INFLUENCE OF HEALTH-FACILITY COLD-CHAIN STORAGE LOGISTICS AND STAFF CAPACITY ON THERMO-STABILITY OF LIVE-ATTENUATED VACCINES IN KISUMU-COUNTY, KENYA

BY

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DECLARATION

DECLARATION

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ABSTRACT

Vaccines are integral in the control of infectious diseases globally. Successful immunization programs require robust cold-chain logistics and efficient service-delivery systems to ensure they remain within recommended temperature range to guarantee their stability and efficacy. In sub-Sahara Africa, approximately 15-20% of vaccine equipment are faulty while transport and electricity infrastructure pose additional challenges. Despite new technologies for tracking vaccine cold-chain performance, resurgences in live attenuated vaccine preventable childhood diseases are still common indicating potential multiplicity of factors. In Kenya, between 2014 and 2016, there were resurgences of measles, rota and, tuberculosis infections mostly in Kisumu County despite over 80% immunization-coverage and investment in new fridges, these implied potentially more complex unmet cold-chain challenges. Drivers of these outbreaks which are only associated with live-attenuated vaccines were still not clear. The current study assessed influence of health-facility cold-chain storage-logistics and staff-capacity on thermo-stability of live-attenuated vaccines. Specifically, it assessed association between: functionality of fridges, cold-boxes; vaccine-carriers and thermo-stability of vaccines; staff compliance with cold-chain guidelines and thermo-stability of vaccines; staff competency in cold-chain management and thermo-stability of vaccines; and staff cold-chain management perceptions and thermo-stability of vaccines. Analytical cross-sectional design with mixed methods techniques was adapted. Qualitative and quantitative site-level data were collected from 120 of 170 health-facilities using questionnaires. Stratified random sampling and convenient were applied through multi-stage approach. Variable characteristics were summarized descriptively; associations were tested using chi-square and binary logistic regression to identify predictors of vaccines thermo-stability. Qualitative information were coded, categorized and thematically analyzed to identify evolving perspectives through N-Vivo software. Overall fully-functional cold-chain storage logistic were 44.5% (95%C.I, 0.074-0.366; OR 0.165, p<0.001); functional-fridges, 64.2% (95%C.I, 1.332-6.370; OR, 2.913; p=0.007) and vaccine-carriers, 37.5% (95%C.I, 1.462 -6.884; OR 3.172; p=0.003), all associated and predicted thermo-stability of vaccines. Overall-compliance to Cold-chain guideline, 40% (95% C.I, 0.001-0.025; OR, 6.021; p<0.001); use of VVM to dispense vaccine, 42% (95%C.I, 0.645-6.787; OR, 2.085; p=0.022); monitored temperature twice daily, 69% (95%CI, 0.052-0.651; OR, 0.185; p=0.009), were all associated and predicted thermo-stability of vaccines; however, orderly arrangement of vaccines, 49%(95%C.I, 0.000-0.025; χ^2 value,8.520;p=0.004) was only associated. Competency on vaccines-transfer when fridges were faulty, 53.3%(95%C.I, 0.955-7.397; OR, 2.658; p=0.031); and use of VVM stages to dispense vaccines, 55.8%(95%C.I, 0.127-0.988; OR, 3.540; p=0.047) were associated and predicted outcome of vaccines thermo-stability; conversely overall-competency 67% was not, similar to overall perception, 61.7%, except for perception on vaccines transfer,75%(95%C.I, 0.682-5.847; OR, 1.997; p=0.007); otherwise, perception on vaccines arrangement, 61.7%(95%C.I, 0.890-9.821; χ^2 value, 7.023; p=0.030), was only associated. Vaccines at substantial private-facilities were at a higher-risk of thermo-instability due to marked lapses in compliance and in-adequate support supervision. Live-attenuated vaccines comparatively showed higher level of thermo-instability except for BCG hinting the notion that associates them with occasional outbreaks of vaccines preventable child-hood illnesses. There is need for KEPI managers to strengthen support supervision and extend provision of WHO recommended fridges to private facilities.

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LIST OF ABBREVIATIONS AND ACRONYMS

ANC	Ante Natal Clinic
BCG	Bacilli Calmette-Guérin
CHW	Community Health Worker
CDC	Centre for Disease Control
CTC	Controlled temperature chains
DPT	Diphtheria, Pertussis and Tetanus
ECTC	Extended Controlled Temperature Conditions
EPI	Expanded Program for Immunization
EVSM	Effective vaccine store management
FEFO	First Expired First Out (i.e. dispensed out first)
FT2	Fridge Tag two
GAVI	Global Alliance for Vaccines and Immunization
GIVS	Global Immunization Vision and Strategy
GoK	Government of Kenya
GVAP	Global Vaccine Action Plan
HepB	Hepatitis B vaccine
Hib	Hemophilas influenza type b
HIV-	Human Immune Deficiency Syndrome
ILR	Ice-lined refrigerator
IPV	Inactivated Polio Vaccines
IMR	Infant Mortality Rate

KDHS	Kenya Demographic Health Survey
KEPI	Kenya Expanded Program for immunization
KHIS	Kenya Health Information system
KTAGI	Kenya Technical Advisory Group on Immunization
LMIC	Low and Middle-Income Countries
MCH /FP	Maternal and Child Health / Family Planning
MCV1	Measles combined vaccine 1 (i.e. given @ 1 year)
MCV2	Measles combined vaccine 2 (i.e. given @ 2 year booster)
MDVP	Malty Dose vaccine Policy
MoH	Ministry of Health
NGO	Non-Governmental Organization
NIP	National Immunization Programme
NNT	Neonatal Tetanus
OPV / Pol	Oral Polio Vaccine,
PCV/ PCV10	Pneumococcal Conjugate Vaccines
R.I	Routine Immunization
ROTA	Rota vaccine (e.g. Rota1 means first dose of Rota vaccine)
SCM	Supply Chain Management
T D	Tetanus and Diphtheria vaccine
TT	Tetanus Toxoid vaccine
UNICEF	United Nations Children Funds
VVM	Vaccine Vial Monitor
WHO	World Health Organization

Operational Definition of Terms

Capacity (Staff Capacity): The level of staff **competency** in respect to awareness of the cold-chain procedures requirements; their **perception**; and ability to **comply** with the guideline procedures

Cold-box: These are larger containers purposely manufactured to be used for transportation of larger quantities of vaccines specifically from regional stores to District stores or big facilities. They can also be used for temporary storage when a refrigerator breaks down.

Cold-chain: A system of transporting and storing vaccines within a recommended temperature range of +2 to +8 degrees Celsius (°C) beginning from the manufacturer to the consumer.

Cold-chain storage logistics: These are refrigerators; cold-boxes; vaccine carriers and ice packs meant to store or transport vaccines at health facility levels based on provided for guidelines.

Cold trace - Remote Temperature Monitoring (RTM): A device planted on fridges to monitor their temperatures and remotely inform specific managers through their mobile phones on any temperature excursion for immediate action to prevent vaccines risk of instability

Compliance: Staff level of adheres to the cold-chain management guideline in carrying out the services to clients to ascertain quality in the services

Competence: Staff aware of cold-chain management guidelines specifications/ requirements and has ability to perform when instructed to do so

Efficiency: An attribute of performance that is measured by examining the relationship between specific products of the health care system and the resources used to create that product.

Efficiently Functional fridge: Fridge is able to maintain temperature between $+2^0$C- $+8^0$C continuously for at least 36 hours when not on power or show no alarm over a month
Efficiently functional cold box: Cold-box is able to maintain temperature below + 8^0C for at least 36 hours

Efficiently functional vaccine carrier: Carrier able to maintain temperature below $+8^0$C for at least 8 hours

Facility Ownership: the Organization which run or manage the facility in terms of either, Government/ Public, Private or Faith Based

Facility Level: The stratified operation level of a facility as per Kenya Essential Packages for Health (KEPH) policy guideline

Functional: Ability to perform the expected (i.e. effective: ability to meet intended objective)

Health facility: Any licensed unit or institution authorized by Ministry of health to offer immunization services among other medical services. This may be Public, Private or Faith based facilities from level two and above.

Ice - packs: These are flat rectangular plastic containers filled with water or gel, used in vaccine carriers, cold boxes or refrigerators to maintain temperatures.

Immunity: Immunity is the ability of the human body to defend itself from specific pathogenic organisms or tolerate the presence of materials indigenous to the body (self), and to eliminate foreign materials. It is usually indicated by the presence of antibody to that organism.

Immunization: This is the Sensitization of body to develop immunity or antibodies for specific pathogenic organisms.

Inactivated vaccines: These are vaccines produced by growing viruses or bacteria and then inactivating or killing them with heat or chemicals. They cannot grow in a vaccinated individual and therefore cannot cause the disease. Multiple doses are required for full protection.

Live- attenuated vaccines: These are vaccines which are derived from disease-causing viruses or bacteria that have been weakened under laboratory conditions but not killed such that if exposed to higher temperature than recommended, they lose their stability, effectiveness or potency.

Logistics: another word for equipment, i.e. cold-chain storage logistics are equipment for vaccines storage

Non-functional fridge: Fridge cannot sustain temperature between $^{+}2^{0}$C and 8^{0}C for at least12 hours without power. Or shows alarm (s) while on un-interrupted power flow

Non-functional cold box: Box cannot maintain temperature below+ 8^{0}C for 12 hours

Non-functional vaccine carrier: carrier cannot maintain temperature be +8^{0}C for 6 hours

Partially functional fridge: Fridge able to maintain temp between +2^{0}C - +8^{0}C continuously for at least 12 < 36 hours when not on power and show no alarm while on continuous power flow.

Partially functional cold-box: Cold box maintains temp below + 8^{0}C for at least 12 < 36 hours

Partially functional Vaccine carrier: carrier maintains temp below + 8^{0}C for at least 6 hours

Perception: staff thoughts on specific cold chain management procedures. The process by which an individual gives meaning to the provided for procedures

Routine immunization: This is a timely and regular health system management approach through which clients' world-wide access life-saving vaccination from authorized health facilities.

Shelf-life: The period of time during which a vaccine, when stored under approved conditions, is expected to comply with the specifications. The shelf-life is determined by stability studies.

Thermo-stable: Stability of vaccines in respect to heat excursions, measured by using VVM garget placed on each vaccine vial and graded in four levels which are stage1, stage2, stage3 and stage4. The first two stages are qualified as thermo-stable whiles the last two unstable.

Vaccination: This is the act of introducing antigen to a body of a client either through injection or oral with an aim of the vaccine to sensitize the body to develop immunity.

Vaccine: A substance used to stimulate the production of antibodies and provide immunity against one or several diseases, prepared from the causative agent of a disease, its products, or a synthetic substitute, treated to act as an antigen without inducing the disease.

Vaccine carriers: These are containers recommended for use in transporting small quantity of vaccines from district stores to service delivery points and during immunization sessions.

Vaccine Vial Monitor: A heat-sensitive label attached to vaccine vials to measure cumulative heat exposure from time of production to the time of use in a client. It gradually and irreversibly changes colour, from light to dark, when vaccine is exposed to heat. It warns a health worker as to when a vial of a vaccine should be discarded due to altered stability or potency.

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CHAPTER ONE:

INTRODUCTION

1.1 Background of the Study

Cold-chain system is one most critical process of ensuring vaccines remain viable until it is administered to clients (Diana, *et al.*, 2019; Franzel, *et al.*, 2017a; Asha, 2017 and WHO, 2015c). In sub-Sahara Africa, approximately 15-20% of installed vaccine equipment are faulty while transport performance and electricity infrastructure pose additional logistical challenges to quality assurance (WHO, 2015c). Despite improved distribution support systems and new technologies for tracking vaccine cold-chain performance with remarkable improvement in immunization coverage, resurgence in vaccine preventable childhood diseases are still common, indicating potential multiplicity of unapparent factors.

Naturally, vaccines undergo biodegradation during long term storage under cold-chain conditions but are hastened when storage logistics malfunction or mishandled (WHO/UNICEF, 2016; WHO, 2015d; Ashok, e*t al*., 2016). Vaccines in Expanded Program for Immunization (EPI), whether live-attenuated (Measles-rubella, Oral Polio, Rota and BCG) or inactivated, (PCV10, Tetatnus Toxoid, DPT/HepB/hib and IPV) are only considered viable when they are capable of inducing a protective immune response (WHO, 2019). However, there is need for additional evidence regarding the logistics components of service delivery functions to ensure quality performance. Such components including fridges; cold-boxes and vaccine-carriers, still contribute significantly to thermo-instability of vaccines in Kenya (MoH, 2019).

Vulnerability of vaccines to wide temperature excursions outside the recommended range increases when there is poor compliance to the guidelines by staff. In sub-Sahara Africa, compliance remains

low to average in different regions affecting vaccine thermo-stability in differing degrees (Yauba, *et al.,* 2019; 2018; Bogale, *et al*., 2019; 2018; and Maglasang, *et al.,* 2018) and by level of service delivery (Diana, *et al.,* 2019). Compliance with prescribed immunization procedures which are: vaccines transfer; dispensing of vaccines at VVM stage2; monitoring of temperature twice daily; arrangement of vaccines in fridge; discarding of certain vaccines within six hours of dilution; placement of diluents in fridge and defrosting of fridges are crucial in sustaining vaccines thermo-stability (MOH, 2019; JSI *et al*., 2019). The government of Kenya introduced new technologies for monitoring temperature, such as fridge tag2 and VVM device which do not depend on human monitoring to function. While they show better prospects of tracking staff compliance in sustaining thermo-stability period of vaccines (MOH, 2019), proper use of the data they generate to institute quality improvement interventions at facility level is in doubt.

Competency of staff towards cold-chain guideline implementation is crucial factor in sustaining the viability of vaccines in respect thermo-stability; however, it varies from each country to another and even within health facilities (Yauba, *et al.,* 2019; Bogale, *et al*., 2019; Yassin, 2019). Whereas most studies done to determine staff's competency in cold-chain management establish that competency does not operate in isolation, few studies show interactions across intra-personal factors such as perception of the staff to comply with guidelines, personal expectancies and motivations for complying with the procedure hence maintenance of vaccines viability at health facility level (Karp *et al.,* 2015). Competency, perceptions, motivations and expectancies are proximal factors to intentions to implement desired behavior and contribute to service providers making rational decision in handling detected logistical gaps and hence cold chain breaches (Lutukai, *et al.,* 2019). However, Ministry of health still reports gaps in staff competency among a

number of regions within the country (MoH, 2019). It is a possibility that the reported upsurge of immunize-able diseases in Kisumu could be linked to staff factors.

Perception of staff on their expected task is a significant factor in acceptance and satisfaction of their anticipated roles (MOH 2018). It is expected that good perception creates a positive working environment in their work station towards strengthening the relationship between performance and the outcome. In contrast, a negative perception affects output level and degenerates to lack of response to pressing needs of cold-chain management referred to in this study as inefficient or poor compliance by staff world over (Ogboghodo, *et al.,* 2017; Kumar A S *at al.,* 2017 and WHO/UNICEF 2016). However, apparent outbreaks of immunize-able diseases among people already vaccinated and enormous vaccines wastage common in low and middle income countries including Kenya can be linked to performance behavior issues (Karp *et al.,* 2015).

Stable vaccines contribute significantly to the decline of childhood morbidity, disability and mortality rates from vaccine preventable diseases world-wide; however, there is still gaps in addressing child health in respect to unattainable immunization targets (WHO/UNICEF, 2020; Ogboghodo, *et al.*, 2017; WHO, 2015a). A failed immunogenicity among vaccinated clients precipitates realization of unexpected diseases upsurge in a population; satisfactory immune response therefore calls for viable vaccines; unfortunately, vaccines are easily destabilized if the cold-chain management is inefficient (MoH, 2019; and WHO, 2015b). Ineffective cold-chain or compromised capacities of staff are common challenges world over but worse in low and middle-income countries (Lydon, *et al.,* 2015; Karp, *et al.,* 2015). Thermo-stability of vaccines is therefore crucial for a successful immunization program (MoH, 2019). There are indications that vaccines are

becoming much less efficacious in many low and middle-income countries particularly in Africa including Kenya (WHO, 2021; Patel *et al.,* 2011).

World Health Organization and Kenya Health Information System (appendix 6, 7, 8, 9, 10 and14) report on incidences of vaccine preventable diseases and vaccines wastage, both agree that upsurge of diseases preventable by live-attenuated vaccines is persistently higher than those preventable by inactivated vaccine in exception of polio world over for decades (WHO, 2021; WHO, 2020; and KHIS 2014 to 2019). There were confirmed high incidences of Rota Diarrhoea, measles, rubella and tuberculosis almost every year in Kisumu (KHIS, 2041 to 2019), this imposes concern, hence questioning the efficiency of cold-chain storage logistics and staff capacity in maintaining the thermo-stability of these particular antigens at health facility level where vaccines are initially stored while still thermo-stable.

1.2 Statement of the problem

Recent evidence from facility national surveys indicates that maintaining cold-chain systems at the service delivery points remain a major challenge despite availability of cold-chain infrastructure and operational guidelines. One considered factor is that, mass immunization campaigns, especially for Polio and Measles, gives relatively a better disease control results than routine immunization process due to higher efficiency and conscientious adherence to cold-chain management guidelines. This variance indicates potential lapses or fewer rigors in cold-chain management during routine immunization services. In addition, sub-optimal performance among staff was realized despite availability of guidelines and job aids at facilities; staff support supervision as well as regular training of immunization staff indicated that there could be other issues yet to be understood.

Vaccines naturally undergo instability during long-term storage under cold-chain conditions but this is hastened when storage logistics malfunctions, or mishandled. Antigens are considered stable only when they have the capability to induce immune response among the vaccinated thus protects from diseases. Outbreak of immunize-able diseases in a population of the vaccinated is an evidence of failed immunogenicity. Verification of cold-chain systems' quality performance is thus essential to guarantee safety, stability and potency of vaccines.

Kenya Health Information system in the year 2014 to 2016 reported upsurge of diseases preventable through vaccination by live attenuated vaccines (measles, rota and tuberculosis) among a number of Counties in Kenya, the resurgences were comparatively more in Kisumu despite meeting recommended vaccination coverage of above 80% in this period, and investment in new fridges. The trends of these outbreaks were relatively lowest in Counties with lower climatic temperature like Kiambu and Kericho among others. Predictable frequent Immunize-able diseases outbreaks in Kisumu hinted that there might be unmet cold-chain system challenges in respect to maintaining thermo-stability of live-attenuated vaccines, and so begged the question on what specific factors or breaches in the cold-chain management it might be.

Whereas sub-optimal functioning of equipment may usually be captured during site support supervision visits by the program leadership, and in monthly reports, questionable vaccines handling operational inefficiencies, such as health facility cold-chain storage-logistics and staff capacities have not been systematically examined for their influence in exposure of the live attenuated vaccines to extremes of temperature in the County.

1.3 Justification of the Study

Childhood immunization is universally accessible but quality and effectiveness of cold-chain as well as safety of vaccines, especially at the level 2 health facilities in developing countries like Kenya remains a concern in light of frequent upsurges of vaccine preventable diseases. Challenge of vaccines instability is global, it led to innovative introduction of an electronic logger, fridge tag2 device (Figure 2.2) in 2015 by WHO; with an overall aim of helping in the improvement of quality monitoring of fridges functionality; consequently, maintains thermo-stability period of stored vaccines at health facility, this helps strengthen the assessment of fridge functionality status. Baseline information from County Government of Kisumu indicated that fridge tag2 monthly monitoring reports had inconsistencies in cold-chain management in respect to timely response to cold-chain management procedures among a number of health facilities (MOH, 2015).

Vaccine Vial Monitor (VVM) gadgets, (Figure 2.1), a basic tool for clinical quality monitoring of vaccines' stability status, revealed occasional wastage upsurge of live-attenuated vaccines in Kisumu County being relatively higher than inactivated vaccines; it seemed having not been given adequate attention by staff in respect to expected prompt action whenever it turned to stage two (MoH, 2015). Again, most heat-damaged vaccines though identified through the use of vaccine VVM and discarded, some seemed to slip through and administered to clients leading to a gap between the vaccinated and immunized clients, thus precipitate the need to identify the contributing factors (Zipursky, *et al.,* 2017). He encourages that laboratory titer and VVM give similar and accurate findings in respect to estimating thermo-stability and potency status of vaccines exposed to adverse temperature and so should be considered as one in a resource limited regions (Zipursky, *et al.,* 2017), a fact which is also encouraged by World Health Organization (WHO, 2019).

Mass immunization campaigns which are associated with better compliance to cold-chain management procedures prove to be more efficient than routine which is the study area of interest; for instance, mass campaigns for Measles and Polio achieved better diseases control results (MoH, 2018). Baseline information from County Government of Kisumu indicated that fridge tag2 monthly monitoring reports had inconsistencies in cold-chain management in respect to timely response to cold-chain management procedures among a number of health facilities. Vaccine Vial Monitor tags revealed occasional wastage upsurge of live-attenuated vaccines in Kisumu County being relatively higher than inactivated vaccines. This study therefore explored various aspects of the routine immunization program to determine sources of the discrepancies.

The data collected has helped the study to verify and conclude on the level of cold-chain management status in routine immunization services at Kisumu County in respect to live-attenuated vaccines. The identified challenges are amenable to quality improvement interventions and would be implemented according to needs; the findings of this study are therefore useful for policy makers, service delivery managers and providers to develop quality improvement interventions for various contexts with an overall aim of directly addressing Sustainable Development Goal number three, specifically, child health among others.

1.4 General Objective

To assess influence of health facility cold-chain storage-logistics and staff capacity on thermo-stability of live-attenuated vaccines in Kisumu-county, Kenya

1.4.1 Specific Objectives

1. To establish the association between functionality of fridges; cold-boxes; vaccine carriers and thermo-stability status of live-attenuated vaccines at health facilities in Kisumu County.

2. To establish association between staff compliance to cold-chain management guideline and thermo-stability status of live attenuated vaccines at health facilities in Kisumu County.

3. To determine association between competency of staff in cold-chain management and thermo-stability status of live attenuated vaccines at health facilities in Kisumu County.

4. To determine association between staff cold-chain management perceptions and thermo-stability status of live attenuated vaccines at health facilities in Kisumu County.

1.5 General Hypothesis

H_0. Health facility cold-chain storage-logistics and staff capacity have no influence on thermo-stability of live-attenuated vaccines in Kisumu-county, Kenya.

1.5.1 Hypotheses

- **H_{o1}**: Fridges; cold boxes; and vaccine carriers have no association with thermo-stability status of live attenuated vaccines at health facilities in Kisumu County
- **H_{o2}**: There is no association between staff compliance to cold-chain management guidelines and thermo-stability status of live attenuated vaccines in health facilities in Kisumu County.
- **H_{o3}**: There is no association between staff competency in cold chain management and thermo-stability status of live attenuated vaccines at health facilities in Kisumu County.
- **H_{o4}**: There is no association between staff perception on cold chain management procedures and thermo-stability of live attenuated vaccines at health facilities in Kisumu County.

1.6 Significance of the Study

The study established significant cold-chain lapses at the health facility-level as a result of dysfunctional cold-chain equipment and low staff-capacity to perform that require multipronged

improvement intervention to resolve, particularly at level 2 facilities. This calls for the attention of national government to facilitate immunizing health facilities with functional-fridges with sustainable power-sources and strengthen support-supervision to enhance efficiency in cold chain management at the facility level to help mitigate considerable thermo- instability of vaccines and related consequences like diseases-resurgence or vaccines wastages; consequently boost immunization coverage in Kisumu County**.**

1.7 Scope of the study

The study covered the whole of Kisumu County, including all the six Sub Counties then, (Kisumu East; Kisumu West; Seme; Muhoroni; Nyakach and Nyando). A sample of 120 out of 170 immunizing health facilities in the County participated, these were 83 public health facilities; 3 faith based; and 34 private, based on their numerical strength. The study maintained sample size at 70% to ascertain results validity.

1.8. Delimitation of the study

Kisumu Regional store (i.e. KEMSA) though situated within Kisumu County was purposely not included in the study, reason being, all antigen to be collected from the regional store must be confirmed and verified to be thermo-stable before being dispensed to any Sub County EPI stores; The study did not test stabilizers; adjuvant; nor preservatives at laboratory level (i.e. titer) but relied upon vaccine vial monitors staging as indicators, as is encouraged by Zipursky *et al*., (2017).

CHAPTER TWO:

LITERATURE REVIEW

2.1 Introduction

While vaccines have been integral to the dramatically declining rates of infectious diseases' morbidity and mortality which have been enjoyed over the course of the last century, the health benefits of vaccines have not been shared equally across the globe (Karp, *et al.,* 2015). Since 2000, there has been a concerted effort to realize the full, equitable public health impact of vaccines in the process of meeting the sustainable Development Goals and the supporting goals of the Global Immunization Vision and Strategy, and Global Vaccine Action Plan developed by UNICEF (WHO-UNICEF, 2016). Vaccines in Expanded Program for Immunization (EPI) as per the time of the study were; live attenuated (Measles-rubella, OPV, Rota and BCG) and inactivated vaccines (PCV10, Tetatnus Toxoid, DPT/HepB/hib and IPV) and are considered viable when they are capable of inducing an immune response, that is clinically indicated by VVM stage (WHO, 2019).

