AN EVALUATION OF THE KNOWLEDGE AND PRACTICES OF PRIMARY HEALTH CARE NURSES IN THE COLLECTION OF CLINICAL SPECIMENS AT THE KING CETSHWAYO DISTRICT, KWAZULU-NATAL, SOUTH AFRICA.

Bhekisiwe Thobekile Mthethwa
Student Number: 20100579

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Supervisor: Dr Ayisha Razak

Co-supervisor: Mrs Padmini Pillay

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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is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources).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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Signature of student Date

Approved for final submission

23 June 2022

Dr A. Razak _____

PhD Date

Mrs P. Pillay _____

M Nursing Date

Abstract

Introduction and background

The burden of diseases in South Africa (SA) increases the demand for several clinical specimens to be collected and analysed at the clinic level and to provide an initial diagnosis of diseases. The primary purpose of the clinical specimen collection is to conclude on the clinical diagnosis, give proper clinical management, and monitor disease progression of patients. In 2019, the South African National Health Laboratory Services reported an increasing rate of specimen rejection due to pre-analytic errors for Primary Health Care (PHC) clinics. The insufficient knowledge and incorrect practices by nurses during specimen collection resulted in specimens being deemed unsuitable for analysis thus were rejected by the laboratory services, leading to delayed patient diagnosis and treatment.

Aim of the study

The study aims to evaluate the knowledge and practices of nurses in the collection of clinical specimens that may lead to rejections in Primary Health Care clinics.

Method

Quantitative, non-experimental, cross-sectional descriptive survey design was used to conduct the study. Consecutive sampling method used to select the 22 fixed primary health care (PHC) clinics and one CHC under King Cetshwayo Health District. The target population consisted of professional and enrolled nurses from the selected clinics. Sample size was 352 respondents. A checklist and a self-administered questionnaire was used to gather information on specimen collection. Data was analysed using SPSS version 27 and descriptive statistics was used to describe the data graphically and in frequency distribution tables.

Results

The study results on knowledge and practices of nurses in specimen collection, showed that the majority of respondents (97%) n=326 displayed necessary knowledge on four main areas of specimen collection which are: preparation and identification; collection and handling; courier and results handling and the availability of specimen collection material. The respondents also displayed significant knowledge in the specimen collection and handling section with an 89% (n=299) response to colour coding for specimens and 81% (n=272) for the volume of the specimen in the container.

Conclusion

The study showed that three phases of specimen collection which are: specimen and patient preparation (pre-analytical), collection and analysis (analytical) as well as results handling (post-analytical) can influence each other negatively or positively. The positive influence is when the availability of all specimen collection consumables, proper nurses training (structure) and use of correct procedures (process) enables nurses to collect the specimens correctly so that accurate results will be produced (outcome). The negative influence is when the unavailability of some specimen collection consumables and inadequate training results in nurses using incorrect procedures to collect specimens; therefore, inaccurate results will be produced by the laboratory delaying patients' diagnosis and treatment.

Dedication

I dedicate this dissertation to all the nurses working at the Primary Health Care clinics.

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Glossary of Terms

Accreditation: Certification of an institution for a specified period, recognizing it as a nursing education institution with the capacity to offer a prescribed nursing programme, upon compliance with the Council's prescribed accreditation requirements, criteria and standards for Nursing Education and Training (South African Nursing Council 2013).

Enrolled/Staff nurse: A person educated to practise basic nursing in the manner and to the level prescribed by Government Notice No. R.171 (South Africa, Department of Health 2020: 10).

Nurse: A person registered in a category under section 31(1) to practise nursing or midwifery (South Africa, Department of Health 2020: 4).

Primary health care: Is the 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 (Clarke 2014: 17).

Professional nurse: Is a person who is qualified and competent to independently practise comprehensive nursing as prescribed under section 58(1)(q) of the Nursing Act, 2005 (Act No. 33 of 2005), in the manner and to the level prescribed and who is capable and registered with the South African Nursing Council under Government notice No. R.425 of 22 February 1985. The person is responsible and accountability for such practice (South African Department of Health 2020: 6).

Specimen Rejection: Rejection occurs when the specimen is unsuitable for analysis resulting in inaccurate results reported (Plebani *et.al.* 2014: 44).

Quality Assurance: The practice of managing the way internal and external services are provided to achieve, maintain and enhance quality (Williams 2016: 97).

List of Acronyms

Acronym	Full term
AIDS	Acquired Immune Deficiency Syndrome
CLI	Clinic-Laboratory-
DBS	Dried blood spot
DHS	District Health System
DOH	Department of Health
EDTA	Ethylene-diamine-tetra-acetic acid
EID	Early Infant Diagnosis
ELL	Essential Laboratory List
EMTCT	Elimination of mother- to- child transmission
HIV	Human Immune Virus
ICSM	Integrated Clinical Services Management
ICRM	Ideal Clinic Realization Management
IPC	Infection Prevention and Control
LIS	Laboratory Information System
NCD	Non-Communicable Diseases
NDOH	National Department of Health
NHLS	National Health Laboratory Services
NHS	National Health System
NICD	National Institute for Communicable Diseases
PAP	Papanicolaou Test
PCR	Polymerase Chain Reaction
PHC	Primary Health Care
PFMA	Public Financial Management Act
PPE	Personal protective equipment

PPT	Plasma Preparation Tube
PPTICRM	Permanent Perfect Team for Ideal Clinic Realisation and Management
QIP	Quality Improvement Plan
QMS	Quality Management System
SANC	South African Nursing Council
SOP	Standard Operational Procedure
SST	Serum Separator Tube
TAT	Turn-around time
TTP	Total Testing Process
WHO	World Health Organisation

CHAPTER 1: OVERVIEW OF THE STUDY

1.1 Introduction and background of the study

Due to the increasing burden of diseases in South Africa, the National Department of Health (NDOH) renders several priority health programmes that are offered at the Primary Health Care (PHC) clinics such as Tuberculosis (TB), Human Immune Viral infections (HIV) and cancer, amongst others. The PHC clinics are the first level of care where the clients seek treatment before being referred to the next level of care, which is the hospital. The clinics are therefore expected to provide quality care as much as possible. Therefore, there has been an increasing demand for different clinical specimens to be collected and analysed at the clinic level to provide an initial diagnosis of diseases. The clinical specimen is defined as any sample of body fluid or tissue that is collected to perform an analysis for disease diagnosis and monitoring. The primary purpose of the clinical specimen collection is to conclude on the clinical diagnosis, give proper clinical management and monitor disease progression of patients (South African Department of Health 2020 and National Health Laboratory Services 2016: 21).

The burden of diseases in South Africa (SA) increases the need for prompt diagnosis, treatment as well as disease monitoring. Abbas, Mukinda and Namane (2017: 2) stated that the laboratory tests alone contribute to about 70-80% in diagnosis of patients. The nurses at the PHC clinics function independently in ensuring that specimens are collected correctly for analysis which in turn prevents wasteful and fruitless expenditure. It is thus, the primary responsibility of the nurses at PHC clinics to ensure that specimen collection material is available, specimens are accurately collected and stored and transported correctly to decrease analysis errors. Hence, specimen results will be accurate and can be used effectively for patient treatment (South African Department of Health and National Health Laboratory Services 2016: 16).

There are different phases of specimen collection whereby a series of errors can occur, resulting in specimens being unsuitable for analysis. Those specimens will then be rejected by the laboratory (Goswami, Roy and Goswami 2014: 4). The quality of specimen collection should be maintained throughout all phases to minimise rejection errors by following the prescribed guidelines set by the South African Department of Health. To ensure the provision of quality, affordable and sustainable health laboratory services to the public of South Africa, the Department of Health works together with the National Health Laboratory Services NHLS (South African Department of Health and National Health Laboratory Services 2016: 3).

NHLS is a national public entity established in terms of the National Health Laboratory Service Act 37 of 2000 to provide clinical support services to the national, provincial and local Departments of Health and perform analysis of specimens. As a measure to ensure quality diagnostic processes, the PHC Ideal Clinic Laboratory Handbook and Toolkits were developed for all the PHC clinics to align NHLS strategy to both the Department of Health (DOH) priorities and the national burden of diseases. The PHC Ideal Clinic Laboratory Handbook serves as a step-by-step guide for nurses for the collection of specimens that are suitable for analysis. It also provides an integrated package of essential healthcare services at the PHC level in all districts and a single, standardised health system (South African Department of Health and National Health Laboratory Services 2016: 5).

The overall aim of the Handbook is to achieve a synergistic approach to achieve optimal health outcomes (South African Department of Health and National Health Laboratory Services 2016: 3). The clinical guidelines are used to define the PHC Essential Laboratory List (ELL) as approved by the National Health Council in 2015. The main purpose of the ELL is to guide the cost-effective selection of laboratory testing towards improving the quality of care rendered thus complying with the Public Finance Management Act (PMFA) (Act No. 1 of 1999) on expenditure.

1.2 Problem Statement

Certain requirements are necessary for the clinical specimens to be processed effectively by a laboratory to obtain accurate results in the expected turnaround time. The insufficient knowledge and incorrect practices by nurses during specimen collection result in specimens being deemed unsuitable for analysis therefore rejected by the laboratory services. These incorrect practices are referred to as rejection errors or rejection criteria which in turn cause delays in treating the patients and increases costs and unnecessary treatment given to patients (Steinhobel, Massyn and Peer 2015: 12).

PHC clinics within the King Cetshwayo district have a reported average of 3-5% rejection rate which is more than the 2.37% national rejection norm. According to the NHLS report for quarter one and quarter four of 2019, sub-districts under King Cetshwayo district had an average of rejected specimens as follows: uMhlathuze 3.94%; uMthonjaneni 4.90%; Nkandla 3.51%; uMfolozi 4.2% and with the King Cetshwayo district having an average of 3.88 % (South African National Health Laboratory Services 2019: 7). The high percentages of rejected specimens as reported by NHLS from PHC clinics is due to errors encountered during the pre-analytical phase — that is, during patient preparation, specimen collection, storage and transportation phase. The rejection occurs when the specimen is unsuitable for analysis and the consequence is inaccurate reporting of results (Plebani *et al*. 2014: 44).

NHLS as the provider of surveillance support for communicable diseases, occupational health and cancer for the South African National Department of Health, in their 2018/19 report stated that from quarter one of 2019 to quarter four of 2019 there has been an increasing rate of specimen rejections due to pre-analytic errors at PHC clinics alone (South African National Health Laboratory Services 2019: 8). It is believed that insufficient knowledge on basic principles of specimen collection and incorrect practices by nurses during specimen collection, may have led to a huge

number of specimens being rejected. Specimen rejection serves as an important quality indicator that may have negative consequences by delaying treatment to patients (Karcher and Lehman 2014: 1003).

Surveys by the Department of Health on quality standards monitoring also identified the clinic-laboratory interface (CLI) challenges at both the PHC facility and laboratory levels when it comes to laboratory services as indicated below:

- Non- standardised clinic-laboratory processes.
- Multiple non-integrated request forms in distribution.
- Specimen collection materials availability and management.
- Inconsistent courier collection.
- Non-structured recording of laboratory results.
- Inadequate guidelines on the collection, storage, packaging and transportation of laboratory specimens

(South African Department of Health and National Health Laboratory Services 2016: 18).

There are three main phases of specimen collection and testing where errors leading to rejection have been reported: pre-analytic phase, analytical phase and post-analytical phase. The description of these phases for the purpose of the study excludes laboratory analysis.

- Pre-analytical phase: this phase includes all steps from the time the clinician orders the test until it is collected. The errors reported pre-analytically, account for approximately 70% of rejections caused by, among others, poor

patient identification, no labelling, no test specified, no clinic specified (Abbas *et al.* 2017: 6).

