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Vaccines, Immunization and Health
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**FACTORS CONTRIBUTING TO WASTAGE OF MEASLES-RUBELLA AND
BACILLUS CALMETTE–GUÉRIN VACCINES AT HEALTH FACILITIES:
CASE STUDY OF ROMBO DC, TANZANIA**

**Dissertation Submitted to the University of Rwanda in partial fulfillment of
the requirement for the degree of Masters in Health Supply Chain
Management (MHSCM)**

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YEAR 2022

DECLARATION

I, **Remig John**, 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 in its entirety or in parts. Any parts, words or ideas, of the dissertation, however, limited, which are quoted from or based on other sources, have been acknowledged as such without exception. It has also been subjected through the anti-plagiarism system and found to be compliant and this is the approved final version of the dissertation.

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Although the views and opinions expressed in the report remain my own, my ability to engage with the debates and discussions remain the responsibility of my supervisor and the other lecturers in the University Rwanda.

DEDICATION

First, I dedicate this study to the Almighty God, thank you for the guidance, strength, power of mind, protection and skills and for giving me a healthy life. All these, I offer to you Father God.

Second, I dedicate this research report affectionately to:

My Supervisor, Professor Diana Philemon Mwiru

Third, My parents, Mr. G. F Mtey and Mary John Massawe

Fourth, My Children, Dorcas, Brian, Alice, Albert, Maryline and Derick

Last, to My Sisters, Lilian, Mariana, Getrude, and Edina

ABSTRACT

The multi-dose lyophilized vaccines (Measles/Rubella and Bacillus Calmette–Guérin vaccines) have limited time for use after reconstitution and hence have an avoidable wastages which make vaccinators to hesitate to open the vial for few clients. In line with this the study sought to assess the rate of vaccine wastage at the facility and further examine the influence of vaccinators and vaccine handlers' education, attitude and practices on MR and BCG vaccines wastage.

To achieve the intended objectives a structured questionnaire and vaccine stock monitor in tool were used to gather data from the vaccinator and vaccine handlers in 34 vaccination facilities in Rombo district, Kilimanjaro Tanzania. The data collected covered one year, a period before Covid-19 pandemic and during Covid –19 pandemic (July 2019 to June 2020).

The average vaccine wastage mean was 32.03% and 59.53% for MR and BCG vaccine respectively, likely wise the average wastage for un-open was 0.52% and 2.12% for MR and BCG vaccines respectively. Where for opened vial wastage was 27.28% and 57.09% for MR and BCG vaccines respectively. Before Covid-19 the average wastage was 23.09% and 57.94% for MR and BCG vaccines while during Covid-19 the average wastage was 32.51% and 60.47% respectively. Most of the service providers were knowledgeable and they had positive attitude on MR and BCG vaccine wastage, stock management and usage strategies to reduce wastage. The study also revealed a positive relationship between knowledge and practice where increased knowledge lead to proper practices which in turn reduces vaccine wastage.

The vial size was the main contributing factors for MR and BCG vaccine wastages at the health facilities. Rescheduling days for vaccination was a strategies for reducing vaccine wastage fearing open vaccines for few clients. Attitude was observed to negatively relate to vaccine wastage that is a positive attitude to managing vaccine results into decrease in vaccine wastage and vice versa.

The study recommends for improved knowledge of the vaccinators and vaccine handlers for them to be able to perfect their practices which include proper scheduling of the vaccination dates and number of the clients.

Keywords: Vaccine wastage, MR and BCG, Vaccinator knowledge, Attitude and practice

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ABBREVIATIONS AND ACRONYMS

BCG	Bacillus Calmette–Guérin
CMHS	Collage of Medicine and Health Sciences
DC	District Council
DPT	Diphtheria Pertussis Tetanus
EEFO	Earlier Expired First Out
EPI	Expanded Programme for Immunization
FEFO	First Expired First Out
HBV	Hepatitis B Virus
IRB	Institutional Review Board
LGA	Local Government Authority
MCV	Measles containing vaccine
MDV	Multi-dose Vaccine
MDVP	Multi-dose Vial Policy
MoH	Ministry of Health
MR	Measles Rubella
NRHM	National Rural Health Mission
RCH	Reproductive and Child Health
TZS	Tanzanian Shilling
UIP	Universal Immunization Programme
UNICEF	United Nations International Children's Emergency Fund
VVM	Vaccine Vial Monitor
WHO	World Health Organization

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CHAPTER ONE

INTRODUCTION

1.1 Background information

Immunization programs rely heavily on the effectiveness of supply chain systems, from manufacturing to storage, transport and other supporting health products, to ensure that the right supply is available in the right quantity, at the right place, when needed (at the right time) and in the right condition for effective health services for the population(1). Vaccination is still an important means of preventing diseases mostly caused by viruses and bacteria(2). It is the safest means and reliable method to prevent disease conditions and hence save people's lives(3). More than 20 diseases, such as diphtheria, tetanus, Tuberculosis, pertussis, Hepatitis B and C, influenza, measles, and others are now protected by vaccines worldwide(4).

The effective use and management of the vaccine through the cold chain is crucial due to its sensitivity and costs thus, the cold chain has to be maintained from manufacturer, storage, distribution till when the vaccine is administered to the patient/client(1). For successful vaccine administration, health workers managing vaccines must have the requisite knowledge and skills to do their work when administering vaccine(5). Likewise, vaccinators need to be equipped with skills and knowledge in vaccine management to minimize wastage without losing the opportunities(6).

Vaccine wastage is defined as the loss of unopen (closed) and open vaccines due to vial under-utilized, breakdown, theft, missing, or failure to get required dose from the vial as well as exposure to unfavourable conditions(7). The vaccine is wasted due to different circumstances for unopen (closed) and open vials. The wastage in Unopen (closed) vials is usually due to improper cold

chain management which can be due to heat, freezing, vial breakage, expiry, theft and missing inventories while the open vials are due to the unused amount after opening which at the end has to be discarded. This could be the result of improper session plan, incorrect target population, facility size, target population and doses per vial size(8).

Some vaccines, such as Measles/Rubella, yellow fever and Bacillus Calmette–Guérin, made through complex manufacturing process (lyophilisation) are packaged in multi-dose vials due to high storage and transportation costs when packed as a single dose(9). Measles/Rubella are manufactured in 10doses/vial, Yellow fever in 10doses/vial and Bacillus Calmette–Guérin in 20doses/vial, these vaccines are to be discarded 6 hours after reconstitution(10). On the other hand liquid prepared vaccines such as Tetanus, Polio, diphtheria and others that can be used for 28 days after vial opening. Lyophilized vaccines need special care, since improperly stored and reconstituted vaccine when used, could be fatal(11).

The wastage after opening the vial is unavoidable for lyophilized vaccine since it has to be discarded after six (6) hours. In order to avoid wastage of resources used to procure vaccines, Vaccine wastage should be within the acceptable rates(10). Globally, it is recommended by WHO (11) (12) that, the wastage for lyophilised vaccine packed in 10 to 20 doses per vial ranges from 15% to 50%. However, there is evidence that global wastage guidelines have led to healthcare professionals being hesitant to open a vial for only one or few children due to the possibility that this will result in a significant number of doses being wasted(13).

A study conducted in India by Mehta (8) shows that, the wastage for Bacillus Calmette–Guérin vaccine is 64.69% and Measles-Rubella vaccines is 32.59%. A similar study conducted in Nigeria by Wallace (6) to assess the knowledge, attitude and practice on Multi-dose vial vaccines wastage,

showed that 90% of the respondents reported that, they have discussed with the district supervisors the need to reduce vaccine wastage to acceptable target. Another study was conducted in Zambia by Krudwig (14) to assess the differences in wastage based on vial size for MCV. The findings revealed that, wastage for 5-dose vials was 16.2% compared to wastage of 10-dose vials which was 30.5%. There is a handful of studies conducted in East Africa and Tanzania in particular to assess the vaccinator's related factors and their influence on vaccine wastage. Specifically, less has been conducted to assess the influence of vaccinators' knowledge, attitude and the practice on wastage of Measles/Rubella and Bacillus Calmette Guérin vaccine in Tanzania.

Vaccine wastage needs to be controlled and it poses the challenge in cold chain management. Managing it requires vaccinators to have knowledge on how to plan the sessions and remind mothers on the dates for vaccination. This is important in reducing wastage without missing the opportunities(6). Also, the wasted vaccine needs to be documented to ensure vaccine security in health supply chain. This study therefore sought to assess the wastage rate for of Measles/Rubella and Bacillus Calmette–Guérin vaccine and the extent to which vaccinators' knowledge, attitude and practices contribute to vaccines wastage management.

1.2 Problem Statement

Vaccine wastage is important thing to consider from the facility to National level. Without considering the data on the vaccine wastage from the facilities to national, the country can face serious shortage or incur extra costs expired vaccine(8). The cold supply chain needs to be well equipped with good storage equipment and skilled personnel with ability to prevent or minimize wastage of vaccines.

Various reports have shown that half of the vaccines produced globally are wasted at facility level thus there is a need for improving monitoring and control (15). The introduction of the different vaccines forms, and challenges due to cold chain management have brought the complexity in vaccine wastage control across the cold chain management(16). The complexity raises on the form of manufacturing where they are frozen and dried (lyophilized) vaccine and the liquid preserved vaccines as reported in different studies in the world. A handful of studies have been conducted to assess the extent of wastage for lyophilized vaccines at facility level in East Africa including Tanzania.

For lyophilic vaccines such as Measles/rubella and Bacillus Calmette–Guérin vaccine can stay for 6 hours after opening while the liquid preserved one can stay even 28 days according to WHO Policy Statement for Multi-vial vaccine(11). There are some cases where these vaccines are discarded due to expiration, vial breakage, and inappropriate vial freezing(17).

Although there are other variables that influence vaccine wastage, other factors to consider include the size of the facility, the target vaccination population, the estimated number of children to be vaccinated in each vaccination session, the number of doses per vial, and the vaccine formulation(17). Normally the vaccine wastage happens in both open and unopened (closed)

vaccine vials. The wastage for unopen (closed) vials should be avoided at all storage levels and is recommended by WHO, (16) that, at facility level should be less than 1% wastage for lyophilized unopen (closed) vial.

Furthermore, at the facility level, the vaccinators and vaccine handlers have different knowledge, attitude and practices towards vaccine wastage. Although vaccine wastage is unavoidable to some extent especially for unopened (closed) vials, countries have put strategies such as training and supervision to reduce vaccine wastage due to its procurement costs and effects of stock outs. It is believed that, most of the vaccines are wasted at the service delivery point compared to elsewhere in cold supply chain management(11).

Also, training, and supervision to vaccinators and cold chain manager at the service delivery point is the key determinant for knowledge, attitude and improving the practices of the vaccinator to reduce wastage without missing the opportunities. The study conducted in Ethiopia and Nigeria (18),(19) revealed that, there is a gap on knowledge, attitude and practice to vaccinators and those handling vaccines and hence causing a significant lose to financial due to vaccine wastage at facilities. The data obtained from Tanzania, National vaccine Information Management system shows that, wastage for Measles/Rubella vaccine is about 14.47% while Bacillus Calmette–Guérin 52.69% which shows the significant difference on wastage between the two vaccines. The WHO, (12) recommended that, wastage for lyophilized vaccines such as Measles-Rubella and Bacillus Calmette–Guérin should range from 15% for campaigns and 50% for routine vaccination at the facility level.