Three fundamental goals underlie the GIVS and many country-level immunization strategies are: increasing vaccine coverage to ensure extended immunization to all children; increasing vaccine effectiveness by ensuring that the vaccines delivered are optimally efficacious and simple to administer and minimizing the total system cost of immunization programs (Karp *et al.,* 2015). Significant progress toward achieving these goals has been made by Global Alliance for Vaccines and Immunization. Alliance Partners (Karp, *et al.,* 2015). Cold-chain management and storage at these facilities level are largely heterogeneous and potential impact of these on vaccine viability is still understudied, especially in the context of devolved healthcare system (Karp, *et al.,* 2015).

Immunization has been very effective public method to control or eliminate various childhood vaccines preventable diseases (WHO, 2019; Karp, *et al.*, 2015). Characteristics of an ideal vaccine includes: satisfactory immunogenicity to generate high level of protection against target diseases; safe; heat stable; able to remain potent; and provides long lasting protection, the effectiveness of an immunization program depends on multiple procedures aimed at maintaining vaccines stability, potency and safety throughout the process from manufacturing; central storage, transport, field storage and handling (WHO, 2019; Ogboghodo, *et al.*, 2017). Cold-chain management system is the most critical processes of ensuring vaccines retain stability and quality throughout self-life. Whereas this is constantly monitored by automated vaccine vial monitors, often necessary response actions are limited (Yauba, *et al.*, 2019; Kumar, *et al.*, 2017; WHO, 2015c; and Asha, 2017).

The Kenya Expanded Program for Immunization (KEPI) is rendered through routine immunization services or during Supplemental Immunization Activities (SIAs), as mass campaigns (MoH, 2019). The Division of Vaccine and Immunization, which is a unit in Ministry of Health, at the National headquarters, coordinates the services and ensures universal quality immunization coverage for infants below one year with exception of Measles Rubella (MoH, 2019). Despite the devolvement of County governance in Kenya, immunization as a program is not devolved but operates through coordination of national government (MoH, 2019). The National government therefore, through coordination of the Division of Vaccines and Immunization (DVI) ensures that supplies and maintenance of cold-chain equipment such as freezers; refrigerators; cold boxes and vaccine carriers are up to the expectations for quality vaccines storage (MoH, 2019). The program is integrated with maternal health services to promote public participation; demand creation; monitoring; and evaluation; these facilitates capacity strengthening (MoH, 2019).

In summary cold-chain system (Appendix 11) ensures sustainability of vaccines' potency which is referred to here as thermo-stability (MoH, 2019). An efficiently functional cold-chain system at facility level requires four basic categorized factors, which are: sufficiently functional fridges on sustained power supply; functional cold-boxes and vaccines carriers with ability to maintain temperature between $+2^0$C and $+8^0$C throughout specified time as stipulated in the guidelines; competent staff who understand the guidelines requirements; motivated staff who has interest and will to implement prescribed procedures; and staff who actually comply to the provided for guidelines, specifically; ensures that diluents for use are in fridge/carrier; extra set of ice-packs in a reserve during outreach; arrangement of vaccines are in order within the fridges; defrosts fridge; dispense vaccines at VVM stage two out first; observes FEFO/FIFO sequence; monitor temperature twice daily including weekends; staff who transfer vaccines when a fridge is faulty or when there is power blackout for over ten hours; one who use multi-dose vaccines for maximum of four weeks; and measles-rubella together with BCG vaccines discarded within six hours of dilution (MoH, 2019). It is unclear how service providers perceive or comply with these requirements and what challenges might exist that may be adversarial to the cold chain processes.

2.2 Functionality of Fridges; Cold-boxes and Vaccine Carriers

Stable vaccines contribute significantly in preventing morbidity; disability and mortality hence the promotion of good health indicators among children below five years worldwide (WHO, 2019; WHO, 2015a; Karp, *et al.,* 2015). Loss of vaccine stability due to any lapses has a considerable adverse impact on the success of immunization program. Vaccines stability refers to their ability to retain physical, chemical, biological, biopharmaceutical and microbiological properties within specified limits to assure clinical performance throughout self-life (Masataro, *et al.,* 2019;

Mychaleckyi, *et al.*, 2016; Parker, *et. al.*, 2015). This is detectable in clinical set ups through use of vaccine vial monitor (VVM) gargets which are attached to each vaccine vial (Figure 2.1).

Figure 2:1 Vaccine Vial Monitor (VVM) (Adapted from MOH, 2019)

Both adverse heat events (occurring when vaccines experience temperatures ≥8^{o}C for over 10 continuous hours) and adverse cold events (occurring when vaccines experience temperatures ≤−0.5^{o}C for at least one continuous hour) lead to degradation of vaccines immunological properties, consequently compromising their protective efficacy to the individuals receiving them.

Ram in Damoh District of Mathya Pradesh, establish that 57% of health facilities under study reported frequent power failure; but only 7% had unstable oral polio vaccines (Ram, *et al.*, 2018). Stability of other antigens was not reported. Kumar in a similar study found 20% of fridges with frozen vaccines while 30% had power failure; however, did not report vaccines stability status (Kumar, *at al.*, 2017). These may portray that challenges in cold chain management storage logistics may not singularly contribute to antigens stability but other associated factors combined. Similarly, Mychaleckyi and Parker while evaluating the impact of inactivated poliovirus vaccine in

separate studies; specifically, the implications for the polio eradication endgame; established that IPV boost immunity in the intestinal mucosa among individuals previously immunized with oral poliovirus vaccine, the mucosal protection were stronger following a booster dose of IPV than oral poliovirus vaccine, especially in older children (Mychaleckyi, *et al.,* 2016; Parker, *et al.,* 2015). This more or less Makes health workers question the functionality status of our storage equipment.

A study which aimed at comparing the capability of different attributes of refrigerators (types, purposes and years of utilization of refrigerator) in controlling temperature for vaccine storage among 155 health care facilities in Bangkok, Thailand, established that pharmaceutical refrigerator had the highest mean of capability at 96.61%; better than all types of domestic refrigerators. In conclusion, a pharmaceutical refrigerator was found ideal and highly recommended for utilization at every storage level. Nonetheless; regular maintenance and calibration was also recommended to keep refrigerators for sustainable capability in controlling the temperature (Somying, 2017). This is vital information which seemed to have been ignored by the cold-chain leadership structures in Kenya from Sub County level. Private health facilities operate mainly on domestic fridges in Kisumu County.

A fridge, Cold-box and Vaccine-carriers are said to be efficiently functional when they are capable of maintaining temperature as prescribed under normal operational circumstances (MoH, 2019). For instance, an efficiently functional fridge should be able to maintain temperature between $+8^0$C and $+2^0$C for at least thirty six hours without power supply; or show no alarm while on a continuous power flow; while, efficiently functional cold-box with frozen Icepacks maintains temperature below $+8^0$C for at least thirty six hours; and efficiently functional vaccine carrier with ice packs is should maintain temperature below 8^0C for at least eight hours (MoH, 2019). The equipment effectiveness levels are measured by a fridge tag2 device, (*Figure 2.2*).

***Figure 2:2- Fridge Tag 2. (Adapted from MOH, 2019*)**

Studying the effectiveness of fridges, cold boxes and vaccine carriers would help in finding out any gap in cold-chain management that contributes to instability of live attenuated vaccines (Yakum, *et al.*, 2015a, b; MoH, 2018). Cold-chain and logistics management systems have expanded drastically over the past twenty years or so, with the introduction of more new vaccines and the frequent mass campaigns to control specific diseases, such as polio, measles, rubella, and tetanus. CDC and Yakum argue that, these confer additional load on the fridges, frequent opening, and operational challenges due to different vaccine requirements (CDC, 2016, Yakum, *et al.*, 2015a, b; MoH, 2018).This argument is worth an evaluation to verify its validity.

A cross-sectional study done in Cebu, Philippines, to assess the cold-chain management of vaccines discovered that storage units and equipments were available in 52.4% of the facilities; meaning the remaining 47.6% did not have refrigerators yet 22.7% stored vaccines. About 90.9% of the health

facilities did not have access to a generator for back up of power supply and only 9% had a voltage stabilizers connected to the refrigerators, while refrigerators that had thermometers were 68.2 % (Maglasang, *et al.,* 2018). However, there was no statistical association between the statuses of stored vaccine and cold-chain functionality status, a core interest in this study.

Maintaining vaccines at proper temperatures has become more complex than in the past as some new vaccines are inactivated by exposure to freezing while other vaccines are damaged by heat exposure (Franzel, *et al.,* 2017b). Whereas guidelines and job aids are available per facility to guide practice by immunization providers and managers, their level of compliance remains unclear, in context where consistent support supervision is lacking; there is need for new innovations in the program to help meet increasing demands (Franzel, *et al.,* 2017b; Njunguna, *et al.,* 2015).An observation which is very consistent with the suspected gaps in this study.

Childhood immunization is universally accessible but quality and effectiveness of cold-chain as well as safety of vaccines in developing countries like Kenya remains a concern in light of frequent upsurges of vaccine preventable diseases. Cold-chain system management is most critical process of ensuring these vaccines remain viable until administered to the clients in respect to thermo-stability (Karp, *et al.,* 2015). The need to keep vaccines cold in the face of high ambient temperatures and unreliable access to electricity is a challenge that limits vaccine coverage; consequently, few number of clients end up immunized against the specific diseases; the cost of immunization therefore worsens as a result of vaccines wastage due to thermo-instability precipitated by heat excursions, making the aim of protecting all children against immunize-able diseases becomes elusive for the program. The challenge is worse in low and middle-income countries (Karp, *et al*., 2015).

A cross-sectional study done in East Gojam zone of Amhara region, Ethiopia to assess factors affecting vaccine cold chain management practices in immunizing health institutions, through descriptive statistics and Logistic regression analysis established that, 76.7% of the facilities had functional refrigerators; 35% had a functional generator for backup service and 46.6% had a car/motorbike for transportation of vaccines in case of refrigerator/power failure. (Bogale, *et al.,* 2019), however, none of these studies has associated Cold box and Vaccine carriers with quality of vaccines in the cold-chain.

Cold chain logistical needs vary from one region to another, for instance types of fridges and freezers, power availability, climatic situation, and solar consistency, economical status of a country among others (WHO, 2016). The same observation is echoed by Yauba, *et al.,* (2019) when they established 7% of health facilities in Cameroon were unequipped with any refrigerator; while 3% were equipped with broken refrigerators; and the remaining 3% with domestic refrigerators; Consequently, 38% of health facilities which were below level five did not have refrigerator (Yauba, *et al*., 2019). The study looked into how facility operation level influenced the operation and established that only level 5 and above had fridges unlike in Kenya that has up to level two with glaring gaps in power supply to the fridges.

Kumar conducted a cross-sectional evaluation study on cold-chain management practice in Durg district of Chattisgarh, with an aim of ascertaining the status of cold-chain equipment, they established that 20% of the fridges had frozen vaccines; 70% reported frequent power failure; 30% of the fridges did not defrost the fridges; 65% of the fridges had normal temperature and were functioning normally, 74% of the staff had adequate knowledge (Kumar, *et al.,* 2017); however, the study missed to inform us whether the lapses had any association with vaccines stability.

2.3 Compliance to Cold-chain Management and Thermo-stability of live-attenuated Vaccines

All personnel who administer vaccines should be familiar with the storage and vaccine handling procedures, this also includes those who deliver / accept vaccine shipments; and have access to the unit(s) where vaccines are stored; vaccines storage and handling training should be provided to all new personnel involved, including temporary staff; continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine (Krishnappa, *et al.,* 2016). Compliance to cold-chain management guidelines is critical in improving time vaccines spend within the correct range thus sustaining their stability (MoH, 2019; Lutukai, *et al., 2019;* WHO, 2015c; WHO, 2015b).

A cross-sectional prospective, quantitative and qualitative study which assessed medicines' cold-chain storage conformity with the requirements of the World Health Organization at public, faith-based, and private health facilities of the Eastern Province of Rwanda while using both convenience, stratified, and purposive sampling techniques established that overall compliance by staff to cold chain storage guideline was at 75.0%. The conformity found in refrigerators in public health facilities was 56.0%, in Faith Based, 100.0%, while in private it was 70.0%. (Nyirimanzi *et al.,* 2023), the study adapted a similar approach in respect to methodology and design it has specified individual health facility compliance level, however missed to inform the reader whether the conformity level had any association with the vaccines or drugs conditions in the fridges.

Kenya's Ministry of Health guidelines emphasizes the importance of proper vial labeling, after it has been reconstituted, whereas labeling practices may vary across jurisdictions, the practices must be clear and included in the routine protocols (MoH, 2019; PHAC, 2015). If the expiry date is Sept

2015, the vaccine may be used up to midnight on September 30, 2015 (MoH, 2019). Once multi-dose vials have been opened, they remain viable for the duration of a specific shelf-life, as indicated by the manufacturer. The shelf-life varies by vaccine type. One is to mark the vial with the date it was reconstituted upon opening the vial according to local guidelines and discard when the shelf-life has expired. Once vaccines have been reconstituted, they expire within six hours, independently of the expiration date provided by the manufacturer (MoH, 2019 and Karp, *et al.,* 2015).

A study conducted by Asamoah in Ghana to assess practices, competency and perception of health care service providers in respect to cold chain management found out that, majority (66.7%) of the facilities had their vaccine vial monitors correctly attached to the vaccines, Facilities with functional fridge tags (66.7%), and those with appropriate refrigerator to store vaccines (58.3%). However, the study observed that 91.7% of the facilities did not have policies and guidelines on cold chain management. Worse; all facilities (100%) did not have a contingency plan in place (Asamoah, *et al.,* 2021). The study had a valid approach in discovering gaps in the cold chain management; however, missed to report of stability status of vaccines in the cold-chain thus requires a follow up to further investigate any statistical association between the two.

Vaccines are required to be maintained between +2°C and +8°C (+35°F to +46°F) during an off-site clinic and should be stored in a properly packed, insulated container, hence the need for use of enough frozen ice-packs to maintain the cold-chain. The number of vaccines placement within the fridge or with frozen ice-packs inside vaccine carriers /cold boxes depend on container size; the ambient temperature, and the volume of vaccine. The combination of insulated container and packing material should be qualified to take into account these variables in order to maintain

vaccines between +2°C and +8°C (+35°F to +46°F) during an off-site clinic; that the containers must remain closed as much as possible (Karp, *et al.*, 2015).

In practice, additional inclusion of non-vaccine items, such as food and medicine vials have been observed, tasks that require a high level of staff compliance, increases vulnerability of the vaccines to wide temperature excursions outside the recommended range (heat or freeze) due to poor compliance. Recent studies show that staff compliance with recommended guidelines remains low to average in different regions (Yauba, *et al.*, 2019; 2018; Ringo, *et al.*, 2017; Saraswati, *et al.*, 2017 and Yakum, *et al.*, 2015b). New technologies for monitoring temperature, such remote temperature monitoring (RTM) device which do not directly require individual staff compliance with the task for its accuracy promising show better prospects of improving the ability of the system to maintain thermo-stability of vaccines.

Chukwu carried out a descriptive study in Abuja Nigeria to examine the quality of practice of supply chain management of cold chain products in line with the World Health Organization's Expert Committee report on Specifications for Pharmaceutical Preparations. He established that most of the storage facilities assessed (66.7%) did not meet up to the required standards of quality management for cold chain products. In addition, 50.4% of retail and hospital pharmacy facilities performed poorly in cold chain management practices. Most facilities (66.7%) did not have their equipment calibrated, 43.6% of the hospital and retail pharmacies assessed did not have an automated system to cater for power failure while 37.6% do not perform a temperature check on cold chain products before receiving from suppliers (Chukwu, *et al.*, 2022). The study has shown that there is a significant gap in compliance performed and that there was limited availability and use of validated quality monitoring systems for cold chain medicines in these facilities, similar gaps

may be contributing factors in the cold-chain system within Kisumu and so warrant a follow up study.

Immunization and other decentralized public services often suffer from a dearth of capable managers in practice. Common problem is that authority and responsibility for immunization are divided in decentralized health systems whereby Sub-County level managers are charged with optimizing immunization and other health services down to community levels through support supervision and provision of updates on job or through organized forums. Decision-making processes are fragmented and complex in this case and mediated by both technical and political considerations; worse, challenged by constrained resources (Karp, *et al.,* 2015).

2.4 Competency of staff on Thermo-stability Status of Live Attenuated Vaccines

Competency in this context refers to staff having proper training, preferably updates in the last three years of service prior to this exercise; staff having specific expected knowledge / awareness on cold-chain management procedures. Competency is influenced by level of one's training, it is said to be efficient if one is adequately orientated on the guideline, the variables directly influence the efficiency of cold-chain management, particularly compliance to specifications of the guideline hence maintenance of vaccines thermo-stability (Yassin, 2019 and Yauba, *et al.,* 2018). It is paramount that the management regularly updates employees with relevant basic requirements to improve efficiency in the delivery of services; more specifically innovations for improving identified gaps in the cold chain management (MOH, 2019; and WHO/UNICEF, 2016).

Competency of an employee has significant relation with expected service output or targeted outcome of an organization (Makki, *et al.,* 2018). It must be adequate to facilitate quality services to

the increasing number of vaccines for more children (MoH, 2019). Competency level and practice among staff widely vary by context and across components of the cold-chain management system (MoH, 2019; WHO/UNICEF, 2016). Hassen assessed cold-chain status and practices of immunization in India; applied a cross-sectional approach and established that; temperature of 27.3% were not within the normal range over a month; 54.5% did not arrange vaccines in fridge orderly; and 56% of staff were competent in cold-chain management (Hanson, *et. al.*, 2017), however, other variables were not captured. While, a similar cross-sectional study in Ethiopia among 232 health workers established that 57.6% of staff had a satisfactory competency and those who routinely use guidelines were 75%; and that nurses had better competence (Yassin, 2019). Both studies did not touch on any association to vaccines stability which is an interest in this study.

Dairo conducted a study in Ibadan of Nigeria to establish factors which affect vaccines handlings and storage among immunization service providers; 73% were aware of vaccine handling and storage guidelines with 68.4% having ever read it. About 65.0% had received training on vaccine management. Incorrect handling practices reported included storing syringes with vaccines (13.7%) and maintaining vaccine temperature using ice blocks (7.6%). Also, 43.0% were competent on vaccine handling. Competency of staff and their access to updates on vaccines' management were established to be associated with quality vaccines handling; at odd ratios of 10 and 5.3 respectively (Dairo *et al.*, 2016). Dairo study shares common variables with this study; however, misses to specify variance in stability of vaccines under study which is a cardinal focus under this study.

A study done by Bogale in Ethiopia with an aim of assessing factors affecting vaccine cold chain management practices among 37 immunizing health facilities, established that 48.3% knew the correct vaccine storage temperature; 38.3% of respondents had expected competency on vaccine

handling in the cold chain. Competency level and professionalism were significantly associated with quality management of vaccines (Bogale, *et al.,* 2019). The study had limited variables that could not adequately measure the competency of service providers; consequently, it felt short of specifying whether there was a relationship between competency and vaccines status in fridges.

Zelalem conducted a cross-sectional study to assess knowledge and practices of health care workers on cold chain management and associated factors in public health institutions in Amhara region, of North West Ethiopia. Through a multistage approach, random sampling method was used to select three hundred and ninety six participants. The study established that about 21.7% of respondents had good knowledge level on cold chain management. Training on cold chain management and availability of guideline at the health facility were established to be of significance to quality cold chain management. Likewise, being urban residence was also recognized as statistically significant to quality cold chain management (Zelalem, 2020). The urban variable in the study is very valid to this study and needs a follow up to rule out its association to power supply to the fridges in use.

2.5. Perception on Thermo-stability Status of Live Attenuated Vaccines

Perception is operationally defined in this study as staff thought; the process by which an individual gives meaning to the provided for procedure, or the level of motivation staff have towards the provided for cold-chain management procedures; Perception is most often influenced by environmental factors. It dictates level of staff compliance to guidelines in service delivery; consequently, dictates the expected outcome so requires much attention by management of every viable organization (Yassin, 2019; and Yauba, *et al.,* 2018).

A Study designed to evaluate vaccines exposure to temperature outside recommended range during storage and transport in Cameroon, established that freezing level was higher at facility level (51%) than at district level (31%). Heat exposure was also higher at facility level than district level; however, the levels were not indicated. Staff motivation level, gap in knowledge and use of outdated equipment were identified as main contributing factors (Yauba, *et al.,* 2018).These give an impression that more attention should be directed towards facility level in respect to finding out how specifically does the staff perception influence the quality of cold chain; how the perception can be improved and what influences the perception.

A cross-sectional study done in Ethiopia to assess perception of vaccinators and vaccines handlers on vaccines and cold-chain management in public health facilities established that forty-one (32.3%), 33 (26%), 40 (31.5%), and 24 (18.9%) vaccinators and vaccine handlers perceived that placing food and drinks with vaccines; opening refrigerators greater than 3 times a day; usage of reconstituted vaccines after 6 hours and usage of vaccine after expiration was acceptable (Mohamed, *et al.,* 2021). However, the study did not expose the data to statistical analysis to verify whether any of the variables under study had any association with the stability of the vaccines in use which is a core desire in this study.

Perception being a thought of a staff in implementing the expected task; the motivation level in carrying out her/his responsibilities of implementing the specifications in the cold-chain guideline, directly influence cold-chain management either positively or negatively (MOH, 2018). A health worker who is less motivated would be less concerned to take up his/her responsibility, this in the long run degenerates to not responding to pressing needs in cold-chain management which eventually lead to thermo-instability of vaccines (Karp, *et al.,* 2015). It is possible to identify one's

perception by asking them their views pertaining specific responsibilities; their readiness to perform certain specified tasks, and most studies done with aim of determining staff competency and perception in cold-chain guidelines establish that most staff are competent but have poor perception; very few comply with guidelines despite high level of competency (Karp, *et al.,* 2015).

A number of studies conducted on staff perception in respect to vaccines and cold-chain handling are purely descriptive; few provide inferential information, an interest that this study has. For instance, Wallace conducted a study in Nigeria to assess wastage rates and related vaccinator perception, He only highlighted descriptive data, addressing reasons why vaccines wastage happen beyond the agreed limit; vial breakage (58%), discarding doses 6 hours after reconstitution (43%) and vial exposure to high temperature (37%). Some cited vial spillage (57%) and inability to retrieve all doses from the vial (34%). They believed that leading reasons for facility-level wastage were discarding doses six hours after reconstitution (47%), an indications that staff are not comfortable with the procedure (Wallace, *et al.,* 2017).

Staff perception towards articulation of specific procedures in service delivery is enhanced by active involvement by management at various level of the program such as planning, implementation, monitoring and evaluation (Kacholi, *et al.,* 2021). Cold-chain management requires highly motivated staff willing to comply with the specifications despite un-conducive environment such as mal-functioning infrastructure, or unexpectedly higher work load than expected; thus consequently promote quality of service delivery (Yassin, 2019; Karp *et al.,* 2015).

A mixed method study which was designed to assess healthcare providers' competency, perception, practices, and challenges regarding cold chain management in Ghana, and was exposed to descriptive; inferential statistics and thematic analysis, established that overall, 67.4% of the staff

had right perception toward cold chain management, in other words were comfortable with the provided for guideline for use. However, the study established a weak and statistically insignificant relationship between participant's competency and perception toward cold chain management. The participants nonetheless raised concerns about inadequate personnel, erratic power supply, logistical constraints, and transportation difficulties in respect to quality cold chain management (Asamoah, *et al.,* 2021).The study demonstrate that one perception is hardly influenced by level of competency, a fact that encourage any researcher to separate the two variables in a mission to improve quality of antigens in the cold chain, which is a call heeded in this study.

Perception of staff on their expected task is a significant factor in acceptance and satisfaction of their expected roles. A good perception creates a positive working environment in their work station, while a negative perception affects their output level (WHO/UNICEF, 2016). Perception depends on supervisor's actions and behaviors toward staff, if the organizations are perceived as unfair, therefore, the benefits can diminish rather than enhance staff positive perception and performance (Kumar, *at al.,* 2017 and Ogboghodo, *et al.,* 2017). Good perception by staff strengthens the relationship between performance and the expectation of a satisfactory outcome (Ogboghodo, *et al.,* 2017; Kumar, *at al.,* 2017; and WHO/UNICEF, 2016). Perception as key employee competencies has a significant positive and direct impact on service performance. Employee perception is important for better performance in service business. Managers need to pay more attention for employee thoughts to ensure winning service performance (Makki, *et al.,* 2018). The concept of efficient cold-chain system management that ensures a prolonged stability of vaccines that meets the manufacturers' prescription to help sustain the efficacy has been studied

globally but still remains with gaps regarding functionality status of storage equipment and staff capacity that requires a follow up study particularly at health facility level.

2.6 Theoretical Frameworks

Vaccines are delicate biological substances that can become less effective or destroyed if they are either frozen; or allowed to get too hot / exposed to direct sunlight or fluorescent light (Karp, *et al.*, 2015, MOH, 2019). Loss of vaccine effectiveness is cumulative and cannot be reversed; thus, one handling vaccines remains responsible for their potency at every stage of the cold-chain (MOH, 2019). For Vaccines to sustain their potency/ stability, cold Chain system must remain efficiently functional from the manufacturer; during transport, up to service delivery point, the health facilities and community by maintaining temperature at the expected range of 35°F (2°C) to 45°F (8°C) (MOH, 2019).