- Analytical phase: this phase includes all steps taken after the specimen is collected and sent to the laboratory. For this study, this phase will include all steps followed during the collection of the specimen, packaging and storage until it reaches the laboratory. During sample collection, the reported errors are clotted or haemolysed samples, insufficient volume and use of incorrect tubes. About 30% of rejections are due to clotting of specimens related to the procedure followed during specimen collection (Abbas *et al*. 2017: 6).

- Post-analytic phase: this phase includes all steps from the time the test is reported at the laboratory, results interpreted and received by the clinic. Other errors are the use of incomplete request forms and insufficient volume of specimens which contribute to rejection errors (Abbas *et al.* 2017: 5). The delays due to errors result in unnecessary treatment given to patients, high health costs and waste of financial resources when specimens must be repeated (Abbas *et al.* 2017: 3).

1.3 Aim of the study

The study aims to evaluate the knowledge and practices of nurses in the collection of clinical specimens that may lead to rejections at Primary Health Care clinics.

1.4 Objectives of the study

The objectives of the study are:

- To identify the available specimen taking and storage resources as per PHC laboratory guideline (handbook).
- To observe the practices applied by nurses before, during and after collecting specimens.
- To determine the nurses' knowledge on basic principles of collecting different specimens.

1.5 Research questions

- What is the available specimen taking and storage resources?

- What practices are applied by nurses before, during and after taking specimens?

- What knowledge do nurses have on basic principles of taking different specimens?

1.6 Significance of the study

The burden of disease in South Africa requires accurate diagnosis, disease monitoring and control. This helps the country in preventing disease deterioration and spreading. Clinical specimens play a major role in the investigation and monitoring of disease. Accurate analysis of specimens depend on the pre-analytic processes applied by nurses when collecting specimens (Singh and Singh 2019: 236). Dikmen, Pinar and Akbiyik (2015: 377), in their study to evaluate knowledge on specimen collection, established that there was a specimen rejection rate of 6% in emergency laboratories. They further concluded that documentation of rejected samples and periodic training of healthcare personnel is vital. The documentation helps in improving the total quality management of the diseases and promotes patient safety. Insufficient knowledge on specimen collection makes healthcare providers prone to committing pre-analytic errors that may lead to specimens being rejected. Identifying these errors and providing education on procedures for specimen collection is essential (Saffar *et al*. 2020: 61).

Saffar *et al*. (2020: 62) stated that some studies found that inappropriate ordering and interpretation of results contributed to about 35%-37% overlooked or delayed diagnosis for patients. Their findings revealed a lack of knowledge on specimen collection procedures. The DOH objective is for health facilities to diagnose and treat any disease timeously before complications intensify as well as to monitor disease

progression (South Africa Department of Health and National Health Laboratory Services 2016: 5). According to NDOH surveys conducted for quality assurance at the PHC facilities, the status quo reported is that patients experience low-quality service delivery, with non-integrated care that is not aligned with the patients' needs. Furthermore, patient waiting time in clinics is two to five hours; with 79% of the time spent waiting for services. The surveys also suggest that essential medical supplies are often not available at the clinic therefore this leads to inaccurate results reported which increases patients' waiting time. The integrated laboratory services aim at improving the clinic-laboratory interface (CLI) to offer effective and efficient healthcare services with the broader goal of improving patient outcomes (South African Department of Health and National Health Laboratory Services 2016: 21).

In South Africa, there is paucity in the research conducted at the PHC clinic setting therefore this research study will help to identify any gaps in the practices carried out during specimen collection and provide a basis for improvement.

1 .7 Operational definitions

Enrolled/Staff nurse: Is a person educated to practise basic nursing in the manner and to the level as prescribed in terms of Government Notice No. R. 171 8 March 2013 on the recommendation of the South African Nursing Council, Section 45(1) (q) of the Nursing Act, 1978 (Act 50 of 1978) (South African Department of Health 2020: 10).

Nurse: Is a person registered in a category under section 31(1) to practise nursing or midwifery (South African Department of Health 2020: 4).

Primary health care: Is the essential care based on practical, scientifically sound and socially acceptable methods and technology that is 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 (Clarke 2014: 17).

Professional nurse: Is a person who is qualified and competent to independently practise comprehensive nursing in the manner and to the level prescribed and who is capable and is registered with the South African Nursing Council under Government notice No. R.425 of 22 February 1985 thus assuming responsibility and accountability for such practice (South African Department of Health 2020: 6).

Specimen Rejection: Rejection occurs when the specimen is unsuitable for analysis resulting in inaccurate reporting of results (Plebani *et al.* 2014: 44-8).

Quality Assurance: Is the practice of managing the way internal and external services are provided to achieve, maintain and enhance quality (Williams 2016: 97).

1.8 Chapter outline

The study is arranged in the following chapters:

Chapter 1: Introduction

The chapter outlines the background of the study, statement of the problem, the aims and the objectives of the study.

Chapter 2: Literature review

The chapter discusses the different literature on specimen collection and rejection and the quality improvement as well as outlining the theoretical framework that supports the study.

Chapter 3: Methodology

The chapter discusses the study setting, sampling and data collection method.

Chapter 4: Presentation of the results:

The chapter outlines the results of data collection process.

Chapter 5: Discussion, conclusion and recommendations

The chapter discusses the results of the study and highlights the recommendations based on the results.

1.9. Conclusion

In this chapter, the study was introduced and the background to the research was provided. The aims and objectives of the study were highlighted. Significance of the study was clarified. The problem statement was explained and concepts were defined. The next chapter focuses on the literature pertinent to the study.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter aims at reviewing literature on specimen rejection as well as nurses' knowledge and practices in the collection of specimens. The literature review adds to the body of knowledge about rejection errors that may occur during the three phases of the quality assurance cycle of specimen collection as well as strategies applied to improve quality in specimen collection. The literature reviewed provides insight on the role of primary healthcare nurses in specimen collection. The relevant studies were identified by literature from different journals, books and online journals namely PubMed and Google Scholar using search words such as 'specimen rejection', 'pre-analytic errors,' 'nurses' knowledge' and 'quality'.

To achieve optimal health care at the clinics, norms and standards should be set to enable a uniform approach for the measurement of quality. The purpose of laboratory standard setting is to formulate a basis for expected performance, promote accountability with limited bias and ensure that evidence is always available when required (Dhotre, Dhotre and Shaik 2020: 67). Specimen rejection is defined by Karcher and Lehman (2014: 1003) as any blood, urine or other sample for which one or more tests ordered cannot be performed as the specimen does not meet laboratory acceptability criteria. According to Karcher and Lehman (2014: 1003), specimen rejection has negative consequences when it comes to patient safety or health as delays may occur. Dikmen *et al.* (2015: 384) reported that more than 6% of specimen rejection poses a risk to patients' safety.

The specimens go through three phases where errors can be reported: pre-analytical, analytical and post-analytical phase (Abbas *et al.* 2017: 5). Studies that have been conducted on the criteria for specimen rejection discovered that errors in the pre-analytic phase contributed to a large percentage of specimen rejection by laboratories. Insufficient knowledge and incorrect practices are the common

contributory factors to specimen rejection (Plebani *et al.* 2014: 44). Pre-analytic phase is the phase that starts from patient preparation to when the specimen is being collected. Rejection errors are associated with high rates of recollection, delays in result availability and high rates in hospitalisation (Karcher and Lehman 2014: 1006).

Abbas *et al.* (2017: 4) stated that specimen rejection leads to higher costs of healthcare and therefore recommended that continuous education and training is necessary to reduce pre-analytic errors. In support, Musabaike *et al.* (2018: A26) stated that specimen rejection not only causes delays in patient diagnosis and treatment but also results in wastage of staff time and resources. Lippi *et al.* (2013: 229) stated that pre-analytic errors are found to be much more noticeable in turn-around time monitoring, which is the time between the collection of specimens to the availability of results. Mismatching of patients with the specimens has been reported as the second error of specimen rejection, this is due to failure to complete the specimen request form properly and incorrectly labelled specimens (Cao *et al*. 2016: 1141). Dhotre *et al.* (2020: 68) however, argued that insufficient volume is the second most reported rejection error. Consequently, 23% of rejected specimens have been found to be due to have insufficient volume leading to poor mixing during processing (Plebani *et al*. 2014: 45).

To provide an integrated health approach to patients, Plebani *et al. (*2014: 48) without reservation, concluded that, in order to prevent errors, a certain level of standardisation needs to be followed, in ensuring that specimen collection equipment is available, correct procedures are followed, before, during and after specimen collection.

2.2. Specimen rejection criteria worldwide

The literature discusses the rejection errors and strategies applied by different countries such as Europe and Africa in trying to improve systems as well as nurses' practices to reduce rejection errors. Strategies implemented in South Africa and its provinces particularly KwaZulu-Natal in strengthening laboratory services are discussed in relation to introduction of Primary Health Care Ideal Clinic Laboratory services (South African Department of Health 2018: 2).

2.2.1 Pre-analytical errors

The laboratory data from a submitted specimen is reliable when the specimen is adequately collected, labelled, stored and transported to the laboratory in a correct manner as prescribed by the laboratory standards. Nurses upon rendering care to patients when collecting specimens can in the process commit errors which deem specimens unsuitable for analysis (Goswami *et al.* 2014: 1). The sample collection is mostly performed by nursing staff therefore these errors can rarely be identified by the laboratory staff in the pre-analytical phase. Ye *et al.* (2018: 5) found that in China, most of the phlebotomy procedures were performed by nurses particularly in the in-patient (97%), emergency (72%) and outpatient departments (39%).

Bunjevac *et al.* (2018: 2) conducted their studies in hospital settings and have concluded that the pre-analytic phase contributes to a larger percentage of about 75% of rejection errors. Bunjevac *et al.* (2018: 2) emphasised that the pre- analytic phase is the vulnerable phase in specimen collection because it decides whether the specimen will be suitable for analysis or not. Pre-analytic phase is described by Karcher and Lehman (2014: 1006) as the phase that starts from patient preparation to when the specimen is being collected. These errors are associated with a high rate of recollection, delay in availability of results and a high rate of unnecessary hospitalisation. Goswami *et al.* (2014: 4) concurred by proving that approximately 56% of laboratory errors occur during the pre-analytic phase. A study by Atay *et al.* (2014: 377) that was conducted in Turkey and was of the same mind, that, pre-

analytic phase errors occur at the point of entry when specimens are requested by a clinician.

Quality control projects that were implemented in the past as posited by Kumar, Barti and Singh (2020: 29) focused on the analytical phase, and neglected the pre-analytical errors in the process, therefore, monitoring of pre- and post-analytical phases for finding errors and corrective actions for the same are needed to achieve better test reporting. The quality of the specimen collected by nurses depends on the effectiveness of the sampling process, therefore, all three phases of the total testing process can be evaluated through quality indicators which are objective measures of quality (Murray 2021: 196)

2.2.2 Incorrect patient identification

The patient as well as specimen collection equipment preparation is crucial during this stage. Goswami *et al.* (2014: 3) discovered that at least 1.9% of rejections was due to inappropriately labelled samples. For manual or handwritten labelling, each tube must be labelled at the time of the collection by the clinician with the required information (Atef and Faraj 2017: 11). It is important to identify the patient to collect the right sample. Whenever identification of the patient is done, it is always prudent to use two identifiers being the name of the patient and the unique identification number with date of birth or identity number. The in-patients should wear wrist bands with identification information which is verified by the clinician whenever the samples are collected from the patient (Sareen and Dutt 2018: 1).

