in place		
Yes	81	94.2
No	5	5.8
Any vaccine which reaches the VVM discarding stage in fridge during the visit		
Yes	2	2.3
No	84	97.7
Vaccine and diluents quantities, batch no and expiry date recorded		
Yes	61	70.9
No	25	29.1
VVM status recorded?		
Yes	61	70.9
No	25	29.1
Calculation of vaccine wastage rate		

Yes	61	70.9
No	25	29.1

Considering that only lack of proper stock of vaccines in refrigerators is the challenge in stock management in the public facilities. It was important to ascertain who among the levels of hospitals have this challenge. Table 7 shows that it is especially the dispensaries that have this challenge (72.1%).

Table 9: Physical stock checks are completed each time a monthly or before ordering the next request per Level of health institution

			Level of health institution				
			Dispensary	Health centre	Sub county Hospital	Vihiga County Referral Hospital	Total
Physical stock checks are completed each time a monthly or before ordering the next request?	No	Count	24	1	0	0	25
		% of Total	38.1	5.6	0.0	0.0	29.1
	Yes	Count	61.9	17	4	1	61
		% of Total	1.2	94.4	100	100	70.9
Total		Count	63	18	4	1	86
		% of Total	100.0	100.0	100.0	100.0	100.0

The observational schedule also endorses the results from the immunizing healthcare workers regarding the status of stock management practices.

4.6 Knowledge level of the Vaccine cold chain handlers on effective vaccine management

The study sought to examine the level of knowledge among immunizing healthcare workers and handlers on effective vaccine management in public health facilities in Vihiga County. Table 9 shows that the immunizing healthcare workers and handlers knew how to condition icepacks (88.4%); prevent vaccine freezing during transport (88.4%) and knew the antigens that were

eligible for the four weeks open vial policy (76.7%). Those antigens were OPV, IPV, TT, PENTAVALENT (70.9%). Further, they disagreed that opened multi-dose vial policy (MDVP) are kept for the next immunization sessions with visible labels (87.2%). Further, majority knew that it took 6 hours after which the reconstituted vaccines were discarded (97.7%). However, they did not know how many hours a fridge should be turned on after vaccine arrival (61.6%).

Table 10: Level of knowledge among healthcare workers on vaccine cold management practices

Variable	Frequency	Percentage
Knowing how to condition icepacks		
Yes	76	88.4
No	10	11.6
Knowing how to prevent vaccine freezing during transport		
Yes	76	88.4
No	10	11.6
Knowing antigens eligible for the four weeks open vial policy		
Yes	66	76.7
No	20	23.3
which ones?		
OPV, IPV, TT, PENTAVALENT	61	70.9
PCV10,TT,OPV	2	2.3
TT,OPV,	3	3.5
Opened multi-dose vial policy (MDVP) kept for the next immunization sessions with visible labels		
Yes	11	12.8
No	75	87.2
Knowing after how many hours the reconstituted vaccines are discarded		
Yes	84	97.7
No	2	2.3
How many hours?		
6 hrs	84	97.7
Not Applicable	2	2.3
Knowing how many hours fridge should be turned on after its arrival		
Yes	33	38.4
No	53	61.6
If Yes, after how many hrs?		

24hrs	33	38.4
NA	53	61.6

Further, from the analysis on knowledge of among immunizing healthcare workers and handlers on effective vaccine management, all the immunizing healthcare workers and handlers knew that 2-8°C was the WHO recommended temperature range for vaccines stock in the refrigerator. However, many did not know all the heat, cold and light sensitive vaccines (57.0%). Also, many of them knew how to engage in correct demonstration of temperature reading (70.9%), read and interpret VVM (100.0%), whether the HF are made following Early Expiry First Out (EEFO) in practice (70.9%), the correct interpretation of shake test (50.0%) and the correct placing thermometer inside deep freezer (70.9%)

Table 11: Level of knowledge among healthcare workers on vaccine cold management practices (Cont'd)

