

A Descriptive Study into the Cold Chain Management of Childhood Vaccines by Nurses in Primary Health Care Clinics in the uMgungundlovu District

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DECLARATION

This is to certify that the work is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously been submitted in any form to the Durban University of Technology or to any other institution for assessment or for any other purpose.

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DEDICATION

This study is dedicated to my mother, whose life has inspired me to live out my dreams. To my husband Alvin ,daughter Tesslyn, son Darren and his wife Ria, my nephew Denzil, family and friends for their constant support and encouragement in my studies. They were the sources of inspiration and motivation during this study.

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GOD BLESS YOU ALL!

ABSTRACT

INTRODUCTION

This research was a descriptive study into the cold chain management of childhood vaccines by nurses in Primary Health Care Clinics in the uMgungundlovu District. It is imperative for health professionals to follow the procedures and policies set out by the immunisation and health manuals by of the World Health Organization. The success of any childhood vaccination programme depends on how well nurses and health professionals are able to adhere to the laws, regulations and procedures. There is also a need for clinics and health institutions to be flexible enough to deal with certain constraints so that the vaccination programmes are not interrupted for extended periods of time but rather run efficiently and benefit the intended population. As a result pandemics are easily avoided and a healthy generation of children will bring about a better society.

METHODOLOGY

The study was carried out in two phases i.e. an observational study and a self-administered questionnaire. In the first phase, the observational study was carried out at 14 different clinics in the uMgungundlovu District. In the second phase, the cold chain management of vaccines by nurses was explored by means of a self-administered questionnaire.

RESULTS

The key findings of the observational study include that on most occasions policy was not being implemented. Furthermore there were no contingency plans to deal with equipment and electricity issues, no monitoring and evaluation systems, poor recording keeping, poor management of the cold box, access to stock and the actual management of the cold chain for vaccines.

The self-administered questionnaire was completed by 276 nurses via a simple random sample from the different clinics. The most salient aspects of the research in this phase of the study revealed that education and experience of the nurses are crucial to the sustainability of the childhood immunisation programme. Not surprisingly, some of the findings were similar to that of the observational study. Issues surrounding equipment and electricity, monitoring and evaluation systems, poor recording keeping, poor access to stock and ordering of stock were prevalent in this phase of the research as well.

CONCLUSION

Recommendations have been made for ongoing communication between the Department of Health, the District Office of Health and clinics so that the short and long term problems identified are solved.

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ACRONYMS

BCG - Bacillus Callmete Guerin
DPT - Diphtheria Pertussis Tetanus
EPI - Expanded Program on Immunisation
GIVS - Global Immunisation Vision and Strategy
GPHC - Government Primary Health Care
PHCF - Private Health Care Facilities
HIV - Human Immunodeficiency Virus
HBV - Hepatitis B Vaccine
MDG - Millennium Development Goal
MDT - Multi Dose Vial
OPV - Oral Polio Vaccine
PHC - Primary Health Care
UNICEF - United Nations Children's Fund
VMAT - Vaccine Management Assessment Tool
VVM - Vaccine Vial Monitoring
WHO - World Health Organization

GLOSSARY

ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI): AEFI are medical incidents that take place after an immunisation, causes concern and are believed to be caused by the immunisation (Expanded Programme on Immunisation in South Africa, the Vaccinators Manual, 2012).

THE COLD CHAIN MANAGEMENT SYSTEM: The cold chain is the system of transporting and storing vaccines within the safe temperature range of two degrees Celsius to eight degrees Celsius. The cold chain begins from the time the vaccine is manufactured, moves through to the distribution centres and ends when the vaccine is administered (National Vaccine Storage Guidelines Strive for five, 2005).

COMMUNITY HEALTH CENTRE: is a health centre where there is a 24 hour maternity service, a referral section with specialists and an outpatient department to service the local catchment area (Department of Health, 2001).

ENROLLED NURSE: A second level nurse who provides patient care under direction of the registered nurse (SANC, 2005).

MOBILE CLINIC: A mobile clinic is a specially outfitted truck which consists of examination rooms, laboratory services, and special medical tests to those in remote areas who have access to little or no medical facilities (The Mobile Health Clinic, 2009).

PRIMARY HEALTH CARE (PHC): PHC is:

Essential care based on practical, scientifically sound and socially acceptable methods and technology, made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part of both of the country's health system, of which it is the central function and

main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and the community with the national health system, bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care service. (Declaration of Alma-Ata International Conference on PHC, WHO, 1978).

REGISTERED/PROFESSIONAL NURSE: is a person who is qualified to practice comprehensive nursing independently and one who is capable of assuming responsibility and accountability for such practice (SANC, 2005).

RECONSTITUTION: The process of adding a diluent to a powdered vaccine to prepare a solution or suspension e.g. measles vaccine (Vaccine Storage and Handling Toolkit, 2012).

CHILDHOOD VACCINE: A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles disease causing micro-organism. The agents stimulates the body's immune system to recognise the micro-organism as foreign, destroys it and 'remembers it', so that the immune system can more easily recognise and destroy any of these micro-organisms that it encounters (National Vaccine Storage Guidelines Strive for 5, 2013).

CHAPTER 1: BACKGROUND TO THE STUDY

1.1 INTRODUCTION

The focus of this descriptive study was on the cold chain management of vaccines by nurses in local Primary Health Care (PHC) clinics in the uMgungundlovu District. The cold chain is the system of transporting and storing vaccines within the safe temperature range of two to eight degrees Celsius (National Vaccine Storage Guidelines Strive for 5, 2013: 2). The vaccine cold chain begins with the cold storage unit at the vaccine manufacturing plants and extends through the transport of vaccine to the distributor, then the delivery provider and ends with the administration of the vaccine to the patient (Vaccine Storage and Handling Toolkit, 2012: 9).

A vaccine must have two characteristics, one is safety and the other is potency. Vaccines lose their potency if they are not stored or transported at an appropriate temperature range. Once the potency is lost, it cannot be regained. The damaged vaccine must be destroyed. This leads to inadequate stock and wastage of expensive vaccines. Furthermore, children who receive vaccines that are not potent will not be protected from diseases (Handbook for Vaccine and Cold Chain Handlers, 2010: 7).

After reviewing the literature, it was discovered that there were a limited number of studies that focus on cold chain management of vaccines in the South Africa. As a result, this study aims to add to the existing body of knowledge on the cold chain management of vaccines from a South African perspective.

The research study was conducted in two phases. In the first phase, an observational study was conducted by the researcher using a structured observation guideline. Fourteen clinics were selected, using the interval sampling technique. At these clinics the researcher observed whether the cold chain for

vaccines was maintained according to National, Provincial and Operational guidelines. In the second phase, the cold chain management of vaccines by nurses was explored by means of a self-administered questionnaire.

The key findings of the observational study included that on most occasions policy was not being implemented. Furthermore there were no contingency plans to deal with equipment and electricity issues, no monitoring and evaluation systems, poor recording keeping, poor management of the cold box, access to stock and the actual administration of the vaccines.

In the second phase, self-administered questionnaire was completed by 276 nurses who were selected via a simple random sample from the different clinics. The most salient aspects of the research in this phase of the study revealed that the education and experience of the nurses are crucial to the sustainability of the childhood immunisation programme. Not surprisingly, some of the other findings were similar to that of the observational study, including issues surrounding equipment and electricity, monitoring and evaluation systems, poor record keeping, poor access to stock and ordering of stock were prevalent in the research as well.

The results of this study can be used to reinforce nurses' knowledge of the cold chain management of vaccines. Positive aspects of the study can be highlighted to nurses. The possible gaps that exist in their cold chain system and processes of cold chain management have been identified. Recommendations arising from this study will be presented to the PHC manager in the District Office of Health as well as the professional nurses in charge of clinics in order to carry out strategies for improvement of vaccine management. The results of this study can also assist in empowering nurses to obtain greater job satisfaction, knowing that they are knowledgeable and can be confident when consulting with mothers and children and providing the best possible care to them when they are visiting immunisation clinics.

Nurses must adhere to the five rights of vaccine handling and Storage (Rittle, 2008: 277). Clinics must ensure they have the right nurse in charge of vaccine

management, use the right procedures to maintain the cold chain, ensure the right vaccine storage unit is available, the right temperature monitoring tool is used and the vaccine is stored at the right temperature. If these five rights are adhered to vaccine efficiency will be maintained and disease will be prevented (Rittle, 2008: 277). Therefore it is imperative for health professionals to follow the procedures and policies set out by the immunisation and health manuals by the World Health Organization in order to ensure effective management of the cold chain for vaccine safety.

The introduction will set a background by providing an overview on Primary Health Care (PHC), the immunisation global strategy, the history of vaccines, the Expanded Programme on Immunisation (EPI) in South Africa (Expanded Programme on Immunisation, 2012) and the cold chain system for vaccines.

1.2 PROBLEM STATEMENT

According to the Vaccine Handling and Storage Toolkit (2012: 9) vaccines must be stored correctly from the time they are manufactured until the time they are administered to children. The exposure of vaccines to heat or cold can reduce the vaccines potency, thus increasing the risk of children not being protected against vaccine-preventable diseases (Vaccine Handling and Storage Toolkit, 2012: 9). 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 EPI activities without cold chain equipment resulting in a threat to the cold chain for vaccines (Ateudjiu *et al.*, 2008: 101).

When children are immunised 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 be a liability for providers' practices (Vaccine Handling and Storage Toolkit, 2012: 12).

Evidence from studies conducted in Australia (Carr, Byles, and Durrheim, 2009: 35), Matthias, (2007: 3980) in Mozambique (De Timoteo Mavimbe and Bjune, 2003: 21), in Indonesia (Nelson *et al.*, 2004: 99), in China (Ren *et al.*, 2009: 745), in Thailand (Techatawat, Varinsathein and Rasdjarmrearnsook, 2007: 1328) and in Papua New Guinea (Wirkas *et al.*, 2007: 691) indicate that good vaccine practices are lacking even in developed and still developing countries. Examples of these include inadequate temperature monitoring, unreliable equipment and use of incorrect fridges.

Limited research has been carried out in South Africa with regard to cold chain management of vaccines. Thus, this study assessed how cold chain for vaccines was maintained on receipt, storage and usage in PHC clinics in the uMgungundlovu District.

1.3 PURPOSE

The purpose of this study is to investigate the management of the cold chain of childhood vaccines by nurses in Primary Health Care (PHC) clinics in the uMgungundlovu District.

Studies into the cold chain management of vaccines in clinics and doctors' practices have been conducted in many countries e.g. India, China, New Zealand, Australia and Indonesia. However, there are a limited number of studies that address the cold chain management of childhood vaccines in a South African context. This presented the opportunity for a study into the cold chain management of childhood vaccines in PHC clinics in the uMgungundlovu District.

A study conducted in South Africa by Wiysonge *et al.*, (2012: 578) concludes that nurses face numerous challenges in the management of the cold chain of vaccines despite the many advances in immunisation in South Africa. According to Wiysonge *et al.*, some of these challenges include insufficient financial resources, a shortage of human resources and a lack of knowledge of nurses regarding vaccine management. These inefficiencies will lead to vaccines becoming compromised and losing their potency (Craig, 2008: 20). As a result, these

vaccines will not be beneficial to children. The WHO has created a set of practice guidelines for different service levels. These guidelines address immunisation techniques, vaccine monitoring, cold chain management and reporting systems, providing a framework that healthcare personnel can follow to ensure vaccines are delivered as intended. In order to address the aforementioned challenges, it is imperative that nurses maintain the cold chain for vaccines as guided by WHO, as these are an essential part of successful immunisation programs (Wiysonge *et al.*, 2012: 578).

A quantitative descriptive survey design was used for this study. To achieve this, a self-administered questionnaire was handed out to registered nurses in PHC clinics in the uMgungundlovu district. The study was also supported by observations using a structured observation guide. Data obtained from both the questionnaires and observations were analysed and used to draw appropriate conclusions.

In the uMgungundlovu district, there are 71 PHC clinics, in which 445 registered nurses are employed.

The study took place in two phases:

- **Phase one**: An observation study was conducted using a sample size of 14 nurses from the 69 PHC clinics.
- **Phase two**: A survey was conducted using a self-administered questionnaire. A random sample size of 276 nurses was selected to complete a self-administered questionnaire.

1.4 OBJECTIVES OF THE STUDY

The objectives of this study were:

- To compare current processes of the cold chain management of vaccines against best practice and in accordance with global, national and provincial guidelines;
- To investigate current processes of the cold chain management of vaccines by nurses in PHC clinics in the uMgungundlovu District; and

- To contribute to the current body of knowledge and recommend potential solutions to the problems encountered in the cold chain management of vaccines in PHC clinics.

1.5 SIGNIFICANCE OF THE STUDY

After reviewing the literature, as presented in Chapter 2, it was found that there are a limited number of studies that focus on cold chain management in the South African context. As a result, this study aims to add to the existing body of knowledge on the cold chain management of vaccines from a South African perspective. It is intended that the results of this study could be used to reinforce nurses' knowledge on the cold chain management of vaccines. Positive aspects of the study will be highlighted to nurses. The possible gaps that exist in their cold chain system and processes of cold chain management have been identified. Recommendations will be made to the PHC manager in the District Office of Health as well as the registered nurses in charge of clinics on strategies for improvement of vaccine management. The results of this study can also assist in empowering nurses to obtain greater job satisfaction, knowing that they are knowledgeable and can be confident in consulting with mothers and children and providing the best possible care to them when they visit PHC clinics.

1.6 STRUCTURE OF THE DISSERTATION

- Chapter 1: Introduction and background to the study.
- Chapter 2: Literature review.
- Chapter 3: Research methodology.
- Chapter 4: Presentation of results.
- Chapter 5: Discussion of results, conclusion, limitations, recommendations.

1.7 CONCLUSION

Effective cold chain management is vital to ensure that vaccines are administered in a potent state to their recipients, thus providing necessary protection against diseases. Due to limited research carried out on vaccine management in South Africa, the quality of vaccine management at clinics in South Africa is unknown, presenting an opportunity to investigate the management of the cold chain system in a South African context.

The following chapter discusses existing literature on the management of the cold chain system, in order to gain a broader view on the topic under investigation.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

The reviewing of literature is a key step in the research process. Literature reviews enable the researcher to gather information about current theoretical and scientific knowledge regarding particular phenomena under study and allows deductions to be made on what is known and what is unknown (Burns and Grove, 2007: 135). According Polit and Beck (2008: 757) a literature review is a critical summary of the research on a topic of interest, often prepared to put a research problem in context.

This chapter focuses on previous research studies conducted globally, in African countries and in South Africa and evaluates the available literature to give a wider perspective on the body's response to vaccines, the cost effectiveness and benefits of immunisation, the introduction of EPI in South Africa and how the cold chain for vaccines is maintained from the time of receipt in the facility until the time of administration to children.

2.2 PRIMARY HEALTH CARE (PHC) IN SOUTH AFRICA

Primary Health Care (PHC) was introduced in South Africa in April 1994 by the Department of Health to cater for the health needs of all South African citizens (Republic of South Africa, 2000: 3). It was during this time that the government implemented two important policies. The first was free health services to all pregnant women and children under six years of age and the second was universal access to PHC for all South African citizens. The introduction of PHC gave rise to a number of clinics and health care programs (Republic of South Africa, 2000: 3).

South Africa was one of the countries that attended the International Conference in Primary Health Care that was held in Alma-Ata Russia in 1978. At this conference, PHC was defined as:

Essential care based on practical, scientifically sound and socially acceptable methods and technology, made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part of both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and the community with the national health system, bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care service (Declaration of Alma-Ata International Conference on PHC, WHO, 1978).

According to section VII of the declaration of Alma-Ata, PHC includes:

1. Education about prevailing health problems and methods of preventing them.
2. Promotion of food supply and proper nutrition.
3. Adequate supply of safe water and basic sanitation.
4. Maternal and child health, including family planning.
5. Immunisation against major infectious diseases.
6. Prevention and control of locally endemic diseases.
7. Appropriate treatment of common diseases and injuries.
8. The provision of essential drugs.

(Declaration of Alma-Ata International Conference on PHC, WHO, 1978: 428).

The South African Government is committed to PHC component five above which is immunisation against major infectious diseases, by targeting childhood communicable diseases in order to reduce the burden of diseases among children under the age of six. In South Africa, immunisations are free at all PHC and mobile clinics (Republic of South Africa, 2000: 3).

EPI has added more vaccines to the schedule and expanded its access to more geographical areas (Hattingh, Dreyer and Roos, 2008: 157-161).

2.3 IMMUNISATION GLOBAL STRATEGY

Immunisation programmes are globally recognised as the most effective type of health intervention (Ngcobo, 2008: 9). Since the launch of the EPI in 1974, millions of deaths have been prevented every year by delivery of infant immunisation through national immunisation programmes (Cold Chain for Vaccines: WHO 1998). In 2005 the World Health Organization (WHO) and the United Nations children's Fund (UNICEF) endorsed the Global Immunisation Vision and Strategy (Wolfson *et al.*, 2008: 27). The primary objective of GIVS is to reduce vaccine-preventable disease mortality and morbidity by two-thirds by the year 2015. This is aligned with the achievement of Millennium Development Goal Four, which calls for a two thirds reduction of under-five mortality rate by the year 2015 (Wolfson *et al.*, 2008: 27).

The effectiveness of immunisation programs is related to the quality of the practice of those who implement them (Cold Chain for Vaccines WHO, 1998). To maintain vaccines perfectly from the time they are made to the time they are administered requires an adequate cold chain infrastructure, compliance to national guidelines, and effective management of cold chain (Cold Chain for Vaccines WHO, 1998). However, in most countries the delivery of potent vaccines and the practice of quality vaccine maintenance remains a challenge.

A study conducted by Wiysonge *et al.*, (2012: 578) in South Africa concludes that nurses face numerous challenges in the management of the cold chain of vaccines despite the many advances in immunisation in South Africa. Some of these challenges include insufficient financial resources, a shortage of human resources and a lack of knowledge of nurses regarding vaccine management. These inefficiencies will lead to vaccines becoming compromised and degraded. As a result these vaccines will no longer be potent and will not be beneficial to children. To overcome this challenge the cold chain for vaccine must be effectively managed (Cold Chain for Vaccines WHO, 1998).

2.4 THE HISTORY OF VACCINES

In the pre-vaccine era, epidemics were greatly feared as the majority of people died from diseases due to the fact that very little was known about diseases. In the 17th century it is estimated that smallpox caused 60 million deaths (Baker, 2010: 18).

Henderson, Barrio and Grabenstein (2008: 774-797) state that the vaccine era started in 1796 with Edward Jenner developing a vaccine against smallpox. The ultimate success of Edward Jenner's efforts was realised in 1979 when WHO certified that smallpox had been eradicated (Henderson *et al.*, 2008: 774-797).

According to Baker (2010: 18) new targets have been set by WHO to eradicate polio and measles. Furthermore, Hadler *et al.*, (2008: 1542) state that prior to 1974 vaccination programmes in developing countries were restricted to the urban elite and children of school-going age were the main target, in spite of the fact that younger children are often more vulnerable to the diseases. According to Baker (2010: 18) less than 5 percent of children under the age of one year were being vaccinated against six killer diseases namely, polio, diphtheria, tuberculosis, pertussis, measles and tetanus.

The EPI was introduced by WHO in 1974 with the aim of vaccinating all children below the age of one year against the six killer diseases (Baker, 2010: 18). South Africa is in fortunate position to be able to include many of these new options into the National EPI and adjust the EPI schedule according to the disease profile of the country (Baker, 2010: 18).

2.4.1 EXPANDED PROGRAMME OF IMMUNISATION IN SOUTH AFRICA

According to the National Department of Health, the main purpose of the EPI is to prevent deaths and reduce suffering from diseases that can be prevented by childhood immunisation. Immunisation against these diseases e.g. measles, polio, diphtheria, whooping cough, tetanus, hepatitis B, haemophilus, influenza type b, tuberculosis, pneumococcal diseases and diarrhoea caused by the rotavirus,

remains the most cost effective public health intervention currently available (EPI in South Africa, 2012: 11).

The EPI in South Africa (2012: 11) states that in line with GIVS, South Africa has taken a lead in the African region by introducing new vaccines in an effort to provide additional protection for children from some of the common causes of morbidity and mortality.

Several milestones have been reached in the history of the EPI schedule in South Africa. These include:

- 1995- Hepatitis B was introduced;
 - 1999- Haemophilus influenza type b (Hib) vaccine was introduced;
 - 2000- Converted from percutaneous to intradermal route of BCG vaccine
 - 2002- Neonatal tetanus was eliminated;
 - 1989 - South Africa was declared polio-free.
 - 2008- Conjugated pneumococcal and rotavirus was introduced;
 - 2009- Change from whole cell pertussis vaccine to acellular pertussis vaccine, which has a better side effect profile;
- Oral live polio vaccine replaced by inactivated polio, which does not have the risk of vaccine-associated paralytic polio; and
- The addition of the Hib booster at eighteen months.

(Baker, 2010: 18).

South Africa is in the fortunate position to of being able to include many of these new options into the National EPI and adjust the EPI schedule according to the disease profile of the country (Baker, 2010: 18).

The EPI is an essential part of a comprehensive PHC package for South Africa which lays down norms and standards for EPI activities to be performed in local clinics (EPI in South Africa, 2012: 11). The PHC Package for South Africa (Department of Health, 2000) includes the following norms and standards on immunisation and vaccines:

Norms:

- All clinics must provide immunisations five days a week.
- The District Communicable Disease Control Co-ordinator must visit clinics three monthly to review EPI coverage, vaccine supply and cold chain management for vaccines. The co-ordinator must help to solve problems, provide necessary information on EPI activities.
- Every clinic should have a senior staff member trained in EPI and who can act as a focal point for EPI programmes.

Standards:

- References, prints and educational materials:
 - Copies of latest EPI SA vaccinators manual;
 - Cold chain and immunisation operational manual;
 - Guidelines on immunisation in South Africa;
 - Current circulars on EPI;
 - Patient information pamphlets and posters.
- Equipment:
 - Correct needles and syringes;
 - A working refrigerator, properly packed, with a thermometer and temperature recordings.
- Medicines and Supplies:
 - An uninterrupted and monitored cold chain for vaccines.
- Competent staff:
 - To conduct EPI activities and management of cold chain for vaccines.

The South African government has shown commitment in ensuring children living in South Africa are protected from vaccine preventable diseases to uphold the constitutional rights of the child to an environment that is free of infections (Ngcobo 2008: 10).

2.4.2 THE COLD CHAIN SYSTEM

Vaccines are sensitive biological substances that with time lose their potency, especially when exposed to heat, sunlight and cold (Safe Vaccine Handling, Cold Chain and Immunisation WHO, 1998). Once a vaccine's potency has been lost, it

cannot be restored and these vaccines will no longer provide protection against the target disease (Mugharbel and Wakeel, 2009: 86).

In light of this, the cold chain system provides an effective means for storing and transporting vaccines in a potent state, from the manufacturer to the person being immunised (Guidelines for Vaccine Storage and Distribution: New Zealand, 2012: 7).

The common elements of all cold chain systems are a series of storage and transport links through a network of fridges, freezers and cooler boxes that keep vaccines at an optimum temperature, which is two to eight degrees Celsius (Safe Vaccines Handling, Cold Chain and Immunisation WHO1998; Guidelines for Vaccine Storage and Distribution: New Zealand 2012, Vaccine Storage and Handling Guidelines Milvax 2012; The Cold Chain, WHO 1988).

In the health facility, there are a number of ways of checking that the temperature in the vaccine fridge remains within a safe range. These include

- A working dial thermometer hanging vertically in the middle of the vaccine fridge or,
- A fridge tag could also be placed in the middle shelf of the fridge to monitor the temperature of vaccines.

The temperature should be read and recorded twice a day on a temperature chart. If the temperature stays outside the safe temperature range or if the fridge tag alarms, then immediate action is necessary (EPI in South Africa, 2012: 56).

According to the Guidelines for Vaccine Storage and Distribution New Zealand, (2012: 7) freezing and subjecting vaccines to heat are the most common reasons for vaccine damage and ultimately, wastage. According to these guidelines, the following vaccines are freeze-sensitive:

- Diphtheria;
- Tetanus and cellular pertussis;
- Hepatitis B;
- Haemophilus influenza type B;

- Inactivated polio (IPV);
- Meningococcal;
- Pneumococcal;
- Human Papillomavirus;
- Rotavirus; and
- Vaccine Diluents.

The most heat-sensitive vaccines are:

- Measles Mumps Rubella;
- IPV;
- Bacille Calmette Guerin (BCG); and
- Chicken pox.

From the above, it is evident that vaccines can be damaged through both heat and cold. This emphasises the importance of the cold chain system within an immunisation programme as it ensures that vaccines are maintained at the correct temperatures and thus, guarantees the effectiveness of vaccines in such programmes.

According to the study conducted by Carr, Byles, and Durrheim (2009: 34), in order to ensure the success of immunisation programmes, it is imperative that nurses ensure the maintenance of vaccines in their original state, through the cold chain system.

Many global studies, such as those conducted in Vietnam by Hipgrave *et al.*, (2006), in China by Wang *et al.*, (2007), and in Indonesia by Nelson *et al.*, (2004), have found that attention to maintenance of correct temperatures during storage and use of vaccines is a challenge for staff. According to these studies challenges that staff face were due to non-competent personnel managing the vaccines, equipment used for vaccine management not being effective and procedures not being efficient.

Evidence from studies conducted in Australia by Carr, Byles and Durrheim (2009: 35) and Matthias *et al.*, (2007: 3980), in Mozambique by De Timoteo Mavimbe and

Bjune (2003: 21), in Indonesia by Nelson *et al.*, (2004: 99), in China by Ren *et al.*, (2009: 745), in Thailand by Techatawat, Varinsathein and Rasdjarmrearnsook (2007: 1328) and in Papua New Guinea by Wirkas *et al.*, (2007: 691) indicate that good vaccine practices are lacking even in developed countries. Examples from these studies include use of incorrect and faulty refrigerators, vaccines being subjected to extreme cold and heat during transportation and storage in the refrigerator, lack of knowledge amongst nursing staff who manage vaccines and failure to follow policy, guidelines and procedure regarding cold chain management.

According to the Cold Chain Manual (WHO 1998: 10) an effective cold chain system comprises of three major elements:

- Personnel, who use and maintain the equipment and provide the health service;
- Equipment for safe storage and transportation of vaccines; and
- Procedures to manage the programme and control the distribution and the use of vaccines.

Craig, (2008: 19) states that there are several important reasons to maintain the cold chain. These include:

- Vaccines are biological products that lose their potency over time and this will result in reduced immune responses and inadequate protection against disease;
- Immunisers have a professional responsibility to ensure that vaccines are potent, safe and effective when children are being immunised in order to ensure high levels of disease control and public confidence in vaccine programmes; and
- Vaccines are expensive and immunisers have a responsibility to not waste this scarce resource.