Dhotre *et al.* (2020: 69), in support, stated that it is important that a nurse properly identifies the patient against the clinical record before taking the specimen by emphasising the use of scanners as the proper way of identifying the specimen against the patient. This agrees with the study conducted in New York by Forest *et al.* (2017: 106) whereby they discovered that, a large proportion of rejected specimens were due to mislabeled specimens (54%), while 33.0% of rejected

specimens were due to incomplete request forms and 8.0% were due to unsigned requisitions. However, Forest *et al.* (2017: 106), also proved that implementation of an electronic ordering system decreased ordering and labeling errors from 2.5% to 1.2%. Furthermore, Brent (2016: 164) concluded that labeling errors could be reduced when using two patient identifiers.

The study conducted by Leonard *et al.* (2020: 266) which aimed at investigating the nature of pre analytical quality monitoring practices, discovered that 100% of rejected specimens pointed at specimen labeling and request form completion. Communication between laboratory technicians and nurses requesting the tests is vital to minimize ordering errors and ensure correctness (Jegede, Mbati and Gwarzo 2017: 1). On the contrary Goswami *et al.* (2014:4) found that rejection due to improperly filled forms (2%), improperly labelled samples (1.9%) were of a lower percentage. Sareen and Dutt (2018: 2), in India, discovered that mislabelled specimens and the lack of information on the requisition form prevented the laboratory from processing the samples on time further delaying diagnosis and patient care. Damato and Rickard (2015: 99) stressed that the unnecessary recollection of specimens contributes to delays in the patients' diagnosis and treatment and may potentially increase patients' length of stay in hospitals. Saffar *et al.* (2020: 61) suggested that insufficient knowledge makes healthcare providers more prone to inappropriate ordering mistakes which lead to missed or delayed diagnosis.

2.2.3 Haemolysis

There are other errors that contribute grossly to specimen rejection, which are mainly caused by the technique applied when the nurses collect that particular specimen as requested. Haemolysis is described as the rupturing (lysis) of red blood cells (erythrocytes) and the release of their contents (cytoplasm) into surrounding fluid for example, blood plasma. Unsecured line connections, contamination, difficult

collections and incorrect needle size, as well as improper tube mixing and incorrectly filled tubes are all causes of haemolysis (Park, Konge and Anthony 2017: 691). Goswami *et al.'s* (2014: 4) study discovered that the most common causes for rejection among blood samples were haemolysed specimens (78.57%), followed by clotted specimens (6.93%). These were due to unnecessary delays between collection, lack of proper mixing of samples and delays in submission of samples. There was a low percentage of specimen rejection due to low quantity (3.86%), excessive quantity (3.57%) or spillover (3.07%) – these were mostly due to faulty technique by the nurses collecting blood. Rejection due to improperly filled forms (2%) and improperly labeled samples (1.9%) were of even lower percentage. Haemolysis in China has been proven to be the leading cause of rejection followed by clotting and incorrect volume (Kang *et al* 2020: 4),

Howanitz, Lehman and Jones (2015: 901) state that although haemolysis is a general problem in specimen processing, recent studies have indicated that the frequency of haemolysis is highly common among health institutions. Haemolysis is influenced by the type of training provided and competency of the nursing personnel collecting the specimens, the equipment used to collect the specimens and the quality control measures applied during specimen collection (Gannon *et al.* 2020: s130). Although dried blood spot (DBS) was the preferred technique which was aimed at reducing haemolysis errors in babies, pre-analytical variables for DBS have not been adequately considered for many years by researchers (Grüner, Stamboul and Ross 2015: 1), Inalegwe *et al.* (2016: 74) in Nigeria, discovered that for DBS specimens, primary health clinics had a three-fold higher rate of sample rejection. The major reasons for rejection were improper sample collection (26.3%), improper labeling (16.4%) and insufficient blood (14.8%). Grüner *et al.* (2015: 2) also preferred dried spot blood specimen for children because it can be preserved for longer periods, with no possibility of haemolysis.

Plebani (2016: 1884) stated that the common reasons given for rejection in most studies were haemolysis but in others, clotted specimens and/or insufficient volumes of samples are also common. wan Azman *et al.* (2016: 94) supported this statement that haemolysed specimens can be as high as 3.3% of all laboratory samples, thus accounting for about 40% to 70% of all unsuitable samples. Howanitz *et al.* (2015: 904) also proved that haemolysis interferes with a lot of laboratory measurements, resulting in the incorrect interpretation of patients' samples which poses a threat to their lives. On the other hand, Witek *et al.* (2017: 47) found that haemolysis might be due to taking blood specimens after exercise. This is an important measure to prevent rejections related to storage and transportation. Lay, Pinar and Akbiyik (2014: 1002) conducted a study in Turkey which reported that increased staff turnover necessitates periodic educational improvement to improve errors that occur during specimen collection.

2.2.4 Specimen volume

Wadhwa (2020: 354) reported that insufficient volumes of specimen accounted for 40% of rejected specimens. The study conducted in Burkina Faso on Tuberculosis (TB) diagnosis for younger children using Gene X-pert (GXP) assay, reported that the implementation of methods to collect sputum samples in children who were unable to expectorate, remained a challenge. They ended up performing assay on 1.0 ml of fresh sample or sterile pellets if the sample volume was not sufficient following the manufacturer's recommendations (Marcy 2016: 1162). Sputum specimens with sub-optimal volume (less than 5ml) may not be processed as this may produce a false-positive result (South African Department of Health and National Health Laboratory Services 2016: 43). Myatt *et al.* (2017: 43) stated that together with the amount of the specimens, nurses should also record colour and consistency of the sputum specimen.

The stool specimens can also be rejected if the volume does not meet the criteria for analysis (Tung and Hays 2019: 23). Grüner *et al.* (2015: 5) stated that unlike venepuncture method, dried blood spot specimen requires less blood volume, and

this was most important in paediatric diagnostics where blood collection is non-invasive, simple and inexpensive. In contrast, Chiku *et al.'s* (2019: A278) study in Zimbabwe found out that even with the improved dried blood spot testing for infant HIV diagnosis, insufficient samples still accounted for 73% of all rejected specimens in rural PHC clinics.

Seventy percent of the specimens were not properly analysed due to overfilled tubes/jars. Overfilling of the specimens caused a lot of challenges when patients' results were interpreted (O'Byrne and Orser 2018: 123). However, Dorlan and Cornish (2013: 255) proved that the setting where the specimen was collected had a measure in rejection criteria but with multidisciplinary education urine specimen, collection outcomes were improved. In the United States, the liquid-based technique for cervical cancer specimens allows for easier interpretation and reduces errors associated with specimen volumes. Specimen adequacy provides direction to the nurses on whether the specimen is suitable for analysis or not (Mansour and Limaiem 2020: 2). By observing specimen adequacy and applying quality control for cervical cancer screening in Rio de Janeiro, Brazil, Gomes *et al.* (2018: 341) found that 12.97% of specimens were rejected and 2.65% were considered unsatisfactory for analysis.

2.2.5 Ethylene-Diamantine-Tetra-Acetic acid (EDTA) contamination and clotting

EDTA contamination occurs when the additive of one specimen tube gets into another specimen bottle. This is common among blood specimens. Blood collection tubes must be filled in a specific sequence to minimise contamination of sterile specimens, avoid possible test result error caused by carryover of additives between tubes and reduce the effect of micro clot formation in tubes (Ye *et al.* 2018: 5). Clotted specimens account for 0.09% of specimen rejections in Spain and 0.30% in the United States of America (Kang *et al.* 2020: 6). Rooper *et al.* (2017: 3) found that clotting was the most common cause of rejection accounting for 52.8% of rejections

and the second cause, haemolysis being 41.8%. Incorrect mixing after blood collection causes clotting of blood specimens (Dikmen *et al.* 2015: 377).

Bezuidenhout *et al.'s* (2018: 452) study on the effects of storage temperature and time, found that incorrect storage had a negative effect on the analysis of urine specimens. The recommendation was that specimens should be stored at temperatures between 4-8°C when analysis would be delayed beyond 12 hours. Alavi *et al.* (2020: 23) found that 14.9% of specimens were rejected due to clotting. Gross clots can be easily detected by visual inspection of the specimen however micro clots are sometimes difficult to detect. The presence of clots could be attributed to increased blood to anticoagulant ratio and improper mixing of the blood after dispensing in the tube with anticoagulant. The significant finding was that an error could be due to improper mixing of the blood sample and overfilling of the EDTA/ citrated tubes (Alavi *et al.* 2020: 23).

2.3 Specimen rejection criteria in South Africa

In South Africa, more focus is on early diagnosis of diseases like HIV, cervical cancer and Tuberculosis (TB) as well as initiation of treatment to improve treatment efficacy with decreased recurrence of diseases (Dasari *et al.* 2015: 1). There is limited literature on specimen rejection but some of the studies conducted proved that PHC clinics had the highest rejection rate of 4.0%, while secondary and tertiary healthcare clinics had rejection rates of 2.6% and 1.3%, respectively (Inalegwe *et al.* 2016: 76). In all nine provinces in South Africa, the NHLS conducted up to five million tests but still experienced challenges with specimen quality and delivery of results. Specimen rejection for viral load tests alone costs the country about R554 896 ($37.68) (Dunning 2017: 1160).

It was found that 81.5% of all rejected specimens were due to pre-analytical errors, with 49.5% due to insufficient sample volume while 22.2% were due to incomplete

request forms (Girdwood *et al.* 2019: 776). Most of the studies conducted in South Africa based their concern on the early diagnosis of diseases and prompt initiation of treatment. It is further stated that a delay in diagnosis and initiation of treatment for HIV infected babies was mostly associated with prolonged turnaround time in the early 90's (Moyo *et al.* 2018: 560). TAT is defined as the time taken from requisition of diagnostic tests until clinical decisions are made based on the test results (Bhattarai and Manandhar 2018: 26).

Mazanderani *et al.* (2017: 1) conducted a study in Gauteng, South Africa, on infant HIV diagnosis and found that 73.4% of specimens were rejected due to incompleteness of the request form, 12% of specimens were old and 14.6% was due to incorrect laboratory handling. On the other hand, the study conducted in KwaZulu-Natal on dried blood spot, found that insufficient specimen volume comprised 48.9% of the total number of rejections resulting from pre-analytical problems. Among other reasons for rejections were inadequate information supplied on the test request form, incorrect clinical indication for the test and poor specimen quality, such as incorrect specimen type, specimens that were too old for analysis and specimen cards that were expired (Govender, Parboosing and Siyaca 2016: 351).

Shisana *et al.* (2014: 138) reported that inadequate specimens remained a challenge in the collection of specimens for cervical cancer screening leading to rejections and delays in prompt treatment. Shisana *et al.* (2014: 138) also found that there was no standardised training on collection of different specimens in the nursing curriculum, the skill was only acquired through experience in the nursing field and phlebotomy practice was a specialised qualification mostly found in private hospitals. Mbatha *et al* (2017: 2) in KwaZulu-Natal, successfully implemented patient self-sampling for cervical smears when testing for Human Papilloma Virus in the community due to high rejections, however; the collection of specimens remained the nurses' role in the PHC clinics (Crous and Armstrong 2016: 347).

Magwai, Warasally and Naidoo (2020: 95) found that in Durban, KwaZulu-Natal, rejections dropped from 1.4% to 1.2% after introduction of dried blood spot. However, in the Western Cape, Abbas *et al.* (2017: 8) found that 40% of rejected specimens had a negative effect on patients' care. The rejection rate remained the same despite the training provided. Crous and Armstrong (2016: 343) agreed that in Gauteng, 40% of rejected specimens were due to pre-analytical errors and they had a negative impact on patient management. These authors questioned the phlebotomy practice by the nursing staff collecting the specimens.

Mazanderani *et al.* (2018: 250) furthermore stated that in the Gauteng province there were delays in providing antiretroviral treatment (ART) to HIV positive babies because 64.4% specimens were rejected due to pre-analytical errors and 6.2% of specimens had inconclusive results. On the contrary, Dorman (2018: 462) found that until the introduction of genotype testing (Gene-Expert), prolonged turnaround remained is a major cause for delayed diagnosis and initiation of treatment for TB and HIV co-infected patients.

