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SAFE HANDLING, STORAGE, AND MANAGEMENT OF VACCINES AT SELECTED PRIMARY HEALTH CARE FACILITIES IN BUFFALO CITY METROPOLITAN, EASTERN CAPE PROVINCE.

By

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DATE: April 2022

DECLARATION ON PLAGIARISM

I, Andiswa Zimkitha Mazwembe-Hoho, student number 201806973 hereby declare that I am fully aware of the University of Fort Hare's policy on plagiarism, and I have taken every precaution to comply with the regulations.

14 April 2022

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Signature Date

DEDICATION

This mini-dissertation is dedicated to my two daughters, Alunamda and Unothando Hoho for their love, understanding, sacrifice and support during this study. A special gratitude to my late loving mother Nontsikelelo Mavis Mazwembe for instilling in me the spirit of hard work, endurance, and never to give up on a valuable course in life. To my little sister Onodwa Mazwembe, I hope my success shall motivate you to never give up on your dreams of furthering your studies.

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CERTIFICATION

This mini-dissertation entitled “safe handling, storage, and management of vaccines in primary health care facilities in Buffalo city metropolitan in Eastern Cape” meets the regulation governing the award of the degree of masters of public health of the university of Fort Hare and it is approved for the contribution to scientific knowledge and literary presentation.

18 May 2022

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Signature of the Supervisor: Dr N. Mangi Date

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ABSTRACT

Background

The World Health Organization has a standardized tool for assessing vaccine handling and management. South Africa has adopted WHO tools to suit its own conditions of supply and storage of vaccines, the WHO tool is a guideline for managing vaccines. Importantly, every person handling or supervising handling of vaccines should own this manual (s) and use it as a reference for the handling, storage, and management of vaccines and related items.

Aim

The aim of this study was to examine safe handling, storage, and management of vaccines by health care workers in PHC facilities of BCM Municipality.

Methodology

A quantitative research approach and descriptive design was used to assess the safe handling, storage, and management of vaccines in PHC facilities in BCM in EC.

Results

The results showed that safe handling, storage, and management of vaccines in PHC facilities in BCM does not comply fully on safe handling, storage, and management of vaccines. The overall compliance rate was 86%, and this indicated that healthcare workers have knowledge of what is required to be compliant with safe handling, storage, and management of vaccines.

Conclusion

Safe handling, storage, and management of vaccines in PHC facilities in BCM is conditionally compliant as the healthcare workers have moderate-to-satisfactory knowledge.

Keywords: Assessment, vaccines, safe handling, storage, Primary healthcare workers,

LIST OF ABBREVIATIONS

BCM : Buffalo City Metropolitan
DOH : Department of Health
EPI : Expanded programme of immunization
HIV : Human Immunodeficiency Virus
IPD : Invasive Pneumococcal Disease
PCV : Pneumococcal Conjugated Vaccine
PHC : Primary Health Care
SA : South Africa
SPSS : Statistical Package for Social Services
WHO : World Health Organization
UNICEF: United Nations Children's Fund

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CHAPTER ONE

INTRODUCTION AND BACKGROUND TO THE STUDY

1.1 INTRODUCTION

Safe handling, storage and management of vaccines are important, as the potency of vaccine are vital in children inoculation. Vaccine management is crucial as cold chain maintenance remains one of the biggest challenges in South Africa due to improper management of vaccines (Department of Health, 2013:46). Management of vaccines includes materials, equipment, and procedures that maintain vaccines within a specific temperature range from the time of manufacture until it is administered to the patient. Vaccines should be stored between 2ºC and 8ºC to maintain their potency (Hattingh, 2015:72-73). Their degeneration affects not only the countries' disease state, but also has a negative impact on the cost to the country. Proper vaccine storage, handling, and management play a very important role in protecting individuals and communities from vaccine preventative diseases (Department of Health, 2012: 7-14).This study, therefore, was to examined the proper handling, storage, and management of vaccines in selected public facilities in BCM.

Vaccines are biological substances that may lose their effectiveness quickly if exposed to extreme temperatures, that is, too hot or too cold especially during transportation, storage and use. They naturally biodegrade over time and when stored outside the recommended temperature range. Thus, loss of vaccine potency may speed up during transportation and storage a process that cannot be reversed. The loss of potency result in vaccines failing to protect or become inactive for their intended use, resulting in wastage (Department of Health, 2012: 25). Vaccines that are stored inappropriately can have a serious impact on public health and contributes towards patient safety risks. Vaccines are expensive and limited in supply, therefore inappropriate storage can result in vaccine wastage, increased

pressure on vaccine supply and financial loss to the government (Department of Health, 2012: 7-14).

All vaccines have an expiry date determined by the manufacturer. The expiry date also known as the shelf-life of a vaccine, is the time known for the vaccine to stay within acceptable specifications for potency and chemical stability (Ontario Minister of Health, 2018:8). When vaccines are removed from storage by a healthcare professional to be administered to a patient, the vaccine expiration date and storage temperature should be checked before use. Doses of expired vaccines administered unaware or mistakenly are invalid and therefore are not to be counted, and should be repeated. If an expired vaccine administered mistakenly was a live virus vaccine, one should wait at least four weeks before repeating it. Furthermore, if the vaccines are inactive then re-administration of the dose is required as soon as possible (Canadian Medical association Inc, 2016:1-2).

1.2 BACKGROUND OF THE STUDY

There are different types of vaccines and must be handled as stipulated by the manufacturer's manual book, for an example: the live-attenuated influenza vaccine is stored frozen and must be discarded after 60 hours at refrigerator temperatures (Kumru et al., 2014:237-259). In addition, BCG vaccines must be discarded after 8 hours of reconstitution while kept at refrigerator temperature during this time. If either of these vaccines is used or administered without following the manufactures manual, the dose administered will not provide the desired effect for the child and therefore putting them at risk of acquiring the diseases or being prone to infection (Centre for Vaccine and immunology Inc, 2016:1). Storage and handling errors decrease potency and reduce effectiveness and protection against infectious diseases. The errors also cost the governments money in wasted vaccine and revaccination. It may also lead to the patient losing confidence with the immunization, especially when vaccines do not provide immunity against the infectious diseases that they were intended for (Alberta Health Services, 2016:2-4). Such issues have led the researcher to assess the handling, storage, and management of vaccines in Primary Healthcare facilities in BCM.

The World Health Organization has a standardized tool for assessing vaccine handling and management, and South Africa is adopting it to suit its own conditions of supply and storage of vaccines. It is a guideline for managing vaccines and their associated products at all levels of health care facilities. Each person handling or supervising vaccines, whether a pharmacist, a nurse or any other health care professional should own a manual and use it as a reference to the handling, storage, and management of vaccines and related items (World Health Organization, 2019:82). This study aims to investigate the safe handling, storage, and management of vaccines at the PHC facility in BCM.

The effectiveness of vaccines depends on safe handling, storage, and management. Therefore, if all these three elements are sustained which are safe handling, storage and management of vaccines, it could lead to a successful immunization programme. In order to achieve a successful immunization programme, vaccines should be conserved from manufacturing through administration by maintaining proper cold chain infrastructure, and effective management. Healthcare workers need to have adequate knowledge to manage the cold chain (Hinman, 2015:707-710). To improve the management of vaccine, WHO has created a set of guidelines for different service levels, which include immunization technique, vaccine monitoring, cold chain management, and reporting system. However, these guidelines are often practically quite difficult to implement in the field due to various factors like infrastructure challenges, lack of resources, improper delivery system, and high workload in healthcare facilities, and limited human resources and capacity in remote facilities. In some instances, the healthcare workers have to cope with the assigned jobs without adequate training such as cold chain management. This often contributes to challenges of adhering to WHO guidelines and standards for the cold chain management. Although there is a high budget for vaccines, there has been also reports of epidemics concerning vaccine-preventable diseases (South African Immunization Programme Debunked, 2016: 318-319). Therefore, this research focused on assessing the knowledge and practice of PHC healthcare workers handling, storage and management of vaccines in BCM.

1.3 PROBLEM STATEMENT

Safe handling, storage and management of vaccines in Primary Healthcare facilities was uncertain at Buffalo City Metropolitan. There was a lack of literature in Eastern Cape Province with regards to safe handling, storage and management of vaccines. This presents both theoretical and practice gap in this area. South Africa remains one of top countries that are underachieving in EPI. This is against high budget allocated every year for EPI programme (Provisional Budget Framework, 2017:104). This scenario points to a possible gap in safe handling, storage and management of vaccines (Bateman, 2016:318-319).

Over the years, there has been an increase in the number of wasted vaccines due to improper handling, storage and management of vaccines in PHC facilities. Similarly, there has been an increase in the outbreak of the infectious disease that could have been prevented by EPI programme (Cassius-Frederick et al., 2015;76). Therefore, this points to a gap between vaccine handling, storage and management. These incidents are among the motivation for this study.

In order for the EPI programme to be effective, vaccine management needs to be implemented properly. Therefore, safe handling, storage and management of vaccines is vital to maintain potency for an effective immunization programme. Failure to provide safe vaccines can have a negative effect on people and the community resulting in consequences, such as revaccination, litigations against the PHC facilities and the loss of community confidence with healthcare workers and vaccines provided (World Health Organization, 2015:8). This study contributes in providing literature on the safe handling, storage and management of vaccines in PHC facilities in BCM.

1.4 AIM OF THE STUDY

The aim of this study was to examine safe handling, storage, and management of vaccines by health care workers in PHC facilities in BCM.

1.5 OBJECTIVES OF THE STUDY

The main objectives of the study was:

(i) To evaluate the safe handling of vaccines in Primary Healthcare facilities in Buffalo City Metropolitan.

(ii) To assess the storage of vaccines by healthcare workers in Primary Healthcare facilities in Buffalo City Metropolitan.

(iii) To describe the management of vaccines by healthcare workers in Primary Healthcare facilities in Buffalo City Metropolitan.

1.6 RESEARCH QUESTIONS

The study sought to answer the following questions:

(i) How did healthcare workers in PHC facilities handle vaccines?

(ii) How were vaccines stored at PHC facilities in BCM?

(iii) How did healthcare workers in PHC facilities manage vaccines?

1.7 SIGNIFICANCE OF THE STUDY

The study on safe handling, storage and management of vaccines will contribute to the improvement PHC functions. The findings of this study will inform policy making and reviews with regards to safe handling, storage and management of vaccines in BCM. This will contribute to the improvement in provision of efficient and safe vaccines to the public, by ensuring the success of the EPI programme by eradicating the vaccine preventable diseases.

Furthermore, this research contributes to the body of knowledge by providing literature on safe handling, storage and management of vaccines at PHC facilities in BCM. This important because it was found that there are limited number of studies that focus on safe handling, storage, and management of vaccines at PHC facilities in the South African context. This study adds to the existing body of knowledge on

the safe handling, storage, and management of vaccines in PHC facilities from a South African perspective.

The results of this study are useful in reinforcing the healthcare worker's knowledge on the safe handling, storage, and management of vaccines in PHC facilities. Positive aspects and possible gaps were highlighted to healthcare workers, and suggest recommendations on strategies for improvement of safe handling, storage, and management of vaccines in PHC facilities.

1.8 DELIMITATION AND LIMITATION OF THE STUDY

1.8.1 DELIMITATIONS OF THE STUDY

The study focussed on safe handling, storage, and management of vaccines in PHC facilities in BCM. The reason for selecting PHC facilities in BCM was high number of wasted vaccines resulting to waste money spent by the government to procure vaccines (Department of Health, 2017:4). This implied poor handling, storage and management of vaccines in PHC facilities, hence the motivation for this study.

1.8.2 Limitation of the study

This study only used quantitative method to collect data. The findings of the study can only apply to PHC facilities in BCM and cannot be generalized to other PHC facilities due to the small area and specific sample size. The findings, however, can be used as a benchmark for other PHC facilities in other municipalities.

1.9 OPERATIONAL DEFINITIONS OF KEY TERMS

Safe	Patient consultation, effective communication with patient, caregiver, ang agent of patient to ensure administration of vaccine safely (South African Pharmacy Council, 2021:13).
Handling	Handling is the process by which a vaccine is taken out of the refrigerator to be

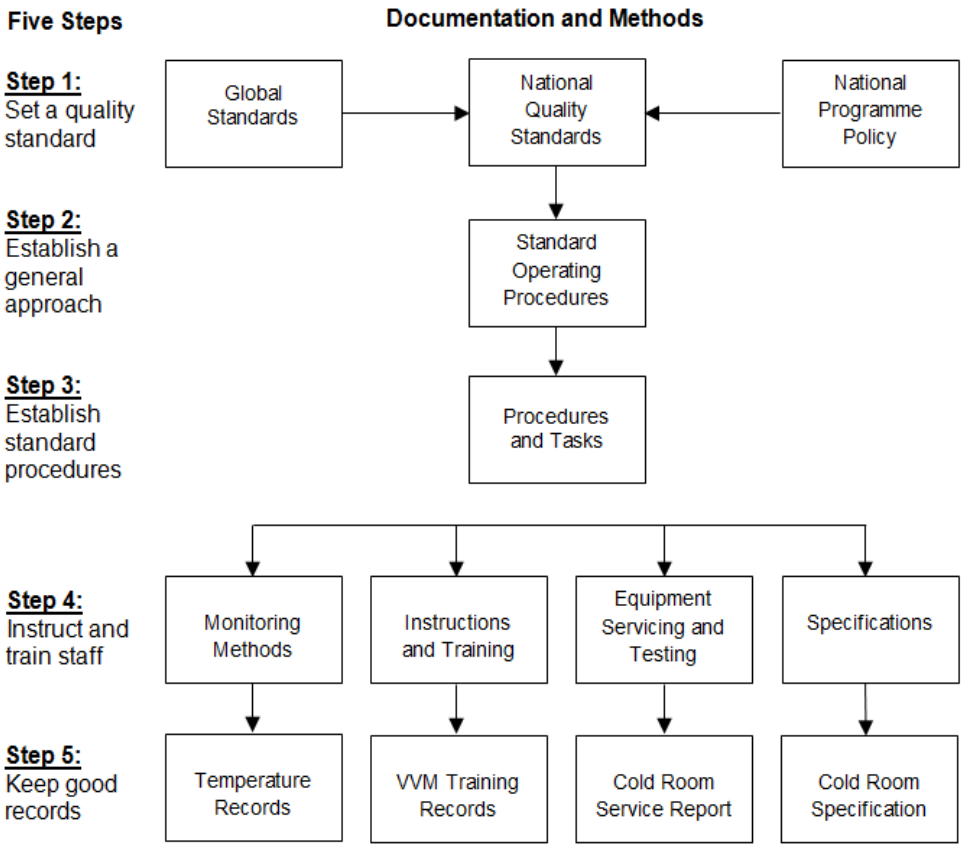
	administered, as it must be taken out only when it will be used and protected from the light. All the unused vaccines must be returned immediately to the refrigerator (Department of Health, 2013:87).
Storage	Demonstrate knowledge of vaccine stability and storage requirements. Manage the transportation, storage, and administration of vaccines according to cold chain requirements (South African Pharmacy Council, 2021:13).
Management	The activity of running and controlling a business or similar organization (University of Oxford, 2012:104). In this study, this means the controlling of vaccines from being received up until they are administered to a patient.
Vaccine	Vaccination is a simple, safe, and effective way of protecting you against harmful diseases, before you come into contact with them. It uses your body's natural defences to build resistance to specific infections and makes your immune system stronger. Vaccines train your immune system to create antibodies, just as it does when it's exposed to a disease. However, because vaccines contain only killed or weakened forms of germs like viruses or bacteria, they do not cause the disease or put you at risk of its complications (World Health Organization, 2015:8)

	A vaccine is an immuno-biological substance designed to produce specific protection against a given disease. They are sensitive biological products, where some are sensitive to freezing, some to heat and others to light . Bhatnagar et al., 2018:44)
Cold chain	It is a system of storing and transporting vaccines at recommended temperatures from the point of manufacturing to the point of use (World Health Organization, 2015:92)
Immunization	It is a process by which a person becomes protected against a disease through vaccination. Immunization is an effective method of preventing childhood disease, immunisation is also known as one of the most successful, equitable and cost-effective public health interventions worldwide and more people than ever are being reached with EPI. According to (Ansong et al., 2018:2).

1.10 CONCEPTUAL FRAME WORK ON SAFE HANDLING, STORAGE AND MANAGEMENT OF VACCINES

Conceptual framework are formulated to explain, predict, and understand phenomena, and in many cases, to challenge and extend existing knowledge within the limits of critical bounding assumptions (Kivunja et al., 2018:45). The conceptual framework for this study is based on the purpose of the cold chain system to ensure effective safe handling, storage, and management of vaccines in PHC facilities. This

is important to enable administration in a potent state to the person being immunised. The WHO proposes a framework (Figure 1) for effective cold chain management of vaccines in addition to National, Provincial and other operational guidelines. This framework is made up of nine constructs, split into five strategic steps. As recommended by WHO, these five steps should be followed to ensure safe handling, storage, and management of vaccines in PHC



(Adapted from (WHO, 2015) Vaccine Management, Immunisation, Vaccine, and Biological guidelines).

Figure 1.10.1: Conceptual Framework about safe handling, storage and management of vaccines

The first step is setting the quality standard. This is the step in which quality models available for safe handling, storage, and management of vaccines in PHC facilities are identified. Staff allocated to PHC facilities must practice nursing duties regarding the safe handling, storage, and management of vaccines in PHC facilities based on

national programme policy guidelines as recommended by WHO and UNICEF. Following the policy guidelines in the selected quality model ensures that the integrity of vaccines is maintained.

In step two, a general approach to safe handling, storage, and management of vaccine in PHC facilities is established. Overall requirements for vaccine safe handling, storage, and management are identified. Thereafter, standard operating procedures are prepared and adopted.

Step three entails establishing standard procedures. Specific tasks and procedures for safe handling, storage, and management in PHC facilities are identified. These tasks and procedures were set out to ensure that standard of performance prepared in step two are achieved.

Instructing and training staff is a vital step in this process. In order to carry out each task competently, staff were instructed and trained during orientation programmes and in-service training. It was also important to ensure sufficient equipment for cold chain management. Equipment servicing and testing should be done on a regular basis.

Lastly, it is suggested that good records are kept. This was to ensure that the task has been carried out effectively. In doing this, vaccine programme managers can verify that sound safe handling, storage, and management in PHC facilities was in place and has been maintained over a period of time.

This framework provides the foundation for determining the level of quality of the safe handling, storage, and management of vaccines in PHC facilities. In addition, assessing vaccine management using this framework enables nurses to highlight the strengths and weaknesses of safe handling, storage, and management of vaccines in PHC facilities and introduce the changes where necessary.