In spite of that there are strategies for Measles/Rubella elimination in the world, on which the improvement of the immunisation coverage has been considered while considering ways to

decrease the wastage of the vaccines(20). Therefore, this study assess the extent of wastage, stock management and monitoring, vial usage and practice for Measles/Rubella and Bacillus Calmette–Guérin vaccine at health facilities level. It captures information before Covid-19 pandemic (July – Dec 2019) and during Covid-19 (Jan – June 2020). Further, vaccinator’s and the vaccine handler knowledge, attitude and practice towards vaccine wastage for multi-dose vaccines (Measles-Rubella and Bacillus Calmette–Guérin) at the point of service delivery as assessed using WHO standards.

1.3 Objectives

1.3.1 General Objectives

The main objective of the study was to assess wastage and factors contributing to wastage of Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities in Rombo DC, Tanzania.

1.3.2 Specific Objectives,

Specific objectives of the study to this end are to:

- i. Assess the wastage rate of Measles-Rubella and Bacillus Calmette–Guérin vaccines for open and unopen (closed) vaccines at the health facilities from July 2019 to June 2020.
- ii. Assess vaccinator's and vaccine handlers' knowledge and its influence on the stock management and monitoring, vaccine wastage and vial usage for Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities.
- iii. Assess vaccinator's and vaccine handlers' attitude and its effect on the stock management and monitoring, vaccine wastage and vial usage for Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities.

- iv. Assess vaccinator's and vaccine handler's practices and their influence on the stock management and monitoring, vaccine wastage and vial usage for Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities.
- v. Examine strategies taken by vaccinators and vaccine handlers to reduce wastage of vaccines for Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities.

1.4 Research Questions

1.4.1 General Research Question

What is the wastage rate of Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities in Tanzania and what factors contribute to the wastage?

1.4.2 Specific research questions

- i. What is the wastage rate of Measles-Rubella and Bacillus Calmette–Guérin vaccines for open and unopen vaccines at the health facilities?
- ii. To what extent vaccinator's and vaccine handlers at health facilities possess relevant knowledge on the stock management and monitoring, vaccine wastage and vial usage for Measles-Rubella and Bacillus Calmette–Guérin vaccines?
- iii. How does the attitude of vaccinators and vaccine handlers at health facilities contribute to stock management and monitoring, vaccine wastage and vial usage for Measles-Rubella and Bacillus Calmette–Guérin vaccines?
- iv. How vaccinators and vaccine handlers' practices at health facilities contribute to the stock management and monitoring, vaccine wastage and vial usage for Measles-Rubella and Bacillus Calmette–Guérin vaccines?

- v. What strategies are put in place by vaccinators and vaccine handlers to reduce wastage of vaccines for Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities?

1.5 Significance of the study

There are evidences shown in various studies in different area which show alert on vaccines wastage, Thus, WHO (11) has recommended that, each country has to put efforts in reducing wastage of the vaccines at all levels. The findings of the study contribute to knowledge and practice. The findings of the study show the extent of the wastage of Measles-Rubella and Bacillus Calmette–Guérin vaccines contributed by inadequate knowledge, negative attitude and malpractice in vaccine monitoring and stock management. These findings are useful to the vaccinators and vaccine handlers for them to minimize vaccine wastage. Further the results are also relevant to other stakeholders at national level for improved vaccine procurement planning and management. Vaccine vial size, vaccine management and immunisation services during the pandemics are issues to consider in order to minimize vaccine wastage and save national resources. The findings of the study have also contributed to the knowledge by empirically testing factors that contribute to vaccine wastage in the Tanzanian context.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter discusses the literature reviewed relevant to this study. The chapter is organized into three sections. Section one is the introduction while section two presents the definition of the key terms. Section three presents the detailed review of various studies conducted in the area worldwide. The chapter ends with the conceptual framework that guided the study.

2.2 Definitions of the key terms

- i. **Vaccines** “*applies to all biological preparations, produced from living organisms, that enhance immunity against disease and either prevent (prophylactic vaccines) or, in some cases, treat disease (therapeutic vaccines)*”(4).
- ii. **Lyophilized vaccines:** These are freeze-dried powder form vaccines, which supposed to be reconstituted with a special/specific diluent before administered to client(9). Freeze-dried vaccines are live, attenuated vaccines that have been preserved by a process called freeze-drying, which requires the regulated removal of the water content.
- iii. **Vaccine Vial Monitor** –is a scientific timing and temperature integrated indicator with a heat-sensitive substance on the surface and a reference ringed around(5).
- iv. **Vaccine wastage of the facility-** Is defined as the total loss of open and unopen (closed) vaccine vials(21).

2.3 Empirical Literature Review

Although WHO has maintained the standard of vaccines wastages based on the number of doses per vial of vaccines, some vaccinators and vaccine handlers in health facilities have questionable knowledge and attitudes towards the practice of vaccination to reduce vaccine wastage. The study conducted in India by Lilly (21) revealed that, the average wastages of 10-dose vaccines was (64.69%) for Bacillus Calmette–Guérin (BCG) and 32.59% for Measles vaccine. The reasons for the high wastage of Bacillus Calmette–Guérin was low beneficiary attendance and low attendance of the sessions(21). Similar study conducted by Wallace (17) to a randomly selected facilities in 24 districts in Cambodia the facilities with large population had lower wastage compared to lower facilities. This study revealed the higher mean liquid vaccine wastage of 0% to 27% compared to lyophilized vaccines which varies from 60% to 81%. Furthermore, in that study (17) the general knowledge, attitude and practices of the respondent's show that, the reasons for wastage for lyophilised vaccines was the remaining doses which discarded 6hours after reconstitution is 61% while the wastage due to vial breakage is 31%.

A study conducted in Gambia (22) utilized randomly selected health facilities from Urban and Rural facilities. The findings revealed that vaccine wastage for lyophilized vaccine BCG, Measles and Yellow fever ranges between 18.5% - 79%, 0 – 30.9% and 0 – 55% respectively while for liquid preserved are due to breakage or expiry. The respondents in the study were knowledgeable on the vaccine wastage. Another study conducted in Ethiopia by Mohammed (18) shows that, 54.3% of the key informants have satisfactory knowledge of cold chain management 45.7%; had positive attitude, and 48.8%, have good practice respectively. Also, the study conducted in Nigeria

by Wallace (6) revealed that, 91% had the knowledge on the wastage and the national target, among those 78% responded that they have been told on need to reduce vaccine wastage.

In another yet assessment conducted in Urban India at primary health care setting by Chinnakali (23) (UNICEF) and National Rural Health Mission (NRHM) revealed that, vaccine wastage for Universal Immunization Programme (UIP) at the site is 70.9% for Bacillus Calmette–Guérin (BCG) and 39.9% for Measles. Similar study conducted in Rural India (24) the studies assessed the vaccine wastage based on doses per vial for measles vaccines contain 5doses/vial. The findings revealed that, the average vaccines wastage was 46.5% which is high compared to rural areas. The main reasons for higher wastage were highly associated with factors such as; cold chain failure and inadequate mobilization of the beneficiaries.

Vaccines wastage at facility level contributes more than 50% of the vaccines wastage in the supply chain system according to WHO, 2014 report (11). This has been proved by various studies although some of the studies such as that conducted by Wallace in Cambodia (17) have suggested that, training and supervision improved knowledge, attitude and practices of the vaccinator's and vaccine handler in cold chain management which can help to reduce vaccine wastage. Similar study conducted in Nigeria by Wallace (6)to assess the knowledge on vaccine stock management and practice shows that, 97% of the vaccinator request vaccine to LGA when the stock is low. Among those, 33% of the vaccinators uses target population to request vaccines, 53% use previous administered vaccines while the 12% are not clear. Therefore, vaccines wastage at facility level is a challenge and is associated with the knowledge, attitude and practice of the vaccinator and vaccine handler in reducing the vaccine wastage.

2.4 Conceptual framework

The conceptual framework for vaccine wastage of the Measles- Rubella (MR) and Bacillus Calmette–Guérin (BCG) at the Health facilities developed to show how vaccines are wasted through various sources at the health facility level. These vaccines are wasted before opening and after opening the vial. This study was guided by the Conceptual Framework developed by Zahraei (13). According to this conceptual framework factors contributing to vaccine wastage for open vials are vaccine session plan, target of the vaccination, target population, store equipment (cold chain), the facility size and the doses per vials. For unopen (closed) vials is contributed by vial break, overstock, expiry, temperature monitor failure and missing inventory. This illustrated in figure 1 below.

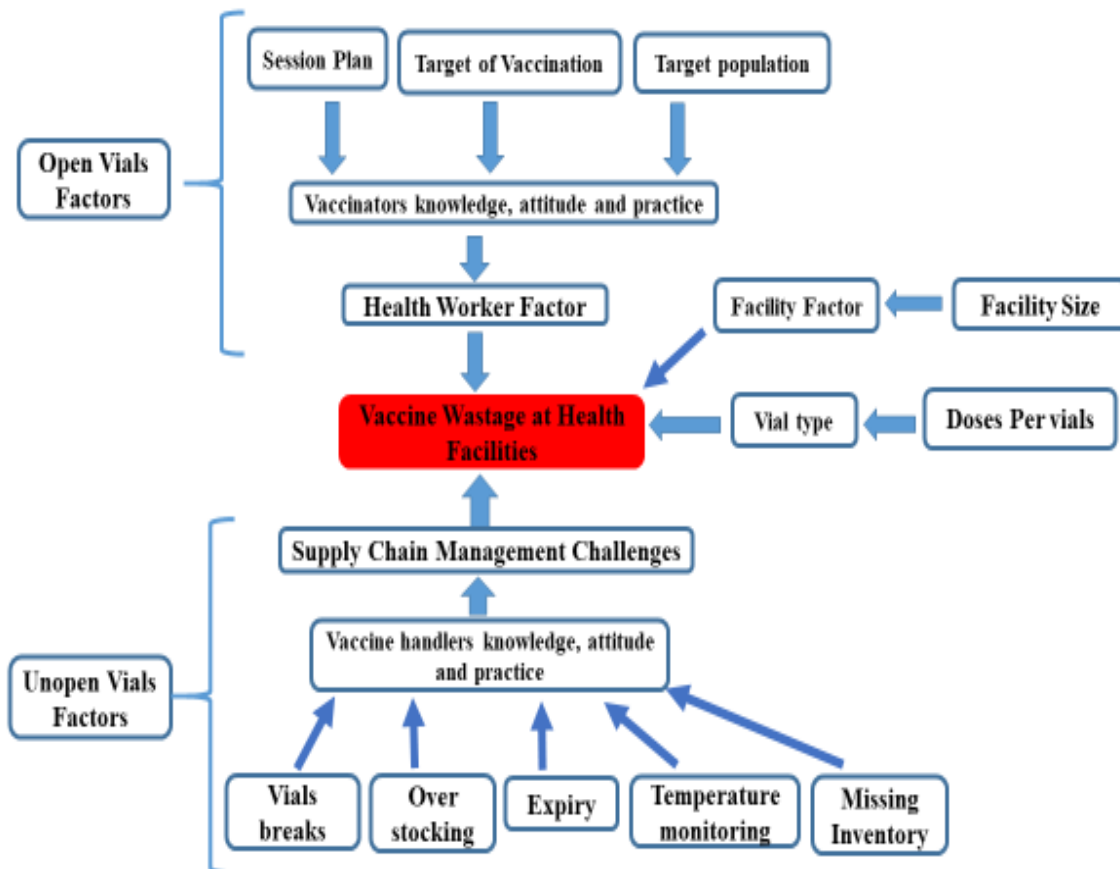


Figure 1: Conceptual Framework Zahraei (13)

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Research Design

The study design is retrospective longitudinal descriptive in nature where available data has been used to answer the research questions. The study assesses the wastage rate at facilities and factors that contribute to the wastage for Measles-Rubella and Bacillus Calmette–Guérin at all council facilities for 1 year before outbreak of Covid-19 pandemic and during Covid –19 pandemic (July 2019 to June 2020). Also, the study assesses the level of the knowledge, attitude and practices of vaccinators and vaccine handlers, and the extent to which they contribute to poor or proper management of vaccine at facility level resulting into vaccine wastage.