Although Moyo *et al.* (2018: 562) had proven that between 2015 and 2016, the implementation of the South African National Consolidated Guidelines for the management of HIV and TB had increased the testing rate from 39% to 93%, the rejection rate also remained high for HIV CD4 count and viral load specimens due to pre-analytical errors. Mazanderani *et al.* (2017: 2), in their study in South Africa on infant HIV diagnosis, found that 73.4% of specimens were rejected due to incompleteness of the request form, 12% of specimens were old and 14.6% was due to incorrect laboratory handling.

2.4. Improving quality of laboratory services in specimen collection globally

Quality control in laboratory services is defined by Cadman (2014: 9) as “a management function whereby controls of the quality of raw materials, assemblies, produced materials and components; services related to production; and management, production and inspection processes is exercised for the purpose of preventing undetected production of defective material or the rendering of faulty services”. Communication breakdown between clinicians and technicians, human error and lack of standardisation have contributed greatly to poor workflow in the specimen collection process. Countries with limited resources could maximise health benefits of their patients by improving workflow in the laboratory, which is a cost-effective approach (Mwogi *et al.* 2020: 2).

The World Health Organisation (WHO) has tried to maintain a standard of healthcare especially for all developing countries over the years. Due to financial inequalities in the health system, most countries struggled to provide optimal access to quality health for their communities, with the indicator for quality of healthcare remaining poor. This indicator is measured by the proportion of clients satisfied with healthcare system provided (Williams 2016: 98). In this regard, quality indicators serve as a vital tool to monitor processes performed in the laboratory. Quality indicator is also a tool that enables the healthcare provider to quantify the quality of specimen collection to the health outcomes (Wadhwa 2020: 354).

In April 2008, the WHO Injection Safety programme which is part of the Department of Essential Health Technologies at WHO Headquarters in Geneva; convened a meeting for consultation on best practices for phlebotomy, blood collection and to develop guidelines. These guidelines were produced to improve the quality of blood specimen collection and the safety of phlebotomy for nurses and patients, by promoting best practices in phlebotomy (Cadman 2014: 10). Some countries, for example, America and Canada have well-developed structures which Kringos *et al.* (2013: 686) added, that a strong PHC foundation is vital, whereby the countries channel financial resources to improve the status of the first level of healthcare which

are the clinics. Although this foundation gives best results to quality health, the question is whether data collected currently to evaluate the availability of resources can still provide the same results due to financial constraints faced by different countries in the sub-Saharan countries which have burden of acute diseases (Mash *et al.* 2018: 1). Furthermore Kringos *et al.* (2013: 686) suggested that studies done in well-developed countries like United States concluded that they have increased rates of avoidable hospitalisation due to their focus on curative and rehabilitative health services with limited availability of Primary Care clinics which focuses on preventive and promotive health.

Rochefort (2020: 334) reported that the Canadian Federal government had full control over their health service delivery, with a total of 70% accountability on health expenditure. On the contrary, Canada still struggled with the issue of service quality that resulted in the public being dissatisfied. In their Strategic Plan, more focus was placed on four priority themes namely: patient experience, quality and safety, outcomes and value for money. The value for money in Europe was measured against patients' experience of care as suggested by Kurfi *et al.* 2013: s19) who substantiated that, provision of adequate Primary Health Care improved access to quality care decreases the rate of costly hospitalisation.

The United Kingdom adopted the quality risk profile by collecting information to forecast any risky event that might jeopardise quality health. Risk assessment uses surveillance indicators which are Reportable Events indicating Danger in the Health System especially in three focal areas that is: leadership and governance, patient safety and patients' rights. Paying attention to these focal areas can improve access to a good quality healthcare system (Dhotre *et al.* 2020: 71). In China, Kang *et al.* (2020: 3) mentioned that in 2008 the International Federation of Clinical Chemistry and Laboratory Medicine launched a 'Laboratory Errors and Patient Safety' project which aimed at developing a common model of quality improvement to prevent specimen rejection. The project focused more on public hospitals where there was

more than 65.2% rejection rate compared to 34.8% in specialised hospitals. The introduction of technology for specimen collection and processing has played a major role in the improvement of quality. In Russia, the introduction of DBS technology had proven to be the most effective method to address sample volume and storage temperature errors (Malsagova *et al.* 2020: 248).

In 1978, during the International Conference on Primary Health Care at Alma Ata, the World Health Organisation together with different countries of the world declared that a Primary Health Care (PHC) approach was to be adopted by developing countries of the world as the best health strategy (Rifkin 2018: n.d). Declaration of Alma-Ata defines Primary Health Care as "essential healthcare based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the manner that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination" (African National Congress 1994: 19).

Alhassan, Nketiah-Amponsah and Arhinful (2016: 16) found that the introduction of National Health Insurance (NHI) in Ghana in 2003 contributed significantly to utilisation of health services and health outcomes. However, the drop in the quality of healthcare was still reported. Financial escalation and lack of monitoring remained threats to the successful implementation of NHI in Ghana. At the International Conference on Primary Health Care and Health Systems in Africa held in Ouagadougou, Burkina Faso from 28 to 30 April 2008, the African member states signed the declaration. The Declaration aimed at achieving better health for Africa in the new millennium. The 400 member states of the World Health Organisation African Region then had to develop their own framework for implementation of the Declaration to ensure quality improvement for PHC. The focus was on the following aspects:

Leadership and governance for health;

Health service delivery;

Human resources for health

Health financing

Health technology

(Simen- Kapeu, Reserva and Ekpini 2021: s49)

Of the nine guiding principles of the policy document for implementation of the declaration, the issue of equal access to essential services was mentioned. This had to be ensured by proper planning; ensuring adequate allocation of resources and application of measures to improve access to health services (Kredo *et al.* 2019: 2). Although Quality Management System (QMS) have noted little application in Nigeria, an effective QMS is critical to the success of the laboratory testing networks (Inalegwe *et al.* 2016: 78).

Saffar *et al.* (2020: 61) concluded that effective teaching methods of laboratory medicine should be considered for training curricula on better clinical decisions and outcomes. However, in comparison, Abbas *et al.* (2017: 10) reported that specimen rejection rates remained the same before and after training as there was no significant improvement. Forest *et al.* (2017: 108) stated that the use of the electronic requisitions project in Columbia contributed to the decrease in mislabelling of samples and requisition forms. They further demonstrated that implementation of a computerised barcode-based tracking system reduced the blood sample rejection rate in Columbian laboratories from 1.82% to 0.17%.

Simple and readily available technology had been proven to improve specimen outcomes. Due to the lack of a standardised sample referral system, Nigeria was faced with a high cost of CD4 testing and long turnaround time. In 2018, the Nigerian Federal Ministry of Health (MOH) established a National Integrated Specimen Referral Network (NISRN) to expand access to quality CD4 cell count testing. The

aim was to attain a safe, cost-effective, productive and secured referral system involving external logistics providers (Abiodun *et al.* 2020: 6). Between 2013 and 2014, Zambia also managed to overcome poor health outcomes associated with prolonged turnaround time in HIV diagnosis by introducing mobile phones and text messaging to send results to clinics. Availability of results improved from 38% to 91% (Sutcliffe *et al.* 2017: 3).

Lay *et al.* (2014: 1002) based on a study in Turkey, recommended that increased staff turnover necessitated periodic educational improvement to improve errors that occurred during specimen collection. Mwogi *et al.* (2020: 11) supported the implementation of technology-based solutions to assist in efficient processing of orders stating that this can be achieved by using computerised order entry approaches to communicate quality results to clinicians. Such a solution will have to be tailored for resource-limited settings that might have limited technological infrastructure and financial resources. In the Elimination of Mother to Child Transmission programme as recommended by WHO at eSwatini, it had been proven that the introduction of DBS testing using polymerase chain reaction technology played a major role in improving HIV testing outcomes. The researchers were able to successfully trace and link 68.2% of the babies tested for HIV at birth (Teasdale *et al*. 2020: 240). To improve nurses' knowledge of specimen collection in Ethopia, Kue *et al.* (2021: 2) developed the clinical specimen collection training package with information on specimen collection processes focusing on commonly collected types of specimens. Kue *et al.* (2021: 2) also designed the trainer's manual to be used during clinical specimen collection training.

2.5 Improving laboratory services in South Africa

South Africa as a country is still affected by quadruple burden of diseases namely:

- Communicable diseases such as Tuberculosis, HIV/AIDS, Malaria;
- Maternal and Child mortality;

- Trauma and injuries; and
- Non-communicable diseases (NCD) such as hypertension and diabetes mellitus (Baron and Padarath 2015: 3).

These diseases reduce life expectancy of the population especially in three provinces namely KwaZulu-Natal, Mpumalanga and Limpopo due to their poor socio-economic background (South African Department of Health 2020 and National Health Laboratory Services 2016: 10). Non-communicable diseases contribute 20% of unnatural deaths reported, while violence and trauma contribute to 9%. Maternal mortality is estimated at 625 per 100 000 live births with 31.1 neonatal deaths per 1000. South Africa had implemented numerous strategies in the health system to improve access to quality healthcare that is provided by these facilities. The healthcare system in South Africa has evolved since 1994 towards improving PHC services. The implementations of strategies that are beneficial to the community have been proven to have an influence in quality health and quality life of the recipients (Hirsch, Molnar and Chang 2013: 53). A healthy life is a result of functional and cost-effective health system. The South African Department of Health (2017b: 11) reported on the outcome of two of the Negotiated Service Delivery agreements which stated that although this was going to be a good strategy, the challenges persist in inhibiting the achievement of the desired outcomes.

Hopkins, Doherty and Gray (2018: 2) stated that the increased rate of burden of diseases as well as the cost of specimens sent to laboratory, the South African Department of Health resorted to adopting the point of care testing modalities which are ideal for the 'one stop shop' approach being implemented at the PHC facilities. The point of care technology offers inexpensive, large-scale rapid screening programmes for communicable diseases such as HIV, TB, sexual transmitted infections and malaria, especially in the deep rural communities, hence reducing the chances of specimen rejection (Hopkins, Doherty and Gray 2018: 2).

Currently in South Africa, TB is still the leading cause of death due to its association with poor socio- economic conditions. To improve the turnaround time of sputum specimens and to ensure prompt initiation of TB treatment, South Africa had adopted the new diagnostic tests, including the rapid Gene-Xpert technology. This ensured efficient diagnosis and initiation of treatment of new smear-positive and drug-resistant TB cases (Hopkins *et al.* 2018: 1). Technau *et al.* (2017: 2) agreed that the point of care modality was successful for early infant diagnosis, whereby in 2014 they implemented a universal birth HIV diagnosis programme at Rahima Moosa Mother and Child Hospital in Johannesburg, South Africa. The researchers aligned HIV testing for babies with birth and six weeks immunisations. Technau *et al.* (2017: 5) stated they were able to diagnose n=91(1.4%) babies out of n=6377 that were tested and only n=57 (0.9%) specimens were rejected due to errors.

2.5.1 Ideal Clinic Initiative

An 'Ideal Clinic' is described as "a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes and sufficient bulk supplies. It uses applicable clinical policies, protocols and guidelines, and it harnesses partner and stakeholder support" (South African Department of Health 2018: 2). The Perfect Permanent Team for Ideal Clinic Realization and Maintenance (PPTICRM) again took a front seat in the improvement of access to health. The powers for implementation were decentralised to all the health districts in all the provinces in SA (Hunter *et al.* 2017: 114). The Ideal Clinic initiative aspires to transform PHC services and it serves as the system that could offer the NHI an accreditation for the PHC facilities by strengthening the public healthcare system and ensuring consistently delivered good quality healthcare (Gray and Vawda 2018: 10).