1.11 Reliability and Validity of the Study

Reliability refers to how consistently a method measures something. If the same result can be consistently achieved by using the same methods under the same circumstances, the measurement is considered reliable (University Park Institution Review Board, 2017:4-6). The researcher recorded and used data that was available from the self-administered questionnaire, to assess reliability of the results obtained from the healthcare workers they may be asked to complete the same questionnaire two times with an interval of one week, so that the test results can be compared to assess stability of scores the results would still be the same.

Validity refers to the extent to which a research design is scientifically sound or appropriate (Struwig et al., 2019:1-10). Validity in this study was designed to provide results that were appropriate to generalize to the population of interest, hence it was easy at the end to draw a conclusion about the lager group of healthcare workers from which the sample is taken.

A pilot test was conducted to determine time, reliability of the study, to improve the study design, before the performance of the actual study. An assessment was done using the same questionnaire during the pilot test, to evaluate feasibility of some components of the study such as resources and data management. Ten healthcare workers were used to collect data; the data collected responded to the research question. The time spent in the pilot test showed that the study objectives were achievable on time, therefore, no amendments were made after the pilot test was completed to the questionnaire as the results were relevant to the study.

1.12 Ethical considerations

Ethical clearance was requested from the University of Fort Hare Research Ethics Committee, Faculty of Health Sciences. Permission to conduct research at BCM Primary Healthcare facilities was requested from the Eastern Cape Province Department of Health, and the BCM research committee. The principles of respect for human dignity, justice, privacy were strictly upheld.

1.13 DATA MANAGEMENT

Confidentiality is a condition in which the researcher knows the identity of a research subject but takes steps to protect the identity from being discovered by others (Burns et al., 2013:19) Names of the healthcare workers were kept confidential and the PHC facilities they work in also was not mentioned, and therefore their identity is only known by the researcher and not the reader.

1.14 INFORMED CONSENT

The participants were fully informed about the study and were requested to sign an informed consent form, they were informed about the potential benefits, risks, and procedure of the study and they were offered the opportunity to ask questions. The participants were informed that the findings were processed as a research report, but their identity was kept confidential; that participation was voluntary; hence, they were free to withdraw at any given time. The participants signed the informed consent form without being coerced.

Informed consent is a legal requirement before one can participate in a study (Burns et al., 2014:32). Every participant should be given an opportunity to choose whether to participate in the study. Informed consent include four elements, which are disclosure of essential study information to the study participant; comprehension of this information by the participant, competence of the participant to give consent, and voluntary consent of the participant to take part in the study.

1.15 CONFIDENTIALITY, ANONYMITY, AND PRIVACY

Confidentiality is a basic ethical principle while anonymity is one way in which Confidentiality is maintained. Complete anonymity exists when the participant's identity cannot be linked, even by the researcher, with his or her response (Burns et al., 2013:100). In this study, anonymity was achieved by not putting the names of the participants on the questionnaire. The reader of the research study at the end was able to link any information to any participant.

On the other hand, privacy is the freedom people have to determine the time, extent, and general circumstances under which information was shared with or withheld form others. Private information include a person's attitude, beliefs, behaviours, opinions, and records (Burns et al., 2013:105).

1.16 RESPECT

Respect for persons is a basic human right. Research participants are autonomous individuals who have the right to choose to either participate or not in the research (Bateman, 2016:318-319). In this study, the researcher ensured that the participants give informed consent to participate, and prior to the respondents' giving consent, the study was fully explained to them, with risks and benefits being highlighted. The participants were informed that the participation was voluntary and were free to withdraw should they so wish. The participants were asked to sign a written consent form.

1.17 DATA COLLECTION PROCEDURE

The data was collected through a self-administered questionnaire targeting all the nurses handling and managing vaccines at PHC facilities in BCM. The researcher explained what the research entailed. After seeking the permission of the participants, a consent form was signed. To reduce the cost of travel, questionnaires were given to the nurse on duty to distribute to other nurses. Closed ended questions were utilised. These questions are useful in limiting participants from giving unnecessary information.

1.18 DATA ANALYSIS

The Statistical Package for the Social Sciences (SPSS) computer program version 24 was used for data analysis with the assistance of a statistician. This computer program computes frequency, summaries, mean, standard deviation and other inferential functions such as T-test. The program also generates tables, graphs,

diagrams, statistical pies and representative characteristics or values, such as averages and percentages.

1.19 CHAPTER OUTLINE

The study was structured according to the University of Fort Hare guidelines for a mini dissertation as follows:

Chapter One: This chapter covers the study background, problem statement, purpose of the study, research questions, objectives, significance of the study, delimitation and limitations, definition of terms and conceptual framework.

Chapter Two: This chapter covers the literature on the history of vaccines and the review of international and local literature on safe handling, storage and management of vaccines.

Chapter Three: This chapter covers the research approach and design, study setting, population and sampling, data collection and analysis, as well as ethical considerations.

Chapter Four: This chapter present the results, and the discussion of the results.

Chapter Five: This chapter covers the limitations of the study, conclusion and recommendations.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

In the previous chapter, the researcher focused on the background of the study, problem statement, aim, research questions and objectives, significance of the study, delimitations and limitations, definition of terms, as well as the conceptual framework. In this chapter the researcher focused on the literature review on compliance of safe handling, storage, and management of vaccines at PHC facilities in BCM. The overall purpose of this chapter was to present a brief review of the existing literature, theories, models and practices related to safe handling, storage, and management of vaccines at selected primary healthcare facilities in Buffalo city metropolitan, Eastern Cape Province. This will enhance the understanding of the existing research, and determine what was known on the topic and how well this knowledge is established.

Literature review is the selection of available documentation (both published and unpublished) on the topic under the study. The documentation contains information, ideas, data and evidence from a particular standpoint to fulfil certain aims and objectives. It also expresses certain views on the nature of the topic and how effective evaluation of these documents was concerning the research being under taken (Ridley et al., 2016:56). Furthermore, it is the part of the thesis where there was extensive reference to related research and theory. It is were corrections was made between the source text and research along with these sources. The literature review is where one identifies the theories and previous research, which may have influenced the choice of the research topic and the methodology adopted (Ridley et al., 2016:57).

The researcher sourced literature from books, journals articles, theses, and dissertations. The google scholar search engine was very useful in searching for literature dating from the year 2012 to 2022. The key words that was used to search for the literature was vaccines, safe handling and management of vaccines, and

vaccine storage. The literature on safe handling, storage, and management of vaccines at PHC facilities in the Eastern Cape was inadequate. The available studies was from other provinces, such as Western Cape and Gauteng. There are also limited studies within the health sector on safe handling, storage, and management of vaccines in PHC facilities. In this chapter, the researcher discusses the history of vaccines, compliance status of international countries as well as African countries, their standards, and the impact of non-compliance on healthcare users and vaccines.

2.2 HISTORY OF VACCINES

The history of vaccines can be traced back to the 18th century. From the late 19th century vaccines development occurred in the laboratory. However, in the 20th century, it became possible to develop vaccines based on immunologic markers. In the 21st century, molecular biology permitted the development of vaccine that was not possible before. Since the first development of a vaccine in 1970, (vaccine for smallpox) an expanded program on immunization was developed which targeted polio, tuberculosis, measles, diphtheria, pertussis, and tetanus (World Health Organization, 2015:72). Many of these diseases was very common, but now they are minimal due to vaccination. This programme is regarded as one of the most successful medical advancement ever developed, as it saves the lives of children (World Health Organization, 2015:8). In South Africa, over the years there has been newer vaccines, allowing protection against haemophilus influenza type B, streptococcus pneumonia, hepatitis B, human papillomavirus and rotavirus. These vaccines are making a huge impact on the health of South African children by providing prevention against infectious diseases (Department of Health in South Africa, 2017:56).

The Expanded Programme on Immunization (EPI) was launched in 1974 by the World Health Organization (WHO) with the aim of controlling vaccine preventable disease such as diphtheria, pertussis, tetanus, poliomyelitis, measles and pulmonary TB. It was one of the most powerful and cost effective public health programmes aimed at improving child survival and reducing child mortality rate. Immunization was the cornerstone of primary healthcare, and remains the most cost effective public

health intervention currently available. It prevents infectious conditions that are debilitating, fatal and have the potential to cause huge public health burden, both financial and socially in South Africa (Mothiba et al., 2016:1-2)

Globally, every year about 5.9 million children die before the age of 5 years, with over two-thirds of these deaths being conditions that could be prevented or treated with simple and affordable interventions. Immunization is one of the most cost-effective preventive health intervention, and it can prevent morbidities, mortalities, and disabilities. For example, experience with the smallpox eradication program showed the world that immunization is the most powerful and cost-effective weapon against vaccine-preventable diseases. It is estimated that immunization against vaccine-preventable diseases can save 2-3 million lives every year (Ngcobo et al., 2017:535).

A vaccine is an immuno-biological substance designed to produce specific protection against a given disease. They are sensitive biological products, where some are sensitive to freezing, some to heat and others to light. Vaccine potency is the ability to adequately protect the vaccinated person, can diminish when exposed to inappropriate temperatures. Once lost, the vaccine's potency cannot be regained. Hence, for effective implementation of the EPI, factors like cold-chain and vaccine management needs greater focus, attention, knowledge, and skills (Bhatnagar et al., 2018:44). The quality of vaccines is one of the important factors for the success of the immunization program, which in turn depends on proper storage and handling. If vaccines are stored outside the recommended temperatures for a considerate time, its potency will be adversely affected thereby reducing protection from vaccine preventative disease. The principles of vaccine storage consist of proper installation of thermometers, maintenance of appropriate temperatures, recording temperatures, and storage at recommended temperature range (Biradar et al., 2013:2).

Since the World Health Organization (WHO) launched the Expanded Programme on Immunisation (EPI) worldwide in 1974 with six basic antigens (BCG, poliomyelitis (polio), diphtheria, tetanus, pertussis, and measles), there was a significant expansion in the EPI schedule. Depending on the country, a fully immunized child now needs at least six routine immunization visits to receive between six and 13

antigens in the first year, and from 13 to 20 injections by two years of age. In South Africa (SA), protection is provided against 16 infectious vaccine-preventable diseases including measles, mumps, rubella, varicella, hepatitis B, diphtheria, tetanus, pertussis (DTaP), Haemophilus influenzae type b (Hib), polio, influenza (flu), rotavirus, and pneumococcal disease. For polio vaccination, in addition to the oral polio vaccine, the injectable polio vaccine is now required globally and is given in South Africa as a combination vaccine. Despite the availability of combination vaccines, multiple injections are required at several immunization visits to deliver the recommended antigens. In 2009, the South African EPI schedule was revised, with the introduction of among others, pneumococcal conjugate vaccine (PCV), an injectable given at six and fourteen weeks. This addition, therefore, increased the number of injections to three at the six and fourteen-week immunization visits. The South African Vaccinators Manual also specified that both the PCV and Hepatitis B injections should be administered intramuscularly in the right thigh, and the DTaP-IPV/Hib injection in the left thigh of infants under one year of age (Tabana et al, 2016:2).

Immunization is an effective method of preventing childhood disease. The backbone for the success of the immunization program is cold-chain, safe handling, storage, and management of vaccines. These are effective preventative strategies to control infectious diseases. The success of the EPI is highly dependent on the supply chain system of vaccines that meet the six rights of the supply chain. The right vaccine in the right quantity at the right place at the right time, in the right condition and at the right cost. The cold-chain is a system of storing and transporting vaccines at the recommended temperatures, from the point of manufacture to the point of use. The cold-chain system is vital as vaccines may be ineffective due to the failure of the cold-chain system. If a vaccine is exposed to high temperature, light or low temperatures, it can be damaged and lose its potency or effectiveness. Once the vaccine potency is lost it cannot be restored. Hence, care must be taken to ensure that vaccines do not lose their potency before their intended use. All vaccines are to be stored between temperatures 2ºC -8ºC to retain their potency (Sinha et al., 2017:390-391).

Furthermore, immunisation is also known as one of the most successful, equitable and cost-effective public health interventions worldwide and more people than ever are being reached with EPI. According to (Ansong et al., 2018:2)., in 2011 an estimated 109 million children less than one year representing, eighty-three percent (83%) were vaccinated with 3 doses of DPT (DPT3) vaccines, 84% (110 million) with measles and about 88% (114 million) with the BCG vaccine. Immunization currently prevents an estimated 2-3 million deaths from Diptheria-Pertussis-Tetanus (DPT) and measles annually. Immunisation is the most cost-effective preventative health intervention presently known. It is the most important gift any healthcare worker can give to a child (Yakum et al., 2015:145).

Table 2.1 below illustrates the history of South Africa from the launch of the six vaccines in 1974, to current used vaccines. It is clear that transformation has occurred and the newly developed vaccines over the years have minimized communicable illnesses and deaths.

Table 2.1: History of vaccines in South Africa

Live attenuated	Killed whole organisms	Purified proteins or polysaccharides	Genetically engineered
18th Century			
Smallpox (1798)			
19th Century			
Rabies (1885)	Typhoid (1896)		
	Cholera (1896)		
	Plague (1897)		
Early 20th Century, first half			

Live attenuated	Killed whole organisms	Purified proteins or polysaccharides	Genetically engineered
Tuberculosis (bacille Calmette–Guérin) (1927)	Pertussis (1926)	Diphtheria toxoid (1923)	
Yellow fever (1935)	Influenza (1936)	Tetanus toxoid (1926)	
	Rickettsia (1938)		
20th Century, second half			
Polio (oral) (1963)	Polio (injected) (1955)	Anthrax secreted proteins (1970)	Hepatitis B surface antigen recombinant (1986)
Measles (1963)	Rabies (cell culture) (1980)	Meningococcus polysaccharide (1974)	Lyme OspA (1998)
Mumps (1967)	Japanese encephalitis (mouse brain) (1992)	Pneumococcus polysaccharide (1977)	Cholera (recombinant toxin B) (1993)
Rubella (1969)	Tick-borne encephalitis (1981)	Haemophilus influenzae type B polysaccharide (1985)	
Adenovirus (1980)	Hepatitis A (1996)	H.influenzae type b conjugate (1987)	
Typhoid (Salmonella TY21a) (1989)	Cholera (WC-rBS) (1991)	Typhoid (Vi) polysaccharide (1994)	

Live attenuated	Killed whole organisms	Purified proteins or polysaccharides	Genetically engineered
Varicella (1995)	Meningococcal conjugate (group C) (1999)	Acellular pertussis (1996)	
Rotavirus reassortants (1999)		Hepatitis B (plasma derived) (1981)	
Cholera (attenuated) (1994)			
Cold-adapted influenza (1999)			
21st Century			
Rotavirus (attenuated and new reassortants) (2006)	Japanese encephalitis (2009) (Vero cell)	Pneumococcal conjugates* (heptavalent) (2000)	Human papillomavirus recombinant (quadrivalent) (2006)
Zoster (2006)	Cholera (WC only) (2009)	Meningococcal conjugates* (quadrivalent) (2005)	Human papillomavirus recombinant (bivalent) (2009)
		Pneumococcal conjugates* (13-valent) (2010)	Meningococcal group B proteins (2013)

Source:(Dlamini et al., 2016:233-244)

2.3.1 GLOBAL VIEW OF SAFE HANDLING OF VACCINES IN PRIMARY HEALTH CARE FACILITIES

All healthcare workers who receive deliveries, handle, and administer vaccines should be familiar with the storage and handling policies and procedures of vaccines at facilities. All plans and standard operating procedures for handling, storage and managemnet of vaccines should be kept near storage units and all healthcare workers should know where to find them (Motaze et al., 2018:233-244). Preventing loss of vaccine potency during handling is increasingly important as new and more expensive vaccines are introduced that require proper handling to avoid waste in spoilage. The cold-chain refers to the continuum of safe handling practices, including material, equipment and procedures that maintain vaccine within the temperature range from the time they are manufactured to the time they are administered (Weir et al., 2014:1050).

Proper vaccine handling has been an importanat factor in preventing and eradicating many common vaccine-preventable disease. Each year vaccine handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to handle vaccines properly reduce vaccine potancy, resulting in inadequate immune responses in patients and poor protection against the disease. Patients can lose confidence in vaccines and providers if they have to be revaccinated because the vaccine received may have been compromised (Follett et at., 2018:49). To obtain optimum results from vaccines, the following step should be employed:

- Cold-chain flow chart (Vaccine cold-chain)

Cold-chain flow chart is a system designed to protect and maintain vaccine viability. To maintain an effective vaccination programme, vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold reduces vaccine potency, therefore increasing the risk that recipients will not be protected against vaccine-preventative diseases. Cold-chain is the system used to effectively distribute and maintain vaccines. The cold-chain flow chart begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distribution and then to the facilities, and ends with the

administration of the vaccine to the recipient. Proper storage temperatures must be maintained at each stage in the chain or the vaccine may be damaged and become ineffective.

The cold-chain flow chart

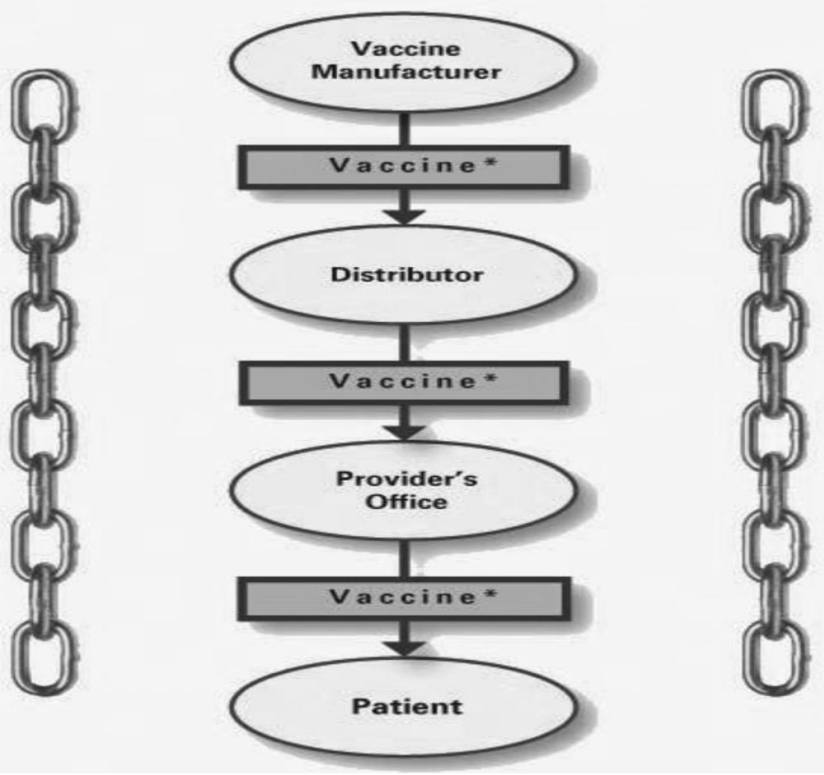


Figure 2: The cold-chain flow chart (Department of Health, 2017:4).