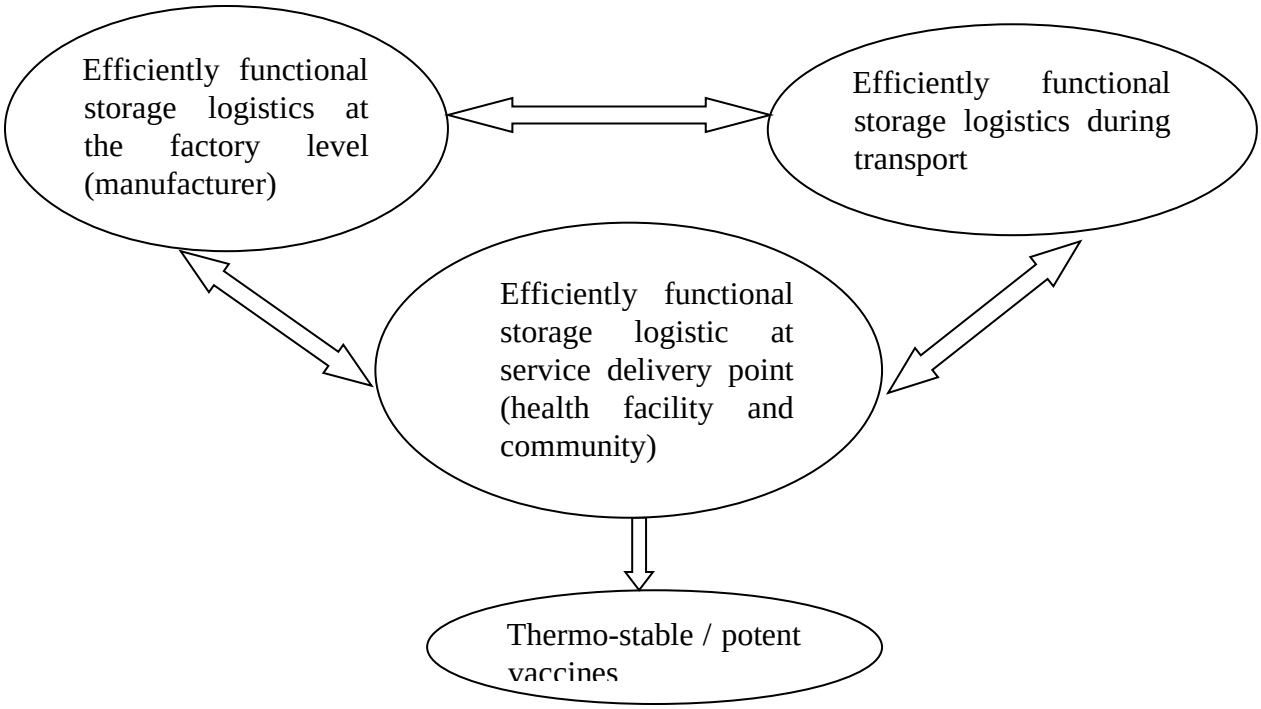

Fig 2.3 Theoretical Framework for sustaining thermo-stability of vaccines world-wide (source: MOH, 2019)

The requirements for thermo-stability of vaccines, (Figure 2.3) dictate a need for an efficient functional cold-chain storage logistics/ technology which are described under this study as fridges, cold-boxes and vaccine carriers (Karp, *et al.,* 2015). Technology in cold-chain is complete when power supply is also factored in. Technology does not work in isolation but depends more on the Capacity of staff to operate it (Karp, *et al.,* 2015, MOH, 2019). Capacity of staff is defined as level of staff compliance to guideline provisions; their competency and positive perception on guidelines dictates; which are closely associated with facility ownership and the level of operation, referred to as system design or environment status by Karp, (Karp, *el al.*, 2015).

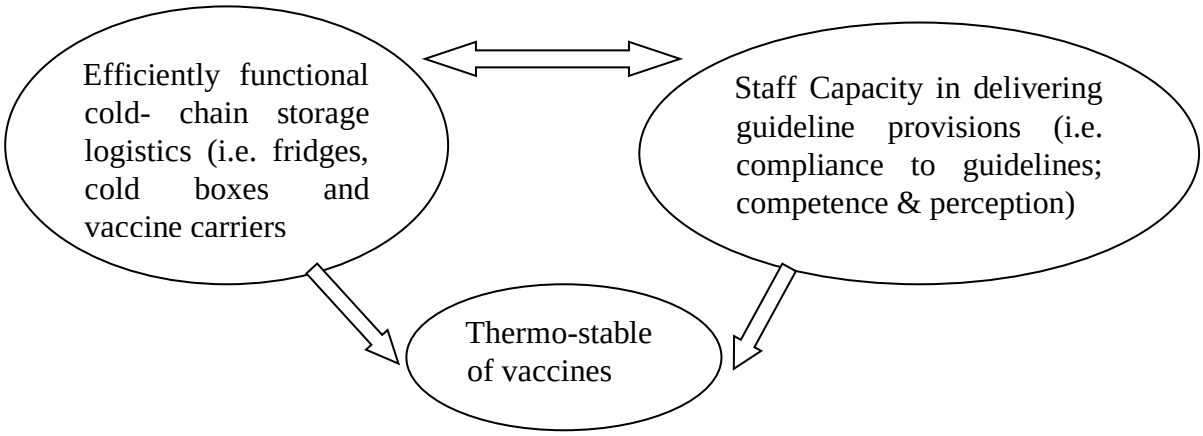

Fig 2.4 Theoretical Framework for improving vaccine thermo-stability to increase vaccine impact in low and middle-income countries (source: Karp et al., 2015)

2.7 Conceptual Frame Work

The framework, (Figure 25) is based on the main pillars of cold-chain management which are service providers' capacity to adhere to the guidelines; and the functionality level of the equipment to address the objectives of the study. In the context of the study, the main drivers of quality cold-chain management are competency levels and perception nature of a service provider. When a service provider is well equipped with expected competency, and is motivated to serve, he/she will be capable of facilitating a conducive environment that maintains thermo-sustainability of vaccine.

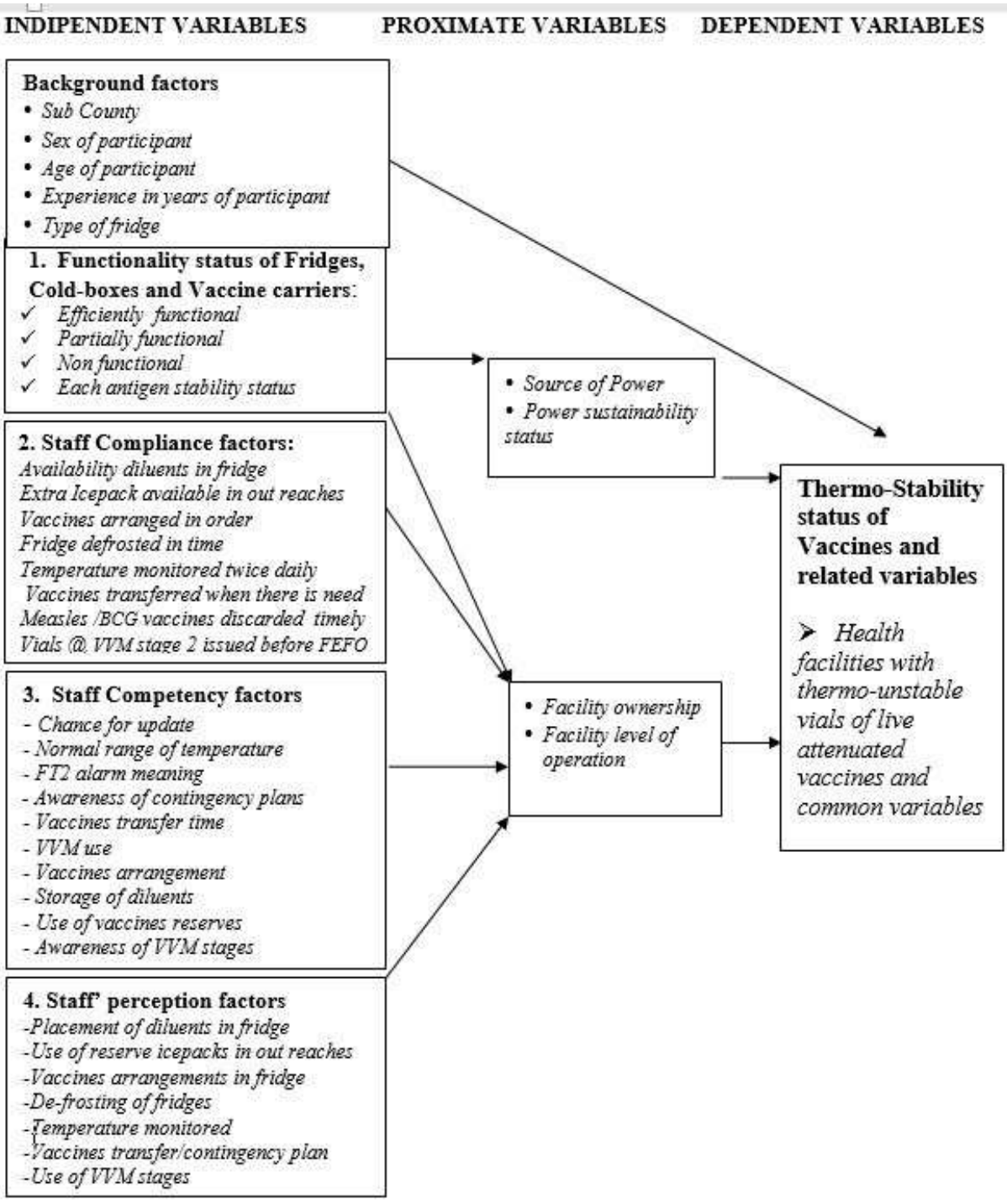

Figure 2:5 Conceptual Frame-work influence of equipment and staff capacity on vaccines thermo-stability

CHAPTER THREE:

METHODOLOGY

3.1 Introduction

In this chapter the research thinking is summarized. It reveals the approaches taken and portrays the design applied, the population sampling technique adapted, the sample size, data collection tools and methods; the reliability and validity of the research instrument are specified. Also included are the statistical models that are used to test the hypothesis.

3.2 Study Area

The study was conducted at immunizing health facilities in Kisumu County. Kisumu was purposively selected due to comparative higher resurgences of most diseases immunize-able by live attenuates vaccines such as measles; Rota diarrhea and tuberculosis (Appendices 8, 9 and 10). Data indicate that measles out- breaks in the County were hardly consistent with vaccination coverage trends for a period of time prior to this study, thus was unlike other randomly sampled Counties in Kenya (Appendices 12 and 16). Kisumu is also one of the Counties in Kenya that are classified as risk zones for measles Outbreak (MoH, 2018). The County is located in Western Kenya along the shores of Lake Victoria and covers an approximate area of 2,086 square kilometers. It lies between latitude 0°2' North; 0°15' South, and between longitudes 34° - 35° East (Appendix 18). It has an average room temperature ranging from 22^0C to 36^0C and seasonal rainfall which are non-predictable with a projected population of 1,115,014 people; an average of 3.5 per cent of the population were targeted children for immunization and 3.8 per cent represented antenatal mothers who are to be immunized against tetanus (KNBS, 2019**).**

At the time of the study the County had about 170 functional static immunizing health facilities which regularly provided routine immunization services (Appendices 35 to 40), they were; Public; Private and Faith based. Apart from clustering of health facilities based on their ownership, they were further stratified into either level two or three and above. Health sector, particularly, at Kisumu County experiences challenges of inadequate functional infrastructures such as partially functional storage equipment and irregular power supply to some facilities. There are scarce skilled human resource; for instance a level two health facility having an average of two nurse staff instead of five; a fully functional Maternal Child Health and Family Planning (MCH/FP) clinic at level four health facility having an average of six nurses instead of twelve; inadequate financial allocations compromises quality of immunization services among others (MOH, 2015). However, it is worth noting that the County has gradually improved in terms of immunization coverage from 75% in 2014 to above 82% (KHIS, 2014; 2015; 2017; 2018 and 2019).

3.3 Study Design

This was cross-sectional analytical observation study design applying both quantitative and qualitative approaches of data collections based at health facilities which were authorized to offer immunization services by Ministry of Health. In each sampled facility, Nurses who were on duty and charged with responsibility of managing cold-chain logistics and vaccines were procedurally interviewed to assess their competency and perception levels in cold-chain management. In a facility where such nurses were more than one, a simple random sampling was conducted to settle on one respondent. Storage logistics were then observed to assess their functionality status; vaccines thermo-stability status; and the level of compliance by staff on the provided for procedures.

3.4 Study Population

The study population was service providers in the 170 health facilities. All happened to be nurses.

3.4.1. Target Population:

Target population were nurse staff at health facilities which are allowed to offer immunization services and mandated to handle vaccines, alongside storage logistics such as fridges, cold boxes and vaccine carriers within Kisumu County.

3.4.2 Inclusion Criteria

The following criteria were used to include a participants in the study: The staff had to come from a registered health facility in Kisumu County which is authorized to offer routine immunization services according to the county government of Kisumu; these facilities were either to be public; faith based; or private; the respondent must have been assigned the responsibility of managing the cold-chain logistics and vaccines at the facility level including outreaches as per the duty roster in the facility.

3.4.3 Exclusion criteria

Service providers who were neither authorized to handle cold chain logistics nor vaccines from the 170 immunizing health facilities sampled facilities was not qualified to participate in the study.

3.4.4 Sampling Frame

Sampling frame included a list of one hundred and seventy health facilities in Kisumu County which offered routine immunization to pregnant women and children below one year.

Table 3:1 Sample Frame (Immunizing Health Facilities, in Terms of Ownership and Levels)

Sub-County	Level 3 & Above Hospitals			Health Facility Level 2			Facilities Total Per Sub County
	Public	FB	PR	Public	FB	PR	
KISUMU EAST	9	3	10	14	0	11	47
KISUMU WEST	3	0	4	13	0	3	23
MUHORONI	3	0	2	18	0	8	31
SEME	3	0	0	21	1	0	25
NYANDO	3	0	3	14	0	0	20
NYAKACH	4	0	4	13	0	3	24
TOTAL POPULATION	**25**	**3**	**23**	**93**	**1**	**25**	**170**

Key: *Ownership (i.e. Public health facilities; FB – Faith Based organization facilities; PB – Private health facilities. (Health department, government of Kisumu County 2016*)

3.4.4 Sample Size

In the study, Yamane's (1967) in Israel, G.D., (2013**)** simplified formula was adapted to calculate sample sizes in each stratum. The sample size estimation is considered a 95% confidence level and precision level, e = 0.5; the formula addresses the degree of variability in the attributes being measured and so, efficiently addresses the study purpose as demonstrated (Makki, *et al.,* 2018; Krebs, *et al.,* 2006; D'Andrrea , *et al.,* 2017; and Otabor, *et al.,* 2016).

$$\mathbf{n} = \frac{\mathbf{N}}{1 + N(e)^2}$$

Where: N = Population size; **n** = Sample size required; **e** = precision level (0.05); **1** = Statistical figure; while, Level of significance = 0.05.

Therefore sample size **=** ***170 / (1+170(0.05)^{2,}***

= 170 / (1+0.425), = 170/1.425

= 120 health facilities (with 1 fridge observed and 1 staff per facility interviewed). A total of one hundred and twenty health facilities were included in the study. In each facility one fridge for vaccines and a maternal child health in-charge was selected on day of visit.

Table 3:2 Sample Size Distribution

Sub County	Population	Level 3 And Above (Hospitals)		Level 2 Health Facilities		Total: Health Facilities / Samples
		GOK	FB /PR	GOK	FB / PR	
KISUMU EAST	POPULATION	6	13	17	11	47
	SAMPLE	4	9	12	8	33
KISUMU WEST	POPULATION	3	4	13	3	23
	SAMPLE	2	3	9	2	16
MUHORONI	POPULATION	3	2	18	8	31
	SAMPLE	2	1	13	6	22
SEME	POPULATION	3	0	21	1	25
	SAMPLE	2	0	15	1	18
NYANDO	POPULATION	3	3	14	0	20
	SAMPLE	2	2	10	0	14
NYAKATCH	POPULATION	4	4	13	3	24
	SAMPLE	3	3	9	2	17
TOTAL		**25**	**26**	**93**	**26**	**170**
SAMPLE		18	18	65	19	120

Key: GoK *– Government of Kenya (Public health facilities);* ***FB*** *– Faith Based organization facilities;* ***PR*** *– Private health facilities*

3.4.5 Sampling Procedures

Multistage random sampling approach was adapted to accommodate the hetero-gene-city of the study population characteristics (ownership and levels of operation) and give equal chance to every participant as encouraged by Mugenda and Yamane (Mugenda, *at el.,* 2003; and Yamane, 1967). Initially (first stage) health facilities were clustered into Sub-Counties; second stage, they were clustered into Public; faith based; and private; third stage, the same facilities were then stratified into either level three and above, or two. Stratified random sampling technique was applied to identify specific facilities to be involved. A duty roster in use per health facility was then used to

randomly sample a service provider in facilities where there was more than one staff charged with responsibility of managing cold-chain and vaccines. Purposive sampling was also done where there was a single staff in the facility in charge of cold chain management (Mugenda, *et al.*, 2003; and Yamane, 1967).

3.5 Data Collection Tools and Procedure

The study used semi-structured questionnaire customized to capture data for objectives one and two (Appendices 30 and 31); that is, the assessment of the associations between functionality level of fridges, cold-boxes, vaccine carriers and thermo-stability status of live-attenuated vaccines; and whether compliance level by staff on cold-chain guideline had any association with thermo-stability of live attenuated vaccines. The next tools were semi structured questionnaires and a Likert scale (Appendices 32 and 33) customized to measure competency and perception of staff on cold-chain guideline procedures and association with thermo-stability of live attenuated vaccines at facility level respectively. Likert's scale is highly recommended tool when a researcher wants to convert his/her qualitative data into quantitative information (Mugenda, *et al.*, 2003).

Data collection involved visiting each sampled facility each morning before the opening of fridge and at 2pm before vaccines are returned to fridge. In each facility, immunization service provider on duty on that material day was randomly sampled especially in a situation where they were more than one as guided by duty rosters; however, service providers who were alone were conveniently recruited. Administer questionnaire indicating their competency and perception on cold-chain management guideline as stated in (MOH, 2019). Fridges, cold boxes and vaccines carriers were also observed through the guidance of the semi- structured checklist and Fridge tag2 gadgets to assess both compliance level by staff to cold-chain management guidelines and functionality status

of the cold-chain storage logistics. The reports from fridge tag2 device and VVMs' color codes, guided the determination of the association between variables under study.

3.5.1. Units of analyses and observation

Immunizing health facility /Service providers who manage cold-chain storage logistics (i.e. fridges; vaccine carriers and cold-box) and vaccines was the unit of analysis; while the fridges, vaccine carriers and cold-boxes were the units of observations.

3.5.2 Validity and Reliability

For the purpose of ensuring that the quality of the data collected were valid and reflected the true picture on the ground, a number of preparations were under taken by the researcher; first, the identification of 12 enumerators and training them on the tools to orient them on the objectives of each tool and questions, so that when they would be asking the questions at the field, the response from the subjects would be able to address the intended objectives for quality analysis at the end; second, the tools were made reliable through test and retest till an Alpha of 0.8093 was obtained in similar health facilities which were not within the sample of the study (Gliem, *et.al.*, 2003). The tools were then reviewed according to the findings before the actual exercise, all of which were made in English language; third, every data tool was cleaned by both enumerators and researcher to rule out possible errors before entry.

3.6 Data Analysis and Interpretation

Data were coded and cleaned to ensure that each and every tool used was accurately administered based on the objectives. Where omission was detected, a revisit was conducted to ensure that the accurate information was documented. This was then followed by quantitative data entry into SPSS

version 20 soft-ware data base for analysis; consequently, qualitative data captured from the field for objective one and two were categorically coded and entered into Quality Solution Research (QRS) N-Vivo software, then categorized and thematically analyzed; Coding frame for the qualitative data is well demonstrated in appendix 50, (Miles, *et al.,* 2014*; and* Lewins, *et al.,* 2007). Examination was made to isolate, identify and rectify any inconsistency.

Overall quantitative data analysis flowed from descriptive, bivariate then lastly the predictors of stability were adjusted for in a binary logistic regression model. The association between independent on outcome variable under each of the objectives were ascertained by Pearson Chi-square statistical analysis and Fisher's exact test in cross tabulation (Karl Pearson, 1995).

Stability status was organized per antigen. The live attenuated vaccines that the study focused on were: Oral Polio Vaccine (OPV), Measles/Rubella (MR), Bacille Calmette Guerin (BCG) and Rotavirus (ROTA). The other vaccines in the fridges whose thermo-stability were initially reported just for comparison purposes were: Inactivated Polio Vaccine (IPV), Tetanus Toxoid (T.T), Diphtheria, Pertussis, Tetanus, Hepatitis-B / Haemophilus Influenza-b (Pentavalent) and Pneumococcal Vaccine 10 (PCV10). Each antigen was classified as thermo-stable or thermo-unstable based on the operational definition of stability (VVM stage 1 and 2 were rated thermo-stable, while VVM stage 3 and 4 as thermo-unstable). The overall percentage of thermo-stability was calculated by dividing the counts for the rating "thermo-stable" for each facility by the 8 antigens and multiplying by 100. The median of vaccine thermo-stability rating was then used as the grouping criteria for thermo-stability.

3.6.1 Functionality Status of Cold-Chain Equipment

Functionality status of equipment was initially classified as fully functional, partially functional and nonfunctional for fridges, cold boxes and vaccine carriers. To get the overall functionality level of cold chain per health facility, variables were converted into continuous by assigning values to the status of each equipment, such that fully functional equipment was assigned 1, partially functional 0 and non-functional -1. The count for each facility was done and divided by the product of number of cold chain equipment that is 3, (the maximum functionality rating) and converted to percentage. Those with 100 percent functionality score were reclassified as having functional cold chain and those with less were classified as not having full functional cold chain so as to run 2x2 cross tabulations for chi-square statistics. Nonetheless, the qualitative information at this objective was coded, categorized and analyzed thematically to identify evolving themes.

3.6.2 Staff Compliance to Cold-Chain Management Guideline

Apart from the overall analysis for all variables, compliance to cold chain management guidelines within the facilities as an objective was also tested based on thirteen aspects drawn from principles of cold chain management namely: diluents for immediate use placed in a fridge or carrier; availability of extra icepacks during outreach; arrangement of vaccines in fridge defrosted as per the policy guideline; temperature monitored twice daily and recorded; manual temperature record is consistent with temperature record in FT2; vaccines transferred when there is need; measles/rubella and BCG vaccines discarded within six hours of dilution and multi-dose vaccines being used for a maximum of 28 days. Others were; vials with VVM stage 2 are issued ahead of those of those with first expiry and VVM is recorded for all issued vaccines in ledger book. A compliant (Yes) was coded 1, while non compliant (No) was coded “0”. This count of compliance per facility for each of

the thirteen aspects was then converted to overall compliance by dividing it by 13 and made into a percentage. These were then made into binary variable using a score of 70% which was a median as the grouping criteria; those facilities with percentage compliance rating from 70% and above were rated as compliant to cold chain management guidelines; consequently, qualitative information was coded, categorized and thematically analyzed.

3.6.3 Competency Level of Staff in Cold-Chain Management

The competency of the staff as an objective was measured by seven aspects namely: awareness of normal range of temperature for effective vaccine storage; interpretation of FT2 Alarms; action to take for Fridge fault beyond their ability to resolve; action to take for vaccines in fridge with fault that can't be resolved immediately; handling vaccines based on VVM; stock management based VVM stage and early expiry and arranging vaccines as per heat sensitivity. An awareness score (Yes) was coded 1, while non awareness score (No) was coded "0" The count for each of the seven per respondent were done and divided by 7 and multiplied by 100 to convert into percentage. Overall competency was converted into bivariate variable by classifying those who had at least 70% as competent and those who got less as in competent as grouping criteria.

3.6.4 Staff Perceptions to Cold-Chain Management

This was measured by a 5 point Likert scale. The Likert scale aspects were assigned numeric values with provision for reverse coding for those that were negatively worded. The numeric values assigned were: strongly agree (5); agree (4); neither agree nor disagree (3); disagree (2) and strongly disagree (1). The median for Likert scale rating for each of the 9 variable for standard vaccine management was established. These medians were used to regroup perception under each aspect as either "right perception" or "wrong perception" to allow bivariate analysis. Overall

perception was established by adding the rating per aspect for each respondent and dividing by 45 (bearing in mind the maximum score for Likert scale is 5 and that the aspects assessed per respondent are 9) and converted to percentage. This was equally converted to bivariate data using the median (80% as grouping criteria where those with perception rating less than the median were classified as having wrong perception (coded 0) and those with perception rating more than or equal to the median were classified as having right perception (coded 1).

3.7 Ethical Considerations

To help safeguard credibility of this study and also protect rights and privacy of participants a number of consideration were undertaken; first, approval was sought and obtained from school of post graduate studies and Maseno University Ethics Review Committee. Approvals were also sought and obtained from the Director of Medical services Kisumu and the entire six sub County Medical Officers of Health. Each health facility in charges gave permission to access respective facility to conduct research.

Finally, all respondents were taken through research procedures explaining to them their rights to participate, benefits, risks, anonymity and confidentiality as follows: Participation in the study was to volunteer, a participant was free to participate or not, free to decline answering some parts of the questions which they were not comfortable with and would still remain in the study, that there were no direct benefit to one as a participant; however, participation was to help provide ideas and information that would enhance quality of immunization services in Kisumu County and beyond. The information obtained was to be kept confidential under lock and key; with a pass word on a private computer; and could only be shared with one's permission; that, a participant's name was

not to be required but each health facility MFL code. Both hard and soft copies of the generated data were then stored in lockable cabinet and pass-word protected computer.

