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

Assessment of vaccines cold chain management practices in public health facilities of Rwanda. A case of Gasabo District, Kigali City

A dissertation submitted in partial fulfilment of the requirements for the degree of

MASTER PROGRAM IN HEALTH SUPPLY CHAIN MANAGEMENT

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DECLARATION

I, Gisèle IRAGUHA, hereby declare that the thesis has been written by me without any external unauthorized help, that it has been neither presented to any institution for evaluation nor previously published I its entirety or in parts. Any parts, words or ideas, of the thesis, however limited, which are quoted from or based on other sources have been acknowledged as such without exception.

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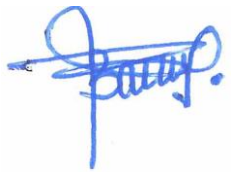
Signature  Date 28/02/2022

DEDICATION

This work is dedicated to my lovely husband Victor Mivumbi NDICUNGUYE and our children Enzo SANGWA, Miguel SHIMWA, Ivy HIRWA, and Zoé INEZA

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Glory to Almighty God for His endless love, grace and protection throughout my studies.

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ABSTRACT

Background: Immunization program faces many challenges including maintaining vaccines potency. To maintain vaccines quality, cold chain guidelines as recommended by World Health Organization (WHO) should be followed. In Rwanda, healthcare workers are supposed to use fridge tags as temperature monitoring devices used in the management of vaccines cold chain in health facilities. However, health providers may not follow the recommended practices in their routine work due to several reasons. **Objective**: The main objective of this study was to explore the vaccines cold chain management practices. **Method**: This was descriptive cross-sectional design using a mixed-method approach. Data were collected among vaccinators handling vaccines in health centres located in Gasabo district, Kibagabaga hospital's catchment area. The data were collected from downloaded reports from fridge tags; qualitative and quantitative data were collected using a structured questionnaire in Kobo toolbox software. The analysis has been done using STATA and Excel. **Results:** In this study, most of the respondents (94%) had received a formal training on cold chain management and all of them received supervision on vaccine and cold chain management. All (100%) visited health facilities had functional refrigerators exclusively reserved for vaccines as well as fridge tags devices for temperature monitoring. Generally, this study revealed good knowledge on vaccine cold chain management among vaccinators. The main cold chain management challenges revealed by this study include the lack of maintenance plan (77%), untrained assistant vaccinators (59%), lack of power backup generators (23.5%), irregularity of power supply (11%) and fridge tag alarm (11%).

Conclusion: Best practices are the backbone of effective cold chain system as they prevent loss of vaccines and preserve cold chain equipment. In this study, data downloaded from the fridge tags have shown high temperatures above the recommended range in all the visited health facilities, however most of respondents had good knowledge, attitudes and practices towards vaccine cold chain management. Although, there are challenges in cold chain management, vaccinators had managed to find temporal and long term solutions towards those challenges. Regular supportive supervision, trainings and availability of functional cold chain equipment contribute to the sustained and effective cold chain system.

Key terms: cold chain, fridge tag, immunization, refrigerators, vaccinator, vaccines

LIST OF SYMBOLS AND ACRONYMS

BCG: Bacillus Calmette–Guérin

CCE: Cold Chain Equipment

CHAI: Clinton Health Access Initiative

COVID19: Coronavirus Disease of 2019

DNA: Deoxyribonucleic Acid

DRC: Democratic republic of Congo

DT: Diphtheria and Tetanus

DTP: Diphtheria, Tetanus and Pertussis

EPI: Expanded Program on Immunization

EVM: Effective Vaccine Management

FEFO: First Expiry First Out

GAVI: Global Alliance for Vaccines and Immunization

HBV: Hepatitis B Vaccine

Hib: Haemophilus Influenza/Hepatitis B

LCD: Liquid Crystal Display/not downloadable)

MDVP: Multi Dose Vial Policy

MMR: Mumps Measles and Rubella

MR: Measles and Rubella

OPV: Oral Poliomyelitis Vaccine

PQS: Performance, Quality and Safety

RNA: Ribonucleic Acid

TMS: Temperature Monitoring Studies

UNICEF: United Nation Fund for Children

USAID: United State Agency for International Development

VVM: Vaccine Vial Monitor

WHO: World Health Organization

DEFINITION OF KEY TERMS

Cold chain: is a system of maintaining vaccines potency in controlled low temperatures throughout the storage and transport from the manufacturer up to the service delivery point.

Effective Vaccine Management: is a national EPI planning process endorsed and supported by WHO and UNICEF launched in 2009 to assess and prioritise improvements in the immunisation supply chain.

Fridge-tag: The Fridge-tag is the intelligent temperature monitor for the continuous monitoring of sensitive vaccines and pharmaceuticals stored in medical refrigerators & freezers. The Fridge-tag measures the ambient temperature every minute and immediately issues an alert when the alarm limit is exceeded.

Immunization: is the process whereby a person become immune against infectious diseases through vaccination

Vaccinator: is a healthcare provider who administer vaccines to the beneficiaries

Vaccines: are biological products administered to human beings in order to stimulate the body's immune system against infectious diseases

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CHAPTER 1: INTRODUCTION

1.1. Background

Immunization is one of the most successful public health interventions which saves millions of lives every year(1). Between 2010 and 2018, 23 million deaths were averted with the measles vaccine alone. Considering the number of infants vaccinated annually, more than 116 million or 86% of all infants born were vaccinated and this was highest level ever reported(2). Nowadays, more than 20 life-threatening diseases can be prevented by immunization(2) .

Vaccines are biological products that are used to prevent diseases. When vaccines are effective they create the intended immunity in the vaccinated person's body and it is at this time the vaccinated person become immunized(3). Some vaccines are produced from the same microorganisms or toxins which cause diseases, but they are modified to become harmless to human bodies. The three main ways of vaccines production use are live microorganisms, killed microorganisms, and toxoids. In addition to this and with advanced technologies, there are also some vaccines which are produced using genetic engineering technologies such as recombinant DNA Hepatitis B vaccine and recombinant RNA in vaccine against Corona virus disease of 2019 (covid19) (4).

All vaccines are sensitive biological products that lose their potency progressively. The potency of vaccines is the ability to give the intended protection against diseases. Once vaccines are exposed to temperatures against recommended ranges; the potency is lost and returning vaccines to correct storage conditions cannot restore it, it is permanent and irreversible(4).

In 2014, 20% of health facilities in low- and lower-middle-income countries did not have any cold chain equipment to store vaccines and protect them against heat damage(6). The same author added that, of the equipped health facilities, only 2% had a functional cold chain that used optimal cold chain technologies. The remaining 78% of facilities were equipped with cold chain equipment that was either not functional or that used obsolete technology, putting vaccines at risk of temperature damage(6).

A review of the literature revealed widespread freezing at many levels of the vaccine-distribution system(7) whereas emphasis is frequently placed on preventing vaccine heat exposure, with many immunization providers unaware that monitoring and preventing vaccine freezing is also

essential(8,9). The GAVI (Global Alliance for Vaccines and Immunization) has reported that three in four African countries lacked adequate systems for proper vaccine handling, leading to expired vaccines or damaged vaccines during storage and transit which contribute to the increase of vaccines wastage and stock-outs(10). The health facilities also need knowledgeable health care providers who are willing to manage the vaccine cold chain and are able to handle problems encountered. In addition to having good and well-functioning cold chain equipment, there is a need for commitment from decision makers to ensure health care providers are trained regularly, continuous on the job training are provided and challenges are solved in a timely manner(11,12)

The USAID (United States Agency for International Development) assessment conducted in Tanzania and Democratic Republic of Congo has shown that cold chain of vaccines is hindered by lack of knowledge of healthcare providers in handling vaccines and poor, outdated or broken cold chain equipment including temperature monitoring equipment(13); other studies conducted in different countries revealed gaps in the knowledge of healthcare workers involved in cold chain management(14 - 16).

Although the last effective vaccine management (EVM) report conducted in Rwanda (2018) revealed promising results for most of the criteria assessed, some gaps and challenges in vaccine cold chain management from the central vaccine store up to service delivery points were reported(16). Therefore, this study aimed to identify vaccines cold chain management practices, highlight the challenges encountered and provide information on how vaccinators address the challenges met.

1.2 Problem statement

Since 2009, the WHO (World Health Organization has initiated the EVM assessment in order to assess the performance of immunization supply chain system in countries. There are 9 criterions to be assessed and the findings from that assessment enable identification of key strengths, weaknesses and bottlenecks of the immunization supply chain system; from the findings also comprehensive improvement plan is developed to address the gaps and improve the performance of the system(6).