The South African NDOH and NHLS had jointly developed the PHC laboratory handbook to improve the quality-of-service delivery and patient care as the country moves towards the full implementation of integrated services through the Integrated Clinical Services Management (ICSM) and Integrated Chronic Disease Management

(ICDM) model. ICDM is a model of managed care that provides for integrated prevention, treatment and care of chronic patients at primary healthcare level to ensure a seamless transition to 'assisted' self-management within the community by taking a patient-centric view that encompasses the full value chain of continuum of care and support (Asmall 2014: 1722).

The handbook aimed at providing standardisation when collecting specimens and to provide cost effective services to patients. The management of laboratory services forms the Sub-Component 13 of the Ideal Clinic assessment dashboard (South African, Department of Health and National Health Laboratory Services 2016: 11). Standards are described by Thimesch (2018: 18) as documents developed through the consensus process that clearly identifies specific, essential requirements for materials, methods or practices for use in an unmodified form. They may contain discretionary elements which are clearly identified.

South Africa's commitment to early diagnosis and to reduce errors prompted the initiation of programs that focused on Early Infant Diagnosis (EID) to curb TB and HIV related morbidity and mortality thus impacting positively on child health outcomes. This was achieved through the introduction of guidelines, standard operating procedures and community-based interventions (Celletti *et al.* 2017: 114). Dunning *et al.* (2017: 1163) concur that as much as in South Africa the DBS technology improved EID outcomes; it still recommended that the follow-up tests should be done at different ages for negative results because of the incorrect feeding practices that might expose the babies to the HIV virus. Between 2013 and 2016, the diagnosis guidelines in South Africa had shifted to the recommendation of the nucleic acid-based test for HIV diagnosis which further improved diagnosis from 13.1% to 24.8% (Smith *et al.* 2019: 140). Moyo *et al.* (2018: 562) proved that between 2015 and 2016, the implementation of the South African National

Consolidated Guidelines for the management of HIV, improved child health outcomes.

2.6 Cost of specimen rejection

The cost of specimen rejection poses tremendous challenges and financial burden on those communities affected by the disease (Peterson *et al.* 2018: 56). If a specimen is poorly collected, the results may be inaccurate and misleading to the clinician and the patient may have to undergo the inconvenience of repeat testing which might be painful or stressful (Cadman 2014: 9). The assessment of rejection rates is vital for quality laboratory measures because of the negative impact that collection errors have to patient care. Unreliable laboratory results ultimately affect patient care and in most cases an error in judgment leads to medical negligence (Sareen and Dutt 2018: 1). Yahya and Nasir (2019: 35) found that in Europe, the total cost of specimen rejection ranged from €22000 (R404 3332.35) to €5.9 million (R108 434 585.88) per annum and further demonstrated that a reduction in the number of rejected samples due to pre-analytical errors could lead to significant cost savings for most institutions in the United Kingdom and Turkey. The recollection of rejected specimen leads to prolongation of the turn-around time (TAT) and have a negative impact on the clinical decision making (Kang *et al.* 2020: 2).

The cost of rejected specimens is estimated at $337.05 (R4418.70) for each hospital out-patient per annum. Nurses mainly contributed to 85.64% of collected specimen errors and 4% by laboratory staff (Rooper *et al.* 2017: 4). The consequences of specimen rejection are the need to recollect a new specimen which leads to the delay in the processing and reporting of specimen results. The outcomes of specimen recollection and delay in reporting causes dissatisfaction about the quality of services rendered. The diagnosis and treatment for the patient is also compromised (Ye, Wang and Zhao 2018: 420). When the rejection rate is high, it is associated with increased length of stay for hospitalised patients and for outpatients

it is associated with delays in diagnosis and poor management outcomes (Bodansky, Lumley and Chaknaburty 2017: 37).

The specimen rejections have a detrimental effect on patients' care as well as financial implication due to a lengthy stay in hospital (Green 2013: 1175). Delayed turnaround time also increases the rate of length of stay in the hospitals. Mazanderani *et al.* (2018: 248) stated that PCR specimen rejection resulted in the delay in diagnosing and wastage of resources associated with missed opportunities in the prevention of mother to child transmission of HIV.

2.7. Role of nurses in the specimen collection process

This section entails the role of nurses in the specimen process. Figure 2.1 illustrates the seven steps of the specimen collection process namely: completion of request form; collection of specimens; packaging; storage; collection by a courier; managing results; ordering specimen collection equipment and accessing additional information (South African Department of Health 2017b: 16). Thimesch (2018: 1) stated that nurses play an important role in the collection of specimens and mentioned its importance in the three areas that require specimen collection in the health field:

Diagnostic and screening described as the way to figure out what is wrong with a patient

•Therapeutic assessment that is to develop the correct treatment or choose the right drugs

•Monitoring health to make sure the therapy or treatment is working

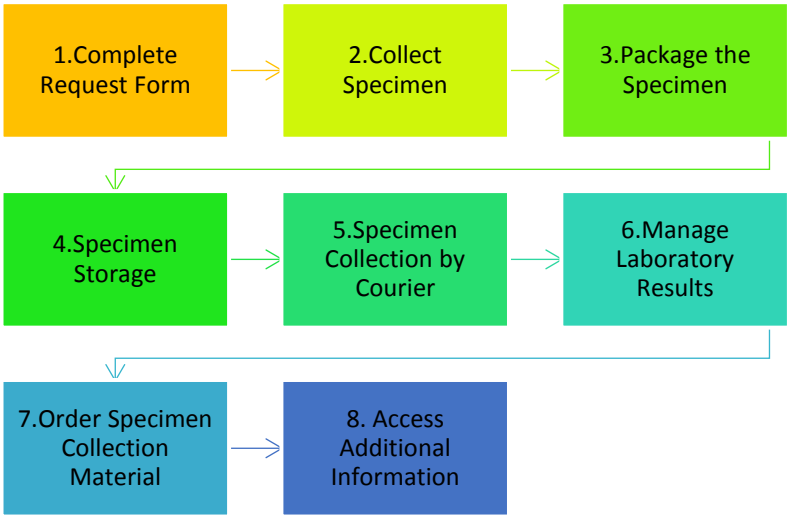

Figure 2.1 Specimen Collection Process (South African Department of Health and National Health Laboratory Services 2016: 16)

2.7.1. Completion of request form

The handbook provides a step-by-step guide to complete the request form as well as comply with the minimum clinical data set requirements such as patient identifier to ensure that proper patient identification begins at the registration process. The registration process occurs when a patient is admitted to a hospital or short-term care facility (Atef and Faraj 2017: 2). Prior to collection of specimens, clinicians should consider that laboratory investigations should be requested for a particular clinical indication and not as a routine procedure. The authorised requesting clinician must have a clear indication and define the reason for each laboratory investigation. The nurses should adhere to correct sample labeling techniques with labeling of tubes must be done before sample collection. Nurses should also note that laboratory investigations do not replace the need for a clinical examination of the patient. If results are unavailable, tests should not be repeated (South African Department of Health and National Health Laboratory Services 2016: 22).

Labeling errors are generally of three types. Firstly, an unlabeled container or requisition form meaning that the container or requisition form may lack proper

patient identification. The second type of error is when the container is identified as one patient while the accompanying requisition form states a different patient. The third type is when the requisition form and the container are correctly labelled but the specimen is collected from the wrong patient (Sareen and Dutt 2018: 2). The availability of complete information is to ensure that the laboratory data is matched to the correct patient and that the appropriate age and gender adjusted reference intervals are supplied to ensure that the laboratory results are sent to the appropriate health facility. To ensure that the laboratory can determine viability of the specimen for processing, the information of the clinician requesting the test on the form is essential as the person collecting the specimens might not be the same person as the requester (National Health Laboratory Services 2016: 23). It is mandatory for the following information to be filled on the request form (N1 or N2):

. Facility name

· Patient's folder number

· Patient's national identification (ID) number or passport number (if available)

· Patient's name

· Patient's surname

· Patient's Date of birth

· Patient's Gender

· Clinicians' name

· Health care worker's HPCSA/SANC number

· Health care worker's signature

· Collection Date

(National Health Laboratory Services 2015: 71).

The origin and the type of specimen should also be stated, for example: throat swab, urine or cervical smear. Brief clinical symptoms can be described to assist in the

extent of specimen processing and results interpretation (South African Department of Health 2020 and National Health Laboratory Services 2016: 24).

2.7.2. Collect specimen

This section in the manual provides a step-by-step guide to collection of the various specimens required for the tests as identified in the Essential Laboratory List (ELL) for PHC clinics. The ELL gives guidance on which specimens can be collected by a nurse at the PHC level. The nurses should be familiar with the ELL to avoid taking unnecessary specimens that are only ordered by the doctors (South African Department of Health 2020 and National Health Laboratory Services 2016: 31). Atef and Faraj (2017: 3) recommends that pre-collection of the specimen, patient consent must be obtained and he/she must be aware of the prerequisite for certain specimens like starving and drinking a lot of water amongst others. For manual or handwritten labels, each tube must be labeled with the required information at the time of the collection (Atef and Faraj 2017: 11). The nurse should avoid distractions when labeling specimens, have the patient spell his or her name and always ask for a date of birth (Thimesch 2018: 3).

Infection prevention and control practices should always be observed before and after touching the patient that is handwashing, wearing of the personal protective gear such as gloves and an apron. This is to prevent cross-infection and occupational injuries when collecting the specimens. The nurse should identify and assemble the individual specimen collection materials required before collecting the specimen (South Africa Department of Health 2020 and National Health Laboratory Services 2016: 35). Nurse must wash their hands using soap and warm water for at least 20 seconds and dry their hands thoroughly with a paper towel. Strict aseptic techniques should be followed when collecting specimens to avoid contamination by spraying the hands with an alcohol-based solution. All used specimen collection equipment should be disposed of in the correct disposal bags and containers to avoid infecting other patients (South African Department of Health 2020 and National Health Laboratory Services 2016: 36). The nurse must wear personal protective

equipment and can protect themselves by treating all specimens as infectious (Thimesch 2018: 17).

According to the manual developed by Atef and Faraj (2017: 9), all additive tubes must be filled to their stated volumes. Caps of tubes must not be removed to fill other tubes or transfer blood specimens from one tube to another even if they are the same type. Allow blood to fill the tube until the maximum stated volume is reached. (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 37). Blood collection tubes must be filled in a specific sequence to minimize contamination of sterile specimens and avoid possible test result error caused by carryover of additives between tubes as well as reduce the effect of micro clot formation in tubes (South African National Health Laboratory Services 2015: 93). Test tubes have anticoagulants and preservatives therefore it is important that these are not cross- contaminated. It is important that clinicians collecting specimens draw blood in a particular order (Thimesch 2018: 9).

The nurse must use good phlebotomy techniques to avoid hemolysis or venous stasis. To augment low specimen volumes by transferring blood from tubes containing anticoagulants/preservatives into clotted blood specimens should not be attempted. All gel containing vacutainer tubes (yellow top) and clotted (red top) blood specimens should be collected first based on the order of draw. Thereafter, collect specimens that require an anticoagulant or preservative (Atef and Faraj 2017: 9). Tubes containing additives should be mixed by inverting tubes at least 8-10 times for proper uniform mixing of anticoagulants with patient blood. These tubes should not be shaken vigorously as this might cause lead to haemolysis. Expired specimen collection tubes should not be used as it may cause loss of vacuum resulting in inadequate volume and changes in blood due to the additive ratio (Sareen and Dutt 2018: 3).