3.2 Location of the study

This study was conducted at council level in all public and private health facilities which provide vaccine and immunization services to people living in Rombo District Council, Kilimanjaro Region in Tanzania. The Council has semi-urban and rural areas where some of the population receive immunisation services through planned and unplanned sessions per month.

3.3 Target and Study Population

The targeted respondents of this study were health staffs providing vaccination services at private and public health facilities located in Rombo District Council, Kilimanjaro Region, Tanzania. The study population was the number of health workers at Rombo District council in the 34 health facilities for the period of July 2019 to June 2020. Where the number of doses used is equivalent to the number of children vaccinated.

3.4 Sample Size

Multiple factors were considered to determine and decide on the study sample size. The factors that influenced the sample size included objectives of the study, the financial resources, study time frame and the nature of the research itself (25). All health facilities which offer immunisation services at the council were visited. Vaccinators and the vaccine handlers in those health facilities were the respondents for the study.

The 34 health facilities provide the immunisation service (2 hospitals, 5 health centres and 27 dispensaries). Among these, there was at least one health care worker who deals with cold chain management and immunization services to beneficiaries and hence was interviewed. Fifty nine (59) health workers from all visited facilities who provide immunization services at Rombo District Council constituted the respondents of the study.

3.5 Sampling Procedures

Purposive sampling was used to obtain sample from all facilities providing immunization services at the council. All the health care workers (vaccinator and vaccine handlers) dealing with the cold chain management and vaccination at Reproductive and Child Health Unit (RCH) in 34 assessed health facilities were included in the study. The minimum number of the respondents per facility was one staff and the maximum number was four respondents. There are 11 health facilities at the council that do not offer the vaccination/immunization services, these did not participate in this study.

3.6 Types of data

To achieve the intended research objectives, both primary and secondary data were used.

3.6.1 Primary data

The structured questionnaire was used to collect data the 34 health facilities. Primary data obtained by the questionnaire which was administered in person and the researcher administered it in person to all respondents. The questionnaire elicited data from the vaccinator's and vaccine handlers'. To achieve the intended research objectives the questionnaire elicited data on their knowledge, attitude and practices on lyophilized stock management and monitoring, vaccine vial usage and vaccines wastage at the health facility.

3.6.2 Secondary data

Secondary data were also gathered and supplemented the primary data. Secondary data were gathered from the facility registers, monthly and quarterly vaccination reports and tally sheets,, monthly vaccination reports, daily vaccination follow-up, vaccines inventory data, vaccines wastage data, and transaction data from the ledger book and issue vouchers.

3.7 Data Collection Tool

A structured questionnaire was administered by the researcher to the vaccinator and vaccine handlers at the health facilities. A vaccine stock management and monitoring tools which is attached with the questionnaire was used to collect the dependent variables (DV). The WHO monitoring vaccine wastage guideline developed in 2005 (11) was used to assess vaccine wastage, at facilities. Data on independent variables for the study were collected from the health facilities, this included information on the number of doses wasted due to various reasons such as expiry, missing inventories, vial break, temperature variability and overstocking. The knowledge, attitude

and practices information's are the independent variable (ID) which shows variability to the key informants.

3.8 Validity

Piloting was done to few respondents (vaccinators) to test the validity of the questionnaire. Vaccine wastage data was collected using Monthly summary wastage tool obtained from (16) combined with developed questionnaire for assessment of the vaccinator's knowledge, attitude and practice as extracted from (18), (17) and (19) respectively. Therefore, data collected was a quantitative data and thus the mixed method analysis (quantitatively and qualitatively) used to get the vaccine wastage, vaccinator and vaccine handler's knowledge, attitudes and practice towards lyophilized vaccine.

3.9 Reliability

The study used existing tools that have been used in other studies and produced similar results. This study produces the results of the average wastage for Measles-Rubella and Bacillus Calmette–Guérin at facility level per month. This includes the knowledge, and the cause of the wastage at storage area and reconstituted vaccines. Cronbach Alpha was used to test for the reliability in which value of 0.7 was the cut-off point (Malhotra, 2019). The Cronbach Alpha scores was 0.91 indicating that the scale used was reliable.

3.10 Data collection techniques

A structured questionnaire was administered in person to vaccinator/vaccine handler by the researcher at the health facilities. Also, vaccine wastage data was collected through adopted structured tool to capture sources of wastage and their amount for one year from July 2019 to June 2020.

3.11 Data analysis

The data collected from the registers such as children follow up register, vaccination register, Monthly vaccination report, tally sheets and vaccines ledger book for the period of July 2019 to June 2020 was used to calculate the vaccine wastage rate. The formula used to calculate the vaccine wastage at facility level is:

- i. **Vaccine wastage rate for unopened vials** = $\frac{\text{Number of discarded doses}}{\text{Start balance} + \text{number of received doses}} \times 100$
- ii. **Vaccine wastage rate for open vials** = $\frac{\text{Number of wasted doses}}{\text{Number of supplied doses}} \times 100$

Further, the questionnaire was coded and analysed by Statistical Package for Social Sciences (SPSS) to get the causal relationship between vaccinator's knowledge, attitude and practices and the vaccine wastage. The qualitative data was analysed through coding the responses followed by making themes where the similar responses were noted and counted.

3.12 Ethical considerations

This study was initiated after obtaining approval from the Review Board of the Faculty of Medicine and Health Sciences, University of Rwanda. Then, the ethical clearance letter ref No: CMH/IRB/299/2021 was obtained from CMHS Institutional Review Board (IRB) from Directorate of Research and Innovation of University of Rwanda. A letter of acceptance Ref No: HWR/E.10/14/VOL.IV/126 was then obtained from the Executive Director of Rombo District Council - Tanzania. The study participants were informed prior to being interviewed through the consent form. They had the right to choose whether or not to participate (voluntary participation).

CHAPTER FOUR

DATA ANALYSIS AND RESEARCH FINDINGS

4.0 Introduction

The previous chapter presented discussions on the methodology that was used to conduct the study. This chapter presents the findings of the study. The chapter is organized in three sections. Section one presents the descriptive analysis on the study variables. Section two provides the inferential statistics and the chapter concludes with the summary.

4.1 Demographic Information

The study collected information about the respondents. These includes gender, working experiences, level of education, job title and health cadre. This information were very crucial to study. The results are stipulated on table 1 below

Table 1: Demographic Information

Background Characteristics	Respondent (N=59)	Number (%)
Gender of the vaccinator	Male	06 (10.17%)
	Female	53 (89.83%)
Work Experience	Less than 5years	14 (23.73%)
	More than 5years	45 (76.27%)
Level of Education	Certificate	32 (54.24%)
	Diploma	26 (44.07%)
	Degree	01 (1.69%)
Job title	Vaccinator	02 (3.39%)
	Vaccine handler	0 (0%)
	Both vaccinator and vaccine handler	57 (96.61%)
Health cadre	Nurse	23 (38.98%)
	Nurse assistant	16 (27.12%)
	Midwifery	18 (30.51%)
	Health officer	02 (3.39%)

Table 1 shows that, total number of the respondents were 59 where most of them are vaccinator and vaccine handler 57 (96.61%) and 02 (3.39%) were the vaccinators. Of the 59 respondents, 53 (89.83%) were female and 06 (10.17%) were male. Most of the respondent where having the experience of more than five (5) years 45 (76.27%) while few 14 (23.73%) having the experience of less than five (5) years. The level of their education, 32 (54.24%) had certificate, 26 (44.07%) had diploma and 01 (1.69%) degree. Among those, 23 (38.98%) were nurses, 16 (27.12%) were nurse assistant, 18 (30.51%) were nurse midwifery and 02 (3.39%) were health officers. These results are in line with the existing myth that nursing is a profession for women.

2 The Wastage rate of Measles-Rubella and Bacillus Calmette–Guérin vaccines

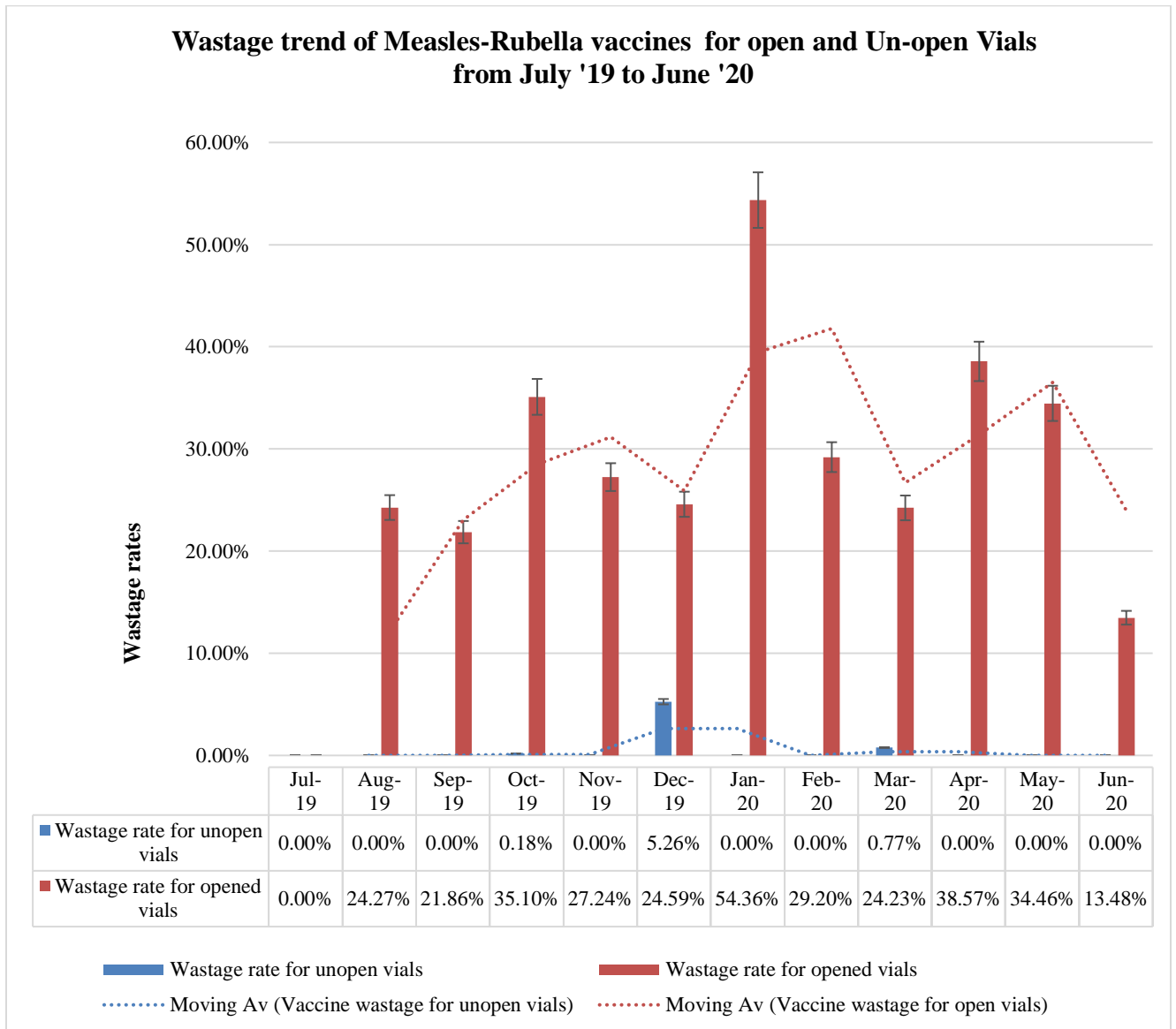
The vaccine wastage for Measles-Rubella and Bacillus Calmette-Guerin divided into two categories. That is unopened (closed) vials and for opened vials. Table 2 shows, the wastages for unopened (closed) and opened MR and BCG vaccines from July 2019 to June 2020.