Therefore, competent personnel, effective equipment and efficient procedures are vital parts of the cold chain system.

Potency of vaccines should be maintained in order to obtain full benefit of immunisation programmes. The safety of the vaccine is linked to the adverse events following immunisation (AEFI) programme (Craig, 2008:19). Therefore nurses must ensure every effort is made to retain the safety of vaccines.

2.3 THE BODY'S RESPONSE TO VACCINES

Immunisation is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease (EPI South Africa, 2012).

Once a vaccine is administered to a person for a specific disease, the body responds to the vaccine by developing antibodies to that disease e.g. diphtheria. In so doing, the vaccine provides protection from the disease (Levine *et al.*, 1998). According to the medical dictionary an antibody is a type of protein made up of white blood cells in response to a foreign substance; each antibody can bind only to a specific antigen in order to destroy it.

Infection occurring after immunisation may be due to primary or secondary vaccine failure. Primary vaccine failure is due to the lack of seroconversion following immunisation (Mast *et al.*, 1990: 2433-2529). Secondary vaccine failure is described as an initial protective response that wanes over time (Mast *et al.*, 1990). Primary and secondary vaccine failure results in the vaccine becoming ineffective thus, not providing lifelong immunity (Mast *et al.*, 1990). Mast *et al.* (1990) further state that vaccine failure occurs due to improper storage of vaccines, thus highlighting the importance of effectively managing vaccines.

The success of immunisation depends on vaccine effectiveness which is impacted by the storage of vaccines and how they administered (Levine *et al.*, 1998).

2.4 THE COSTS AND BENEFITS OF IMMUNISATION

Vaccine preventable diseases result in significant costs to individuals, the health care system and society. These include saving costs related to: repeated visits to health care providers, hospitalization, premature deaths, loss of time from work for parents to care for sick children and sick children lose time from school (Canadian Immunisation Guide, 2013: 6). Therefore immunisation against vaccine preventable diseases e.g. measles, and tetanus is a good investment and is offered free of charge at local clinics (Republic of South Africa, 2000: 3).

Brenzel *et al.*, (2006: 408) conducted a study that analysed the cost, the scaling up of the EPI and the introduction of new vaccines into the programmes. The study also focussed on the epidemiology of diseases preventable through immunisation and estimates the disease burden with and without immunisation. During this study the authors reviewed 102 estimates of total immunisation programme costs of 27 countries. They concluded that immunisation with the EPI vaccines is a highly cost effective public health intervention (Brenzel *et al.*, 2006: 408). They further state that immunisation has a significant effect on reducing mortality and morbidity from childhood diseases (Brenzel *et al.*, 2006: 408).

South Africa is committed to ensuring that children receive effective vaccines and high vaccine coverage levels. Recently South Africa included pneumococcal conjugate vaccine and the rotavirus vaccine into the schedule (Barnighausen *et al.*, 2010: 842). The authors also state that not only will these vaccines reduce death and disease but will also lead to productivity gains, contributing to South Africa's economic development and also benefit unvaccinated children.

2.5 THE VACCINE MANAGEMENT ASSESSMENT TOOL

According to WHO (2005:79) the purpose of the Vaccine Management Assessment Tool (VMST) is to investigate the knowledge and practice of vaccine management by health staff at levels of the cold chain. The tool comprises 11 key indicators which are scored zero for a response of "No" and one for a response of "Yes" or "Not applicable" which are scored zero. The sum of these scores is normalised to give an overall score for each criterion on a scale of zero to five. The 11 indicators are:

- Vaccine arrival procedures;
- Vaccine storage temperatures;
- Cold storage capacity;
- Buildings, cold chain equipment and transport;
- Maintenance of cold chain equipment and transport;
- Stock management;
- Effective vaccine delivery;
- Correct diluents use for freeze-dried vaccines;
- Effective use of Vaccine Vial Monitors(VVM);
- Multi-dose vial policy; and
- Vaccine waste control.

The scores are then used to graphically demonstrate the strengths and weaknesses of a country's cold chain management for vaccines and to stimulate necessary changes wherever needed. Support and training can then be provided to the identified areas to overcome these deficiencies (VMAT WHO, 2005: 79).

The Vaccine Storage and Handling Guidelines Ontario (2012: 3) and Vaccine Storage and Handling Guidelines (2011: 5) emphasise the importance of at least annual inspection of facilities by Public Health Units. This is to ensure proper management of vaccine inventories, reduce vaccine wastage, provide education strategies to minimise vaccine wastage and ensure vaccine safety and effectiveness (The Vaccine Storage and Handling Guidelines Ontario, 2012: 4).

2.6 ADHERENCE TO NATIONAL POLICY AND GUIDELINES ON VACCINE MANAGEMENT

According to the National Guidelines for Vaccine Storage and Distribution – New Zealand (2012: 15) and the Vaccine Storage and Handling Toolkit (2012: 7) immunisation programs and practices must have written protocols for routine storage and handling and emergency procedures for the cold chain management of vaccines.

The Vaccine Storage and Handling Guide (2011: 5) states that staff should be knowledgeable regarding vaccine storage and handling. There should be at least two staff members who are responsible for vaccine management.

In the study conducted by Bankole *et al.*, (2010: 78) in Nigeria the authors visited 1000 privately owned health facilities. During the first visits they interviewed the health care workers on cold chain for vaccines activities e.g. storage of vaccines, reading the vaccine vial monitor and vaccine monitoring. They found knowledge amongst health care workers was poor. On-the-spot training according to WHO guidelines was given to staff on vaccine management. A vaccine audit was also conducted. During the audit they found that 90 percent of the 900 fridges were faulty and were being shared with laboratory reagents and drugs. The fridge temperatures were not monitored, no recordings were done and fridges were without electricity. They revisited these health facilities in 2009 and found great improvement in the cold chain management and knowledge of staff was noted. In 92 percent of the facilities it was noted that the cold chain for vaccine fridges was greatly improved. This study concluded that in order to maintain vaccines perfectly conserved from manufacturer to administration an adequate cold chain infrastructure, compliance to standards and effective management are required. Similar studies were conducted by Carr, Byles, and Durrheim (2009: 36), Mathias *et al.*, (2007: 3980) and Samyant, *et al.*, (2007) prove adherence to these guidelines are often lacking therefore resulting in vaccines losing their potency.

Carr, Byles, and Durrheim (2009: 36) conducted a study in New South Wales (Australia) to assess the vaccine cold chain integrity in general practices. During this study, 256 general practice nurses participated by filling in a questionnaire on vaccine management and an audit was conducted on vaccine refrigerators in the Hunter region. Analysis of the data obtained revealed that in 98 percent of general practices where the practice nurse was authorised to immunise, acceptable vaccine cold chain management practices were significantly more likely. This was not evident in 83 percent of general practices where the practice nurse was not authorised to immunise. The study further revealed that 19 percent of general practices did not maintain a fridge temperature range of two to eight degrees

Celsius and 42 percent of these practices used bar fridges where temperatures fluctuated between too high and too low (Carr, Byles, and Durrheim, 2009: 37).

Thakker and Woods (1992: 756) conducted a study in the United Kingdom on the storage of vaccines in five health clinics and 45 general practices. Questionnaires were handed out to nurses in the clinics. The refrigerator temperatures were monitored in eight practices for a period of two weeks. The results of the study revealed that in six of the eight practices selected for monitoring of the refrigerator temperature, the vaccines were either exposed to subzero temperatures or temperatures as high as 16 degrees Celsius. Furthermore, there was no evidence of bi-daily refrigerator temperature recordings and no written procedures or policies to indicate the action to be taken when vaccines were compromised. In this study a total of 40 staff responded to the questionnaire and only 16 of the staff were aware of the National Storage Guidelines for vaccines. The study also revealed a lack of knowledge on vaccine management which ultimately leads to vaccines being exposed to a wide range of adverse temperatures. Thakker and Woods (1992: 756) expressed the need for staff responsible for vaccine management to be trained in order to adhere to National Guidelines and standard operating procedures on vaccine management. Although this study was conducted in 1992, similar weaknesses are still observed in the cold chain management of vaccines today, due to lack of adherence to guidelines and policy. This can be identified in recent studies discussed below.

2.7 THE STORAGE AND HANDLING OF VACCINES

According to the Cold Chain Module (WHO 1998: 8), the cold chain system is a means for storing and transporting vaccines in a potent state, from the manufacturer to the person being immunised. The cold chain system comprises of three major elements:

- personnel, who use and maintain the equipment and provide the health service;
- equipment, for the safe storage and transportation of vaccines; and
- procedures, to manage and control the distribution and use of vaccines.

One of the very first studies conducted on cold chain management of vaccines was in Ohio by Lerman and Gold (1971). In this study the researchers questioned whether the storage of vaccines had any link to the outbreak of measles in previously immunised children in Ohio. The study revealed that 14 of the children immunised with the measles vaccine by a particular physician, had presented with an attack of measles. Upon further investigation it was discovered that the measles vaccine in the physician's practice was stored in the refrigerator door. Variations in refrigerator temperature occurred due to the opening and closing of the door. The vaccines were subjected to temperatures of between zero to eighteen degrees Celsius. These findings suggested that vaccines were not maintained at the proper temperature throughout the cold chain and subsequently lost their potency, possibly resulting in measles outbreak.

A study carried-out in eight health districts in Cameroon by Ateudjieu *et al.*, (2008: 101) revealed that the targeted health districts were not compliant with the standard operating procedures. Almost 25 percent of health facilities were conducting EPI activities without cold chain equipment resulting in a threat to the cold chain for vaccines.

2.8 VACCINE STORAGE EQUIPMENT

At the local clinics vaccines are stored in a refrigerator dedicated for storage of vaccines only. During the immunisation session vaccines required for the day are stored in the cold box. The cold box is lined with ice packs. A thermometer is used in the refrigerator and the cold box to monitor the temperature. A temperature of two to eight degrees Celsius must be maintained in the refrigerator and the cold box to ensure vaccine potency (Vaccine Storage and Handling Toolkit, 2012: 9).

2.7.1 REFRIGERATOR, COLD BOXES AND THERMOMETERS

The Vaccine Storage and Handling Toolkit (2012: 27) recommend stand-alone refrigerators or freezers and purpose built refrigerators for storing of vaccines. The bar refrigerator is not suitable for vaccine storage as it is a very small combination unit (Vaccine Storage and Handling Toolkit, 2012: 27).

A study was conducted by Carr, Byles, and Durrheim (2009: 35) in New South Wales in which 256 practice nurses participated by filling in a questionnaire. During the site visits the researchers conducted an audit using a checklist on all refrigerators used for vaccine storage. The results from the study showed that of the 49 (19 percent) of general practices that used bar type refrigerators, the temperature fluctuated between being too high or too low. The authors recommend that bar-type refrigerators for storing vaccines be outlawed as they pose a threat to vaccine integrity. Similar concerns were raised about the bar-fridge for vaccine storage in a study conducted in Australia by Page *et al.* (2008: 896). This study supported the use of the purpose built refrigerators as the best method for vaccine storage, as recommended by the Vaccine Storage and Handling Toolkit (2012: 27).

The National Vaccine Storage Guidelines Strive for Five (2005: 2) states that vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to get too hot or if they are exposed to direct sunlight and it is recommend that vaccines must be stored at a temperature range between two to eight degrees Celsius.

Recording of the fridge temperature must be done twice daily. If at any time, the temperature is outside the normal range of two to eight degrees Celsius, immediate corrective action is necessary as recommended by The National Vaccine Storage Guidelines Strive for Five (2005: 14).

The correct number and placement of icepacks inside the cold box is important as too few ice packs can fail to maintain the internal cold box temperature and too many icepacks have the potential to harm the vaccines (Rogers *et al.*, 2010: 339). The authors state that a thermometer must be placed in the cold box next to the vaccines and the temperature of the cold box must be monitored hourly and displayed outside the cold box (Rogers *et al.*, 2010: 339). By monitoring the temperature hourly the nurse will be able to identify if vaccines are still potent and safe to use.

Barber-Hueso *et al.*, (2009: 139) conducted a cross-sectional study in Spain. This study reviewed 50 immunisation points and 68 refrigerators using a structured questionnaire. The results revealed that for 75 percent of the vaccine refrigerators, the correct temperature was not maintained. In addition, no refrigerator temperature recordings were documented.

A similar cross sectional study was conducted in health facilities in three African countries, namely, Ghana, Kenya and Uganda. The study was conducted by Burstein, *et al.* (2012: 525) to assess the quality of cold chain for vaccine storage from mid-2012 to late 2012. A total of 661 facilities were surveyed. During the study, the temperatures of the cold boxes and fridges at these facilities were recorded and compared to the National Vaccine Storage Guidelines Strive for Five (2005). In most of the health facilities surveyed the temperatures of the fridges and cold boxes were four degrees Celsius outside the normal range. There was no documentation of temperature or cold chain equipment. The authors state that there remains significant room for improvement in vaccine storage management in Ghana, Kenya and Uganda (Burstein *et al.*, 2012: 525).

Goel *et al.*, (2008: 37) compared the state of cold chain maintenance during a polio immunisation campaign in Chandigarh India from the year 2001 to 2006. The results revealed that in 2006, monitoring of the cold chain, with regards to recording of fridge temperatures and countersigning by supervisors, improved to 95.5 percent as compared to 23 percent in 2001. The results from this study showed that temperature maintenance improved over time. This was evident by the adequate maintenance of temperature charts. However, the authors stated there was still room for improvement and constant efforts are required to maintain the cold chain for vaccines.

Similar concerns were raised by a study conducted in Western India by Naik, Rupani and Bansal (2013: 1395). Concerns noted by them included, use of expired vaccines, lack of backup generators, lack of knowledge by staff on how to read the vaccines vial monitors, conduct the shake test for frozen vaccines and record the temperature of the fridge. The authors recommended periodic training, capacity building supervision and monitoring for cold chain handlers,

The National Vaccine Storage Guidelines Strive for Five (2005: 5) state that no food or any other goods must be stored in the refrigerator. This ensures that staff do not continuously open and close the refrigerator door unnecessarily, causing fluctuation in fridge temperatures, ultimately causing vaccines to become compromised. A study conducted by Barber-Hueso *et al.*, (2009: 139) showed that 33.8 percent of fridges evaluated, stored food, suggesting that the vaccine cold chains in immunisation centres were not being maintained according to National Vaccine Storage Guidelines. A study conducted in Mozambique by De Timoteo Mavimbe and Bjune (2003:21) further supports the findings of the abovementioned studies. In addition, this study revealed that vaccine fridges also stored laboratory reagents and various other drugs. This misuse of the cold chain for vaccines is supported by results found in studies conducted in Madrid by Molina *et al.*, (2002: 333) and in India by Roa *et al.*, (2012: 19).

A cross-sectional study was conducted in Saudi Arabia by Mugharbel and Wakeel (2007:83). The authors compared the use of vaccine chain tools in ten Governmental Primary Health Care (GPHC) facilities to the use of these tools in five Private Health Care Facilities (PHCF). To enable the comparison, the authors used a checklist based on the World Health Organization criteria for vaccine management. The study revealed that less than 20 percent of PHCFs maintained proper vaccine temperatures during storage as compared to 100 percent in GPHC facilities. Better cold chain practices were maintained in GPHCs with regard to the placement of the fridge away from direct heat and sunlight, recording of fridge temperatures twice daily, packing of vaccines in the fridge and in a cold box according to guidelines of WHO and the knowledge of staff regarding backup systems in case of cold chain failure. The overall results of this study revealed that PHCFs did not comply with standards defined by WHO and that the PHCF staff needed constant supervision and training regarding cold chain tools. A similar study was carried-out by Gazmararian *et al.*, (2002: 246) in which a comparison of primary care physicians' offices and paediatricians' offices revealed that paediatric offices had better compliance to guidelines for vaccine management.

A study conducted in eight health districts in Cameroon by Ateudjieu *et al.*, (2008: 101) revealed that the targeted health districts were not compliant with the standard operating procedures related to cold chain management of vaccines. Almost 25 percent of health facilities were conducting EPI activities without cold chain equipment. The authors noted that the electricity supply in Cameroon was unreliable and 79.4 percent of facilities reported interruption of power on a regular basis but had no standby generators available. The study further revealed that vaccines were not stored correctly on the top and bottom shelves of the fridge, vaccines and diluents were not stored together, fridges were over-packed not allowing air to circulate and used vaccines were not marked appropriately. The authors recommend that in order to overcome the gaps identified in cold chain management of vaccines in Cameroon, the health authorities should identify innovative strategies such as computerised temperature monitoring systems for cold chain of vaccines, as recommended in the study conducted by Schlumberger *et al.*, (2011: 264). Schlumberger *et al.*, (2011: 264) recommend that in order for staff to effectively manage the cold chain for vaccines, there should be constant supervision and training in cold chain management, access to guidelines and availability of cold chain tools and equipment for staff.

An outbreak of measles in Cape Town, South Africa, In1993 prompted Coetzee (1993: 543) to carry-out a study on vaccine storage procedures in General Practitioners' rooms. A standardised questionnaire was used to conduct telephonic interviews. A sample of 103 practitioners was used. The study revealed that 81 percent of practitioners did not monitor the fridge temperature as they did not have appropriate temperature devices. Food and cold drinks were stored in the fridge in 54 percent of the cases and 60 percent of the practitioners' stored vaccines in the doors. These findings are consistent with studies conducted globally and on the African continent. These include studies conducted in Gujarat (Patel, Raval and Pandit, 2011: 20) in Mozambique (De Timoteo Mavimbe and Bjune, 2003: 21) and in Ghana, Kenya and Uganda (Burstein *et al.*, 2012: 525).

Thermometers are a critical part of good storage and handling practice. The common types of thermometers used in vaccine fridges are dial and digital (National Vaccine Storage Guidelines Strive for 5, 2013: 22). Thermometers

should be placed in the centre of the fridge. The temperature of the fridge must be monitored twice daily and recorded on the temperature chart which is placed on the front of the fridge. If the fridge temperature drops below two degrees Celsius and goes above eight degrees Celsius action needs to be taken to avoid vaccine becoming compromised. (National Vaccine Storage Guidelines Strive for 5, 2013).

Barber-Hueso *et al.*, (2009: 139) conducted a cross-sectional study in Spain. This study reviewed 50 immunisation points and 68 refrigerators using a structured questionnaire. The results revealed that for 78 percent of the vaccine refrigerators, the correct temperature was not maintained. In addition, no refrigerator temperature recordings were documented. Ateudjieu *et al.*, (2008: 5) in their study conducted in Cameroon stated that innovative strategies such as computerized temperature monitoring of the cold chain for vaccines could be used to protect their potency.

2.9 EVIDENCE OF FREEZING OF VACCINES

According to Immunisation, Vaccines and Biological (WHO-2011: 1), improperly maintained or outdated refrigeration equipment, poor compliance with cold chain procedures, inadequate monitoring and poor understanding of the dangers of vaccine freezing contribute to weakness in the cold chain.

In a study conducted in Indonesia by Nelson *et al.*, (2004: 99) the authors used data loggers to monitor temperatures of the Hepatitis B vaccine from the manufacturer to the point of use. Baseline conditions and three intervention phases were monitored. In 75 percent of the shipment of vaccines, freezing temperatures were recorded. The highest rates of freezing occurred during transport from province to district, storage in district-level ice lined refrigerators and storage in refrigerators in health centres. The researchers concluded by stating that the use of simple strategies, such as the use of selective transport that store vaccines at ambient temperatures and the use of VVM to detect heat damage to vaccines as these could reduce freezing, reduce costs and increase capacity of vaccines in Indonesia.

Nelson *et al.*, (2004: 99), Ren *et al.*, (2009: 745), Techatawat *et al.*, (2007: 1328), Turner, Laws and Roberts (2011: 278), Wirkas *et al.*, (2007: 691) and Zipursky *et al.*, (2011: 34) conducted studies in Indonesia, China, Thailand, Papua New Guinea and Chad, respectively, on how vaccines which are exposed to freezing temperatures lose their potency due to the inactivation of key organic components. Such losses in the potency of vaccines results in vaccines becoming ineffective. This poses potential danger to patients who receive these vaccines, as well as a financial loss for immunisation programmes.

Matthias *et al.*, (2007: 3980) conducted a systematic literature review of studies from January 1985 to June 2006 which investigated vaccine freezing in the cold chain. These authors recommended that more rigorous and comprehensive studies be conducted to examine the exposure of vaccines to freezing temperatures through all transport and storage segments of the cold chain.

When vaccines are subjected to freezing the shake test (see Appendix 7) is done to determine if the vaccine can still be used.

2.10 VACCINE VIAL MONITORS

Studies conducted in India by Samant *et al.*, (2007: 617) and in Gujarat by Patel, Raval and Pundit (2011: 17) focused on the relationship between the Vaccine Vial Monitor (VVM) (see Appendix 8) and the cold chain infrastructure. WHO mandates that all vaccines which have VVMs must indicate the heat exposure that negatively affects vaccine potency (WHO, 1999). Patel, Raval and Pundit (2011:17) revealed that 98.8 percent of the facilities they visited showed VVMs of stage one and two of freeze vaccines. Furthermore, reconstitution time was not documented on the vaccine vial. Samant *et al.*, (2007: 617) in their study concluded that the further away vaccines travelled from the central vaccine stores to sub-health centres, the more likely the VVM changes from stage three to stage four. These stages indicate that vaccines have lost their potency and should be discarded. The VVM remains a cost effective way which ensures that potent vaccines are delivered to children.

2.11 KNOWLEDGE AND PRACTICES OF STAFF HANDLING AND ADMINISTERING VACCINES

The Vaccine Storage and Handling Toolkit (2012: 24) and the National Vaccine Storage Guidelines (2005: 6) recommend that staff who handle and administer vaccines should receive training regarding vaccine storage and handling policies and procedures. Training should also be integrated into the orientation programme. Training should be recommended when the EPI programme is updated and new vaccines are added on.

Widsanugorn *et al.*, (2011:177-185) conducted a cross-sectional study in hospitals and primary health care centres, to assess healthcare workers' knowledge and practices regarding the EPI and cold chain system in Thailand. The researchers concluded that nurses' knowledge in hospitals were better than in primary health care centres. This study also supports the findings in studies conducted in Riyadh by Al-Ayed (2006: 19), in Turkey by Uskun *et al.*, (2008:949) and in China by Li, Hang and Liu (2009: 885). These researchers have strongly recommended that continuous training and supervision on EPI and cold chain management of vaccines be carried out in order to ensure that immunisation is effective and vaccine failures are prevented.

Mallik *et al.*, (2011: 128) conducted a baseline survey on cold chain equipment in Kolkata, India. This study assessed the changes that occurred in cold chain management after an intervention undertaken to improve the cold chain management status. The intervention involved the reorganising of cold chain points and training in cold chain management based on the guide of the Government of India. Prior to the intervention there were gross discrepancies in availability of cold chain equipment, lack of knowledge amongst staff on cold chain guidelines and lack of monitoring and supervision. The success achieved through the intervention resulted in significant improvement in care of cold chain equipment, placement of vaccines in the refrigerator and appointment of a cold chain handler at every immunisation centre. Other gaps identified in cold chain systems in this study included non-availability of backup generators and a

separate cold chain room, which is mainly dependent on policy makers and funding.

2.11 CHALLENGES NURSES FACE WITH VACCINE MANAGEMENT

A study conducted by Wiysonge *et al.*, (2012: 578) in South Africa concludes that nurses face numerous challenges in the management of the cold chain of vaccines despite the many advances in immunisation in South Africa. These include insufficient financial resources, a shortage of nurses and a lack of knowledge of nurses regarding vaccine management. These challenges will lead to vaccines becoming compromised and less potent. As a result, these vaccines will not be beneficial to children. The strategies the authors proposed in order to overcome these challenges included, training, supervision and regular auditing to improve performance of vaccine management.

2.12 ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

Aderibigbe, Osagbemi and Bolarinwa (2010: 496-499) conducted a descriptive retrospective study on Adverse Events Following Immunisation (AEFI) in four cities in Nigeria. The study was conducted from January 2004 to June 2006. They state that concluded that just over half (50.9 percent) of all documented cases of AEFI were local swelling and abscess formation at the injection site and about 49 percent of the reactions were due to administration of diphtheria, pertussis and tetanus vaccines (DPT). This study postulates that these AEFI could have been due to the source of vaccines, cold chain equipment and maintenance thereof and the technique of administering the vaccines. The study emphasises the importance of ensuring a safe supply of vaccines and the necessary maintenance of cold chain equipment to ensure continuous potency of vaccines, thus preventing AEFI. This finding is supported by a retrospective analysis of reports in children between zero and seventeen years of age conducted by Aagaard, Hansen and Hanson (1998-2007: 283) in Denmark. During the study period 1,365 reports were received of which 60 percent were reports on AEFI in children.

According to WHO (State of the Worlds Vaccines and Immunisation, 2003: 11) all vaccines that are prequalified by WHO for supply through UNICEF and United

Nations agencies conform to WHO regulatory standards. If vaccines are not manufactured and tested to appropriate standards they can cause harm and fail to protect children against the targeted diseases. The potency and safety of vaccines is sometimes compromised by programme errors thus resulting in AEFI (WHO State of the Worlds Vaccines and Immunisation, 2003: 11).

2.13 VACCINES WASTAGE

Improving the use of vaccine supplies and avoiding unnecessary wastage often depends upon better management. Wastage of vaccines can occur from central stores, during transportation and at immunisation sessions (Cold Chain Vaccines and Safe Injection Equipment management WHO, 2008: 46). The factors associated with vaccine wastage can be classified as unavoidable or avoidable. Unavoidable wastage includes reconstituted vaccines that have to be discarded at the end of the immunisation session. Avoidable vaccine wastage factors include poor stock management, cold chain failure that exposes vaccines to high or low temperatures, administration of incorrect dose of vaccines, loss breakage and theft of vials (Cold Chain Vaccines and Safe Injection Equipment management WHO, 2008: 46).

In a study conducted in New Zealand between 2002-2008 the researchers randomly included temperature monitor cards in vaccines that were distributed from the national stores to delivery sites. During this time six monthly reports were documented and analysed to identify changes in freeze and heat exposure failures for vaccines. When cold chain failures were identified a range of changes were implemented such as improving equipment, systems, policies and procedures, education and training and increased provider attention, in order to strengthen the cold chain for vaccines (Turner, Laws and Roberts, 2011: 280). The study revealed that the heat failure in vaccines was reduced from 3 to 0.3 percent, freeze failures in vaccines decreased from 16 to 2 percent and overall vaccine wastage was reduced from 17 to 2 percent. Therefore this study concludes that through improving equipment, systems, policies and procedures and education and training, vaccine wasting can be reduced thus reducing costs for the country (Turner, Laws and Roberts, 2011: 280).