Vaccine manufacturing is the responsibility of the manufacturer. After manufuring they are then distributed by the manufacturer to the required facilities. The vaccines arrive at the provided facilities in the accepted temperature range which is 2-8ºC. They are stored and handled according to the manufacturer's instructions to maintain the cold-chain.

According to WHO , there are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Vaccines exposed to temperatures outside the recommended ranges can have reduced potency and protection. Storage and handling errors can cost thousands of dollars in wasted vaccine and revaccination. Errors can also result in

the loss of patient confidence when repeat doses are required. It is better to not vaccinate than to administer a dose of vaccine that has been mishandled. Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built (Duclos et al., 2015:233-239).

A study conducted in eight health districts in Cameroon revealed that the targeted health districts were not compliant with the standard operating procedures. Almost 25% of health facilities were conducting the Expanded Program Immunization (EPI) activities without cold-chain equipment. When children are immunized with vaccines exposed to inappropriate temperatures they need to be re-vaccinated. Vaccine recalls result in extra doses of vaccines for children, increased costs for providers, damage to public confidence in vaccines and can also become a liability for providers' practices. Evidence from studies conducted in different countries indicate that good vaccine practices are lacking even in developed and developing countries. Examples of these include inadequate temperature monitoring, unreliable equipment and use of incorrect fridges (Fekadu et al., 2018:118-122).

2.3.2 Global view of storage of vaccines by healthcare workers at Primary health care facilities

All vaccines are sensitive biological substances and lose their potency quickly if they are not stored per manufacturer's guide. The rate of loss increases as vaccines are exposed to higher or freezing temperatures. In order to maintain their quality, vaccines must be continuously stored at the appropriate temperatures from the time they are manufactured until the moment of use. Different vaccines require different storage conditions. What is correct for one vaccine may be dangerous for another. It is therefore vital to know the correct storage conditions for each vaccine. Diluents are specific to their vaccines, hence are not interchangeable. For an example, a diluent made for measles vaccines must not be used for reconstitution of BCG, yellow fever or any other type of vaccine. Moreover, diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting a different type of vaccine produced by another manufacturer (Motaza et al., 2018:37).

For the vaccination programme to be effective and provide maximum protection, it is essential for vaccines to be stored in optimum conditions which are between 2ºC and 8ºC. If vaccines become too hot or too cold, their effectiveness may be compromised. Vaccines must never be frozen because in addition to vaccine deterioration, this increase reactogenicity by irreversible denaturing of the protein in the vaccine. This causes the emulsion in the vaccine to become unstable and produces hairline cracks in the ampoule, vial or prefilled syringes potentially contaminating the contents. Any glass spicules produced may also cause serious local adverse reaction. These factors may results in the failure of the vaccine to stimulate the intended immune response, therefore providing poor protection to the individual (Chiodini, 2014:45).

Vaccine storage practices are only as effective and successful as the staff that implements them. A well-trained staff, familiar with key storage principles is critical to ensuring the potency of vaccine supply and the safety of patients. Knowledgeable staff can also save significant costs on wasted vaccines, and prevent loss of credibility among patients who must be revaccinated due to a storage error (Follett et al., 2018:49).

To obtain optimum results when it comes to storage of vaccines, the following steps should be employed when training healthcare workers:

- Cold-chain training as part of new employee orientation
- Annual refresher courses for all staff involved in immunization, storage and handling activities.
- Whenever new vaccines are added to the inventory
- Whenever recommendations for storage of vaccines are updated.
- There should be a vaccine coordinator, a person designated to the primary vaccine coordinator for the facility. This person will be responsible for ensuring all vaccines are stored correctly.
- Appoint a second staff member to serve as an alternative in the absence of the primary coordinator. Both coordinators should be fully trained in routine and emergency policies and procedures.

- Responding to temperature excursion (out of range temperature), maintaining all documentation, such as inventory and temperature logs (Follett et al., 2018:89).

Vaccine storage and temperature monitoring equipment

To fully ensure the safety of the vaccine, the following equipment is recommended:

- Stand-alone refrigerator with enough space to accommodate your maximum inventory without crowding.
- Digital data logger (DDL) with a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) for each unit and at least one backup in case of a broken or malfunctioning device.
- Transport situations also require special equipment, such as emergency transport containers and digital data loggers for each container (additional data loggers may be required if there are more containers than storage units).
- If a purpose-built unit is not available, use a stand-alone household unit. If you must use a household-grade, combination refrigerator/freezer unit, only use the refrigerator compartment for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures.
- Use a separate stand-alone freezer to store frozen vaccines. Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/ freezer unit under any circumstances. These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment (National Health Science, 2015:16-19).
- Make sure the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season) without crowding.
- Remove any deli, fruit, and vegetable drawers from refrigerator units. This provides extra space for water bottles to help maintain stable temperatures and prevents the use of the drawers for storing food, beverages, or vaccines.
- Use safeguards to ensure the doors of the unit remain closed for example, self-closing door hinges, door alarms, door locks, etc. (Chiodini, 2014:39).

Figure 2.8: illustration of how domestic refrigerator can be used to store vaccines, at Primary healthcare facilities.

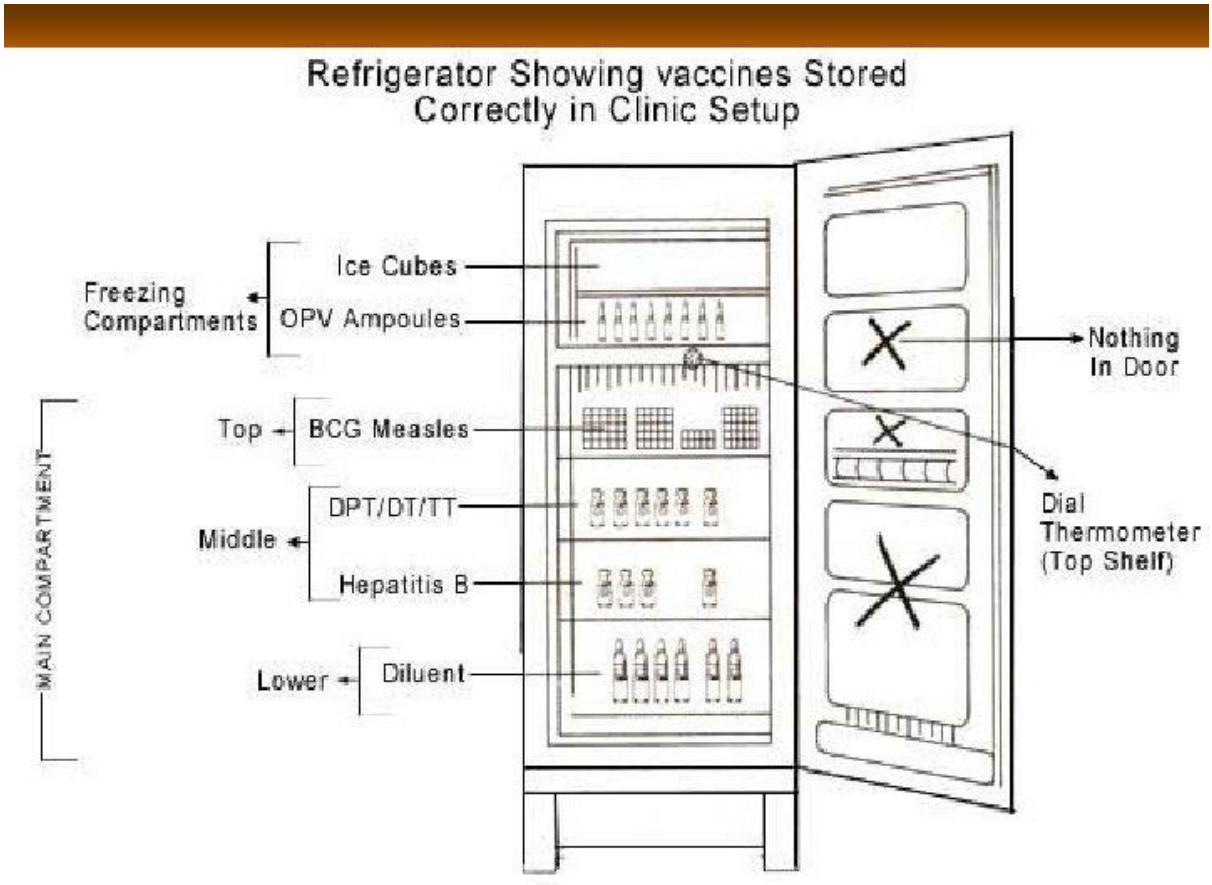


Figure 2.8: Allustration of a domestic refrigerator (WHO, 2012:461-476)

According to (WHO, 2012: page), vaccines must be stored properly from the time they are manufactured up until they are administered. Proper maintenance of vaccines during transport is known as the cold-chain. A proper cold-chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine. By following a few simple steps and implementing best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive. Vaccines are fragile and they must be maintained at the temperatures recommended by vaccine manufacturers and protected from light at every link in the cold-chain. Most live virus vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to

temperature fluctuations (e.g., extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions (out-of-range temperatures) that can have a cumulative negative effect.

2.3.3 GLOBAL VIEW ON MANAGEMENT OF VACCINES BY HEALTHCARE WORKERS IN PRIMARY HEALTH CARE FACILITIES

In order for vaccine management to be efficient, three major elements are required. These include well-trained personnel, reliable transport or storage equipment and efficient management procedures. The absence of any of these would lead to a deficient cold-chain system. Health care workers play an important role in maintaining an undisrupted cold-chain, as they are the last point of contact between the vaccines and the recipient. Hence, it is very pertinent that they are trained and supervised regularly in order to ensure efficient practice of cold-chain management (Madsen, 2017:42).

To maintain vaccine perfectly from its manufacture through administration requires an adequate cold-chain infrastructure, compliance to standards and effective management. At the end of the chain, primary healthcare providers must have adequate knowledge to manage the cold-chain of obtain optimum results on the management of vaccines (Gunnar, 2017:1), the following steps should be employed:

2.3.3.1 VACCINE INVENTORY MANAGEMENT

All vaccines need to be received upon delivery by a trained healthcare worker, stored and handled correctly. Vaccines are expensive, so it is important to make sure there is accountability for every dose received and used by the facility. Therefore, even if the vaccine is administered, wasted, compromised, expired, or transferred, it is important to keep accurate records that helped the facility in ordering and rotating stock regularly, thus ensuring the availability of vaccines for patient's needs (Follett et al., 2018:45).

- Vaccine Deliveries
- Scheduling and receiving deliveries

All staff members who might accept vaccine deliveries must be aware of the importance of maintaining the cold-chain. They should be trained on ensuring that upon delivery, vaccines are checked in and stored correctly, and notify the vaccine coordinator of the new vaccine inventory. The person arranging for deliveries should know which staff member will be available to receive them, considering holidays, vacations, and any changes in the facility's hours of operation.
The vaccine-shipping container is not to be left unpacked and unattended, as they need immediate attention to maintain their potency and cold-chain (Follett et al., 2018:52).

- Unpacking deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit when unpacking deliveries. The shipping container should be examined for signs of physical damage. The content should be checked against the packing list to be sure they match. The packing list will show the maximum time vaccines can be in transit based on the shipment date. Check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products. The cold-chain monitor (CCM) should be checked for any indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). Notably, CCMs are for one-time use and should be thrown away after being checked (Follett et al., 2018:55).

2.4 INTERNATIONAL CONTEXT OF SAFE HANDLING, STORAGE, AND MANAGEMENT OF VACCINES

Vaccine are among the greatest advances in global health and development. For over two centuries, vaccines have safely reduced the scourge of diseases like polio, measles and smallpox, helping children grow up healthy and happy. They save more than five lives every minute preventing up to three million deaths a year. Thanks to immunization efforts worldwide, children are able to walk, play, dance and learn. Vaccinated children do better at school, with economic benefits that ripple across

their communities. Today vaccines are estimated to be one of the cost effective means of advancing global welfare (UNICEF, 2020:2).

UNICEF harness solar power, mobile technology and telemetric to ensure vaccine reach all children without losing their effectiveness from exposure to extreme heat or cold weather conditions. As one of the world's largest buyers of life saving supplies UNICEF negotiate the lowest prices, and they buy in bulk so as to cut costs while increasing efficiency on saving more lives. This has facilitated the introduction of new vaccines to children living in the poorest countries in a more sustainable way (UNICEF, 2020:7).

Immunization is one of the most impactful and cost-effective public health interventions available, averting over 4 million deaths every year. In addition to offering protection from preventable disease, immunization also brings children and families into contact with health systems, providing any avenue for the delivery of the basic health services and laying the foundation for primary healthcare (WHO, 2017:3). In 2019, the World Heal Organization (WHO) declared vaccines hesitancy to be one of the top threats to public health. While vaccine hesitancy is as old as vaccination itself, the nature of the challenge continues to shift with the social landscape as it is the key drivers of under vaccination across the globe.

According to (WHO 2019:82) every country has a national immunization programme and vaccines are viewed as one of the safest, most cost-effective, and successful public health intervention to prevent deaths and improve lives. Ever since the introduction of the EPI in 1974 with the initial focus being on the childhood vaccine preventable diseases over four daces ago, the addition of the new vaccines has increased the breadth of protection provided by immunization, to include vaccinations for protection of older children, and adolescents. Committed to its goal of universal access to all relevant vaccines for all at risk, the EPI continues to work in synergy with other public health programmes to control infectious diseases and achieve better health for all populations everywhere.

Immunization is hailed as one of the most important public health interventions known for saving millions of lives every year. Vaccines are responsible for the

eradication of smallpox and polio if stored at recommended temperature ranges, and a well-functioning cold-chain is at the centre of ensuring potent vaccines reach their intended population in an adequate and timely manner (Hanson et al., 2017:2127-2133). Vaccines are sensitive biological substances that gradually lose their potency with time, and its loss of potency can be accelerated when stored out of the recommended range of temperature. A proper storage of vaccine at the recommended temperature conditions is vital so that vaccines potency is retained up to the moment of administration (Yakum et al., 2015:2).

In the United States, it is widely reported that immunization is faced with several programmatic issues including demographic factors such as difficulty in reaching out to target population, human factors such as poor motivation for vaccination and insufficient knowledge and skills required (WHO 2019:82). The various approach in addressing the challenges regarding the immunization programs are widely captured in the WHO training module for health care workers and managers which can be adopted and adapted by all WHO member states. To sustain these benefits, vaccinators must observe the standard practices before, during and after vaccination. WHO recommends that standard guidelines for immunization in practice should ensure that before vaccination, immunization healthcare workers should have the capacity to identify the right patient at the right time, identify, prepare and administer the right vaccine and correct dosage using the right cold-chain practices. Inspecting vaccine and diluent are critical in reducing adverse events following immunization. This is done by carefully examining the vaccine vial monitor (a label containing a heat-sensitive material that is placed on a vaccine vial to register cumulative heat exposure over time) to select the vaccine in a good state (Ansong et al., 2018:2).

Furthermore, It is important to ensure that cold-chain system is maintained through regular monitoring of the refrigerator. The standard protocol recommends two times monitoring (morning and afternoon) and recording the temperature on a chart reference (Doclos et al,. 2015:233-239). Cold-chain monitoring is still a major challenge, and this study suggests that only about 56 percent of health facilities fill their temperature charts systematically twice a day as recommended (Yakum et al.,

2015:1-7). Furthermore, there is also persistently registered outbreaks of vaccine-preventable disease such as measles even with high vaccine coverage seen as one of the major issues of EPI in Cameroon. Power supply in Cameroon is one of the major issues in remote areas, as hydroelectricity is the cheapest and main power source in urban and semi-urban areas, but it is not available in many rural localities, where solar, natural gas and in some occasions generators are the main source for cold-chain (Ateudjieu et al., 2013:2-7).

2.5 AFRICAN CONTEXT: SAFE HANDLING, STORAGE, AND MANAGEMENT OF VACCINES

Vaccine storage capacity remains insufficient in Nigeria. The current available capacity of cold-chain storage for vaccines covers only 30 percent of routine maximum demand. This implies that significant cold storage capacity expansion is still required. Despite the introduction of solar-powered refrigerators and the use of new tools to monitor supply levels, adequate vaccine storage facilities are one of the major problems facing Nigeria (Shittu et al., 2016:293-300).

In Mozambique, the minister of health supported the EPI into Primary Healthcare facilities in order to institutionalize the programme. The minister discovered shortfalls that hinder the programme from being successful, which included limited human resource capacity, and major workflow at the most remote facilities that administer the EPI. Newly assigned jobs without adequate training such as in cold-chain management, often contributes to the challenge of adhering to the WHO guidelines and standards for the cold-chain management. Another challenge that was discovered was the issue of the infrastructure. In order to maintain vaccine, it requires an adequate cold-chain infrastructure, compliance to standards and effective management (Gunnar, 2017:1).

2.6 SOUTH AFRICAN CONTEXT: SAFE HANDLING, STORAGE, AND MANAGEMENT OF VACCINES

The purpose of the Expanded Programme on Immunisation (EPI) is to prevent childhood infections using vaccines and eventually to reduce the burden of diseases by preventing the circulation of these infectious agents in the community. In South Africa the number of vaccines used for childhood immunisation has increased from

the six vaccines in 1994 to 11 in 2015. The eleven vaccines protect against the following conditions: Tuberculosis, Polio, Rotavirus, Diphtheria, Pertussis, Tetanus, Haemophilus influenzae type b (Hib), Hepatitis B, Pneumococcal infections and Measles. In communities where children are not protected through vaccination programmes, vaccine-preventable infections can cause outbreaks. Through strong immunisation and surveillance programmes with adequate investment of time, money and hard work, it is possible to control outbreaks, eliminate and even eradicate some of these infections (National Department of Health, 2017:76).

Vaccines are widely acknowledged to be the most successful medical advance ever, they continue to save hundreds of thousands of lives annually. History is full of descriptions of the devastation brought on population by infectious diseases before the age of vaccination. Huge number were killed by diseases like measles and smallpox, and hundreds left paralysed. The aim of the National Department of Health is to ensure that 90% of all children are fully immunised by the age of one year (National Department of Health, 2020:49). The expanded programme on immunisation has taken disease control to the next level by not only providing protection against infectious conditions and also introducing new vaccines in an effort to provide additional protection for children from some of the common causes of mortality and morbidity (National Department of Health, 2015:43).