3.8 Study Limitation

The study only captured vaccines thermo-stability level using vaccines vials monitors, other variables such as stabilizers; adjuvant; preservatives; and biological variables which required laboratory titer test were not included, these did not affect the findings as explained by Zipursky, *et al*., (2017). The sample size was maintained at 70% to take care of any intervening factors; consequently ensure results validity (Yamane, 1967).

3.9 Dissemination and utilization of the research findings

There are already two publications from this study to index journals, the International Journal for Health, Medicine and Nurses Practice; and International Journal for Innovation Research and Development have been made. Further activities will be arranged for policy makers at various level of the government. The findings shall also be presented as a feed back to Kisumu County Health stakeholders' forum.

CHAPTER FOUR:

RESULTS

4.1 Introduction

This chapter reports the findings by objectives and is organized as per the conceptual framework. The results for every objective flow from descriptive analysis, bivariate analysis for inclusion criteria (p= value of ≤0.05) in the final binary logistic model which has been used for making inference between predictor and outcome variables. p= values, Chi-square values; Odds Ratios and 95% confidence interval (CI) were used to demonstrate significance and the strength of association between selected variables. Significance was assumed at p= value ≤0.05 in the final model.

4.1.1 Socio-Demographic Characteristics of Respondents and Facility Information

Table 4:1.1 presents the distribution of the demographic characteristics of the respondents and facility characteristics. A total of 120 respondents were interviewed as were the number of facilities surveyed. The mean age of the respondents was 41.5±10.3. Those below 35 years were 33.3%, while 75.8% of who were females, while males were 24.2%. Majority, 87.5% of the staff had worked for more than 2 years. Out of the health facilities visited 69.2% were public; most (71.7%) were level 2. Private and faith based facilities were 30.8%. Fridges which met the standard for EPI operations were 75%. A total of 58.3% of the fridges had sustainable power supply while 41.7% were not. None of the variables had association with thermo-stability of any vaccines.

Table 4:1.1 Staff and Facility Characteristics:

Variable		Frequency n (%)	χ^2 value (95% CI)	p-value
Gender	Male	29(24.2)	0.272(0.573-0.743)	0.602
	Female	91(75.8)		
	Total	120(100)		
Experience in years	Less 2 years	15(12.5)	1.720(0.195-0.355)	0.190
	Two years and above	105(87.5)		
	Total	120(100)		
Age in years	21-35 years	40(33.3)	0.817(0.337-513)	0.366
	More than 35 years	80(66.7)		
	Total	120(100)		
Facility Ownership	Government	83(69.2)	0.102(0.747-0.886)	0.739
	Private/Faith Based	37(30.8)		
	Total	120(100)		
Level of operation	Level 2	86(71.7)	0.158-0.309	0.190
	Level 3 and above	34(28.3)		
	Total	120(100.0)		
Types of fridge	EPI	90(75.0)	0.545(0.512-0.688)	0.461
	Non-EPI	30(25.0)		
	Total	120(100.0)		
Power sustainability	Yes	70(58.3)	2.882 (0.059-0.174)	0.090
	No	50(41.7)		
	Total	120(100.0)		

Key: Significance was determined by Pearson Chi-square analysis; CI=confidence Interval and P≤0.05 was significant;

4.1.2 Thermo-stability Status of Vaccines per Sub County

Overall thermo-stability of vaccines was looked at across each Sub County based on vvm. All Sub counties reported some level of thermo-instability; Kisumu East had 54.5% thermo-stable; Kisumu West, 50%; Muhoroni, 59.1%; Nyakach, 58.8%; Nyando, 42.9%; and Seme 22.2%. In overall the average thermo-stability level of vaccine was 49.2%; meaning, a half of the health facilities visited had at least one antigen thermo-unstable, all of which were live attenuated vaccines (Table 4.1.2).

Table 4:1.2 Sub County and thermo-stability level for all antigens

			Stability of Live Attenuated Vaccines		Total
			Unstable	Stable	
Sub County	Kisumu East	% within Sub County	45.5%	54.5%	100.0%
		% of Total	12.5%	15.0%	27.5%
	Kisumu West	% within Sub County	50.0%	50.0%	100.0%
		% of Total	6.7%	6.7%	13.3%
	Muhoroni	% within Sub County	40.9%	59.1%	100.0%
		% of Total	7.5%	10.8%	18.3%
	Nyakatch	% within Sub County	41.2%	58.8%	100.0%
		% of Total	5.8%	8.3%	14.2%
	Nyando	% within Sub County	57.1%	42.9%	100.0%
		% of Total	6.7%	5.0%	11.7%
	Seme	% within Sub County	77.8%	22.2%	100.0%
		% of Total	11.7%	3.3%	15.0%
Total		% within Sub County	50.8%	49.2%	100.0%
		% of Total	50.8%	49.2%	100.0%

4.1.3 Overall Thermo-stability Status of each Vaccine in the County

The study established that Oral polio vaccine was most affected, 43.3% (n=52) of the facilities visited for the study had at least one thermo-unstable oral polio vaccine in the storage equipment. Measles /rubella vaccines were reported to be thermo-unstable in 25% (n=30) of the facilities visited and Rota were unstable in 10% (n=12) of the same facilities; however, it was worth noting that BCG vaccine though classified as live attenuated vaccine was unexpectedly more thermo-stable than two inactivated vaccines, sharing thermo-stability level with tetanus toxoid (Table 4:1.3).

Table 4:1.3 Thermo-stability rating per Antigen

Antigens as EPI Program	**Thermo-stability rating per antigen**	
	Thermo-stable n (%)	**Thermo-unstable n (%)**
Oral Polio Vaccine (OPV)	68(56.7)	52(43.3)
Measles /Rubella Vaccine (MR)	90(75)	30(25)
Bacille Calmette Guerin (BCG)	119(99.2)	1(0.8)
Rotavirus Vaccine	108(90)	12(10)
Inactivated Polio Vaccine (IPV)	113(94.2)	7(5.8)
Tetanus Toxoid	119(99.2)	1(0.8)
Pentavalent (DPT/HepB/Hib)	117(97.5)	3(2.5)
Pneumococcal Vaccine 10 (PCV10)	120(100)	0(0.0)

Key: n=120

4.2 Association between Functionality of Fridges; Cold-boxes; Vaccine carriers and Thermo-stability status of Live-attenuated Vaccines

This section presents the findings of objective one which was assessing whether functionality status of fridges; cold boxes and vaccine carriers had any association with thermo-stability status of live attenuated vaccines.

4.2.1 Association between Functionality Level of Cold Chain Storage Logistics and Thermo-stability Status of Live-attenuated Vaccines at the Facility Level

Functionality status was classified as either fully functional or partially functional. Result indicate, 64.2% (n=77) of the fridges were fully functional while the remaining 36% (n=43) were partially

functional, Cold box (n=20) were 100% fully functional. It should be noted that cold boxes were only found in 20 health facilities under study, all of which were level three and above, meaning it was not a mandatory equipment in all facilities, meanwhile 37.5% (n=45) of Vaccine carriers were fully functional with the rest classified as partially functional; in overall 44.5% of the facilities had fully functional cold chain containers while the rest were partially functional (Table 4.2.1).

The study recognized that functionality status of the fridges was associated with the stability of live-attenuated vaccines and the statistical output shows a significant difference between what was expected and what was observed (95%C.I, 0.000-0.025; χ^2 value, 7.396; p=0.007), hence null hypothesis was rejected; the same was observed with all vaccines in the fridge (Appendix 45); nevertheless, cold boxes under study were established to be fully functional (100%), so, there was no statistical computation generated due to lack of a comparable arm. Vaccine carriers were also established to be statistically significant to the thermo-stability of live attenuated vaccines (95%C.I, 0.000-0.025; χ^2 value, 8.822; p=0.003), (Table 4.2.1); the same applied for all vaccines found in the fridge (Appendix 46 and 47). The overall cold-chain functionality was closely associated with thermo-stability of live-attenuated vaccines (95% C.I, 0.000-0.025; χ^2 value, 22.646; p<0.001) hence null hypothesis rejected.

Table 4:2.1 Association between fridges; cold-boxes; vaccine carrier's s and thermo-stability of live attenuated vaccines

Variable		Frequency n (%)	χ^2 value (95% CI)	p-value
Fridge Functionality	Fully functional	77(64.2)	7.396(0.000-0.025)	**0.007**
	Partially functional	43(35.8)		
Cold box functionality	Fully functional	20(16.7)	N/A	N/A
	Not applicable	100(83.3)		
	Total	120(100.0)		
Vaccines carrier functionality	Fully functional		8.822 (0.000-0.025)	**0.003**
	Yes	45(37.5)		
	No	75(61.5)		
	Total	120(100.0)		
Overall Cold-chain functionality	Fully functional		22.646 (0.000-0.025)	**0.000**
	Yes	53(44.2)		
	No	67(53.8.0)		

Key: Significance was determined by Pearson Chi-square analysis; CI=confidence Interval. Values in bold are statistically significant at P≤0.05, df=degree of freedom

4.2.2 Observed Cold-chain factors and Thermo-stability status of live attenuated vaccines

Through the aid of Quality Solution Research (QRS) N-Vivo, the qualitative data captured for this objective impression; some health facilities had partially functional fridges with history of erratic power supply but all their antigens were thermo-stable. The specific facilities ordered only enough vaccines from Sub County EPI store which could only last for four to five weeks; they dispensed vaccines at VVM stage two; and were strictly monitoring temperature twice daily, this gave an impression that, gaps in the cold chain functionality were efficiently addressed by adequate staff capacity in cold-chain procedure (Table 4.2.2).

Table: 4:2.2 Observed Cold-chain factors and Thermo-stability of live attenuated vaccines

OPEN CODING	*CONCEPT (AXIAL CODING)*	*CATEGORIES (SELECTIVE CODING)*	*THEORY (THEME)*
• Partially functional fridges but antigens stable, (VVM 1 or 2) • Order vaccines per demand; • Monitor temperature daily • Comply to VVM2 application	• Cold-chain functionality compromised • Staff comply to cold-chain guidelines • Vaccines are thermo-stable	Staff complied with the guideline maintained vaccines thermo-stability	Gaps in the cold chain functionality was efficiently addressed by adequate staff capacity in cold-chain procedure
• Erratic power flow to fridges but antigens stable (VVM stage 1 &2) • Order vaccines per demand; • Monitor temperature daily • Comply to VVM2 application			

4.2.3 Cold-chain functionality and predictors of Thermo-stability of live attenuated vaccines

Through Binary logistic regression model predictors of thermo-stability level of vaccines in respect to cold-chain functionality status were established. Thermo-stability of live attenuated vaccine was dependent variable, while fridges, cold boxes; vaccine carriers and overall functionality level of the cold chain were the independent variables. Partially functional is used as the reference category. Fridge functionality was established to predict thermo-stability level of live attenuated vaccines (95%C.I, 1.332-6.370; OR, 2.913; p=0.007). Vaccine carriers functionality status was also established to be of significant and predicted thermo-stability status of the live attenuated vaccines (95%C.I, 1.462 -6.884; OR 3.172; p=0.003), the same was also observed with overall functionality of cold-chain (95%C.I, 0.074-0.366; OR 0.165, p<0.001) as indicated (Table 4.2.3).

Table 4:2.3 Cold chain functionality and predictors of Thermo-stability of live attenuated vaccines

Cold chain Management Compliance		Stability of Live Attenuated Vaccines n (%)		OR	95% CI	*p*-value
		Stable	Unstable			
Fridge functional	Yes	45 (76.0)	14 (24.0)	2.913	1.332-6.370	**0.007**
	No	29(5.0)	32(95.0)			
Vaccine carrier functional	Yes	30(66.7))	15(33.3)	3.172	1.462 -6.884	**0.003**
	No	29(38.7)	46 (61.3)			
Overall functionality	Yes	38(64.4)	14 (35.6)	0.165	0.074-0.366	**<0.001**
	No	21(34.4)	47(65.6)			

Key: Odds Ratios (OR) and 95% Confidence Intervals (95% CI); p= Values in bold are statistically significant at P≤0.05; OR is the exponent of B; and "No" being the reference categories of operation

4.3 Staff Compliance Level to Cold Chain Management Guideline and Stability Status of Live Attenuated Vaccines

This section presents the findings of objective two which assessed how staff compliance level to Cold chain management guidelines would be associated with stability status of live attenuated vaccines at health facility level.

4.3.1 Association between Staff Compliance to Guideline and Thermo-stability of vaccines

The findings indicated that diluents for immediate use being in fridge or vaccine carriers were (69%)observed; availability of extra icepacks during outreach (72.2%); arrangement of vaccines in fridge that allows air circulation (98%); vaccines in fridge arranged as per the guideline (49%); fridge defrosted as per the policy guideline (78%); temperature monitored twice daily and recorded was at (69%); manual temperature record is consistent with temperature record in FT2 (40%); vaccines transferred when there was need (56%); measles/rubella and BCG vaccines discarded within six hours of dilution observed by (90%); multi-dose vaccines used for a maximum of 28

days observed by (18%). Others were Vials at VVM stage 2 being issued ahead of those with first expiry (42%); VVM recorded of all issued vaccines in ledger book during review period(63%); and overall compliance (40%), (Table 4.3.1).

Compliance on Cold-chain management by staff had various elements some of which were associated with vaccine thermo-stability while others were not. The following variables were established to had statistical association with thermo-stability of live attenuated vaccines: Availability of extra icepacks during outreaches (95%C.I, 0.006-0.077; χ^2 value, 3.906*; p*=0.048); procedurally arranging vaccines in fridge (95%C.I, 0.000-0.025; χ^2 value,8.520*;p*=0.004); Fridge temperature being monitored twice daily (95%C.I, 0.000-0.053; χ^2 value 4.214*; p*=0.040); MR & BCG discarded within 6 hours of dilution (95%C.I, 0.000-0.025; χ^2 value, 5.632; *p*=0.030); Multi-dose vaccines used for a maximum of 28 days (95%C.I, 0.001-0.065; χ^2 value,3.897; *p*=0.048); Vials with VVM stage 2 being issued ahead of FEFO (95%C.I, 0.000-0.040 χ^2 value, 5.648; *p*=0.017); and the overall compliance to cold chain guideline were all established to be statistically significant and associated with thermo-stability of live-attenuated vaccines (95%C.I, 0.000-0.025; χ^2 value, 8.520 *p*<0.001), so, null hypothesis stand rejected (Table 4.3.1).

Table 4:3.1 Associations between Staff Compliance & Thermo-stability of Live Attenuated Vaccines

Cold chain Management Compliance		Stability of Live Attenuated Vaccines		χ^2 value	95% CI	*P*= Value
		Stable	Unstable			
Diluents for immediate use in fridge or Carrier	Yes	44(60.2)	39(39.8)	1.593	0.107-0.243	0.207
	No	15(40.5)	22(59.5)			
Availability of extra icepacks in outreach	Yes	22(61.6)	6(38.4q1)	3.906	0.006-0.077	**0.048**
	No	37(40)	55(60)			
Arrangement of vaccines in fridge allowing air circulation	Yes	59(50.4)	58(49.6)	2.976	0.188-0.346	0.244*
	No	0(0)	3(100.0)			
Vaccines arranged in fridge as per guideline	Yes	37(62.7)	22(37.3)	8.520	0.000-0.025	**0.004**
	No	22(36.1)	39(63.9)			
Fridge defrosted as per the policy guideline	Yes	47(50.0)	47(50.0)	0.121	0.682-0.835	0.728
	No	12(46.2)	14(53.8)			
Temp. monitored twice daily and recorded	Yes	46(55.4)	37(44.6)	4.214	0.000-0.053	**0.040**
	No	13(35.1)	24(64.9)			
Temperature register is consistent with FT2	Yes	25(52.1)	23(47.9)	0.272	0.605-0767	0.600
	No	34(47.2)	38(52.8)			
Vaccines transferred when there is need	Yes	34(59.7)	33(40.3)	0.151	0.609-0.774	0.697
	No	25(47.2)	28(52.8)			
MR/BCG discarded within 6 hours	Yes	57(47.2)	51(52.8)	5.635	0.000-0.025	**0.030***
	No	2(16.7)	10(83.3)			
Multi-dose vaccines used for < 28 days	Yes	15(68.2)	7(31.8)	3.897	0.001-0.065	**0.048**
	No	44(44.9)	54(55.1)			
Vials with VVM stage 2 are issued before FEFO	Yes	31(62)	19(38)	5.648	0.000-0.040	**0.017**
	No	28(40.0)	42(60.0)			
VVM recorded on Vaccines ledger book	Yes	41(54.7)	34(45.3)	2.421	0.046-0.154	0.120
	No	18(23.0)	27(77.0)			
Overall compliance to cold-chain guideline by staff	Yes	35(87.5)	5(12.5)	8.520	0.000-0.025	**0.000**
	No	24(30.0)	56 (70.0)			

*Key: Significance was determined by Pearson Chi-square analysis unless for P***** which is by Fisher's exact test**.** Values in bold are statistically significant at P≤0.05*

4.3.2 Observed Compliance factors and Thermo-stability of Live Attenuated Vaccines

The qualitative data captured under this objective were also analyzed through an aid of Quality Solution Research (QRS) N-Vivo. Unusual observation captured in respect to guideline compliance were that; foodstuff and non-EPI drugs were stored with vaccines in some fridges; specifically, milk, water, Oxytocins and Kaletra drugs (*Appendix13*), that was unethical; in some specific private health facilities, diluted BCG and Measles-rubella vaccines were found returned to fridge; missing label on some re-usable/multi-dose vaccines returned to fridge; worse, some kept in a tray against the guideline (*Appendix 17 and 46)*. All these facilities reported some thermo-unstable vaccines, giving an impression that, In-adequate capacity in cold-chain management among staff, mostly from private health facilities precipitated thermo-instability of live attenuated vaccines. These were observed as resulting from weak support supervision from senior management level (4.3.2).

Table: 4:3.2 observed Compliance factors and Thermo-stability of vaccines

OPEN CODING	***CONCEPT (AXIAL CODING)***	***CATEGORIES (SELECTIVE CODING)***	***THEORY*** *(THEME)*
• Food stuff and non-EPI drugs in fridge • less support supervision, • vaccines unstable • level 2 private facilities	• Lack of compliance to cold-chain procedures by staff • Inadequate support supervision • Vaccines thermo-unstable	Failure by staff to comply to guideline precipitated by weak support supervision is linked to vaccines thermo-instability	Inadequate capacity in cold-chain management among staff precipitated thermo-instability of vaccines affecting most level 2 private facilities
• Diluted BCG / Measles returned to fridge at level 2 private facility • less support supervision • vaccines unstable			
• Opened, re-usable antigens not labeled but in fridge • vaccines thermo-unstable • less support supervision			
• All antigens kept in one tray in fridges at few private facilities • Less support supervision			

4.3.3 Staff compliance and predictors of Thermo-stability of live attenuated vaccines

Binary logistic regression model was applied to determine the predictors of thermo-stability level of vaccines in respect to staff compliance to cold-chain procedures. The dependent variable was taken as vaccine thermo-stability and different elements in staff compliance as the independent variables. "Yes", was used as the reference category. Staff compliance to temperature monitored twice daily and recording (95%CI, 0.052-0.651; OR, 0.185; *p*=0.009); Temperature register being consistent with that of FT2 (95%C.I, 1.337-9.112; OR, 5.054; *p*=0.017); and VVM used recorded ledger book (95%C.I, 0.645-6.787; OR, 2.085; *p*=0.022); and overall compliance (95% C.I, 0.001-0.025; OR, 6.021; p<0.001) were all established to predict thermo-stability of live attenuated vaccines (Table 4.3.3).

Table 4.3.3 Staff compliance and predictors of Thermo-stability of live attenuated vaccines

old chain Management Compliance		Stability of Live Attenuated Vaccines		OR	95% CI	P Value
		Stable	Unstable			
Availability of extra icepacks during outreach	Yes	12(66.7)	6(33.3)	0.566	0.137-2.339	0.432
	No	38(41.3)	54(58.7)			
Vaccines arranged in fridge as per the guideline	Yes	37(62.7)	22(37.3)	0.578	0.185-1.806	0.346
	No	22(36.1)	39(63.9)			
Temperature monitored twice daily and recorded	Yes	46(55.4)	37(44.6)	0.185	0.052-0.651	0.009
	No	13(35.1)	24(64.9)			
Temperature register is consistent with that of FT2	Yes	25(52.1)	23(47.9)	5.054	1.337-9.112	**0.017**
	No	38(52.8)	34(47.2)			
MR & BCG discarded within 6 hours of dilution	Yes	57(47.2)	51(52.8)	0.598	0.110-0.998	0.883
	No	2(16.7)	10(83.3)			
Multi-dose vaccines used for a maximum of 28 days	Yes	15(68.2)	7(31.8)	1.092	0.273-4.373	0.901
	No	44(44.9)	54(55.1)			
VVM used and recorded on all Vaccines ledger	Yes	41(54.7)	34(45.3)	2.085	0.645-6.787	**0.022**
	No	18(40.0)	27(60.0)			
Overall compliance	Yes	35(87.5)	5(12.5)	6.021	0.001-0.025	**<0.001**
	No	24(30.0)	56 (70.0)			

Key: Odds Ratios (OR) and 95% Confidence Intervals (95% CI); p= Values in bold are statistically significant at P≤0.05; OR is the exponent of B; and "No" being the reference categories of operation

4.4 Association of staff competence and thermo-stability of live-attenuated vaccines

Competency of staff was varied; 85% (n=102) were aware of temperature ranges; 64.2% (n=77), were aware of how to interpret FT2 alarms; 74.2% (n=89), new action to be taken when fridge was faulty; 53.3% (n=64) were aware of how to handle vaccines based on VVM; and overall competency 55.8% (n=67). The study established two aspects of staff competency to be associated with thermo-stability of vaccines; these were: action to be taken when fridge is faulty, (95%C.I, 0.028-0.122; χ^2 value, 3.940; p=0.047); and use of VVM stage (95%C.I, 0.028-0.122; χ^2 value 4.003; p=0.045); however, overall competency was not, hence null hypothesis was accepted (Table 4.4.1).

Table 4.4.1 Association of staff competence and thermo-stability of live-attenuated vaccines

Competency aspects		Stability of Live Attenuated Vaccines		χ^2 value	95% CI	p-value
		Stable	Unstable			
Aware of the temperature range for vaccine storage	Yes	48(47.1)	54(52.9)	1.209	0.226-0.470	0.272
	No	11(61.1)	7(38.9)			
Accurately Interprets FT2 Alarms	Yes	35(45.5)	42(54.5)	1.185	0.312-0.488	0.276
	No	24(55.8)	19(44.2)			
Aware of action to take when fridge is faulty	Yes	39(43.8)	50(56.2)	3.940	0.028-0.122	**.0.047**
	No	20(64.5)	11(35.5)			
Aware of how to handle vaccines when fridge is faulty	Yes	53(51.5)	50(48.5)	1.525	0.265-0.435	0.217
	No	11(64.7)	6(35.3)			
Aware of VVM staging	Yes	39(48.1)	42(51.9)	0.103	0.846-0.954	0.748
	No	20(51.3)	19(48.7)			
Aware of how to handle vaccines based on VVM/ Exp	Yes	26(40.6)	38(59.4)	4.003	0.028-0.122	**0.045**
	No	33(58.9)	23(41.1)			
Aware of how to arrange vaccines based on heat sensitivity	Yes	26(56.5)	20(43.5)	1.615	0.165-0.318	0.204
	No	41(55.4)	33(44.6)			
Overall staff competency	Yes	31(46.3)	36(53.7)	0.510	0.436-0.614	0.475
	No	28(52.8)	25(47.2)			

Key: Odds Ratios (OR) and 95% Confidence Intervals (95% CI); p= Values in bold are statistically significant at P≤0.05; OR is the exponent of B; and "No" being the reference categories of operation

4.4.2 Staff competency and predictors of thermo-stability of live-attenuated vaccines

Binary regression analysis was carried out to identify predictors of thermo-stability of live attenuated vaccines in respect to staff competence on cold-chain procedures. The following variables predicted thermo-stability of the vaccines under study: staff awareness of action to be taken when fridge has a fault (95%C.I, 0.955-7.397; OR, 2.658;p=0.031); awareness on how to handle vaccines based on expiry date/VVM *(*95%C.I, 0.127-0.988*;* OR,3.540*; p*=0.047*)* and staff awareness of what to do with vaccines at vvm stage3 and 4 (95%C.I, 0.890-9.821; OR, 8.301 p=0.020). However other variables did not predict (Table 4.4.2).