The EVM assessments conducted in 70 countries from 2010 to 2014 have revealed that against the WHO recommended standards in vaccine management only 14% met the temperature monitoring

standards; 8% met the maintenance standards; 18% met the stock management standards and 33% met vaccine management standards(6). This remains a challenge in cold chain management.

The EVM assessment conducted in Rwanda in 2018 and other EPI supervision reports found gaps and challenges in vaccine cold chain management from the central vaccine store up to service delivery points. This EVM assessment highlighted that among the main challenges there is inaccurate temperature monitoring records, untrained personnel in charge of vaccine management and unavailable preventive maintenance and contingency plans for CCE(17) and these challenges lead to inappropriate handling of vaccines and loss of vaccines potency.

Therefore, this study aimed to explore vaccinators' knowledge, attitudes, and practices towards vaccines cold chain management in Rwandan health facilities and to inform decision makers on how to fill the gaps revealed by the study.

This assessment enabled the researcher to collect the data from selected health facilities located in Gasabo District, Kibagabaga Hospital's catchment area, to analyse them, to document and publish the vaccine cold chain management practices; it also provided guidance on potential solutions to identified issues especially on when and how to respond in the event of an emergency such as lack of power back up, cold chain equipment failure, a power supply failure or any other situation that puts vaccine at risk.

1.3 Research Question

1. How is the vaccine temperature monitoring being carried, recorded, and stored at health facilities?

2. What are the knowledge, attitudes and practices of vaccinators regarding cold chain management; and how they manage challenges while handling vaccines.

1.4 Research Objective:

The general objective of this study was to assess vaccinators' knowledge, attitudes and practices towards vaccines cold chain management in Gasabo district, Kibagabaga hospital's catchment area and to provide potential solutions to the identified challenges.

1.5 Specific objectives

To perform this study, the following are specific objectives:

1. To determine if vaccines are stored in the recommended temperature according to the extracted data from fridge tags;
2. To assess the knowledge, attitudes, and practices of vaccinators regarding vaccines cold chain management;
3. To identify the cold chain management challenges faced by vaccinators and their strategies to address those challenges.

Significance of the study

To the best of our knowledge, there is no published studies conducted on the vaccines cold chain management practices in Rwandan health facilities. Therefore, this study aimed to explore the practices of vaccinators on vaccines cold chain management practices. This assessment enabled the researcher to collect the data from selected health facilities, to analyse them, to document and publish the vaccine cold chain management practices in Gasabo District; it has also provided guidance on potential solutions to identified issues related to vaccines cold chain management.

CHAPTER 2: LITERATURE REVIEW

2.1. Overview of the study topic

WHO recommends that all vaccines should be strictly stored in the recommended temperature ranges at all tiers. Practices exposing vaccines to both high and sub-zero temperatures are widespread in both developed and developing countries at all levels of health systems(18).

To ensure good storage and distribution practices, effective, well-managed temperature monitoring and record-keeping procedures are crucial. These procedures help to ensure that: vaccine quality is maintained throughout the vaccine supply chain; vaccine is not wasted due to exposure to heat or freezing temperatures at fixed storage locations or during transport; cold chain equipment performs according to recommended standards; and when problems arise, they are rapidly detected and corrective action is taken(19).

As the studies conducted previously have shown that cold chain challenges may happen at any level of the chain but very common and critical at periphery level(20), the Performance, Quality and Safety (PQS)2 project in Immunization, Vaccines and Biologicals Department of UNICEF has approached temperature monitoring device manufacturers to develop a temperature monitoring device with the following features:

(a) Capacity to store the last 60-day temperature recordings that can be checked through a history mode and read through an LCD (liquid crystal display/not downloadable);

(b) Pre-set alarms for high (above +8°C over 10 hours continuously) and low (-0.5°C and lower for 1 hour continuously) temperature exposures;

(c) Display the highest and lowest temperatures reached as well as their duration compared to pre-set alarms through the history mode.

Compared to the regular thermometers, the manufactured device Fridge-tag® has the following advantages among others: (a) ensure uninterrupted temperature monitoring in the refrigerator; (b) data retention for the last 60 days to enable monitoring temperature, (c) easy handling and no software needed to analyse the data; (d) pre-set alarms to warn health workers if there are any

violations of cold-chain system; and (e) provides detailed information on violations (minimum and maximum temperatures reached and the duration of each violation in hours and minutes)(21).

2.2 Vaccines storage conditions

Vaccines are biological products that require to be stored and transported within a cold chain and their temperature range requirements are based on the data supplied by the manufacturers. It is very important to monitor vaccines' temperature to ensure that the vaccinated person is immunised as intended; once vaccine potency is lost, it cannot be regained(19). Each vaccine has its own specific storage requirements so it is extremely important to know how long, and at what temperature each vaccine can be stored. Vaccines which are most sensitive to heat are OPV, DT and Hib; the most sensitive vaccines to freezing are DTP, HBV and Hib (liquid; and the most sensitive vaccines to light are BCG, Measles, MR, MMR (4).

Regarding the immunization supply chain, vaccines are stored at different levels and their temperature storage conditions change accordingly. At the central and regional levels of the cold chain, OPV must be kept frozen between -15°C and -25°C, and other vaccines are stored at between +2°C and +8°C. At district and health facility levels all vaccines should be stored at between +2°C and +8°C. The vaccine's cold chain equipment varies depending on the storage level of the health system. Among the cold chain equipment, there are cold and freezer rooms used at central and regional levels; refrigerators and freezers which are used to district and health facilities; and there are also cold boxes and vaccines carriers used during transportation from one level to another(22).

Despite the above-stated vaccine's storage conditions, there are still gaps in its compliance at different levels of the cold chain management observed in developed countries as well as in lower and middle income countries. In 2014, WHO has revealed that 20% of health facilities in low and lower-middle income countries did not have any cold chain equipment to store vaccines and protect them against heat damage. Of the equipped health facilities, only 2% had a functional cold chain that used optimal cold chain technologies. The remaining 78% of facilities were equipped with cold chain equipment that was either not functional or that used obsolete technology, putting vaccines at risk of temperature damage(6). In Africa, studies show that poorly maintained equipment, untrained personnel, and lack of administrative commitment are the main causes

hindering vaccine's storage conditions. An assessment conducted in Ghana, Kenya and Uganda highlights that an average of sixteen percent of the sampled facilities were not compliant with the guidelines laid out by regulatory authorities and fifty percent of these facilities had temperatures excursions for 4°C or more outside the recommended temperatures(23).

A study conducted by CHAI (Clinton Health Access Initiative) in 9 African countries plus India, has found that many countries are struggling to maintain required storage temperatures, with 17–33% of CCE across four countries found to be inactive at the time of assessment(24). Temperature monitoring studies (TMS) have found that active CCE (Cold Chain Equipment) is often not functioning properly, with significant temperature control problems. Malfunctions are common at the facility level, where CHAI and partner-supported TMS have found that between 29% of CCE are exposing vaccines to freeze risk(24). The EVM assessment of 2018 conducted in Rwanda has also revealed some poor vaccines storage conditions where temperature monitoring study recommendations are not implemented at the central level and lack of reports from temperature monitoring devices observed at the health facility level(25).

2.3 Vaccinators' knowledge and practices in cold chain management

Having skilled and knowledgeable health care providers in charge of the cold chain management is one of the pillars of successful immunization programs but many studies conducted in different countries around the world have revealed remarkable gaps in cold chain management due to lack of skills or poor practices of health care providers in charge of cold chain management (24,26,27). A study conducted in Ethiopia found that only 24.4% of the respondents have been trained on cold chain management and 27.6% are the ones who have been supervised on cold chain management(1). The same authors reported that, below half of respondents (48.8%) had positive attitudes and practices regarding cold chain management(1).

A study conducted in Nigeria revealed that 22.11% of the respondents stored vaccines incorrectly and 67.9% had poor practices regarding cold chain management(15).

Another study conducted in India has recommended relevant trainings for health care providers handling vaccines as improper vaccine storage was still observed in 10% of assessed health facilities(28). The same study reported that only 61.8% of the respondents had correct practices in

defrosting the freezers, 33% of assessed facilities had no proper record of temperature, only 45% of the health centres had an electrical power generator, and 90% of these health centres reported frequent power failures.