2.14 RECORD KEEPING FOR VACCINES

All immunisation facilities must have written policies, procedures and protocols in place regarding vaccine management. Maintaining stock records are critical for vaccine inventory management (Vaccine Storage and Handling Toolkit, 2012: 82). Records must be maintained on vaccine balances, vaccines administered and wasted fridge temperature records, fridge servicing and records of in service and training of staff on vaccine management. Records must be kept for a period of three years. Proper documentation helps to prevent wastage of vaccines (Vaccine Storage and Handling Toolkit, 2012).

A study was conducted in seven regional vaccine depots, eighteen health clinics and central vaccine stores in Swaziland. At the health clinics the authors found that documentation for vaccine management was poor. They found that vaccine stock levels were not established and physical count of vaccines not documented in 37 percent of the clinics. Furthermore, vaccine wastage was recorded in log books however only 13 percent of the clinics maintained records for calculation of wasted vaccines. The authors recommend that staff be trained on vaccine management and recording (Nxumalo *et al.*, 2006).

The current study was conducted in Primary Health Care (PHC) clinics in the uMgungundlovu district, KwaZulu-Natal (KZN). KZN forms part of the nine provinces in South Africa and has a population of 10.6 million. There are nine hospitals, four community healthcare centres and 70 PHC clinics in the uMgungundlovu district. All four of these health centres cater for all the health needs of the people living in the district.

2.14 CONCLUSION

It is evident from the literature reviewed, that many gaps and weaknesses are present at every stage of the cold chain such as healthcare workers who lack knowledge on the management of vaccines, lack of electricity, the mismanagement of equipment and the poor transportation infrastructure. Due to these gaps vaccines lose their potency, thus, making children more vulnerable to

childhood vaccine preventable diseases. Therefore, at the end of the chain primary healthcare providers must have adequate knowledge and regular in-service training on vaccine management, ensure availability of generators in case of power failure, and ensure proper management of vaccine fridges and cold boxes in order to maintain an effective cold chain for vaccines.

Chapter 3 presents the research methodology used to guide the study. It describes the research design, the research instruments used to obtain data, the validity and reliability of the research instruments, the data collection process, the method for analysing the data collected. In addition to this, the chapter presents the conceptual framework that was used to guide the study.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter presents the research methodology used to guide the study. It describes the research design, the research instruments used to obtain data, the validity and reliability of the research instruments, the data collection process, the method for analysing the data collected. In addition to this, this chapter presents the theoretical framework that was used to guide the study.

The researcher collected data from five local Municipalities in the uMgungundlovu district. The districts were Impendle, Mkhambathini, Richmond, Msunduzi and uMngeni local municipalities.

Data were collected in the months of August and September 2013. A total of 52 clinics were visited and random samples of 276 nurses were selected to participate in the study by completing the self-administered questionnaire. In addition, the observation study was conducted in 14 clinics, located in the aforementioned districts.

3.2 RESEARCH DESIGN

Polit and Beck (2012: 58) describe the research design as being the architectural backbone of the study in that it allows the researcher to identify measures to reduce bias, stipulate the frequency of data collection, provide the answer to questions and guides the comparisons that will be made. From this it can be deduced that the research design has a strong influence on the reliability and relevance of the results attained and thus provides a solid base for the research study.

According to Burns and Grove (2009: 22) quantitative research is a formal, objective, systematic process in which numerical data is used to obtain

information. Burns and Grove (2009: 22) also state that descriptive studies offer researchers a way to discover new meaning to describe what already exists, determine the frequency with which something occurs and to categorise information.

In light of this, a quantitative descriptive survey design was selected for this study and was conducted in two phases. In the first phase, an observational study was carried out by the researcher using a structured observation guideline. At each of the 14 clinics selected, using interval sampling technique, the researcher observed if the cold chain for vaccines was maintained according to National, Provincial and Operational guidelines. Observations were recorded on a pre-planned checklist that contained the aforementioned guidelines. In the second phase, the cold chain management of vaccines by nurses was explored by means of a self-administered questionnaire. Enrolled and registered nurses working in the immunisation room were included in both phases of this research study.

3.3 CONCEPTUAL FRAMEWORK

The purpose of the cold chain system is to ensure effective transport and storage of vaccines to enable their 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 operational guidelines. This framework was adapted for this study, to aid in investigation of the cold chain for vaccines. 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 quality vaccine programmes.

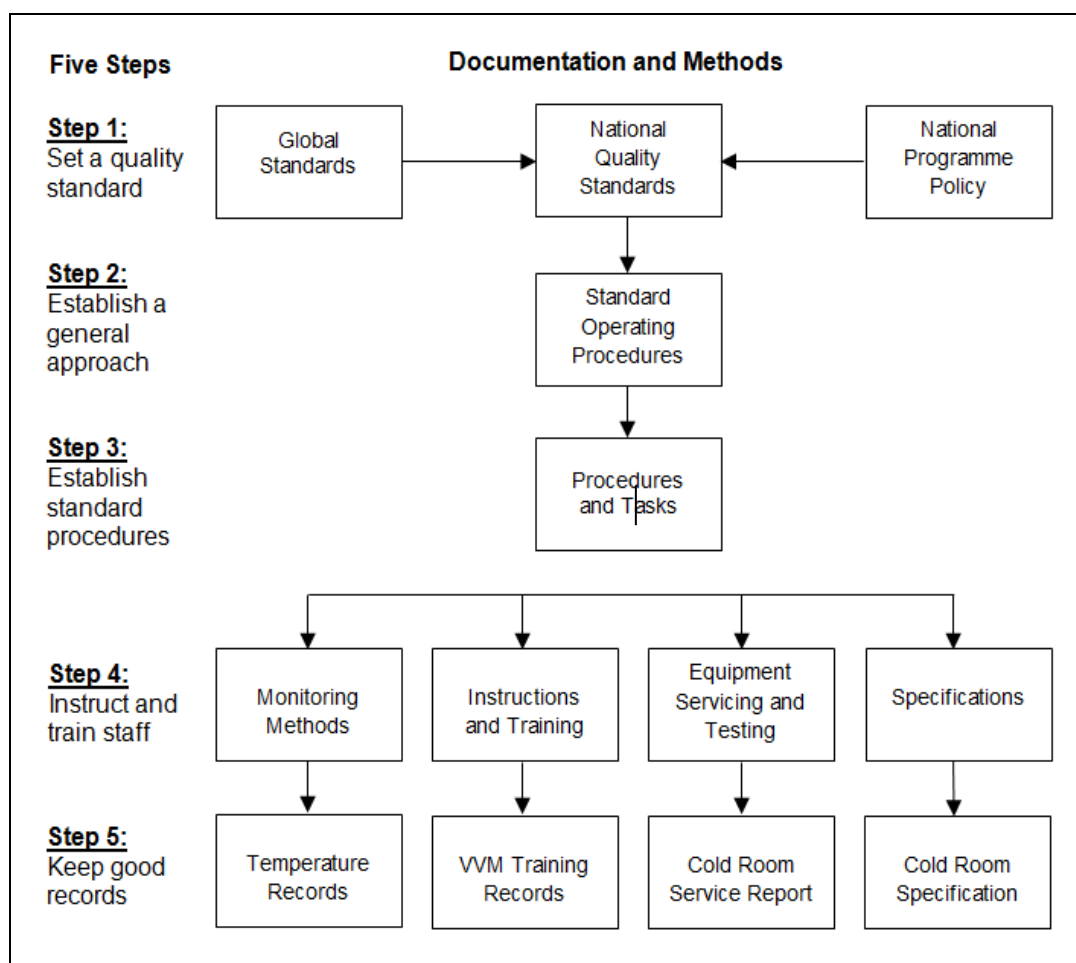


Figure 1.1: Conceptual Framework Adapted from Vaccine Management (WHO, 2005) immunisation, vaccine, biological guidelines.

The first step is setting the quality standard. This is the step in which quality models available for vaccine management are identified. Staff allocated to PHC clinics must practice nursing duties regarding the management of vaccines 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 vaccine management is established. Overall requirements for vaccine management are identified. Thereafter, standard operating procedures are prepared and adopted.

Step three entails establishing standard procedures. Specific tasks and procedures for vaccine management are identified. These tasks and procedures

are 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 are instructed and trained during orientation programmes and in-service training. It is 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 will ensure that the task has been carried out effectively as, in doing this, vaccine programme managers can verify that sound vaccine management is in place and has been maintained over a period of time.

This framework provides the foundation for determining the level of quality of the management of vaccines at the selected clinics. In addition, assessing vaccine management using this framework enables nurses to highlight the strengths and weaknesses of vaccine management and introduce the changes where necessary.

3.4 STUDY SETTING

The study setting for this research was naturalistic in order to ensure that the obtained results mirror the reality of managing the cold chain for vaccines in the daily workings of the clinics in the uMgungundlovu District.

There are 11 Health Districts and 646 clinics in the KZN province (KZN Department of Health, 2009). KZN has a total population of 10.6 million. Pietermaritzburg, the capital city of KZN, falls within the uMgungundlovu district. There are three Community Health Centres, three Gateway clinics, fourteen Mobile Clinics and nine hospitals in the uMgungundlovu district, all of which function at different levels and specialise in different areas of health. There are 71 PHC clinics and this is the patient's first entry into the health system. The study was carried out at 71 PHC clinics in the uMgungundlovu district of KZN, Pietermaritzburg, where nurses completed the questionnaires.

3.5 SAMPLING PROCESS

A sample can be described as a sub-selection of the research population. According to Polit and Beck (2012: 275) samples characteristics should closely resemble those of the entire population, to be considered as representative of the population. There are 11 Health Districts and 646 clinics in the province of KwaZulu-Natal. The uMgungundlovu district has 71 PHC clinics. These clinics include:

- Provincial, fixed and mobile clinics;
- Community health centres;
- Gateway clinics;
- State-aided clinics;
- Mobile state-aided clinics; and
- Local government fixed and mobile clinics.

There are approximately 445 registered nurses employed at these clinics (KZN Department of Health, 2012) representing the total research population for this study. For the purpose of this study, 69 clinics were utilised as two clinics were used in the pilot study.

3.5.1 PHASE ONE

For the observation study 20 percent of the 69 clinics were chosen, which equated to 14 PHC clinics. Thus, the sample comprised of 14 nurses who were randomly selected, one from each clinic. Clinics were randomly selected by using interval sampling. All 69 clinics were listed on a page and every fifth clinic was chosen for the observation study. The observation study was conducted using a structured observation guide (Appendix 4).

3.5.2 PHASE TWO

A self-administered questionnaire was distributed to a representative sample of 377 (Appendix 3). This sample size was calculated at a confidence level of 95 percent with a 5 percent margin of error and a response distribution of 50 percent. The sample size was chosen in consultation with a professional statistician (Appendix 6). All 69 PHC clinics were used in this phase and included both fixed and mobile clinics.

The fish bowl technique, a random sampling approach, was used to select participants. Thus, all nurses working in the clinic for that day had an equal chance of being chosen for the study. Each nurse's name was entered on a slip of paper and put into a bowl. The slip was drawn, the name was noted, the slip was replaced, the bowl was shaken and the next slip was selected. This process continued until six nurses were chosen per clinic and until total of 377 nurses was reached.

A sample is chosen to be representative of the research population. Inclusion and exclusion criteria ensure that there is accuracy in the sampling process therefore in the results obtained from this study. Inclusion criteria are applied to choose applicable participants for the study whereas exclusion criteria guide who will be excluded from the study. The following criteria were applied to the study:

INCLUSION CRITERIA:

- All full-time nurses employed at provincial and government PHC clinics in the uMgungundlovu district.

EXCLUSION CRITERIA:

- Nurses in private PHC clinics;
- Student nurses employed at PHC clinics.

3.6 DATA COLLECTION PROCESS

According to Burns and Grove (2009), data collection is the process of acquiring participants and collecting information from these participants that is relevant to the study. The authors further state that ensuring consistency and controls during the data collection process ensures the integrity and validity of the study. With that in mind the data collection process occurred in two phases. The first phase was an observation study which used a structured observation guide as a means of recording the researcher's observation. The second phase warranted the use of a questionnaire which was developed through careful review of the existing literature and in accordance with the framework suggested by WHO for effective cold chain vaccine management. The first part of the questionnaire is applicable to fixed clinics as it pertains to questions on the refrigerator and cold box. The second part of the questionnaire pertains to mobile clinics (Appendix 3B). Nurses working mobile clinics use the cold box only for storage of vaccines and no refrigerators are available therefore the questionnaire pertains to cold boxes only.

3.6.1 PHASE ONE

For the duration of the observation study the researcher was stationed in the immunisation room from 08: 00 a.m. to 04: 00 p.m. at a clinic, daily, for 14 days. During this time, the nurse in the immunisation room for that day was observed. Using the structured observation guide, the researcher noted how the nurse maintained the cold chain for vaccines. Written informed consent was obtained prior to observations (Appendix 5A). The actual immunisation procedure was not observed. For the purpose of this study the researcher requested to view all policies, procedures and documentation pertaining to cold chain management of vaccines in local clinics to see available and if clinics were compliant with cold chain management for vaccines. Phase one was conducted first, followed by phase two.

3.6.2 PHASE TWO

For this second phase of data collection, confidentiality was maintained by not recording any names of nurses or clinic names on the questionnaires or the observation guide. To maintain anonymity, codes were assigned to clinics. All 69 clinics were listed. A random number was allocated to each clinic along with the district, in which the clinic is located. Coding started from one to 69 and clinics were coded as – 1 P.M.Burg, 2 P.M.Burg and so on.

The purpose and benefits of the study were explained to the participants prior to obtaining their written consent to participate in the study, via an informed letter of consent which was attached to the questionnaire (Appendix 5B). The questionnaire and a self-addressed envelope were given to each registered nurse personally at the beginning of the month. A drop off box was provided to each clinic where nurses placed their completed questionnaires. The drop off box was handed over to registered nurse in charge and was locked in the nurse's station. The completed questionnaires were collected at the end of the month.

3.7 PILOT STUDY

To assist in the development of the research instrument, and to test the methods that were used in the study, a pilot study was conducted. A pilot study also helps to increase the reliability and validity of measures by allowing the researcher to identify inconsistencies and determine the quality of the research instrument as an accurate tool for data collection. The pilot study included experts in the field of vaccine management as well as lecturers who are PHC trained. A sample of four academics in the field of vaccine and two clinics were included in the pilot study. Subsequently, minor changes were applied to the questionnaire. Data collected during the pilot study was not included as part of the research data. Thus, the two clinics included in the pilot study were excluded from the main research study.

3.8 DATA ANALYSIS

Data analysis aims to reduce, organise and give meaning to the data, in order for meaningful conclusions to be drawn (Burns and Grove, 2009). For this study data was analysed using descriptive statistics, such as frequency and cross tabulations

and different types of graphs. Inferential statistics were used to make inferences about the population. These include methods such as Chi-square tests for categorical data and t-tests/ANOVA for continuous data. Non-parametric tests were used. A numerical system of data analysis was used through computerised data analysis software. The Statistical Package for the Social Sciences (SPSS) version 20.0 was used to analyse the quantitative data for the questionnaire and the observation study conducted. Data was reduced and analysed with the assistance of a statistician (Appendix 5).

3.9 RELIABILITY AND VALIDITY OF THE INSTRUMENT

According to Polit and Beck (2008) reliability is the degree of consistency or dependability with which an instrument measures an attribute. In addition Polit and Beck (2008) state that the reliability of a quantitative measure is an important criterion for assessing its quality. The researcher ensured that the same questionnaire was administered to all participants for this study and the same structured observational guide was used in all PHC clinics.

Validity, according to Polit and Beck (2008), is the degree to which the instrument measures what it is intended to measure. Content validity was tested by choosing experts in the field of vaccine management, academics and nursing lectures who are PHC trained, in order to test the validity of the data collection tool. The researcher ensured validity by including questions pertaining to this study only.

3.10 ETHICAL CONSIDERATIONS

The research proposal was cleared by the Durban University of Technology Ethics Committee (Appendix 7). The researcher described the purpose, procedure, and benefits of the study to all participants. A letter of information was also distributed to all registered nurses prior to the study. A letter seeking permission to conduct the research study was written to both the Department of Health (Appendix 1A) and the District Office of Health (Appendix 2A). Permission to conduct the study was granted by the Department of Health (Appendix 1B) and the District Office of Health (Appendix 2B).

Written informed consent was requested from the nurses prior to completing the structured observational study (Appendix 5A) and the questionnaire (Appendix 5B). Participation in the study was voluntary and participants were informed that they were able to withdraw from the study as they wished. Confidentiality was maintained by not entering participants' names on the questionnaire and observation guide. In addition codes were assigned to clinics to maintain confidentiality. Responses to questionnaires and the observation study records were also kept confidential.

3.11 CONCLUSION

This chapter detailed the research methodology, ethical considerations and the conceptual framework that were employed in the study. The following chapter will present the results obtained through this process.

CHAPTER 4: PRESENTATION OF THE RESULTS

4.1 INTRODUCTION

The previous chapter outlined the methodology adopted in conducting this study. This chapter presents the data obtained from the study. An observation guideline checklist and a self-administered questionnaire were used to collect the data from nurses employed in urban, rural, mobile and CHC clinics. The objectives of the study and the observation guidelines (Appendix 4) were used to guide the findings of the observation study.

Section A1 presents the findings related to the observation guidelines checklist. This is followed by Section A2, which presents the findings of the self-administered questionnaire (Appendices 3A and 3B).

2.5 SECTION A1: PHASE ONE – OBSERVATION STUDY

4.2.1 DEMOGRAPHIC DATA

The observation study was conducted in five urban clinics, five rural clinics, two CHC and two mobile clinics. A total of fourteen nurses were observed. Both the nurse and the clinic to which the nurse belonged were evaluated against the criteria discussed below.

4.2.2 CURRENT PROCESSES OF COLD CHAIN MANAGEMENT

4.2.2.1. POLICIES, PROCEDURES AND GUIDELINES OF COLD CHAIN MANAGEMENT AS SUGGESTED BY NATIONAL/GLOBAL STANDARDS OF WHO

An observation guideline checklist with fifteen criteria was used to observe whether nurses followed policy, procedures and guidelines in the management of the cold chain for vaccines.

Table 4.1: Policies, procedures and guidelines

	Urban		Rural		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
1.1 Policies, procedures and guidelines available for vaccine management.	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.2 Are contingency plans in place for problems with equipment/electricity used in the cold chain management of vaccines?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.3 Is there evidence of maintenance to cold chain equipment available?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.4 Is there evidence of filling in of stock cards for vaccines?	100.0	0.0	60.0	40.0	100.0	0.0	100.0	0.0	85.7	14.3
1.5 Is there evidence of physical inventories of vaccine stock?	0.0	100.0	1.0	100.0	100.0	0.0	0.0	100.0	14.3	85.7
1.6 Is there evidence of dedicated room for vaccine Storage and immunisation procedures?	80.0	20.0	100.0	0.0	0.0	100.0	50.0	50.0	71.4	28.6
1.7 Is vaccine wastage managed according to policy?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.8 Are there vaccine wastage reports available?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.9 Is evidence of vaccine wastage data available to make operational changes?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.10 Is their evidence of shake test for frozen vaccines?	20.0	80.0	0.0	100.0	0.0	100.0	0.0	100.0	7.1	92.9
1.11 Is there evidence of records of adverse incidents?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.12 Is there evidence of records of in case of recall /batch numbers for vaccines?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
1.13 Is the emergency tray available and fully equipped?	40.0	60.0	20.0	80.0	0.0	100.0	0.0	100.0	21.4	78.6
1.14 Is there evidence of training on emergency reactions?	20.0	80.0	0.0	100.0	0.0	100.0	0.0	100.0	7.1	92.9
1.15 Is there evidence of good vaccine records i.e. temperature records .training record, cold room service reports?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0

As can be seen in Table 4.1, there are fifteen criteria relating to policy, procedure and guidelines of cold chain vaccine management. Thirteen of the clinics observed have a large negative alignment 100% (n=0) for policy, procedure and guidelines. In these clinics there was no written evidence of contingency plans for faulty equipment and electricity failure, maintenance of equipment, management of vaccine waste, training records and managing of AEFI. There was evidence of filling in of stock cards in 85.7% (n=12) clinics and in 14.3% (n=2) clinics this was not evident.

In 71.4% (n=10) of clinics there was compliance with having a dedicated room for vaccine storage and procedures. There was non-compliance in 28.6% (n=4) of the clinics observed.

Record keeping regarding in-service training for nurses, cold room service reports, and records on (AEFI) and records for recall of batch numbers were not documented in 100% (n=14) clinics.

4.2.2.2. STANDARDS OF COLD CHAIN MANAGEMENT

The criterion used for standards of cold chain management during the observation study was based on the National/Global standards of vaccine management according to the WHO.

The observation guideline checklist was used to observe whether nurses maintained the standards of cold chain for vaccine management regarding vaccine arrival procedures, refrigerator, cold box, use of vaccine during immunisation procedure and availability of vaccine stock and equipment.

4.2.2.3. VACCINE ARRIVAL PROCEDURE

Four criteria, as seen in Table 4.2, were used in the observation study to observe how the nurse in the immunisation room responded to and stored vaccines when they arrived.

Table 4.2: Vaccine arrival procedure

	Urban		Rural		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
2.1 Does the nurse respond immediately when vaccines arrive in clinic?	40.0	60.0	60.0	40.0	0.0	100.0	50.0	50.0	42.9	57.1
2.2 Does the nurse check vaccines for discrepancies, leakage and breakage before receipt?	60.0	40.0	60.0	40.0	0.0	100.0	50.0	50.0	50.0	50.0
2.3 Are vaccines stored immediately on receipt?	40.0	60.0	80.0	20.0	0.0	100.0	50.0	50.0	50.0	50.0
2.4 Are vaccines packed according to the first in first out principle?	80.0	20.0	80.0	20.0	0.0	100.0	50.0	50.0	64.3	35.7

Table 4.2 indicates that there was almost a balance in criteria that scored “Yes” (n=7) as there were those which scored “No” (n=7). For each of the criteria on vaccine arrival procedures, for example (vaccines stored immediately on receipt) it was observed that 50% (n=7) of the clinics scored “Yes” and 50% (n=7) scored “No”.

4.2.2.4. REFRIGERATOR

During the observation study fourteen criteria as indicated in Table 4.3 was used to observe the refrigerator in which vaccines were stored.

Table 4.3: Refrigerator

	Urban		Rural		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
3.1 Is the refrigerator appropriate to store vaccine? Size, freezer compartment for icepacks?	80.0	20.0	80.0	20.0	0.0	100.0	50.0	50.0	64.3	35.7
3.2 Is the refrigerator is dedicated for vaccines only?	100.0	0.0	80.0	20.0	50.0	50.0	100.0	0.0	85.7	14.3
3.3 Is the refrigerator temperature between (2 - 8 °C)?	60.0	40.0	60.0	40.0	0.0	100.0	100.0	0.0	57.1	42.9
3.4 Is the temperature of the refrigerator recorded on chart twice daily?	20.0	80.0	20.0	80.0	0.0	100.0	100.0	0.0	28.6	71.4
3.5 Is the refrigerator packed correctly with vaccines and diluents?	0.0	100.0	40.0	60.0	0.0	100.0	50.0	50.0	21.4	78.6
3.6 Is the refrigerator overstocked?	60.0	40.0	20.0	80.0	0.0	100.0	50.0	50.0	35.7	64.3
3.7 Is there enough air circulating between vaccines?	20.0	80.0	0.0	100.0	0.0	100.0	0.0	100.0	7.1	92.9
3.8 Are there vaccines on the door?	20.0	80.0	0.0	100.0	0.0	100.0	0.0	100.0	7.1	92.9
3.9 Does the vaccine stock correspond with the diluents stock?	20.0	80.0	20.0	80.0	0.0	100.0	50.0	50.0	21.4	78.6
3.10 Are vaccines frozen?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
3.11 Is the refrigerator in a locked room or does the fridge has a lock and key?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
3.12 Is there a working thermometer hanging in the correct place?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
3.13 Do not unplug refrigerator signage on plugs	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
3.14 Do not open vaccine fridge signage on fridge door	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0

Table 4.3 - shows that for criteria 3.10- 3.14 100% (n=14) of the clinics scored “No”, indicating non-compliance. In the first nine criteria it was observed that clinics were partially compliant. The “Yes” scores ranged between 7.1%-85.7% and the “No” scores ranged between 64.3%-96.1%.

4.2.2.5. COLD BOX

During the observation study five criteria as indicated in Table 4.4 was used to observe the standards of cold chain management related the cold box.

Table 4.4: Cold Box

	Urban Rural		Mobile		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
4.1 Is the cold box in a good condition and right size?	80.0	20.0	60.0	40.0	100.0	0.0	100.0	0.0	78.6	21.4
4.2 Is there a working thermometer in the cold box?	60.0	40.0	20.0	80.0	100.0	0.0	50.0	50.0	50.0	50.0
4.3 Is the temperature of the cold box between 2-8 degrees?	20.0	80.0	20.0	80.0	0.0	100.0	50.0	50.0	21.4	78.6
4.4 Is the cold box packed correctly i.e. 6 ice packs?	20.0	80.0	0.0	100.0	100.0	0.0	50.0	50.0	28.6	71.4
4.5 Are ice packs conditioned before use?	20.0	80.0	0.0	100.0	100.0	0.0	0.0	100.0	21.4	78.6

During the observation study it was observed that for criteria 4.2 50% (n=7) of the clinics scored “Yes” and 50% (n=7) of the clinics scored “No”. For criteria number 4.1 78.6% (n=11) of the clinics scored “Yes” and 21.4% (n=3) scored “No”. Criteria 4.3, 4.4, and 4.5 were rated strongly “No” with the scores ranged from 71.4% to 78.6%. The “Yes” scores in these criteria ranged from 21.4% to 28.6%.

4.2.2.6. USE OF VACCINE DURING SESSION

During the observation study three criteria as indicated in Table 4.5 were used to observe the use of vaccines during the immunisation session.

Table 4.5: Use of vaccine during session

	Urban		Rural		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
5.1 Vaccines are left out of cold box for long period of time during immunisation	40.0	60.0	40.0	60.0	100.0	0.0	0.0	100.0	42.9	57.1
5.2 Vaccines drawn up in advance for the entire session and left in cold boxes	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0
5.3 Are two or more vaccines mixed in the same syringe during the immunisation session?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0

During the observation study it was observed that 42.9% (N=6) clinic vaccines were left out of the cold for a long time during the immunisation session and 57.1% (n=8) were partially compliant with this criteria.

All clinics 100% (n=14) were complaint with not drawing up vaccines in advance and not mixing vaccines in the same syringe.

4.2.2.7. OPEN VIAL POLICY

During the observation study there were two criteria as indicated in Table 4.6 for observing the open vial policy of vaccines during the immunisation session.