Table 4.4.2 Staff competency and predictors of thermo-stability of live-attenuated vaccines

Aspects of staff competency		Frequency n (%)	OR	95%CI	p-value
Overall Competency	No	53(44.2)	Ref.	0.94-1.305	0.118
	Yes	67(55.8)	0.350		
Aware of action to be taken when fridge is faulty	No	31(25.8)	Ref.	0.955-7.397	**0.031**
	Yes	89(74.2)	2.658		
Awareness of how to handle vaccines based on Expiry Date and VVM	No	56(46.7)	Ref.	0.127-0.988	**0.047**
	Yes	64(53.3)	3.540		
Awareness of what to do with Vaccines in Stage 4	No	3(2.5)	Ref.	0.890-9.821	**0.020**
	Yes	117(97.5)	8.301		

Key: Odds Ratios (OR) and 95% Confidence Intervals (95% CI); p= Values in bold are statistically significant at P≤0.05; OR is the exponent of B; and "No" being the reference categories of operation

4.5 Association of staff Perception on Cold-chain Management Guideline and thermo-stability Status of Live attenuated Vaccines

This section reported the findings of objective four, the staff perception on cold-chain management guideline and their association with thermo-stability of vaccines. The study established that 78.3% (n=94)of the staff had right perception pertaining to how diluents for immediate use should be

handled; 50.8% (n=61) of the staff had right perception on how to use icepacks during outreaches; 61.7% (n=74) had right perception on arrangement of vaccines to allow air circulation and in consideration of sensitivity to heat; 67.2% (n=77) had right perception on defrosting of fridges; 72.5% (n=87) on charting of temperature; 75%(n=90) on vaccines transfer; and 65.5% (n=75) had right perception on use of vvm in dispensing vaccines, consequently, overall perception of staff was 61.7% (n=74), (Table 4.5.1).

The following staff perception categories were established to have close association with live attenuated thermo-stability status; the perception towards vaccines arrangement in fridge based on temperature sensitivity (95%C.I, 0.890-9.821; χ^2 value, 7.023; p=0.030); and staff perception towards vaccines transfer to another functional fridge (95%C.I, 0.031-0.089; χ^2 value, 5.384; p=0.020); however, overall staff perception did not show any association (Table 4.5.1), a similar finding was also observed for all vaccines (Appendix 49).

Table 4.5.1 Association between staff Perception and thermo-stability of Live-attenuated Vaccines

Perception		Compliance with cold chain management		χ^2 value	95% CI	p-value
		Yes	No			
Perception towards diluents for immediate use put in fridge	Right	50(53.2)	44(46.8)	0.404	0.035-0.682	0.525
	Wrong	12(46.2)	14(53.8)			
Perception towards Icepacks being conditioned before use	Right	37(57.8)	27(42.2)	2.074	0.200-0.344	0.150
	Wrong	25(44.6)	31(55.4)			
Perception towards having extra icepack for outreaches	Right	36(47.5)	25(52.5)	2.684	0.100- 0.233	0.101
	Wrong	26(44.1)	33(55.9)			
Perception on arrangement of vaccines to allow air circulation	Right	45(53.1)	29(46.9)	0.201	0.663-0.820	0.654
	Wrong	19(48.7)	20(51.3)			
Perception towards vaccines arrangement in fridge based on temperature sensitivity	Right	45(60.8)	29(39.2)	7.023	0.000-0.025	**0.030**
	Wrong	17(37.8)	28(62.2)			
Perception towards defrosting the Fridges regularly	Right	44(57.1)	33(42.9)	2.580	0.093-0.224	0.108
	Wrong	18(41.9)	25(58.1)			
Perception towards charting KEPI fridge temp. twice daily	Right	47(54.0)	40(46.0)	0.703	0.411-0.589	0.402
	Wrong	15(45.5)	18(54.5)			
Perception towards Vaccines transferred to another fridge	Right	41(45.6)	49(54.4)	5.384	0.031-0.089	**0.020**
	Wrong	21(70.0)	9(30.0)			
Perception toward prioritizing VVM 2 to Expiry date	Right	36(48.0)	39(52.0)	1.077	0.312-0.488	0.299
	Wrong	26(57.8)	19(42.2)			
Overall perception on cod-chain procedure	Right	30(48)	32(52)			
	Wrong	35(60.3)	23(39.7)	1.7	.8-3.5	.147

Significance was determined by Pearson Chi-square analysis. Values in bold are statistically significant at P≤0.05.

4.5.2 Staff perception on guideline procedure and predictors of vaccines thermo-stability

Though regression analysis was performed to identify predictors of thermo-stability of live attenuated vaccines in respect to staff perception on cold-chain guideline procedures; staff perception towards defrosting of the fridges (95%C.I, 0.518-9.121; OR, 2.173; *p*=0.039) and Transfer of vaccines when fridges had default *(*95%C.I, 0.682-5.847; OR, 1.997; *p*=0.007*)* were

established to be of statistical significance and predicted thermo-stability of live attenuated vaccines (Table 4.5.3).

Table 4.5.2 staff perception and predictors of vaccines thermo-stability

		Frequency n (%)	OR	95%CI	p-value
Overall Perception	Wrong	58(48.3)	Ref.	0.175-2.553	0.557
	Right	62(51.7)	0.669		
Perception towards Vaccines being arranged in fridge based on their temperature sensitivity	Wrong	45 (37.5)	Ref.	0.142-1.425	0.175
	Right	75(62.5)	0.450		
Perception towards defrosting the Fridges regularly	Wrong	43(35.8)	Ref.	0.518-9.121	**0.039**
	Right	77(64.2)	2.173		
Perception towards Vaccines being transferred to another functional fridge when there is fridge fault	Wrong	30(25.0)	Ref.	0.682-5.847	**0.007**
	Right	90(75.0)	1.997		

Odds Ratios (OR) and 95% Confidence Intervals (95% CI); p= Values in bold are statistically significant at P≤0.05; OR is the exponent of B; and "No" being the reference categories of operation

CHAPTER 5:

DISCUSSION

5.1 Functionality of Cold-chain Storage Equipment

Government facilities are 100% compliant with EPI fridges; however, in private facilities there are 0.0%; worse, there are insignificant support supervision by program leadership to the same private institutions, particularly clinics which are level two, these created an impression that there was a managerial biasness, which sort of provided reasons why private health facilities had comparatively more gaps than public institutions in most variable under study. Ministry of health highlights the need of strengthening regular support supervision to all service providers to help them sustain quality service provision and efficient cold-chain system for the sake of maintaining vaccines viability (MoH, 2019); however facilities which were less supervised had more nonfunctional challenges in Kisumu County.

Cold-chain storage equipment functionality status was a determinant of thermo-stability status of live-attenuated vaccines. Whereas it is expected that 100% of cold-chain equipment should be functional and on sustained power supply to maintain thermo-stability of all vaccines (MoH 2019), the overall efficient cold-chain functionality was (44.2%); fridges functionality (64.2%); and vaccine carriers' functionality (37.5%), all elicited significant relationship with vaccines thermo-stability. In Kisumu, 58.3% of fridges were on sustained power supply; worth noting, was that, all fridges were vulnerable to unacceptable temperature excursions and thermo-instability during power outages. JSI in Kenya found slightly higher proportion of functional fridges, only 10 - 20% malfunctioning (JSI. *et. al*., 2019). The findings depict a fundamental gap in the cold-chain system at health facility level that requires a focus from management. It also alludes to what Karp observed

that, efficient functional equipment for cold-chain at health facility-level is still elusive globally (Karp, *et al.*, 2015).

The study established that generators which might have provided back-ups were available in only 21% of these health facilities; worse, only10% were functional, all were manually operated with operational cost being reported as unsustainable by some facilities, this worsened by response inertia; however, Kisumu County would be termed better off if compared to what Maglasang found in Philippines, where about 90.9% of the health facilities did not have access to a generator for back up (Maglasang, *et al.,* 2018), a finding which is accredited to strengthened partnership between national government and GAVI. Cold-chain system requires a functional power supply and prompt attention whenever there is a power outage event for the sake of quality antigens. Power supply in western Kenya is largely erratic (MOH, 2015) thus increasing vaccine vulnerability.

The nature of vaccines thermo-instability observed within the cold-chain system at health facility level in Kisumu, confirmed that live attenuated vaccines (OPV; measles-rubella; and ROTA) were at a higher risk than the inactivated vaccines (IPV, Penta T.T and PCV10) except for BCG which was 99.2% thermo-stable, surprisingly more thermo-stable than most inactivated vaccines. The finding agreed with observation made by Mychaleckyi and Parker who established in separate studies that OPV is at a very higher risk of thermo-instability so recommended a booster doses of IPV to improve immunity among individuals previously immunized with OPV (Mychaleckyi, *at al.,* 2016, and Parker *et al.,* 2015,). This justifies the need for additional attention to live attenuated vaccines by stakeholders in respect to maintaining their thermo-stability; however, Ram found only 93% of thermo-stable OPV (Ram *et al.,* 2018), credited for efficient cold-chain functionality.

Even though the level of facility operation did not indicate any association with vaccines thermo-stability, level two private facilities had multiple cold-chain system gaps in respect to functionality of fridges, most of which, 41.5% were using electric grid power source without any backup, yet power outages was occasionally experienced. Malfunctioning of the cold-chain equipment at the health-facility level contributed significantly to the observed thermo-instability status of live-attenuated vaccines; nonetheless, a similar study by Kumar in India found 30% of fridges with power failure (Kumar, *at al.,* 2017); this difference could be attributed to increasing power supply arrangements by national government in Kisumu County. Breach in cold-chain can be disastrous in terms of epidemic outbreaks and potential costs involved. Cold-chain system maintenance in Kenya remains a responsibility of the division of vaccine and immunization at National level despite health unit being a devolved function of the Counties government. It's still unclear how well these roles and their implementation are being integrated.

Overall functionality of storage equipment were of significance; however, the study only established that 44.2% of the health facilities had fully functional cold-chain storage equipment, this seem to agree with what Franzel observed in her study that Cold-chain equipment may fail or underperform in almost 20 to 50% of GAVI-eligible countries due to factors related to power supply, so recommended solar drive fridges as most preference (Franzel, *et al*., 2017b). However, Kisumu County is yet to adapt that due to National government arrangement of availing electricity to all government institutions. Ministry of Health believes that it is possible to have dysfunctional storage equipment with vaccines in Kenya, precipitating vaccines degradation (MOH, 2019).

5.2. Association between Staff Compliance to Cold-chain Management Guidelines and Stability Status of Live attenuated Vaccines at Health Facilities in Kisumu County

The overall compliance by staff on cold chain procedure was established to be very low, 33.3% but was highly associated with vaccines thermo-stability. WHO recommends at least 85% orderly arrangement of vaccines in the fridge (WHO, 2015c). Similarly, Koskei observed 50% orderly arrangement of vaccines in fridge in Pockot (Koskei, *et al.,* (2017); Bogale in Amhara region observed 53.4% (Bogale *et al*., 2019), indications that the management is yet to give adequate attention to guideline compliance in many Countries. Use of extra icepack during outreach and VVM to dispense vaccines by service providers as recommended by the Ministry of health (MOH, 2019) was not regular. This significantly impacted negatively on thermo-stability of vaccines and attributed to laxity in the program managers.

Though multi-dose vaccines use for 28 days as recommended, significantly improved thermo-stability of vaccines, it was only observed in 18% of the facilities, a finding which affected OPV more than any other antigen. Likewise, use of VVM staging for dispensing vaccines, a new innovation which helps in reducing vaccine wastage and prolonging their stability period, was observed by very few facilities, 42%. Other non-compliance issues noted were: availability of foodstuff and non-EPI drugs in few fridges at level two private health facilities; diluted BCG and Measles-rubella vaccines returned to fridges; opened re-usable vaccines not labeled. All these facilities reported high level of thermo-unstable vaccines, credited to inadequate support supervision by program managers. Ministry of Health reiterates that poor vaccine-handling practices have large financial consequences, thus there is need for service providers to adhere to the guidelines (MOH, 2019). Recent studies confirm that compliance of staff to guidelines remain low

to average in different regions (Yauba, *et al.*, 2019; 2018; and Ringo, *et al.*, 2017; Saraswati, *et al.*, 2017). This observation is likely due to the possibility that, program managers are yet to give service providers right approach in improving crucial aspect of the program.

5.3 Association between Competency Level of Staff on Cold chain Management and Stability Status of Live Attenuated Vaccines at Health Facility Level

The study findings revealed that overall competency of staff on cold-chain management was above average, 55.8% but below WHO standards of 85%. Hanson, *et al.*, (2017) and Yassin, (2019) observed that 57.6% health professionals had a satisfactory awareness, yet those who routinely use guidelines effectively were 75%. This observation could be attributed to the fact that awareness alone does not promote quality of services; nonetheless, other factors such as team work; regular consultation among service providers and program linked managers would significantly facilitate quality outcome in respect to maintaining the thermo-stability of live attenuated vaccines.

Both awareness of action to be taken by staff for vaccines when a fridge was faulty and how to handle vaccines when VVM was at stage2, were also below WHO expectation of 85%; however, they both contributed significantly to maintenance of thermo-stability of vaccines; WHO appreciates that competency level among staff, vary by context and across components of the cold-chain management system (WHO/UNICEF, 2016), an observation which was also reflected in this study. Lutukai, in other words found that Nurses were relatively more competent on vaccines management as compared to other cadres (Lutukai, *et al.*, (2019). Kisumu County; however, had only nurses allowed to handle vaccines and cold-chain storage logistics in sites visited. The findings are ascribed to government policy (MoH, 2019), that recommend the program to be rolled out

through nursing department who are occasionally updated on various innovations of maintaining the cold chain and vaccines viability. This qualifies the reason why private practitioners are only licensed to offer routine vaccination whenever a qualified nurse staff is availed.

5.4 Association between Staff Cold-chain Management Perceptions and Stability Status of Live Attenuated Vaccines at Health Facility Level

The findings in this study indicated considerable gaps on staff perception towards cold-chain management procedures. Perceptions were assessed in regard to performing the expected tasks. The overall right perception on cold-chain management was above average 51.7%; this was comparatively better than what Mohamed found in Ethopia 33.4 % (Mohamed *et al.,* 2021) but less than what Asamoah got in Ghana, 67.4% (Asamoah, *et al.,* 2021). However, it should be noted that perception alone has no significant influence on vaccines stability but eclectic variables in the cold-chain system management. Yassin, *et al.,* (2019) and Yauba, *et al.,* (2018) observe that perception dictates level of staff compliance to guidelines in service delivery and so, contributes to the expected outcome of viable vaccines.

The study established that institutions which were less supervised by program coordinators, particularly the level two private facilities, had both un-conducive working environment and striking cold-chain management gaps which were attributed to wrong perception by staff resulting from lack of motivation from the program linked leadership. Health workers with wrong perception would be less concerned to take up his/her expected responsibilities, which in the long run degenerates to not responding to pressing needs of cold-chain management which eventually lead to thermo-instability of vaccines (Karp, *et al.,* 2015 and WHO/UNICEF, 2016). Staff perception

depend on supervisor's actions and behaviors toward them, if a supervisor is perceived as unfair, the benefits from said staff diminish rather than enhance (Kumar *at al.,* 2017).

Perception on vaccine transfer to a functional fridge, 75% was significant and predicted vaccines thermo-stability; a finding which agrees with what Ogboghodo, *et al.,* (2017) observed that good perception by staff strengthen relationship between performance and the expectations of satisfactory outcome and credited for close support supervision by the program lined teams. The same is encouraged by Kacholi who advocate that staff perception towards articulation of specific procedures in service delivery is enhanced by active involvement by management at various level of the program such as planning, implementation, monitoring and evaluation (Kacholi, *et al.,* 2021). However, none of these studies ever reported the same.

CHAPTER SIX:

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

6.1 Summary

The study had an aim of establishing influence of facility level cold-chain storage logistics and staff capacity on thermo-stability status of live-attenuated vaccines in Kisumu County. It established that, overall low functionality of cold-chain storage logistics and poor staff compliance to the guidelines significantly contributed to limited thermo-instability of live attenuated vaccines; these were secondary to among other things, limited support supervision to facilities which were considerably affected and lacked approved logistics support.

6.2 Conclusions

1. Fridges and vaccine carriers which were not functional, significantly contributed to thermo-instability of live attenuated vaccines, particularly those at the private facilities. Functionality of fridges and vaccine carriers is critical to cold-chain storage logistics at health facility level.

2. Overall staff compliance to cold-chain guidelines was below average and this also was contributory to thermo-instability of live attenuated vaccines at health facility level.
3. Overall competency of staff on cold-chain management was below the WHO recommended threshold of 85% but had no direct association with vaccines stability status, indicating the important role of compliance with guidelines as a desirable behaviour, such as improved handling of VVM to monitor vaccines is critical in this set up.

4. The staff at level two private facilities, who also had limited access, to support supervision were the ones more likely to have poor perception of cold-chain management. These factors mediated their compliance and hence performance regarding cold-chain guideline.

6.3 Recommendations from the Study

6.3.1. Programmatic and Organizational:

1. There is need for Expanded Program on Immunization line managers to extend provision of recommended functional fridges and vaccines carriers to level two private facilities which have shown gaps and risk of vaccines instability.

2. There is urgent need for line managers of Expanded Program on Immunization to equally strengthen support supervision to staff in level two private health facilities marked with common gaps in compliance; competency and perception in cold-chain management, for updates on novel cold-chain management to strengthen their capacity.

3. Live attenuated vaccines should not be practically stored at level two private facilities for more than two weeks except for BCG.

6.3.2 Recommendation for future study

There is a need to establish impact of these results on clinical outcomes at population level.

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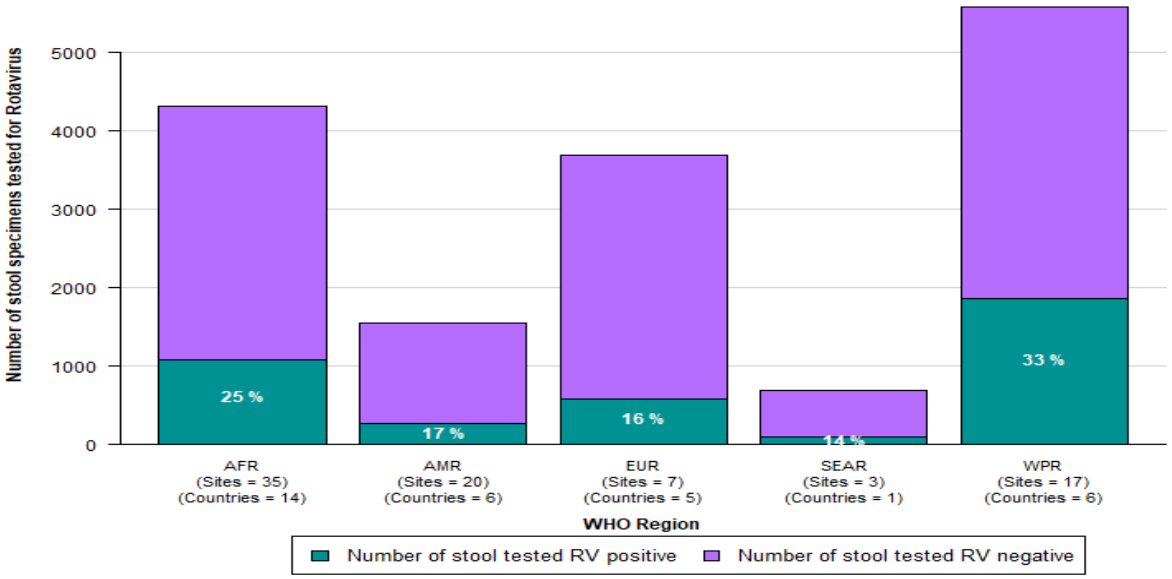
APPENDICES

Appendix 1: Global Rota Virus Incidences



Source: (WHO 2020)

Appendix 2: Incidence Time Series for Kenya

Diseases	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005
Diphtheria	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Measles	439	822	63	128	95	354	190	_	2'395	95	1'218	1'282	1'516	1'847	153
Pertussis	_	6	_	3	_	_	_	_	_	_	_	_	_	_	_
Polio	0	0	0	0	0	0	14	3	1	0	19	0	0	2	0
Rubella	66	24	14	331	422	651	299	_	610	473	1'305	1'280	387	517	341
Tetanus (neonatal)	_	_	_	317	32	36	1	2	_	7	9	30	52	38	56
Yellow fever	0	0	0	3	0	0	0	0	0	0	_	0	0	0	0

Source: (*WHO 2021*)

Appendix 3: Percentage Target Population Vaccinated by Antigen Kenya

Vaccines	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005
BCG	84	82	76	86	74	81	95	84	92	99	75	95	92	92	85
DTP1	88	85	76	84	81	88	84	89	95	93	80	90	89	90	85
DTP3	83	81	71	78	78	81	84	83	88	83	75	85	81	80	76
HepB3	86	81	71	78	78	81	_	83	88	83	75	85	81	80	76
Hib3	86	81	71	78	78	81	_	83	88	83	75	85	81	80	76
IPV1	81	77	67	59	_	_	_	_	_	_	_	_	_	_	_
MCV1	81	79	68	75	75	79	79	93	87	86	74	90	80	77	69
MCV2	54	45	35	32	28	_	_	_	_	_	_	_	_	_	_
PCV1	87	85	78	84	81	88	88	88	131	_	_	_	_	_	_
PCV2	83	81	74	79	77	83	86	82	_	_	_	_	_	_	_
PCV3	83	81	71	78	75	81	84	82	85	_	_	_	_	_	_
Pol3	79	84	69	76	71	81	84	82	88	83	71	85	76	77	70
RCV1	_	79	68	_	_	_	_	_	_	_	_	_	_	_	_
Rota1	87	80	76	80	75	62	_	_	_	_	_	_	_	_	_
Rotac2	82	78	67	74	66	38	_	_	_	_	_	_	_	_	_
TT2+	62	61	47	61	55	55	77	_	76	72	60	85	78	72	72

Source: (*WHO 2021*)

Appendix 4: Incidence Time Series for United Republic of Tanzania

Diseases	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005
Diphtheria	_	_	_	_	_	_	0	0	0	0	0	0	0	0	0
Measles	120	74	852	33	30	88	185	1'668	1'622	167	1'574	3'413	7'726	2'362	23
Pertussis	_	_	_	_	_	_	0	0	0	0	0	0	0	0	0
Polio	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rubella	65	34	28	24	45	529	116	55	18	121	0	0	_	87	151
Tetanus (neonatal)	0	0	_	_	_	2	0	0	0	5	6	6	18	11	7

Source: (*WHO 2021*)

Appendix 5: Percentage Target Population Vaccinated by United Republic of Tanzania

Vaccine	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005
BCG	99	99	99	99	99	99	104	104	103	99	93	89	89	102	91
DTP1	99	99	99	99	99	99	100	99	98	98	90	88	89	94	95
DTP3	98	98	97	97	98	97	91	92	92	91	85	86	83	90	90
HepB3	98	98	97	97	98	97	91	92	92	91	85	86	83	90	90
Hib3	98	98	97	97	98	97	91	92	92	91	85	_	_	_	_
IPV1	98	75	_	_	_	_	_	_	_	_	_	_	_	_	_
MCV1	99	99	99	90	99	99	99	97	95	92	91	88	90	93	91
MCV2	88	84	79	71	57	29	_	_	_	_	_	_	_	_	_
PCV1	99	99	99	99	99	99	94	_	_	_	_	_	_	_	_
PCV2	98	99	98	98	98	98	86	_	_	_	_	_	_	_	_
PCV3	97	98	97	96	95	93	80	_	_	_	_	_	_	_	_
Pol3	98	91	96	93	96	97	91	90	91	94	88	89	88	91	91
RCV1	99	99	99	90	99	99	_	_	_	_	_	_	_	_	_
Rota1	99	99	99	99	99	99	95	_	_	_	_	_	_	_	_
Rota2	98	98	97	96	98	97	85	_	_	_	_	_	_	_	_
TT2+	97	94	91	87	94	93	79	79	76	73	74	73	73	74	81

Source: (*WHO 2021*)

Appendix 6: Immunization Coverage per Antigen in Kisumu County

Period	BCG Coverage	DPT 3 Coverage	DPT – D.O.R	M-R D.O.R	PCV3 cover.	FIC < 1YR	M-R @ 1	FIC @ 2	Rota 2	T.T2 + in Pregnancy
2019	74.1	78	3.3	-3.6	78	80.4	80.2	34.1	76.1	56.2
2018	76.3	82.5	2.3	0.83	82.5	80.1	80.5	36.2	79.7	62.5
2017	78.8	71.8	10.2	-2.3	72.5	72.5	72.6	28.2	73	57.7
2016	84	81.3	3.4	-3.1	81.4	81.6	82.2	26.5	78.4	68.3
2015	73.6	82.3	6.9	-3.1	82.2	82.3	83	20.5	76.8	72.1
2014	83.4	81.1	7.2	-4.1	80.9	75.8	79.7	10.1	19.6	65.7

Key: DOR- dropout rates; FIC- Fully immunized Child; M-R- Measles-rubella vaccine

(Source: KHIS2 2014- 2019)

Appendix 7: Vaccines Wastage Rates in Kisumu County

Period	PCV 10 W.R	T.T W.R	DPT/ HepB / hib. W.R	IPV W.R	Measles/ Rubella W.R	OPV W.R	BCG W.R	ROTA W.R
2019	0.58	18.4	2.7	1.2	30.6	18.1	42.2	2.0
2018	-0.59	16.1	1.4	0.8	34.8	16.8	46.4	2.4
2017	1.6	16.2	2.8	2.1	40.4	14.6	38.8	1.7.
2016	-4.3	15.3	1.8	1.6	28.9	20.1	52.1	3.4
2015	-7.9	15.7	1.6	0.4	38.0	15.2	42.3	2.1
2014	-1.2	31.4	2.3	1.2	34.4	14.8	48.4	3.0

Source: KHIS 2014- 2019

Appendix 8: Under five Pneumonia and diarrhea incidence rates in Kisumu County

Period	Pneumonia incidence rate under 5 years	under 5's treated for diarrhea
2019	5.5	14
2018	3.3	16.4
2017	2.7	12.6
2016	3.7	19.1
2015	4.5	18
2014	3.9	21.4