Table 2: Wastage rates for MR and BCG vaccines (Closed and opened Vials)

Period	MR vaccines wastage averages			BCG vaccines wastage averages		
	Opened vial	Un-open vials	Average wastage	Opened vial	Un-open vials	Average wastages
July 2019 – June 2020	27.28%	0.052%	27.80%	57.09%	2.12%	59.21%

Figure 2 shows the trend of MR vaccine wastages for the period of July 2019 to June 2020 for closed vials and opened vial vaccines with their moving averages in that period.

Figure 2: Measles-Rubella Vaccine wastage trend



The average measles/rubella wastage rate for un-open vials is 0.52% while the average wastage rate for opened vials is 27.28%. The Figure 2 shows that, the highest wastage rate for unopened (closed) vaccine occur on December 2019 with the rate of 5.26% due to expiries of MR vaccines while the lowest was 0.00%. For the opened vials shows that, the average wastage was 27.28% while the highest wastage rate occurred on January 2020 with the rate of 54.36% due Covid-19

pandemic was at the peak and most of clients were on fear to be infected with and the lowest wastage occurred on July 2019 with the rate of 0.00%.

On comparison the wastage of Measles/Rubella vaccines six month before Covid-19 pandemic (July 2019 – December 2019) the average wastage for unopened (closed) vials was 0.91% and during six month of pandemic (January 2020 – June 2020) was 0.13%. These revealed that, the supply chain factors such as expiry, and missing inventories caused more vaccine wastage six months before than during Covid-19 pandemic. For the opened vials, six month before Covid-19 pandemic (July 2019 – December 2019) the wastage rate for Measles/Rubella vaccines was 22.18% while during the Covid -19 pandemic was 32.38%. This suggest that, factors such as target vaccination attendance, and session plan could have been affected by Covid-19 pandemic which caused few clients to attend to the facilities for vaccination and hence more vaccine wastage at service delivery point. Table 2 below shows, wastage of MR vaccines before and during Covid-19 pandemic for open and unopen (closed) vials.

Table 3: Wastage of MR vaccine before and during Covid-19 pandemic

Factor for Measles/Rubella Vaccine (10doses vial)	Duration (Months)	Average Wastage rates (%)
Unopened (closed) vaccine vial	July 2019 – December 2019	0.91%
	January 2020 – June 2020	0.13%
Opened vaccine Vial	July 2019 – December 2019	22.18%
	January 2020 – June 2020	32.38%

Figure 3: Wastage rate trend for BCG vaccines

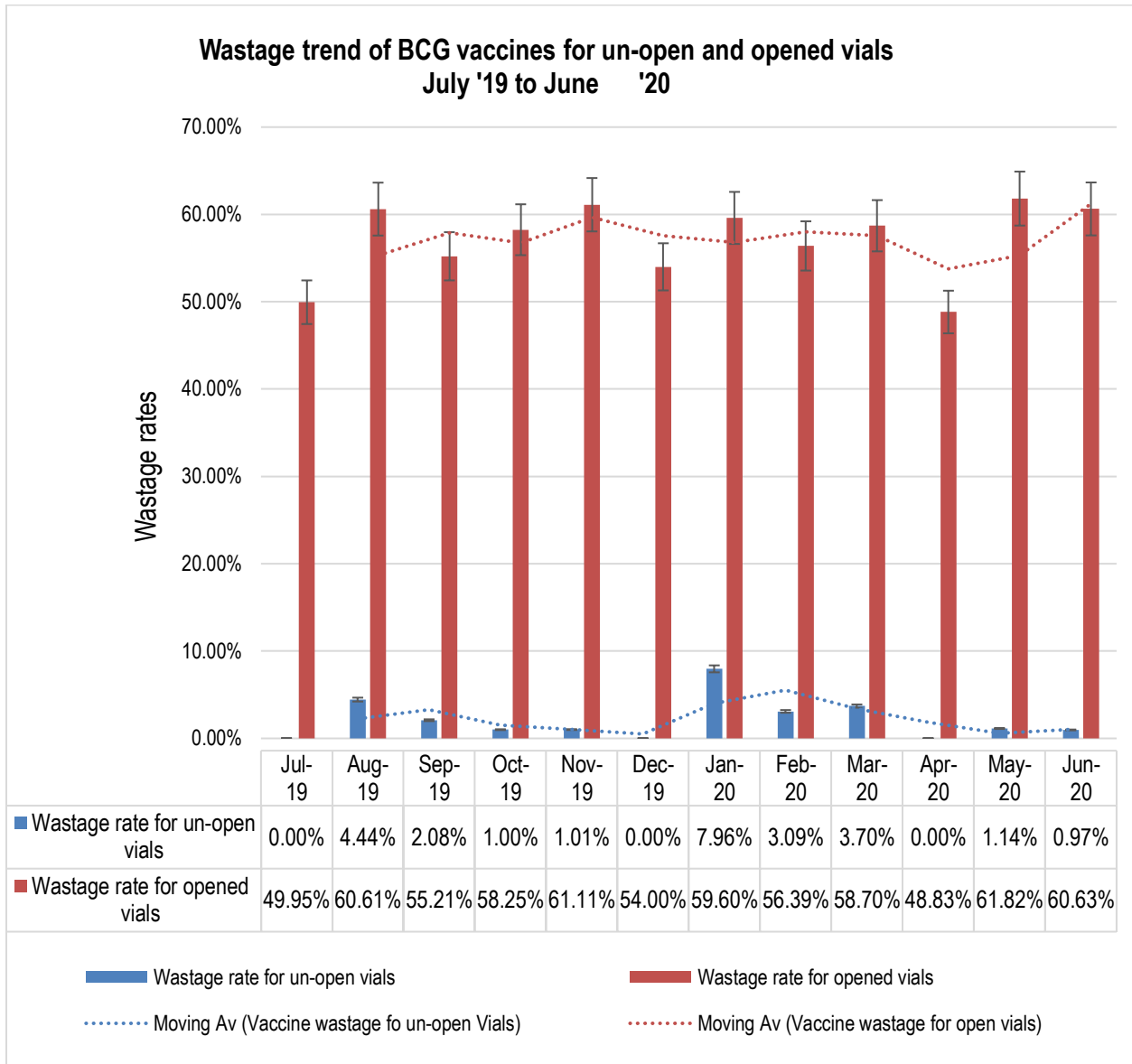


Figure 3 above shows that, the average Bacillus Calmette–Guérin vaccine wastage rate for un-open vials is 2.12% while the average wastage rate for opened vials is 57.09%. The highest wastage rate for unopened (closed) vials occur on January 2020 with the rate of 7.96% due expiry of the vaccines while the lowest wastage rate was 0.00%. For opened vials shows that, the average

wastage was 59.21% with the highest wastage rate occurred on May 2020 with the rate of 61.82% and 48.83% the lowest wastage rate on April 2020.

Comparing the wastage of Bacillus Calmette–Guérin vaccines six month before Covid-19 pandemic (July 2019 – December 2019) the average wastage for unopened (closed) vials was 1.42% and during pandemic six month (January 2020 – June 2020) was 2.81%. These revealed that, the supply chain factors such as expiry, and missing inventories has affected the wastage trend and thus much more wastage during Covid-19 pandemic. For the opened vials, six month before Covid-19 pandemic (July 2019 – December 2019) the wastage rate for Bacillus Calmette–Guérin vaccines was 56.52% while during the Covid-19 pandemic (January 2020 – June 2020) was 57.66%. These show that, factors such as targeted vaccination attendance, and session plan could have been affected by Covid-19 pandemic and hence more vaccine wastage due to decrease in number of children who attended to the facilities for vaccination. Table 3 below shows, the BCG vaccine wastage before and during Covid-19 pandemic for open and un-open vials.

Table 4: Wastage of BCG vaccine before and during Covid-19 pandemic

Factor for Bacillus Calmette–Guérin Vaccine (20doses vial)	Duration (Months)	Averages Wastage rates (%)
Unopened (closed) vaccine vial	July 2019 – December 2019	1.42%
	January 2020 – June 2020	2.81%
Opened vaccine Vial	July 2019 – December 2019	56.52%
	January 2020 – June 2020	57.66%

4.3 Knowledge of the vaccinator's and vaccine handlers

The total of fifty nine (59) health care providers who provide vaccination and vaccine management were interviewed. Among those, 48 (81.34%) were trained on vaccination and cold chain

management, while 53 (89.83%) had supervised in cold chain management, vaccination and stock management. 49 (83.05%) knows about vaccine wastage at the facility, where 30 (50.85%) of them, said that wastage of MR and BCG affect the facility stock while 28 (47.46%) responded that the wastage does not affect the vaccines stock. Forty five (76.27%) respondents knows to calculate the vaccine wastage and 54 (91.53%) responded that, vaccine wastage is calculated on monthly bases.