The extended programme of immunisation is the most cost effective healthcare intervention, preventing morbidity and mortality associated with vaccine preventable diseases. It is the pillar in prevention of antimicrobial resistance. Therefore Successful EPI programme can play an important role in improving public health in South Africa through increased vaccination coverage, which is essential for protection against infectious disease and increasing herd immunity. It is important to also create awareness about the importance of vaccination, and to provide access to vaccines for children up to the age of 12 years. Thereby providing an opportunity for all children who have missed any routine vaccination to get vaccinated (Pharmaceutical Society of South Africa, 2018:16).

In South Africa, the challenges identified by the Expanded Program on Immunization were healthcare workers who had insufficient knowledge of vaccines and

immunization management. Furthermore, healthcare workers were not practicing the EPI according to WHO recommended standards and guideline (Mothiba et al., 2016:52). For the past three years, South Africa remains one of the top five countries underperforming in EPI in the whole of the African countries according to WHO standards (Bateman, 2016: 317). Although SA's national budget provides exclusively for vaccines purchase of R1.4 billion each and every year, it is still underperforming. This is because it is under prioritizing other factors that hinder a successful immunization programme such as human resource, social mobilization, transport, training, monitoring, and evaluation. Adherence to cold-chain in South Africa is lacking.

According to WHO, approved fridges for vaccines are supposed to have an internal continuous monitoring device with a temperature chart on the outside of the fridge on which readings are manually recorded twice a day beginning and end of shift to ensure that vaccines remain between 2ºC and 8ºC. However, in practice WHO standards are not adhered to. All vaccine vials carry a temperature and time-sensitive vaccine vial monitor tag of a light square within a dark circle. If the square turns the same colour as the circle or becomes darker, the vial must be discarded. Notably, healthcare workers that handle and manage vaccine are not well trained and equipped to be able to manage vaccine properly. That is why in South Africa most vaccine wastage is due to mismanagement, improper storage and lack of knowledge about cold-chain management (Bateman, 2016:319).

Vaccine deterioration increases reactogenicity by irreversible denaturing of the protein in the vaccine. This causes the emulsion in the vaccine to become unstable and produces hairline cracks in the ampoule, vial or prefilled syringe, potentially contaminating the contents (Chiodin, 2014:53). To achieve a successful immunization program, there is a vaccine cold-chain flow chart that needs to be followed by every healthcare worker.

2.7 Provincial context: Safe handling, storage and management of vaccines

Immunization is the cornerstone of Primary Health Care and an important gauge of the quality of the health service in a country, it is also an indicator of how far a

country is from preventable disease outbreaks. Immunization is one of the most cost effective public health interventions available and SA has implemented a comprehensive immunization schedule (National Department of Health, 2015:65).

Furthermore; Immunizations help save lives, prevent serious illnesses, and are recognized as one of the most effective public health interventions available today. The success of these programs depends heavily upon the high immunization coverage of the target group and vaccine inventory management, including proper storage, handling and management of vaccines. By understanding and implementing proper vaccine storage and handling practices, staff in health care provider premises can play a critical role in improving the health by ensuring that the administered vaccines retain their potency and that vaccine wastage is reduced (Department of Health, 2017:4).

The Expanded Programme on Immunisation (EPI) has contributed immensely to the reduction of deaths in children due to infectious diseases and has made a substantial contribution to human development (National Department of Health, 2020:23) . The EPI in South Africa became an entity in 1995 with the birth of democracy. An uninterrupted supply of vaccines at different supply chain levels is a basic component of a functional immunization programme and care service. There can be no progress toward achieving universal health coverage and sustainable development without continuous availability of essential medicines and vaccines in healthcare facilities. Shortages of vaccines, particularly at health facility level is an issue of grave concern that requires urgent attention in the eastern cape province (Iwu, 2019:23). Immunisation is the most cost-effective public health intervention currently available. No other undertaking, not even the development of antibiotics has had as much impact in lowering mortality.

The Expanded Programme on Immunization (EPI) in South Africa has made significant progress in the control of vaccine-preventable diseases. One of the challenges the EPI faces in the Eastern Cape Province are vaccine stock-outs are multifactorial and may be linked to a broader systems issue. These factors include challenges at higher levels such as delays in the delivery of stock from the pharmaceutical depot; health facility level factors, which include a lack of

commitment from healthcare workers and managers; human resource factors, such as, staff shortages, and lack of skilled personnel. Therefore, there is a compelling need to address the factors associated with shortages of vaccines in health facilities (Ngcobo et al., 2017:535-538).

2.8 Buffalo City Metropolitan context: safe handling, storage and management of vaccine

During the past two decades, immunisation has saved millions of lives and prevented countless illnesses and disabilities in South Africa (SA). However, vaccine-preventable diseases are still a threat. Immunization stimulates the immune system to provide protection against specific infection. Immunisation helps strengthen a child's immune system to fight diseases like polio, measles and many more. A vaccine-preventable disease that might lead to a 1 or 2 week illness in an adult, could prove deadly for infants, children or elderly people. Vaccination protects oneself and one's family. For example, adults are the most common source of pertussis (whooping cough) infection in infants, which can be deadly for the latter (South African Government, 2022:22).

In 2018 second quarter performance on immunization coverage in children under one year, BCM has identified that there is a need to improve on the growth of immunization at community and facility level. One of the non-government organization Kheth 'Mpilo has employed a community based programme manager in order to strengthen and resolve the poor performance (Buffalo City Metropolitan Municipality, 2020:11).

In 2021. The municipality called upon all the residence of BCM residence to take note of rabies outbreak as a five year old boy died as result following a dog bite. After several incidence were reported, BCM decided to undertake a vaccination drive. This was a joint drive together with the department of agriculture and BCM health services, disaster management and public participation. The first vaccination took place at unit three in Mdantsane, the vaccination team were not just stationed in one place but went from street to street to be accessible (Buffalo City Metropolitan

Municipality, 2021:4). The EPI in South Africa (EPI-SA), which became an entity in 1995 with the birth of democracy

2.9 CONCLUSION

The literature review revealed that despite the availability of vaccines and guidelines, safe handling, storage and management of them is also vital. Hence, the quality of vaccines is one of the important factors for the success of the immunization program. If vaccines are stored outside the recommended temperature for a considerate time, their potency will be adversely affected thereby reducing protection from vaccine-preventative disease. The principles of vaccine storage consist of proper installation of thermometers, maintenance of appropriate temperatures, recording temperatures, and storage of vaccines at recommended temperature ranges.

Literature shows that African countries strive to comply with the health standards with regards to safe handling, storage, and management of vaccines in PHC facilities. Therefore, this study sought to address some of the gaps in the safe handling, storage and the management of vaccines by healthcare workers in Buffalo City Metropolitan. Most of the low-income African countries have also introduced the EPI program in recent decades. Even though most of those countries are poor, there is definitely an upward trend in the improvement of the standards, contributing to the safe handling, storage, and management of vaccines in PHC facilities. In South Africa safe handling, storage, and management of vaccines in PHC facilities is unsatisfactory. This is due to the shortage of staff, lack of training in EPI program and supervision.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter focuses on the following research components: research approach, design, sample size, sampling techniques, data collection methods and instruments, the validity and reliability of the instrument, data collection procedure, ethical considerations, and data analysis. (Burns et al., 2013:8) define a research design as "a blueprint for conducting a study with maximum control over factors that may interfere with the validity of the findings". In this chapter, the researcher describes the research methods employed in the study and the reasons why these methods were considered to answer the questions and address the research problem. The term methodology is understood as "the activity or business of choosing, reflecting upon, evaluating and justifying the approaches you use in data collection" (Burns et al., 2012:42).

3.2 RESEARCH APPROACH

Primarily, there are three research approaches, that is, quantitative, qualitative and mixed methods. This study adopted a quantitative approach, which is defined as a formal, objective and systemic process in which numerical data are used to obtain information about a topic (Grove et al., 2013:32). The quantitative approach towards scientific inquiry emerges from a branch of philosophy called logic positivism, which operates on strict rules of logic, truth, laws, and predictions. Quantitative research is conducted to test theory by describing variables (descriptive research), examining relationship amongst variables, and determining cause and effect interaction between variables (Burns et al: 2013:41). The rational for choosing this research approach was to determine the extent of the problem and its occurrence, by quantifying the variation. Mean and standard deviation scores were used to measure the occurrences and variations.

3.3 RESEARCH DESIGN

A research design compromises strategies and methods for research that extend the decision from general assumptions to thorough methods of data gathering and reasoning (Creswell, 2013:5). According to Burns and Grove (2013: 216-222), descriptive research design is used to provide a picture of a situation as it naturally happens. It may be used to justify current practices and make judgement and also to develop theories.

A descriptive research design was used for this study to obtain a picture of how healthcare workers safe handle, store, and manage vaccines at BCM in PHC facilities. The descriptive research design was chosen to answer the research questions and to achieve the study objectives. With this design, the researcher can also generalize or draw an inference to the population under study. It also limits the chances of manipulation of the data and protects the study against bias (Burns et al., 2013:45)

3.4 RESEARCH SETTING

The research setting refers to the location where the study is conducted, and it is selected based on the purpose of the study (Burns et al., 2013:276). It is the environment within which research studies are undertaken. It has an important consequence for the research in relation to the type of data that can be collected and the interpretation of the results (Grove et al., 2013:32). Quantitative research deals in numbers, logic, and it focuses on numeric and unchanging data detailed. The requirements for a research settings from a quantitative perspective are;

- The data is usually gathered using a structured research instrument
- The results are based on lager samples sizes that are representatives of the population
- The research study can usually be replicated or repeated, given its high reliability
- The researcher has a clearly defined research question to which objectives answered are sought

- All aspects of the study are carefully designed before data is collected
- Data are in the form of numbers, statistics, often arranged in tables, charts, figures, or other non-textual form.
- The researcher uses tools, such as questionnaires or computer software to collect numerical data (Creswell et al., 2013:27).

The setting for this study was the Buffalo City Metropolitan Primary Health Care facilities. The metropolitan has the following sub-districts:

- East London, which as 23 PHC facilities and 4 mobile clinics,
- Bhisho, which has 7 PHC facilities,
- King William's Town, which has 19 PHC facilities and 3 mobile clinics,
- Townships of Mdantsane that has 13 PHC facilities and 3 mobile clinics, and
- Zwelitsha, which has 2 PHC facilities.

The BCM consists of 74 PHC facilities in total (Buffalo City Metropolitan Municipality, 2021:4).

3.5 POPULATION

A population is defined as a particular group of individual, families, organizations, and communities who are the focus group of the research. This is the total of the research group that the researcher focuses on and to which the obtained results should be generalized (Burns et al., 2014:250).

The population for this study was all the healthcare workers (professional nurses, enrolled nurses, pharmacist assistants, pharmacists and enrolled nursing assistants) working in Primary Healthcare facilities in Buffalo City Metropolitan. The total number of healthcare workers in the study area is estimated at 1662 (Eastern Cape Department of Health, 2018:1).

The target population of this study included all the healthcare workers on duty in the PHC facilities during data collection period.

3.6 SAMPLE AND SAMPLING PROCEDURE

According to (Burns 2013:59-60), sampling involves selecting a group of people, events, behaviour or other elements with which to conduct a study. When elements are persons, they are known as subjects. The participants were selected from the delineated target population in a way that the individuals in the sample represent as nearly as possible the entire population. This decision has a major impact on the meaning and generalizability of findings.

In this study, sampling was done in a logic and systematic manner. A total sample of 148 healthcare workers, who are champions in handling, storage, and management of vaccines in PHC facilities in BCM were selected. The sample of 148 healthcare workers include the professional nurses, pharmacist, Pharmacist assistants, professional nurses and nursing assistance that handle, storage and manage vaccines at PHC facilities in BCM. The 148 of healthcare workers incorporates two healthcare workers from the 74 PHC facilities in BCM which makes them 148 in total. From the 148 healthcare workers only 72 healthcare workers were able to participate in the study, as only one healthcare worker participated in the study from each facility, while the other healthcare worker would be busy working while conducting the study with the other one. Therefore: the sample size of the study is 72 healthcare workers that handle, store and manage vaccine in PHC facilities in BCM. Convenient sampling was used to select the healthcare workers that handle, store and manage vaccines in PHC facilities in BCM. Convenience sampling is a non-probability sampling technique where samples are selected from the population only because they are conveniently available to the researcher (Mohamed et al., 2017:23).

Calculations of a sampling size:
Confidence level + - 85% -Z score=1.44
Margin of error +- 5%
Standard Deviation = 5
Necessary Sample Size= (Z-Score)2 X Std deviation (1-Std deviation)/ (Margin of error)2

Necessary sample size= (1.44)2 X 5(0.5)/(0.05)2
Necessary Sample Size = 7.2/0.1
Sample size = 72
(Adapted from: (Brydges, 2019:36)

3.7.1 INCLUSION CRITERIA

The healthcare workers that handle, store and manage vaccines were included in this study. All the healthcare workers that were on duty during the time of data collection and willing to participate in the study were included in the study.

3.7.2 EXCLUSION CRITERIA

Healthcare workers who were on leave during data collection period and those that do not handle, store, or manage vaccines were excluded from the study.

3.8 RESEARCH INSTRUMENTS/TOOLS

A research instrument is a measurement tool designed to obtain data on a topic of interest from research participants. Research instruments are measuring tools such as questionnaires, scales, tests, and surveys among others. In this study, a structured questionnaire was used as a research instrument. The questionnaire was adopted from NHS Foundation Trust (2015).

The questionnaire consists of closed-ended questions that aim at maintaining control over extraneous variables. The questionnaire was self-administered to obtain data from the nurses on handling, storage, and management of vaccines. The questions were in a logical sequence, covering four sections namely: demographic, handling, storage and management of vaccines in PHC facilities. The sectioning was useful to allow for meticulous documentation of events. The questionnaire was in English language.

3.9 DATA MANAGEMENT

Data management refer to the care and maintenance of the data produced during the course of research cycle. It is an integral part of the research process that helps in ensuring that data is properly organized, described, preserved, and shared (Bateman, 2016:320). In managing the data for this study, confidentiality was maintained by storing the data in a locked (and key) cabinet at the University of the Fort Hare.

3.10 DATA COLLECTION

Data collection is the gathering of information relevant to the purpose, objectives and questions of the study. Before data can be collected, permission was granted from the relevant authorizing bodies and consent from the participants (Burns et al., 2014:47). After receiving clearance from the relevant bodies, the operational managers were furnished with the clearance certificates and made appointments with the targeted healthcare workers that handle, store and manage vaccines at PHC facilities. Participants were informed about the study and invited to participate.

The healthcare workers agreed to take part in the study and signed a consent form. Consequently, 64 healthcare workers were issued questionnaires to assess safe handling, storage, and management of vaccines at PHC facilities in BCM. Due to covid-19, 8 PHC facilities were closed, while healthcare workers were in quarantine as they had tested positive for covid-19. The category of the healthcare workers that participated in the study were staff nurses, pharmacist, pharmacist assistant and professional nurses of which were the champion participants in this study. Vaccines were handled, stored and managed by different categories in different clinic. The participants were selected based on their roles and responsibilities. The data was collected during working hours.

3.11 DATA COLLECTION PROCEDURE

The data collection procedure outlines how the research intends to answer the research question. It explains how data was collected and how the results was obtained (Brink et al., 2018:133). Data was collected by the researcher after receiving clearance from the relevant gate-keepers. The researcher furnished the clinic managers and the operational managers with the clearance certificates and secured an appointment with the targeted healthcare workers.

In each PHC facility, only one healthcare worker participated in the study, as one was working in the section where vaccines were handled, stored and managed. The healthcare workers were selected based on their role and responsibility with vaccines. After consent was given by the healthcare workers to participate on the study, the research explained to them and were made aware that their identity was kept confidential.

The questionnaire was printed and distributed in-person to the healthcare workers. The participants were required to answer four sections in the questionnaire, namely demographic section to determine the age, sex and gender of the healthcare worker, handling, storage and management of vaccines. The questionnaire had closed-ended questions in form of true or false answers. The data was collected by the researcher during working hours between 08h00 in the morning to 16h00 in the afternoon. The equipment used to collect data was the questionnaire and a pen which were all provided by the researcher.

3.12 DATA ANALYSIS

Data analysis is the process of exploring and organizing raw data to make meaning. It involves categorizing, manipulating, summarizing data and describing it in a meaningful manner (Brink et al., 2018:165). This process gives the researcher an idea of patterns, outliers and missing information.

To begin the analysis, the data from the questionnaire was entered in a separate spreadsheet according to the four categories of the questionnaire namely; demographic, safe handling, storage and management. A Statistical Package for the Social Sciences (SPSS) version 24 for analysis was used with the assistance of the statistician. The SPSS program generates frequency tables, graphs, diagrams, statistical pies and representative characteristics or values, such as averages and percentages.

Data was summarized using descriptive statistics which allowed the researcher to organize data in ways that give meaning and facilitate insight (Burns et al., 2014:170). This method was used to describe the basic features of the data, it provides simple summaries about the sample and measures, and they form the basis of every quantitative analysed data.

3.13 Reliability and Validity of the Study

Reliability is the consistency with which an instrument measures the attribute it intends to measure. An instrument is said to be reliable if its measures accurately the score of the attribute under investigation (Burns et al., 2013:200-220). This means that if the study could be repeated by another researcher, the findings would still be the same.

3.13.1 Reliability

The data collection tool has been adopted from (National Health Science Foundation et al., 2015:16-19), the researcher has only recorded data that is available from the self-administered questionnaire, which means there were no alterations on the data obtained. The data collected was retrievable because a study number was allocated for each healthcare worker, thus making it possible to assess the reliability of the collected data by another researcher. This was, therefore, accounted for the reliability of the data.

3.13.2 VALIDITY

The data collection tool that was used for the study was content validity. It includes all the elements relevant to the study. The data collection tool was structured in a way that it allowed for the determination of whether safe handling, storage and management was compiled by in PHC facilities in BCM.

Validity on the other hand, is the extent to which the method of measurement includes all the major elements relevant to the concept being measured (Burns et al., 2013:216).

3.14 ETHICAL CONSIDERATIONS

Ethics are the moral principles that govern a person's behaviour. Research ethics may be referred to as doing what is morally and legally right in research. They are actually norms for conduct that distinguish between right and wrong, and acceptable and unacceptable behaviour (Tripathi et al.,2017:4).