2.4 Challenges of cold chain management

The common challenges met by health care providers managing the vaccine's cold chain are less supportive supervisions and trainings regarding vaccine cold chain management; lack of appropriate cold chain equipment including refrigerators, freezers, cold boxes, vaccine carriers and also temperature monitoring devices; the power break which exposes vaccines to temperature excursions especially the heating; and there is also equipment failure causing freezing or heating of the vaccines(15). An evaluation of cold chain monitoring conducted in Malaysia has shown a gap of training among healthcare providers handling vaccines, the potency test was not done regularly, the lack of contingency plan in case of a power cut or other problems of cold chain equipment, and those challenges were leading to expiration of some vaccines and increased wastage.(29)

The studies conducted in Nigeria and Ethiopia found that cold chain challenges result in knowledge gaps of healthcare, poor vaccine handling practices, and lack of timely potential solutions by health workers (14,30–32). Therefore, an assessment conducted in Kenya highlighted that a remote temperature monitoring system with improved data review is a nice tool suggested to be used in resources limited settings and the results demonstrated that the real-time alarms for temperature excursions increased staff's awareness of cold chain performance and their responsiveness to temperature excursions and facilitated the long term decisions for recurring cold chain issues(33).

The EVM assessments conducted in Rwanda in 2015 and 2018 have also revealed poor temperature recording, lack of interpretation of data, lack of freeze indicators in vaccines cold boxes and carriers, poor skills to perform shake test in case of freezing exposure, and lack of knowledge to implement multi dose vial policy (MDVP)(28)

2.5 Conceptual framework

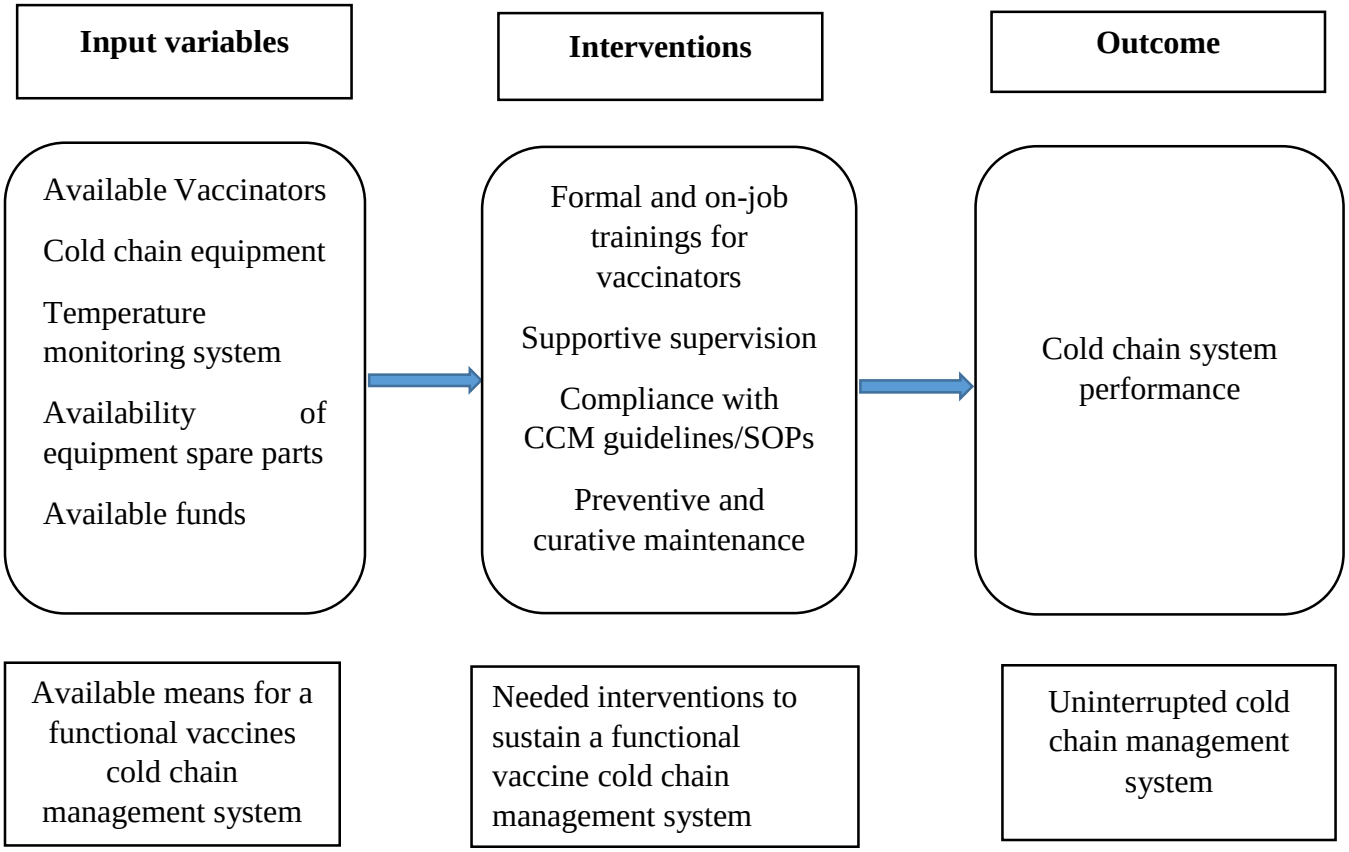

Figure 1: Conceptual framework

This study has revealed a relationship between a performing Cold chain system in health facility and key inputs such as the availability of vaccinators who handle vaccines and monitor the temperature; functional cold chain equipment, reliable temperature monitoring system and availability of equipment spare parts. Therefore, those inputs are influenced by formal and on-job trainings for vaccinators, supportive supervisions, compliance with cold chain management guidelines/SOPs, and regular maintenance towards a performing cold chain system

2.6 Gap analysis

A successful vaccine cold chain management is a system which requires human resources, cold chain equipment, funding and committed leadership. As per the EVM global data analysis carried out by WHO and UNICEF, most of the countries fail to meet temperature monitoring standards at any level of the health system; preventive maintenance system gets weaker progressively from central to health facility level; and only 25% of the countries were meeting the standard of vaccine management(34). And as seen in the reviewed literature, there is a gap in the knowledge and practices of cold chain management compared to the required standard of WHO(35).

CHAPTER 3: METHODOLOGY

3.1. Study setting

This study was conducted in Gasabo district, Kibagabaga hospital catchment area with its 16 public health centres. Gasabo district is located in the north east part of Kigali City the capital of Rwanda and has population of 530907. Kibagabaga hospital's catchment was selected because Gasabo district is the largest district in Kigali city with mix of rural, semi-urban and urban settings which enabled the researcher to document findings from both rural, semi-urban and urban health facilities. The health facilities were grouped into five categories as follow: firstly, Kibagabaga hospital, urban Health Centres, Health Centres in semi urban area, Health Centres in rural area/ far from hospital, and lastly, Health Centres without power back-up generator

3.2. Study Design

This study was a descriptive cross-sectional design using both quantitative and qualitative methods. The quantitative approach was used to assess if vaccines are stored in recommended temperature ranges along with the entire cold chain system, to identify knowledge, attitudes, and practices of health care providers. The qualitative approach was used to assess the temperature records downloaded from fridge tags; to identify challenges faced by vaccinators while managing cold chain at their health facilities and to find out different strategies they use to handle those challenges.

3.3. Source of data

In this study, fridge tags data recorded for a period of the past 60 days from the day of health facilities' visit were extracted. In addition, data related to knowledge, attitudes, practices, challenges, and strategies were collected from vaccinators using a structured questionnaire in Kobo toolbox software plus direct observation at health facilities.

3.4. Study population and sampling

Healthcare providers (vaccinators) responsible for vaccines management (ordering, receiving, storing, vaccination, and maintenance of CCE) were assessed to determine their knowledge and attitudes in using and interpreting data from the fridge tags, find out the cold chain challenges they are facing during vaccines' handling and the strategies to address those challenges. In each health

facility included in the research, the vaccinator was interviewed. Vaccinators were selected because they are the ones involved in managing vaccines' cold chain. Therefore, no other health care providers could better answer the vaccines cold chain management-related questions.

In total 17 vaccines, stores/ public health facilities located in Gasabo District/Kibagabaga hospital's catchment area were all assessed, sixteen vaccinators from 16 selected health centres and 1 hospital EPI supervisor participated in this study. Gasabo District geographical location is very interesting with facilities located in urban area, semi-urban area and others in rural area. We believe that 17 health facilities provide enough data to indicate a general picture of the vaccines cold chain management practices

3.5 Data collection and instruments

To assess that vaccines are kept in recommended temperature ranges, each and every refrigerator storing vaccines has a functional temperature monitoring device called fridge tag which is able to record temperature data for 60 days. A direct observation was performed to record the practices. In addition, a semi structured questionnaire was developed to collect information related to vaccinators knowledge, attitudes, and practices, challenges faced, and strategies that they use to address those challenges. These data were collected using face to face interviews at the health facility.