Among the respondents, 12 (20.34%) said that, the wastage of MR and BCG affect the vaccine supply in the facility by which 8 (57.14%) said it cause some of the clients to miss vaccination opportunities while 2 (14.29%) respondents said, wastage causes regular stock out of the vaccine at the facility where 4 (28.57%) respondents said, it causes shortage of vaccine and missing opportunities to clients. On asking the main causes of MR and BCG vaccine wastage, the responses where 56 (77.78%) due to discarded vaccine doses which remain 6hours after reconstitution, 7 (9.72%) are due to VVM changes, 4 (5.56%) vial breakage 2 (2.78%) vaccine spillage and 3 (4.17%) other reasons. Table 4 below shows, the responses from the respondents

Table 5: Respondent characteristics towards the knowledge to MR and BCG vaccines wastage

<i>Training on vaccination and vaccine management (N=59)</i>	<i>Responses</i>	<i>Percentage (%)</i>
Received training	48	(81.34%)
Not Trained	11	(18.66%)
<i>Supervision on vaccination and cold chain management (N=59)</i>		
Received supervision	53	(89.83%)
Not Received supervision	6	(10.17%)
<i>Knows about wastage of MR and BCG vaccines (N=59)</i>		
Knows about wastage of MR and BCG vaccine	49	(83.05%)

Don't know about wastages of MR and BCG	10	(16.095%)
<i>Wastage affect Stock management (N=59)</i>		
Vaccines Stock affected by wastage (<i>decrease stock</i>)	30	(50.85%)
Vaccines Stock not affected by wastage	28	(47.46%)
Don't know	1	(1.69%)
<i>Knows to calculate the wastage (N=59)</i>		
Knows to calculate	45	(76.27%)
Don't know	14	(23.73%)
<i>How often wastage is calculated (N=59)</i>		
Monthly bases	54	(91.53%)
Quarterly	2	(3.39%)
Annually and quarterly	2	(3.39%)
Don't know	1	(1.69%)
<i>Effect of wastage on Supply to facility(N=59)</i>		
Has effect on supply	12	20.34%
Has no effects on supply	46	77.97%
Not responded	1	1.69%
<i>How it affect supply (N=14)</i>		
Missing opportunities to clients	8	57.14%
shortage of vaccine and missing opportunities to clients	4	28.57%
Regular stock out of vaccines at the facility	2	14.29%
<i>Main cause of wastages (N=72)</i>		
Spillage of vaccine	2	2.78%
Discarding doses which remain 6hours after reconstitution	56	77.78%
VVM change due to exposure to high temperatures.	7	9.72%
Breakage of vial	4	5.56%
Other reasons	3	4.17%

Note: N = The total number of responses as mentioned by the respondents

4.4 Attitude of vaccinators and vaccine handlers at health facilities

The attitude of the vaccinator and vaccine handler at the health facilities was measured by seven questions scale which was administered by the researcher. The responses from the participants were rated as 1=strong disagree, 2=Disagree, 3=Neutral answer, 4=agreed, and 5=strong agreed. Those didn't answer rated 0=don't know. The positive attitude was defined as the calculated attitude above the average mean while the negative attitude is below average mean. Neutral was taken at the average mean. Forty-eight (81.36%), 28 (47.46%), 53 (89.83%), 54 (91.53%), 57 (96.61%), 47 (79.66%) and 55 (93.22%) of the respondents had positive perceptions that, avoid placing drinks and foods in vaccine refrigerator, need for labelling vaccine when opened, vaccine refrigerator should not be opened more than twice a day, reconstituted vaccine should be used within 6 hours, vaccines should be used before being expired, vaccine has to be discarded when expired, VVM change into dark, when freeze, and when exceed 6 hours after opening had to be discarded and when transporting vaccine should use water packed in a cold box. Table 5 below illustrate the attitude from 59 respondents.

Table 6 Attitude of the vaccinator and vaccine handlers

General vaccine wastage attitude	Response from respondent (N=59)								
	Strong disagree	Disagree	Neutral	Agree	Strong Agree	Don't know	Mean	STDV	STD ERROR
Placing foods and drinks in vaccine's refrigerator affects the vaccines potency.	0 0%	0 0%	1 1.69%	8 13.56%	48 81.36%	2 3.89%	9.8	±18.9	7.7
An "open when needed label" be placed on the door of every vaccine refrigerator	28 47.46%	9 15.25%	1 1.69%	6 10.17%	15 25.42%	0 0%	9.8	±10.5	4.3
Vaccine refrigerators should be opened < 2 times a day	0 0%	0 0%	1 1.69%	5 8.47%	53 89.83%	0 0%	9.8	±21.2	8.7
Reconstituted vaccines should be used before 6 hour after opening vial.	0 0%	1 1.69%	1 1.69%	2 3.89%	54 91.53%	1 1.69%	9.8	±21.6	8.8
Vaccines should be used before expiration.	0 0%	0 0%	0 0%	2 3.89%	57 96.61%	0 0%	9.8	±23.1	9.4
Vaccines should be discarded when freeze, VVM changed to dark, expired exceed 6hr after open.	0 0%	0 0%	6 10.17%	6 10.17%	47 79.66%	0 0%	9.8	±18.4	7.5
Vaccines requiring conditioned icepacks during transportation.	0 0%	0 0%	0 0%	4 6.78%	55 93.22%	0 0%	9.8	±22.2	9.1
Averages	4 6.78%	1.4 2.42%	1.43 2.42%	4.7 8.13%	47 79.66%	0.4 0.80%	9.8	±18.28	7.5

4.5 Practices of the vaccinator and Vaccine Handlers at the facility

The total of 59 participants (respondents) had different practices on vaccination of MR and BCG vaccines where 50 (56.82%) responses said that, vaccine vial of MR or BCG is opened only for a certain pre-scheduled days, 28 (31.82%) said they just wait children to gather to a certain number before opening a vaccine while 10 (11.36%) open the vial when eligible child arrived at the facility. After opening the vial, 56 (96.92%) respondent said that the vaccine has to be kept for 6hours, 2 (3.39%) said kept for a whole day and 1 (1.69%) responded differently.

The study revealed 92 responses of the main causes of wastage for un-open vials vaccines; 28 (30.43%) answered no cause of wastage for un-open vial vaccine while 22 (23.91%) said the main cause is expiry. On the major strategy for reducing wastage at the facility, 50 (35.21%) respondents said that MR and BCG are scheduled for a certain day only while 32 (22.54%) respondents said waiting children to gather a certain number before opening the vial is used to minimize wastage. Other responses were 31 (21.83%) open vial stored at appropriate temperature, 12 (8.45%) to practice FEFO, 11 (7.75%) to improve cold chain management and 6 (4.23%) mentioned other reasons. Table 6 shows the responses of the respondents about the vaccination practices at the health facilities.

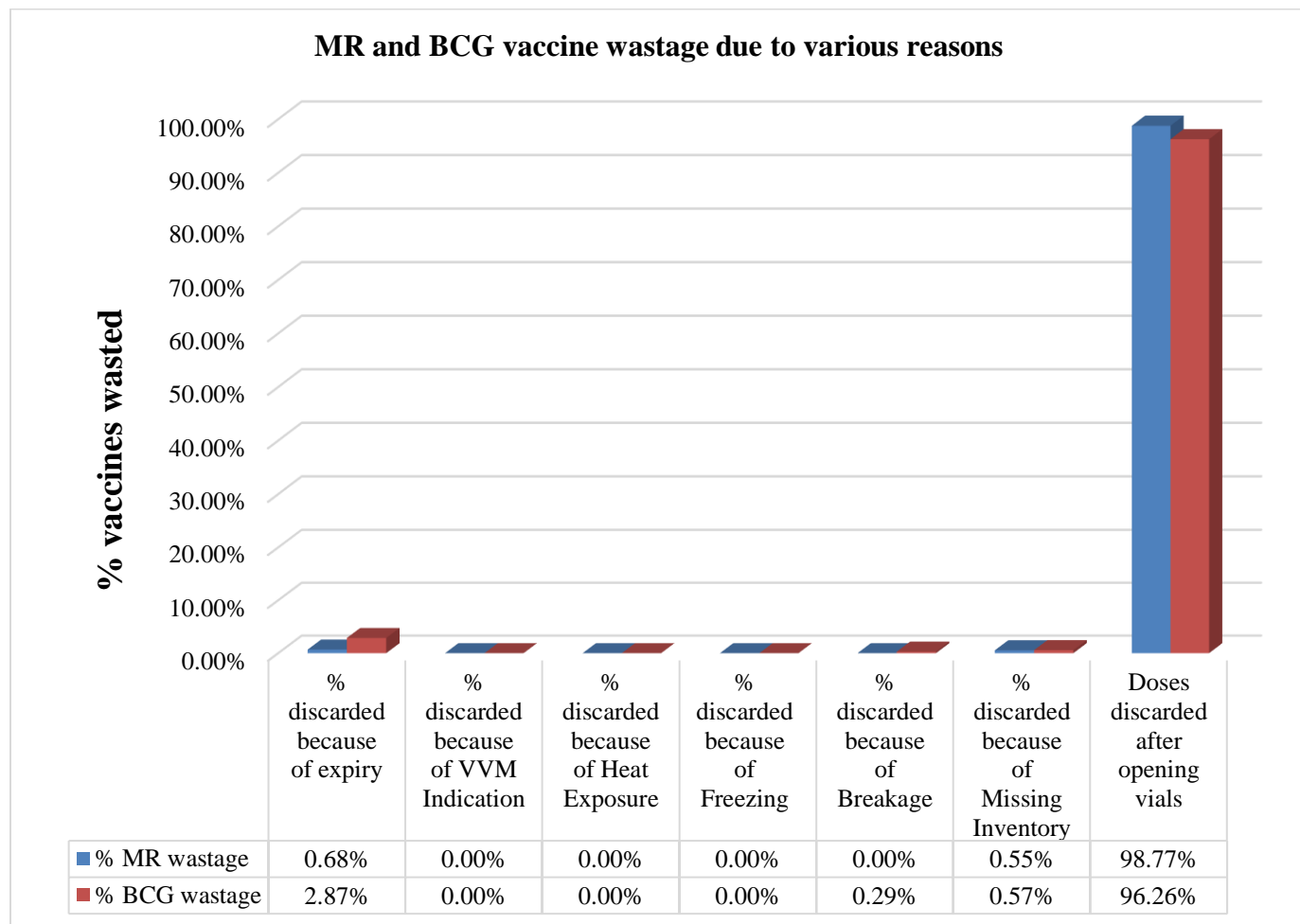
Table 7: Practices of the Vaccinators and Vaccine handlers at the facility

Vaccinator and vaccine handler Practices	Number	Percent
<i>When vaccine vial open (N=88)</i>		
As soon as an eligible child comes to the facility	10	11.36%
Waiting for children to gather to a certain number before opening a vaccine.	28	31.82%
Only on certain arranged days (pre-scheduled day) (mentioned)	50	56.82%
<i>Use after reconstitution MR or BCG vaccine (N=59)</i>		

Vaccinator and vaccine handler Practices	Number	Percent
Up to a days	2	3.39%
Within 6hours	56	94.92%
Others	1	1.69%
<i>Strategies for reducing vaccine wastage (N=142)</i>		
MCV and BCG are used for certain days (schedules vaccination)	50	35.21%
Waiting children to gather for a certain number before opening a vial.	32	22.54%
Open vial is stored into appropriate temperature for 6hours.	31	21.83%
Practice Earliest Expired First Out (EEFO).	12	8.45%
Improve cold chain management	11	7.75%
Other reasons	6	4.23%
<i>Causes of vaccine wastage for un-open vials (N=92)</i>		
Expiry	22	23.91%
Discarding unused vials returned from an outreach session.	0	0.00%
VVM indication	16	17.39%
Freezing	6	6.52%
Heat exposure	11	11.96%
Breakage	5	5.43%
Missing inventory	4	4.35%
Theft	0	0.00%
No wastage	28	30.43%

Note N = the number of responses as mentioned by the respondents

Figure 4: Wastage of MR and BCG due to various reasons at the facility



From July 2019 to June 2020 the total vaccines supplied to the facilities were 25,230 doses of MR and 23,440 doses of BCG vaccines. Among those, 7,014 (27.80%) doses of MR vaccine were wasted while 13,879 (59.21%) doses of BCG vaccines were wasted. On findings amount contributed to wastage of the vaccines it shows that, 6,928 (98.77%) wasted doses of MR vaccines, contributed from reconstituted vaccine and 13,360 (96.26%) wasted doses of BCG vaccines, contributed after vaccine reconstitution. The reason for more vaccine wastage in BCG than MR was due to vial size and supply chain management challenges caused by expiries and vials breakage where BCG contain 20 doses per vial while MR 10 doses per vial thus when the BCG vial opened there is a high risk for wasting many doses compared to MR vaccine.