The researcher obtained clearance from the University of Fort Hare Research Ethics Committee reference no 2020=01=004=HohoA, to make sure that the rights, needs, values, and desires of healthcare workers and institutions were safely guarded. Permission to gain access to BCM Primary Healthcare facilities was requested from the Eastern Cape Department of Health ethics committee and the BCM research committee. In addition to the clearances, the following ethical issues were strictly upheld:

3.14.1 INFORMED CONSENT

Informed consent is a voluntary agreement to participate in the research. It is not merely a form that is signed but is a process, in which the subject has an understanding of the research and its risks. It is essential before and after enrolling a participant in a study. It must be obtained for all types of human subject research

including diagnosis, therapeutics, interventional, social and behavioural studies. Obtaining consent involves informing the subject about his and her rights, the purpose of the study, the procedure to be undertaken, and the potential risks and benefits of participants. The research participants must participate willingly (Brink et al., 2018:32). Informed consent was received from all the participants after the researcher had informed the healthcare worker about the purpose of the study and how the process of data collection. The healthcare workers were informed about the potential benefits, risks, and procedure of the study and they were offered an opportunity to ask questions. Healthcare worker were informed that the findings will be processed as a research report, but their identity was kept confidential. Participation was voluntary; hence they were free to withdraw at any given time. The healthcare workers signed the informed consent form without being coerced. Informed consent is “a legal requirement before one can participate in a study” (Burns et al., 2013:319). Every healthcare worker was allowed to choose whether or not to participate in the study. Informed consent includes four elements: disclosure of essential study information to the study participant; comprehension of this information by the healthcare worker, competence of the healthcare worker to give consent, and voluntary consent of the healthcare workers to take part in the study.

3.14.2 Confidentiality, Anonymity, and Privacy

Confidentiality is a basic ethical principle, while anonymity is one way in which Confidentiality is maintained. Complete anonymity exists when the participant’s identity cannot be linked even by the researcher (Burns et al., 2013:100). Invasion of privacy occurs when healthcare workers information is shared without their knowledge. Breach of confidentiality, therefore, can occur when an unauthorised person is given access to the data collected.

In this study, anonymity was achieved by excluding the healthcare workers names on the questionnaire, and separating the questionnaires from the consent forms to eliminate the possibility of the identification. The data collected was kept in a locked cabinet and the computer storing the electronic data was protected by a password, known by the researcher only. No details of the healthcare were entered on the questionnaire. The data will be discarded five year after the completion of this

research in accordance with the South African Medical Research Council guidelines on the responsible conduct of research (South African Medical Research Council, 2019:12). When the time comes for the destruction of the questionnaires, they will be shredded, and data will be deleted permanently.

Privacy is the freedom people have to determine the time, extent, and general circumstances under which information can be shared with or withheld from others. Private information includes a person's attitude, beliefs, behaviours, opinions, and records (Burns et al., 2014:105).

3.14.3 RESPECT

Research participants should be given the right to self-determine, if they are interested in participating in the study or not (Burns et al., 2013:137) . Respect for persons is a basic human right. Healthcare workers are autonomous individuals with the right to choose to either participate or not in a research.

In this study healthcare workers were treated with respect throughout the data collection process. The researcher ensured that the healthcare workers gave full informed consent to participate in the study. The study was explained to the healthcare workers clearly, indicating risks and benefits of participating. The healthcare workers were also informed that participation was voluntary and they were free to withdraw should they wish to do so. There were no benefits promised to the healthcare workers for participating in the study.

3.15 SUMMARY OF THE CHAPTER

In this chapter, the research methodology was discussed. The data collection process, data analysis and ethical consideration were explained. The research results and discussion are presented in the next chapter.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1. RESULTS AND DISCUSSION

4.1.1 INTRODUCTION

This chapter focuses on the presentation of findings. The study sought to achieve the following objectives:

- To evaluate the safe handling of vaccines in Primary Healthcare facilities in Buffalo City Metropolitan.
- To assess the storage of vaccines by healthcare workers in Primary Healthcare facilities of Buffalo City Metropolitan.
- To describe the management of vaccines by healthcare workers in Primary Healthcare facilities in Buffalo City Metropolitan.

In this chapter, the discussion of findings is done focusing on the objectives of this study as stipulated above. The discussion has been further be fitted against the available literature on compliance with healthcare standards for vaccines handling, storage and management.

4.2 DEMOGRAPHY OF RESPONDENTS

The sample was made of 64 healthcare workers and therefore, the study obtained 100% response rate. Due to covid- 19, 8 PHC facilities were closed, while healthcare workers were in quarantine as they had tested positive for covid-19. That is why only 64 healthcare workers were issued the questionnaire instead of 72 as initially planned to assess safe handling, storage, and management of vaccines in PHC facilities in BCM. From the sample, 47 (73.4%) were females, and 17 (26.6%) were males. In terms of age, 45 participants (70.3%) were aged between 26-49 years. The racial background of all the healthcare worker was black. All the healthcare workers were permanently employed. The distribution of the healthcare workers with respect to the rest of the demographic variables is shown below. Since all the healthcare workers were black and employed, the race and employment variables were

dropped from all onward analysis. In onward analysis, the one healthcare worker with high school education was combined into the group of diploma holders to have 47 (73.5%) diploma holders. With respect to marital status, the divorced healthcare worker was combined with the single category.

Table 4.2.1 bellow presents the distribution of healthcare workers according to gender, age group, race, educational level, employment status, marital status and work experience.

Table 4.2.1: Distribution of healthcare workers by demographic characteristics

Characteristic		Category	Frequency	Percent
Gender		Female	47	73.4
		Male	17	26.6
Age group	(18-25 Years)	1	9	14.1
	(26-49 Years)	2	45	70.3
	(50 -65 Years)	3	10	15.6
Race		Black	64	64
Educational level		Degree	17	26.6
		Diploma	46	71.9
		High School	1	1.6
Employment status		Permanent	63	98.4
		Student	1	1.6
Marital status		Divorced	1	1.6
		Married	28	43.8
		Single	35	54.7
Experience	(1-12 Months)	1	11	17.2
	(1-5 Years)	2	24	37.5
	(4-10 Years)	3	29	45.3

Figure 4.2.2: The distribution of healthcare workers based on age.

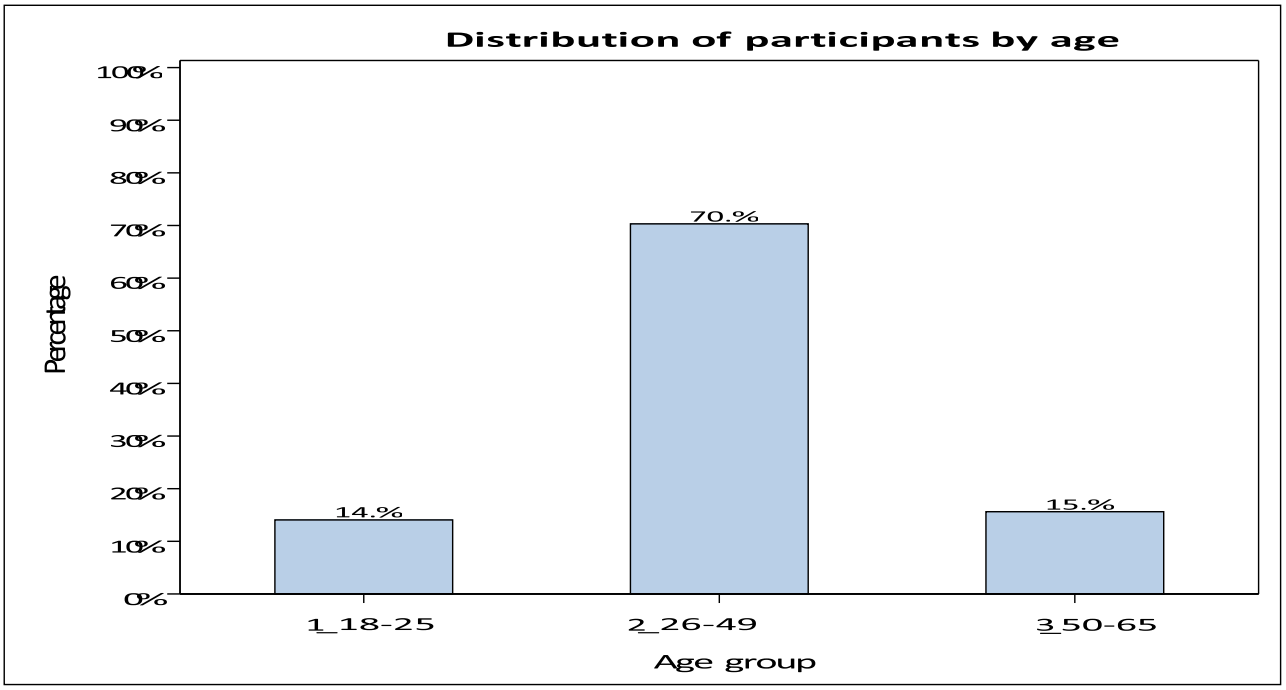


Figure 4.2.3 The distribution of healthcare workers based on level of education

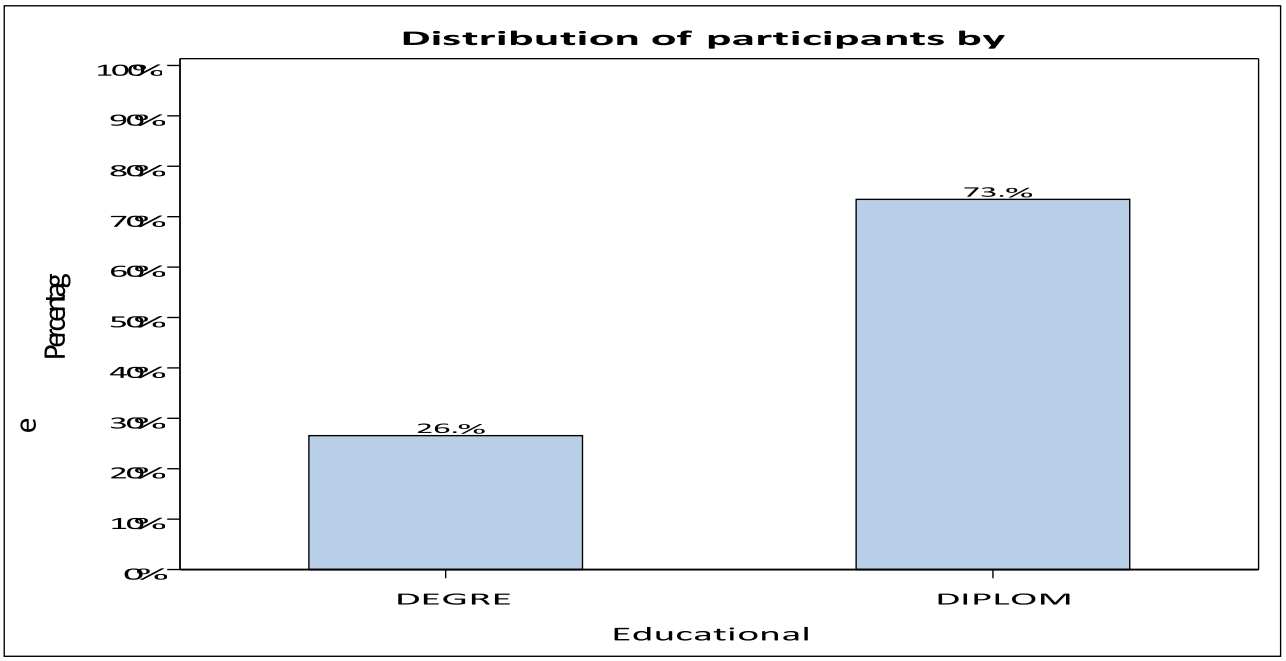


Figure 4.2.4 The distribution of healthcare workers based on marital status

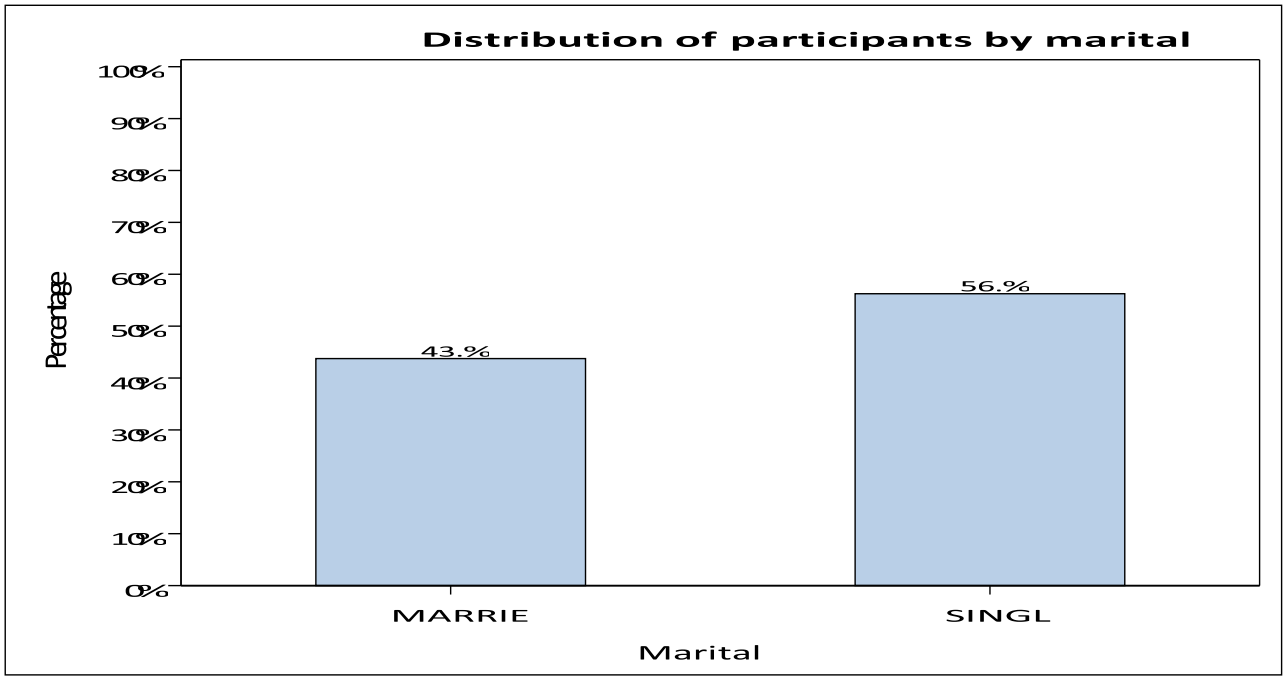
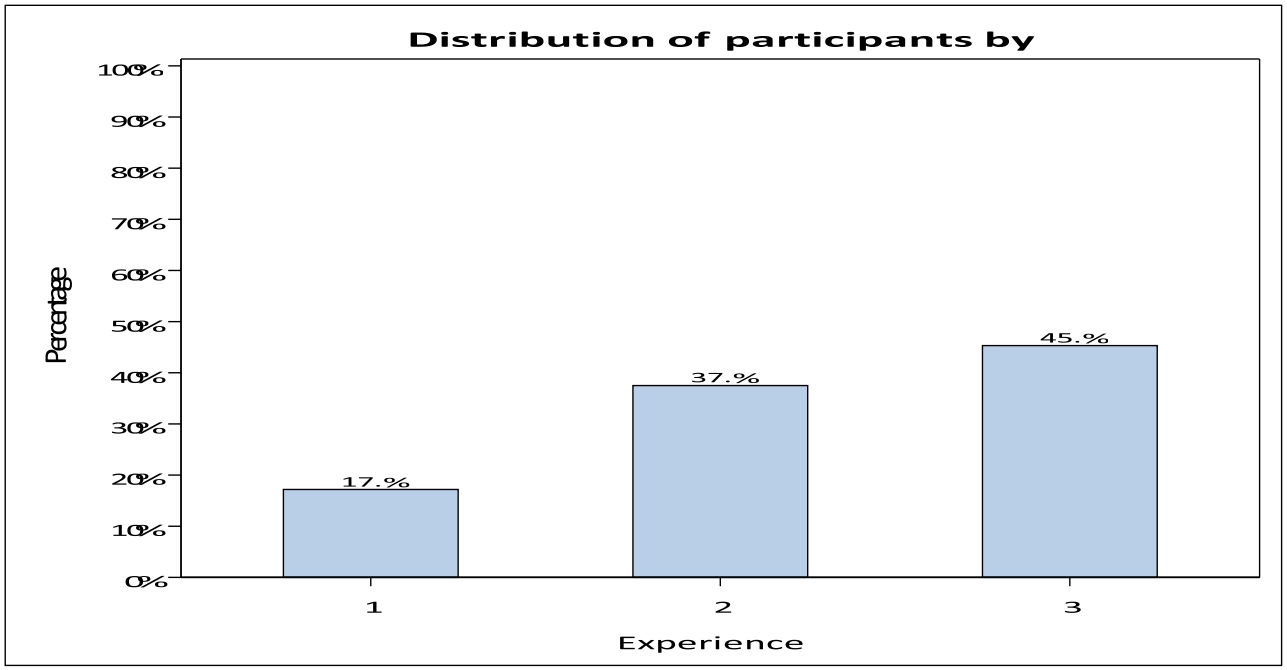


Figure 4.2.5 The distribution of healthcare workers based on work experience



4.2.1 DEMOGRAPHIC DISCUSSION

Immunization can be considered as the most precious gift that a healthcare worker can give to a child, and it remains the most cost-effective preventative health intervention presently known. Immunization can dramatically reduce morbidity and

mortality from many serious diseases. However, the vaccine requires that the cold-chain is monitored continuously to guarantee vaccine quality (Yokumetal., 2015:1-2). Vaccines are sensitive biological substances that gradually lose their potency with time. The loss of potency can be accelerated when stored out of the recommended range of temperature (Soleimani et al., 2021:2). Any loss of potency in a vaccine is permanent and irreversible. Consequently, proper storage of vaccines at the recommended temperature conditions is vital so that vaccine potency is retained up to the point of administration (Grasso et al., 2014:352).

This study indicated that healthcare workers with more than four years of work experience had a better knowledge on handling vaccines. Therefore, they were more likely to handle the expanded program on immunization. The healthcare workers were competent in rendering their services (immunization), having worked an average of seven years, amounting to an extensive work experience. Furthermore, their experience was directly in the area of immunization, and they were bound to develop self-competency awareness to a high level. It was further revealed that the healthcare workers that had the highest competency level in preparing and administering the vaccines, vaccine storage and use of the cold-chain system (Pregamol et al., 2018:208-218). All healthcare workers need to have adequate knowledge in the EPI to be able to maintain the potency of vaccines and their effectiveness.

Demographic results, 45 (70.3%) of the healthcare workers out of 64 between the age group of 26-49 years had less training and knowledge about the expanded immunization program. Perhaps, this is because they were only trained upon assumption of their duties on the EPI. However; there was no refresher course or training to update them about any new information with regards to EPI every year, or as changes occurred. Research provide evidence that both pre and in-service trainings are essential for the development of healthcare workers' competence in immunization data management, and analysis at all levels of the health system (Follett et al., 2018:49). Therefore, the health care workers should go for training and development with an opportunity to expand their knowledge and skills and to allow healthcare workers to strengthen their skills and reach to a higher level of competency.