Table 4.6: Open vial policy

	Urban		Rural		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
6.1 Does the nurse record the date and time on the open vials?	20.0	80.0	40.0	60.0	0.0	100.0	50.0	50.0	28.6	71.4
6.2 Is the expiry date on vials checked prior to administration?	20.0	80.0	20.0	80.0	0.0	100.0	50.0	50.0	21.4	78.6

Two criteria were used to observe the open vial policy in the observation study. As seen in Table 4.6 above, it was observed that 71.4% (n=10) of clinic nurses scored

“No” and failed to record the date and time on opened vials of vaccines. In 28.6% (n=4) nurses scored “Yes” and were compliant with this criteria. It was observed that 21.4% (n=3) of clinic nurses scored “Yes” and were compliant with checking the expiry date on vaccine vials prior to administration of the vaccine, whereas 78.6% (n=11) of the clinic nurses scored “No” and were non-complaint with this criteria.

4.2.2.8. MULTI-DOSE VIAL (MDV)

During the observation study four criteria were used as indicated in Table 4.7 to observe the nurses using the multi-dose vial during the immunisation session.

Table 4.7: Multi-dose vial

	Urban		Rural		Mobile		Community Health Centre		Total	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
7.1 Is the policy maintained regarding sterility and reconstitution?	40.0	60.0	60.0	40.0	0.0	100.0	0.0	100.0	35.7	64.3
7.2 Are opened vials of free zed vaccines discarded after six hours?	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0
7.3 Is the VVM used outside the cold chain?	20.0	80.0	20.0	80.0	0.0	100.0	0.0	100.0	14.3	85.7
7.4 Is there evidence of VVM training?	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0	0.0	100.0

As seen in table 4.7 35.7% (n=5) of clinic nurses scored “Yes” and were complaint with policy regarding sterility and reconstitution of vaccines whereas 64.3% (n=9) of clinic nurses scored “No” and were non-complaint with this criteria.

One hundred percent (n=14) of clinic nurses scored a strong “Yes” regarding compliance with discarding free zed vaccines after six hours of an immunisation session.

It was observed that 14.3% (n=2) of the clinics nurses scored “Yes” that they used the vaccine outside the cold chain whereas 85.7% (n=14) scored “No” and were compliant with this criteria.

During the observation study 100% (n=14) of the clinic nurses answered “No” regarding evidence of vaccine vial monitor training.

4.2.2.9. EQUIPMENT AND STOCK AVAILABLE

During the observation study one criterion was used as indicated in Table 4.8 to observe the availability of vaccine equipment and stock.

Table 4.8: Equipment and stock available

		Clinic				Total
		Urban	Rural	Mobile	Community Health Centre	
8.1 Are sufficient syringes, needles and sharps containers available for immunisation session?	Yes	80.0%	80.0%	100.0%	100.0%	85.7%
	No	20.0%	20.0%			14.3%
Total		100.0%	100.0%	100.0%	100.0%	100.0%

As seen in the above Table 4.8 only one criterion was used to observe the availability of equipment and stock in the clinics. It was observed that 85.7% (n=12) were compliant with availability of stock and equipment and 14.3% (n=2) clinics were non-compliant with this criteria.

4.3 SECTION A2: PHASE TWO – SELF-ADMINISTERED QUESTIONNAIRE

4.3.1 INTRODUCTION

The questionnaire was the primary tool used to collect data for phase two of the study. The questionnaire was distributed to registered and enrolled nurses at clinics within the uMgungundlovu district. The responses from the questionnaire were captured on Microsoft Excel and then transported into the Statistical Package for the Social Sciences (SPSS) database. This data was analysed using SPSS version 21.0. The descriptive statistics are presented in the form of graphs, cross

tabulations and other figures for the qualitative data that was collected. Inferential techniques include the use of correlations and chi-square test values; which are interpreted using the p-values.

4.3.2 THE SAMPLE

The sample consisted of enrolled and professional nurses at clinics within the uMgungundlovu district. In total, 377 questionnaires were administered and 276 were returned which gave a response rate of 80%.

4.3.3 THE RESEARCH INSTRUMENT

The research instrument consisted of 76 items, with a level of measurement at a nominal or an ordinal level. The questionnaire was divided into three main sections which measured various themes as illustrated below:

Section A	: Biographical data
Section B	: Vaccine Management
Question B1	: Policy
Question B2	: Vaccine Management
Question B3	: Vaccine Refrigerator
Question B4	: Cold Boxes
Question B5	: Clinical Practice
Section C	: Guidelines and Policy

4.3.4 RELIABILITY OF THE RESEARCH INSTRUMENT

The reliability of the research instrument refers to the adequacy with which items in the instrument measure what they are intended to measure. Cronbach's alpha is a measure of internal consistency within the research instrument and demonstrates how closely related a set of items are as a group. Cronbach's alpha coefficient was calculated to determine the internal reliability of the research instrument and indicates the reliability of the data collected through the research instrument. Table 4.9 reflects the Cronbach's alpha score for all the items that constituted the questionnaire.

Table 4.9: Cronbach's Alpha Coefficient

Question	Section	Number of Items	Cronbach's Alpha
B1	Policy	4 of 4	.877
B2	Vaccine Management	16 of 16	.657
B3	Vaccine Refrigerator	26 of 26	.879
B4	Cold Boxes	8 of 8	.768
B5	Clinical Practice	5 of 7	.709
Overall		61 of 61	.925

A reliability coefficient of 0.70 or higher is considered acceptable according to Polit and Beck (2008: 453). As can be seen from Table 4.9 all questions in Section B of the questionnaire meet the minimum requirement value, with only Question B2 being slightly below.

The overall reliability score of 0.925 exceeds the recommended value of 0.70. This indicates a high overall degree of acceptable, consistent scoring for the items and it can be concluded that the research instrument is highly reliable.

4.3.5 PRESENTATION OF THE RESULTS

This section presents the results of the self-administered questionnaire.

4.3.5.1. SECTION A – BIOGRAPHICAL DATA

This section summarises the biographical characteristics of all respondents who participated in this study. This included: types of clinics, age, gender and racial distribution, experience and professional or enrolled nurse.

4.3.5.1.1. TYPES OF CLINICS

The types of clinics that were sampled were classified as urban, rural or mobile clinics. The break-down of these classifications are illustrated in Figure 4.1.

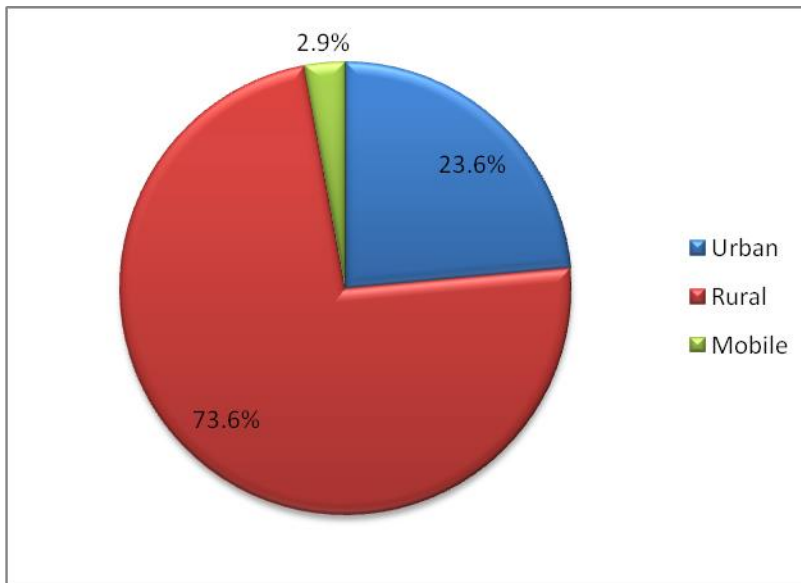


Figure 4.1: Types of Clinics

Figure 4.1 shows that nearly three-quarters or 73.6% (n=203) of participants worked in rural clinics, followed by 23.6% (n=65) of participants from urban clinics, with the smallest number of participants with 2.9% (n=8) working in mobile clinics.

4.3.5.1.2. AGE, GENDER AND RACE DISTRIBUTION

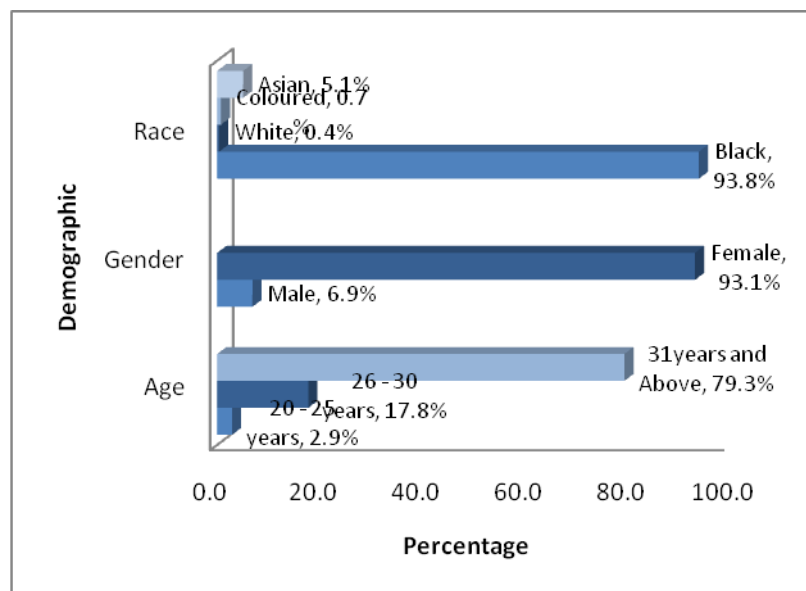


Figure 4.2: Age, Gender and Race Distribution

The sample consisted of participants of various races. The breakdown of this being, Asian 5.1% (n=14), Coloured 0.7% (n=2), White 0.4% (n=1) with the majority of participants being Black with 93.8% (n=259).

The ratio of males to females who participated in this study was approximately 1:13, with males forming 6.9% (n=19) and females forming 93.1% (n=257) of the population, respectively. The age of participants in this study ranged from 20 to above 31 years, with 2.9% (n=8) of the participants between 20 and 25 years old, 17.8% (n=49) of participants between 26 and 30 years of age and the majority of participants older than 31 years old, forming 79.3% (n=219) of the total.

4.3.5.1.3. EXPERIENCE

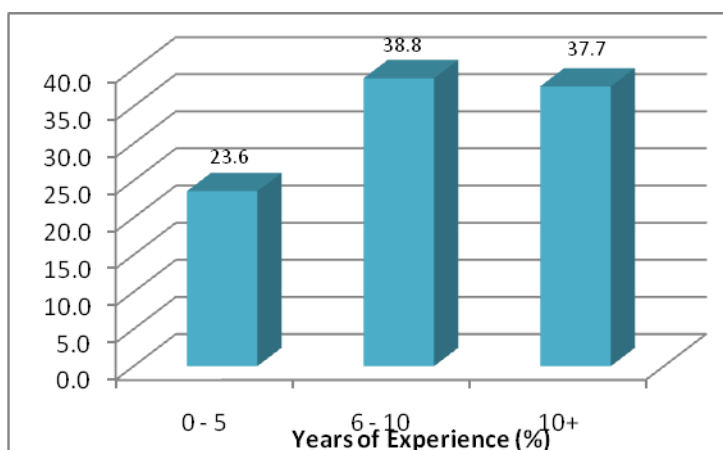


Figure 4.3: Experience of the respondents

37.7% (n=104) of the sample had more than 10 years of work experience. The majority of participants 38.8% (n=107) had between six and ten years of work experience, with only 23.6% (n=65) of participants having worked for less than 5 years. More than three-quarters of the participants (76.4%) had more than 5 years' experience and 37.7% (n=104) had more than 10 years of work experience. The constitution of the sample indicates a mature and experienced grouping of respondents. This is useful as the responses derived can be regarded as informed opinion. This is also borne out in terms of the consistent scoring as observed from the high reliability values.

4.3.5.1.4 TRAINING IN VACCINE MANAGEMENT

Table 4.10: Training in vaccine management and involvement in vaccine management

	Involved in vaccine management	Total
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		Yes	No	Sometimes	
Training in vaccine management	Count	120	14	70	204
	% within Training in vaccine management	58.8%	6.9%	34.3%	100.0%
	% within Involved in vaccine management	88.2%	28.0%	77.8%	73.9%
	% of Total	43.5%	5.1%	25.4%	73.9%
	Count	16	36	20	72
	% within Training in vaccine management	22.2%	50.0%	27.8%	100.0%
	% within Involved in vaccine management	11.8%	72.0%	22.2%	26.1%
	% of Total	5.8%	13.0%	7.2%	26.1%
Total	Count	136	50	90	276
	% within Training in vaccine management	49.3%	18.1%	32.6%	100.0%
	% within Involved in vaccine management	100.0%	100.0%	100.0%	100.0%
	% of Total	49.3%	18.1%	32.6%	100.0%

The cross-tabulation in Table 4.10 reveals that 58.8% (n=120) of participants who are trained in vaccine management are involved in vaccine management whereas 6.9% (n=14) of participants who are trained in vaccine management are not involved in vaccine management. 34.3% (n=70) of participants who are trained in vaccine management are sometimes involved in vaccine management.

From Table 4.10 it is also evident that 22.2% (n=16) who are not trained in vaccine management are involved in vaccine management. The majority of participants, 50.0% (n=36) who have indicated that they are not trained in vaccine management, are also not involved in vaccine management. In addition to this, 27.8% (n=20) of participants who are not trained in vaccine management, are sometimes involved in vaccine management.

4.3.5.1.4 REGISTERED AND ENROLLED NURSES

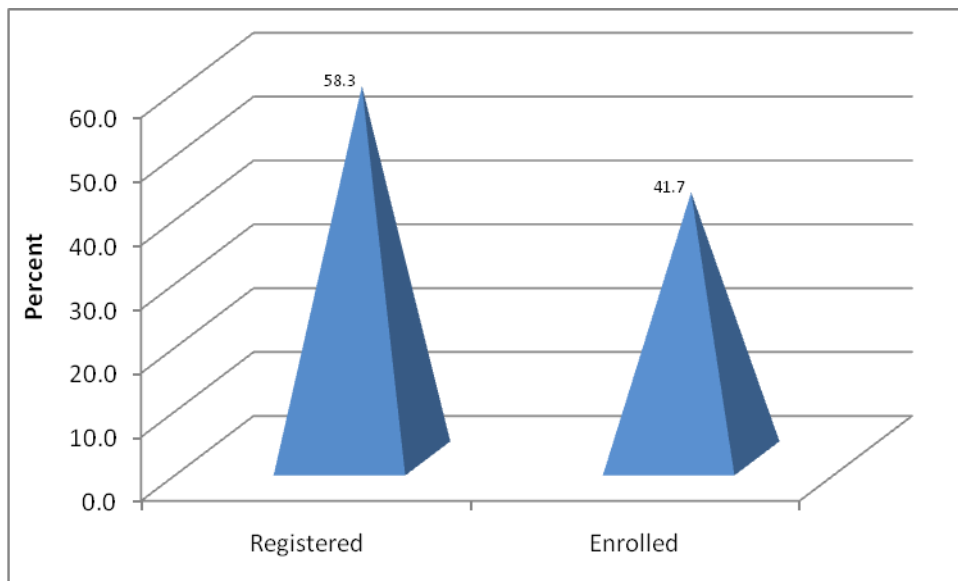


Figure 4.4: Classification of the nurses

The ratio of Registered nurses to Enrolled nurses was approximately 3:2, with 58.3% (n=161) of participants indicating that they were registered nurses and 41.7% (n=115) being enrolled nurses.

4.3.5.2. SECTION B – VACCINE MANAGEMENT

The section that follows analyses the scoring patterns of the participants per variable per section. Negative statements were categorised as “Never” and positive were labelled “Always”. The results are first presented using summarised percentages for the variables that constitute each section. Results are then further analysed according to the importance of the statements.

4.3.5.2.1. QUESTION B1: POLICY

This section deals with cold chain policies. The summarised scores are represented in Figure 4.5.

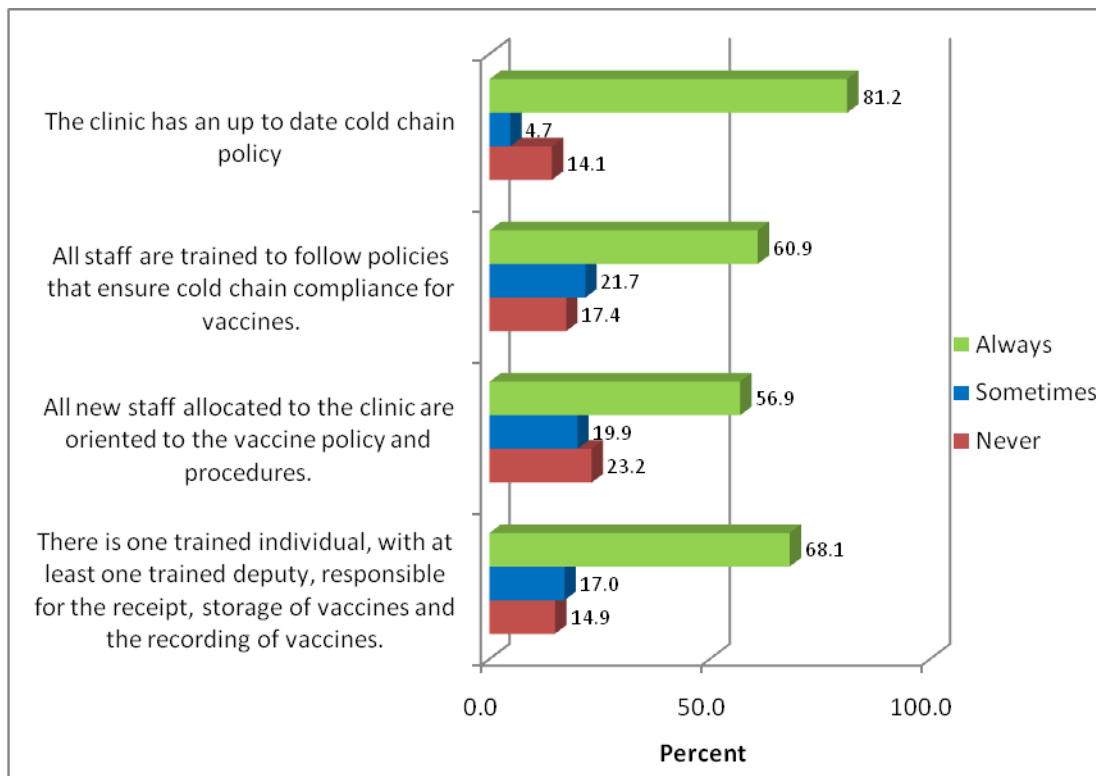


Figure 4.5: Cold chain policies

Figure 4.5 shows that a large number of participants, 81.2% (n=224) agree that the clinic always has an up to date cold chain policy while 14.1% (n=39) indicate that the clinic never has an up to date cold chain policy and a small number 4.6% (n=12) have indicated that the clinic sometimes has a cold chain policy that is up to date.

The results show that 60.9% (n=168) believe that all staff are trained to follow policies that ensure cold chain compliance for vaccines whereas only 17.4% (n=48) believe that staff are not trained and 21.7% (n=60) believe that staff are sometimes trained to follow these policies.

The results further show that 56.9% (n=157) of all new staff allocated to the clinic are always oriented to the vaccine policy and procedures, 19.9% (n=55) indicated that staff are sometimes trained and 23.2% (n=64) stated that new staff are never oriented to the vaccine policy and procedures.

In addition to the above, the results show that 68.1% (n=188) of participants indicate that there is one trained individual with at least one trained deputy

responsible for the receipt and storage of vaccines and the recording of vaccines while 14.9% (n=41) state that this is never the case and 17.0 % (n=47) indicate that this is sometimes the case.

The average score for “Always” for this section is 66.8%.

There was large number of respondents 81.2% (n=224) who believed that the clinics have an up-to-date cold chain policy. The other statements have levels of agreement with “Always” 62% of the time. For these statements, there are as many respondents who chose “Sometimes” as those who selected “Never”.

To determine whether the differences were significant, chi-square tests were done by variable. The null hypothesis tested the claim that there were no differences in the scoring options per statement. The results are shown in Table 4.11.

Table 4.11: Chi-square Tests

	Chi-Square	df	Asymp. Sig.
The clinic has an up to date cold chain policy	287.761	2	.000
All staff are trained to follow policies that ensure cold chain compliance for vaccines.	94.957	2	.000
All new staff allocated to the clinic are oriented to the vaccine policy and procedures.	69.326	2	.000
There is one trained individual, with at least one trained deputy, responsible for the receipt, Storage of vaccines and the recording of vaccines.	150.457	2	.000

Since all of the significance values (p-values) are less than 0.05 (the level of significance), it implies that the distributions per option were not even. That is, the differences between “Always”, “Sometimes” and “Never” were significant. Further, this means that all the differences observed in all of the graphs are significant (see Appendix10 – Excel table).

4.3.5.2.2. QUESTION B2: VACCINE MANAGEMENT

This section deals with management of vaccines as listed in the sixteen criteria below. The summarised scores are shown in Figure 4.6.

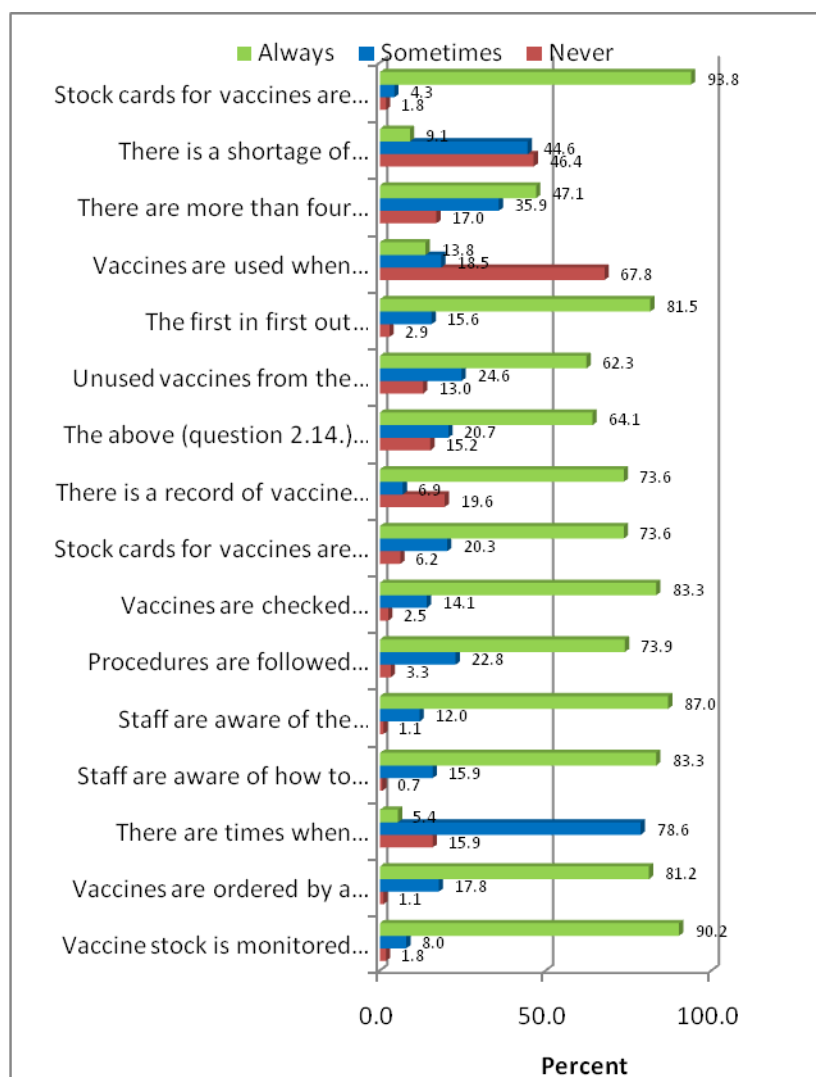


Figure 4.6: Vaccine Management

Findings were as follows:

- A large majority of participants, 93.8% (n=259) indicate that stock cards for vaccines are always kept with only 4.3% (n=12) indicating that this is sometimes the case and a small number 1.8% (n=5) indicating that this is never the case.
- With regard to vaccine management 46.4% (n=128) have specified that there is never a shortage of needles, syringes and sharp containers with 44.6% (n=123) indicating that there is sometimes a shortage and only 9.1% (n=25) indicating that there is always a shortage in their clinic.

- 47.1% (n=130) indicated that there is always more than a four week supply in the refrigerator while 35.9% (n=99) stated that this is sometimes the case and 17.0% (n=47) stated that this is never the case.
- The majority of participants, 67.8% (n=187), specified that vaccines are never used when the inner square is as dark as the outer circle or darker. 18.5% (n=51) state that this is sometimes the case and 13.8% (n=38) indicated that vaccines are always used when the inner square is as dark as the outer circle or darker.
- A large majority 81.5% (n=225) indicated that the first-in first-out principle applies when packing and using vaccines. 15.6% (n=43) stated that this principle is sometimes applied with a small percentage and 2.9% (n=8) stated that this principle is never applied.
- 62.3% (n=171) stated that unused vaccines from the clinic session are clearly marked as being out. 24.6% (n=68) stated that this sometimes happens and 13.0% (n=36) indicated that this never happens.
- 64.1% (n=177) indicated that unused vaccines from the above results are used in the next clinic session. 20.7% (n=57) stated that this is sometimes followed while 15.2% (n=42) indicated that this principle is never followed.
- 73.6% (n=203) of participants stated that in the case of recall, there is a record of vaccine batches, while 6.9% (n=19) stated that records are sometimes kept and 19.6% (n=54) stated that records are never kept in case of recall.
- 73.6% (n=203) of participants assured that stock cards for vaccines were correctly filled in, while 20.3% (n=56) stated that cards are sometimes correctly filled in and a small 6.2% (n=17) of respondents stated that stock cards are never filled in correctly.
- 83.3% (n=230) of participants agreed that vaccines were always checked against the order for discrepancies and leakage. 14.1% (n=39) indicated that vaccines are sometimes checked and only 2.5% (n=7) stated that vaccines are never checked against orders.
- 73.9% (n=204) stated that procedures for recording the date and time, vaccine types brands, quantities, batch numbers and expiry are always followed when vaccines are received, while 3.3% (n=9) stated that these

procedures are never followed and 22.8% (n=63) stated that these procedures are sometimes followed.

- 87.0% (n=240) of participants indicated that staff are always aware of the urgency of packing vaccines immediately on receipt. 12.0% (n=33) of nurses stated that staff sometimes pack vaccines on receipt while a small number of respondents 1.1% (n=3) say that staff never pack vaccines immediately on receipt.
- A large majority of participants 83.3% (n=203) perceived that staff are aware of how to read and check the cold chain monitor when unpacking vaccines. 15.9% (n=44) perceived that staff are sometimes aware to go about doing this and a negligible 0.7% (n=2) perceived that staff are never aware of doing this.
- A small number of participants 5.4% (n=15) stated that there are always times when vaccines are out of stock whereas 78.6% (n=217) stated that this is sometimes the case and 15.9% (n=44) stated that this is never the case.
- 81.2% (n=224) of participants stated that vaccines are always ordered by a designated person. 17.8% (n=49) stated that vaccines are sometimes ordered by a dedicated person and 1.1% (n=3) stated that there is no dedicated person to order vaccines.
- The majority of the participants, 90.2% (n=249) stated that vaccine stock is always monitored prior to ordering. 8.0% (n=22) stated that vaccine stock is sometimes monitored before ordering and a small percentage of respondents 1.8% (n=5) stated that vaccine stock is never monitored prior to ordering.