Source: KHIS2 2014- 2019

Appendix9: Tuberculosis incidences in Kisumu County and National Reports

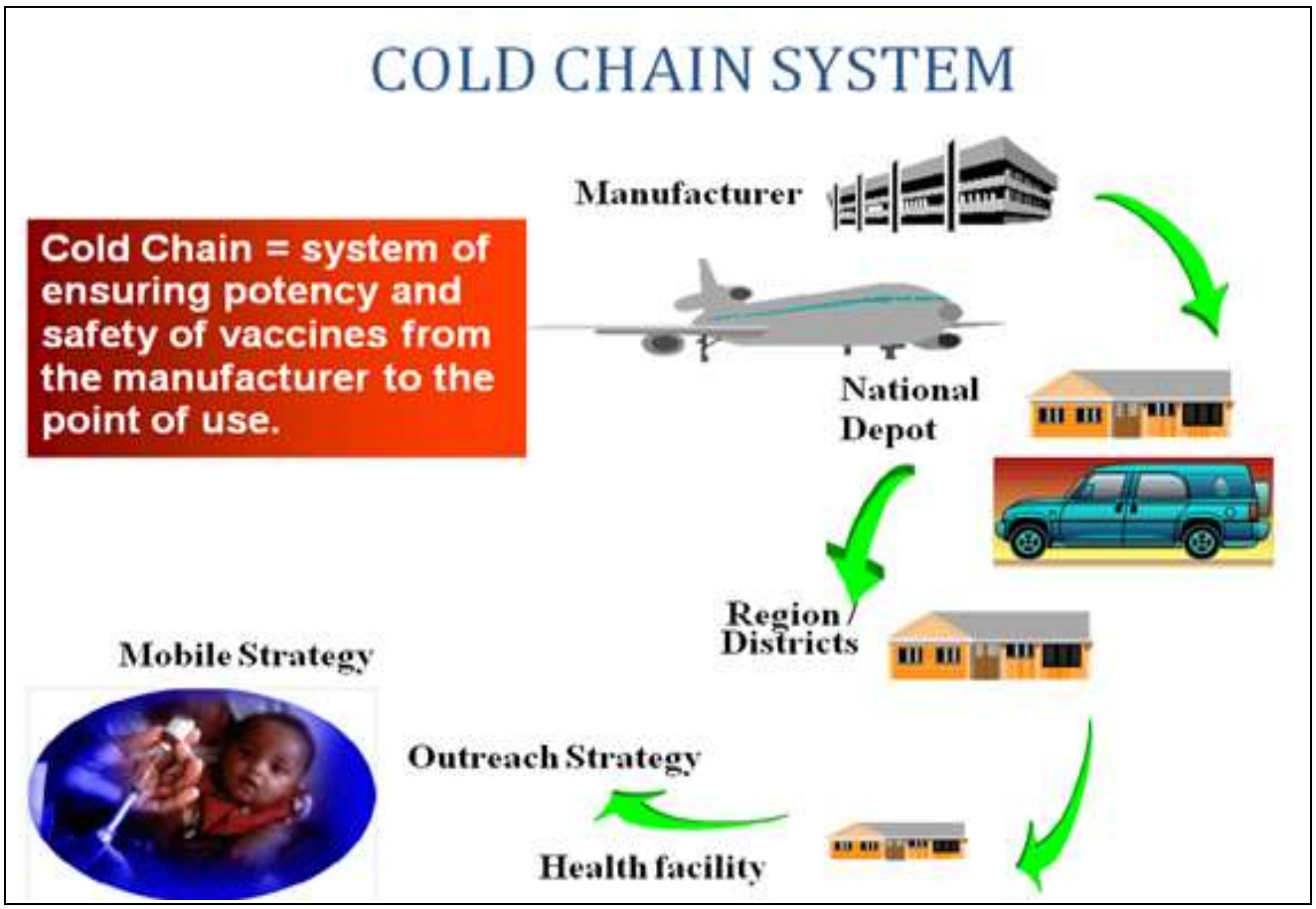
Period	Bacteriological confirmed TB cases in Kisumu	Total TB cases notified to the national program.	Death rate(all forms)	Proportion of bacteriological confirmed TB patients Cured nationally
2019	1129	2209	6.2	58.6
2018	1268	2834	6.1	33.5
2017	1472	2492	8.1	44.8
2016	379	612	6.5	69.4
2015	387	584	7.6	39.8
2014	324	543	6.8	36.9

Source: KHIS2 2014- 2019

Appendix 10: Immunization Coverage Verses Morbidity Rates per selected County

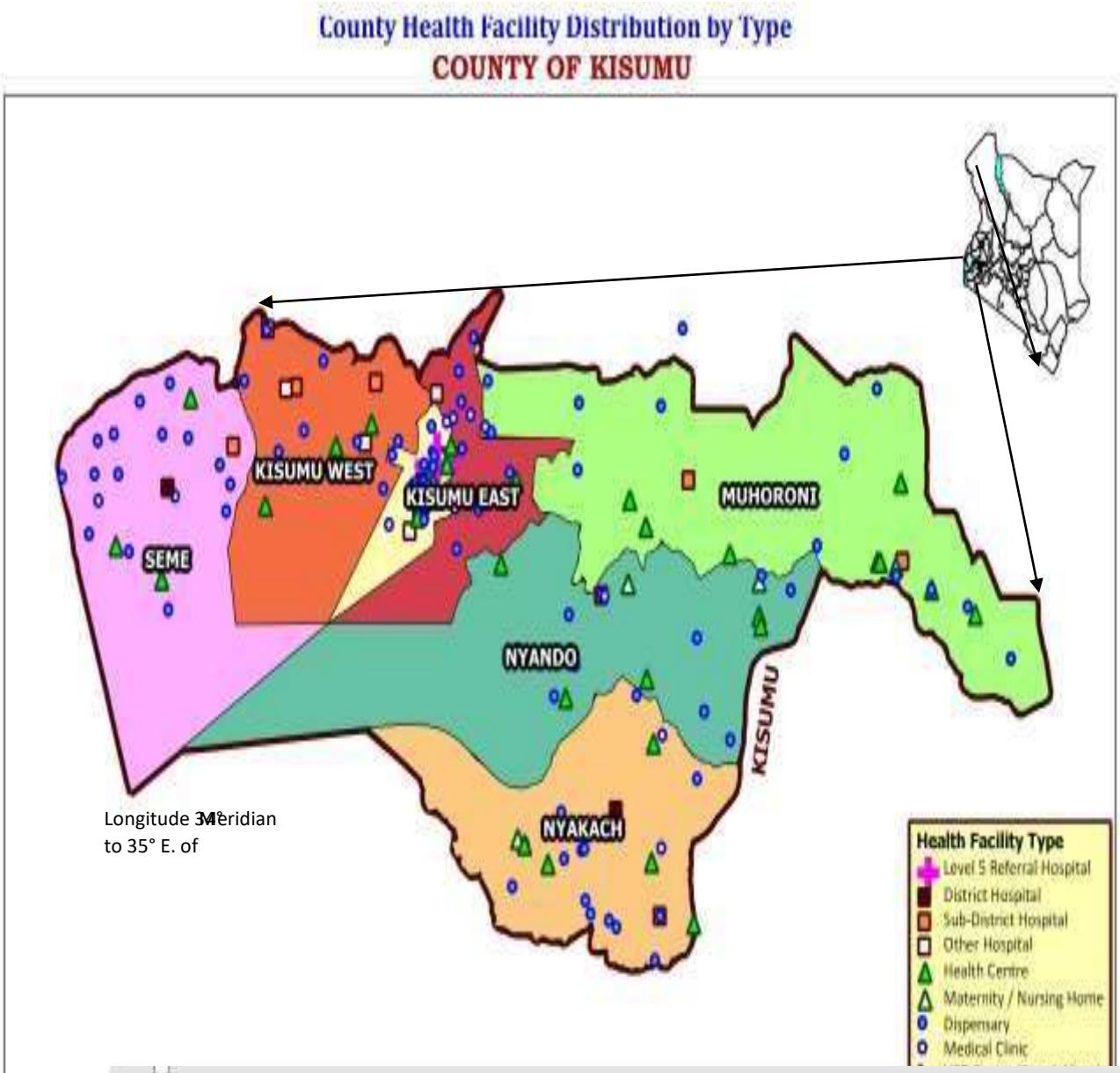
NAME OF COUNTY 2014, 2015,2016	MORBIDITY PER ANTIGEN PER YEAR					FIC	measles immunize coverage %
		Diphtheria	% of Measles attack	%< 5 yrs Rx with Diarrhaoea	% Tetanus cases		
2014	Kisumu County	0	0.67	0.21	0.08	75.8	79.7
	Homa Bay C	0	0.54	0.12	0.02	67.2	70.4
	Kericho County	0	0.24	0.04	0.01	57.5	62.7
	Kiambu County	0	0.22	0.02	0.01	85.1	86.1
	Mombasa C	0	0.32	0.10	0.04	72.8	71.8
2015	Kisumu County	0	1.0	0.18	0.09	82.3	83
	Homa Bay C.	0	0.4	0.14	0.07	78.9	81
	Kericho County	0	0.4	0.08	0.01	63.8	66.9
	Kiambu County	0	0.3	0.03	0.01	92.7	94
	Mombasa C	0	0.2	0.15	0.05	84.2	84.3
2016	Kisumu County	0	0.3	0.19	0.08	84	84.7
	Homa Bay C.	0	0.2	0.18	0.04	75.5	76.9
	Kericho County	0	0.1	0.10	0.02	58.4	63.3
	Kiambu County	0	0.08	0.04	0.01	88.9	90.9
	Mombasa C	0	0.3	0.14	0.03	77	76.9

Appendix 11: The Cold Chain System

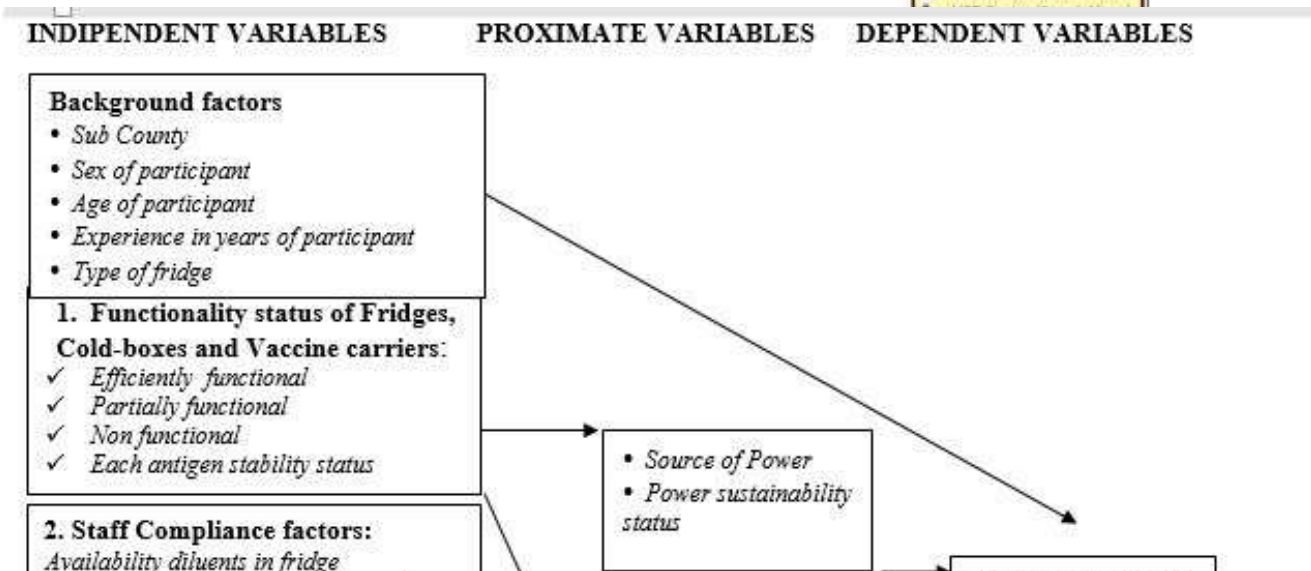


MoH 2012

Appendix 12: Map of Kisumu County



Longitude 34° E. of Meridian to 35° E. of



Appendix 13: Food stuff and non EPI drugs placed in the Fridge

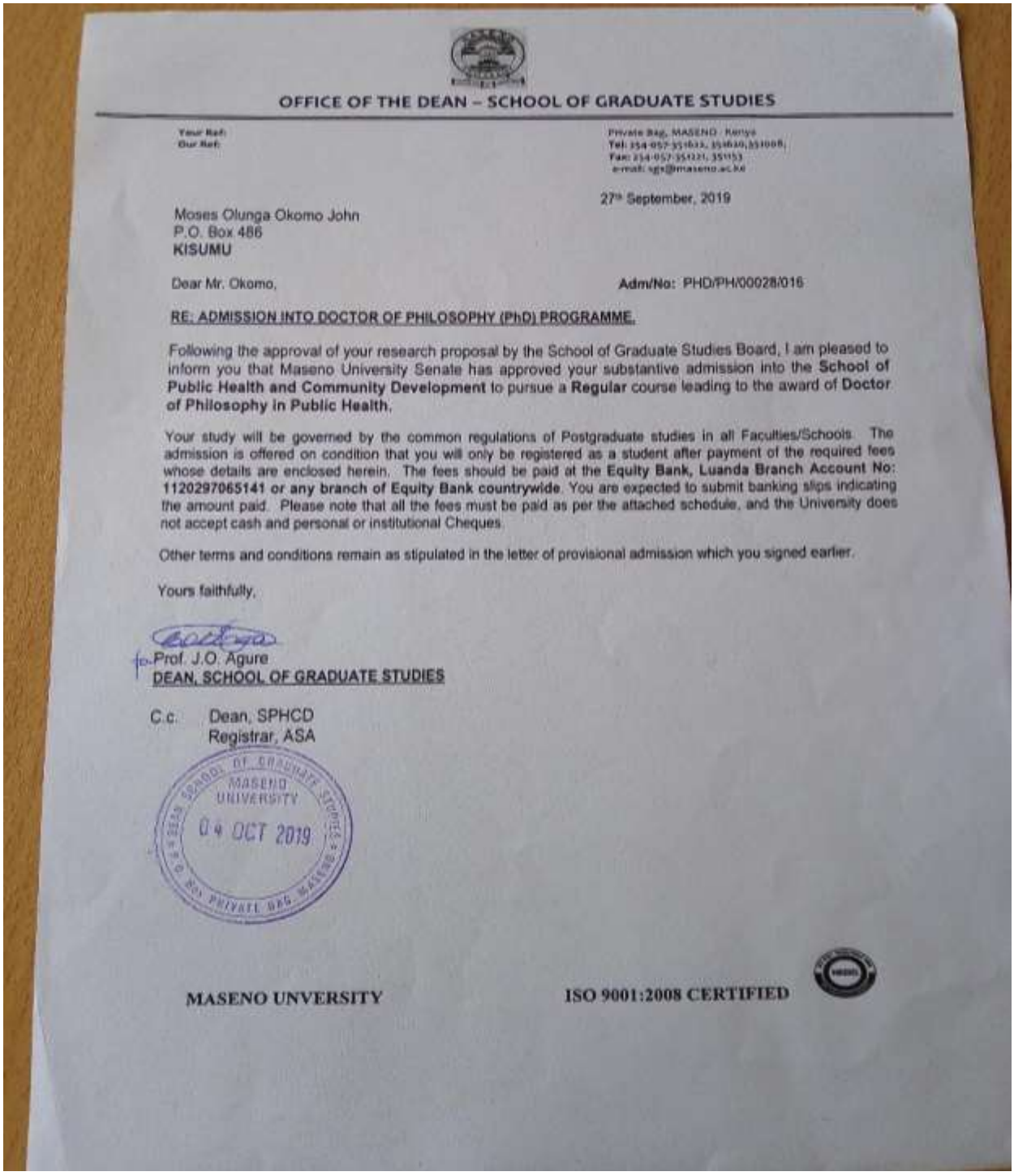
Appendix 14: Antigens at VVM Stage Four

Appendix 15: Arrangement of Vaccines in Fridge

Appendix 16: Placement of Antigens in One Tray and Position

Appendix 17: Used Antigen and Drug on Self without a Tray

Appendix 18: Letter of Admission into Doctor of Philosophy Programme



OFFICE OF THE DEAN – SCHOOL OF GRADUATE STUDIES

Your Ref:
Our Ref:

Private Bag, MASENO - Kenya
Tel: 254-057-351622, 351620,351008,
Fax: 254-057-351221, 351153
e-mail: sgs@maseno.ac.ke

27th September, 2019

Moses Olunga Okomo John
P.O. Box 486
KISUMU

Dear Mr. Okomo,

Adm/No: PHD/PH/00028/016

RE: ADMISSION INTO DOCTOR OF PHILOSOPHY (PhD) PROGRAMME.

Following the approval of your research proposal by the School of Graduate Studies Board, I am pleased to inform you that Maseno University Senate has approved your substantive admission into the **School of Public Health and Community Development** to pursue a **Regular** course leading to the award of **Doctor of Philosophy in Public Health.**

Your study will be governed by the common regulations of Postgraduate studies in all Faculties/Schools. The admission is offered on condition that you will only be registered as a student after payment of the required fees whose details are enclosed herein. The fees should be paid at the **Equity Bank, Luanda Branch Account No: 1120297065141 or any branch of Equity Bank countrywide**. You are expected to submit banking slips indicating the amount paid. Please note that all the fees must be paid as per the attached schedule, and the University does not accept cash and personal or institutional Cheques.

Other terms and conditions remain as stipulated in the letter of provisional admission which you signed earlier.

Yours faithfully,

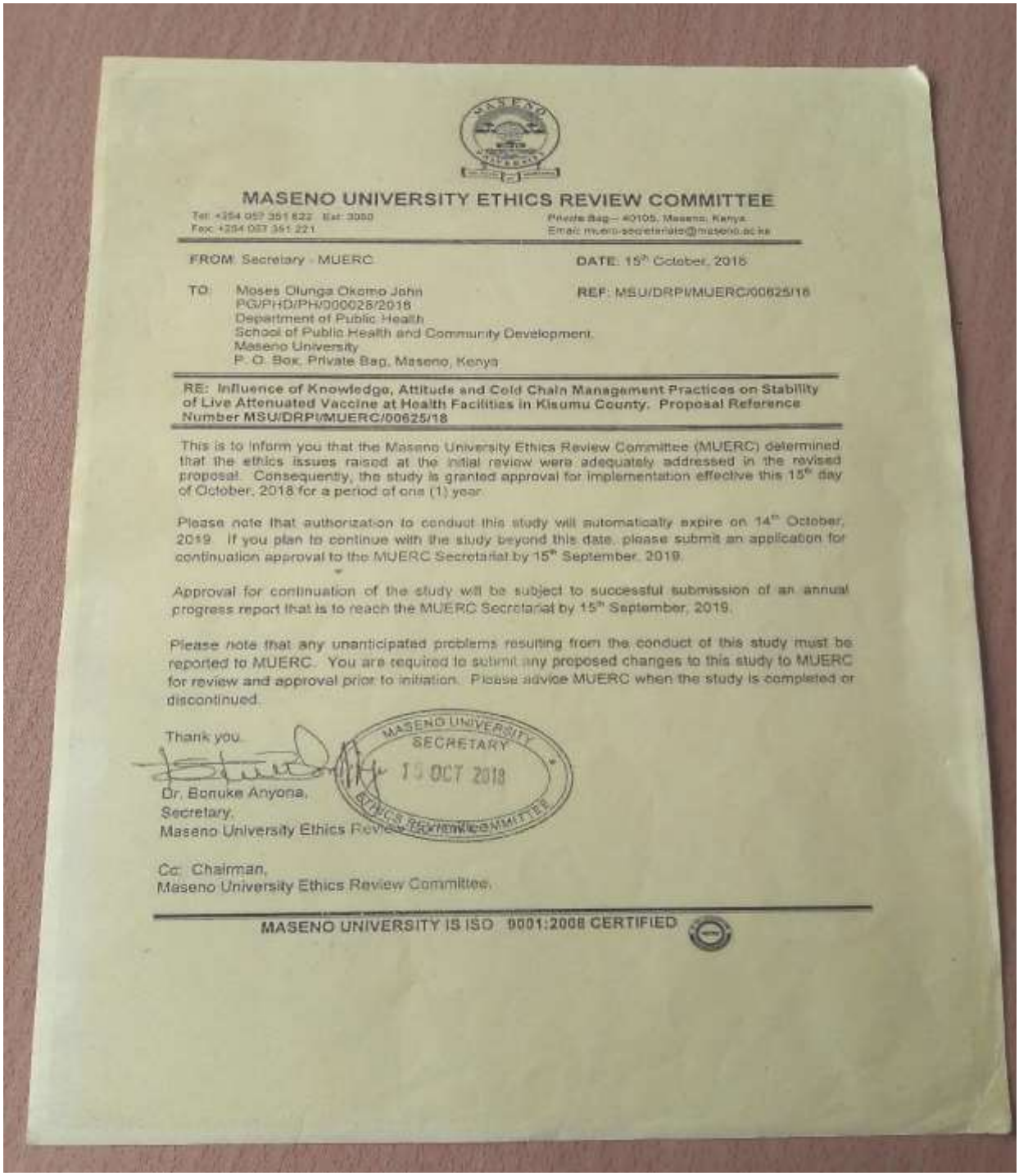
for Prof. J.O. Agure
DEAN, SCHOOL OF GRADUATE STUDIES

C.c. Dean, SPHCD
Registrar, ASA

SCHOOL OF GRADUATE STUDIES
MASENO UNIVERSITY
04 OCT 2019
P.O. Box PRIVATE BAG, MASENO

MASENO UNVERSITY **ISO 9001:2008 CERTIFIED**

Appendix 19: Maseno University Ethical Review Committee's Letter of Approval



MASENO UNIVERSITY ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
Fax: +254 057 351 221

Private Bag – 40105, Maseno, Kenya
Email: muerc-secretariat@maseno.ac.ke

FROM: Secretary - MUERC

DATE: 15th October, 2018

TO: Moses Olunga Okomo John
PG/PHD/PH/000026/2016
Department of Public Health
School of Public Health and Community Development
Maseno University
P. O. Box, Private Bag, Maseno, Kenya

REF: MSU/DRPI/MUERC/00625/18

RE: Influence of Knowledge, Attitude and Cold Chain Management Practices on Stability of Live Attenuated Vaccine at Health Facilities in Kisumu County. Proposal Reference Number MSU/DRPI/MUERC/00625/18

This is to inform you that the Maseno University Ethics Review Committee (MUERC) determined that the ethics issues raised at the initial review were adequately addressed in the revised proposal. Consequently, the study is granted approval for implementation effective this 15th day of October, 2018 for a period of one (1) year.

Please note that authorization to conduct this study will automatically expire on 14th October, 2019. If you plan to continue with the study beyond this date, please submit an application for continuation approval to the MUERC Secretariat by 15th September, 2019.

Approval for continuation of the study will be subject to successful submission of an annual progress report that is to reach the MUERC Secretariat by 15th September, 2019.

Please note that any unanticipated problems resulting from the conduct of this study must be reported to MUERC. You are required to submit any proposed changes to this study to MUERC for review and approval prior to initiation. Please advice MUERC when the study is completed or discontinued.

Thank you.

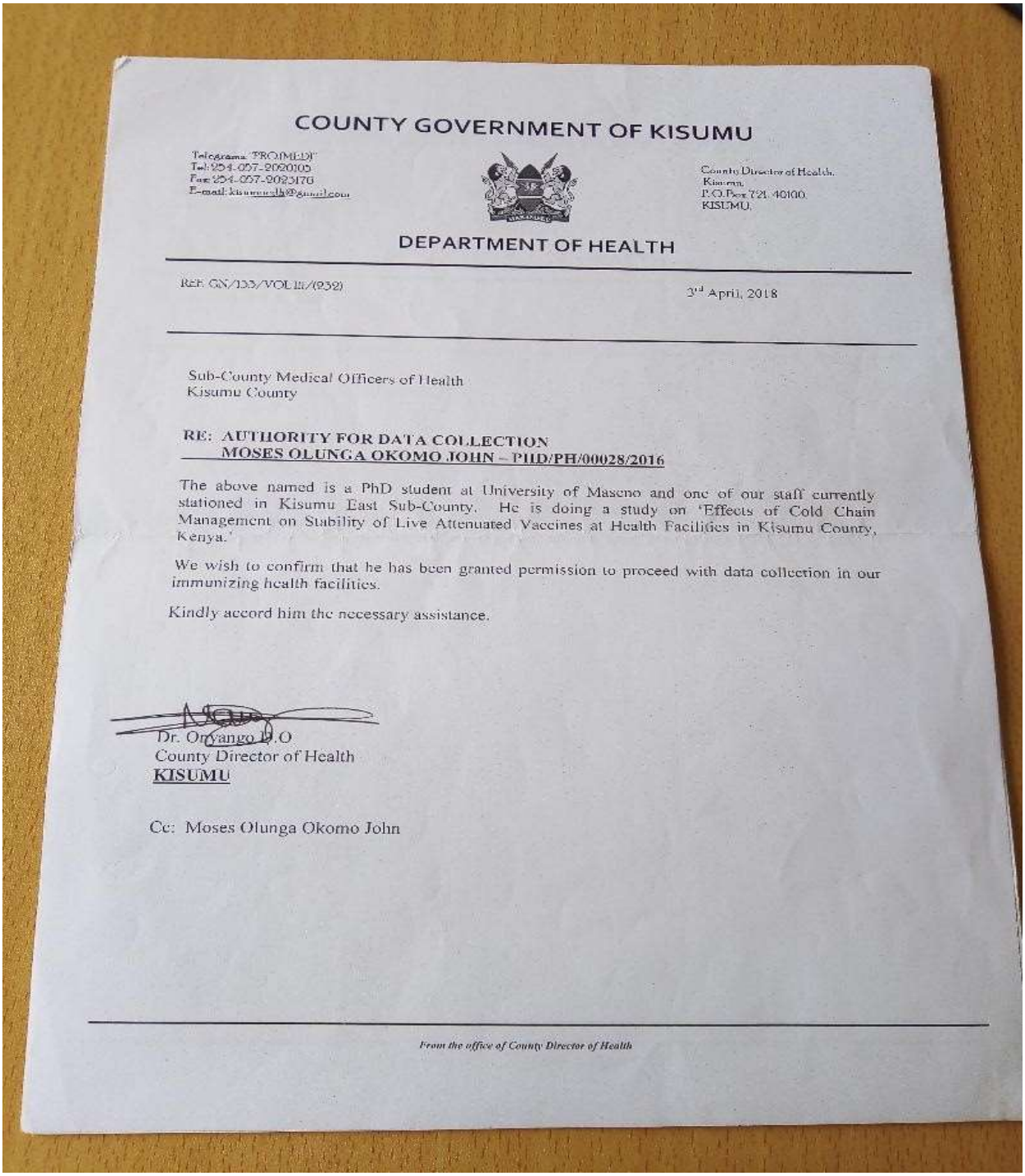
MASENO UNIVERSITY SECRETARY 15 OCT 2018 ETHICS REVIEW COMMITTEE

Dr. Boniface Anyona,
Secretary,
Maseno University Ethics Review Committee

Cc: Chairman,
Maseno University Ethics Review Committee.