The evidence shows that although pre-service training is fundamental, it does not adequately prepare the healthcare workers with the necessary skills and competencies to collect, analyse and use data (Nicol et al., 2019:1-14). Lack of training and knowledge about the EPI programme in healthcare workers is due to a number of reasons, which include the inadequacies of the training curriculum, this become irrespective to current needs of the changing trends in technology and also keeping the healthcare workers knowledge updated with new vaccine being introduced into the system, and new technology used to monitor vaccine temperature to ensure that vaccines are always within recommended temperature range. Continuous learning and development programmes will increase the knowledge of healthcare workers to ensure optimal and current skills are often missing despite their vitality (Nicole et al., 2019:1-14). Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Further training and refreshers are essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine (Centre for Disease Control and Prevention, 2021:21).

Correct practices were also influenced by gender and age. As seen from the demographics results, the majority of the healthcare worker were females (47 out of 64). Most facilities had only two healthcare workers who were responsible for the broad EPI. This would be considered as a strain, since some facilities had 25 to 60 patients to attend to daily. Sometimes only one healthcare worker would be on duty if the other one falls ill or is on leave. This present a serious staff shortage, hence affecting the effectiveness and quality of services rendered.

Evidence also showed that marital status had an influence with the safe handling, storage and management of vaccines in PHC facilities. From the demographic results, it is seen that there was 54.7% of single healthcare workers and 43.8% of married healthcare workers. Married healthcare workers more likely to stay in one place for longer due to family stability and job satisfaction and therefore this creates more knowledge and work experience for them.

4.3 VACCINE HANDLING, STORAGE AND MANAGEMENT

Vaccine handling, storage and management was assessed using twenty (20) questions, ten on storage, five on handling and five on management. Three variables, one for each section were derived from these questions as the sum of correct handling, storage and management practices. The distribution of responses to the individual items/questions are presented in frequency distribution tables and the three derived variables are summarised graphically using bar charts.

4.4 VACCINE HANDLING

The key research question was, how are vaccines handled in PHC facilities?
The results show that the majority of healthcare responded yes to all the questions, with every healthcare worker responding with yes on the issue of immediate vaccine storage upon receipt. In this section, all questions should have been answered in the affirmative (Yes), if vaccine handling was to be 100% in compliance. To the contrary, some healthcare workers responded in the negative on all four items with the highest negative (No) response being 20.3% for availability of a deputy to order and receive vaccine in the absence of the designated individual, followed by 18.7% for availability of a handling and storage policy.

Table 4.4.1 Table shows the distribution of healthcare workers responses on the vaccine handling.

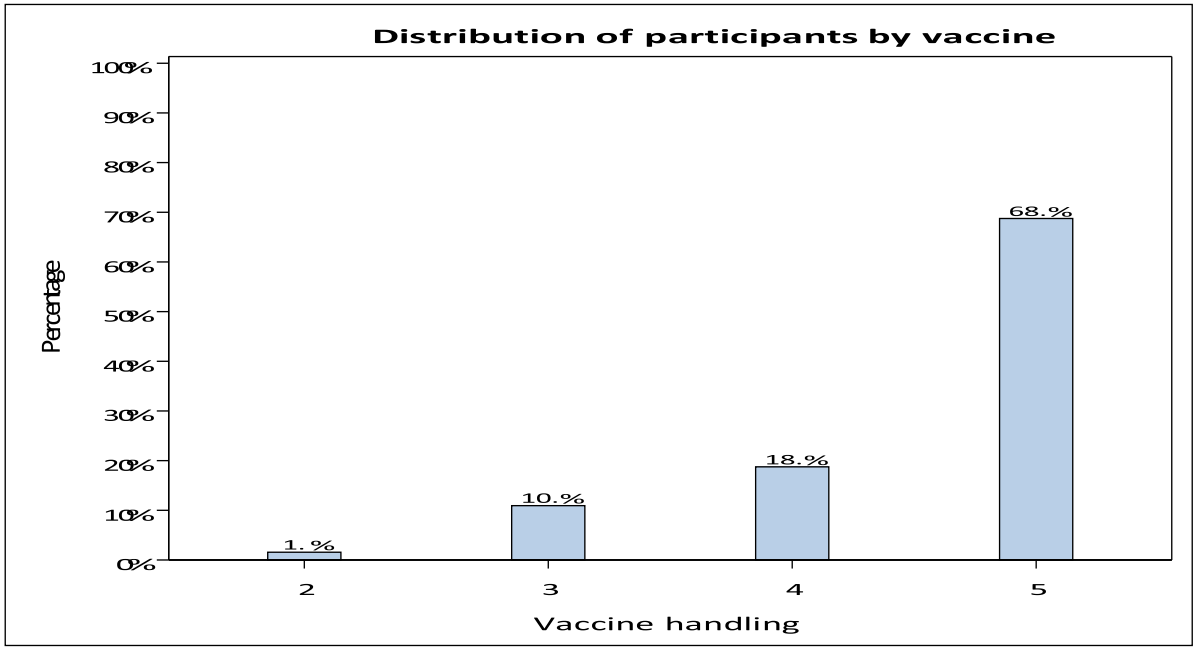
Table 4.4.1 Results for vaccine handling

Vaccine handling items	Yes	No
Designated vaccine ordering-receiving individual	61 (95.3)	3 (4.7)
Deputy to the designated order-receive duties	51 (79.7)	13 (20.3)
Availability of vaccine handling and storage policy	52 (81.3)	12 (18.7)
Immediate vaccine storage on receipt	64 (100.0)	0 (0.0)
Manufacturer details recording	63 (98.4)	1 (1.6)

A vaccine handling score variable was derived as the total of affirmative (Yes) responses to the five items/questions as shown in the table above. This variable had values from 0 (all negative) to 5 (all positive).

The bar chart below shows that the majority of the healthcare workers answered in affirmative (yes) in all the five questions (68.8%), followed by those who answered exactly one question in the negative (18.8%). The rest of the distribution is shown in the graph. The graph shows that none of the healthcare workers scored zero (0) or one (1).

Figure 4.4.2 Distribution of healthcare workers by vaccine handling



4.4.1 VACCINE HANDLING DISCUSSION

The safe handling of vaccine is very important to ensure the efficacy of the vaccine. Proper vaccine handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases (Centre for Disease Control and Prevention, 2021:43). Vaccination is one of the most effective public health interventions worldwide, in saving lives and improving health. For vaccines to be effective and provide maximum protection, they need to be handled in optimum conditions. If vaccines are handled inappropriately, their effectiveness may be compromised. Inappropriate handling of vaccine may result in inhibiting the intended

immune response, therefore providing poor protection against the diseases to the public (Manaja et al., 2018:1059). Proper vaccine handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases. Vaccine quality is affected by proper handling. Handling errors can result in revaccination of many people, hence causing a significant financial loss due to wasted vaccines. For an example: Spillage or leakage during reconstitution, loss of sterility due to touching of the rubber vial cap, inadequate shaking of the vaccine before use and incomplete aspiration of reconstitution vails. Previous research shows that failure to handle vaccines properly can reduce vaccine potency, resulting in inadequate immune response in patients and poor protection against diseases (Chiodin, 2014:45-46). Hence, vaccines need to be handled appropriately as recommended by the manufacturer and WHO.

The WHO recommends that each healthcare facility should have a designated healthcare worker, who is trained and educated on vaccine handling to avoid vaccine wastage (Bogale et al., 2019:1-6). These healthcare workers should be responsible for all the ordering and receiving of vaccines, organizing vaccines within the refrigerator, and there should be a vaccine coordinator in case the designated healthcare worker is on leave or falls sick. In the facilities visited during data collection, there was one healthcare worker responsible for all vaccine responsibilities. There was one deputy healthcare worker to carry the duties in case the assigned healthcare worker falls ill or is on leave.

In this study, safe vaccine handling was evaluated using five questions. The results showed that 44 healthcare workers (68.8%) out of the 64 healthcare workers answered all the questions in the affirmative (yes), proving that correct handling of vaccines were followed. On the other hand, 12 healthcare workers out of the 64 (18.8%) answered one question with a no indicating a room for improvement with vaccine education and work supervision. The negative responses were 13 healthcare workers (20.3%) for the availability of a deputy order-receiver individual and 12 healthcare workers (18.7%) for the availability of a handling and storage policy. These results showed that 44 (68.8%) of the healthcare workers knew the correct practices on how to handle vaccines. While 20 (31.25%) of the healthcare workers lacked knowledge in certain areas of vaccine handling, and this can be

resolved by introducing training and development of present employees to increase their knowledge and improve service delivery. Generally, it was evident that correct practices were followed in handling vaccines in the facilities. However, the new healthcare workers joining the field immediately after graduating from the university lacked adequate knowledge on vaccine handling. This was due to a lack of training and experience in the field.

On the other hand, it was evident that experienced healthcare workers had adequate knowledge and a better understanding of the correct practices in handling of vaccines. Therefore; training of newly appointed healthcare workers id vital and also a refresher training on an annual basis should be implemented to ensure that all healthcare workers are up to date with any new information with regards to the EPI programme.

4.5 VACCINE STORAGE

The key research question was, how are vaccines stored in PHC facilities? Vaccine storage was assessed based on ten items/questions. A perfect storage practice would be one in which all the items are answered in the affirmative, except the question on manual calibration of thermometers. The distribution in the table below shows that, indeed, the majority of the healthcare workers responded in the positive on the majority of items/questions, except for the thermometer calibration question. The highest negative responses were recorded for items/questions on exclusive use of fridge for vaccines storage (43.8%), daily before-after working day temperature recording (23.4%), and the fridge was medical/pharmaceutical (21.9%). The rest of the results are shown in the table below.

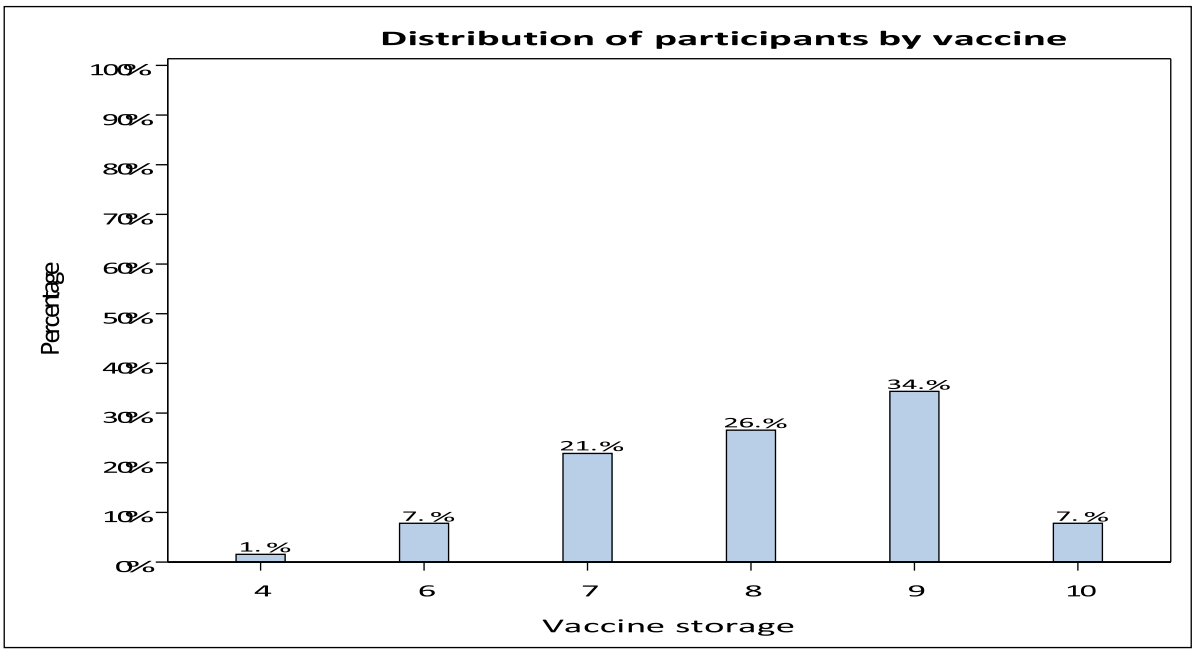
Table 4.5.1 Results for vaccine storage

Vaccine storage items	Yes	No
1. Medical/Pharmaceutical refrigerator use	50 (78.1)	14(21.9%)
2. Proper location of refrigerator within facility	62 (96.9%)	2 (3.1%)
3. Min/Max thermometer use	58 (90.6%)	6 (9.4%)

4. Manual calibration of thermometer	17 (26.6%)	47(73.4%)
5. Temperature recording at start and end of the day	49 (76.6%)	15(23.4%)
6. Alternative storage during refrigerator defrosting	63 (98.4%)	1 (1.6%)
7. Expiry date based on vaccine rotation	63 (98.4%)	1 (1.6%)
8. Refrigerator exclusively for vaccine storage	36 (56.2%)	28(43.8%)
9. Even vaccine distribution within refrigerator	58 (90.6%)	6 (9.4%)
10. Temperature requirements adherence	60 (93.8%)	4 (6.3%)

A vaccine storage score variable was derived as the total of correct responses to the ten items/questions on vaccine storage as listed in the table above. The distribution of the derived vaccine storage variable is shown in the bar chart below. This variables take values from 0 to 10. The bar chart shows that only 7.8% of participants correctly answered all ten questions. About a third (34.4%) of participants scored nine correct responses out of ten, followed by 26.6% who scored eight correctly, and then 21.9% who scored seven correctly. None of the healthcare workers scored less than four (4) correct responses out of ten (10) questions. The rest of the results is shown in the graph below.

Figure 4.5.2 Results for vaccine storage



4.5.1 VACCINE STORAGE DISCUSSION

Vaccine potency and shelf-life depend on correct storage temperature. The success against vaccine-preventable diseases is attributable to proper storage of vaccines (Karen et al., 2012:100). Vaccine exposed to the temperature outside the recommended ranges can have reduced potency and protection. Therefore, vaccines must be stored properly for a successful immunization program (Surjif et al., 2020:62-66). Immunization is an important means of controlling serious infectious diseases, and careful attention to vaccine storage is essential to ensure optimal vaccine effectiveness. Paying careful attention to vaccine storage is therefore necessary to avoid loss of vaccine potency (Grasso et al., 2014:352).

The BCM like many other municipalities rely on donated refrigerators, cold-chain boxes for storing and transporting vaccines from Non-Government Organizations. However, some of these refrigerators fail to meet the minimum norms and standards set by WHO for vaccines. Consequently, they negatively impact on the quality of vaccine handling and cold-chain reliability. For example, the refrigerators may fail to maintain the recommended temperature range of 2ºC-8ºC and the risk of vaccine freezing.

This study established that the healthcare facilities participating in the EPI program in BCM PHC facilities had functioning refrigerators. For instance, 39 facilities had domestic refrigerators, and 12 facilities had double door refrigerators, while 13 facilities had the gas-electric vaccine storage refrigerator. Some of the PHC facilities had new refrigerators that operated with both electricity and gas. This was a good intervention as it helped in times of power blackouts. Furthermore, the refrigerators had a temperature monitor on them that reflected outside. In such, they do not require a thermometer as the temperature is automatically displayed outside. If the temperature is out of the recommended temperature range of 2ºC-8ºC, an alarm goes off alerting healthcare workers that the temperatures are outside the recommended temperature range or the refrigerator has a fault.

All refrigerators used for vaccines should be WHO-approved (Bateman., 2016:318-319). Domestic refrigerators are not suitable for storing vaccines, as they are not

reliable and tend to have high maintenance costs (Hanson et al., 2017:2127-2133). The ideal refrigerator should have a precise temperature control digital temperature display, with an alarm system, which provides numerous audible or visual alarm function in the event of high or low temperatures. Two-layer glass door refrigerators are recommendable to eliminate the need to open the door to heck stock (World Health Organization, 2021:5).

The ideal refrigerator for vaccines is a two-layer glass door, with an inserted gas to avoid opening the door to check stock. It should have good quality steel wire shelves soaked with lacquer to provide convenient access to stored goods and easy cleaning. It should have an extra insulation around the door to reduce the loss of cold air, and provides energy-saving (Yakum et al., 2015:1-7). The other important aspects include interior lighting (fluorescent is best) to provide a clear view of stored items, automatic defrost function (more convenient) and forced air circulation system to deliver superior temperature uniformly (Minister of Health et al., 2018:15-16). Vaccine refrigerators have a digital temperature monitoring device to confirm that vaccine refrigerator temperature remains between 2°C to 8°C. This device has an alarm for out-of-range temperatures, a low battery indicator, digital display of the current, minimum, and maximum temperatures (Cavallaro et al., 2018:39-44).

When vaccines are not stored correctly, they lose their efficacy. The vaccine potency is affected when stored outside the correct temperature range, hence making it useless. If the vaccine is ineffective, it can lead to a host of issues, including the patient not being fully protected against the disease (Minister of Health et al., 2018:17). The study established that cold-chain equipment, temperature monitoring charts, thermometer, and ice packs were available in all the BCM Primary Healthcare facilities. This indicated full implementation of correct vaccine storage practices.

However, during data collection it was observed that some facilities did not regularly check both the refrigerator and room temperature twice a day as recommended. When the healthcare workers were asked about the reasons for not checking the temperatures as recommended, they complained about being under staffed and having more work load and this can be addressed by employing sufficient healthcare

workers who are qualified. The temperature charts had gaps on certain days, although all the healthcare workers answered that they check the temperature twice a day on the questionnaire. According to Minister of Health (2018), temperatures are supposed to be checked twice a day, that is, at the beginning and end of the day to confirm that vaccine refrigerator temperature remained between 2°C and 8°C.

The facilities had standard operating procedure file that provided information with regards to cold-chain. Furthermore, the SOP's explained how temperatures should be monitored to ensure that the recommended temperatures remain between 2°C and 8°C. The healthcare workers recorded minimum and maximum temperature after each check on the temperature chart. This is because temperature monitoring and recording is one of the most important factors to ensure that vaccine area stored correctly and remain in the best condition (Minister of Health et al., 2018:20).

The study also established in some facilities, there was no vaccine designated refrigerator, as food, water, and other medication were found in some refrigerators storing vaccines. Food and beverages should not be stored in a vaccine storage unit because frequent opening of the unit can lead to temperature instability (Centre for disease control and prevention, 2021:28). It was observed that the refrigerators were dirty. This was evident that cleaning and defrosting of the refrigerators was not done once a month, as recommended. It is vital to clean vaccine refrigerator as the dirt and dust can accumulate and affect the evaporator and condensing coil, causing the fan motors of the refrigerator to run at a minimum speed (Ezeanoloue et al., 2019:10-21). This can cause a drag to the fan blades, leading to air flow around the coil being restricted and affecting the temperature ranges of the refrigerator. The dragging of the fan blades can cause variations of the recommended temperatures for vaccine storage. The dust and dirt can cause a decay in the insulation, and the hinges of the door fridge may rust leading to the door of the refrigerator not closing properly (Alberta Health Services, 2016:2-4). In one facility, an expired vaccine was found. This would imply that there was no evenly distribution of vaccine, but overstocking, which did not allow enough airflow within the refrigerator to maintain the recommended temperature range.