QUESTION B3: VACCINE REFRIGERATOR

This section is concerned with maintenance of the cold chain for vaccines in the refrigerator. As listed below, 26 criteria were used in the questionnaire for the vaccine refrigerator. In order to present these results the criteria was divided into different themes: criteria pertaining to the refrigerator, signage on refrigerator, temperature monitoring, storage of vaccines, interruption in electricity supply and power failure. The summarised scores are indicated in Table 4.18.

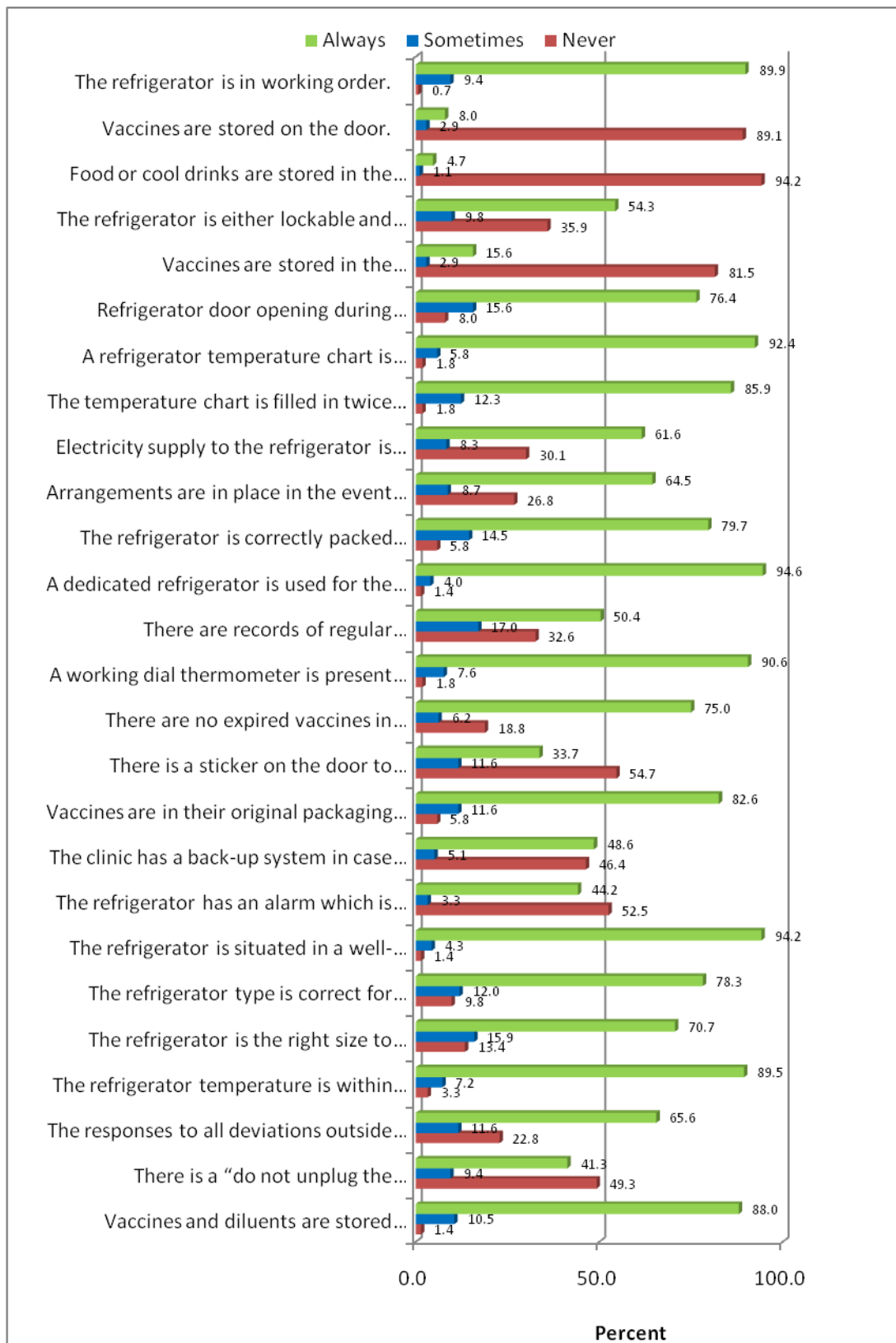


Figure 4.7: Vaccine Refrigerator

4.3.5.2.2.1. CRITERIA RELATED TO THE REFRIGERATOR

- At the local clinics 78.3 % (n=216) of participants agreed the correct type of refrigerator is always used to store vaccines, 9.8 % (n=27) indicated that this is sometimes and 12.0% (n=33) that this never the case.
- 70.7% (n=195) of participants agreed that the refrigerator is the correct size for storage of vaccines, 15.9% (n=43) indicated that this is sometimes and 13.4% (n=38) that this is never the case.
- A large majority of participants, 89.9% (n=248) indicated that the refrigerator is always in working order, 9.4% (n=26) indicated that this is sometimes and a small number 0.5% (n=2) that this is never the case.
- 94.6% (n=261) of participants agreed that the refrigerator is always dedicated for storage of vaccines only, with 4.0% (n=11) indicating sometimes and 1.4% (n=4) indicating never.
- 50.4% (n=139) of participants agreed that there are always records of regular servicing, defrosting and cleaning of the refrigerator, while 17.0% (n=47) agreed that this is sometimes the case and 32.5% (n=90) that this is never the case .
- 94.2% (n=260) of clinic nurses responded that the refrigerator is situated in a well-ventilated area, away from sunlight and heat. 4.3% (n=12) agreed this is sometimes the case and 1.4% (n=4) agreed that this is never the case.
- 44.2% (n=122) of participants agreed that the refrigerator is always fitted with an alarm to detect cold chain breaches, 52.5% (n=145) responded never and 3.3% (n=9) responded sometimes.
- 54.3% (n=150) of participants stated that the refrigerator is always either locked or stored in a lockable room. 9.8% (n=27) responded sometimes and 35.9% (n=99) responded never.

4.3.5.2.2.2. CRITERIA RELATED TO THE TEMPERATURE OF THE REFRIGERATOR

- 92.4% (n=255) of clinic nurses responded that the temperature chart is always placed on the refrigerator and recordings were kept. 5.8% (n=16) responded sometimes and 1.8% (n=5) responded never.
- 85.9% (n=237) of participants responded that the temperature of the fridge is always documented twice daily on the temperature chart. 12.3% (n=34) responded sometimes and 1.8% (n=5) responded never.
- 89.5% (n=247) of the participants responded that the refrigerator is always within the correct temperature range of two degrees to eight degrees Celsius. 7.2% (n=20) responded sometimes and 3.3% (n=9) responded never.
- 65.6% (n=181) responded that deviations in the refrigerator are documented and necessary actions are always taken. 11.6% (n=32) responded sometimes and 22.8% (n=63) responded never.
- The majority of participants, 90.6% (n=250) responded that there is a working dial thermometer in the centre of the refrigerator. 7.6% (n=21) responded sometimes and 1.8% (n=5) responded never.

4.3.5.2.2.3. CRITERIA RELATED TO SIGNAGE ON REFRIGERATOR

- In 33.7% (n=93) of the clinics participants responded that there is always signage on the refrigerator informing staff not to open “vaccine fridge”. 11.6% (n=32) of the participants responded sometimes and 54.7% (n=151) responded never.
- In 41.3% (n=113) of the clinics participants responded that there is always a “do not unplug” sign on the vaccine refrigerator. 9.4% (n=27) of the participants responded sometimes and 49.3% (n=136) of the participants responded never.

4.3.5.2.2.4. CRITERIA RELATED TO INTERRUPTION IN ELECTRICITY SUPPLY AND POWER FAILURE

- 61.6% (n=170) of participants in local clinics responded that the electricity supply to the refrigerator is always safe. 8.3% (n=23) responded sometimes and 30.1% (n=83) responded never.
- At the local clinics 48.6% (n=145) of participants responded that there is a backup system in place for vaccine management in case of power failure. 5.1% (n=5) responded sometimes and 46.4% (n=128) responded never.
- 64.5% (n=178) of participants responded that arrangement were in place in case of refrigerator failure or power failure. 8.7% (n=24) responded sometimes and 26.8% (n=74) responded never.

4.3.5.2.3. CRITERIA RELATED TO STORAGE IN REFRIGERATOR

- The majority of participants, 89.1% (n=245) responded that there is always no vaccines stored on the door of the refrigerator. 1.9% (n=9) of participants responded sometimes and 8.0% (n=22) responded never.
- 94.2% (n=260) of participants agreed that no food or cool drinks were ever stored in the refrigerator. 1.1% (n=3) responded sometimes and 4.7% (n=13) responded always.
- 79.7% (n=219) of participants responded that vaccines are always correctly packed in refrigerator with air circulating in between vaccines while 14.5% (n=40) responded sometimes and 5.8% (n=17) responded never.
- 75.0% (n=207) of participants responded that there is always no expired vaccines in the refrigerator while 6.2% (n=17) responded sometimes and 18.8% (n=52) responded never.
- The majority of participants, 82.6% (n=228) responded that vaccines were always in their original packaging and included the information leaflet while 11.6% (n=32) responded sometimes and 5.8% (n=16) responded never.
- The majority of participants, 88.0% (n=242), responded that vaccines and diluents were always stored correctly while 10.5% (n=28) responded sometimes and 1.4% (n=4) responded never.

4.3.5.2.4. QUESTION B4: COLD BOXES

This section deals with the management of vaccines in the cold box during an immunisation session. These results are presented in Figure 4.8.

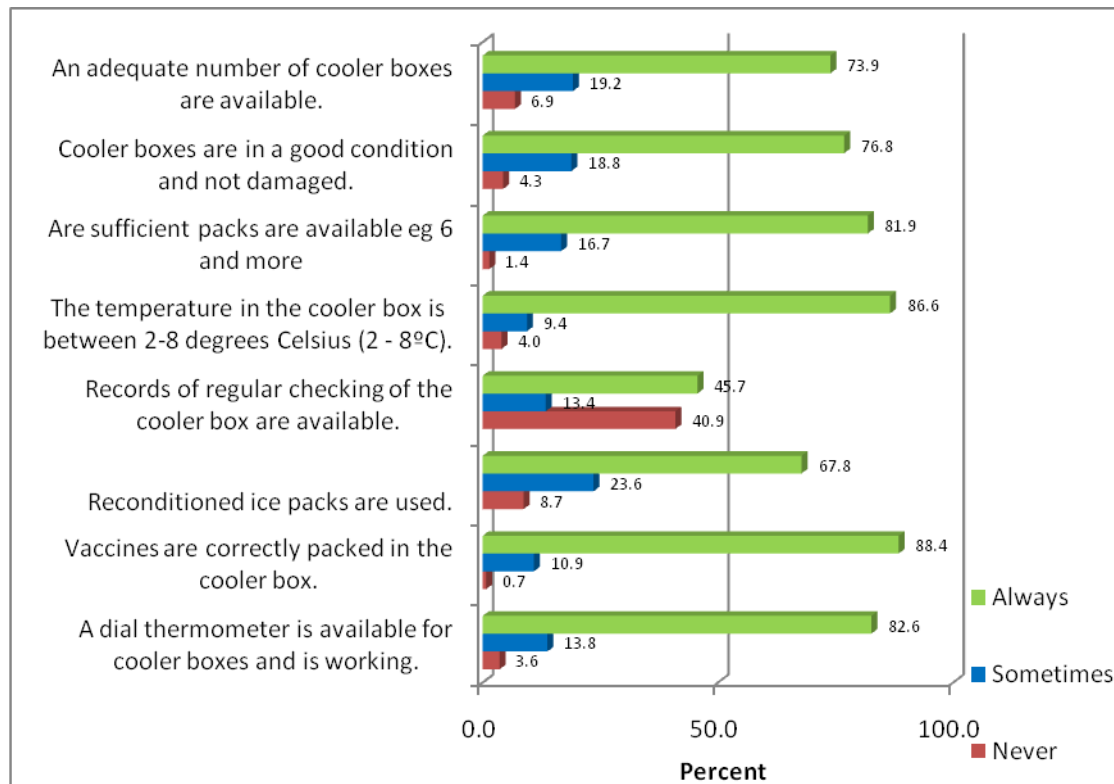


Figure 4.8: The Cold Box

- In regard to cold boxes, the results show that 73.9% (n=204) believe that there is always an adequate number of cooler boxes available while 19.2% (n=53) believe that there is sometimes an adequate number of cooler boxes available and 6.9% (n=19) believe that there is never an adequate number of cooler boxes available.
- 76.8% (n=212) of participants believe that cooler boxes are in a good condition while 18.8% (n=52) believe that cooler boxes are in a good condition sometimes and 4.3% (n=12) believe that cooler boxes are never in a good condition.
- A large number of participants 81.9% (n=226) state that there are always sufficient ice packs available while 16.7% (n=46) state that there are sometimes sufficient packs available while 1.4% (n=4) state that there are never sufficient packs available.

- The majority of participants 86.6% (n=239) indicated that the temperature in the cooler box is between two to eight degrees Celsius while 9.4% (n=26) indicated that this is sometimes the case and 4.0% (n=11) indicated that the temperature is never the case.
- 45.7% (n=126) of participants state that records of regular checking of the cooler box are available while 13.4% (n=37) stated that these records are sometimes available and 40.9% (n=113) indicated that these records are never available.
- 67.8% (n=187) of participants indicated that reconditioned ice packs are always used, 23.6% (n=65) stated that reconditioned ice packs are sometimes used and 8.7% (n=24) stated that reconditioned ice pack are never used.
- A large majority 88.4% (n=244) of nurses stated that vaccines are always correctly packed in the cooler box, 10.9% (n=30) that they are sometimes packed correctly and a negligible 0.7% (n=19) stated that they are never packed correctly.
- The results show that 82.6% (n=228) stated that a dial thermometer is always available for cooler boxes and is working, 13.8% (n=38) stated that a thermometer is sometimes available and 3.6% (n=10) indicated that a thermometer is never available.

4.3.5.2.5. QUESTION B5: CLINICAL PRACTICE

This section investigates the staff awareness of management of allergic reactions to vaccines, the procedure for reconstitution of vaccines and performance of the shake test. These results are presented in the Figure 4.9.

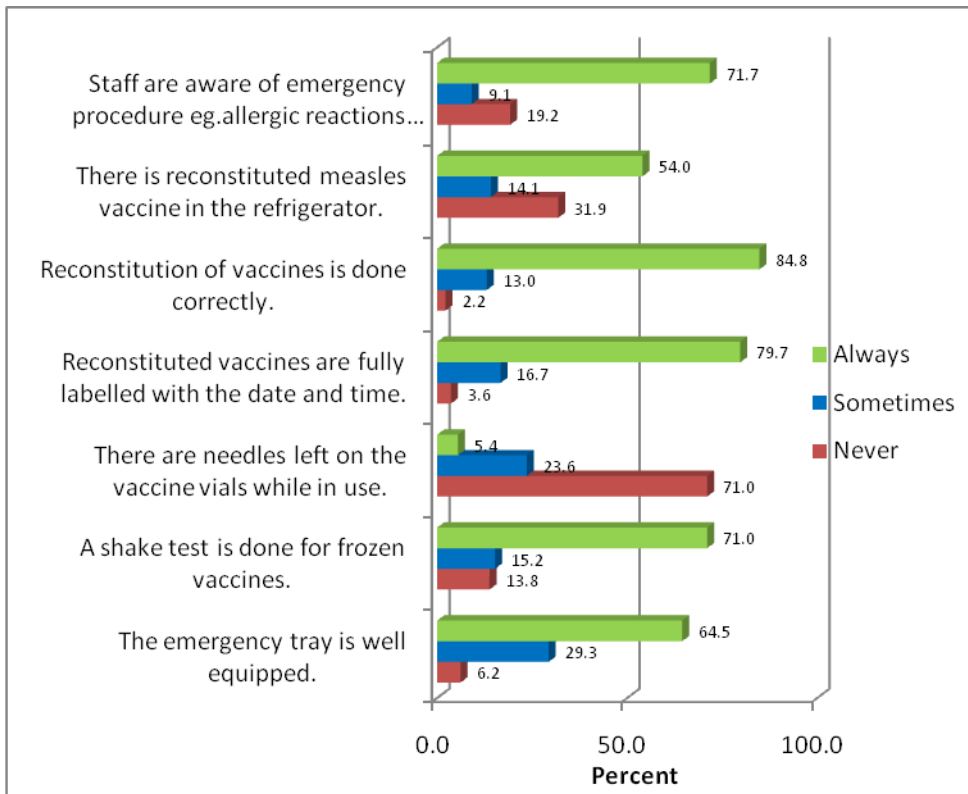


Figure 4.9: Clinical practice of vaccines

- Results indicate that 71.7% (n=198) of participants are always aware of emergency procedure, 9.1% (n=25) are sometimes aware and 19.2% (n=53) are never aware.
- 54.0% (n=149) of participants stated that there is always reconstituted measles vaccine in the refrigerator, 14.1% (n=39) stated that there is sometimes reconstituted measles vaccine in the refrigerator and 31.9% (n=88) stated that this is never the case.
- 84.8% (n=243) of participants stated that reconstitution of vaccines is always done correctly, 13.0% (n=36) of respondents indicated that this is sometimes done correctly and 2.2% (n=6) of respondents indicated that this is never done correctly.
- 79.7% (n=219) of participants stated that reconstituted vaccines are always labelled correctly, 16.7% (n=47) of respondents indicated that this is sometimes done correctly and 3.6% (n=10) indicated that this is never done correctly.
- A small number of participants 5.4% (n=15) stated that there are always needles left on the vaccine vials while in use, 23.6% (n=66) stated that this

sometimes occurs and the majority 71.0% (n=195) stated that this never happens.

- 71.0% (n=195) of nurses stated that a shake test is always done for frozen vaccines, 15.2% (n=42) stated that a shake test is sometimes done and 13.8% (n=39) indicated that a shake test is never done.
- 64.5% (n=178) of nurses have stated that the emergency tray is always well equipped, 29.3% (n=81) that the tray is sometimes well equipped and 6.2% (n=19) stated that the emergency tray is never well equipped.

4.3.5.3. QUESTION C: GUIDELINES AND POLICY

This section investigates the Guidelines and Policy pertaining to emergency plans for breakdown of cold chain equipment, power failure, vaccine wastage and policy on cold chain failure. These are presented in Figure 4.10.

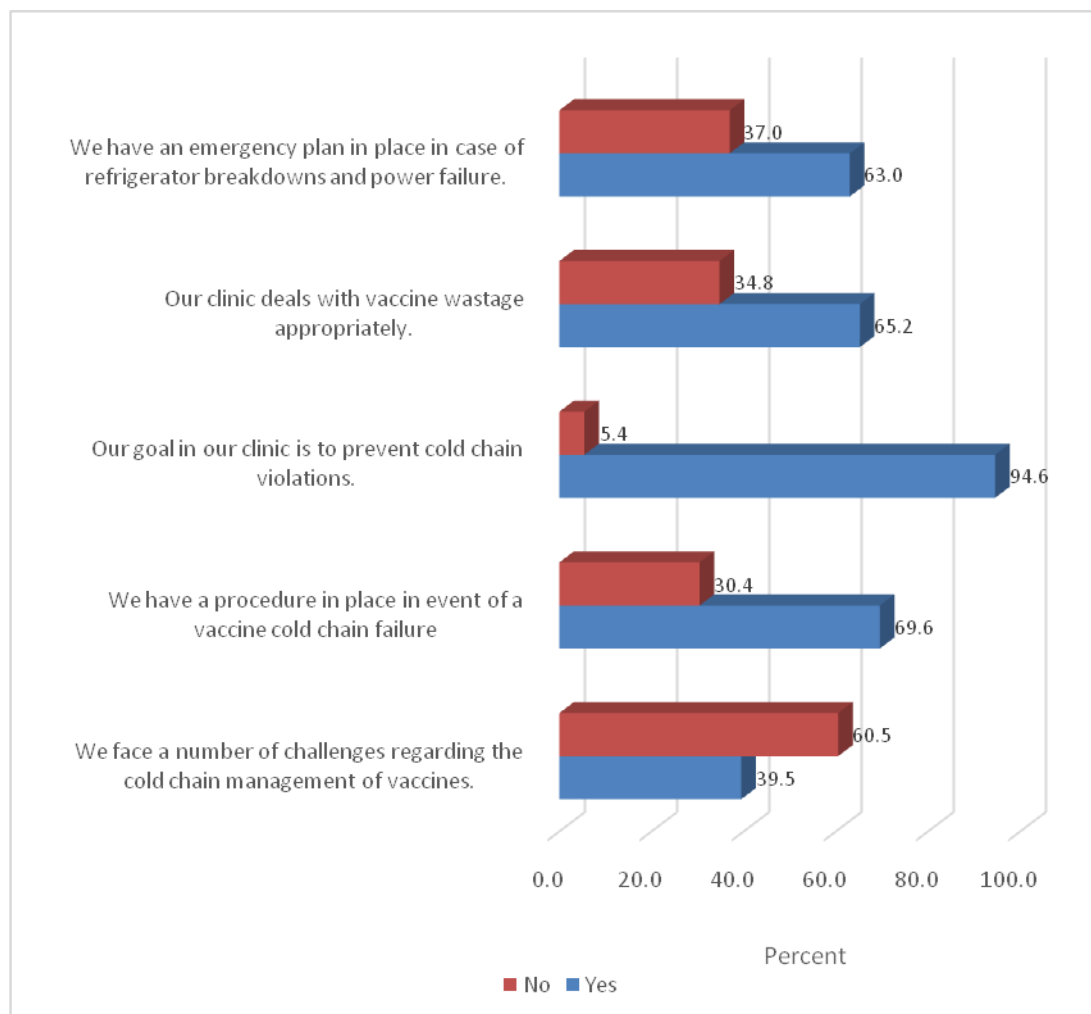


Figure 4.10: Guidelines and policy

- In regard to guidelines and policy, 63.0% (n=174) indicated that there is an emergency plan in place in case of refrigerator breakdown and power failure whilst 37.0% (n=102) stated that there is no emergency plan in place.
- 65.2% (n=180) state that their clinic deals with wastage appropriately whilst 34.8% (n=96) stated that their clinics do not.
- 94.6% (n=261) of participants stated that it is not their goal to prevent cold chain violations whilst only 5.4% (n=15) stated that this is the goal in their clinic.
- 30.4% (n=84) of participants stated that there is a procedure in place in event of a vaccine cold chain failure whilst a large number 69.6% (n=192) stated that there is not.
- 60.5% (n=167) stated that they face a number of challenges in the cold chain management of vaccines whilst 39.5% (n=109) of nurse have said that they do not.

4.3.6. HYPOTHESIS TESTING

The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result is indicated with "p < 0.05". These values are highlighted with an*.

The Chi square test was performed to determine whether there was a statistically significant relationship between the variables (rows vs columns).

The null hypothesis states that there is no association between the two. The alternate hypothesis indicates that there is an association.

The table in Appendix 10 summarises the results of the chi square tests.

The p-value between "Experience" and "There is one trained individual, with at least one trained deputy, responsible for the receipt, storage of vaccines and the

recording of vaccines.” is 0.017 (which is less than the significance value of 0.05). This means that there is a significant relationship between the variables. That is, the experience of a respondent does play a role in terms of whether there is a trained individual available to perform the necessary duties. The direction of the scores can be obtained from the frequency tables in the appendix.

All values without an * (or p-values more than 0.05) do not have a significant relationship.

4.3.7. CORRELATIONS

Bivariate correlation was also performed on the (ordinal) data.

The results indicate the following patterns.

Positive values indicate a directly proportional relationship between the variables and a negative value indicates an inverse relationship. All significant relationships are indicated by a * or **.

For example, the correlation value between “All new staff allocated to the clinic are oriented to the vaccine policy and procedures.” and “There is one trained individual, with at least one trained deputy, responsible for the receipt, storage of vaccines and the recording of vaccines.” is 0.565. This is a directly related proportionality. Respondents agree that the more new staff are trained, the more likely there will be at least one member who will be trained to carry out the necessary duties.

Negative values imply an inverse relationship. That is, the variables have an opposite effect on each other.

For example: The correlation value between “Staff are aware of the urgency of packing vaccines immediately on receipt.” and “There is a shortage of needles, syringes, and sharp containers” is -0.148. Respondents indicate that the more staff are aware of packing vaccines on receipt, the less likely there will be shortages.

4.4. CONCLUSION

This chapter presented the results obtained from this study. Section A1 of this chapter presented results of the observation study. Section A2 of this study presented the results of the self-administered questionnaire. The results of the study will be discussed in the following chapter.

CHAPTER 5: DISCUSSION OF THE RESULTS

5.1 INTRODUCTION

In this chapter, the results presented in the previous chapter will be discussed. Conclusions will be drawn and limitations to the study as well recommendations will be discussed later.

Section A1 below discusses the findings related to the observation study. This is followed by Section A2, which discusses the findings related to the self-administered questionnaire.

The discussion is based on the study objectives, namely:

- To compare current processes of the cold chain management of vaccines in PHC clinics against best practice and in accordance with global, national and provincial guidelines;
- To investigate current processes of the cold chain management of vaccines by nurses in PHC clinics; and
- To contribute to the current body of knowledge and recommend potential solutions to the problems encountered in the cold chain management of vaccines in PHC clinics.

5.2. SECTION A1: OBSERVATION STUDY (PHASE ONE)

For the duration of the observation study the researcher was stationed in the immunisation room from 08: 00 a.m. to 04: 00 p.m. at a clinic daily for 14 days. During this time the nurse in the immunisation room for that day was observed. Using the structured observation guide the researcher noted how the nurse maintained the cold chain for vaccines. The actual immunisation procedure was not observed. For the purpose of this study the researcher requested to view all policies, procedures and documentation pertaining to cold chain management of vaccines in local clinics.

5.2.1. CURRENT PROCESSES OF COLD CHAIN MANAGEMENT

Health care providers who administer vaccines should evaluate their vaccine cold chain policies and procedures on a regular basis to ensure that best practices are followed. All health care facilities should develop a detailed plan on all aspects of vaccine management. This plan should include vaccine ordering, storing of vaccines and monitoring storage conditions (The Vaccine Storage and Handling Toolkit, 2012: 13).

5.2.1.1. POLICIES, PROCEDURES AND GUIDELINES

The observation study revealed that policy, procedures and guidelines were available. However, on most occasions policy had not been implemented. Each immunisation service must have written policies, procedures and protocols in place (National Vaccine Storage Guidelines Strive for 5, 2013: 8).