3.6 Measures to be collected

Variables to be collected include:

3.6.1 Independent variables: social demographic characteristics of the study participants and health facility characteristics,

Cold chain management related knowledge: this was measured using different variables including knowledge about types of vaccines and their sensitivity, knowledge of FEFO/EEFO principles, the correct placing of a thermometer, demonstration of temperature reading, temperature for vaccine storage, interpretation of VVM, and interpretation of shake test.

Cold chain management related attitudes: measured by ranking variables including placing food or drinks in vaccines refrigerator, open vaccines refrigerators ≤ 2 times a day, using reconstituted vaccines within 6 hours or less and using vaccines before their expiration date.

3.6.2 Dependent variables: level of practices: they were measured as follow**:**

Cold chain management practice: measured using different variables including proper arrangement of different types of vaccines in the refrigerator, application of FEFO/EEFO principles.

Vaccine storage: measured using variables including recommended vaccine storage ranges, availability of proper cold chain equipment and temperature monitoring devices.

Direct observation used to measure variables including availability of temperature monitoring chart and maintenance plan, availability of power backup generator and vehicle/motorbike for vaccines logistics and

In addition, challenges faced and strategies used to address those challenges were collected using open-ended questions.

3.7 Data analysis

In this study, we used Microsoft Excel (2016 version) to analyse the data recorded for a period of the past 60 days from fridge tag devices. The descriptive analysis was done to determine the level of knowledge, attitudes and practices of vaccinators towards cold chain management; Besides, challenges and strategies used to address challenges were coded and analysed.

3.8 Ethical considerations

This project was conducted with the approval of the College of Medicine and Health Sciences Institutional Review Board (IRB). Ethical clearance from Kibagabaga hospital was also obtained. All participants provided written informed consent prior to enrolment. Information sheet indicating the purpose of the study, and other study details were provided. Participation was entirely voluntary, and data were obtained anonymously and reported in aggregate form. None of the respondents expressed a desire to discontinue participation after providing consent.

3.9 Study limitation

Due to the limited resources and time constraints, our study was conducted only in Kigali city on small sample size; moreover, the factor that Kigali city study area is nearby central level might have contributed to the vaccinators' good practices as final study results.

CHAPTER IV. RESULTS

The study results are presented under 7 categories: the social demographic, facility fridge tag data, knowledge of healthcare providers on vaccines management, healthcare providers' attitudes regarding vaccine cold chain management, practices, and CCE availability, as well as challenges encountered during cold chain management, and strategies used to address the challenges faced.

4.1 Social Demographic data

In this study, the age of the respondents was diversified between 26 to 53 years, and the majority (47%) is above 46 years old. In all 17 respondents, fourteen 14 (82%) of them were female. It was observed that most vaccinators have A2 level (secondary), a low number has A0 level, however, one supervisor at District Hospital has a master's in public health; nurses are 14 (82%) while 2 are midwives and 1 is a public health officer. The work experience is quite good, because the mean is 16 years, only one respondent has experience of one year.

Most of the respondents (94%) had received a formal training on cold chain management and all of them received supervision on vaccine and cold chain management.

Table 1:Social Demographic data

Age	**%**
26-34 years	11.8
35-45 years	41.2
≥46 years	47.1
Sex	
Female	82.4
Male	17.7
Level of education	
A0	11.8
A1	35.3
A2	47.1
Masters	5.9
Designation	
Midwife	11.8
Nurse	82.4
Public health	5.9
Work experience	
1-5 years	5.9
6-15 year	41.2
16-25 years	52.9
Received training on vaccine and cold chain management	
no	5.9
yes	94.1
Time of last training	
6 months ago	17.7
6 to 12 months ago	64.7
Above 1 year ago	11.8
not trained	5.9
Received supervision on vaccine and cold chain management	
yes	100
Time of last supervision	
6 months ago	82.4
6 to 12 months ago	11.8
Above 1 year ago	5.9

4.2 Temperature monitoring devices data

Even though temperature monitoring and recording is done regularly in all health facilities, the downloaded fridge tags data from 17 visited health facilities contain only high upper alarm limit temperatures and this was observed in all the 17 (100%) visited health facilities. Two (11.7%) respondents have noticed temperature excursions and alarms in the fridge tags over the past 60 days. The figure below represents the upper alarm limit temperature parameters of sixty past days recorded by the temperature monitoring device (fridge tag) from each visited health facility, and we observed high temperature beyond recommended normal ranges to store vaccines.

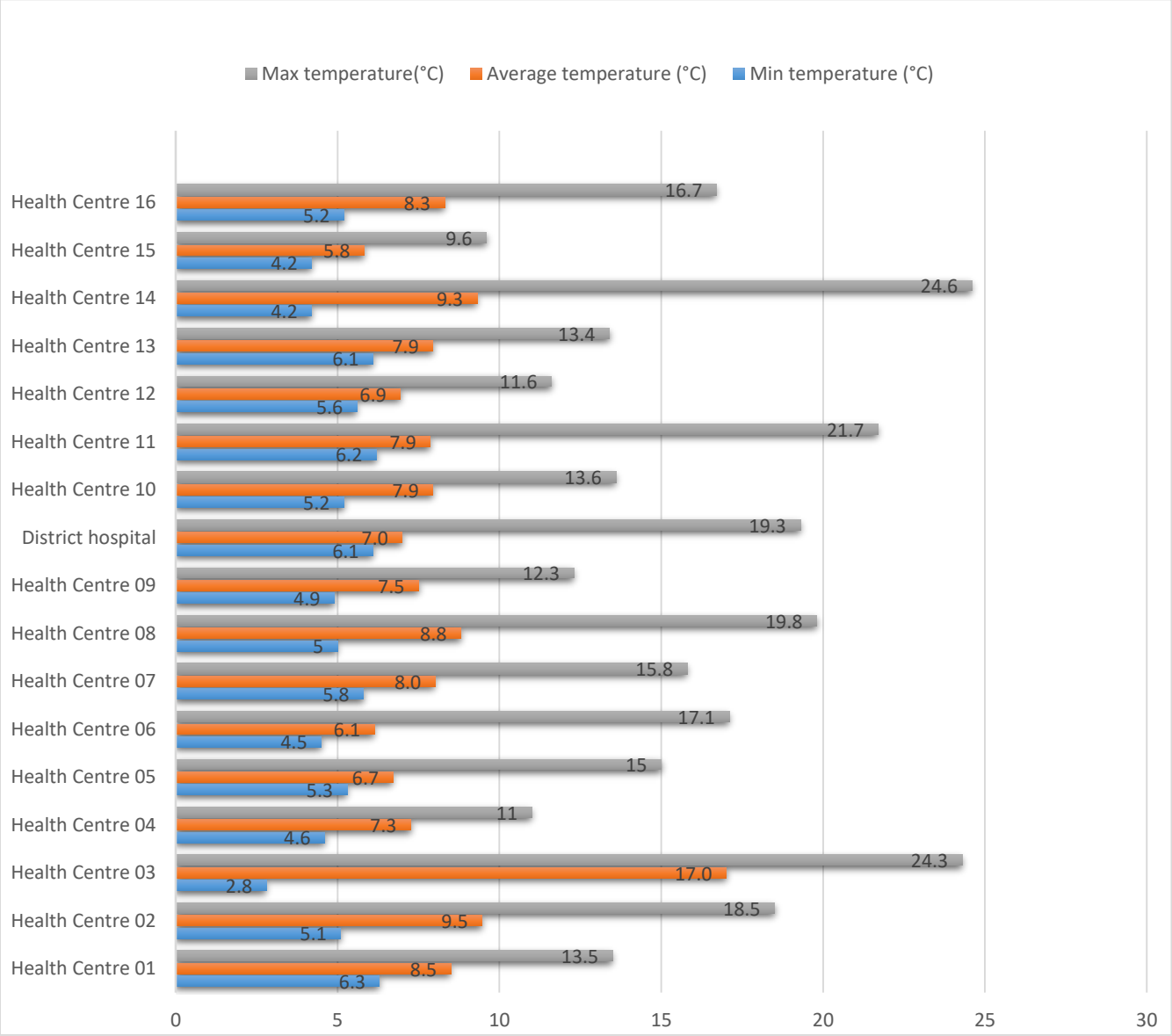

Figure 2:Upper alarm limit parameters from fridge tags of 17 visited HFs

4.3 Knowledge of vaccinators on cold chain management

In this study, all respondents were aware on vaccine's heat and freezing sensitivity, however 88% of the visited facilities had arranged vaccines in the refrigerators according to that sensitivity and 64% of the respondents knew the correct place of the temperature monitoring device inside the refrigerator. The vaccine vial monitor (VVM) and its stages as well as the FEFO (first expiry first out) rule and the multi-dose vial policy (MDVP) were well known by all respondents interviewed. While, the majority (94%) were aware of the shake test and how is performed; however, only eleven (64%) visited health facilities had a national guideline on immunization.