Variable	Frequency	Percentage
Knowing at what temperature range should vaccines stored in refrigerator		
Yes	86	100.0
No	0	00.0
If yes, at what temperature range?		
2-8°C	86	100.0
Naming all heat sensitive vaccines		
Don't know	50	58.1
OPV, MEASLES, BCG	36	41.9
Naming all cold sensitive vaccines		
Don't know	49	57.0
TT, IPV, PENTAVALENT, PNEUMOCOCCAL VACCINE	37	43.0
Naming all light sensitive vaccines		
Don't know	49	57.0
MEASLES, BCG	37	43.0
Correct demonstration of temperature reading		
Yes	61	70.9
No	25	29.1
Knowing how to Read and interpret VVM		
Yes	86	100.0

No	0	00.0
HF having made following Early Expiry First Out (EEFO) in practice		
Yes	61	70.9
No	25	29.1
Knowing the correct interpretation of shake test		
Yes	43	50.0
No	43	50.0
Correct placing thermometer inside deep freezer		
Yes	61	70.9
No	25	29.1

4.7 Factors associated with vaccine cold chain management practices

To assess the extent to which status of vaccine cold chain equipment, knowledge of immunizing health care workers and vaccine handlers and stock management practices influence vaccine cold chain management practices at the public health facilities in Vihiga County, regression analysis was done by computing the significant values from the descriptive analysis. The results are shown in Table 11. Based on the results the adjusted R square of .528 shows that Vaccine cold chain management were predicted by Status of vaccine cold chain equipment, knowledge of healthcare workers and stock management practices at 52.8%. Further, the p-value of .001 is <0.05 showing that status of vaccine cold chain equipment, knowledge of healthcare workers and stock management practices have a significant relationship with vaccine cold chain management.

Table 12: Predictors of vaccine cold chain management practices

Model	Standardized Coefficients Beta	T	Sig.
Constant	.228	.093	.908
Status of vaccine equipment	.536	2.501	.001
knowledge of healthcare workers	.501	2.522	.001
Stock management practices	.372	3.60	.000
Adjusted R Square	.528		

CHAPTER FIVE: DISCUSSION, SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the discussion of findings that compares and contrasts the findings with the reviewed literature. It then presents the summary, conclusions and recommendations that accrue out of the findings. It finally offers recommendations for further research.

5.2 Discussion of findings

This study aimed to assess the vaccine storage and stock management practices in Vihiga county, Kenya. The study revealed that 70.9% of health facilities have at least one functional refrigerator, the findings of this study were observed to be slightly lower compared to a similar survey conducted in Nigeria 92.7% (40). Regarding the contingency plan, 4.7% had power back up which is lower as compared with the study done in Ethiopia which had 31% (41) and Nigeria 30.6% (40). The absence of an alternative source of power for refrigerators might be due to a lack of policy to ensure effective vaccine management at health facilities. Adherence to a routine planned preventive maintenance of refrigerators in Vihiga county Kenya was 7% comparably as low as in Ethiopia (14). This is due to shortage of biomedical staff in the Vihiga county. According to the recommended vaccine storage temperature range (+ 2 °C to + 8 °C), 68.8% of health facilities had a functional Temperature monitoring device in refrigerator which is higher as compared with the study done in Cameroon which had 32.7% functioning thermometers (41). In this study, about 61 (70.9%) of respondents recorded temperature regularly, which is higher than the study conducted in Ethiopian health facilities (14) and Nigeria (40). However, the findings of this study were observed to be slightly lower compared to a similar survey conducted in Cameroon (41).