MASENO UNIVERSITY IS ISO 9001:2008 CERTIFIED

Appendix 20: Administrative Approval from Director of Health Services



COUNTY GOVERNMENT OF KISUMU

Telegrams: "PROMEDI"
Tel: 254-057-2020105
Fax: 254-057-2023176
E-mail: kisumucdh@gmail.com

County Director of Health,
Kisumu,
P.O.Box 721, 40100,
KISUMU.

DEPARTMENT OF HEALTH

REF: GN/135/VOL II/(932)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

Kindly accord him the necessary assistance.

Dr. Ouyango P.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

From the office of County Director of Health

Appendix 21: Administrative approval letter, Kisumu East Sub County

COUNTY GOVERNMENT OF KISUMU

DEPARTMENT OF HEALTH

REF: GN/333/VOL III/(250)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

Kisumu East ✓

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

Approved Authority granted 08/4/2018

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

Kindly accord him the necessary assistance.

Dr. Orwango P.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

Appendix 22: Administrative Approval Letter, Kisumu Central Sub County

COUNTY GOVERNMENT OF KISUMU

Telegrams "PROMED"
Tel: 254-057-2020105
Fax: 254-057-2023176
E-mail: kisumucdh@gmail.com

County Director of Health,
Kisumu,
P.O.Box 729-40100,
KISUMU.

DEPARTMENT OF HEALTH

REF: GN/133/VOL III/(232)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

KISUMU CENTRAL

Approved
Authority granted
12/4/2018

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

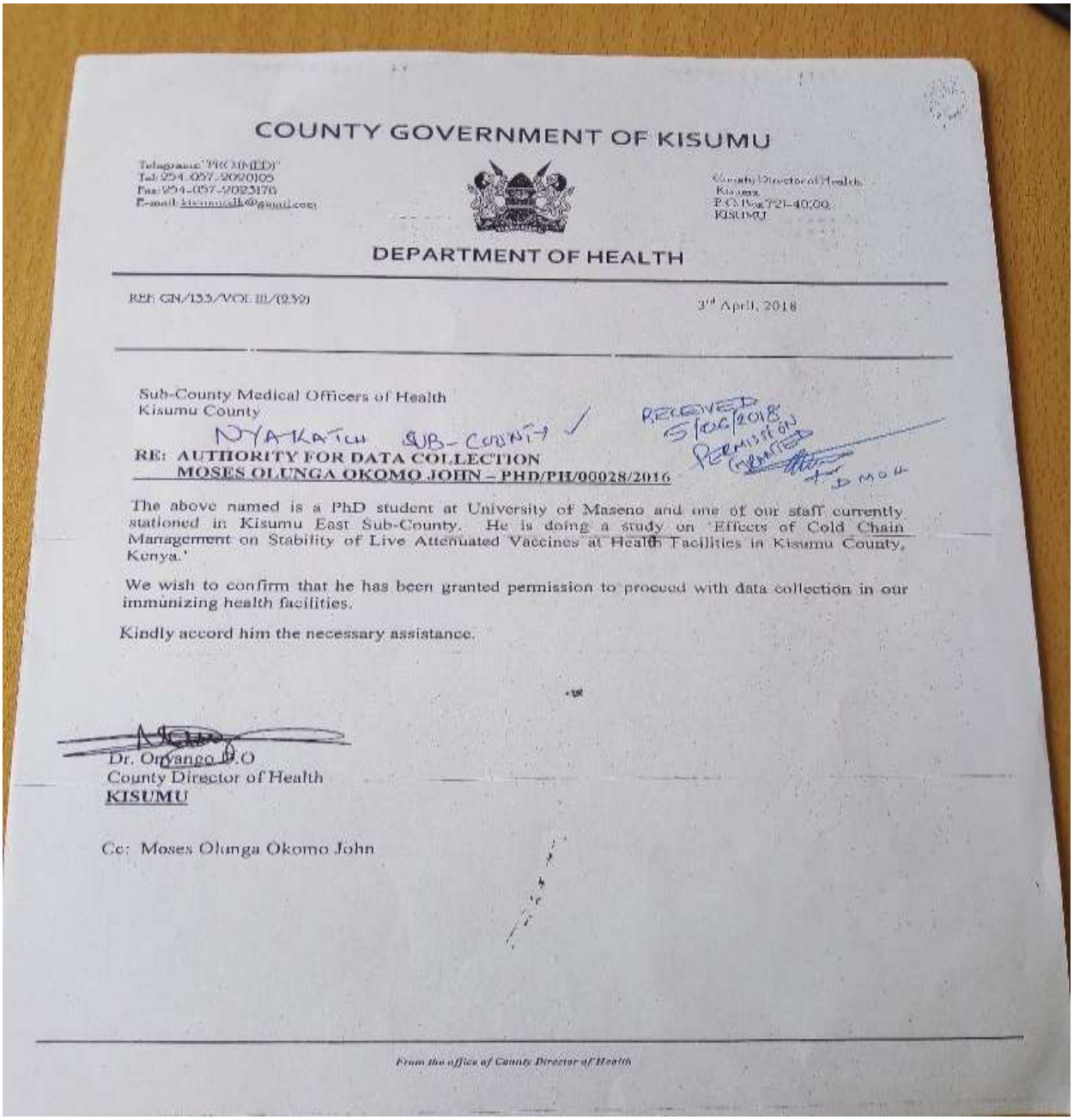
Kindly accord him the necessary assistance.

Dr. Onyango J.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

From the office of County Director of Health

Appendix 23: Administrative Approval Letter, Nyakach Sub-County



COUNTY GOVERNMENT OF KISUMU

Telegrams: "PROMED"
Tel: 254-057-2020105
Fax: 254-057-2023170
E-mail: kisumucdh@gmail.com

County Director of Health,
Kisumu,
P.O. Box 721-40100,
KISUMU.

DEPARTMENT OF HEALTH

REF: GN/133/VOL III/(239)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

NYAKACH SUB-COUNTY ✓

RECEIVED 5/04/2018 PERMISSION GRANTED

DMOH

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

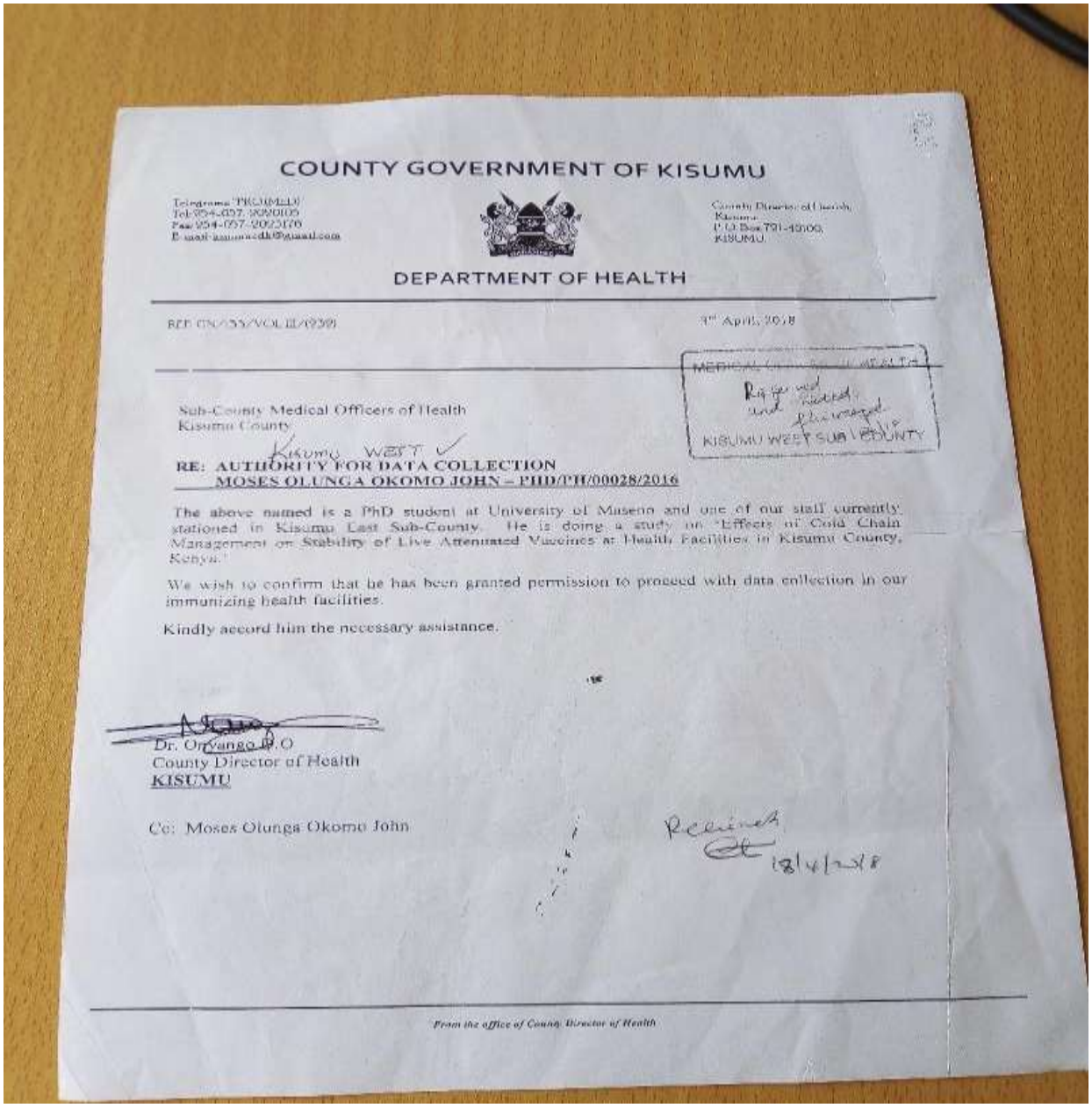
Kindly accord him the necessary assistance.

Dr. Oriyango D.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

From the office of County Director of Health

Appendix 24: Administrative Approval Letter, Kisumu West Sub-County



COUNTY GOVERNMENT OF KISUMU

DEPARTMENT OF HEALTH

REF CN/339/VOL III/(239)

4th April, 2018

Sub-County Medical Officers of Health
Kisumu County

Kisumu WEST ✓

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on "Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya."

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

Kindly accord him the necessary assistance.

Dr. Orwango B.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

Received
18/4/2018

From the office of County Director of Health

Appendix 25: Administrative Approval Letter, Seme Sub-County

Approved
21/11/18

COUNTY GOVERNMENT OF KISUMU

Telegrams "PROMEDI"
Tel: 254-057-2020105
Fax: 254-057-2023476
E-mail: kisumucdh@gmail.com

County Director of Health,
Kisumu,
P.O.Box 791-40100,
KISUMU.

MEDICAL OFFICER OF HEALTH,
SEME SUB-COUNTY,
P. O. Box 60,
KOMBEWA.

DEPARTMENT OF HEALTH

REF: GN/135/VOL III/(139)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

Kindly accord him the necessary assistance.

Dr. Onyango J.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

From the office of County Director of Health

Appendix 26: Administrative Approval Letter, Nyando Sub-County

COUNTY GOVERNMENT OF KISUMU

Telegrams: [illegible]
Tel: 254-057-[illegible]
Fax: 254-057-2023170
E-mail: [illegible]

County Director of Health,
Kisumu,
P. O. Box 721-40100
KISUMU

DEPARTMENT OF HEALTH

REF: GN/133/VOL.III/(250)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00028/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

Kindly accord him the necessary assistance.

Dr. Ouvango P. O
County Director of Health
KISUMU

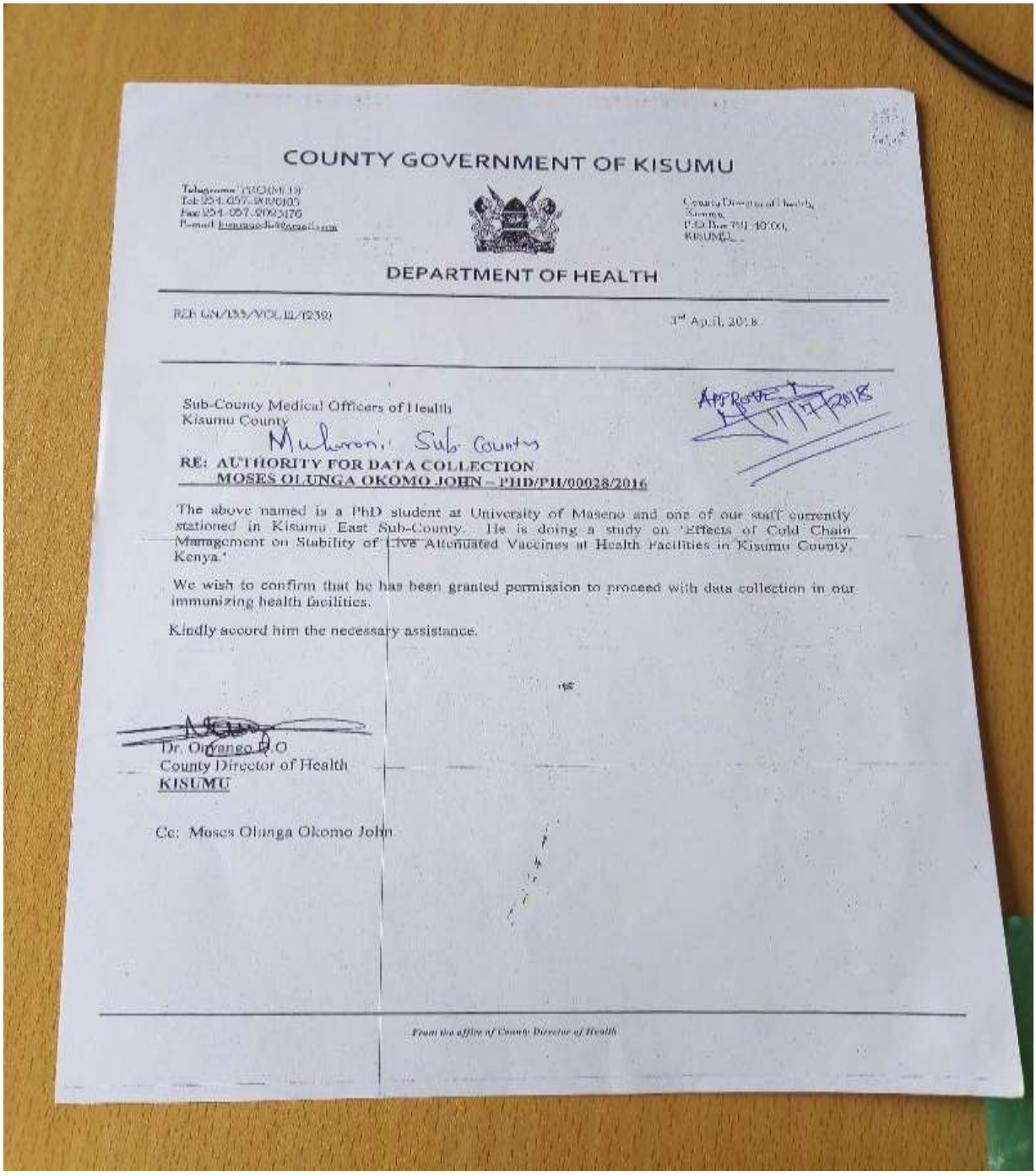
Cc: Moses Olunga Okomo John

RABUOR SUB-COUNTY HOSPITAL
P. O. BOX 26, RABUOR

81/10/2018

From the office of County Director of Health

Appendix 27: Administrative Approval Letter, Muhoroni Sub-County



COUNTY GOVERNMENT OF KISUMU

DEPARTMENT OF HEALTH

REF: GN/133/VOL.III/(239)

3rd April, 2018

Sub-County Medical Officers of Health
Kisumu County

Muhoroni Sub County

APPROVED
17/4/2018

RE: AUTHORITY FOR DATA COLLECTION
MOSES OLUNGA OKOMO JOHN – PHD/PH/00038/2016

The above named is a PhD student at University of Maseno and one of our staff currently stationed in Kisumu East Sub-County. He is doing a study on 'Effects of Cold Chain Management on Stability of Live Attenuated Vaccines at Health Facilities in Kisumu County, Kenya.'

We wish to confirm that he has been granted permission to proceed with data collection in our immunizing health facilities.

Kindly accord him the necessary assistance.

Dr. Onyango P.O
County Director of Health
KISUMU

Cc: Moses Olunga Okomo John

From the office of County Director of Health

Appendix 28: Research Procedures / Consent Form

We are/ I am _____Conducting a study for Moses Olunga Okomo John, a graduate student from **Maseno University** who is pursuing PhD in Public Health. The thesis is about an assessment on the Influence of Health facility level cold-chain storage logistics and staff capacity on stability of live attenuated vaccines in Kisumu County.

The interview would take approximately twenty minutes.

PARTICIPATION

Your participation in this study will be voluntary. (You are free to participate or decide to get out of the interview at any time or for any reason). You can also decline to participate or answer some parts of the questions which you are not comfortable with and still remain in the study. The researcher may exempt interviewing you if conditions arise and will give reasons why.

RISKS

Choosing to be part of this study or not, will not have any negative effect on your relationship with the researcher or their institution.

BENEFITS

There will be no direct benefit to you as a participant; however, your participation will help provide ideas and information that will enhance quality of immunization services in this County and beyond. The benefit shall not only be for targeted clients at the health facilities but also the whole population within the County and beyond.

CONFIDENTIALITY

Information obtained during this study will be considered confidential and would only be shared with your permission. As a participant your name will not be required but a secret code will be provided for the same. Both hard and soft copies of the generated data will be safely discarded after data entry and cleaning.

CONTACT:

This research is being conducted Moses Olunga Okomo John: jomokomo2010@yahoo.com Phone 0720847278.

Thanks.

CONSENT:

I have read this form and agree to participate in this study.

Signature/initials_____ Date: _____

Appendix 29: Tool 1: Background Information:

1) Facility CODE: _____ (name) _____

2) Sub-County: Seme: ☐ Kisumu E; ☐ Nyando; ☐ Kisumu W; ☐ Nyakach ☐ Muhoroni ☐

3) Facility ownership : public ☐, Private ☐; Faith Based ☐

4) Facility level : Two ☐; Three and above ☐

1. Type of fridge: _____

2. Sex : Male ☐ Female ☐

3. Age: ≤35 years ☐; > 35 years ☐

4. Eperience : Less than 2yrs ☐; > 2yrs ☐

5. Number skilled staff in the unit/facility_____

6. **Source of Power and sustainability**:

   a) *Electricity and at least a stand by gas (absorption type)* ☐

   b) *Electricity and a stand by functional generator (compressors type)* ☐

   c) *At least two gas cylinders; one in use, one stand by (absorption type*) ☐

   d) *On solar* . ☐

   e) *Electric grid alone/ without back up option* ☐

   f) *Other, specify* …… ☐

Appendix 30: Tool 2: Questionnaire for Functionality status of Fridges, Cold-boxes & Vaccine Carriers

(Be guided with fridge tag2)

1. ***Fridge functionality status*** *(tick one only)*

a) Efficiently functional ☐ (*Fridge maintains temperature between +2^{0}C- +8^{0}C continuously for at least 36 hours when not on power or show no alarm over a month while on continuous power flow)*

b) Partially functional ☐ *(Fridge maintains temperature between +2^{0}C - +8^{0}C continuously for at least 12 to 36hours when not on power and show no alarm while on continuous power flow)*

c) Fridge is non-functional ☐ *(Fridge cannot sustain temperature between $^+$2^{0}C and 8^{0}C for 12 hours without power. Or shows alarm (s) while on un-interrupted power flow)*

2. **Cold box functionality** *(tick one only)*

a) Efficiently functional: Yes ☐ *(**C**old box is able to maintain temp. below + 8^{0}C for at least 36 hours)*

b) Partially funtional:Yes ☐ *(Cold box maintains temperature below + 8^{0}C for 12 to 36hours)*

c) Non functional: Yes ☐ *(Box cannot maintain temperature below+ 8^{0}C for 12 hours)*

d) Not applicable ☐

3. Vaccines carriers functionality (tick one)

- Efficiently: Yes ☐ *(Carrier able to maintain temp. below +8^{0}C for at least 8 hours)*
- Partially: Yes ☐ *(carrier maintains temp below + 8^{0}C for at least 6 hrs)*
- Non functional: Yes ☐ *(carrier cannot maintain temperature below +8^{0}C for 6 hours)*

4. Indicate the VVM **stage of each antigen in fridge or discarded this month due to instability this month**

	Stages: 1	2	3	4
• Oral Polio Vaccine for this review period/month.	☐	☐	☐	☐
• Measles and Rubella for this review period/month.	☐	☐	☐	☐
• BCG for this review period/month.	☐	☐	☐	☐
• ROTA for this review period/month.	☐	☐	☐	☐
• INACTIVATED POLIO VACCINE for this period/month.	☐	☐	☐	☐
• TETANUS TOXOID this period/month.	☐	☐	☐	☐
• PENTAVALENT (DPT, HepB, hib) this period/month.	☐	☐	☐	☐
• PCV10 for this review period/month.	☐	☐	☐	☐

5. **All antigens stable: Yes** ☐; No ☐

6. **Any other related observation on functionality of fridges, cold boxes and vaccine carriers ……**

Appendix 31: Tool 3: Questionnaire for staff compliance level to cold-chain procedures

(Observe for any of the following.)

1. Diluents for immediate use are in fridge or carrier : **[Yes] [No]**

2. Availability of extra Icepacks in a separate carrier (reserve) during out reaches **[Yes] [No]** N/A.

3. Arrangement of vaccines in fridge allows air circulation as per policy: **[Yes] [No]**

4. Vaccines in fridge are arranged as per the guideline: **[Yes] [No]**

5. Fridge defrosted as per the guideline, if applicable (*No frost formed in fridge*):**[Yes] [No]**

6. Temperature monitored twice daily and recorded: **[Yes] [No]**

7. Temperature register is consistent with that of FT2 **[Yes] [No]**

8. Vaccines transferred when there is need as per the guideline:):**[Yes] [No]**

9. Measles or BCG vaccines are discarded within six hours of dilution: **[Yes] [No]**

10. Multi dose vaccines used for a maximum of 28 days/ 4 weeks **[Yes] [No]**

11. Vials with VVM stage2 issued ahead of FEFO sequence:(*confirm with ledger books*) **[Yes] [No]**

12. VVM recorded in all issued vaccines ledger books **[Yes] [No]**

13. Comment on any other relevant observations noted but not captured by above questions:

……

Appendix 32: Tool 4: questionnaire for staff competency on cold chain procedures

1. Have you had a chance to be trained on EPI / immunization in last three years? **[Yes] [No]**

2. What do you consider as a normal range of temperature at which vaccines should be kept?
   - ☐ -2^0C to $+8^0$C
   - ☐ $+2^0$C to $+8^0$C
   - ☐ Neither of the above
   - ☐ I don't know

3. In case you open a fridge and find out that there is a new alarm on FT2 pointing up, what would be the possible meaning of that?
   - ☐ Limited source of power to fridge/ vaccines are at risk of destabilization
   - ☐ Too much power source to fridge
   - ☐ Neither of the above
   - ☐ I do not know

4.In case the fridge in use has a fault beyond your ability to resolve, which action do you take?