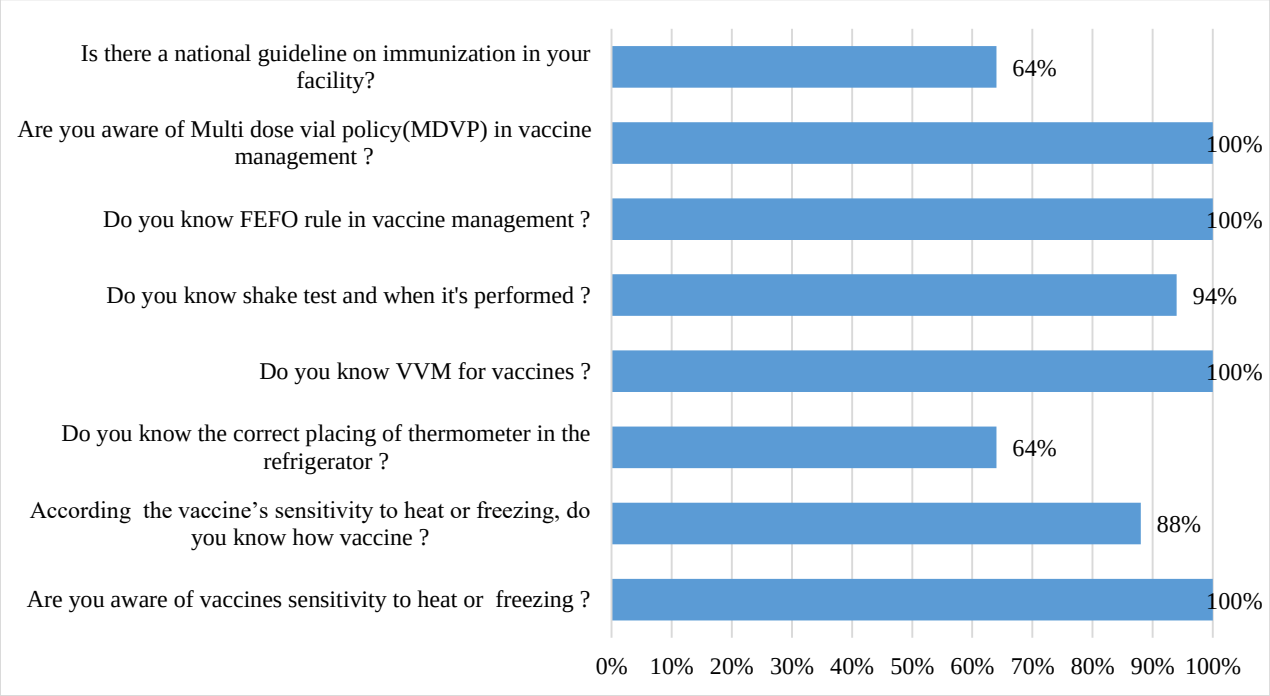

Figure 3: Knowledge of vaccinators on cold chain management

4.4 Vaccinators' attitudes towards vaccine cold chain management

To assess attitudes of vaccinators towards vaccine cold chain management, the respondents had to rank the statements from strongly disagree to strongly agree. The findings indicated that 59% of the respondents strongly agreed and 41% agreed on how placing food and drinks with vaccines in the refrigerator affect vaccine potency; the same figures were observed regarding placing an "open when needed" label on the vaccine's refrigerators and the majority (65%) agreed that vaccine's refrigerators should be opened ≤ 2 times a day.

Among the interviewed respondents, 53% strongly agreed while 47% agreed that all vaccines should be used before the expiration date and the reconstituted vaccines should be used within 6 hours.

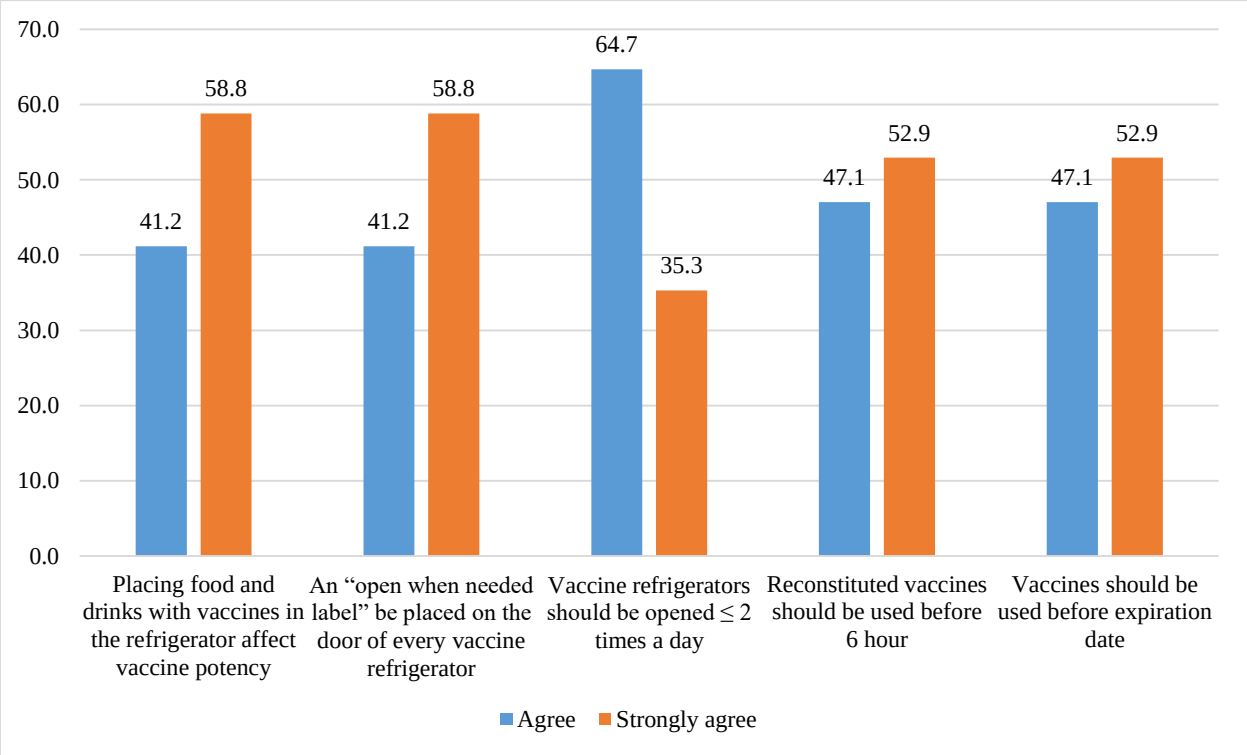

Figure 4:Vaccinators' attitudes on vaccine cold chain management

4.5 Vaccines cold chain management practices and equipment availability

All visited health facilities had at least one functional refrigerator exclusively reserved for vaccines. Among seventeen health facilities, the majority (59%) of them were equipped with Haier ice lined refrigerators; others were equipped with different models respectively presented in the figure below.