The overall stock management practice is effective in public health facilities in Vihiga County except for the lack of proper storage of vaccines in the refrigerator probably due to lack of refrigerators in Dispensaries. This study identified only 49 health facilities (57%) which had proper storage of vaccines in the refrigerator the findings are slightly low to the study done in

East Gojam zone of Amhara region 58.3% (41). The WHO (24) offers a vaccine stock management procedure and guideline rule book. In the guideline, WHO promotes use of a vaccine stock management system that allocates and tracks the whole process of the vaccine from resourcing to final dispensing and evaluation. The result here shows that this is generally done within the public health facilities. Further, the results agree with literature like the cross-sectional study done in Malaysia that observed that effective vaccine stock management ensures that the vaccines are kept and maintained within acceptable standards and the vaccines are continuously and adequately available at the service delivery stage (26). The robust use of VVM in Vihiga County also agrees with literature like the one done by Kartoglu et al. (27) who observed that the Vaccine Vial Monitor (VVM) has remained, consistently, as the best tool that health facilities have used in Europe to monitor and maintain effective stock and vaccine potency management.

The vaccine cold chain handlers were knowledgeable regarding many other elements of vaccine cold chain management. this knowledge coheres with significant literature. 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 (34-35). In this study, about 86 (100%) of respondents knows how to read, interpret and record temperature, which is higher than the study conducted in Ethiopian health facilities (14) and Nigeria (40).

It was found that health workers have limited knowledge on heat sensitive, light sensitive and cold sensitive vaccines 57% very low compared to a study done in East Gojam Ethiopia 96.7% (41). Vihiga is a rural area and the fact that knowledge on vaccine cold chain management was high disagrees with the assertions made by de Timóteo et al. (21) that examined knowledge and skills and practices in vaccine management in Mozambique and found that the knowledge and skills regarding vaccine management was lowest among health care workers in facilities in rural areas and in areas in the periphery of towns and cities.

The current findings shows that vaccine cold chain management were predicted by status of vaccine cold chain equipment, knowledge of healthcare workers and stock management practices at 52.8%. This is slightly higher compared to the study conducted in Ethiopian health facilities, which was at 48% (14). This shows that status of vaccine cold chain equipment, knowledge of

healthcare workers and stock management practices have a significant relationship with vaccine cold chain management.

5.3 Conclusions

The study aimed to assess vaccine storage and stock management practices in public health facilities in Vihiga county. The study indicated that most health facilities have a well-functional refrigeration except for the dispensaries which suffers lack of refrigerators. Although the majority of public health facilities storage conditions were in line with the WHO guidelines, some nevertheless fall short of the recommended storage conditions required for the success of cold chain management due to sharing of refrigerators among the dispensaries. There were no preventive maintenance personnel and preventive maintenance plan in most of the facilities, which coupled with unreliable power supply and lack of power back up, were the major challenge in maintaining the recommended temperature range for vaccine cold chain equipment in public health facilities in Vihiga County. The stock management practices of vaccine cold chain management were in line with the WHO guidelines. Apart from lack of a proper storage of vaccines in the refrigerator, the overall stock management practice is effective in public health facilities in Vihiga County. Healthcare workers' knowledge of the vaccine and cold chain management was quite good for temperature monitoring, interpretation of VVM and documentation in line with the WHO guidelines except for lack of knowledge on Heat sensitive, cold sensitive and light sensitive vaccines. In conclusion the results shows that the vaccine cold chain management is significantly affected by vaccine cold chain equipment, knowledge of healthcare workers and stock management practices.

5.4 Recommendations

5.4.1 Recommendations for Policy and Practice

The management of the public health facilities in Vihiga County, especially those of dispensaries and health centers, should invest in refrigerators and vaccine cold chain equipment maintenance personnel and a maintenance plan. They can do this via resource mobilization or through public private partnerships.

The management of the public health facilities in Vihiga County should adopt clear guidelines that are aligned to the WHO guidelines on proper vaccine storage and stock management practices.

The management of the public health facilities in Vihiga County should review its training manual to make knowledge regarding vaccine cold chain management effective. Such training should thus include knowledge about how many hours a fridge should be turned on after vaccine arrival and knowledge of all the heat, cold and light sensitive vaccines.

5.4.2 Recommendations for Further Research

Further research should be done to engage with an in-depth qualitative study to determine the why aspects of vaccine cold management as the present study was largely quantitative and thus mainly determined the “what.”

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APPENDICIES

Appendix 1: Questionnaire

Q/No:.....