According to Thimesch (2018: 9), expired or tampered with specimen tubes should be discarded since outdated additives might affect interpretation of results. Alcohol should be allowed to dry prior to venepuncture and the appropriate gauge venepuncture needle used for the patient–nothing less than a 25-gauge needle to collect blood. The use of an injection needle and syringe should be avoided at all costs as it might cause haemolysis of the specimen. The use of the vacutainer method is the safest method for blood collection and is also known as the vacuum (evacuated) tube. This method involves a tube, a double-sided needle and a plastic holder. It allows blood to flow directly into the tube which limits contact with the blood. Each tube has a vacuum system that will allow the blood to stop on its own when the desired volume is reached (National Health Laboratory Services 2015: 94). To collect venepuncture specimens from infants and children using the heel-toe or finger-prick method, a clinician should allow drops of blood to collect and fall into the microtainer gently shaking the tube after each drop to prevent clotting. The puncture site should not be squeezed as this will dilute the blood with tissue fluid. A minimum amount of at least 250µl (micro litres) should be collected (South African Department of Health 2020 and National Health Laboratory Services 2016: 41).

The nurse should ensure that the area is well ventilated and is away from other clients before collecting a sputum specimen. In order to obtain the best results, it is preferable to collect the sputum specimen in the morning, but it can be collected at the time of consultation. The patient should be instructed to expectorate sputum from a deep, productive cough with no nasal secretions or saliva into the sterile specimen jar. The healthcare worker must also check that at least 5ml of sputum specimen has been collected. For children who are not able to produce a sputum specimen, a naso-gastric aspirate may be done and submitted to the laboratory (South African Department of Health 2020 and National Health Laboratory Services 2016: 43). When collecting sputum for tuberculosis testing, the patient and the nurse must be careful because the container might contain poisonous additives. Sputum cultures are ordered to determine if there is an infection in the lungs (Thimesch 2018: 46).

The urine specimen is normally a sterile body fluid however, contamination by normal flora from the perineum, urethra and vagina can occur during collection. Although urine can be collected at any time of day, early morning urine specimens yield the best results. Fluids should not be forced to the patient prior to urine collection as this will dilute colony counts and result in potential misinterpretation of results (South African Department of Health 2020 and National Health Laboratory Services 2016: 45). When collecting stool specimens, unformed stool specimens should be obtained. Each container should be filled to one third. Suspected clinical diagnosis should be provided to enhance appropriate processing of the specimen in the laboratory. Not more than one stool specimen should be submitted for any individual patient within a 24-hour period (South African Department of Health 2020 and National Health Laboratory Services 2016: 47).

Barbato *et al.* (2020: 20) stated that the laboratory should be aware of the patient's clinical conditions and of the related physician needs, before handing the results therefore, both the laboratory and the clinic personnel should communicate to guarantee the patient's safety. When collecting urine specimens, nurses should ensure that important information on diet, exercise, possible contamination to be avoided by genital cleaning prior to specimen collection and sample collection time is taken into consideration, as it might jeopardise interpretation of results (Salazar-García *et al.* 2020: 57).

Documentation of the time of collection is equally important. Healthcare workers should be able to use military time when documenting. Military time uses a 24-hour time clock and is useful in healthcare settings so that confusion is eliminated when documenting time for treatment procedures, specimen collections, tests, drug administration and surgical procedures (Thimesch 2018: 49). All used needles should be discarded in sharps containers which is a puncture-resistant, rigid, leak-

resistant container designed to hold used needles safely during collection, disposal and destruction (Cadman 2014: 17).

2.7.3. Package specimen

The steps to be followed after specimen collection are to ensure that all specimens within the facility are recorded in the Facility Specimen Register (N4) and placed in the specimen collection box immediately. The barcode sticker from the PHC/Cytology request form (N1/N2) should be peeled off and placed in the PHC Facility Specimen Register (N4). The following information should be completed in the PHC Facility Specimen Register (N4): date, time and patient folder number. The specimen plastic bag should be sealed, and the samples should be dropped off in the designated area that is, a specimen collection box or specimen fridge/facility cooler box for collection by the NHLS courier according to the stated test specific specimen storage conditions (South African Department of Health 2020 and National Health Laboratory Services 2016: 68).

Nurses should ensure that the specimen is labeled before collection, properly sealed and stored upright in the specimen plastic bags to avoid leakage which might deem the specimen unsuitable for analysis. Specimens should be collected and placed into the transport medium provided for example a cooler box. Specimens should be collected in clean leak-proof sharps containers free from other waxes or oils. Specimens should be kept cool during transportation but should not be frozen (South African Department of Health 2020 and National Health Laboratory Services 2016: 35). All specimens must be packaged carefully to avoid breakage or leakage of the specimen. These should be packed in compliance with the transportation guidelines for medical specimens with at least one completed PHC/Cytology request form (N1/N2) per patient. The request form should never be placed inside the plastic bag with the specimen but must be placed in a plastic pouch outside of the clear plastic bag (National Health Laboratory Services 2015: 231). Cadman (2014: 41) stated that specimens should be packed safely in a plastic leak-proof bag with an outside compartment for the laboratory request form. Placing the requisition form on

the outside prevents contamination of the specimen. If there are multiple tubes, these should be placed in a rack or padded holder to avoid breakage during transportation.

2.7.4 Specimen storage

This section presents a guide on the correct storage of patient specimens prior to and after the daily courier collection time. Sareen and Dutt (2018: 3) stated that the special requirements for transportation of samples should be taught and put in to practice by the nurse or personnel collecting samples. Govender *et al.* (2016: 349) stressed the importance of correct storage in their study and found that some of DBS specimens were unsuitable for analysis because it was old. Specimens must be kept away from direct sunlight and where room temperature exceeds 25°C. Specimens should ideally be stored in the fridge (+- 5°C) to preserve the specimen's integrity. Some specimens can be stored for up to 24 Hours at room temperature (20-25°C). Urine specimens should be stored in the fridge (2-5 °C) (Thimesch 2018: 51).

Some blood samples are required to be stored at body temperature, that is, 37°C. Special heat packs should be prepared to transport these specimens. These specimens should be transported at temperatures of 36°C to 38°C (Thimesch 2018: 46). Stool specimens can be collected at any time of day and can be stored at room temperature for up to 24hours. Where room temperature exceeds 25°C then they can be stored in a refrigerator designated for specimens at 2-5°C. It is important to keep in mind that specimen transport and storage conditions, together with the time interval between collection and testing may affect the quality of test results. Drastic temperature fluctuations could lead to the loss of viability of causative microorganism or overgrowth of normal commensals thus negatively affecting patient care (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 67).

2.7.5. Specimen collection by courier

There is a guide for preparing specimens for collection by courier. Sareen and Dutt (2018: 3) stated that the special requirements for the transportation of samples should be taught and put into practice by nurses or personnel collecting samples. Specimens should be collected in clean leak proof containers free from paraffin and other waxes or oils. These should be kept cool during transportation but should not be frozen (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 35). The best practices for the safe transportation of specimens will improve the quality of results from the laboratory (Cadman 2014: 39). The specimen stability/viability may change over time due to inappropriate storage of specimens (South Africa Department of Health 2020 and National Health Laboratory Services 2016: 68).

A courier service is provided by the NHLS to collect patients' specimens daily. The laboratory manager must provide each facility manager with a written designated collection time schedule (early/mid/late morning and/or early/mid/late afternoon) and clinicians should ensure that they familiarise themselves with the determined collection schedule for their facilities. The courier should arrive daily at the scheduled time. if there are challenges, the escalation procedure should be followed to alert the laboratory manager. The couriers should always be identified by their name tags. The vehicles are branded with the NHLS logo and contact details (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 72).

On arrival at the facility, the courier should report to reception. The designated facility staff must ensure that the number of specimen packages from the specimen collection box/fridge/cooler box corresponds to the number of entries in the PHC facility specimen register (N4). The specimen fridge/cooler box should be checked on each NHLS courier visit to ensure that all specimens are sent timeously. Designated facility staff to hand over specimens that are in the specimen collection box/fridge/cooler box to the courier. The procedure is to rule off after the last

specimen entered in the PHC Facility Specimen Register (N4) and after the specimens are collected by the courier. The NHLS courier personnel transporting the specimens to laboratory must enter their full names, the collection date and the time of the collection in the PHC facility specimen register (N4) (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 75).

2.7.6. Manage laboratory results

The nurses play a crucial role in the management and availability of the laboratory results which ensures that patient is diagnosed and treatment initiated. Confidentiality should be always maintained when dealing with patients' results. There are a number of mechanisms for health facilities to access laboratory results: -

- Printed Laboratory results: This is the primary mechanism for receiving results and there is a routine delivery of printed patient results by the courier. The NHLS courier will deliver printed laboratory results in a sealed envelope to each health facility on a regular basis. Each sealed envelope must display the facility name and the delivered envelope should be the correct one for that facility. Where applicable, staff at the facility signs the log sheet provided by the courier (National Health Laboratory Services 2015: 334).
- Electronic Access to laboratory results: The NHLS SMS printer and the listed laboratory results will be printed automatically by the SMS printer at the facility.
- NHLS web view portal (Trak Care Lab Web view): - This service is available at facilities with a computer and internet access. All users need to be individually registered to use this service. After registration, a clinician will be allocated a username and password to access results.
- Telephonic access: The local laboratory can be contacted telephonically to request for the patient's results using a bar code (South African Department of Health 2020 and National Health Laboratory Services 2016: 77).

Barbato *et al.* (2020: 20) stated that the laboratory should be aware of the clinical patient conditions and of the related physician needs, before handing out the results. Therefore, both the laboratory and the nurses should communicate to guarantee the patient safety. The facility manager must designate a competent professional nurse to review the laboratory results. A nurse should open the sealed envelope and ensure that all results are for that health facility while incorrectly addressed/inserted laboratory results are returned to the courier. All the delivered and SMS printed results should be screened to identify abnormal results and where abnormal results are identified, the patient must be requested to return to the health facility immediately. The professional nurse must enter the date and time of review on each laboratory result sheet and PHC Facility Specimen Register (N4) should be updated by ticking test results delivered with date of review and to monitor turn-around time (South Africa Department of Health 2020 and National Health Laboratory Services 2016: 82).

The results must be reviewed and filed within five working days in the patient's folder by the allocated administrative staff member. On pre-retrieval of the patient's folder for a planned return to the health facility, a nurse should ascertain whether all the laboratory reports have been received and filed. All methods of locating patients' lost results should be exhausted before repeating the specimen collection. A nurse should also update the laboratory results page in the patient folder by entering the date of specimen collection at the top of each column, entering normal results using a black pen and abnormal results using a red pen (South Africa Department of Health 2020 and National Health Laboratory Services 2016: 82).

2.7.7 Ordering specimen collection material

A step-by-step guide to ordering laboratory request forms and specimen collection materials is available from the local laboratory. The PHC Order Book: Materials for Specimen Collection (N3) should be used to request additional specimen collection

materials (NHLS 2015: 71). The nurses should ensure regular stock checks and stock rotation, using oldest stock first and stocks should not reach the expiry date. The requests should be submitted timeously to always ensure sufficient stocks of specimen collection materials at the health facility. The required quantities of request forms (N1 and N2), specimen collection materials and disposables that you need to order should be determined based on entries for the last two weeks in the PHC facility (National Health Laboratory Services 2015: 71).

The following information should be provided for each new N3 register used: register number with each register number entered sequentially, start and end date during which the book was used and the facility name. It is imperative that the health facility manager aligns the requests for specimen collection materials with the number of specimens submitted to the laboratory. The specimen collection materials are provided exclusively for the collection of laboratory specimens and may not be used for purposes other than specimen collection. The completed form should be torn off from the PHC Order Book: Materials for Specimen Collection (N3) and placed in the box with laboratory specimens and handed over to the NHLS courier. The courier will deliver the ordered specimen collection materials within five working days (South Africa Department of Health and National Health Laboratory Services 2016: 87).