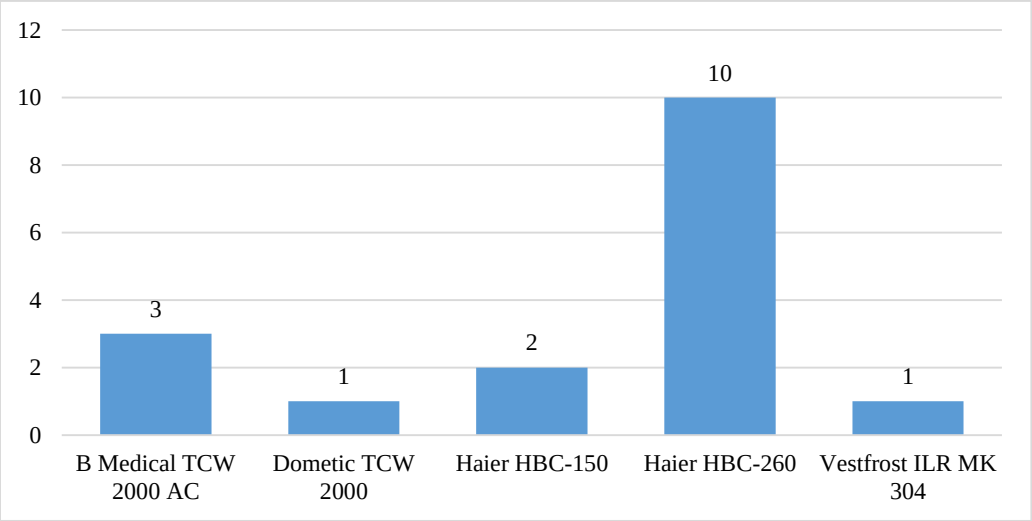

Figure 5:Models of refrigerators

Among the refrigerators of the 17 visited health facilities, 15 of them had temperature monitoring records maintained between 2 to 8 degrees while two of them have had technical issues and temperature excursions in the past 60 days. Tidiness and well arrangement of vaccines were observed in 12 refrigerators (70.5%) out of 17. Three (17.7%) vaccines refrigerators had other things such as oxytocin and lab reagents. The Vaccine management according to FEFO rule, VVM status recording, availability of functional fridge tags and temperature monitoring charts were available, moreover there was personnel in charge of temperature monitoring in all (100%) visited health facilities. There were no expired nor frozen vaccines observed. The functional thermometers were only present in less than half (41%) of visited health facilities.

The power backup generators and their fuel were available only in 13 (76.4%) health facilities; CCE spare parts were available in 9 (52.9%) health facilities while 16 (94.1%) respondents are trained on cold chain maintenance. One (5.9%) in 17 visited health facilities did not have a car or motorbike dedicated for vaccines logistics.

Table 2:Vaccines cold chain management practices and equipment availability

Characteristics	**Frequency**	
	Yes (%)	**No (%)**
Is there functional refrigerator(s) exclusively reserved for vaccines ?	17(100)	
Is refrigerator temperature maintained between 2-8 degrees Celsius ?	15(88.2)	2(11.8)
Are vaccines properly arranged in refrigerator?	12(70.5)	5(29.5)
Anything other than the vaccine stored in refrigerator?	3(17.7)	14(82.3)
Is the vaccine management following FEFO principle?	17(100)	
Is there functional Fridge tag in the vaccine refrigerator(s)?	17(100)	
Is there a temperature monitoring chart available for vaccine's refrigerator?	17(100)	
Is there functional thermometer for refrigerator?	7(41.2)	10(58.8)
Are there expired vaccines present in refrigerator?		17(100)
Is there frozen vaccines present in refrigerator?		17(100)
Is the vaccine packing area protected from direct sun light?	12(70.5)	5(29.5)
Is VVM status of vaccine recorded for each vaccine?	17(100)	
Is there downloaded temperature records from fridge tags for the last two (2) months?	15(88.2)	2(11.8)
Is there a functional backup generator in the facility?	13(76.4)	4(23.6)
Is there a functional car/motorbike to use in vaccines logistics?	16(94.1)	1(5.9)
Is there a trained person for cold chain equipment maintenance?	16(94.1)	1(5.9)
Are spare parts for CCE maintenance available?	9(52.9)	8(47.1)
Is there a permanently assigned personnel for cold chain follow up?	17(100)	
Is fuel for generator available?	13(76.4)	4(23.6)
Is fuel for motor/car available?	16(94.1)	1(5.9)

4.6 Challenges encountered during cold chain management and how they were addressed

The analysis of the interview data has revealed various challenges faced by vaccinators while managing cold chain and how they addressed them.

Major challenges revealed by the study are lack of formal cold chain management training for the assistant vaccinators which was found in more than half (59%) of visited health facilities; lack of maintenance plan in most (77%) health facilities; 23.5% of the visited health facilities were not equipped with power backup generators while the irregularity in power supply was mentioned in 2 health facilities (11.%).

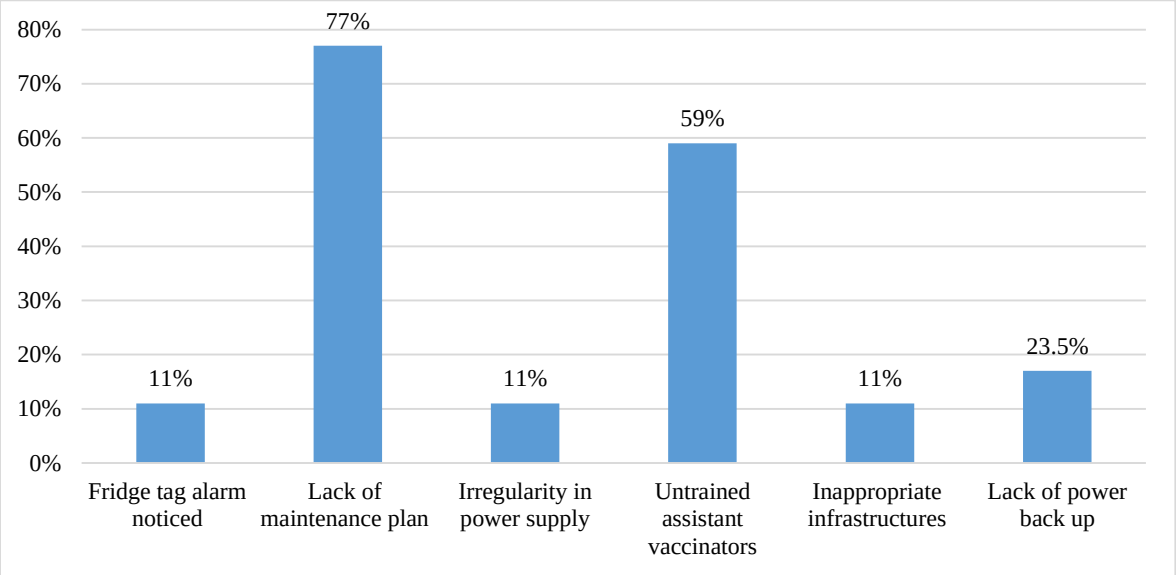

Figure 6: Challenges encountered in vaccines cold chain management

4.7. Strategies used to address faced cold chain management challenges

To address the challenges faced by vaccinators while managing cold chain, ten respondents (59%) have mentioned that once there are damaged vaccines in the health facilities they would report to the higher level (district hospital) and request for new quantities while other 7 (41.2%) would put the vaccines in the quarantine and inform the supervisor. Regarding alarms in fridge tags mentioned by respondents from two health facilities (11.7%), the data were presented to the supervisor and the vaccines refrigerators were technically assessed to determine the cause of the temperature excursions, which caused alarms in fridge tags. On job trainings were temporal solution to support no trained assistant vaccinators as it was observed in the majority (59%) of the visited health facilities. Health facilities having irregularity of power supply are collaborating with the nearest ones with stable power supply to store their vaccines once the CCE are not well functioning. Two (11.7%) health facilities with inappropriate infrastructure have reported it to the hospital management and requested to expand their buildings. The requests for additional CCE from two (11.7%) health facilities without alternative CCE were sent to District hospital.