In this study, the vaccine storage was assessed using ten questions. Perfect vaccine storage practices would be one where all ten questions are answered correctly with a yes answer. The results showed that 50 (78.6%) of the facilities had medical or pharmaceutical refrigerators that were designated for vaccine storage only. Purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze biologics, including vaccines are preferred. These units can be compact, under-the-counter style or large units. If a purpose-built or pharmaceutical-grade unit is not available, a stand-alone, household-grade unit may be an option in some practice settings. If a household-grade, and combination refrigerator/freezer unit must be used, only use the refrigerator compartment.

The freezer compartment of this type of unit is not recommended for storing vaccines and there may be areas of the refrigerated compartment that should not be used (Yakum et al., 2015:1-7). These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. If a facility stocks frozen vaccine, a separate freezer unit is necessary for storage. Notably, vaccines should never be stored in a dormitory-style or bar-style combined unit. These units often have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage (Ezeanoloue et al., 2019:22).

The study established that the refrigerators were well located within the facilities, in an area far from the window and direct sunlight. This was evidenced by 62 (96.7%) of the healthcare worker answering to the affirmative in the questionnaire. The results showed that 58 (90.6%), of the healthcare worker indicated that temperature thermometers were used and recorded on the temperature chart. This indicates the monitoring of temperature and maintaining the recommended temperature ranges. However, in the majority of the facilities 47 (73.4%), calibration of the thermometer was not done, even though it is important to calibrate a thermometer to minimize any measurement errors. Calibration is important to ensure accurate measurements, and accurate measurements are fundamental to the quality, safety, and innovation of most products and services we use and rely on every day (Fluke, 2021:3).

This study established that there were 15 (23.4%) of facilities that were non-compliant to the recording of temperatures at the start and end of the day. Temperature monitoring and recording is one of the most important factors when it comes to ensuring that vaccines are stored correctly and remain in the best condition. Regular temperature monitoring is vital to ensure proper cold-chain management. Recording the temperature twice a day provides evidence that the refrigerator is being monitored, and that regular readings are being taken, which helps to identify practice trend (Yokum et al., 2015:1-2).

To maintain a cold-chain during defrosting and cleaning of the refrigerator, it is important to have an alternative storage cooler box. Literature reveals that cold-chain must always be maintained during the process of cleaning the refrigerators used for vaccines. When cleaning the inside compartment of the refrigerators, vaccine must be removed from the inside of the refrigerator and stored in an appropriate cooled insulated cooler box or container. When cleaning the refrigerator, first it has to be defrosted, then wash all the inside surface and shelves with warm, slightly soapy water and dry with a clean soft cloth, and then plug in the refrigerator. The refrigerator temperature must reach and stabilize within the proper temperature ranges before restocking with vaccines. A minimum of cleaning the refrigerator is annual, but can be done more frequently as needed (Alberta Health Services, 2016:4).

The results of this study showed that 63 (98.4%) of the healthcare workers had alternative storage during defrosting to maintain the cold-chain of the vaccine. This served to be good practice for cold-chain maintenance and proved that proper practice is done. Out of the 64 facilities, only one facility had an expired vaccine.

This proved that even though proper practices were done in the 63 facilities as the FIFO (first in first out) and FEFO (first expiry first out) were followed, and vaccine rotation was done properly, there is still a room for improvement in stock rotation and supervision to obtain a 100% compliance. Correct packing of vaccines and diluent in the refrigerator is vital for vaccines to remain potent. The vaccines should be arranged in such a way as to facilitate air circulation and reading their identification as well as the expiry date. Hence, vaccines whose expiry date is closest should be used first (first to expire, first-out [FEFO] principle). Vaccines whose use-by date has

passed (expired) should not be preserved, but put aside for destruction (Department of Health, 2017:67). Vaccine stock should be rotated to ensure that older stock is placed at the front of the refrigerator so it can be used first. Vaccines must not be stored in the door of the refrigerator. The refrigerator should have a large enough capacity to store the vaccine supplied, and also there must be enough room to allow air to circulate within the vaccine packages (Chiodin, 2014:45-46).

The study also showed that 36 (56.2%) of facilities had a designated refrigerator for the vaccine, while 28 (43.8%) did not have a refrigerator for vaccines only. According to DOH RSA (2017) water bottles should be stored with salt to discourage drinking, they should be stored on the bottom shelf, in the vegetable drawers, and in the fridge door to help stabilize the temperature of the refrigerator. It is recommended to never store food in the vaccine refrigerator to avoid opening the refrigerator continuously as that may affect the temperatures ranges of the refrigerator. If there is no refrigerator available for other medicines, they should be stored completely separate from the vaccines and properly marked.

To maintain vaccine effectiveness, the vaccine must be stored properly at recommended temperature ranges (Eric et al., 2019:2). The effectiveness of vaccines is directly correlated to their proper storage from the time of manufacture to the time it is administered to a patient. Improper storage may result in unsafe vaccines with potential health risk (Grasso et al., 2014:352).. Therefore, it is important to allocate well trained and equipped healthcare workers on the EPI.

4.6 VACCINE MANAGEMENT

They key research question was, how are vaccines managed in PHC facilities? Vaccine management was assessed based on five items, namely, whether there was an individual designated for ordering, receiving and managing vaccines, if out-of-date stock is kept in the refrigerator, immediate reconstitution of freeze dried vaccines, reporting disruptions to cold chain, and monthly maintenance of refrigerator. All should have been answered in the positive (yes), except the issue on keeping out of date vaccines in the refrigerator. The majority of the healthcare

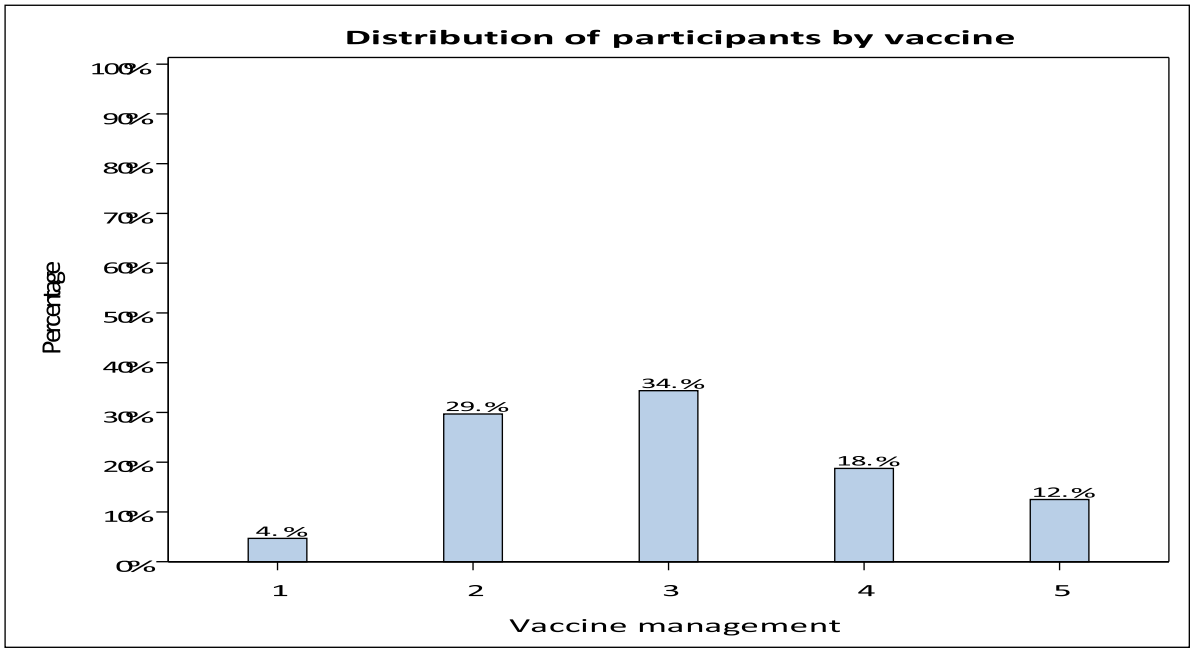
workers answered the questions correctly. On the issue of a designated individual, 58 (90.6%) of participant the presence of such an individual at their facility, 52 (81.2%) did not keep out of date vaccines in the refrigerator, 39 (60.9%) expressed that freeze-dried are immediately reconstituted, 42 (65.6%) reported cold chain disruptions appropriately, and 40 (62.5%) maintained their refrigerators on a monthly basis.

Table 4.6.1 Results for vaccine management

Vaccine management items	Yes	No
Designated responsible individual	58 (90.6)	6 (9.4)
Presence of out-of-date stock	12 (18.8)	52 (81.2)
Freeze-dried vaccines reconstitution	39 (60.9)	25 (39.1)
Reporting of disruptions to the cold chain	22 (34.4)	42 (65.6)
Refrigerator defrosting and cleaning	24 (37.5)	40 (62.5)

The vaccine management variable was derived as the total of responses consistent with proper vaccine management out of the five questions under the section for vaccine management in the questionnaire. The distribution of this variable is represented in the bar chart below. The bar chart below shows that 34.4% of the healthcare workers got three out of five answers correctly, 18.8% got 4 out of 5 and 12.5% responded correctly to all the questions with regards to proper vaccine management practices. The rest of the healthcare workers correctly answered less than three items correctly as reflected in the bar chart below.

Figure 4.6.2 Results for vaccine management



4.6.1 VACCINE MANAGEMENT DISCUSSION

Vaccine management is both managerial and operational functions that seek to ensure that adequate and high-quality vaccines are readily available for immunization service delivery (World Health Organization, 2021:9). Hence, any inadequacies of this critical function could lead to interruptions of vaccine supply. Adequate vaccine management and safety practices are required at all levels of the supply chain and at all times to achieve the goal of immunization program (Al-Abriet al., 2018:742-744).

For cold-chain management to be effective, three major elements are required. These include well-trained healthcare workers, reliable storage refrigerators, and efficient management procedures (World Health Organization, 2017:3). The absence of any of these would lead to a deficient cold-chain system. Healthcare workers play an important role in maintaining an undisrupted cold-chain, as they are the last point of contact between the vaccine and recipient. Hence, they must be trained and supervised regularly to ensure the efficient practice of cold-chain management (Josef, 2020:2). In addition to training and supportive supervision of the healthcare workers, logistics materials and tools for monitoring storage temperature should be available at healthcare facilities. These contribute to encouraging healthcare workers

to put into practice knowledge that has been acquired, hence, supporting effective and efficient immunization (Eric et al., 2019:1).

In this study, the vaccine management was assessed using five questions to describe the management of vaccine by healthcare workers. Hence, for a successful immunization program, cold-chain management needs to be practiced in all healthcare facilities that provide such services. For a successful cold-chain management in PHC facilities, all the five questions should be answered in the affirmative, which entails answering the questions with the answer (yes), to determine the healthcare worker's knowledge. The results showed that 58 (90.6%) of the participants answered positively with regards to their facilities having designated personnel responsible for vaccine management. This proved that proper management practices were being practiced. On the other hand, six (9.4%) of the facilities had no personnel responsible for vaccine management. This calls for improvement for the facilities to have a designated person for vaccine management and to educate the healthcare workers to improve their knowledge and practice on vaccines.

According to (WHO 2015) policies, the findings in this study are consistent with vaccine handling, storage, and management. Indeed, although the study was small, it highlights serious problems with vaccine handling, storage, and management that could jeopardize the success of the immunization program. In particular, 43 of the healthcare workers responsible for vaccine storage had poor knowledge about maintaining the cold-chain and were unaware of the recommendations of vaccine storage. The study further showed that 28 (43.8%) of the facilities had food in their vaccine refrigerators. This means that the refrigerators were opened frequently and that both the code of practice for storing vaccines and the food hygiene regulations were not complied with.

The potency and success of immunization rely on refrigerators, which should meet a maximum and minimum thermometer, storage temperature should be recorded twice daily, and storage of items other than vaccine should be minimized to avoid repeated opening of the refrigerator. The vaccines should be maintained under appropriate

conditions. Moreover, provision of adequate equipment and healthcare workers, staff training in maintaining the cold-chain, and equipment maintenance is necessary.

4.7 Association between vaccine handling, storage, management and biographical characteristics

The key research question was, is there any relationship between biographical characteristics of participants and vaccine handling, storage and management? The variables described above were used to derive new vaccine handling, storage and management variables. These were derived as binary variables with categories representing adequate (appropriate) and inadequate (inappropriate) handling, storage and management. In variable derivation, adequate handling was defined as all five items answered 'yes'. According to the results, this would culminate to adequate storage with at least 8 items were answered 'yes' out of the 10 items, and adequate management with at least 4 items out of the 5 items. The new binary variables were used in the onward analysis of associations with demographic characteristics.

The significance of the associations was assessed using odds ratios and the corresponding 95% confidence intervals. Odds ratios greater than 1 indicate positive associations while those less than 1 indicate negative associations. If the confidence limits of a confidence interval are both greater than one or both less than one, then the association is statistically significant. The tests for associations were carried out at a 5% level of significance, hence the use of 95% confidence intervals. The tables show cross tabulations of vaccine practices and each of the biographical variables, showing the frequencies and the percentages within the category of biographical variable.

4.7.1 Vaccine handling

The research question was, is there any association between vaccine handling and biographical characteristics?

Table 4.7.1 shows the results of association between vaccine handling and the biographical variables.

		Handling		95%CI of OR		
		Adequate	Inadequate		LCL	UCL
Gender	Female	34 (72.3)	13 (27.7)	1.8	0.58	5.83
	Male	10 (58.8)	7 (41.2)			
Age	Age1	2 (22.2)	7 (77.8)	0.03	0.002	0.430
	Age2	33 (73.3)	12 (26.7)	0.3	0.04	2.67
	Age3	9 (90.0)	1 (10.0)			
Education	Degree	10 (58.8)	7 (41.2)	0.5	0.17	1.74
	Diploma	34 (72.3)	13 (27.7)			
Marital status	Married	24 (85.7)	4 (14.3)	4.8	1.38	16.69
	Single	20 (55.6)	16 (44.4)			
Experience	Exp1	5 (45.5)	6 (54.5)	0.2	0.04	0.80
	Exp2	15 (62.5)	9 (37.5)	0.3	0.10	1.24
	Exp3	24 (82.8)	5 (17.2)			

The results show that vaccine handling practices were independent of gender and education. Note that the confidence intervals have a lower confidence limit (LCL) less than one and an upper confidence limit (UCL) greater than one. Age, marital status and experience were found to be significantly associated with vaccine handling practices. The results show that the youngest age group was significantly less likely to have adequate handling practices compared to the other age groups (OR=0.03 , 95%CI (0.002; 0.430)). Similarly, those with the least work experience were significantly less likely to have adequate vaccine handling practices compared to those with more work experience (OR=0.2, 95%CI (0.04 ; 0.80)). Married participants were significantly more likely to have adequate vaccine handling practices compared to the single participants (OR=4.8, 95%CI (1.38; 16)).

4.7.2 VACCINE STORAGE

The research question was, is there any association between vaccine storage and biographical characteristics?

Table 4.7.2 shows the results for association between vaccine storage and the biographical variables.

Table 4. Association between vaccine storage and demographic characteristics

		Vaccine storage		95%CI of OR		
		Adequate	Inadequate		LCL	UCL
Gender	Female	33 (70.2)	14 (29.8)	1.3	0.39	4.16
	Male	11 (64.7)	6 (35.3)			
Age	Age1	5 (55.6)	4 (44.4)	0.5	0.08	3.53
	Age2	32 (71.1)	13 (28.9)	1.1	0.24	4.72
	Age3	7 (70.0)	3 (30.0)			
Education	Degree	11 (64.7)	6 (35.3)	0.8	0.24	2.52
	Diploma	33 (70.2)	14 (29.8)			
Marital status	Married	18 (64.3)	10 (35.7)	0.7	0.24	2.00
	Single	26 (72.2)	10 (41.7)			
Experience	Exp1	8 (72.7)	3 (27.3)	0.8	0.18	4.10
	Exp2	14 (58.3)	10 (41.7)	0.4	0.14	1.44
	Exp3	22 (75.9)	7 (24.1)			

The results above show that vaccine storage is independent of all the biographical characteristics. Note that all the lower confidence limits are less than one and upper confidence limit are greater than one. This shows that there is no significant association between vaccine storage and biographical characteristics.

4.7.3 Vaccine management

The research question was, is there any association between vaccine management and biographical characteristics?

Table 4.7.3 shows the results for the association between vaccine management and the biographical variables and characteristics

		Vaccine management		95%CI of OR		
		Adequate	Inadequate		LCL	UCL
Gender	Female	11 (23.4)	36 (76.6)	0.3	0.08	0.87
	Male	9 (52.9)	8 (47.1)			
Age	Age1	3 (33.3)	6 (66.7)	2.0	0.25	15.99
	Age2	15 (33.3)	30 (66.7)	2.0	0.38	10.61
	Age3	2 (20.0)	8 (80.0)			
Education	Degree	4 (23.4)	13 (76.5)	0.6	0.16	2.13
	Diploma	16 (34.0)	31 (66.0)			
Marital status	Married	5 (17.9)	23 (82.1)	0.3	0.09	0.98
	Single	15 (41.7)	21 (58.3)			
Experience	Exp1	2 (18.2)	9 (81.8)	0.4	0.07	2.00
	Exp2	7 (29.2)	17 (70.8)	0.7	0.21	2.14
	Exp3	11 (37.9)	18 (62.1)			

As shown in the table above, it is only gender and marital status that were found to have significant associations with vaccine management. Females and the married were less likely to have adequate vaccine management practices compared to males (OR=0.3, 95%CI(0.08 ; 0.87)) and singles (OR=0.3 ; 95%CI(0.09; 0.98)).

Healthcare workers that had more than 5 years' work experience had better knowledge on vaccine management, and therefore, they were more likely able to

handle the vaccine management. The healthcare workers with an average of 7 years' work experience, their knowledge resulted to self-competency awareness to a high level of vaccine of vaccine management. The healthcare workers with degree qualification has more skills than the healthcare workers with diplomas. The age group of 26-49 years had less training and knowledge about EPI, due to the lack of training and development and this could negatively affect vaccine management in PHC facilities.