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2.8 Theoretical framework

A framework is an abstract logical structure of meaning. It forms the basis for observations, definition of concepts, research designs, interpretations and generalizations. Description of theories is useful in providing conceptual context for your research problem (Brink, van der Walt and van Rensburg 2017: 118). The theoretical framework used to guide this study is the Donabedian's model of quality

2.8.1. Donabedian's model of quality

Quality in medical diagnostics is essential to provide safe health care to patients. Among other clinical disciplines, laboratory medicine assumes an important role in patient safety (Alavi 2020: 21). The researcher was guided by Donabedian's model of quality as a conceptual model that provides a framework for examining health services and evaluating the quality of health care (Fenny *et al.* 2014: 9). In 1966, Avedis Donabedian firstly described this model to draw information about the quality of care from three categories namely: "structure," "process" and "outcomes". It is imperative that the structures put into place allows processes of care to be carried out, therefore, giving better results to care (Moore *et al.* 2015: 1172). The study conducted by Weisemann-Brenner *et al.* (2014: 180) was guided by Donabedian's theoretical framework of causal relationships, selected structure, process, and outcome indicators that were determined to evaluate both intended and unintended effects of the intervention.

For this study, the model was applied concerning quality specimen collection by nurses in trying to establish whether all these elements can contribute to the improvement of the specimen rejection criterion. Kozuki *et al.* (2017: 12) in their study, used this model to assess the readiness of the healthcare providers by collecting data related to supplies, equipment and their performance in the delivery of quality health care. The categories of this theory were used in conjunction with three phases of specimen collection namely pre-analytical, analytical and post-analytical.

Although there is a connection between structure, process and outcome in the provision of health services, there is a distinction between healthcare quality which involves structure, process, and outcome, and health service quality involving delivery process. The health care quality is viewed as the process of clients making the first contact with the healthcare institution until the results are achieved. The health service quality, on the other hand, can be divided into technical and functional

processes (Polsa *et al.* 2013: 55). In the implementation of health analytics using Donabedian's model of quality, Khalifa and Househ (2021: 23) stated that there are three categories namely, human, technological and organisational.

Technical health service quality involves technology and medical expertise/competence being used in the curing process. This is difficult for clients to assess but it is easy for them to view the outcome. The functional health service quality involves how the services are provided in the facilities (Khalifa and Househ 2021: 23). Functional quality and the process are related, while technical quality and the outcome are also identical but analogous in a way. The three categories of the model are interlinked such that nurses need all resources necessary to carry out nursing procedures to achieve better patient outcomes (Polsa *et al.* 2013: 56) as outline in Figure 2.2 below.

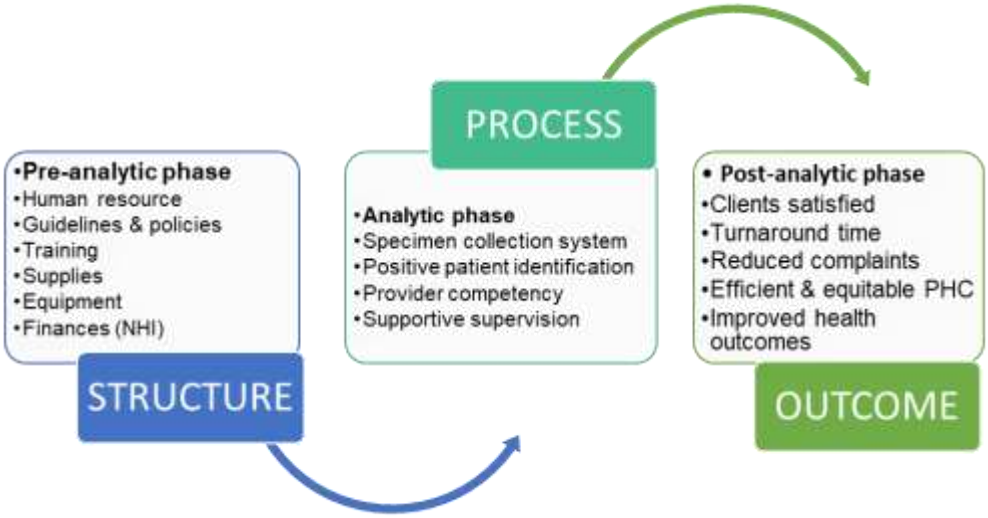

Figure 2.2 Conceptual framework for improving quality of specimen collection (Moore *et al.* 2015: 1172)

2.8.2 Fundamentals of Donabedian's model of quality

As illustrated in the diagram (Figure 2.2), the structure, process and outcome boxes represent the measurements of quality of care when collecting clinical specimens. The structure box refers to the pre-analytic phase, the process box refers to analytical phase and the outcome box is the post-analytic phase. The three boxes represent the three types of information that may be collected to draw inferences about the quality of specimen collection. The first box represents structure, which includes all possible factors that affect the environment in which healthcare is delivered (Rupp 2018: 354). In the context of specimen collection, all relevant structural factors in the pre-analytical phase of specimen collection will be discussed. The second box outlines the various processes that make up how the act of specimen collection is carried out (Rupp 2018: 355). For specimen collection, this entails the analytical phase whereby ordering of laboratory tests and the specimen collection process takes place. The outcomes box represents all the effects of specimen collection in the post-analytical phase, including mislabeled specimens, turnaround times and patient satisfaction with specimen collection (Saathoff 2017: 26).

2.8.3 Structure- Pre-analytical phase

Rupp (2018: 355) described two dimensions of quality in structure/input as a technical and interpersonal relationship between clients and nurses. These dimensions are related in the sense that, to provide good quality care to clients, care should be organised to ensure that personnel needs are considered. The structural factors provide the basis of what resources should be put in place for the nurses to be able to collect specimens. Nurses and other clinicians are human resources that should be available and trained to collect quality specimens. Having healthcare professionals that work with limited resources, may lead to poor service delivery. Furthermore, it was proven that under staffing, heavy workloads and lack of resources contribute to poor quality of care (Humphries *et al.* 2014: 4394). Training of healthcare workers plays a major role in equipping them with the necessary skills to collect quality specimens (Saathoff 2017: 26). Education and training are necessary for all staff carrying out specimen collection procedures. Training should

include an understanding of anatomy, awareness of the risks from blood exposure and the consequences of poor infection prevention and control (Cadman 2014: 40).

The researcher considered that in specimen collection, patientcare should be organised by ensuring the availability of equipment, computers and printers to access results, and other laboratory supplies for example different specimen collection tubes, vacutainer needles, lancet needles, tourniquets, cooler boxes and gloves, that enables quality specimen collection. The unavailability of certain equipment predisposes nurses to committing errors when collecting specimens (Saathoff 2017: 26). Specimen collection equipment should be checked daily and should not be expired. Laboratory request forms and specimen collection materials can be requested using the PHC Order Book. Materials for Specimen Collection (N3) should be used to request additional specimen collection materials (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 86).

The availability of guidelines and policies provides guidance and standardisation on the correct procedure to be followed when collecting specimens. The guidelines for the collection of specimens are provided by the Department of Health and NHLS under the guidance of the National Health Laboratory Service Act 37 of 2000 to provide quality, affordable and sustainable health laboratory and related public health services (South Africa, Department of Health 2020 and National Health Laboratory Services 2016: 3). Guidelines are documents developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. Guidelines may be used as written or modified by the user to fit specific needs (Thimesch 2018: 18). Cadman (2014: 9) stated that standard operational procedures (SOP) are required for each step or procedure, and these should be written and be readily available to health workers for reference thus preventing unnecessary errors when collecting specimens. In view of the use of guidelines Girdwood *et al.* (2020: 6) proved that viral load testing for HIV testing, improved viral suppression to 90% with adherence to clinical guidelines.

The financial implication of service delivery is vital in ensuring that supplies and equipment are purchased to ensure quality specimen collection. The correct practice of nurses in specimen collection will ensure that there is no wasteful expenditure on repeated specimens (Peterson *et al.* 2018: 56).

2.8.4 Process- analytical phase

The process box outlines the various processes that are carried out during specimen collection (Fenny 2014: 10). The analytical phase refers to the sum of all actions that make up healthcare, including diagnosis, patient education and treatment. Processes can be further classified as technical processes and the manner in which care is delivered (Rupp 2018: 356). The process category assumes that certain procedures should be carried out in an orderly manner to ensure the rendering of quality care. Incorrect practices can constrain a commitment to action. Processes information is usually drawn from the patients' files and the healthcare service provided or on behalf of a patient and is appropriately based on scientific evidence of efficacy or effectiveness (Shahangian *et al.* 2020: 420).

Specimen collection systems or processes include: test ordering; specimen identification; preparation; transport; analysis; result reporting and result interpretation and ensuing action. The assessment of appropriateness of laboratory tests ordered for screening, management, diagnosis, monitoring of various diseases or clinical conditions consistent with guidelines and the reduction of wasteful and unnecessary testing (Shahangian *et al.* 2020: 421). Positive patient identification is the vital step of the specimen collection process to ensure that the correct specimen is collected from the correct patient; this in turn ensures quality of the specimen results generated. Sareen and Dutt (2018: 2) recommended that when collecting the specimen, at least two different unique identifiers be used because, when the specimen must be repeated, it creates dissatisfaction from the patients' side. This in return reflects the poor quality of the service provided. Yilmaz and Yilmaz (2019:

117) stated that the name and surname of the patient must be verified before obtaining any samples. The name, registered number, clinic name and the date and time of sample collection should be written on the specimen container label The patient identification process involves the verification of the patient by identifying verbally and reviewing the requisition form to identify what specimens should be collected, then applying the bar code labels on the specimen containers. If the correct identification process is not followed, there might be multiple steps where errors could occur (Saathoff 2017: 5).

Provider competency is significant in the specimen collection for patient safety; it is necessary for nurses to know the sources of errors, try to control them, and to increase the knowledge level of health professionals through in-service training. Clinic nurses play a vital role in collecting and handling specimens and providing information to patients prior to and after testing, therefore their education is of utmost importance (Yilmaz and Yilmaz 2019: 118). According to Durrant *et al.* (2017:1) lack of a solid foundation in specimen collection, nurses may have knowledge gaps in areas such as specimen collection process, infection prevention and control thus compromising patient safety by committing errors.

On supportive management the health facility operational managers are responsible to determine the local NHLS support laboratory and contact details. The NHLS business manager should participate regularly in the quarterly District Health Management Team meetings to address concerns such as poor laboratory performance, turn-around times, availability of specimen collection materials and adherence to agreed laboratory courier collection schedules. Managers should also attend to issues of poor facility performance in terms of rejection criteria like, incomplete request forms, inadequate specimen collection and inappropriate specimen storage. When the local approaches have failed, the local laboratory manager should be contacted and is expected to respond within two working days (South Africa, Department of Health and National Health Laboratory Services 2016:15).

2.8.5 Outcome- post-analytical phase

The outcome is when desirable and expected results are received. Outcomes are the most important indicators of quality regarding the health state of a patient resulting from health care; the assumption is that efficient and equitable PHC improves access to quality health therefore the patients are satisfied with the service and complaints will be reduced (Gorkhe and Rose 2017: 472). Client Satisfaction-Outcome means a desirable health state of a patient resulting from health care; the result achieved among others might be an improvement in the patients' health and satisfaction (Gorkhe and Rose 2017:476). Specimen collection errors may cause significant patient injury or disability, longer lengths of stay, increased healthcare costs, diverted resources, and increased patient dissatisfaction (Saathoff 2017:1).