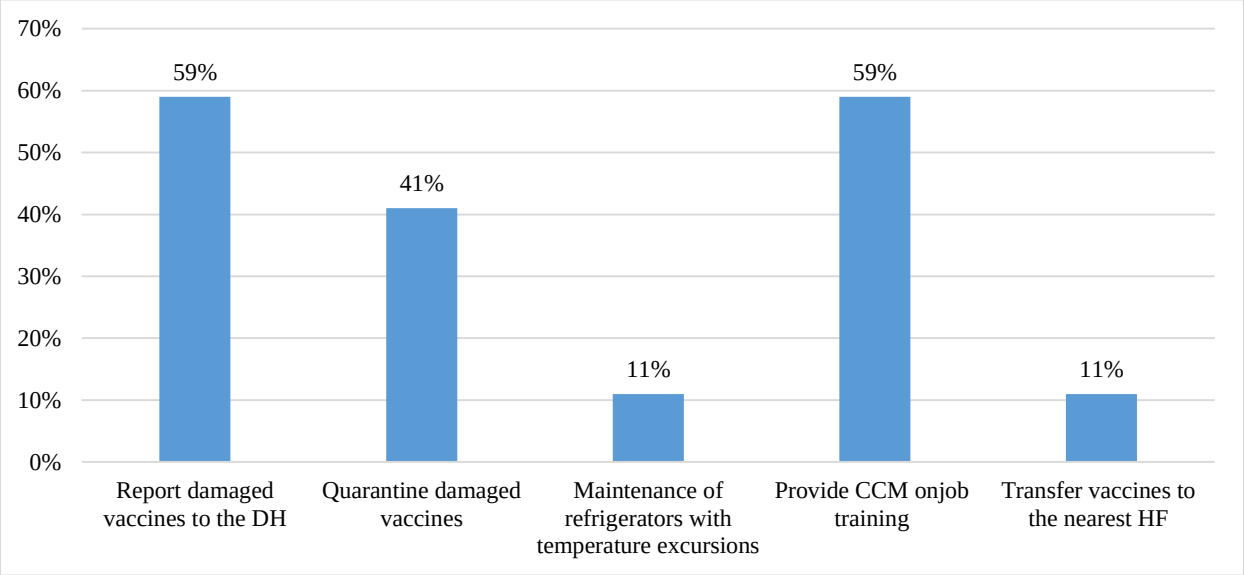

Figure 7: Strategies to address faced cold chain management challenges

CHAPTER V. DISCUSSION

This study aimed at assessing vaccines cold chain management practices among public health facilities located in Gasabo District, Rwanda. The results obtained were based on analysis of health facilities fridge tag data, knowledge, attitudes and practices of vaccinators towards vaccine cold chain management, and CCE availability as well as challenges encountered during cold chain management and how they were addressed; these results will inform decision makers at national, hospital and health centre levels on how to tackle the identified challenges related to vaccines cold chain management in order to protect and preserve vaccines potency.

5.1 Health facilities fridge tag data

In this study, temperature records from fridge tag installed in vaccines refrigerators of the 17 visited health facilities have revealed that upper alarm limits have been higher above 8 degrees Celsius which is different from what was reported from the respondents, this is consistent with studies conducted in Haiti and Kenya whereas reported temperatures were different from the data recorded by the remote temperature monitoring devices(33,36); this similarity may be due to the fact that vaccinators are not familiar with new technologies. The current study revealed that 15 visited health facilities had normal average of the lower and upper alarm limits which were between 2 to 8 degrees Celsius; there were alarms occurred in 2 (11.7%) health facilities. Therefore, those cumulated hours of out-of-range temperatures expose vaccines at heat and change of VVM which later reduce vaccines potency.

Health facilities equipped with Haier refrigerators (70.6%) are the ones with frequent high upper alarm limits with very long duration, this may be due to the quality of the equipment as they are new in the EPI or their compatibility with the source of power.

5.2 Knowledge on vaccines cold chain

In this study, most of healthcare providers have shown good knowledge (89%) on vaccine cold chain management. These results are higher than previous studies conducted in Nigeria 70%, Ghana 68.6%, and Ethiopia 57.6% (1,14,27,37). These findings may be attributed to regular trainings and supportive supervisions provided to vaccinators; the fact that all respondents are involved in daily immunization activities including cold chain management in the visited health facilities and the extended work experience with a mean of 16 years. High level of knowledge

among vaccinators is key in ensuring the potency and safety of vaccines as well as effective maintenance of cold chain system.

The current study revealed that only 64 % of the respondents use EPI guidelines vaccinators while handling vaccines, this was better than in Malaysia whereby only 50% of vaccinators use the guidelines(12). This discrepancy may be due to the rotation and short working period among vaccinators in Malaysia.

5.3 Attitudes on cold chain

This study revealed highest proportion of good attitudes of healthcare providers towards vaccines cold chain management. The findings indicated that 59% of the respondents strongly agreed on how placing food and drinks with vaccines in the refrigerator affect vaccine potency and the majority (65%) agreed that vaccine's refrigerators should be opened ≤ 2 times a day. Among the interviewed respondents, 53% strongly agreed that all vaccines should be used before the expiration date and the reconstituted vaccines should be used within 6 hours.

These findings are much greater from previous studies which revealed that among the respondents only 20.2% in Malaysia and 45.7% in Ethiopia had positive attitudes towards vaccines cold chain management (1,29); this inconsistency may be due to insufficient trainings and supportive supervisions observed in Malaysia and Ethiopia.

5.4 Practices on vaccines cold chain

The findings of this study indicated that all visited health facilities (100%) had at least one functional refrigerator exclusively reserved for vaccines, they all had functional fridge tags inside the refrigerators and they had temperature monitoring charts completed twice daily; all vaccines stored in these health facilities were in good condition as indicated by the VVM indicators attached to all vaccines vials and none of them were frozen.

These findings are better compared to studies conducted in Ethiopia where vaccine refrigerators were available in 23% and fridge tags available in 87.5% health facilities (14); in Southern Nigeria with 68% available refrigerators, 44% available fridge tags(15) and in Ghana where fridge tags were available in 67% health facilities and 8.3% don't have vaccine refrigerator (37). These inconsistencies may be associated to economic and geographical factors in countries where these studies were conducted.

Despite the stated best practices, this study found that vaccines arrangement with regards of heat sensitivity is well performed in only 12 (70.5%) health facilities and it is similar with the findings from a study conducted in Southern Nigeria(15) but less than a study done in Ethiopia(1), these discrepancies may be attributable to the workload of vaccinators on the days of the assessment. Ideally, vaccines refrigerators should not store food, drinks or other products, however 17.7% of visited health facilities had other things than vaccines stored in the refrigerators but it is quiet less than in Ghana where 33% of vaccines refrigerators contained other medical items/biologicals than vaccines(37). This may be due to lack of refrigerators dedicated to other medical items/biologicals within the visited health facilities.

5.5 Challenges encountered while managing vaccine's cold chain

The current study has revealed various challenges regarding vaccines cold chain management encountered by visited health facilities. Four (23.5%) health facilities lack the power backup generator this was higher than findings from South India where 94.2% of assessed health facilities had power backup generators (28) and in Southern Nigeria with 91.7% of health facilities having power backup generators(15), these findings may depend on the regularity of power supply from countries. the irregularity of power source was mentioned in two (11.7%) health facilities which was less than findings from Ghana (37) and Ethiopia (1).

More than half (58.8%)of respondents have mentioned lack of formal training for assistant vaccinators and it is consistent with studies conducted in Ghana(23), Ethiopia(1)(32) and Nigeria(27). This may be caused by lack of financial resources allocated to trainings or high turnover of healthcare providers.

CONCLUSION

Best practices are the backbone of effective cold chain system as they prevent loss of vaccines and preserve cold chain equipment.

In this study, data downloaded from the fridge tags have shown high temperatures above the recommended range in all the visited health facilities, however most of respondents had good knowledge, attitudes and practices towards vaccine cold chain management. Although, there are challenges in cold chain management, vaccinators had managed to find temporal and long term solutions towards those challenges. Regular supportive supervision, trainings and availability of functional cold chain equipment contribute to the sustained and effective cold chain system.

RECOMMENDATIONS

This study has revealed different challenges faced by vaccinators while managing cold chain and our recommendations are addressed to different level as following.

To health facilities:

- Managers of health facilities are advised to make close follow up of cold chain system, power supply and other vaccines related challenges.
- Vaccinators should ensure timely analysis and reporting of temperature records from fridge tags
- Vaccinators are advised to comply with EPI guidelines in order to preserve vaccines' potency and ensure good management of cold chain equipment.
- Vaccinators should elaborate and implement the maintenance plan for cold chain equipment

To district hospital:

- Increase quality supportive supervisions and provide formal trainings for assistant vaccinators in health centers.

To National level

- The Ministry of health through Rwanda Biomedical Centre/Vaccines' program unit is advised to avail the EPI guidelines to health facilities for guidance on proper user and good attitudes toward vaccine cold chain management.
- A close follow up is required in health facilities equipped with Haier (model) refrigerators for timely decision making and preserve vaccine's potency.

The findings of this study highlighted the need to conduct further research in other health facilities of the country so that the real picture and informative situation of vaccine cold chain management would be well documented and timely decisions taken.

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APPENDICES

A. Ethical approvals

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 3rd/11/2021
Ref: CMHS/IRB/**323**/2021

IRAGUHA Gisele
Master's in Health Supply Chain Management
CMHS, University of Rwanda

Dear IRAGUHA Gisele

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled ***"Assessment of vaccines cold chain management practices in health facilities of Rwanda. A case of Gasabo District, Kigali City"***

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance. The ethical clearance is valid for one year starting from the date it is issued and shall be renewed on request. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in this important study.