In addition, the target of vaccination is low at lower level facilities because most of the facilities delivery is less than ten children per month which is equivalent to target to be vaccinated with BCG vaccines. Wastage caused by challenges in stock management and monitoring shows that, expiry 172 (0.68%) doses, 400 (2.87%) doses of MR and BCG respectively. Wastage due to missing Inventory 40 (0.55%) doses, 80 (0.57%) doses of MR and BCG respectively as shown on the figure 4.

4.5 Inferential Statistics

The study examined if there was any relationship between vaccine wastage and knowledge of vaccinators and vaccine handlers, attitude and practices of vaccinators. The table 7 below shows coefficients of correlations capturing the relationship between the vaccine wastage versus combined study variables namely knowledge, attitude and the practice of the vaccine handlers and vaccinators.

Table 8: Relationship between vaccine wastages and Variables

Month	Wastage doses	Knowledge response score	Attitude response scores	Practice response scores	wastage vs Knowledge Coefficient	wastage vs Attitude Coefficient	Wastage vs Practice Coefficient	Knowledge vs practice Coefficient	knowledge vs Attitude Coefficient
Jul-19	949								
Aug-19	1091								
Sep-19	1060								
Oct-19	1165								
Nov-19	1210	65							
Dec-19	918	59	275						
Jan-20	1347	86	148						
Feb-20	1094	71	288						
Mar-20	1268	58	283	81	0.20728	-0.5544	0.3782	0.949162	0.0983
Apr-20	957	104	293	115					
May-20	1088	65	277	19					
Jun-20	1249	164	291	278					

The findings from the table 7 show that, there exists relationship between vaccinators and vaccine handlers' knowledge and practices and attitude. There is high relationship between knowledge and practice this is a second order model to vaccine wastage implying that increased knowledge improve vaccinators and vaccine handlers' practices which contribute to decrease in vaccine wastage. The correlation coefficient was 0.95 which indicate the more knowledge improved the practice also improve due to reasons that, most of the vaccine handlers/vaccinators had formal training on vaccination. This in the end contributes to reduced vaccine wastage in facilities. On the other hand attitude is negatively related to vaccine wastage, that negative attitude towards work results into increased vaccine wastage. The negative attitude of vaccinators and vaccine handlers can be contributed by among other factors the poor working condition including poor motivation package.

CHAPTER FIVE

DISCUSSIONS OF THE FINDINGS AND CONCLUSIONS

5.0 Overview

This chapter discusses the findings by comparing them with findings of similar studies across the continents to provide conclusions based on the study area. The study was conducted at Rombo DC, in Tanzania aimed to assess wastages and the factors that contributing to wastages of MR and BCG vaccines. Also, to find out the association of the wastage factors with the knowledge, attitude and their practices towards the vaccines wastage.

5.1. Specific results

This research study looked at MR and BCG vaccine wastage at health facilities for the opened and unopened (closed) vials before and during Covid-19 pandemic. In relation to vaccinators/vaccine handlers knowledge, attitude and the practices towards the wastages of the vaccines. The study revealed that, the average wastage for un-open vials for the six month before Covid-19 pandemic was 0.91% and 1.42% for (MR and BCG) vaccines respectively while the wastage for unopened (closed) vial vaccine for the six month during Covid-19 pandemic was 0.13% and 2.81% for (MR and BCG) vaccines respectively.

For the opened vials which has to be discarded 6 hours after reconstitution, the average vaccine wastage for the six month before Covid-19 pandemic was 22.18% and 56.52% for (MR and BCG vaccines) respectively while during the Covid-19 pandemic was 32.38% and 57.66% for (MR and BCG vaccines) respectively. The wastage of unopen (closed) vial is low compared to the opened one which is supported by similar study conducted in Iran shows that, the average wastage rate for MR 2doses is 3.9% and 5doses is 10.2% where average wastage for open vials was 29% (13).

Generally, the wastage rate of MR and BCG vaccine at the health facilities was 27.80% for MR and 59.21% for BCG vaccines of 10doses per vial and 20doses per vial respectively. It correlate to study conducted in India shows that, the wastage rate for lyophilized vaccines (MR and BCG) was 32.59% and 64.69% respectively(10) and Northern India 43.42% and 21.67% for BCG and MR respectively(26) where the study conducted in Gambia shows the wastage rate of MR and BCG vaccine ranges from 0 – 30.9% and 18.5% - 79% respectively(22). This study revealed that, the wastage mean was 33.27% and 59.66% for MR and BCG vaccine respectively which somehow lower than the results of the study conducted in Cambodia with mean wastage rate of 60% and 81% for MCV and BCG vaccines respectively(17). With respect to study conducted in rural India (24) for MR vaccine of 5doses per vial shows the wastage is 46.5% and another conducted in Haryana(7) reveal 10doses per vial for BCG vaccines wastage is 77.90%, this shows a significant difference in vaccine wastage due to vial size.

Most of the vaccinators and vaccine handlers 48 (81.34%) are trained on vaccination and vaccine management, 53 (89.83%) got supervised on vaccine stock management and monitoring, vaccine wastage and immunization services. Among those 59 respondents, 49 (83.05%) knows about wastages of MR and BCG vaccines, and 56 (94.92%) knew about vial usage and vaccine stock management. There is similar study conducted in Cambodia support this findings that, most of the health provider had enough knowledge about vaccine stock management and wastage, and they usually plan few sessions per month as a strategies for minimizing wastage for lyophilized vaccines(17). This study is contrary to the study conduct in Ethiopia where 53.5% of vaccinators and vaccine handlers had satisfactory knowledge in vaccine management and control(18).

This study shows 79.66% of the vaccine handlers and vaccinators had positive attitude towards MR and BCG vaccine management, wastage and the vial usage at the facility. Similar study which

conducted in Ethiopia reported that 45.7% of the vaccine handlers and vaccinators had positive attitude to general vaccine cold chain management(18). The difference could be due to studies nature, knowledge of the participants and level of the education and cadre. Although there is a study conducted in Ethiopia support that, Placement of foods and beverages with vaccines, opening refrigerators more than three times a day, use of reconstituted vaccines after 6 hours, and use of vaccine after expiration were all deemed acceptable by 41 (32.3 percent), 33 (26 percent), 40 (31.5 percent), and 24 (18.9%) vaccinators and vaccine handlers, respectively(18).

Despite the WHO (11) recommendation and national guideline that, vaccine has to be open for every opportunity, the study shows that, 56.82% they open the vaccine vial of MR or BCG on arranged days (pre-scheduled days) and 31.82% responded they open after waiting for a certain number of clients to gather. Fifty six (56) 94.92% respondent new that the reconstituted lyophilized vaccine stored for 6hours and the remains has to be discarded. This results similar to study conducted in Nigeria (6), India (24),(26),(27) and Cambodia (17). There are different strategies implemented by vaccinators and vaccine handlers to reduce lyophilized vaccine wastage at the facilities were 35.21% responded they provide vaccination services on certain scheduled days, 22.54% waiting child to gather for certain number and 21.83% practice good storage when vaccine reconstituted for use. There is study support this findings conducted in Cambodia, where 47% of the participants mentioned that, improving outreach session reduce wastage, 34% waiting for a certain number of child to gather before opening the vial(17).

5.2. Conclusions

This study revealed that, most of the vaccinators and vaccine handlers are knowledgeable on vaccine management to minimize the vaccine wastages. Their attitude towards MR and BCG vaccine wastage was good and they usually tried to minimize the vaccine wastage while

considering missing opportunities to clients. They put effort by planning the vaccination sessions, scheduling the days and tried to wait for a certain number of children before opening the vaccine vials. The study shows that, average wastage for lyophilised vaccine (MR and BCG) is 27.80% for MR and 59.21% for BCG vaccine respectively. Furthermore, 27.80% of all wastages of MR vaccines contributed by discarding vaccines after reconstitution due to vial size 98.77%, due to expiry 0.68%, missing inventories 0.55%. The wastages of BCG vaccines contributed by reconstituted vial remains 96.26%, expiry 2.87% Vial breakage 0.29% and missing inventories were 0.57%.

According to WHO (11) wastage of lyophilised vaccine has to range from 10% to 50% globally for pack of 10 to 20doses per vial while for un-open vials wastages has to be less than 1%. For this case, this study revealed that wastage of MR vaccines is 27.80% while BCG vaccine 59.21% which has deviated the WHO ranges. These deviation is due to vial size of BCG vaccines which contain 20doses per vial and MR vaccines contain 10doses per vial both has to be discarded six hours after opening. Also, there are other factors contributed to vaccine wastage such as vial breakage, expiry and missing inventories. All these are the stock management challenges which has to be solved by the vaccine handlers and vaccinators.

Furthermore, Covid-19 pandemic has effects on the vaccine wastage, this study revealed that, there is a significant increase in wastage during Covid-19 pandemic from (23.08% - 32.51%) which is the increment of wastage by 9.43% for MR and from 57.94% - 60.47%) which is the increment of wastage of 2.53% for BCG vaccine.

Therefore, vial size is the main contributing factor for MR and BCG vaccine wastages. This has also, proved by the study conducted in Zambia shows, the wastage of MR vaccine for 10doses was

30.5% while of 5doses was 16.20% which is almost half in reduction of vaccines wastage(14). Also, due to vial size of the vaccines, the study revealed that, there are missing opportunities to clients caused by planning session and scheduling days which caused by the provide to be reluctant to open vaccine (MR and BCG) for few child fearing for high vaccine wastage rate.

5.3. Recommendations

5.3.1 Policy and programmatic recommendations

The lyophilised vaccines such as MR and BCG has to be discarded six (6) hours after opening or the end of vaccination session. At the same time, the National immunization policy recommend that, all children should be vaccinated with BCG vaccine within 14days after birth which is hectic to most of the lower level facilities (Dispensaries) to deliver 20 child within 14 days for planned sessions while other clients neglect to come back for vaccination. For these case, the Ministry of Health and National Immunization Programme has to plan for single vial vaccine so as to provide opportunity to every child delivered at the health facility.

More than half of the BCG vaccine supplied to the health facilities are wasted after six (6) hours on opening or at the end of vaccination session. It is a big loss in terms costs of procurements, transportation costs, and storage costs at various levels. The programme should evaluate the costs of multi-dose (20 doses per vial) versus the single dose or 5 doses vial to rescue the extra costs which could be avoidable.

The National Expanded programme for Immunization should plan for mass immunization and vaccination campaign especially for Measles-Rubella and BCG vaccines. This is because these vaccines are provided upon planned sessions at the health facilities thus there are some of the

clients are missing opportunities due various reasons such as travel costs due to distances, and few clients few clients/child which can lead into stock out.

5.3.2 Recommendations for further studies.

There is need for performing in depth assessment of wastages for liquid and lyophilized vaccine. This will help to get how much vaccine are wasted at different levels and the cost implication which could be managed for better improvement of the programme effectiveness. Furthermore, there is need for a study to assess the vaccination coverage so as to identify if there is a missing opportunities to eligible children due to rescheduling sessions at the health facilities.

5.4. Study limitations and implications for future research

This study was conducted at Rombo District council for lyophilized vaccines. Rombo is just one of the a hundred forty eight districts in Tanzania. There is a need to conduct a country wide study on vaccine wastage for all vaccines. The findings inform strategies for reducing wastage and improving immunization coverage.