Health care facilities should develop and adhere to detailed written routine vaccine storage and handling plan that is updated annually. A written plan helps vaccine providers to remain organised and serves as a reference and training tool as well as providing assurance of proper vaccine management and prevention of vaccine wastage (The Vaccine Storage and Handling Toolkit, 2012: 13). A possible recommendation is that a professional nurse be appointed to constantly examine and evaluate the policies, procedures and guidelines relating to vaccine management. Furthermore it is also recommended that there are regular meetings set up between the professional nurses and the enrolled nurses who are involved in vaccine management so that problems can be solved and matters pertaining to policy, procedures and guidelines can be discussed (WHO, 2005: 79). This proposal is clearly delineated in the Vaccine Management Assessment Tool, WHO (2005) and EPI Cold Chain Standard Operating Procedure Manual (2009). All staff employed at the local clinics must be encouraged to familiarise themselves with policy, procedure and guidelines pertaining to vaccine management in order to ensure the success of immunisation programmes.

It was observed in this study that there were no written contingency plans in place for problems associated with equipment and electricity used for cold chain management of vaccines. Some verbally communicated what actions would be taken in an emergency situation to ensure vaccines are not compromised and the cold chain system is still managed effectively, but there was no evidence of written documentation in this regard.

According to the National Vaccine Storage Guideline Strive for 5 (2013: 8) the following records must be maintained:

- Servicing of the refrigerator and data logger;
- Checking the accuracy of thermometers and batteries;
- Cleaning the refrigerator; and
- Policy in case of power failure.

One cannot overemphasize the importance of a backup plan to deal with problems of equipment being affected by electricity. There has to be some kind of foresight with a contingency plan in place such as a petrol or diesel generator to overcome the problem of a lack of electricity. It is thus imperative that nursing staff develop and communicate their backup plans to senior management of the clinics so that appropriate allocations can be made in the budget to purchase the required equipment so that it is in place when the need arises for implementation of such plans.

The results of the study further revealed that no policy and no reports or monitoring system were available to prevent or control vaccine wastage. According to Watson (2004: 1-3), a written vaccine accountability reporting system is an essential component of any immunisation programme. The author further suggests that vaccine accountability is addressed by:

- Ensuring vaccine loss and wastage is measured;
- Funded vaccines reach the target group;
- Fraud and abuse is eliminated; and
- Always consider budget planning and forecasting for vaccines.

This finding is also noted in studies conducted by Bankole *et al.*, (2010: 78), Carr, Byles and Durrheim (2009: 36) and Thakker and Woods (1992: 756). The recommendation is thus that the senior professional nurse takes responsibility for a policy report monitoring system since vaccines are an expensive commodity and those who administer them must become accountable and realize the seriousness of their role in immunisation programmes and society as a whole.

The results of this study further indicated that 100 percent of the clinics observed had no documentation on criteria for adverse incidents following immunisation. In addition, there were no training records, service room records and records for the maintenance of equipment.

In a study conducted in New Zealand between 2002-2008 the researchers randomly included temperature monitor cards in vaccines that were distributed from the national stores to delivery sites. During this time six monthly reports were documented and analysed to identify changes in freeze and heat exposure failures for vaccines. When cold chain failures were identified a range of changes were implemented such as improving equipment, systems, policies and procedures, education and training and increased provider attention, in order to strengthen the cold chain for vaccines (Turner and Roberts, 2011: 280). The study revealed that the heat failure in vaccines was reduced from 3 percent to 0.3 percent, freeze failures in vaccines decreased from 16 percent to 2 percent and overall vaccine wastage was reduced from 17 percent to 2 Percent (Turner, Laws and Roberts, 2011: 280). This study concluded that through improving equipment, systems, policies and procedures and education and training, vaccine wasting can be reduced thus reducing costs for the country.

Regular workshops and training on vaccine management for nurses at all levels are thus recommended at these 14 clinics. Such workshops should be compulsory for all nurses in the clinics so that there is holistic improvement in the immunisation programmes and as a result negligence or carelessness will not be prevalent in the immunisation programmes. It must then become a stringent policy that any nurse in an immunisation programme they must attend regular in-service training and workshops.

This observation study further revealed that 85.7 percent of nurses adhered to filling of stock cards. This observation is supported by EPI Cold Chain Standard Operating Procedure Manual (2009: 2) which recommends that stock cards must be kept for all vaccines, diluents and cold chain equipment. The stock cards must be kept up to date and must show all receipt and issues of stock and the balance of stock on hand. The manual further states that clinics must never run out of stock as an out of stock situation means missed opportunities and a breakdown in the EPI programme. The nurses should thus be able to act as stock controllers of the vaccines in their respective clinics as well. This finding is highlighted in the study conducted by Wiysonge *et al.*, (2012).

5.2.2. STANDARDS OF COLD CHAIN MANAGEMENT

Vaccines must be stored correctly from the time they are manufactured till they are administered to the patient. Excessive exposure of the vaccine to heat or cold will reduce its potency. Thus, children will not be protected against vaccine preventable diseases. The vaccine cold chain relies on three main elements. These elements include effectively trained personnel, appropriate transport and storage equipment and effective management procedures. These factors ensure a safe cold chain and potent vaccines (The Vaccine Storage and Handling Toolkit, 2012: 9).

5.2.2.1. VACCINE ARRIVAL PROCEDURES

The results of the study revealed that 42.9 percent of nurses observed responded immediately to the arrival of vaccines at the clinic and 57.1 percent did not respond immediately. The maintenance of the cold chain during distribution and arrival of vaccines to the facility is important to ensure the potency of vaccines (The EPI Cold Chain Standard Operating Procedure Manual, 2009: 4). Therefore it is necessary to carefully examine and check the quantity and quality of vaccines which are received.

This study further reveals that 50 percent of nurses checked vaccines for discrepancies, leakage and breakage and stored vaccines immediately on receipt and 50 percent were not compliant. The EPI Cold Chain Standard Operating Procedure Manual (2009: 4) states that the nurse involved in vaccine management must attend to received vaccines immediately and record any discrepancies, leakages and breakages on the delivery note. This is also supported by the Department of Public Health and Safety Health Policy and Strategy Sector - Immunisation Guidelines (2010).

The results of this study revealed that 64.3 percent of clinics were compliant with packing the vaccines according to the first-in-first-out principle and 35.7 percent were non-compliant with this principle. According to the National Vaccine Storage Guidelines-Strive for 5 (2013: 3) the vaccine stock must be rotated so that vaccines with the shortest expiry dates are used first. This practice ensures that vaccines are not wasted as a result of being compromised upon reaching the expiration date (National Vaccine Storage Guidelines-Strive for 5, 2013: 3). It was also observed that there were no checklists available for nurses on vaccines arrival procedures. It is thus recommended to nurses in the clinics who are not following these guidelines to swiftly start adhering to them since a tampered with or altered vaccine is money that is wasted which is unacceptable given the dire need for a healthy society in South Africa.

5.2.2.2. REFRIGERATOR

Analysis of the study results showed that 64.3 percent of the clinics stored vaccines in a refrigerator that was of the correct size, type and had a freezer compartment for icepacks. However, 35.7 percent of refrigerators used in clinics were not complaint. Of these five clinics, four clinics used domestic refrigerators and one clinic used a bar fridge to store vaccines. In one of these clinics the nurse stated that: "The freezer compartment is not working and I take the ice packs home on daily basis for freezing".

According to The National Vaccine Storage Guidelines Strive for 5 (2013: 7) domestic and bar refrigerators are not recommended for vaccine storage as they

increase the risk of adverse vaccine storage events. This is supported by the findings in a study conducted by Carr, Byles and Durrheim (2009: 35) in Australia which recommended that bar-type refrigerators should be outlawed for storage of vaccines as they posed an unacceptable threat to vaccine cold chain integrity. In the bar type fridge the temperatures fluctuated between too high or too low, leading to vaccines being subjected to too much heat or cold thus placing vaccines at a risk (Carr, Byles and Durrheim, 2009: 38). During observation of the clinic in this study that used a bar fridge the cold chain management for vaccines was not maintained according to the WHO guidelines for vaccine storage. In this clinic the fridge was overstocked, vaccines were stored in the door and no thermometer was available to check fridge temperature. This lack of management will have led to vaccines becoming compromised. Such losses in potency of vaccines result in potential danger to patients who receive these vaccines, as well as a financial loss for immunisation programmes due to vaccines been ineffective after being exposed to freezing or to high temperatures. In a similar study conducted in Australia the author recommends that a purpose built refrigerator to store vaccines is more effective than the bar-type refrigerator. The author further states that the temperature control is uneven in different parts of the bar-type fridge. In contrast the purpose built vaccine refrigerators feature a stable, uniform and controlled temperature (Page, 2008: 892).

The findings of the study further revealed that 57.1 percent of the clinics observed maintained the correct fridge temperature between two to eight degrees Celsius and 28.6 percent recorded the temperature twice a day. However, 42.9 percent of the clinics failed to maintain the correct refrigerator and 71.4 percent failed to record the refrigerator temperature twice daily. According to The Vaccine Storage and Handling Toolkit (2012: 53) vaccines must be stored at a temperature of between two to eight degrees Celsius. Exposure outside this range may result in reduced vaccine potency and increased risk of vaccine preventable diseases. The temperature recording chart should be kept on the outside door of the fridge as it is visible to all staff.

Nelson *et al.*, (2007:433), Nelson *et al.*, (2004: 99), Ren *et al.*, (2009: 745), Techatawat *et al.*, (2007: 1328), Turner, Laws and Roberts (2011: 278), Wirkas *et*

al., (2007: 691) and Zipursky *et al.*, (2011: 34) conducted studies in Bolivia, Indonesia, China, Thailand, Papua New Guinea and Chad respectively, on how vaccines which are exposed to freezing temperatures lose their potency due to the inactivation of key organic components. Such losses in potency of vaccines result in potential danger to patients who receive these vaccines, as well as a financial loss for immunisation programmes due to vaccines being ineffective after being exposed to freezing temperatures.

The National Vaccine Storage Guidelines Strive for Five (2005: 14) recommends that refrigerator temperatures be checked and recorded twice daily. Checking and recording the temperature before administration of the vaccine enables the identification of problems before the vaccine is used. During this study it was observed that temperature charts are available in most clinics, however, nurses failed to record findings.

Regarding correctly packing the refrigerator with vaccines and their diluents together, the study revealed that 78.6 percent were non-compliant and 21.4 percent were compliant. According to The Vaccine Storage and Handling Toolkit (2012: 54) diluents must be stored in the refrigerator next to the corresponding vaccines. Diluents packaged separately from their corresponding vaccines may be stored at room temperature or in the refrigerator. Vaccines mixed with incorrect diluents can cause damage to vaccines and can further cause AEFI (The Vaccine Storage and Handling Toolkit, 2012: 54).

The National Vaccine Storage Guideline-Strive for 5 (2013: 12) recommends that refrigerator shelves must not be overcrowded and there must be space in-between vaccine containers to allow for air to circulate. The guideline further states that overstocking of the refrigerator will prevent air circulation and it will be difficult to maintain stable temperatures within the refrigerator. The results of this study revealed that 64.3 percent of the refrigerators were not overstocked and only 35.7 percent of the clinics refrigerators were overstocked. The study also revealed that in 92.9 percent of the fridges there was no circulation of air between vaccines containers and in 7.1 percent of the fridges there was enough air circulating between vaccine packages. It was observed during this study that although

refrigerators were not overstocked, vaccines were not packed according to storage guidelines i.e. vaccines were not stored in their original packaging and together with their diluents. It is therefore recommended that at least two nurses become responsible for regular inspection of the vaccine fridge with respect to checking of the temperature, vaccine stock and general upkeep of fridge since a properly maintained fridge results in effective management of cold chain vaccines. Hence this aspect must be strictly adhered to and nurses must become accountable. Open lines of communication must be maintained amongst all those involved in the immunisation programme to ensure its present and future success.

According to the results of this study, 92.9 percent of clinics did not store vaccines in the door of the refrigerator. It is important to store vaccines appropriately in the refrigerator in order to maintain their integrity (National Vaccine Storage Guidelines Strive for 5 2013: 12). In 7.1 percent of clinics (one clinic) it was observed that vaccines were stored in the door. This clinic used a bar refrigerator which is not compatible with national guidelines. Poor storage directly impacts on the financial constraints placed on the Department of Health since wastage of vaccines results in the wastage of finance.

This study results further revealed that fridge thermometers were available in all 14 clinics observed however, none of the thermometers were working. Most clinics used the thermostat dial in the refrigerator to monitor the fridge temperature. This state of non-working thermometers is contrary to the guidelines of the Vaccine Storage and Handling Toolkit (2012:38). These guidelines state that thermometers are a critical part of good storage and handling practice. Accurate temperature monitoring is imperative for effective vaccine management. This is also supported by Safe Vaccine Handling, Cold Chain and Immunisation Guidelines WHO (1998) which state that if the refrigerator does not have a working thermometer there is no way of telling if the vaccine is being stored at the right temperature and is maintaining its potency.

The observation study further revealed that in all of the clinics there was no “DO NOT UNPLUG” signage on the refrigerator plug and no signage on fridge door stating “DO NOT OPEN VACCINE FRIDGE”. The National Vaccine Storage

Guidelines Strive for 5 (2013: 10) states that the vaccine fridge must be clearly marked “DO NOT TURN OFF OR DISCONNECT THE VACCINE FRIDGE”. Accidental disconnection from the power source can cause heat damage to vaccines, especially if this goes unnoticed for a long period. The guidelines further state that vaccine refrigerators must have the sign “VACCINE REFRIGERATOR DO NOT OPEN”. Reducing the number of times the fridge door is opened, helps to maintain the internal temperature of the fridge (Nelson *et al.*, 2004; Ren *et al.*, 2009; and Zipursky *et al.*, 2011). It is recommended that the signage be bold so that visibility is not a problem and hence the proper guidelines can be followed.

5.2.2.2.1. COLD BOX

The results of this study revealed that in 78.6 percent cold boxes were in good condition and in 21.4 percent clinics the cold boxes were not in good condition or were not the right size. It was observed that in three of the clinics the cold box was either too large or too small and also damaged, therefore vaccines could not be maintained at the correct temperature. The cold boxes should be of a good condition, meaning that it should not be broken or damaged and should have a properly fitting lid (EPI Guidelines WHO-1998: 19). The pros and cons of the cold boxes are listed in (Burstein *et al.*, (2012). It is recommended that the 21.4 percent of the clinics purchase better quality cold boxes. An allocation of the budget of these clinics should be set aside for this part of the immunisation programme.

It was observed in 78.6 percent of the clinics that the temperature range of two degrees to eight degrees Celsius was not maintained and in 21.4 percent the cold box temperature was correctly maintained. In most of these 11 clinics it was found that thermometers were present however the thermometers were not working. Therefore, the nurse was not able to identify if the vaccines were subjected to heat or cold. The U.PATH, final report (2006) states that whilst damage to vaccines due to overheating is gradual, freeze damage is almost instantaneous. According to the EPI Guidelines Department of Health (2010: 12) the temperature of vaccines should be maintained between two degrees and eight degrees Celsius in the cold box and a dial thermometer must be used. The correct thermometer should be included in the cold box for hourly monitoring of the temperature. (Rogers *et al.*,

2010: 339). The nursing staff responsible for immunisation programmes should be responsible for monitoring the cold box temperature hourly to ensure that proper policy are adhered to. This finding is similar to that found by the (Burstein *et al.*, 2012) study conducted in Ghana, Kenya and Uganda.

The results of this study also revealed that in 71.4 percent of clinics the cold box was incorrectly packed and in 28 percent of the clinics the cold box was correctly packed. It was observed in clinics that the ice packs used to line the cold boxes were too large and did not fit the cold box well. With the result the lid of the cold box could not close and the correct temperature within the cold box could not be maintained. This is not in keeping with the Proper Handling and Storage of Vaccines Guidelines by (Rogers *et al.*, 2010: 339). Rogers *et al.*, state that the correct number and placement of ice packs in the cold boxes is important because too few ice packs can fail to maintain the internal temperature and too many ice packs can freeze the vaccines.

This observation study also revealed that 78.6 percent of the clinics used ice packs that were not conditioned before use and only in 21.4 percent of clinics were ice packs conditioned before use. According to the EPI Guidelines (WHO-1998: 19) vaccines must not be frozen. If vaccines are placed directly in contact with the frozen icepack in the cold box it can be destroyed. The EPI guidelines state that the ice packs must be left out for a few minutes until water vapour appears on it before using it in cold box. It is thus recommended that ice packs be properly conditioned and the correct number of icepacks be used in clinics where this aspect is deficient. The nursing staffs need to be trained and educated in this aspect of the immunisation programme considering the vast amount of literature that is available (National Vaccine Storage Guidelines, 2005 and Schlumberger *et al.*, 2011).

5.2.2.3. USE OF VACCINES DURING THE SESSION

The study results revealed that in 57.1 percent of clinics, vaccines were left out of the cold box for a long period of time during the immunisation session and in 42.9

percent vaccines were returned to the cold box immediately after use. It was observed in eight clinics that nurses removed the vaccines from the cold box, thereafter gave the health education to the mother then proceeded to administer the vaccine. In some of these clinics the nurse replaced the vaccine in cold box only after doing the necessary documentation. The Cold Chain and Immunisations Guideline (WHO, 1998: 3-4) states that as soon as the vaccine is administered it must be put back in the refrigerator in order to prevent vaccine violations. When vaccines are out of the refrigerator they must be kept out of direct sunlight and away from any heat source to ensure they do not get damaged. This finding is supported in the studies of Samant *et al.*, (2007), Widsanugorn *et al.*, (2011) and Patel, Ravel, and Pandit (2008) where it was concluded that the potency of the vaccine is only as good as the proper care and handling of the vaccine by the administering nurses. It is also recommended that posters be made and placed in immunisation rooms so as to constantly remind nurses of the policies and procedures of the immunisation process.

This study revealed that in 100 percent of the clinics, nurses did not draw-up vaccines for the entire session nor did the nurses mix two or more vaccines in the same syringe. This good practice is supported by the Vaccine Storage and Handling Toolkit (2012: 54) which discourages pre-drawing of vaccines of vaccine which could lead to the following problems:

- Once vaccines are drawn in the same syringe, it would be difficult to tell them apart and this could lead to administration errors;
- Pre-drawing the vaccines could lead to vaccine wastage and the risk of vaccines being stored under inappropriate conditions will be increased; and
- Bacterial contamination and growth could occur as syringes are designed for immediate use.

5.2.2.4. OPEN VIAL POLICY

The study results further revealed that in 71.4 percent of clinic nurses did not adhere to recording the date and time on the vaccine that was opened and in 28.6 percent of the clinics there was adherence. In 78.5 percent of the clinic nurses

failed to check the expiry date on the vaccine prior to administration and 21.4 percent were compliant. The (EPI Cold Chain Standard Operating Procedure Manual 2009: 29) states that for example, the measles and BCG vaccine, once opened expires after six hours and must be discarded. The date and time must be recorded on the vaccine. The analysis of study results indicated that nurses are not following the guidelines of the open vial policy thus putting babies at risk of AEFI (Aderibigbe, Osagbemi and Bolarinwa, 2010).

5.2.2.5. MULTI DOSE VIAL (MDV)

Analysis of the study results indicate that 64.3 percent of the nurses in the clinics did not adhere to the policy of reconstitution of the dose vaccines and 35.7 percent were compliant with the policy on reconstitution. The Vaccine Storage and Handling Toolkit (2012: 97) states that the specific diluents provided by the manufacturer for that vaccine must be used to ensure adequate potency and safety of the resulting mixture. The EPI Cold Chain Standard Operating Procedure Manual (2009: 20) states that the aseptic technique must be used to reconstitute the vaccine and also when withdrawing from the vaccine vial. The date and time must written on the reconstituted vial (Vaccine Storage and Handling Toolkit, 2012: 99).

The main reasons for this, according to the guideline is that some vaccines expire within a certain time after opening and would not correspond with the date on vaccine vial by the manufacturer, e.g. measles vaccine expires six hours after reconstitution.

The second reason for this is dating opened vials helps the nurse to identify which vial is in use thus preventing vaccine wastage, as naturally, this vial will be used in the next immunisation session before opening another. This is supported by the findings of a study conducted in Nigeria on the measles vaccine (Oyefolu *et al.*, 2006:1). In the study the authors found that expiry time of the vaccine, poor and delayed handling were some of the causes of loss of potency of vaccines. Another study conducted in Gujarat in India, on the measles vaccine support that the recommendation that the reconstitution date and time must be written on the

vaccine vial in order to prevent toxic shock syndrome (Patel, Ravel and Pundit, 2011: 20).

It was observed that in 85.7 percent of the clinics, the vaccine vial monitor (VVM) was not checked before use. In all the clinics there was no evidence of VVM training. The EPI Cold Chain Standard Operating Procedure manual (2009: 22) states that the VVM is a label made of temperature sensitive material used to determine the safety of a vaccine. The monitor on the label is a circle with a small square inside it. This inner square when subjected to heat will change from white to grey and eventually to black. It is therefore imperative that nurses check the status of the VVM prior to administration of the vaccine so that children receive safe, potent vaccines. It must be emphasised that the VVM remains a cost effective way which guarantees the potency of vaccine and a successful delivery to the children thus stressing its importance (Sammant *et al.*, 2006). The VVM must be strictly adhered to and it is thus recommended that nurses involved in immunisation programmes be educated in this regard. Globally this phenomenon is a recipe for success in cold chain management for vaccines if it is followed through at all levels of immunisation.

5.2.2.6. THE AVAILABILITY OF STOCK AND EQUIPMENT

The observation study results revealed that 85.7 percent of the clinics had sufficient stock of needles, syringes and sharp containers. In two clinics there was deficient stock of needles, syringes and sharp containers. It was observed that babies had to wait for their immunisations till the ordered stock arrived. Furthermore, in some clinics the sharp containers were overflowing thus putting staff at risk of needle stick injuries.

The EPI Cold Chain Standard Operating Procedure Manual (2009: 6) further states that clinics must never run out of stock as an out of stock situation means missed opportunities for children's immunisation and a breakdown in the EPI programme. Nursing staff should constantly audit and check stocks so as ensure these problems of a lack of stock are avoided.

5.2.3. CONCLUSION

Section A1 above, discussed the results of the observation study. Following is Section A2, which includes the discussion on results of the self-administered questionnaire.

5.3. SECTION A2: SELF-ADMINISTERED QUESTIONNAIRE (PHASE TWO)

In phase two a self-administered questionnaire was distributed to a representative sample of 377 nurses (Appendix 3). All 69 PHC clinics were used in this phase and included urban, rural and mobile clinics.

The purpose and benefits of the study were explained to the participants prior to obtaining their written consent to participate in the study, via an information letter and informed consent form which was attached to the questionnaire. The questionnaire and a self-addressed envelope were given to each registered nurse personally at the beginning of the month. A drop off box was provided to each clinic where nurses placed their completed questionnaire. The completed questionnaires were collected at the end of the month. A total of 276 questionnaires were returned.

Section A2 presents the results of the study related to the self-administered questionnaire. The discussion is based on the objectives of the study, namely to:

- To compare current processes of the cold chain management of vaccines in PHC clinics against best practice and in accordance with global, national and provincial guidelines;
- To investigate current processes of the cold chain management of vaccines by nurses in PHC clinics; and
- To contribute to the current body of knowledge and recommend potential solutions to the problems encountered in the cold chain management of vaccines in PHC clinics.

5.3.1. TYPES OF CLINICS

The sample was dominated by rural clinics followed by urban clinics and then finally by mobile clinics. The approximate ratio of urban to rural clinics represented in the current scientific setting was 1:3. There are several challenges that the rural clinics face such as shortage of skilled staff, access to vaccines, the administration of vaccines and incorrect storage of vaccines, just to mention a few of the challenges (Health-E: South African Health News Service, 2014). An example of the incorrect storage of vaccinations in a Limpopo rural clinic was that the clinic had to write off R100 000 worth of vaccines rendered useless, due to freezing. Situations such as these, leads to the clinic staff giving a parent a false sense of security if the altered vaccine were to be administered (Health-E: South African Health News Service, 2014).

5.3.2. AGE, GENDER AND RACE DISTRIBUTION

The current research reveals that more females than males were represented in the sample. This is indicative of the fact that the nursing profession is overwhelmingly represented by females. This skewness in the nursing profession has been described as a “gender dilemma” (Marks, 2001). Reasons why few males enter the nursing profession include low pay, nursing is a female dominated profession and the sceptical perception of the public when they see men as nurses (Vere-Jones, 2008). Males are attracted to theatre, surgical nursing and intensive care. These areas are seen as more ‘macho’ than areas like midwifery (Vere-Jones, 2008).

The modal race group was Black respondents whilst the modal age group was 31 years and above. This trend is consistent with the national statistics in the nursing profession in South Africa (South African Nurses Council, 2014). Only 2.9 percent of the respondents in this sample were in the age group 20-25 years and 17.8 percent of respondents were in the age group 26-30 years. This is indicative 79.3 percent of the sample were fairly mature and thus more experienced.

5.3.3. EXPERIENCE

The majority of the sample had 6-10 years (38.8 percent) experience whilst 37.7 percent of the sample had 10 years or more experience in the profession. Thus collectively, over three quarters of the sample i.e. 76.5 percent of the respondents had 6 years or more experience in the profession. According to Istomina *et al.*, (2011:230) nurse education, nurse experience and nurse professional development play a significant role in the evaluation of nurse competence and quality of nursing care. The current sample, given the dominant age group, indicates that nurses should have some level of competency. Thus, one would expect that the results of the self-administered questionnaire would possibly show that the correct practices and policies were in place.

5.3.4. TRAINING AND INVOLVEMENT IN VACCINE MANAGEMENT

The results reveal that only 43.5 percent of the sample participates both in training and involvement of vaccine management whilst 25.4 percent of the respondents sometimes participate both in training and involvement of vaccine management. An alarming statistic is that 13 percent of the nurses do not participate in either training or involvement of vaccine management. In addition 7.2 percent of the respondents that do not participate in training are sometimes are involved in vaccine management. These statistics tell us that more nurses in the sample need to be encouraged to be trained and involved in vaccine management. The ideal situation is that at least 80 percent of the nurses in this sample needed to be trained and involved in vaccine management (Vaccine Storage and Handling Guide 2011: 5 and Thakker and Woods, 1992: 756). Furthermore, there are several training courses available today that can greatly equip nurses in the area of vaccine training and management e.g. vaccine storage and handling guidelines, vaccine storage practices, vaccine temperature monitoring and vaccine inventory management (Rogers *et al.*, 2010). Hence, it is evident from the research that more needs to be done in the area of nurses involvement and training in vaccine management i.e. education in management.