Please answer the questions asked as provided in the spaces given by ticking. Also, first tick your agreement to answering the questions voluntarily before commencing.

() I Agree () I disagree

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

Section 1: Socio-demographic characteristics of the respondents		
No	Characteristics	
1.1	Age of participants (in years)	
1.2	Gender	Male []
		Female []
1.3	Level of education	1.Undergraduate degree []
		2.Diploma []
		3.Certificate []
		4.Others(specify) []
1.4	Number of years in the vaccine department	<2 years []
		2-5 years []
		6-10 years []

		>10 years	[]
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1.5	Have you ever received training related to cold chain and vaccine management?	Yes	[]
		No	[]
	If yes, which types of training	Cold chain management []	
		Vaccine management []	
		Immunization in practice []	
		Others (specify) []	
	If yes, time of the last training(year)	
1.5	Level of health institution	County referral	
		Hospital	[]
		Sub county Hospital	()
		Health center	[]
		Dispensary	[]
	Others(specify)	[]	

Section 2: Status of cold chain equipment in health facilities			
S.N	Question	Response	Remark
2.1	Availability of at least one functional refrigerator in health facilities?	1=Yes 2=No	
2.2	Is the refrigerator placed over wooden platform?	1=Yes 2=No	
2.3	Does the refrigerator 10 cm away from wall?	1=Yes 2=No	
2.4	Type of power supply for fridge?	1=Electricity as main source 2= solar as main source 3=Kerosene as main source 99=Other specify	
2.5	Availability of functional Temperature monitoring device in refrigerator?	1=Yes 2=No	
2.6	If yes, which type?	1=Thermometer 2= Fridge-Tag	
2.7	Is the temperature recorded properly (twice daily and complete)?	1=Yes 2=No	
2.8	Refrigerators with temperature within the recommended range (2-8°C) at the moment data collection?	1=Yes 2=No	
2.9	Refrigerator used exclusively for vaccine storage (free from other products than vaccine, diluents and ice packs)?	1=Yes 2=No	
2.10	Do you have discarded vaccines due to incorrect storage temperatures in the last six months?	1=Yes 2=No	
2.11	Do you record all vaccine discarded due to incorrect storage temperatures?	1=Yes 2=No	
2.12	Available person responsible for cold chain equipment preventive maintenance?	1=Yes 2=No	
2.13	Do you plan preventive maintenance to cold chain equipment?	1=Yes 2=No	

Section 3: Assessment of the vaccine stock management practices in Vihiga County, Kenya			
S.N	Question	Response	Remark
3.1	Do you have a Vaccination micro plan?	1=Yes 2=No	
3.2	Are standard vaccine requisition forms used for ordering and receiving vaccine?	1=Yes 2=No	
3.3	Does health facility have recorded minimum - maximum stock levels?	1=Yes 2=No	
3.4	Physical stock checks are completed each time a monthly or before ordering the next request?	1=Yes 2=No	
3.5	Proper storage of vaccines in the refrigerator?	1=Yes 2=No	
3.6	EPI SOP guideline in place	1=Yes 2=No	
3.7	Is there any vaccine which reaches the VVM discarding stage in fridge during the visit?	1=Yes 2=No	
3.8	Are vaccine and diluents quantities, batch no and expiry date recorded?	1=Yes 2=No	
3.9	Is VVM status recorded?	1=Yes 2=No	
3.10	Do you calculate vaccine wastage rate?	1=Yes 2=No	