Dr Stefan JANSEN
Ag Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal, College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

REPUBLIC OF RWANDA

Kibagabaga...15../12../2021

No2021/HOP.KIBAG/2021

MINISTRY OF HEALTH

KIBAGABAGA HOSPITAL

Po. Box: 6062, KIGALI

Email: kibagabaga.hospital@moh.gov.rw

Gisèle IRAGUHA

University of Rwanda

Dear Gisele,

RE: Your request for data collection

Reference made to your letter requesting for permission to collect the data within Kibagabaga District Hospital for your Research Proposal entitled ***"Assessment of vaccines cold chain management practices in health facilities of Rwanda. A case of Gasabo District, Kigali City"*** based to the approval **No: 007/KBGH_EC/2021** from research Ethic committee, we are pleased to inform you that you are accepted to collect data within Kibagabaga District Hospital. Please note that your study findings must be shared/presented to research committee of the hospital before its dissemination.

Sincerely,

HOPITAL DE KIBAGABAGA

Maj. Dr Ernest MUNYEMANA

Director General of Kibagabaga District Hospital

B. Consent/Assent forms

TITLE OF STUDY

"Assessment of vaccines cold chain management practices in Rwandan health facilities"

A case of Gasabo District, Kigali City

PRIMARY RESEARCHER

Name: Gisèle IRAGUHA

Institution: University of Rwanda

Program: Master in in vaccines, immunization and health supply chain management

Email: iraguha11@gmail.com

Phone: 0788512993/0734054377

PURPOSE OF STUDY

This study aims to assess vaccines cold chain management practices in Rwandan health facilities and provide potential solutions to the identified challenges.

PROCEDURES

A descriptive cross sectional design will be used among healthcare workers that are involved in vaccine cold chain management using temperature monitoring devices in Rwanda Health Centres and hospitals. Both temperature monitoring checklist to capture temperature range data and questionnaire to collect healthcare provider's knowledge and practices will be used.

RISKS

The participation to this study is independent and there is no risk associated to it once there is willingness to participate

BENEFITS

The benefits of participating in this study are the contribution to show the picture of vaccines cold chain practices in Rwandan health facilities and to facilitate decision makers to address identified bottlenecks.

CONFIDENTIALITY

Please do not write any identifying information.

Every effort will be made by the researcher to preserve your confidentiality including the following:

- Assigning code names/numbers for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

COMPENSATION

There will be no compensation to the participation in this interview.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Researcher directly by telephone at **0788512993/0734054377** or at the following email address iraguha11@gmail.com.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's Signature _____ Date _____

Researcher's Signature _____ Date _____

C. Data collection tools

Part 1: Social demographic data

1) Age in years: 20 – 29 [ ] 30 – 39 [ ] 40 – 49 [ ] 50 and above [ ]

2) Sex: Male [ ] Female [ ]

3) Level of Education: Secondary [ ] Diploma [ ] Degree [ ]

4) Designation: Nurse [ ] Midwife [ ] Other(precise):

5) Work experience in years: 1 – 5 [ ] 6 – 10 [ ] 11 – 15 [ ] 16 and above [ ]

6) Received training on vaccine and cold chain management: Yes [ ] No [ ]

7) Time of last training: Less than 6 months ago[ ] 6 to 12 months ago [ ] Above 1 year ago [ ]

8) Received supervision on vaccine and cold chain management: Yes [ ] No [ ]

9) Time of last supervision: Less than 6 months ago [ ]

6 to 12 months ago [ ]

Above 1 year ago [ ]

Part 2: Knowledge of vaccinators on vaccine cold chain management

10) Are you aware of vaccines sensitivity to heat or freezing? Yes [ ] No [ ]

11) According the vaccine's sensitivity to heat or freezing, do you know how vaccines should be arranged in the refrigerator? Yes [ ] No [ ]

12) Do you know the correct placing of thermometer in the refrigerator? Yes [ ] No [ ]

13) Do you know VVM for vaccines? Yes [ ] No [ ]

14) Do you know shake test and when it's performed? Yes [ ] No [ ]

15) Do you know FEFO rule in vaccine management? Yes [ ] No [ ]

16) Are you aware of Multi dose vial policy(MDVP) in vaccine management?

If yes, how is it implemented?

17) Is there a national guideline on immunization in your facility? Yes [ ] No [ ]

Part 3: Vaccinators' attitudes regarding cold chain management (you are required to rank each attitude)

18) Placing food and drinks with vaccines in the refrigerator affect vaccine potency

1. Strongly disagree [ ]
2. Disagree [ ]
3. Agree [ ]
4. Don't know[ ]
5. Strongly agree [ ]

19) An "open when needed label" be placed on the door of every vaccine refrigerator

1. Strongly disagree [ ]
2. Disagree [ ]
3. Agree [ ]
4. Don't know[ ]
5. Strongly agree [ ]

20) Vaccine refrigerators should be opened ≤ 2 times a day

1. Strongly disagree [ ]
2. Disagree [ ]
3. Agree [ ]
4. Don't know[ ]
5. Strongly agree [ ]

21) Reconstituted vaccines should be used before 6 hour

1. Strongly disagree [ ]
2. Disagree [ ]
3. Agree [ ]
4. Don't know[ ]
5. Strongly agree [ ]

22) Vaccines should be used before expiration date

1. Strongly disagree [ ]
2. Disagree [ ]
3. Agree [ ]
4. Don't know[ ]
5. Strongly agree [ ]

Part 4: Vaccines cold chain management practices and equipment availability

23) Is there functional refrigerator(s) exclusively reserved for vaccines? Yes [ ] No [ ]

24) Is refrigerator temperature maintained between 2-8^{0}C? Yes [ ] No [ ]

25) Are vaccines properly arranged in refrigerator? Yes [ ] No [ ]

26) Anything other than the vaccine stored in refrigerator? Yes [ ] No [ ]

27) Is the vaccine management following FEFO principle? Yes [ ] No [ ]

28) Is there functional Fridge tag in the vaccine refrigerator(s)? Yes [ ] No [ ]

29) Is there a temperature monitoring chart available for vaccine's refrigerator? Yes [ ] No [ ]

30) Is there functional thermometer for refrigerator? Yes [ ] No [ ]

31) Are there expired vaccines present in refrigerator? Yes [ ] No [ ]

32) Is there frozen vaccines present in refrigerator? Yes [ ] No [ ]

33) Is the vaccine packing area protected from direct sun light? Yes [ ] No [ ]

34) Is VVM status of vaccine recorded for each vaccine? Yes [ ] No [ ]

35) Is there downloaded temperature records from fridge tags for the last two (2) months?

Yes [ ] No [ ]

36) Is there a functional backup generator in the facility? Yes [ ] No [ ]

37) Is there a functional car/motorbike to use in case of refrigerator failure? Yes [ ] No [ ]

38) Is there a trained person for maintenance? Yes [ ] No [ ]

39) Are spare parts for CCE maintenance available? Yes [ ] No [ ]

40) Is there a permanently assigned personnel for cold chain follow up? Yes [ ] No [ ]

41) Is fuel for generator available? Yes [ ] No [ ]

42) Is fuel for motor/car available? Yes [ ] No [ ]

Part 5: Challenges encountered and how they were addressed

43) Have you ever noticed alarms in the fridge tag? Yes [ ] No [ ]

44) Did you experience temperature excursions for vaccine's refrigerator in the last two (2) months? Yes [ ] No [ ]

If yes, what were the actions taken to respond to that issue?

45) Do you have maintenance plan for vaccine's refrigerator? Yes [ ] No [ ]

If yes, how is it scheduled implemented?

46) Are spare parts for cold chain equipment available whenever needed? Yes [ ] No [ ]

47) What is the average time for DH technician to repair a CCE failed in this facility?

……days

48) How often in a month, you present the records of temperature monitoring devices to the health facility manager for review? ……times/month

49) Do you have an alternative CCE to keep vaccines when the main one fails? Yes [ ] No [ ]

50) What decision do you take when vaccines are damaged in your facility?

1. Discard the vaccines immediately. Yes [ ] No [ ]

2. Put the vaccines in the quarantine and inform the supervisor. Yes [ ] No [ ]

3. Report to the higher level and request for new quantities. Yes [ ] No [ ]

51) What other challenges do you face when managing cold chain equipment?

1. Irregularity in power supply

2. Lack of power backup sources

3. Other (mention it)

52) How do you address these mentioned challenges?