4.8 conclusion

In this chapter, the results and discussion of results were presented. The findings of this study indicate that there are important knowledge gaps for healthcare workers in handling, storage, and management of vaccines in BCM Primary Healthcare facilities. To maintain safe and effective EPI in BCM PHC facilities more efforts are needed in both education, training and supervision. In conclusion, the findings showed that safe handling, storage and management of vaccines practices at PHC facilities in BCM are not fully compliant. The poor operational management, lack of equipment, resources and staff shortage were some of the contributing factors to non-compliance.

The next chapter focuses on the limitations, major findings, recommendations and conclusion of the study.

CHAPTER FIVE

LIMITATIONS, MAJOR FINDINGS, RECOMMENDATIONS AND CONCLUSION

5.1 INTRODUCTION

In the previous chapter the researcher discussed the findings of the study, focusing on the objectives. The primary objective of the study was to assess the handling, storage, and management of vaccine at PHC facilities in BCM, South Africa. This chapter focuses on the limitations, recommendations, and conclusion of the study.

5.2 STUDY LIMITATION

The main limitation of this study is related to a methodological approach. This study was based on a quantitative research approach. This means that some qualitative aspects of handling, storing, and managing vaccines might have been left out. Quantitative method uses closed ended questions that require a yes or no answer. This limited the researcher from probing into more factors that could be contributing to compliance or non-compliance in handling, storage, and management of vaccines in the study area.

The findings only apply to Primary Healthcare facilities in Buffalo City Metropolitan. Nonetheless, these findings can be used to inform further or new research in other municipalities. Despite these limitations, useful conclusions can be drawn out of this study.

5.3 MAJOR FINDINGS

5.3.1 BASED ON RESEARCH QUESTION 1 (SAFE HANDLING OF VACCINES IN PHC FACILITIES IN BCM)

The study concludes that Primary Healthcare facilities in BCM was conditionally complaint to the vaccine's standards, as indicated by an overall percentage of 68.8%. The quality of the Expanded Immunization Program can be improved by proper handling, storage, and management of vaccines in PHC facilities. The

availability of vaccines storage equipment in PHC facilities in BCM is acceptable, as all the clinics had refrigerators that were operational. All the facilities had power source to maintain the cold chain of the vaccine within the recommended temperatures.

The study also concludes that the handling, storage, and management of vaccines was hindered by lack of adequate healthcare workers in the study area. This is because some of the facilities had no vaccine handling policies in place, and there was no designated healthcare worker for ordering and receiving vaccines. In addition, the designated healthcare workers did not receive any in-service training regarding vaccine handling. This implies that they were not up to date with new information with regards to vaccine handling.

5.3.2 BASED ON RESEARCH QUESTION 2 (VACCINE STORAGE AT PHC FACILITIES IN BCM)

The healthcare workers in Buffalo City Metro had moderate to satisfactory knowledge about vaccine storage. The healthcare workers knowledge about vaccine storage in PHC facilities in BCM could be considered as basic. This conclusion is based on the observation that some of the healthcare workers had no knowledge about temperature recording, and exclusive refrigerator for vaccine storage. The results showed that there was a gap regarding vaccine storage. This implies that healthcare workers need in-service trainings and supervision for vaccines to be stored properly. The availability of vaccine storage equipment was acceptable in the facilities in BCM. However, temperature monitoring and recording was unsatisfactory, as temperature charts were not recorded twice a day as recommended. The out of ranges temperatures were not reported and that may have a negative effect on the quality of the vaccine effectiveness. Since vaccines are very fragile biological agents, addressing the knowledge and practice gaps of vaccine handlers cannot be over emphasized.

5.3.3 BASED ON RESEARCH QUESTION 3 (VACCINE MANAGEMENT IN PHC FACILITIES IN BCM)

The study established that poor operational management is one of the major factors that contributed to vaccine non-compliance in the PHC facilities in BCM. The shortage of staff, lack of trainings, and lack of supervision were the other contributory factors. Without capable healthcare workers to properly manage cold-chain equipment according to the stipulated procedures, all cold-chain activities end in futility. With the results from this study showing a strong association between level of knowledge of vaccine management and vaccine management practices, there is need to constantly update knowledge of healthcare workers that handle vaccines through training and frequent monitoring. To address the challenge of prolonged power outages, gas-electric or solar powered refrigerators should be considered in Primary Healthcare facilities in BCM. This is important for effective temperature motoring, and maintenance.

5.4 RECOMMENDATIONS OF THE STUDY

The recommendations are made based on the literature, analysis, and discussion of this study. The recommendations made in this study are generally on addressing the contributory factors to non-compliance to vaccine handling, storage, and management.

5.4.1 RECOMMENDATION: VACCINE HANDLING

I. The newly appointed staff members must be provided with appropriate orientation that include preparation, incorporation, and ongoing support in their duties. Moreover, complete training for healthcare workers as part of annual refresher should be emphasized especially when new vaccines are added to the EPI program or when recommendations change.
II. The available performance management and development systems must be effective to manage and monitor the progress of individual staff members.
III. There should be a primary coordinator for vaccines handling, storage, and management. This healthcare worker should be responsible for ordering-receiving vaccines, and to ensure that all vaccines are stored, handled, and

managed properly. He/she should also be responsible for the review and update of all policies and standard operating procedures in the PHC facilities.

IV. An alternative coordinator should also be appointed, to assist the primary coordinator in fulfilling the duties in their absence.

5.4.2 RECOMMENDATION: VACCINE STORAGE

I. There should be proper refrigerators for the storage of vaccines only, to improve vaccine quality and efficiency. If there is no refrigerator available for other medicine, they should be stored separate from the vaccines and properly marked. The must be maintenance of correct temperatures within the refrigerator, which should be between 2°C to 8°C. The daily temperature logs should be checked twice a day and recorded properly. The PHC facilities should invest more on refrigerators designated only for vaccine storage, no

II. Food or cold drinks should be stored together with the vaccines.

5.4.3 RECOMMENDATION: VACCINE MANAGEMENT

I. The operational managers should pay attention and adhere to the policies of the Department of Health in handling, storage, and management of vaccines in PHC facilities. The operational managers should supervise and manage the provision, implementation, review protocols, policies, and procedures to ensure that they are in line with the current regulations and guidelines.

II. The operational mangers should develop internal protocols such as handling, storage and management policies, standard operating procedures, and review them regularly as required. The policies must be reviewed annually with all staff, including new and temporary staff, and when there is an amendment in Departments of Health, timely communication should be done.

III. Therefore, operational managers need to effectively communicate all the programs and policies of the department to senior and junior staff. The SOPS should be developed to outline how the said policy or program should be implemented to promote safe handling, storage, and management of vaccines in Primary Healthcare facilities in the study area.

IV. Training and development of present employees with an opportunity to expand their knowledge and skills. Furthermore, training and development programs allow employees to strengthen their skills and reach to a higher level of competency. A learning culture should be introduced by developing an annual training schedule that is in line with the departments' vaccine operational plan. All healthcare workers that are champion nurses should consider enrolling for continuous professional development programs to stay relevant and highly competent in their field.

5.5 CONCLUSION

The purpose of this study was to assess the safe handling, storage, and management of vaccines in Primary Healthcare facilities in Buffalo City Metropolitan, South Africa.

With all the research questions answered, the researcher concludes that the objectives of this study were met. Generally, the healthcare workers' knowledge and practices on vaccine handling, storage and management was not satisfactory. This gap would be attributed to factors such as lack of knowledge, insufficient training, under staffing, and supervision. Addressing these challenges can improve the cold chain, which can positively impact on the vaccine potency and efficacy.

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APPENDIX 1: LETTER OF PERMISSION FROM THE DEPARTMENT OF HEALTH

Province of the
EASTERN CAPE
HEALTH

Enquiries: Zonwabele Merile Tel no: 083 378 1202

Email: zonwabele.merile@echealth.gov.za Fax no: 043 642 1409

Date: 27 February 2020

RE: Safe handling, storage and management of vaccines at primary healthcare facilities in Buffalo City, Metropolitan, Eastern Cape, South Africa. (EC_202002_009)

Dear Mrs A. Hoho

The department would like to inform you that your application for the abovementioned research topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.

2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.

3. The Department of Health expects you to provide a progress update on your study every 3 months (from date you received this letter) in writing.

4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.

5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

TOGETHER, MOVING THE HEALTH SYSTEM FORWARD

APPENDIX 2: CERTIFICATE OF CLEARANCE FROM UNIVERSITY OF FORT HARE

FACULTY OF HEALTH SCIENCES
Research Ethics Committee
P.O Box 1054
East London 5200
Tel: +27 (0) 43 704 7368
E-mail: dgoon@ufh.ac.za

University of Fort Hare
Together in Excellence

ETHICAL CLEARANCE CERTIFICATE
REC-100118-054

Certificate Reference Number:	**Ref # 2020=01=004=HohoA**
Project title:	**Safe handling, storage and management of vaccines at primary healthcare facilities in Buffalo City Metropolitan, Eastern Cape, South Africa**
Nature of Project	Masters of Public Health
Principal Researcher:	Hoho A
Student Number:	201806973
Supervisors:	Dr N Mangi Prof E Seekoe

On behalf of the Health Sciences Research Ethics Committee (HREC), I hereby give ethical approval in respect of the undertakings contained in the above-mentioned project and research instruments(s). Should any other instruments be used, these require separate authorization. The Researcher may therefore commence with the research as from the date of this certificate, using the reference number indicated above.

Please note that the HREC must be informed immediately of

- Any material change in the conditions or undertakings mentioned in the document
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research

The Principal Researcher must report to the HREC in the prescribed format, where applicable, annually, and at the end of the project, in respect of ethical compliance.

APPENDIX 3: LETTER OF PERMISSION FROM BUFFALO CITY METRO HEALTH DISTRICT

Province of the
EASTERN CAPE
HEALTH

BUFFALO CITY METRO HEALTH DISTRICT
OFFICE OF THE DISTRICT MANAGER
18 Sheffield Road • Westbank •East London •5200, Eastern Cape
Private Bag X 9015 •Main Post Office, East London • 5200 • Eastern Cape
Tel.: +27 (0)43 708 1797 • Fax: +27 (0)43 708 1836/ 086 245 5023 • Website: www.ecdoh.gov.za
Enquiries: Ms Z Mntuvedwa

INTERNAL MEMORANDUM

To:	BCMHD Health Facilities: Sub-District Manager Clinic Supervisor CHC facility Managers
From:	District Manager
Subject:	Permission to conduct Research Study: Ms A. Z. Hoho
Date:	10 MARCH 2020

Purpose
The purpose of this memorandum is to inform relevant Buffalo City Health District staff and patients of permission granted on research study to be conducted by Ms Andiswa Zimkitha Hoho from the University of Fort Hare.

Background and Exposition of Facts
Ms A Hoho is currently studying towards a master's degree in Public Health with the University of Fort Hare. The title of her research study is **"Safe handling, storage and management of vaccines at primary healthcare facilities in Buffalo City Metropolitan, Eastern Cape, South Africa".**

She has requested for permission to do research at BCMHD Health Facilities. Ms Hoho has submitted all the required documents for a research study in the Eastern Cape Department of Health facilities and as such permission has been granted to her by the Research unit to conduct the study in terms of her research protocol and methodology.

APPENDIX 4: REQUEST FOR PERMISSION TO CONDUCT RESEARCH

University of Fort Hare
Together in Excellence

The Operational Manager

Buffalo City Metopolitan Pramary Health Care Facilities

Eatern Cape Department of Health

Dear Sir/Madam

Request for permision to conduct research study at Buffalo City Metopolitan Pramary Healthcare Facilities.

My name is Andiswa Zimkitha Hoho, and a masters student at the University of Fort Hare. This letter serves to request permision to conduct a research study at Buffalo city metropolitan Primary Healthcare facilities. The rserach is part of my requirements for the completion of my masters degree. The tittle of my research study is, ***Safe handling, storage and management of vaccines at Primary Healthcare facilities in Buffalo City Metropolitan, Eastern Cape, South Africa***.

The aim of this study is to examine safe handling, storage, and management of vaccines by health care workers in PHC facilities of BCM.

I wish to conduct a survey on healthcare professionals, who handle all the vaccines in the facility. The data will be collected using a self-administered questionnaire that will take approximately 20-30 minutes to complete.

Participation in this study is entirely voluntary, and participants can withdraw from participating at any time. The information gathered will be managed confidentially.

There are no direct benefits for the participants, but the recommendations developed from the study will be of benefit to the district and provincial health systems and possibly the entire department.

Copies of the questionnaire and a letter of permission from the ECDoH and BCM health district are attached in this letter. Upon completion of the study, I will provide you with a copy of the summary report.

If you require any further information, please do not hesitate to contact me on the following details. Cell number: 0613071336, e-mail address: azmazwembe@gmail.com.

Thank you for all your assistance in advance.

Yours faithfully,

AZ Mazwembe-Hoho

APPENDIX 5: CONSENT LETTER

University of Fort Hare
Together in Excellence

Letter of consent

INFORMED CONSENT

I hereby agree to participate in research regarding an investigation about **safe handling, storage and management of vaccines at selected primary healthcare facilities in buffalo city metropolitan, Eastern Cape, South Africa.** I understand that I am participating freely and without being forced in any way to do so. I also understand that I can stop this interview at any point should I not want to continue and that this decision will not in any way affect me negatively.

I understand that this is a research project whose purpose is not necessarily to benefit me personally.

I have received the telephone number of a person to contact should I need to speak about any issues which may arise in this interview.

I understand that this consent form will not be linked to the questionnaire, and that my answers will remain confidential.

I understand that if at all possible, feedback will be given to my community on the results of the completed research.

Signature of participant **Date**:……..

APPENDIX 6: RESEARCH INSTRUMENT (QUESTIONNAIRE)

Questionnaire for the nurses

This questionnaire was design to access the knowledge of nurses on handling, storage, and management of vaccines in Buffalo City Metropolitan Primary Healthcare facilities.

Section A – Demographic

Please put a √ (tick) next to the correct answer.

	Question			
1.	What is your gender?	Female	Male	Transgender
2.	How old are you?	18-25	26-49	50-65
3.	What is your race/ethnicity?	Black	White	Other
4.	What is the highest degree or level of school you have completed?	High school	diploma	Bachelor's degree
5.	What is your employment status?	Student	Part-time	Permanent
6.	What is your marital status?	Single	Married	Divorced
7.	How long have you been employed?	1-12 months	1-5years	4-10 years

Section B - Handling of Vaccines

Please answer YES or NO by putting a √ (tick) to the answer

	Question	Yes	No
1.	Is there a named individual who is responsible for ordering, receiving vaccines?		
2.	Is there a named deputy who is responsible for the above the named person absence?		
3.	Are the following available: Safe handling and storage of vaccine policy? Immunization against infectious disease (green book – access via the internet)		
4.	Are vaccines stored immediately on receipt (in the refrigerator)?		
5.	A record is kept of the manufactures name, batch number, and expiry date?		

Section B – Storage of vaccines

Please answer YES or NO by putting a √ (tick) to the answer

	Question	Yes	No
1.	Are vaccines stored in a medical/pharmaceutical refrigerator?		

2.	Is the refrigerator situated far from the heat source, and is there enough space for air to circulate freely around the back of the refrigerator?		
3.	Is the temperature of the refrigerator recorded by a minimum/ maximum thermometer?		
4.	Is the thermometer calibrated manually?		
5.	Is the following storage temperature (2ºC to 8ºC) monitored and recorded at both the beginning and the end of each working day?		
6.	Are vaccines kept in insulated box/bag (cooler box) or alternative refrigerator when the refrigerator is being defrosted?		
7.	Is the stock rotated according to the expiry date and first in and first out (FIFO)?		
8.	Is the refrigerator dedicated to vaccine storage?		
9.	Are vaccines evenly distributed within the refrigerator to allow air to circulate?		
10.	Are vaccines stored correctly, and according to their temperature requirement by manufacture (that is not in the door or touching the sides of the refrigerator)		

Section C – Vaccine Management

Please answer YES or NO by putting a √ (tick) to the answer

	Question	Yes	No
1.	Is there a named individual who is responsible for: Ordering vaccines Receiving vaccines Managing vaccines		
2.	Is there any out of date stock in the refrigerator?		
3.	Are freeze-dried vaccines reconstituted immediately prior to use and used within the manufacturer's recommended period?		
4.	Are all disruptions to the cold-chain reported in line with Trust policy?		
5.	Is the refrigerator checked, defrosted & cleaned on a monthly basis and are records kept?		

Adapted from NHS Foundation Trust (2015).

APPENDIX 7: CONFIRMATION CERTIFICATE OF STATISTICAL ANALYSIS

StatAnalysis Consulting
5 Boqwana Place, Lolo Park, Bhisho 5605
Tel: +27-40-635 0278
Cell: +27-78-966 6219

To whom it may concern

RE: Confirmation of provision of statistical analysis services

This serves to confirm that **_Andiswa Zimkhita Mazwembe-Hoho_** received the following services from us.

Job No:	200903
Job Statistician:	A. Mandeya (BScEd Maths, MSc Biostatistics, MPH)
Project:	Safe handling, storage and management of vaccines in primary healthcare facilities in Buffalo City Metropolitan Municipality in the Eastern Cape province.
Commencement data:	9th of September 2020
Job description:	Data cleaning and analysis as per client request.
Completion date:	1st of November 2020

In the event that you need further details of the services, feel free to contact the Job Statistician on the contact details provided above.

Regards

AMandeya

StatAnalysis Consulting
2021 -09- 20
Statisticians
Cell: 078966 6219, Tel:040 635 0278
Fax: 086 668 0494

APPENDIX 8: CONFIRMATION CERTIFICATE OF PROFESSIONAL LANGUAGE EDITOR

~ Your professional Research Partner~

30 March 2022

Certificate of Professional Language Edit

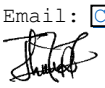
I hereby confirm that, the min-dissertation titled **'SAFE HANDLING, STORAGE, AND MANAGEMENT OF VACCINES AT SELECTED PRIMARY HEALTH CARE FACILITIES IN BUFFALO CITY METROPOLITAN, EASTERN CAPE PROVINCE'** by ANDISWA ZIMKITHA MAZWEMBE-HOHO (Reg. No. 201806973) has been edited and proof read by the editor (s) of ROMITO consulting. The editing was restricted to language usage, spelling, completeness, consistency, and logic flow of sentences. Suggestions to improve the document were also made.

However, the work described herein may not be identical to the final document has the author (s) has a sole prerogative to accept or reject the comments and changes suggested.

Disclaimer: The content and quality of the **dissertation** remains entirely to the author (s). The original copy of the edited document is available for verification at the author's written consent.

ROMITO CONSULTING

ROMITO Language & Writing Consultant
Dr RM Kajiita, PhD.
Email: Consultant@romito.info



Signature

ID: RMT/03/2022/AZM-H