5.3.5. PROFESSIONAL NURSES AND ENROLLED NURSES

We find that there were 16.6 percent more professional nurses than enrolled nurses. This is highlighted by the fact that 41.7 percent of the nurses were still enrolled. An enrolled nurse is one who helps professional nurses with their duties and also helps the lower category of nurses when needed. In most hospitals, enrolled nurses administer medication and help with doctors rounds. Enrolled nurses are also guided by their scope of practice and duties and are under direct and indirect supervision of the professional nurse. They ensure all needs and comforts of the patients are met. They practice within their scope of practice. This result further suggests that there are two different levels of knowledge and expertise in operation.

5.3.6. POLICY: COLD CHAIN POLICY

The results revealed a positive finding in that most clinics always have an up-to-date cold chain policy. Only 14.1 percent of the sample disagreed with this being in place in their respective clinics. We also find that just over 60.9 percent of the sample agreed that all staff are trained to follow policies that ensure cold chain compliance for vaccines whilst 17.4 percent of the sample confirmed that this does not occur. There is comprehensive literature available on cold chain policy such as the EPI Cold Chain Standard Operating Procedure Manual (2009) that can enable the success of implementing the cold chain policy. It is clear from the findings of the research that many staff are not informed and trained in the cold chain policy. Furthermore, only 56.9 percent of all new staff allocated to the clinics are oriented to the vaccine policy and procedures. This is an alarming statistic and further especially considering that 19.9 percent of the respondents agree that this sometimes happens and 23.2 percent agreed that this never happens. To ensure the success of vaccine management this must occur at far higher percentages say at 80 to 100 percent of the time. Unfortunately, in this study setting it is not the case, highlighting an area of dire attention that needs to be addressed in order to ensure the effective management of the cold chain system for vaccines.

The EPI South Africa (2012) has been specifically written for all health care professionals and hence it is the responsibility of all health workers to educate themselves in the cold chain policy specific to South Africa. This is also highlighted in other guidelines as well (Cold Chain Module 3 WHO, 1998, Vaccine Storage and Handling Toolkit, 2012 and National Vaccine Storage Guidelines, 2005). The current research also revealed that 68.1 percent of participants indicated that there is one trained individual with at least one trained deputy responsible for the receipt, storage of vaccines and the recording of vaccines while 14.9 percent state that this is never the case and 17.0 percent indicated that this is sometimes the case. According to the Vaccine Storage and Handling Guide (2011: 5) staff should be knowledgeable regarding vaccine storage and handling and there should be at least two staff members who are responsible for vaccine management. This is imperative for the success of the cold chain policy, so there must be some accountability created and encouraged in the surveyed clinics for this measure to be adhered to.

5.3.7. VACCINE MANAGEMENT

The analysis reveals that the areas of strengths within vaccine management include that stock cards for vaccines are always kept; the first-in first-out principle applies when packing and using vaccines; unused vaccines from the clinic session are clearly marked as being out; vaccines are never used when the inner square is as dark as the outer circle or darker; unused vaccines are used next in the clinic session; in the case of recall, there is a record of vaccine batches; stock cards for vaccines were correctly filled in; vaccines were always checked against the order for discrepancies and leakage; procedures for recording the date and time, vaccine types brands, quantities, batch numbers and expiry are always followed when vaccines are received; staff are always aware of the urgency of packing vaccines immediately on receipt; staff are aware of how to read and check the cold chain monitor when unpacking vaccines; vaccines are always ordered by a designated person and vaccine stock is always monitored prior to ordering since the majority of the respondents agreed that these policies and procedures are being adhered to.

The areas that need attention are the shortage of needles, syringes and sharp containers, since 44.6 percent of the respondents stated that this sometimes happens. A possible way of overcoming this problem is for clinics to continually order these items and constantly have a spare set of these items in their stock (Matthias *et al.*, 2007). Also, constant monitoring of the inventory is necessary to overcome this problem (Matthias *et al.*, 2007). Another area of attention is that there should always be more than a four week supply in the refrigerator because 35.9 percent of the respondents indicated that this is only sometimes the case. Thus there seems to be a lack of proper vaccine supply monitoring amongst the surveyed clinics. Hence, it is recommended that a specific nurse take the responsibility of maintaining the vaccine stock control and inventory.

The results of this study also revealed that 78.6 percent of the respondents stated that vaccines are sometimes out of stock. Again, this highlights a stock control issue amongst the clinics and it is recommended that stock be constantly monitored as well as access to stock. It is also recommended that the clinics have some kind of a back-up plan if access to stock becomes unpredictable. Such a back-up plan would be to consult a private retailer of the vaccines and to perhaps purchase the vaccines at a reduced rate. Access to stock of vaccines and control thereof has been highlighted by Wiysonge *et al.*, (2012: 578).

5.3.8. THE VACCINE REFRIGERATOR

When investigating the vaccine refrigerator, 26 criteria were used to assess this variable. The findings show that 20 of the 26 criteria were being adhered to. The criteria not being adhered to in the surveyed clinics will now be discussed. The study found that 50.4 percent of the respondents agreed that there were always records of regular servicing, defrosting and cleaning of the refrigerator. The refrigerator is the life of the vaccine and it must be well maintained in the clinics at all times.

Furthermore, it was evident in the surveyed clinics that only 44.2 percent of respondents agreed that the refrigerator is always fitted with an alarm to detect cold chain breaches and only 54.3 percent of the respondents agreed that the

refrigerator is always either locked or stored in a lockable room. These issues can be easily solved in the clinics by maintaining an efficient refrigerator with proper principles and good technical staff that would include the nurses themselves (WHO 2005: 79; Vaccine Storage and handling Guidelines, 2011: 5). Furthermore, it was evident in these clinics that there was no regular inspection and quality control of their refrigerators. This must now be implemented i.e. an inspection audit of the refrigerators where the vaccines are being stored must be conducted regularly.

The current study reveals that in 33.7 percent of the clinics, participants responded that there was always signage on the refrigerator informing staff “DO NOT TO OPEN VACCINE FRIDGE” and only 41.3 percent of the clinics participants responded that there was always a “DO NOT UNPLUG” sign the vaccine fridge. These percentages are below the norm indicating that signage on the refrigerators needs to improve. In the observation study it was also highlighted that in all of the clinics there was no “DO NOT UNPLUG” signage on the refrigerator plug and no signage on fridge door stating “DO NOT OPEN VACCINE FRIDGE”. This is indicative of poor cold chain management for vaccines thus indicating that signage on the refrigerators needs urgent improvement. The National Vaccine Storage Guidelines Strive for Five (2005: 10) states that the vaccine fridge must be clearly marked “DO NOT turn off or disconnect the vaccine fridge”. Accidental disconnection from the power source can cause heat damage to vaccines, especially if this goes unnoticed for a long period. The guidelines further state that vaccine refrigerators must have the sign “VACCINE REFRIGERATOR DO NOT OPEN”. Reducing the number of times the fridge door is opened, helps to maintain the internal temperature of the fridge (Nelson *et al.*, 2004; Ren *et al.*, 2009; Zipursky *et al.*, 2011). It is recommended that the signage be bold so that visibility is not a problem and hence the proper guidelines can be followed. This can be easily done in the clinics by nurses or technical staff who take the responsibility to do so. Proper signage is an issue that is highlighted in the Vaccine Storage and Handling Guidelines (2011: 5).

Lastly it is noted that at the local clinics, just under half the respondents i.e. 48.6 percent indicated that there is a back-up system in place for vaccine management

in case of power failure. It is evident that the clinics do not have generators or a contingency plan like solar power panels in case of a power failure in order to protect their vaccines. Measures must now be implemented to deal with issues such as power failure and load-shedding which is prevalent in South Africa (Blaine, 2014). To address this, finances must be allocated in order to purchase generators or solar panels to act as a back-up just in case of power failures or load shedding.

5.3.9. COLD BOXES

The surveyed clinics revealed that seven out of the eight criteria for the management of vaccines in the cold box during immunisation session were adhered to. The area that was not properly adhered to is that of records of regular checking of the cooler box. In the current study 45.7 percent of nurses stated that records of regular checking of the cooler box are available, 13.4 percent stated that these records are sometimes available and 40.9 percent indicated that these records are never available. To resolve the issue of regular checking of records of the cooler box it is suggested that clinics appoint a member of staff who will perform this task efficiently (Cold chain and immunisation manual, 2003; Vaccinators manual, 2012).

5.3.10. CLINICAL PRACTICE

All clinical practices were being properly carried-out in the clinics. These investigated issues included: staff awareness of management of allergic reactions to vaccines; procedure for reconstitution of vaccines, and; performance of the shake test. In this regard nurses working with vaccines must be commended and this is strength of the immunisation practice in clinics. The only practice that needs dire improvement was where 54.0 percent of staff agreed that there is always reconstituted measles vaccine in the refrigerator. This is an incorrect practice in clinics. As highlighted in the Cold Chain Standard Operating Procedure Manual (2009: 29), the measles and BCG vaccines, for example, once opened expire after six hours and must be discarded. The date and time must be recorded on the vaccine. The analysis of study results indicated that if nurses are not following the

guidelines of the open vial policy for freeze vaccines they are subjecting babies to the risk of AEFI e.g. allergic reactions, shock convulsions and rash (Aderibigbe, Osagbemi and Bolarinwa 2010).

5.3.11. GUIDELINES AND POLICY

This section investigated the Guidelines and Policy pertaining to emergency plans in the event of the breakdown of cold chain equipment, power failure, vaccine wastage and policy on cold chain failure. It was found that all of the guidelines and policy had favourable responses in terms of adherence and implementation, except where a small 30.4 percent of respondents stated that there is a procedure in place in event of a vaccine cold chain failure whilst a large number 69.6 percent have stated that there isn't. Also 60.5 percent of respondents stated that they face a number of challenges in the cold chain management of vaccines. It is evident that in these clinics the management has not discussed these issues and implemented solutions in event of a vaccine cold chain failure or addressed the challenges their nurses face in the cold chain management of vaccines. Hence, as previously suggested, generators, solar panels etc. need to be purchased or supplied to the clinics in order to have a back-up supply should there be a power failure. In addition, the challenges nurses face must be tabled and addressed in evaluation meetings in the clinics. This would ensure the smooth facilitation of the cold chain immunisation programmes in these clinics.

5.4. CONCLUSION

Nurses play a vital role in the maintenance of the cold chain to ensure the efficacy and safety of vaccines administered. Maintaining cold chain standards is vital given the large number of vaccines now stored at local clinics and the cost attached to these vaccines.

The results of the study demonstrate that the cold chain for vaccines at local clinics is not maintained effectively thus vaccines are compromised. One of the most significant findings of the study is the need for in-service training and refresher courses for nurses on cold chain management for vaccines. These

courses and in-service training must be based on National, Provincial and Standard Operating Guidelines for vaccine management.

Furthermore, there were no contingency plans to deal with lack of equipment and electricity issues, no monitoring and evaluation systems, poor recording keeping, poor management of the cold boxes and refrigerators and poor access to stock.

The most salient aspects from the questionnaire results were that that education and experience of the nurses are crucial to the sustainability of the childhood immunisation programme. Some of the findings were similar to the observation study. These included issues surrounding equipment and electricity, monitoring and evaluation systems, poor record keeping and poor access to stock.

It is recommended that ongoing training for staff on vaccine management be conducted. Regular audits must be conducted in local clinics by EPI coordinators from the District Office of Health. There should also be ongoing communication between Government, Department of Health and Professional Nurses in charge of clinics to solve problems.

5.5. LIMITATIONS

The clinics visited during the study were very widespread and it was difficult to travel to these remote clinics due to the poor condition of the roads and conditions were worse during rainy weather.

Not all clinics ordered their vaccines on the day of the observation study therefore the vaccine arrival procedure could not be observed. Rescheduling of the study had to be done in three clinics.

Due to the influx of patients and staff shortages some of the nursing staff refused to participate in the study.

5.6. RECOMMENDATIONS

One of the most significant findings of the study is the issue of education. Nurses in clinics need training and refresher courses with respect to the vaccine management. This must be done in order to produce a nursing community that is competent in the management of childhood vaccines. This education can be in the form of training workshops, after hour's classes and childhood vaccine training road shows throughout the KZN province and the rest of South Africa. Hence, there must be communication between the clinics and the Department of Health together with the District Office of Health. Nurses must be encouraged at various levels to upgrade their knowledge and qualifications so that they can become more competent in their profession. Thus, it is recommended that professional nurses and enrolled nurses as well as new allocations of nurses to various clinics be constantly audited by the District Office Management to ensure that childhood vaccine management is part of, and continues to be part of, their training and education.

The access to and control of vaccine stock is an imperative issue within the findings of the research. Although stock cards are available at the clinics in some clinics they are incomplete or incorrectly filled in. It is recommended that clinics appoint and train a member of staff who will monitor and access the vaccine stock on a regular basis. Thus, there has to be a proper inventory system in place in order to facilitate the usage of childhood vaccinations.

Another significant finding in the research is that of the signage on the vaccine refrigerator. There has to be clear and concise signage on the vaccine refrigerator so that proper cold chain policy guidelines can be followed. Thus, it is recommended that a member of staff take the responsibility for placing the correct signage on the refrigerators. This will include signage on the fridge stating "VACCINE FRIDGE DO NOT OPEN" and on the plug on the wall "VACCINE FRIDGE DO NOT UNPLUG" (The National Vaccine Storage Guidelines Strive for Five 2005: 10).

It was also noted that clinics do not have a back-up plan in the event of a power outage. It is recommended that clinics be supplied with generators or install solar panels, in order to ensure that the refrigerators continue to keep running and enable childhood vaccination to continue uninterrupted.

The research also reveals that records of regular checking of the cooler box should be visible. In addition, members of staff should be instructed to take the responsibility of keeping these records with professional nurses and they should be constantly checking and validating these records. A thermometer must be placed in the centre of the cold box and the temperature must be monitored and recorded hourly (Rogers *et al.*, 2010).

The health authorities should identify innovative strategies like computerised temperature monitoring of vaccine cold chain as recommended in the study conducted by Schlumberger *et al.*, (2011: 264). A fridge tag could also be placed in the middle shelf of the fridge to monitor the temperature of vaccines (EPI South Africa, 2012).

Finally, it is evident that the clinics do not seem to have any foresight in terms of addressing the current nursing challenges with the childhood vaccination programme as well as any contingency plans should they be without electricity for extended periods of time. Hence it is recommended that the heads of clinics and other institutions meet on a regular basis to discuss certain solutions to the ongoing problems they experience and hopefully this will lead to the implementation of a more effective childhood vaccination programme.

Future research would involve a larger sample of clinics, perhaps as a representation of the entire country. Statistical models can be incorporated into the data analysis in order to help identify factors associated with proper childhood immunisation such as education, practices and access to vaccination stock. Furthermore, an index can be created from several of the measured variables to help classify a clinic as efficient or inefficient in following the cold chain policy.

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APPENDICES

APPENDIX 1A – Permission Letter to KZN Department of Health

25 Spilsby Avenue

Lincoln Meade

Pietermaritzburg

3201

7th June 2012

Dr Elizabeth Lutge

Health KwaZulu-Natal

Health research and knowledge

Management Secretariat

3330 Langalibalele Street

Natalia Building

Pietermaritzburg

Request for permission to conduct my research study at Mzunduzi clinics

Dear Dr E Lutge

My name is Shamla Pillay and I am currently employed at Greys Nursing Campus as a lecturer. I am presently enrolled as a M-tech student at the Durban University of Technology.

My study is entitled “A descriptive study into the cold chain management childhood vaccines by nurses in Primary health care clinics (PHC) in the uMgungundlovu District.

My objectives of the study are:

- To investigate current processes of the cold chain management of vaccines by nurses in PHC clinics.
- To compare current processes of the cold chain management of vaccines against best practices and in accordance with global, national and provincial guidelines.
- To contribute to the current body of knowledge and problems encountered in the cold chain management of vaccines in South Africa.

A survey will be conducted in all PHC clinics and amongst all registered nurses. The survey will be conducted using a self-administered questionnaire. This study will also be backed up by observations using a structured observation guide. The researcher will also observe nurses vaccine practices in the immunisation room. Participation will be voluntary. Confidentiality will be maintained at all times. Participants will be requested to sign informed consent prior to the study. They will be informed that they are free to withdraw from the study at any stage. This study will not compromise or victimize nurses or patient care in any way. Normal functioning of the clinic will not be interrupted.

If vaccines are managed effectively by nurses then parents and their children enjoy the following benefits:

- Reduction in morbidity and mortality rates of children as they receive potent vaccines
- Adverse incidents following immunisation are reduced.
- Medical expenditure can be saved as immunisation prevents illness.
- Parents save valuable time as immunisation saves time caring for sick babies.
- The government also saves as clinic visits and hospitalization of ill children are reduced.

Studies in cold chain management of vaccines are mirrored throughout countries internationally however, very little research is done in South Africa there hence the researcher has decided to pursue this topic.

Therefore I kindly request your permission to conduct this study in local clinics.

For further information please contact:

Shamla Pillay: Telephone; 0338973188

Email –shamla.pillay3kznhealth.gov.za

Supervisor - Dr I Botha: Telephone 0313732917 Email-izelb@dut.ac.za

Email _izelb@dut.ac.za

Co-supervisor -Ms S Ngcobo Telephone -0722346969

Email _sibongilen@dut.ac.za

Thank you.

Mrs. S. Pillay

APPENDIX 1B – Letter of Approval from KZN Department of Health



health

Department: _____
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management sub-component
10 – 103 Nataka Building, 330 Langalibalele Street
Private Bag X9031
Pietermaritzburg
3200
Tel: 033 – 3953189
Fax: 033 – 394 3782
Email: hkrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM190/13
Enquiries: Mrs G Khumalo
Telephone : 033 – 395 3189

27 August 2013

Dear Mrs S Pillay

Subject: Approval of a Research Proposal

1. The research proposal titled 'A descriptive study into the cold chain management of childhood vaccines by nurses in Primary Health Care clinics in the Umgungundlovu district' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby approved for research to be undertaken at the selected clinics at Umgungundlovu District.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an Interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9031, PIETERMARITZBURG, 3200 and e-mail an electronic copy to hkrkm@kznhealth.gov.za

For any additional information please contact Mrs G Khumalo on 033-395 3189.

Yours Sincerely


Dr. E Lutge
Chairperson, KwaZulu-Natal Health Research Committee
Date: 28/08/13

uMnyango Wezemphilo . Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope

APPENDIX 2A – Permission Letter to the District Manager

25 Spilsby Avenue
Lincoln Meade
Pietermaritzburg
3201
7th June 2012

The District Manager
Mrs MZ Mkhonza
uMgungundlovu District

Request for permission to conduct my research study at Mzunduzi clinics.

My name is Shamla Pillay, I am currently employed at Greys Nursing Campus as a lecturer. I am presently enrolled as a M-tech student at the Durban University of Technology.

My study is entitled “An evaluation of the management of the cold chain of childhood vaccines by nurses in Primary health care clinics (PHC) in the uMgungundlovu District.

Aims of the study are:

- To investigate current processes of the cold chain management of vaccines by nurses in PHC clinics.
- To compare current processes of the cold chain management of vaccines against best practices and in accordance with global, national and provincial guidelines.
- To contribute to the current body of knowledge and problems encountered in the cold chain management of vaccines in South Africa.

A survey will be conducted in all PHC clinics and amongst all nurses. The survey will be conducted using a self-administered questionnaire. This study will also be backed up by observations using a structured observation guide. The researcher will also observe nurse's vaccine practices in the immunisation room. Participation will be voluntary. Confidentiality will be maintained at all times. Participants will be requested to sign informed consent prior to the study. They will be informed that they are free to withdraw from the study at any stage. This study will not compromise or victimize nurses or patient care in any way. Normal functioning of the clinic will not be interrupted.

If vaccines are managed effectively by nurses then parents and their children enjoy the following benefits:

- Reduction in morbidity and mortality rates of children as they receive potent vaccines
- Adverse incidents following immunisation are reduced.
- Medical expenditure can be saved as immunisation prevents illness.
- Parents save valuable time as immunisation saves time caring for sick babies.
- The government also saves as clinic visits and hospitalization of ill children are reduced.

Studies in cold chain management of vaccines are mirrored throughout countries internationally however; very little research is done in South Africa hence the researcher has decided to pursue this topic.

Therefore I kindly request your permission to conduct this study in local clinics.

For further information please contact:

Shamla Pillay: Telephone; 0338973188

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Supervisor - Dr I Botha: Telephone 0313732917 Email-izelb@dut.ac.za

Email -izelb@dut.ac.za

Co-supervisor - Ms S Ngcobo Telephone -0722346969

Email -sibongilen@dut.ac.za

Thank you.

Mrs. .S. Pillay

APPENDIX 2B – Letter of Approval from District Manager



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

UMGUNGUNDLOVU HEALTH DISTRICT OFFICE
OFFICE OF THE DISTRICT MANAGER
Private Bag X9124, Pietermaritzburg,
3200
Bresford House, 282 Langalibalele Street,
Pietermaritzburg, 3201
Tel.: 033-8971 000,
Fax: 033 897 1078
Email: fhule,kunene@kznhes.th.gov.za
www.kznhes.th.gov.za

Enquiries: Mrs. N.M. Zuma - Mkhonza

Ref No: 15/16

Date: 15 AUGUST 2013

TO: MS S PILLAY
GREYS NURSING CAMPUS
PRIVATE BAG X9001
PIETERMARITZBURG
3201


DEAR, MS S PILLAY

**RE: A DESCRIPTIVE STUDY INTO THE COLD CHAIN MANAGEMENT OF
CHILDHOOD VACCINES BY NURSES IN PRIMARY HEALTH CARE CLINICS**

I have the pleasure in informing you that permission has been granted to you by the District to conduct research on "*A descriptive study into the cold chain management of childhood vaccines by nurses in Primary Health Care clinics*". Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Office Committee in the Department of Health.
3. Please ensure this office is informed before you commence your research.
4. The District Office / Facility will not provide any financial resources for this research.
5. You will be expected to provide feedback on your findings to the District Office/Facility.

Thank you


MRS N.M. ZUMA - MKHONZA
DISTRICT MANAGER
UMGUNGUNDLOVU HEALTH DISTRICT

APPENDIX 3A – Questionnaire for the Cold Chain Management of Vaccines in Local Clinics

Instructions to be followed in completing this questionnaire:

- Please ensure that you answer all questions.
- Be as honest as possible when answering questions. Note: there are no right or wrong answers.
- Please ensure that you have signed the declaration of consent.

Section A: Demographic Information

Please select the most appropriate response:

1. Date: _____ 2. Clinic Code: _____
3. Type of Clinic: Urban ☐ Rural ☐ Mobile ☐
4. Your age: 20 to 25 years ☐ 26 to 30years ☐ 31 years and above ☐
5. Work Experience: 0 to 5 years ☐ 6 to 10 years ☐ 11 years and above ☐
6. Your Gender: Male ☐ Female ☐
7. Your Race: Black ☐ White ☐ Coloured ☐ Asian ☐
8. Training in vaccine management: YES ☐ NO ☐
9. Involved in vaccine management: YES ☐ NO ☐ SOMETIMES ☐
10. Registered Nurse ☐ Enrolled nurse ☐

Section B: Vaccine Management.

Please tick the option that best describes your response to the following statements:

1. Policy	Never	Sometimes	Always
1.1. The clinic has an up to date cold chain policy			
1.2. All staff are trained to follow policies that ensure cold chain compliance for vaccines.			
1.3. All new staff allocated to the clinic are oriented to the vaccine policy and procedures.			
1.4. There is one trained individual, with at least one trained deputy, responsible for the receipt, Storage of vaccines and the recording of vaccines.			
2.Vaccine Management	Never	Sometimes	Always
2.1. Stock cards for vaccines are kept.			

2.2. Stock cards for vaccines are correctly filled in.			
2.3. Vaccines are checked against the order for discrepancies and leakage or damage before receiving them.			
2.4. Procedures are followed for recording the date and time, vaccine types, brands, quantities, batch numbers and expiry dates when received.			
2.5. Staff are aware of the urgency of packing vaccines immediately on receipt.			
2.6. Staff are aware of how to read and check the cold chain monitor when unpacking vaccines.			
2.7. There are times when vaccines are out of stock.			
2.8. Vaccines are ordered by a designated person.			
2.9. Vaccine stock is monitored prior to ordering			
2.10. There is a shortage of needles, syringes, and sharp containers			
2.11. There are more than four weeks of stock in the refrigerator.			
2.12. Vaccines are used when the inner square is as dark as outer circle or darker.			
2.13. The first in first out principle applies when using and packing vaccines.			
2.14. Unused vaccines from the clinic session are clearly marked as having been out of the refrigerator.			
2.15. The above (question 2.14.) unused vaccines are used first in the next immunisation session.			
2.16. There is a record of vaccine batches in case of recall.			
3. Vaccine refrigerator	Never	Sometimes	Always
3.1. The refrigerator is in working order.			
3.2. A dedicated refrigerator is used for the Storage of vaccines only.			
3.3. The refrigerator is situated in a well-ventilated area, away from sunlight and heat.			
3.4. The refrigerator type is correct for vaccines.			
3.5. The refrigerator is the right size to store adequate vaccines when the demand increases.			
3.6. The refrigerator temperature is within correct range of (2 - 8°C) all the time.			
3.7. The responses to all deviations outside (2 - 8°C) have been documented and the recommended actions taken.			

3.8. There is a “do not unplug the refrigerator” sign next to the refrigerator.			
3.9. Vaccines and diluents are stored correctly.			
3.10. Vaccines are stored on the door.			
3.11. Food or cool drinks are stored in the same refrigerator that is used to store vaccines.			
3.12. The refrigerator is either lockable and locked or stored in a locked room.			
3.13. Vaccines are stored in the door, bottom drawer or adjacent to the freezer.			
3.14. Refrigerator door opening during immunisation sessions is minimised.			
3.15. A refrigerator temperature chart is present with recording.			
3.16. The temperature chart is filled in twice daily.			
3.17. Electricity supply to the refrigerator is safe examples- switchless plugs, cautionary notices are in place.			
3.18. Arrangements are in place in the event of a refrigerator or power failure.			
3.19. The refrigerator is correctly packed with air circulating between the vaccines.			
3.20. There are records of regular refrigerator servicing, defrosting and cleaning available.			
3.21. A working dial thermometer is present in the centre of the refrigerator.			
3.22. There are no expired vaccines in refrigerator.			
3.23. There is a sticker on the door to remind staff to open the door only when necessary.			
3.24. Vaccines are in their original packaging box and include the information leaflet.			
3.25. The clinic has a back-up system in case of power failure.			
3.26. The refrigerator has an alarm which is activated when the temperature exceeds 8 degrees Celsius (8°C) and falls below 2 degrees Celsius (2°C).			
4. Cold boxes	Never	Sometimes	Always
4.1. An adequate number of cooler boxes are available.			
4.2. Cooler boxes are in a good condition and not damaged.			
4.3. Are sufficient packs are available e.g. 6 and more			

4.5. The temperature in the cooler box is between 2-8 degrees Celsius (2 - 8°C).			
4.6. Records of regular checking of the cooler box are available.			
4.7. Reconditioned ice packs are used.			
4.8. Vaccines are correctly packed in the cooler box.			
4.9. A dial thermometer is available for cooler boxes and is working.			
5.Clinical Practice	Never	Sometimes	Always
5.1. There is reconstituted measles vaccine in the refrigerator.			
5.2. Reconstitution of vaccines is done correctly.			
5.3. Reconstituted vaccines are fully labeled with the date and time.			
5.4. There are needles left on the vaccine vials while in use.			
5.5. A shake test is done for frozen vaccines.			
5.6. The emergency tray is well equipped.			
5.7. Staff are aware of emergency procedure e.g. allergic reactions to vaccines.			
Comments.			