Section 4: The knowledge level of the Vaccine cold chain handlers on effective vaccine management in Vihiga County, Kenya			
S. N	Question	Response	Remarks
4.1	Do you know how to condition icepacks?	1=Yes 2=No	
4.2	Do you know how to prevent vaccine freezing during transport?	1=Yes 2=No	
4.3	Do you know antigens eligible for the four weeks open vial policy?	1=Yes 2=No	
4.4	If, yes can tell me please? (Lists all during she/he says)	
4.5	Are opened multi-dose vial policy (MDVP) kept for the next immunization sessions with visible labeled?	1=Yes 2=No	
4.6	Do you know after how many hours the reconstituted vaccines are discarded?	1=Yes 2=No	
4.7	If yes after how many hours?	After hrs.	
4.8	Do you know how many hours fridge should be turned on after its arrival?	
4.9	If yes hours after arrival?	
4.10	Do you know at what temperature range should vaccines stored in refrigerator?	1=Yes 2=No	
4.11	If yes at what temperature range?	
4.12	Could you name all heat sensitive vaccines?	
4.13	Could you name all cold sensitive vaccines?	
4.14	Could you name all light sensitive vaccines?		
4.15	Correct demonstration of temperature reading?	1=Yes 2=No	
4.16	Do you know how to Read and interpret VVM	1=Yes 2=No	
4.17	Does the HF have made following Early Expiry First Out (EEFO) in practice?	1=Yes 2=No	
4.19	Do you know the correct interpretation of shake test?	1=Yes 2=No	
4.20	Correct placing thermometer inside deep freezer?	1=Yes 2=No	

Appendix 2: Observational Checklist

OBSERVATIONAL CHECKLIST

No.	Description	Yes	No	Comment
A.	Cold Chain Equipment Status			
1	Availability of WHO recommended functional refrigerator in the health facility			
2	Availability of Functional fridge tag			
3	Availability of functional generator/solar for electricity backup.			
B.	Vaccine Stock Management Practice at Public Health Centers			
1	EPI SOP guideline in place			
2	Daily temperature recording chart updated.			
3	Vaccine arrangement as per the recommended standard.			
4	Storage of EPI vaccines with other drugs & Items.			
5	Ice packs correctly placed for freezing in the deep freezer			
6	Vaccine Ledger book in place and updated.			
7	Expired and wasted vaccines are documented in ledger book.			
8	Physical counting of stocks is done on monthly basis.			
9	Practice of Multi-Dose Policy			
10	Emergency/Contingency plan displayed			

Appendix 3: Consent Form

Participants' statement

I have read and understand the provided information concerning the research project, which has also been fully explained to me by the researcher. I do understand the general purpose of the study, the methods used in this research as well as the risks. I have had the opportunity to ask questions to which I have received satisfactory answers from the researcher. I do understand that my participation is voluntary and that I have the freedom to withdraw at any time, without giving a reason and without any cost.

I voluntarily agree to take part in this study.

Participant Name: _____

Participant's signature/Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, having fully discussed the research project and explained the required details of the same to the above-named participant. I believe that the above-named participant has clearly understood, willfully agreed to participate and freely given his/her consent

Researcher's name _____ Date _____

Signature _____

Role in the study; Data collection

For more information contact Eclayne Naswa Wanyonyi Tel. No. +254726382508

Witness

Name _____ Contact information _____

Signature/Thumb stamp _____ Date _____



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REF: MSU/DRPI/MUSERC/01158/22

Date: 25th November, 2022

TO: Eclayne Naswa Wanyonyi
Student Registration Number: 221028869
EAC Regional Centre of Excellence for Vaccine,
Immunization and Health Supply Chain Management
College of Medicine and Health Sciences
University of Rwanda

Dear Madam,

RE: Assessment of Vaccine Storage and Stock Management Practices in Vihiga County, Kenya

This is to inform you that Maseno University Scientific and Ethics Review Committee (MUSERC) has reviewed and approved your above research proposal. Your application approval number is MUSERC/01158/22. The approval period is 25th November, 2022 – 24th November, 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 Maseno University Scientific and Ethics Review Committee (MUSERC).
- 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 Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 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 Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 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 Maseno University Scientific and Ethics Review Committee (MUSERC).

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

Yours sincerely

Prof. Philip O. Owuor, PhD, FAAS, FKNAS
Chairman, MUSERC



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ASSESSMENT OF VACCINE STORAGE AND STOCK MANAGEMENT PRACTICES IN VIHIGA COUNTY, KENYA

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