Some of the vaccinators and vaccine handlers working at health facilities for the period of July 2019 to June 2020 found had transferred to other facilities and changed their duties and responsibilities during data collection. Thus, responses for the found vaccinator/vaccine handlers based on the current situation at the facilities while vaccine wastage data was taken from that period was not interfered.

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1

APPENDICES

Appendix A: List of the health facilities

S/N	Facility Code	Facility Name	Facility Level	Located Village
1	MSHC	Moyo Safi	Health Centre	Kingachi
2	KJD	KirongoJuu	Dispensary	Kirongojuu
3	MRCDD01	Mashati RC	Dispensary	Katangara
4	HH	Huruma	Hospital	Kelamfua
5	MRCDD02	Mkuu RC	Dispensary	Makiidi
6	HAD	Holili AMEC	Dispensary	Holili
7	RD	Rongai	Dispensary	Rongai
8	KD01	Kikelelwa	Dispensary	Kikelelwa
9	ND	Nanjara	Dispensary	Nanjara
10	THC	Tarakea	Health Centre	Mbomai
11	TRCD	Tarakea RC	Dispensary	Motamburu
12	KHC	Karume	Health Centre	Lesoroma
13	UD01	Ubetu	Dispensary	Ubetu
14	KD02	Kahe	Dispensary	Kahe
15	KD03	Kingachi	Dispensary	Kingachi
16	OD	Olele	Dispensary	Kilema
17	MGD	Mashati Government	Dispensary	Katangara
18	KMHC	KirwaMashati	Health Centre	Kirwa
19	UD02	Ushiri	Dispensary	Ushiri
20	MD01	Mahorosha	Dispensary	Mahorosha
21	MD02	Mokala	Dispensary	Mokala
22	SD	Shimbi	Dispensary	ShimbiMasho
23	KD03	Kirokomu	Dispensary	ShimbiMashariki
24	KCD	KirongoChini	Dispensary	KirongoChini
25	KHC	Keni	Health Centre	Mengeni
26	MKD	MengeniKitasha	Dispensary	Mengeni
27	MJD01	MengweJuu	Dispensary	MengweJuu
28	KD04	Kiungu	Dispensary	Mamsera Kati
29	MCD	MengweChini	Dispensary	MengweChini
30	MD03	Mahida	Dispensary	MahidaNguduni
31	HHC	Holili	Health Centre	Holili
32	ID02	Ibukoni	Dispensary	Ibukoni
33	KRCD	Kiraeni	Dispensary	Kiraeni
34	NH	Ngoyoni	Hospital	MengweChini

Appendix B: Activity Work Plan

Activities	May 2021 to July 2021				August 2021 to October 2021				November 2021 to February 2022											
	W1 - W 12				W1 – W12				W1	W2	W3 – W8		W9	W10	W11 - W12		W13	W14	W15	W16
Proposal writing	■																			
Proposal Review and Approval by the University of Rwanda					■															
Literature review	■																			
Questionnaires development									■											
Conduct pilot interview										■										
Questionnaires approval and Data Collection											■									
Transcribe questionnaires													■							
Data analysis														■						
Writing of the findings and Discussion															■					
Recommendations and Conclusion																	■			
Research finalization																		■		
Presentation and defending																			■	
Research Approval																				■
Research Dissemination and publication																				»»»

Appendix C: Informed Consent Form

Title: Factors contributing wastage of Measles-Rubella and Bacillus Calmette–Guérin vaccines at health facilities: case study of Rombo DC, Tanzania

PART I: Information Sheet

Introduction

Measles-Rubella (MR) and **Bacillus Calmette–Guérin** (BCG) vaccines are among the lyophilized vaccines and are usually manufactured in 10doses per vial of **Measles-Rubella** (MR) vaccines and 20doses per vial of **Bacillus Calmette–Guérin** (BCG) vaccines. Thus they need to be discarded 6hours after reconstitution although there are some cases where these vaccines are discarded due to expiration, vial breakage, and inappropriate vial freezing. Also, both open and closed vial vaccine need to be monitored to avoid wastage which could be preventable at the facility. There are studies showed that, the wastage of closed vials is attributable to supply chain management techniques, while the wastage of reconstituted vials is due to the vaccinator's experience and expertise (knowledge and practice). It is recommended that, wastage rate for lyophilized vaccines like MR and BCG range from 15% to 50%. Therefore, the goal of the study is to assess the knowledge, attitude and practice of vaccinator and vaccine handlers on vaccine wastage, stock management and monitoring and vial usage for **Measles-Rubella** (MR) and **Bacillus Calmette–Guérin** (BCG) vaccines at facility level.

Introduction of researcher and the research project

My name is **JOHN Remig** (*Reg. No: 220015495*), a student at the College of Medicine and Health Sciences, the **University of Rwanda**. I am conducting a study on **factors contributing wastage of Measles-Rubella (MR) and Bacille Calmette-Guérin (BCG) vaccines**, stock management and monitoring and vial usage. This study will be done under the supervisor from **University of Dar Es Salaam**, Professor Diana Philemon Mwiru.

Purpose of the research

To collect information on the factors that contributing the vaccines wastage for **Measles-Rubella** and **Bacillus Calmette–Guérin** (BCG) vaccines at health facility level in Rombo District Council, Kilimanjaro Region -Tanzania. This will accompanied with linkage to knowledge, attitude and

practice of the vaccinators and vaccine handlers towards vaccines wastage, stock management and monitoring, and vial usage.

Type of Research Intervention

Wastage of the vaccines at facility level.

Selection of participants

The participant will be those handling the vaccines and the vaccinators at facility which providing vaccination services. These are the potential key informants of the research and they are informed on the vaccine wastage, stock management and vial usage.

Voluntary Participation

Your participation in this study is voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your professional standing or your everyday life. You may change your mind later and stop participating even if you agreed earlier.

Procedures

The structured questionnaire will be filled by self (researcher) the answer provided will take confidentially.

Duration

No group discussion but the assessment will take 20 to 30 minutes per person. Although logistic data could take more than 30minutes depending on the cleanness of data.

Risks and Discomforts

The risks to you as a participant in this study are minimal. During the interview, you may decide to share information. But, again, you may decline to answer any questions that you do not wish to answer or stop the interview at any time, without giving any reasons.

Benefits

There will be no direct benefit to you, but with your participation we hope to improve the vaccine management and monitoring, hence will help to reduce wastage and improvement on vaccine usage.

Reimbursements/ Incentives

You will not receive any payment or any other benefit to take part in this study, but your participation in this research is essential. Only will refund the transportation fees if any

Confidentiality

The participant of the study, you are guaranteed confidentiality by preserving the anonymity of the responses and assured that, the information collected are strictly for statistical purposes.

Sharing of Research Findings

The findings will be shared at various levels (Council and MOHCDGEC-IVD) for decision making such as on how they can put efforts/strategies to reduce vaccines wastage at facility level. We will in the future publish on the process and the results, but you and your feedback will remain anonymous.

Right to refuse or withdraw

To reiterate, you do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the group discussion(s) or interview at any time that you wish without your job being affected.

Whom to contact in case you have questions about your rights as a research participant

All research on human volunteers is reviewed by Permanent Secretary, Ministry Health, Community Development, Gender, Elderly and Children, that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the IRB through the:

Chairperson:

CMHS IRB

Mobile phone: +250 788 490 522

Deputy Chairperson:

CMHS IRB

Mobile phone: +250 783 340 040

If you have any questions about this research, you may address your query to lead investigators:

Local Lead Investigator: John Remig +255 752 275 081 or +255 629 840 811

Supervisor: Professor Diana Philemon Mwiru (UDSM) [Tel:+255 655 270 716](tel:+255655270716)

If you choose to be part of this research study, I will also give you a copy of this consent form to keep for yourself.

Do you have any questions?

Yes No

PART II: Certificate of Consent

I have been asked to participate in

I have read the information provided above. I have asked all the questions, I have at this time. I voluntarily agree to participate in this research study. I may withdraw my consent at any time and stop participation without penalty. By agreeing to be in this research, I have not given up any of my legal rights.

I consent voluntarily to be a participant in this study : Yes / No

I agree to be recorded/..... : Yes / No

Print name of participant:

Signature of participant:

Date (day/month/year): Day..... Month..... Year.....

Print name of Researcher: *John, Remig*

Date (day/month/year): *Day..... Month..... Year.....*

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness:

Signature of witness:

Date (day/month/year): Day.... Month..... Year.....

Thumb print of participant:.....

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of Witness:

Signature of Witness:

Date (day/month/year): Day Month Year

Copy provided to the participant

Appendix D: Data Collection tool

Questionnaire for *Assessment of factors contributing wastage of Measles-Rubella (MR) and Bacille Calmette-Guérin (BCG) vaccines at health facilities: Case study at Rombo District, Tanzania.*

My name is **JOHN Remig** (Reg. No: 220015495), a student at the College of Medicine and Health Sciences, the **University of Rwanda**. I am conducting a study on factors that contributing wastage of **Measles-Rubella (MR) and Bacille Calmette-Guérin (BCG) vaccines, at the health facilities**. The main objective of this study is to assess the wastage rate of Measles-Rubella and Bacillus Calmette–Guérin vaccines at the health facilities with respect to vaccinators and vaccine handlers' knowledge, attitude and practices on stock management and monitoring, and vial usage from July 2019 to June 2020.

You have been selected to participate in this study based on your involvement in vaccine management/ as a vaccinator. Therefore, I request your participation in this study by responding to the questions provided/asked. Your names and response will be confidential and all information will be used for the purpose of the study and not otherwise.

Are you willing to continue with the study?

Yes

No

Facility Code:.....Level of the facility: Date:

S/No	QUESTIONS	RESPONSES	CODE	Go To
1.00: Demographic information				
1.01	Gender of the vaccinator?	Male	1	
		Female	2	
1.02	What is your Work Experience?	Less than 5years	1	
		More than 5years	2	
1.03	What is the level of your Education?	Certificate	1	
		Diploma	2	
		Degree	3	
1.04	What is your job title? (tick one option)	Vaccinator	1	
		Vaccine handler	2	
		Both vaccinator and vaccine handler	3	
1.05	What is your health cadre?	Nurse	1	
		Nurse assistant	2	
		Midwifery	3	
		Health officer	4	
2.00:General knowledge				
2.01	Have you received training on vaccination and/or cold chain management?	YES	1	
		NO	2	
2.02	Have you received supervision on vaccination and/or cold chain management?	YES	1	
		NO	2	
2.03	Is there any wastage of MR and BCG vaccine at the facility?	YES	1	
		NO	2	
2.04	Does the vaccine wastage affect the stock status for MR and BCG?	YES	1	
		NO	2	
2.05	Do you know how to calculate wastage of vaccines for MR and BCG?	YES	1	2.06
		NO	2	2.07
2.06	How often do you calculate wastage for MR and BCG?	Monthly	1	
		Quarterly	2	
		Annually	3	
2.07		YES	1	

	Does the vaccine wastage affect the vaccine supply at your facility?	NO	2	
2.08	If Yes How? (<i>Mention</i>)	Shortage of Vaccine	1	
		Missing opportunities to clients	2	
		Regular stock out of vaccines	3	
2.09	What are the main causes of wastage vaccines at your facility? (Specifically MR and BCG)(<i>respondent has to mention</i>)	Spillage of vaccine	1	
		Remaining doses in the vial	2	
		Discarding doses which remain 6hours after reconstitution	3	
		VVM change due to exposure to high temperatures.	4	
		Breakage of vial	5	
		Exposure to freezing temperatures	6	
		Discarding an open vial with usable vaccine	7	

2.00: General vaccine wastage attitude		Response from respondent					
		Strong disagree	Disagree	Neutral	Agree	Strong Agree	Don't know
2.01	Placing foods and drinks in vaccine's refrigerator affects the vaccines potency.						
2.02	An "open when needed label" be placed on the door of every vaccine refrigerator						
2.03	Vaccine refrigerators should be opened < 2 times a day						
2.04	Reconstituted vaccines should be used before 6 hour after opening vial.						
2.05	Vaccines should be used before expiration						
2.06	Vaccines should be discarded when freeze, VVM changed to dark, expired exceed 6hr after open.						