Section C: Guidelines and Policy

Please tick either yes or no in response to the following statements:

Statement	YES	NO
1. We have an emergency plan in place in case of refrigerator breakdowns and power failure.		
2. Our clinic deals with vaccine wastage appropriately.		
3. Our goal in our clinic is to prevent cold chain violations.		
4. We have a procedure in place in event of a vaccine cold chain failure		
5. We face a number of challenges regarding the cold chain management of vaccines.		
COMMENTS		

APPENDIX 3B - Questionnaire for the Cold Chain Management of Vaccines in Mobile Clinics

Instructions to be followed in completing this questionnaire:

- Please ensure that you answer all questions.
- Be as honest as possible when answering questions. Note: there are no wrong or right answers.
- Please ensure that you have signed the declaration of consent.

Section A: Demographic Information

Please select the most appropriate response:

1. Date: _____	2. Clinic Code: _____
3. Type of Clinic: Urban <input type="checkbox"/> Rural <input type="checkbox"/> Mobile <input type="checkbox"/>	
4. Your age:	20 to 25 years <input type="checkbox"/> 26 to 30years <input type="checkbox"/> 31 years and above <input type="checkbox"/>
5. Work Experience:	0 to 5 years <input type="checkbox"/> 6 to 10 years <input type="checkbox"/> 11 years and above <input type="checkbox"/>
6. Your Gender:	Male <input type="checkbox"/> Female <input type="checkbox"/>
7. Your Race:	Black <input type="checkbox"/> White <input type="checkbox"/> Coloured <input type="checkbox"/> Asian <input type="checkbox"/>
8. Training in vaccine management	Yes <input type="checkbox"/> No <input type="checkbox"/>
8. Training in vaccine management:	Yes <input type="checkbox"/> No <input type="checkbox"/>
9. Involved in vaccine management:	Yes <input type="checkbox"/> No <input type="checkbox"/> Sometimes <input type="checkbox"/>
10. Registered Nurse <input type="checkbox"/>	Yes <input type="checkbox"/> Nurse Enrolled nurse <input type="checkbox"/>

Section B: Transport and Storage of Vaccines Prior to Administration in Mobile Clinics

Please tick the option that best describes your response to the following statements:

Statement	Never	Sometimes	Always
1. The clinic has a documented process/policy in place for preparing for a mobile clinic.			
2. There are adequately sized portable coolers or specialised vaccine cold boxes available, according to the length of storage and transport time and the type of conditions.			
3. Sufficient vaccines are taken for a particular session.			
4. There is sufficient stock of ice packs available according to the session.			
5. Icepacks are conditioned prior to packing the cold box.			
6. The exposure of the vaccines to room temperatures is minimised.			
7. Cool-boxes are packed immediately before dispatch, according to cold chain requirements.			
8. If a refrigerator is not available at a vaccination site, the vaccines are stored in the cool-box until used.			
9. All staff involved in the use of the cold boxes are familiar with and adhere to the manufacturer's instructions.			
10. Cool-boxes are transported in the boots of healthcare workers' cars, not on car seats.			
11. Vaccines removed for an external session are marked before returning them to the refrigerator and these are used at the earliest opportunity.			
12. The cold box temperature is checked on a regular basis during the session.			
Comments:			

APPENDIX 4 – Observation Study Guidelines

Clinic Code: _____ Date: _____ Time: _____

Type of Clinic: Urban ☐ Rural ☐ Mobile ☐

1.Policies, procedures and guidelines	Yes	No
1.1 Policies, procedures and guidelines available for vaccine management. <i>Examples- guidelines for vaccine management according to global, national and standard operating procedures. Evidence of instruction and training on policy and operating procedures on orientation and on-going. Researcher will request this from registered nurse in charge of the clinic.</i>		
1.2. Are contingency plans in place for problems with equipment/electricity used in the cold chain management of vaccines? <i>Examples: Power outages and the break-down of refrigerators. Researcher will request from registered nurse in charge of clinic. (Gas cylinders, generators available) Policy on what to do if problems encountered.</i>		
1.3. Is there evidence of maintenance to cold chain equipment available? <i>Example: Evidence of servicing and testing of equipment. Researcher will request this from registered nurse in clinic.</i>		
1.4. Is there evidence of filling in of stock cards for vaccines? <i>Example: Evidence of recording of stock.</i>		
1.5. Is there evidence of physical inventories of vaccine stock? <i>Example: Evidence of stock balances.</i>		
1.6. Is there evidence of dedicated room for vaccine Storage and immunisation procedures.eg immunisation room		
1.7. Is vaccine wastage managed according to policy? <i>Example: Written evidence is available.</i>		
1.8. Are there vaccine wastage reports available? <i>Example: Reports are available.</i>		
1.9. Is evidence of vaccine wastage data available to make operational changes? <i>Examples: Training and supervision.</i>		
1.10. Is their evidence of shake test for frozen vaccines?		
1.11. Is there evidence of records of adverse incidents?		
1.12 Is there evidence of records of in case of recall /batch numbers for vaccines		
1.13 Is the emergency tray available and fully equipped?		
1.14. Is there evidence of training on emergency reactions?		
1.15 Is there evidence of good vaccine records i.e. temperature records, training record, cold room service reports?		
<u>NB. In order to observe the above the researcher will request the documents referred above from the nurse in charge thereafter observe if the above criteria are met.</u> Observe or question if no vaccine arrives.		
2. Vaccine arrival procedure	Yes	No
2.1. Does the nurse respond immediately when vaccines arrive in clinic?		

2.2. Does the nurse check vaccines for discrepancies, leakage and breakage before receipt?		
2.3. Are vaccines stored immediately on receipt?		
2.4. Are vaccines packed according to the first-in first-out principle?		
<u>NB. This will be observed when vaccines arrive in the clinic. If no vaccines arrive then the researcher will record not applicable.</u>		
3. Refrigerator	Yes	No
3.1. Is the refrigerator appropriate to store vaccine? Size, freezer compartment for icepacks.		
3.2. Is the refrigerator is dedicated for vaccines only? No other drugs		
3.3. Is the refrigerator temperature between (2 - 8°C)?		
3.4. Is the temperature of the refrigerator recorded on chart twice daily?		
3.5. Is the refrigerator packed correctly with vaccines and diluents?		
3.6. Is the refrigerator overstocked?		
3.7. Is there enough air circulating between vaccines?		
3.8. Are there vaccines in the door?		
3.9. Does the vaccine stock correspond with the diluents stock?		
3.10. Are vaccines frozen?		
3.11 Is the refrigerator in a locked room or does the fridge have a lock and key?		
3.12 .Is there a working thermometer hanging in correct place?		
<u>NB. When the nurse opens the refrigerator to take out or pack vaccines the above will be observed.</u>		
4. Cold box	Yes	No
4.1. Is the cold boxes in a good condition and right size?		
4.2. Is there a working thermometer in the cold box?		
4.3. Is the temperature of the cold box between 2-8 degrees?		
4.4. Is the cold box packed correctly i.e. 6 ice packs?		
4.5. Are ice packs conditioned before use?		
<u>NB. When the nurse packs the cold box the above will be observed.</u>		
5 Use of vaccine during session	Yes	No
5.1. Vaccines are left out of cold box for long period of time during immunisation		
5.2. Vaccines drawn up in advance for the entire session and left in cold boxes		
5.3. Are two or more vaccines mixed in the same syringe during the immunisation session?		

6. Open vial policy	Yes	No
6.1. Does the nurse record the date and time on the open vials?		
6.2. Is the expiry date on vials checked prior to administration?		
7. Multi-dose vial	Yes	No
7.1. Is the policy maintained regarding sterility and reconstitution?		
7.2. Are opened vials of free zed vaccines discarded after six hours?		
7.3. Is the VVM used outside the cold chain?		
7.4. Is there evidence of VVM training?		
8. Equipment and stock available	Yes	No
8.1. Are sufficient syringes, needles and sharps containers available for immunisation session?		
<u>NB. Points 5, 6, 7, 8 the nurse will be observed during the immunisation session.</u>		
<u>Comments</u>		

APPENDIX 5A – Informed Letter of Consent: Observation Study



LETTER OF INFORMATION for Observation Study

Dear Participant,

Welcome and thank you for participating in my research study. My name is Shamla Pillay. I am currently employed at Greys Nursing Campus as a lecturer and I am an M.Tech. student at Durban University Technology.

Title of the Research Study: A descriptive study into the cold chain management of childhood vaccines by nurses in the Primary Health Care clinics in the uMgungundlovu District.

Principal Investigator/s/researcher: Mrs Shamla Pillay

Co-Investigator/s/supervisor/s: Dr I Botha (Supervisor) and Ms Ngcobo (Co-Supervisor)

Brief Introduction and Purpose of the Study: The purpose of the study is to investigate the cold chain management of childhood vaccines by nurses in Primary Health Care (PHC) clinics in the uMgungundlovu District. Studies into the cold chain management of vaccines in clinics have been conducted in many countries worldwide. However, there are a limited number of studies that address the cold chain management of childhood vaccines in the South African context. After extensive research the only study found that looks at vaccine storage was conducted by Coetzee (1993) in South Africa. This presents an opportunity for a study into the management of childhood vaccines in PHC clinics in South Africa, more specifically, in the uMgungundlovu district.

Outline of the Procedures:

During the observation study the researcher will be stationed in the immunisation room from 0800 hours to 1600 hours to observe and record how nurses maintain the cold chain for vaccines. The actual immunisation procedure will not be observed. The nurse stationed in the immunisation room for that day will be observed using a structured observation guide (Appendix 4). Written informed consent will be obtained prior to observations. For the purpose of this study I will also require to view all policies, procedures and documentation pertaining to cold chain management of vaccines in this clinic.

Risks or Discomforts to the Participant: None. Please do not feel that your conduct and performance is personally rated, this study only aims to observe the documentation of policies and you will not be identified with a report.

Benefits:

- Positive aspects of the study will be highlighted and gaps will be identified.
- Recommendations will be made to the PHC manager in the District Office of health and the registered nurses in charge of clinics to carry out strategies to improve vaccine management.

Reason/s why the Participant May Be Withdrawn from the Study: None.

Remuneration: None

Costs of the Study: None

Confidentiality: No names of the participants will be entered on the observation guide. Clinics will be assigned codes.

Research-related Injury: Nil

Persons to Contact in the Event of Any Problems or Queries

S Pillay

Greys Nursing Campus

Private Bag X9001

Pietermaritzburg

3201

Phone: (033) 8973188

Fax: (033) 8973500

E-mail: shamla.pillay1@gmail.com

Researcher Supervisor: Dr I Botha (Senior Lecturer D.TECH) **Phone:** (031) 3732917

E-mail: izeb@dut.ac.za

Co-supervisor: Ms S Ngcobo (Lecturer-MSOC)

Phone: 072 234 6969

E-mail: sibongilen@dut.ac.za



CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: 88/12.
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

Full Name of Participant Date Time Signature/Right Thumbprint

I, Shamla Pillay herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Full Name of Researcher Date Signature

Full Name of Witness (If applicable) Date Signature

Full Name of Legal Guardian (If applicable) Date Signature

APPENDIX 5B – Informed Letter of Consent: Questionnaire



LETTER OF INFORMATION-FOR SELF ADMINISTERED QUESTIONNAIRE

Dear Participant,

Welcome and thank you for participating in my research study. My name is Shamla Pillay. I am currently employed at Greys Nursing Campus as a lecturer and I am an M -Tech. student at Durban University Technology.

Title of the Research Study: A descriptive study into the cold chain management of childhood vaccines by nurses in the Primary Health Care clinics in the uMgungundlovu District.

Principal Investigator/s/researcher: Mrs Shamla Pillay

Co-Investigator/s/supervisor/s: Dr I Botha (Supervisor) and Ms Ngcobo (Co-Supervisor)

Brief Introduction and Purpose of the Study: The purpose of the study is to investigate the management of cold chain of childhood vaccines by nurses in Primary Health Care (PHC) clinics in the uMgungundlovu District. Studies into the cold chain management of vaccines in clinics have been conducted in many countries worldwide. However, there are a limited number of studies that address the cold chain management of childhood vaccines in a South African context. After extensive research the only study found that looks at vaccine storage was conducted by Coetzee (1993) in South Africa. This presents an opportunity for a study into the management of childhood vaccines in PHC clinics in South Africa, more specifically, in the uMgungundlovu district.

Outline of the Procedures: This study will be conducted in 69 PHC clinics in the uMgungundlovu District. A quantitative descriptive survey design will be used for the study. To achieve this, a self-administered questionnaire will be handed out to 377 registered nurses in PHC clinics in the uMgungundlovu district. Data obtained from the questionnaires will be analysed and thereafter data will be used to draw appropriate conclusions. You are kindly requested to complete a questionnaire which will take about fifteen minutes of your time. The questionnaire is structured as follows:

Section A – is made up of demographic data. Please tick the box that suits you. All demographic data will be used for statistical purposes only.

Section B – deals with the management of vaccines. Please tick the block that best describes your response.

Section C – deals with guidelines and policy and requires you to tick your response.

Please feel free to comment in the questionnaire as space is allocated for your comments.

Participation in this study is completely voluntary and you may choose to withdraw from the study at any time. Should you be willing to participate, please ensure that you sign the accompanying declaration of consent which gives me permission to make use of your responses, after which you may complete the questionnaire that follows. Anonymity and confidentiality will be maintained at all times. This study will not compromise you in any way and will not result in victimisation.

This research study has been reviewed by the Faculty of Health Sciences and the Higher Degrees Committee and has received ethical clearance from Durban University Institutional Research Ethics Committee.

Kindly answer all questions. Thank you for your willingness to participate in this study.

If you have any queries feel free to contact me or my supervisors at the details provided below.

I appreciate your participation in this study. Thank you for your time.

Risks or Discomforts to the Participant: None

Benefits:

- Positive aspects of the study will be highlighted and gaps will be identified.
- Recommendations will be made to the PHC manager in the District Office of health and the registered nurses in charge of clinics to carry out strategies to improve vaccine management.

Reason/s why the Participant May Be Withdrawn from the Study: None.

Remuneration: None

Costs of the Study: None

Confidentiality: No names of the participants will be entered on the questionnaire. Clinics will be assigned codes.

Research-related Injury: Nil

Thank you.

Shamla Pillay

Persons to Contact in the Event of Any Problems or Queries:

S Pillay

Greys Nursing Campus

Private Bag X9001

Pietermaritzburg

3201

Phone: (033) 8973188

Fax: (033) 8973500

E-mail: shamla.pillay1@gmail.com

Researcher Supervisor: Dr I Botha (Senior Lecturer-D.TECH) **Phone:** (031) 3732917

E-mail: izeb@dut.ac.za

Co-supervisor: Ms S Ngcobo (Lecturer-M SOC)

Phone: 072 234 6969

E-mail: sibongilen@dut.ac.za



CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, Shamla Pillay (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: 88/12.
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

Full Name of Participant Date Time Signature / Right Thumbprint

I, Shamla Pillay herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Full Name of Researcher Date Signature

Full Name of Witness (If applicable) Date Signature

Full Name of Legal Guardian (If applicable) Date Signature

APPENDIX 6 – Letter from Statistician



STATISTICIAN DECLARATION FOR CONSULTATION:

I, Deepak Singh have read **Shamla Pillay's** M.Tech proposal
(student no: [REDACTED]) and given her appropriate recommendations.

Signed..... [REDACTED] Date **20 July 2012**

Sample Size

<p>What margin of error can you accept? 5% is a common choice</p>	<input type="text" value="5"/> %	<p>The margin of error is the amount of error that you can tolerate. If 90% of respondents answer <i>yes</i>, while 10% answer <i>no</i>, you may be able to tolerate a larger amount of error than if the respondents are split 50-50 or 45-55. Lower margin of error requires a larger sample size.</p>
<p>What confidence level do you need? Typical choices are 90%, 95%, or 99%</p>	<input type="text" value="95"/> %	<p>The confidence level is the amount of uncertainty you can tolerate. Suppose that you have 20 yes-no questions in your survey. With a confidence level of 95%, you would expect that for one of the questions (1 in 20), the percentage of people who answer <i>yes</i> would be more than the margin of error away from the true answer. The true answer is the percentage you would get if you exhaustively interviewed everyone. Higher confidence level requires a larger sample size.</p>
<p>What is the population size? If you don't know, use 20000</p>	<input type="text" value="400"/>	<p>How many people are there to choose your random sample from? The sample size doesn't change much for populations larger than 20,000.</p>
<p>What is the response distribution? Leave this as 50%</p>	<input type="text" value="50"/> %	<p>For each question, what do you expect the results will be? If the sample is skewed highly one way or the other, the population probably is, too. If you don't know, use 50%, which gives the largest sample size.</p>
<p>Your recommended sample size is</p>	<p>197</p>	<p>This is the minimum recommended size of your survey. If you create a sample of this many people and get responses from everyone, you're more likely to get a correct answer than you would from a large sample where only a small percentage of the sample responds to your survey.</p>

There are approximately 389 nurses in 71 public health institutions in KZN. One quarter of the institutions will be randomly selected as a sample and all nurses meeting inclusion criteria from within the selected institutions will be investigated. This will equate to a sample size of approximately 20-25% of the total population of patients. It is anticipated that a high response rate (>80%) will be attained using the data collection process outlined below.

For interview procedures, rule of thumb is between 5 – 10 percent of your sample size.

The statistical aspect of the research will encompass the following:

- Descriptive statistics using frequency and cross-tabulation tables and various types of graphs

- Inferential statistics using Pearson's and / or Spearman's correlations
- Testing of hypotheses using chi-square tests for nominal data
- Testing of hypotheses using ANOVA (factorial or mixed factorial)

Testing will be done at a level of significance of 0.05 and 95% level of confidence.

(Additional methods may be used as the need arises.)

Data Collection

Describe how the data is going to be collected, e.g. using a questionnaire.

Procedure

Permission will be obtained from

Data Analysis

The data will be reduced and analysed with the help of a statistician, using the statistical software SPSS version 20.0.

APPENDIX 7 – Ethical Approval of Questionnaire



D U R B A N
UNIVERSITY of
TECHNOLOGY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

20 June 2013

IREC Reference Number: REC 88/12

Mrs S Pillay
25 Spilsby Avenue
Lincoln Meade
Pietermaritzburg
3201

Dear Mrs Pillay

A descriptive study into the cold chain management of childhood vaccines by nurses in Primary Health Care clinics in the uMgungundlovu district

The Institutional Research Ethics Committee acknowledges receipt of your final data collection tool for review.

We are pleased to inform you that the questionnaire has been **APPROVED**; you may now proceed with data collection on the proposed project.

Yours Sincerely



Dr D F Naude
Chairperson: IREC

APPENDIX 8 – The Vaccine Vial Monitor

1.4 How does the VVM work?

The **inner square** of the VVM is made of heat sensitive material that is light at the starting point and **becomes darker** with exposure to heat.





At the starting point, the inner square is a lighter colour than the outer circle. From then on, until the temperature and/or duration of heat reaches a level known to degrade the vaccine beyond acceptable limits, the inner square remains lighter than the outer circle.

At the discard point, the inner square is the same colour as the outer circle. This reflects that the vial has been exposed to an unacceptable level of heat and the vaccine degraded beyond acceptable limits. The inner square will continue to darken with heat exposure until it is much darker than the outer circle. Whenever the inner square matches or is darker than the outer circle, the vial must be discarded.



Figure 2: VVM Locations

The vaccine vial monitor...

	Inner square lighter than outer ring. If the expiry date has not been passed, USE the vaccine.
	At a later time, inner square still lighter than outer ring. If the expiry date has not been passed, USE the vaccine.
	Discard point: Inner square matches colour of outer ring. DO NOT use the vaccine.
	Beyond the discard point: Inner square darker than outer ring. DO NOT use the vaccine.

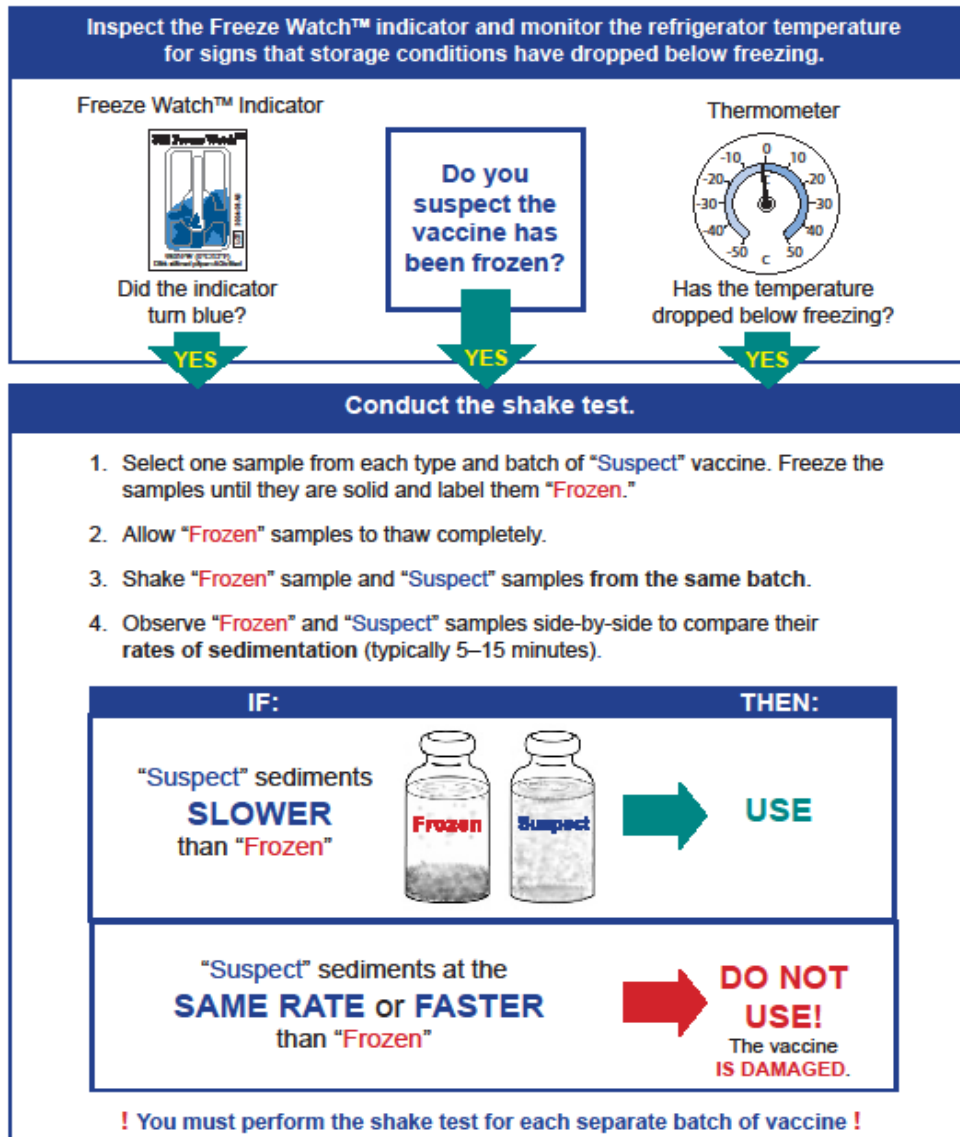
(World Health Organization, 2002, page 4)

APPENDIX 9 – How to Carry Out the Shake Test

Has your vaccine been damaged by freezing?

Freezing damages the potency of DPT, DT, Hep B, and TT vaccines. It is important to identify when vaccines have been damaged by performing the steps below.

Regularly inspect your vaccine refrigerator for signs of freezing. If you suspect that vaccine has been frozen, use the shake test to determine whether the vaccine should be used (any vaccine that is frozen solid or is not homogeneous should be discarded immediately).



Supported by PATH's USAID-funded HealthTech program and its Children's Vaccine Program.

August 2003

(World Health Organisation, 2011, page 28)

APPENDIX 10 – Statistics: Chi-Square Test

	Chi-Square	df	Asymp. Sig.
Clinic	2.571	3	.463
Is there evidence of filling in of stock cards for vaccines?	7.143	1	.008
Is there evidence of physical inventories of vaccine stock?	7.143	1	.008
Is there evidence of dedicated room for vaccine storage and immunisation procedures?	2.571	1	.109
Is there evidence of shake test for frozen vaccines?	10.286	1	.001
Is the emergency tray available and fully equipped?	4.571	1	.033
Is there evidence of training on emergency reactions?	10.286	1	.001
Does the nurse respond immediately when vaccines arrive in clinic?	0.286	1	.593
Does the nurse check vaccines for discrepancies, leakage and breakage before receipt?	0	1	1.000
Are vaccines stored immediately on receipt?	0	1	1.000
Are vaccines packed according to the first in first out principle?	1.143	1	.285
Is the refrigerator appropriate to store vaccine? Size, freezer compartment for icepacks?	7.143	1	.008
Is the refrigerator is dedicated for vaccines only?	7.143	1	.008
Is the refrigerator temperature between (2 - 8 °C)?	0.286	1	.593
Is the temperature of the refrigerator recorded on chart twice daily?	2.571	1	.109
Is the refrigerator packed correctly with vaccines and diluents?	4.571	1	.033
Is the refrigerator overstocked?	1.143	1	.285
Is there enough air circulating between vaccines?	10.286	1	.001
Are there vaccines on the door?	10.286	1	.001
Does the vaccine stock correspond with the diluents stock?	4.571	1	.033
Is the cold boxes in a good condition and right size?	4.571	1	.033
Is there a working thermometer in the cold box?	0	1	1.000
Is the temperature of the cold box between 2-8 degrees?	4.571	1	.033
Is the cold box packed correctly i.e. 6 ice packs?	2.571	1	.109
Are ice packs conditioned before use?	4.571	1	.033
Vaccines are left out of cold box for long period of time during immunisation	0.286	1	.593
Does the nurse record the date and time on the open vials?	2.571	1	.109
Is the expiry date on vials checked prior to administration?	4.571	1	.033
Is the policy maintained regarding sterility and reconstitution?	1.143	1	.285
Is the VVM used outside the cold chain?	7.143	1	.008
Are sufficient syringes, needles and sharps containers available for immunisation session?	7.143	1	.008