_____

5.In case you are on duty and confirm that the fridge is actually faulty, without immediate resolutions, what do you do with vaccines? _____ (*mark **yes** if said transfer*) **[Yes] [No]**

6. How do you interpret VVM stages? (*Observe, mark appropriately*). Competency, **[Yes] [No]**

7. What are you expected to do with vaccine whose VVM indicated as below: (competent, **[Yes] [No)**
   a) Stage1? _____*(use)*
   b) Stage 2? _____*(use first)*
   c) Stage 3? _____*(do not use)*
   d) Stage 4? _____ *(do not use)*

8. Please list how routine vaccines in EPI should be arranged in a fridge (*i.e. from most sensitive to heat, to least; tick yes if arrangement is consistent with the below*). **[Yes] [No)**
   - ✓ OPV _____
   - ✓ M/R _____
   - ✓ BCG; _____
   - ✓ ROTA _____

9. A particular vaccine vial in fridge is at VVM stage2 while another batch expires earlier, which is the right action to take? (*Competent, mark yes is mention the first option* **[Yes] [No])**
   - ☐ one on VVM stage 2 dispense first
   - ☐ One which is to expire first dispensed first

Appendix 33: Tool 5: Likert scale for staff perception on cold-chain procedures:

Below are statements on vaccines management. Please, indicate your thought and feelings in respect to level of agreement or disagreement.
Key: ***[1]****=Strongly Disagree* ***[2]****=Disagree* ***[3]****=Neither Disagree nor Agree* ***[4]****=Agree* ***[5]****=Strongly Agree*

	Statement	**Response**
1	Diluents for immediate use should be put in fridge	[1] [2] [3] [4] [5]
2	Extra icepack should be carried in an empty carrier for outreaches	[1] [2] [3] [4] [5]
3	Vaccines should be arranged in fridge to allow air circulation	[1] [2] [3] [4] [5]
4	Vaccines should be arranged in fridge based on their temperature sensitivity	[1] [2] [3] [4] [5]
5	Fridges should be de-frosted every time there is a frost	[1] [2] [3] [4] [5]
6	It is vital to monitor and chart KEPI fridge temperature twice daily	[1] [2] [3] [4] [5]
7	Vaccines must be transferred to another functional fridge immediately there's confirmed malfunctioning	[1] [2] [3] [4] [5]
8	Vaccine whose VVM stage is above two should be discarded	[1] [2] [3] [4] [5]
9	Vaccines at VVM STAGE 2 should be issued instead of FEFO criteria	[1] [2] [3] [4] [5]

10. Which section of the guideline would you prefer readjusted for quality cold chain management (any overall observation on cold-chain guideline)? –----------

---

Appendix 34: Nyakach Sub-County Immunizing Health Facilities

FACILITIES	OWNERSHIP			LEVEL
	PUBLIC	PRIVATE	FB	
KATITO SCH	✓			3
RAE	✓			2
ONYUONGO	✓			2
KIBOGO	✓			2
CHERWA	✓			2
SONDU H/C	✓			2
RADIENYA	✓			2
NYABONDO			✓	4
OBOCH	✓			2
SIGOTI H/C	✓			2
NYAMARIMBA S/C H	✓			3
GARI	✓			2
ANDING'O OPANGA H/C	✓			2
KUSA H/C	✓			2
BOLO		✓		3
SANGO ROTA H/C	✓			2
ST. JANE		✓		3
BONDE	✓			2
NYABOLA	✓			2
PEDO	✓			2
PAP ONDITI C.H	✓			3
KANDARIA	✓			2
KEPISTORE	✓			4
AIC NYAKACH			✓	3
BETHLEM		✓		2
KEN GEN CLINIC		✓		2
RANGUL DISPENSARY	✓			2
TOTAL FACILITIES	**17**	**5**	**2**	

Appendix 35: Seme Sub-County Immunizing health facilities

FACILITY	OWNERSHIP			LEVEL
	PUBLIC	PRIVATE	FAITH BASED	
KOMBEWA CH	✓			4
MIRANGA SCH	✓			3
MANYUANDA SCH	✓			3
RATTA HC	✓			2
BODI HC	✓			2
ARITO LANGI DISP	✓			2
RODI DISP	✓			2
LANGI DISP	✓			2
KUOYO KAILA DISP	✓			2
ONYINJO DISP	✓			2
LOLWE DISP	✓			2
ASAT DISP	✓			2
ORIANG ALWALA DISP	✓			2
ORIANG KANYADWERA	✓			2
OPAPLA DISP	✓			2
NDURU KADERO	✓			2
KORWENJE DISP	✓			2
BAR KORWA HC			✓	2
KOLENYO DISP	✓			2
OSEURE DISP	✓			2
DAGO DISP	✓			2
BONGU KONYANGO DISP	✓			2
OTIENO OWALLA DISP	✓			2
TOTAL	**24**	**0**	**1**	

Appendix 36: Muhoroni Sub-County Immunizing health facilities

FACILITY	OWNERSHIP			LEVEL
	PUBLIC	PRIVATE	FAITH BASED	
Muhoroni County Hospital	✓			3
Koru Mission Hospital			✓	3
Koru Dispensary		✓		2
Kopiti Nursing Home		✓		3
Muhoroni Sugar dispensary		✓		2
Chemelil health Centre	✓			2
Nyangoma Hospital	✓			3
Masogo Hospital	✓			3
Kasongo Hospital	✓			3
Makindu H/C	✓			2
Chemelil GOK H/C	✓			2
Kandege H/C	✓			2
Ogra Nursing Home		✓		2
Nyakungura H/C	✓			2
Obumba H/C	✓			2
Miwani Dispensary	✓			2
Rehema Dispensary		✓		2
TamuH/C	✓			2
Kopere H/C	✓			2
St. Vincent hospital		✓		2
Jaber disp.	✓			2
Rachar Sugar belt hosp	✓			2
Masambanidisp	✓			2
Yago disp.	✓			2
Ramula disp	✓			2
mama Pliste H/C		✓		2
MirangaDisp	✓			2
MilenyeDisp	✓			2
Ogen disp.	✓			2
KasongoDisp	✓			2
TOTAL	**20**	**10**	**1**	

Appendix 37: Nyando Sub-County Immunizing Health Facilities

Facility	OWNERSHIP			LEVEL
	PUBLIC	PRIVATE	FAITH BASED	
1)AHERO SUB COUNTY	✓			3
2)AHERO MEDICAL		✓		3
3)AWASI MISSION			✓	2
4)BUNDE DISPENSARY	✓			2
5)HOLO DISPENSARY	✓			2
6)KADINDA	✓			2
7)KATOLO	✓			2
8)KANASIA	✓			2
9)MAGINA	✓			2
10)NYAKONGO	✓			2
11)OLASI	✓			2
12)OREN	✓			2
13)HOPE MEDICAL CENTRE		✓		2
14)WANGANGA	✓			2
15)ABSALOM	✓			2
16)HONGOGOSA	✓			2
17)KANYAGWAL	✓			2
18)KODUOL	✓			2
19)KOMWAGA	✓			2
20)NYANGANDE	✓			2
21)OKANA	✓			2
22)RABUOR	✓			3
23)KEPI STORE	✓			4
TOTAL	**20**	**2**	**1**	

Appendix 38: Kisumu East Sub-County immunizing Health Facilities

FACILITY	OWNERSHIP			LEVEL
	PUBLIC	PRIVATE	FAITH BASED	
1)JARAMOGI O. ODINGA TRH	✓			5
2)KISUMU COUNTY HOSPITAL	✓			4
3)AGAKHAN		✓		5
4)AVENUE HOSPITAL		✓		5
5)NIGHTINGALE HOSPITAL		✓		4
6)MILIMANI HOSPITAL		✓		3
7)MARIESTOPES HOSPITAL		✓		3
8)JALARAM HOSPITAL		✓		3
9)ST. MONICA HOSPITAL			✓	3
10)ST ELIZABETH HOSPITAL			✓	3
11)ST CONSLATA HOSPITAL		✓		3
12)GITA S/C HOSPITAL	✓			3
13)LUMUMBA S/C HOSPITAL	✓			3
14)MIGOSI S/C HOSPITAL	✓			3
15)STAR HOPITAL		✓		3
16)PAND PIERI H/C			✓	2
17)KMET CORCKRAN H/C		✓		2
18)DISCIPLES OF MERCY DISP.			✓	2
19)NYALENDA DISP	✓			2
20)KOWINO DISP.	✓			2
21)RAILWAYS DISP.	✓			2
22)ADMINISTRATIVE DISP.	✓			2
23)POLIC DISP.	✓			2
24)KIBOS PRISON DISP.	✓			2
25)CHIGA DISP.	✓			2
26)KIBOS SUGAR DISP.	✓			2
27)SIMBA UPEPO DISP.	✓			2
28)OLPS DISPENSARY			✓	2
29)CENTRAL CLINIC	✓			2
30)RING ROAD CLINIC		✓		2
31)GOT NYABONDO DISP.	✓			2
32)KUOYO DISPENSARY	✓			2
33)KOTUNGA DISPENSARY	✓			2
34)GEVA CLINIC		✓		2
35)ORONGO DISPENSARY	✓			2
36)NYALUNYA DISPENSARY	✓			2
37)ST. JUDE DISPENSARY		✓		2
38)ST. VINCENT CLINIC		✓		2
39)ST. LYDIA OKORE DISP.	✓			2
40)FHOK CLINIC		✓		2
41)OASIS		✓		3
42) MANYATTA CLINIC		✓		2
43) MAISHA ORPHANS		✓		2
44) AHAVA CLINIC		✓		2
45)NYAMASARIA		✓		2
46) KEPI	✓			4
47)ST. GEORGES		✓		2
TOTAL FACILITIES	**22**	**15**	**5**	**47**

Appendix 39: Kisumu West Sub-County Immunizing Health Facilities

FACILITY	OWNERSHIP			LEVEL/ TIRE
	PUBLIC	PRIVATE	FAITH BASED	
1.Chulaimbo SCH	✓			3
2.Siriba Dispensary		✓		2
3.Sunga Dispensary	✓			2
4.Mbaka Oromo Disp.	✓			2
5.Maseno Mission Hosp.			✓	3
6.Masaba Hospital		✓		3
7.Maseno University Clinic		✓		2
8.Nyahera SCH	✓			3
9.SOS Medical Clinic		✓		2
10.Ober Kamoth H/C	✓			2
11.Ojolla Dispensary	✓			2
12.Rota Dispensary	✓			2
13.LwalaKadawa Disp.	✓			2
14.Riat Dispensary	✓			2
15.Mainga Dispensary	✓			2
16.Airport Health Centre	✓			2
17.Usoma Dispensary	✓			2
18.Kodiaga Health Centre	✓			2
19.St. Marks Dispensary	✓			2
20.Kisumu airport Int.		✓		2
21.Port Florence Hospital		✓		3
22.KEMRI CDC C clinic		✓		2
TOTAL	**14**	**7**	**1**	

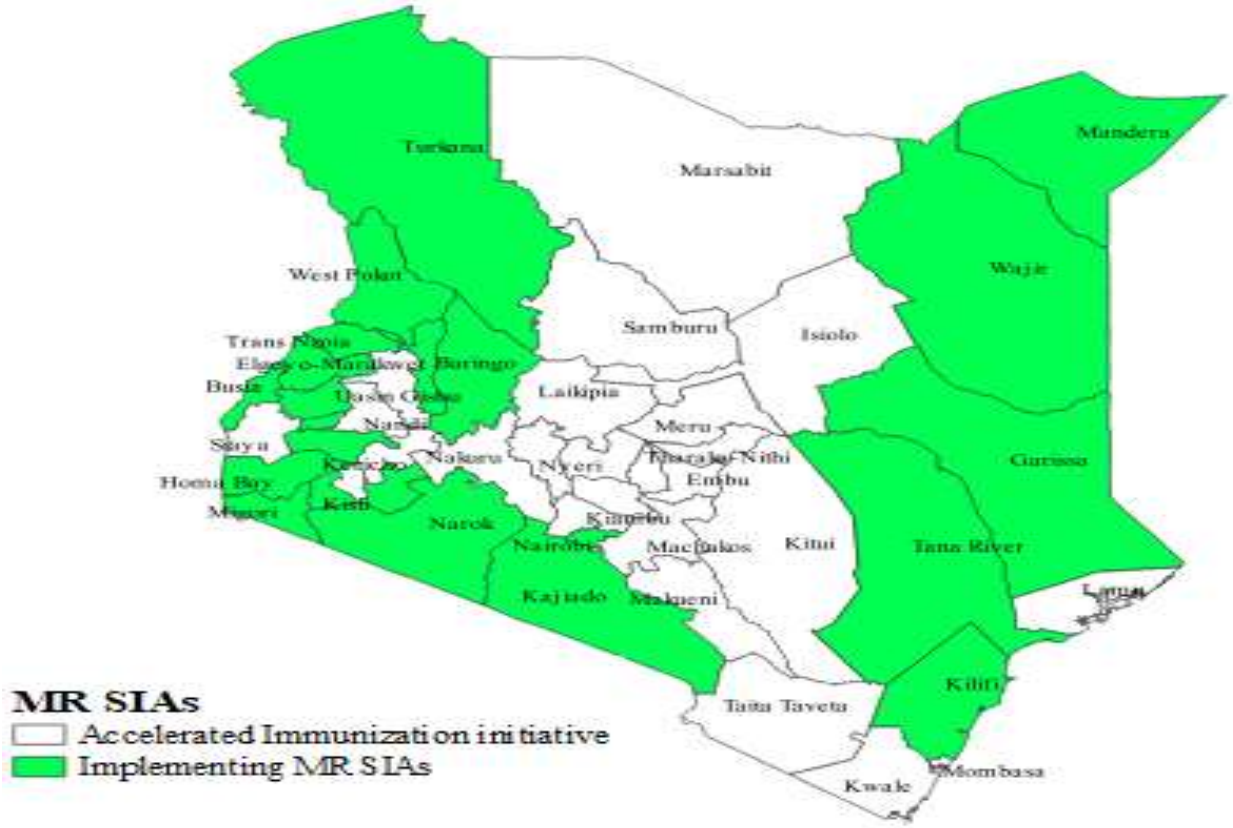
Appendix 40: Routine Immunization Schedule

	Age	Antigen	Disease Prevented
1	**Birth**	**BCG**	Tuberculosis
		OPV	Polio
		HEP.B	Hepatitis B
2	**6 Weeks**	**DPT**	Diphtheria, Pertussis, Tetanus
		HIB	Hemophilia Influenza Type B
		HEP B	Hepatitis B
		OPV	Polio
		PNEUMOCOCCAL	Pneumonia
		ROTA VIRUS	Rotavirus
3	**10 Weeks**	**DPT**	Diphtheria, Pertussis, Tetanus
		HIB	Hemophilia Influenza Type B
		HEP B	Hepatitis B
		OPV	Polio
		PNEUMOCOCCAL	Pneumonia
		ROTA VIRUS	Rotavirus
4	**14 Weeks**	**DPT**	Diphtheria, Pertussis, Tetanus
		HIB	Hemophilia Influenza Type B
		HEP B	Hepatitis B
		OPV	Polio
		PNEUMOCOCCAL	Pneumonia
		ROTA VIRUS	Rotavirus
5	**6 Months**	**VIT A**	Vitamin A Deficiency
6	**9 Months**	**MEASLES**	Measles
		YELLOW FEVER	Yellow fever
7	**18 MONTHS**	**MEASLES**	Measles

Appendix 41: Fridge Tag2 in use and Un-discarded Measles –Rubella after use

Appendix 42: Cold trace - Remote Temperature Monitoring (RTM) Device

Appendix 43: Counties classified under highest risk of M-R outbreak and marked for implementation for M-R Supplementary Immunization Activities in June 2021



Bomet	*Bungoma*
Homabay	*Kisii*
Kilifi	*Baringo*
Kakamega	*Mandera*
Narok	*Turkana*
Wajir	*Trans-nzoia*
Elgeyo-marakwet	*Vihiga*
Migori	*Busia*
Kisumu	*Nairobi*
Kajiado	*Garissa*
West-pokot	*Tana river*

Source: DHIS 2014-2019

Appendix 44: Association between functionality of fridges and thermo-stability of Live-Attenuated vaccines

			Stability of Live Attenuated Vaccines		Total	95%CI; χ^2 value; df; p-value
			Unstable	Stable		
Fridge functionality	Fully functional	Frequency	32	45	77	0.000-0.025; 7.396; 1; **0.007**
		% within Fridge functionality	41.6%	58.4%	100.0%	
		% of Total	26.7%	37.5%	64.2%	
	Partially functional	Frequency	29	14	43	
		% within Fridge functionality	67.4%	32.6%	100.0%	
		% of Total	24.2%	11.7%	35.8%	
Total		Frequency	61	59	120	
		% within Fridge functionality	50.8%	49.2%	100.0%	
		% of Total	50.8%	49.2%	100.0%	

Key: Significance was determined by Pearson Chi-square analysis.Values in bold are statistically significant at P≤0.05.df=degree of freedom; CI=confidence Interval

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Appendix 45: Association between functionality of fridges with stability of all types of vaccines

			Stability of the vaccines		Total	**95%CI; χ^2 value; df; p-value**
			Unstable	Stable		
Fridge functionality	Fully functional	Frequency	27	50	77	0.000-0.025; 40.835; 1; **0.000**
		% within Fridge functionality	35.1%	64.9%	100.0%	
		% of Total	22.5%	41.7%	64.2%	
	Partially functional	Frequency	41	2	43	
		% within Fridge functionality	95.3%	4.7%	100.0%	
		% of Total	34.2%	1.7%	35.8%	
Total		Frequency	68	52	120	
		% within Fridge functionality	56.7%	43.3%	100.0%	
		% of Total	56.7%	43.3%	100.0%	

*Key: Significance was determined by Pearson Chi-square analysis**.** Values in bold are statistically significant at P≤0.05.df=degree of freedom; CI=confidence Interval*

Appendix 46: Association of Functionality of vaccine carriers with stability of live-attenuated vaccines

			Stability of Live Attenuated Vaccines		Total	**95%CI; χ^2 value; df; p-value**
			Unstable	Stable		
Vaccine carriers functionality	Fully functional	Frequency	15	30	45	0.000-0.025 8.822; 1; **0.003**
		% within Vaccine carriers functionality	33.3%	66.7%	100%	
		% of Total	12.5%	25.0%	37.5%	
	Partially functional	Frequency	46	29	75	
		% within Vaccine carriers functionality	61.3%	38.7%	100%	
		% of Total	38.3%	24.2%	62.5%	
Total		Frequency	61	59	120	
		% within Vaccine carriers functionality	50.8%	49.2%	100%	
		% of Total	50.8%	49.2%	100%	

Key: Significance was determined by Pearson Chi-square analysis. Values in bold are statistically significant at P≤0.05.

Appendix 47: Association of Functionality of vaccine carriers with Thermo-stability of all types of vaccines

			Stability of the vaccines		Total	**95%CI; χ^2 value; df; p-value**
			Unstable	Stable		
Vaccine carriers functionality	Fully functional	Frequency	10	35	45	0.000-0.025 34.787; 1; **0.000**
		% within Vaccine carriers functionality	22.2%	77.8%	100.0%	
		% of Total	8.3%	29.2%	37.5%	
	Partially functional	Frequency	58	17	75	
		% within Vaccine carriers functionality	77.3%	22.7%	100.0%	
		% of Total	48.3%	14.2%	62.5%	
Total		Frequency	68	52	120	
		% within Vaccine carriers functionality	56.7%	43.3%	100.0%	
		% of Total	56.7%	43.3%	100.0%	

*Key: Significance was determined by Pearson Chi-square analysis**.** Values in bold are statistically significant at P≤0.05.*

Appendix 48 Association between Overall cold-chain functionality and thermo-stability of Live-Attenuated Vaccines

			Stability of Live Attenuated Vaccines		Total	95%CI; χ^2 value; df; p-value
			Unstable	Stable		
Cold chain functionality	Nonfunctional	Frequency	47	20	67	0.000=0.025, 22.646; 1; **0.000**
		% within Cold chain functionality	70.1%	29.9%	100.0%	
		% of Total	39.2%	16.7%	55.8%	
	Functional	Frequency	14	39	53	
		% within Cold chain functionality	26.4%	73.6%	100.0%	
		% of Total	11.7%	32.5%	44.2%	
Total		Frequency	61	59	120	
		% within Cold chain functionality	50.8%	49.2%	100.0%	
		% of Total	50.8%	49.2%	100.0%	

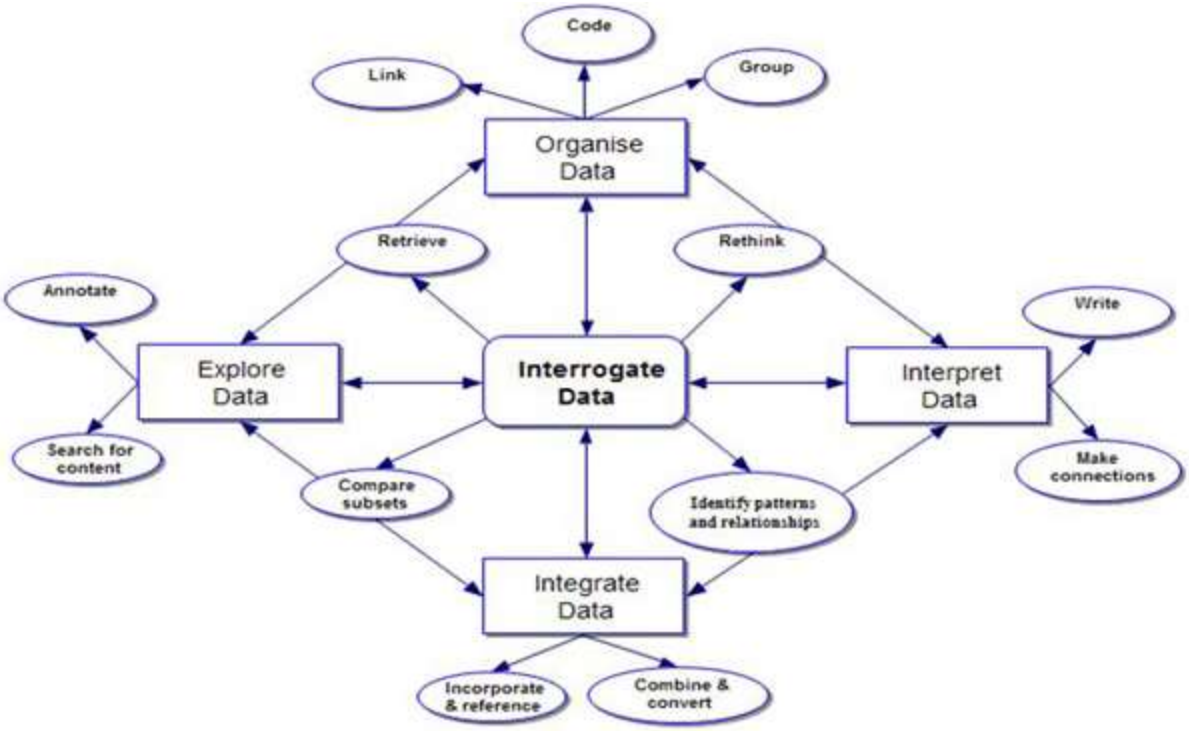
Significance was determined by Pearson Chi-square analysis.. Values in bold are statistically significant at P≤0.05.

APPENDIX 49 Association between Staff Perceptions on Cold-chain Management and thermo-stability Status of all Vaccines

Perception Aspect		Stability of Live Attenuated Vaccines		Chi-square value	95% CI	P value
		Stable	Unstable			
Perception towards diluents for immediate use being in the fridge	correct	52(55.3)	42(44.7)	1.2	.5-3	.630
	wrong	13(50)	13(50)			
Perception towards Icepacks being conditioned before use	correct	36(56.3)	28(43.8)	1.2	.6-2.5	.624
	wrong	29(51.8)	27(48.2)			
Perception towards having extra icepack for outreaches	correct	37(60.7)	24(39.3)	1.7	.8-3.5	.147
	wrong	28(47.5)	31(52.5)			
Perception towards Vaccines being arranged in KEPI fridge to allow free air circulation	correct	45(55.6)	36(44.4)	1.2	.6-2.6	.660
	wrong	20(51.3)	19(48.7)			
Perception towards arrangement of vaccines in fridge based on their temperature sensitivity	correct	47(63.5)	27(36.5)	2.7	1.3-5.8	**.009***
	wrong	18(39.1)	28(60.9)			
Perception towards defrosting the Fridges regularly	correct	44(57.1)	33(42.9)	1.4	.7-3	.381
	wrong	21(48.8)	22(51.2)			
Perception towards charting KEPI fridge temperature twice daily	correct	49(56.3)	38(43.7)	1.4	.6-3.1	.442
	wrong	16(48.5)	17(51.5)			
Perception towards vaccines being transferred to another functional fridge when there is a fridge fault	correct	45(50)	45(50)	0.5	.2-1.2	.113
	wrong	20(66.7)	10(33.3)			
Perception toward prioritizing VVM2 to Expiry date	correct	40(53.3)	35(46.7)	1.0	0.4-.9	.813
	wrong	25(55.6)	20(44.4)			
Overall staff perception towards cold-chain management procedures	correct	30(48)	32(52)	1.7	.8-3.5	.147
	wrong	35(60.3)	23(39.7)			

Key: Significance was determined by Pearson Chi-square analysis unless for P which is by Fisher's exact test. Values in bold are statistically significant at P≤0.05; df=degree of freedom; CI=Confidence Interval*

APPENDIX 50, Qualitative Analysis Coding Frame:



Qualitative tasks and CAQDAS tools, adapted from LEWINS and SILVER (2007)