2.07	Vaccines require conditioned icepacks during transportation						
3.00 General Vaccination Practices							
3.01	When is the vaccine vial opened?	As soon as an eligible child comes to the facility	1				
		Waiting for children to gather to a certain number before opening a vaccine.	2				
		Only on certain arranged days (pre-scheduled day) (<i>mentioned</i>)	3				
3.02	How long can reconstituted vaccine (MCV or BCG) be stored?	Kept up to.....days	1				
	hours	2				
3.03	What are the strategies for reducing vaccine wastage at your facility? (<i>respondent has to mention them</i>)	MCV and BCG are used for certain days (schedules vaccination)	1				
		Waiting children to gather for a certain number before opening a vial	2				
		Open vial is stored into appropriate temperature for 6hours	3				
		Practice Earliest Expired First Out (EEFO)	4				
		Improve cold chain management	5				
		<i>Other reasons</i>	6				
3.04	What are the main causes of vaccine wastage for un-open vials at your facility? (<i>respondent has to mention</i>)	Expiry	1				
		Discarding unused vials returned from an outreach session	2				
		VVM indication	3				
		Freezing	4				
		Heat exposure	5				
		Breakage	6				
		Missing inventory	7				
		Theft	8				
No wastage	9						

Vaccine Monitoring tool for Measles-Rubella (MR)

Vaccine wastage for Measles-Rubella (MR) July 2019 to June 2020

Target Population:

Month	Starting balance	# of doses received	# of doses consumed	# of doses received from other facilities	# of doses issued to other facilities	Number of doses discarded because of					Total # of doses discarded	End balances	Proportional wastage rate	
						Expiry	VVM Indication	Heat Exposure	Freezing	Breakage				Missing Inventory
July 2019														
Aug 2019														
Sept 2019														
Oct 2019														
Nov 2019														
Dec 2019														
Jan 2020														
Feb 2020														
March 2020														
Apr 2020														
May 2020														
June 2020														

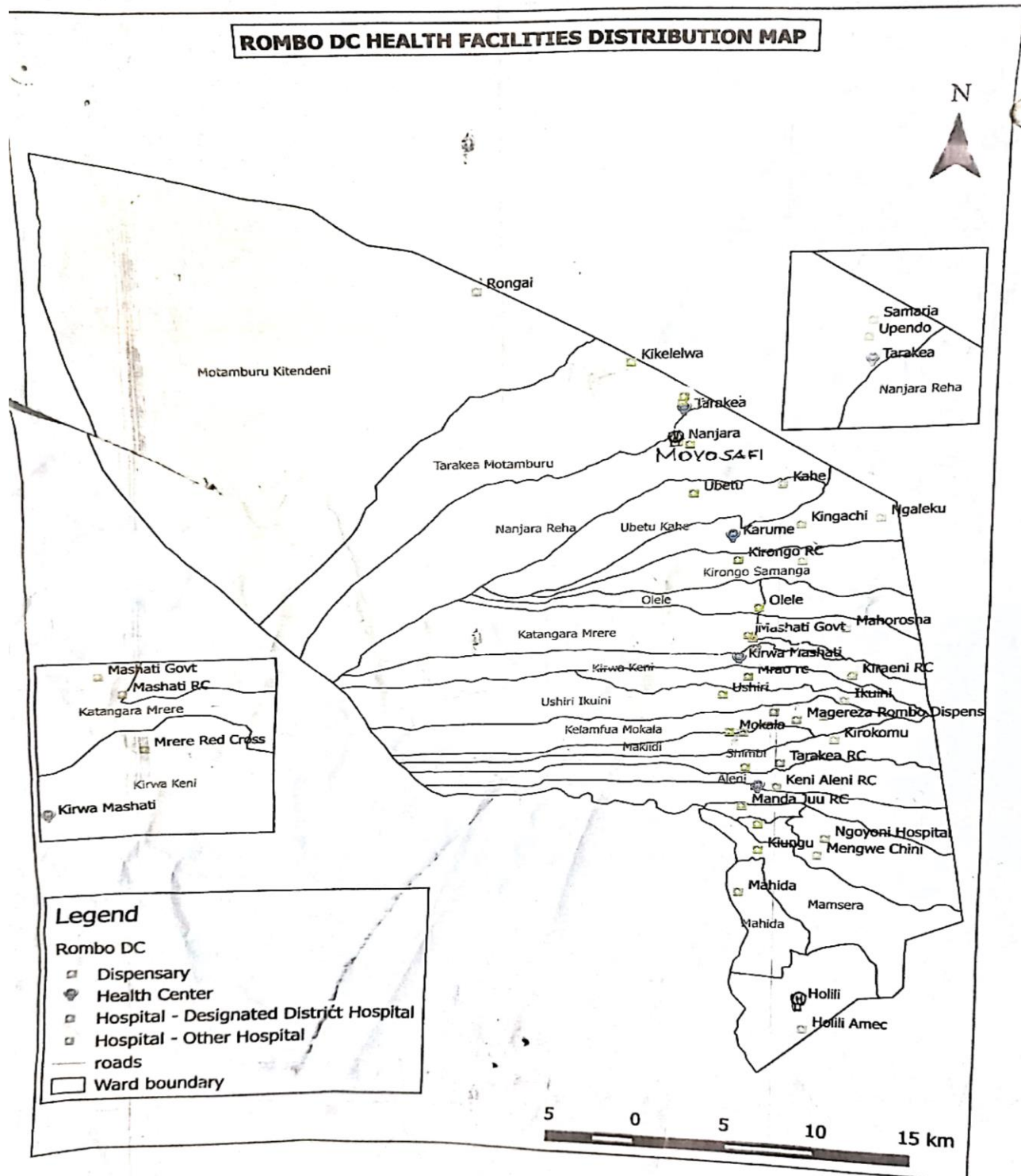
Vaccine Monitoring tool for BacilleCalmette-Guérin (BCG)

Vaccine wastage for BacilleCalmette-Guérin (BCG) July 2019 to June 2020

Target Population:

Month	Starting balance	# of doses received	# of doses consumed	# of doses received from other facilities	# of doses issued to other facilities	Number of doses discarded because of					Total # of doses discarded	End balances	Proportional wastage rate	
						Expiry	VVM Indication	Heat Exposure	Freezing	Breakage				Missing Inventory
July 2019														
Aug 2019														
Sept 2019														
Oct 2019														
Nov 2019														
Dec 2019														
Jan 2020														
Feb 2020														
March 2020														
April 2020														
May 2020														
June 2020														

Appendix E: Rombo DC Map



Appendix F: Study Budget

S/N	Activities	Costs USD
1	Proposal Writing (Stationaries, Internet)	100.00
2	Assistant data collectors (2 persons) allowance @TZS300,000	300.00
3	Transport costs (Data collection) @100USD for 3 persons	300.00
4	Data collection other costs	300.00
5	Data Analysis and consultancy	100.00
6	Report Writing (Stationaries and Internet services)	200.00
7	Living Expenses (During report defending)	600.00
8	Final Dissertation (Printing and binding)	100.00
9	Research Dissemination and Publication	500.00
10	Other Expenses	200.00
11	Contingency Budget (5% of the whole budget)	135.00
	Total costs for the Dissertation	2,835.00

Appendix G: Authorization Letter

JAMHURI YA MUUNGANO WA TANZANIA
OFISI YA RAIS
TAWALA ZA MIKOA NA SERIKALI ZA MITAA

Anuani ya Simu "TAMISEMI" DODOMA
Simu Na: +255 26 2321607
Nukushi: +255 26 2322116
Barua pepe: ps@tamisemi.go.tz



Mji wa Serikali – Mtumba,
Mtaa wa TAMISEMI,
S.L.P. 1923,
41185 DODOMA.

Unapojibu tafadhali taja:-

Kumb. Na. AB. 307/323/01

02 Septemba, 2021

Katibu Tawala wa Mkoa,
Ofisi ya Mkuu wa Mkoa,
S.L.P. 3070,
KILIMANJARO.

Yah: **KIBALI CHA UTAFITI.**

Tafadhali rejea somo tajwa hapo juu,

2. **Bw. John Remig** ni Mfamasia katika Hospitali ya Rufaa ya Mkoa wa Songwe ambae kwa sasa anafanya Shahada ya Uzamili katika Chuo Kikuu cha Rwanda, anahitaji kufanya Utafiti katika Mkoa wa Kilimanjaro kwenye Halmashauri ya Wilaya ya Rombo.

3. **Kichwa cha habari cha Utafiti** wake ni Ufuatiliaji wa kuharibika kwa chanjo za surua na kifua kikuu katika vituo vya kutolea huduma za Afya katika Halmashauri ya Wilaya ya Rombo.

Sababu ya Utafiti; Kwakuwa chanjo hizi zimetengenezwa katika ujazo wa Dozi ishirini (20) Surua Dozi kumi (10) Kifua Kikuu na pia zinatakiwa zitumike ndani ya masaa sita (6) baada ya kufungua kichupa chanye Chanjo husika.

4. Kwa barua hii, ninaomba uridhie ili afanye Utafiti kwa kuwa ni takwa la kisheria ili kukamilisha Elimu yake katika Shahada ya Uzamili (**Msc. Health Supply Chain Management University of Rwanda**).

Ninakushukuru kwa ushirikiano wako.

Handwritten signature of Dkt. N. A. Kapologwe in cursive script.

Dkt. N. A. Kapologwe
Kny: **KATIBU MKUU**

Appendix H: Ethical Approval

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION



UNIVERSITY of
RWANDA

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 20th /10/2021
Ref: CMHS/IRB/299/2021

John Remig
Master's in Health Supply Chain Management
CMHS, University of Rwanda

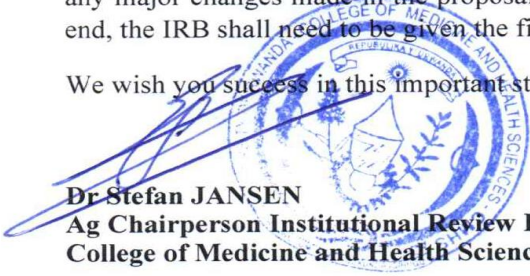
Dear John Remig

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled *“Factors influencing wastage for measles-rubella and bacillus Calmette–Guérin vaccines at health facilities: case study of Rombo DC, Tanzania”*

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

Appendix I: Similarity Index Report

FACTORS CONTRIBUTING TO WASTAGE OF MEASLES-RUBELLA AND BACILLUS CALMETTE-GUÉRINVACCINES AT HEALTH FACILITIES: CASE STUDY OF ROMBO DC, TANZANIA

ORIGINALITY REPORT

6%	6%	1%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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3	etd.aau.edu.et Internet Source	<1%
4	stjohnsea.org Internet Source	<1%
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