Specimens must be re-drawn when rejections occur; furthermore, the pain and inconvenience associated with specimen collection are the most important concerns regarding the quality of patient care (Hankins 2017: 10). Turn-around time monitoring, result interpretation and continuous quality improvement on specimen collection as stated by Dangre and Giardino (2020: 11) leads to improved health outcomes and reduced complaints; thus, having efficient and equitable services.

2.8.6 Theoretical assumption

Donabedian's theory of quality concerning specimen collection assumes that:

- All nurses are given standardised education before implementation.
- After users are trained, they are expected to deliver quality health care.
- Nurses are expected to implement procedures by following guidelines.
- Provider competence is vital in the provision of health care.
- Adequate funding needs to be in place to support the quality of health.
- New technology should be introduced to promote continuous quality improvement.
- Correct processes to be followed when rendering nursing duties.
- Modified work processes reduce or eliminate future errors.
- Quality healthcare results in improved access to health facilities.

- Quality healthcare results in client satisfaction and reduced complaints.
- Continuous quality improvement leads to efficient and equitable health outcomes.
- Each factor can affect another if not correctly linked.

2.9 Conclusion

In this chapter, the literature on specimen collection and rejection errors globally and in South Africa was reviewed. The quality improvement measures applied in different countries were also reviewed. The roles of nurses in specimen collection process were highlighted and costs associated with specimen rejection were clarified. The theoretical framework and its applicability to the study was also discussed. The next chapter will focus on the methodology adopted for this study.

CHAPTER 3: METHODOLOGY

3.1. Introduction

In this chapter, the discussion focuses on the paradigm, research design, population and sampling, data collection process, data analysis and ethical consideration. The methodology is defined as the steps, procedures, and strategies for gathering and analysing data in a study (Polit and Beck 2016: 733).

3.2. Paradigm

A paradigm refers to a particular way of viewing phenomena that encompasses a set of philosophical assumptions and guides one's approach to asking questions (Grove, Burns and Gray 2013: 702). Research paradigms guide scientific discoveries through principles and assumptions (Park, Konge and Anthony 2020: 690). Polit and Beck (2016: 11) describes a paradigm as a world view, a general perspective on the complexities of the real world. The positivist paradigm dominates nursing research and this approach involves using orderly, disciplined procedures with tight control.

This study was conducted within a positivist paradigm to evaluate whether nurses working in PHC clinics have the necessary knowledge of specimen collection and whether their practices were effective in preventing specimen rejection errors. Positivists' scientific approaches involves using orderly, disciplined procedures with tight controls of the research situation to test the researcher's hunches about the phenomena being studied and relationships among them (Polit and Beck 2016: 12). Quantitative statistics can be used objectively to verify the facts.

3.3. Research design

Research design is defined as a detailed plan according to which the research is conducted (Grove *et al.* 2013: 195). The design of this study was non-experimental, cross-sectional descriptive survey design.

3.3.1 Quantitative design

A quantitative descriptive survey provides a numerical description of trends, attitudes or opinions of the population (Gray, Grove and Sutherland 2016: 192). To gather evidence for a study using a structured method to collect needed information, the quantitative design was applied. This study quantitatively evaluated knowledge and practices of nurses in quality specimen collection to improve on specimen rejection status for the primary health care clinics. This quantitative approach evaluated the knowledge and practices of nurses not only on measures for the outcome of access to quality healthcare but also gave insights on how and why specimen rejection produces certain intended and unintended effects and allows for a more in-depth evaluation approach. Grove *et al*. (2013: 23) stated that quantitative research is a formal, objective, systematic process implemented to obtain numerical data for understanding aspects of the world. The information gathered is numeric information that is obtained from a formal measurement and is analysed statistically (Polit and Beck 2016: 14).

3.3.2 Descriptive survey

Polit and Beck (2016: 226) stated that by using descriptive research, researchers can observe, describe and document aspects of a situation as it naturally occurs and sometimes serves as a starting point for hypothesis generation. The research problem identified by the researcher called for a specific approach to conduct the study. When a researcher wants to understand the best predictors of outcomes, a quantitative approach is best. It is also a suitable approach to use to test a theory or explanation (Creswell 2014: 50).

A descriptive design may also be used to develop theory, identify problems with current practices and determine what others are doing regarding similar phenomena, therefore variables cannot be manipulated easily (Grove *et al*. 2013: 215).

Descriptive surveys may be used to identify problems with current practice and to justify the current practice. The study was conducted on the natural phenomena for the nurses therefore their behaviour and practice could not be manipulated (Grove *et al.* 2013: 195).

Descriptive designs are also concerned with gathering information from a representative sample of the population (Grove *et al.* 2013: 223). The term survey is used in two ways. In a broad sense, it means descriptive or correlational study. In a narrow sense, the term is used to describe a data collection technique in which the researcher uses questionnaires or personal interviews to collect data about a population (Grove *et al.* 2013: 224). The design was chosen to identify patterns of variables and to compare and contrast groups on selected variables (Polit and Beck 2016: 87). A descriptive survey for this study was relevant because it was to identify problems with current specimen collection practices and to justify it.

3.4. Research setting

The research setting is the physical location and conditions in which data collection takes place (Polit and Beck 2016: 743). The study was conducted at the 22 fixed primary health care (PHC) clinics and one CHC under King Cetshwayo Health District (South Africa, Department of Health 2017a: 3). King Cetshwayo Health District is located north-east of the KwaZulu-Natal province. The district comprises five local municipalities referred to as the sub-districts namely uMhlathuze, Mthonjaneni, uMfolozi, Nkandla and uMlalazi It has one regional hospital, one tertiary hospital, six district hospitals, one Community Health Centre, 63 fixed clinics, and 14 mobile teams with 66 mobile stopping points (Baron and Padarath 2015: 117). Non-probability purposive sampling method was used to select the two sub-districts (uMhlathuze and uMfolozi) out of the five sub-districts as indicated by Figure 3.1 below.

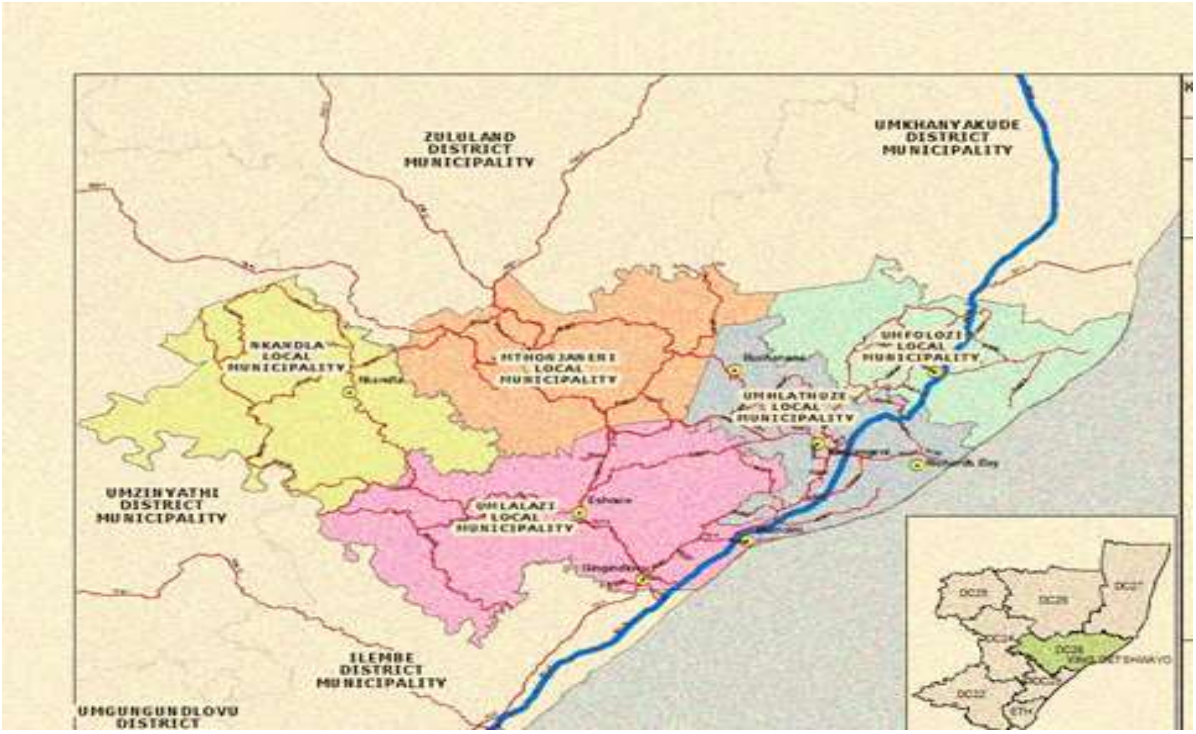

Figure 3.1: Map showing the location of King Cetshwayo District in KwaZulu-Natal Province and the sub-districts (South Africa, Department of Health. 2017a: 3).

3.5 Population

The total population consisted of professional nurses and enrolled nurses who are working in all fixed PHC clinics under the King Cetshwayo District employed by the Department of Health and the district partner Broad Reach Health Care. According to the Nursing Act 33 of 2005, a professional nurse is a person who is qualified and competent to independently practice comprehensive nursing in the manner and to the level prescribed and who is capable of assuming responsibility and accountability for such practice (Searle, Human and Mogotlane 2014: 174). Professional nurses are nurses trained for four years to assess, diagnose and treat patients in the absence of a doctor. Their assigned tasks are to collect blood and cervical specimens in the primary health care setting.

The enrolled nurses have undergone a two-year training programme and they are entrusted with carrying out duties and performing procedures including specimen collection. Enrolled nurses only collect specimens like sputum and urine in terms of section 58(1)(f) of the Nursing Act, 2005 (Act No. 33 of 2005) and Scope of Practice for Enrolled Nurses (Government Notice No. R. 171) (South African Department of Health 2020: 10). The total population of nurses for five sub-districts was 926. The target population was professional and enrolled nurses from 23 clinics from the uMhlathuze and uMfolozi sub-district.

3.6 Sampling

Sampling is defined by Polit and Beck (2016: 275) as a process of selecting cases to represent an entire population so that inferences can be made about that particular population. Sample in simple terms is a part or fraction of a whole or a subset of a larger set (Brink *et al.* 2017: 132). The sample defines the selected group of people or elements included in the study. Samples must be representative of the population in a way that the characteristics are closely approximated to that of the population studied (Polit and Beck 2016: 275). Representativeness of the sample also means the sample is similar to the population and representativeness is important if the researcher wants to generalise from the sample to the target population (Grove *et al.* 2013: 123).

The sample is believed to represent the population of choice because all primary health care clinics have professional and enrolled nurses. The nurses contribute to a safe and effective environment and also play a major role in providing independent functions of the health services in the absence of the doctor. They also ensure the availability of resources for the provision of quality healthcare to clients (Booyens 2012: 158).

Non-probability purposive sampling method was used to select the two out of the five municipalities. According to Gray *et al.* (2016: 329), purposive sampling is a non-probability sampling method where the researcher selects participants based on personal judgement on the most informative one. The researcher purposely sampled two sub-districts namely uMhlathuze and uMfolozi. The two sub-districts were purposely sampled since the clinics under them have a high number of patient headcount per day, for example, Thokozani clinic at uMhlathuze had an average headcount of 250 patients per day compared to Samungu at Nkandla that had an average headcount of 40 patients per day (Steinhobel, Massyn and Peer 2016: 413). The total number of clinics under uMhlathuze and uMfolozi sub-district was 23 including the CHC out of the 63 clinics in the district. The researcher targeted all 14 clinics, one CHC under uMhlathuze and eight clinics under uMfolozi sub-district (total 23) (South African Department of Health 2017a: 3).

3.7 Sample size

The sample size selected from the 23 clinics was 352 professional and enrolled nurses. All professional and enrolled nurses from the selected clinics were consecutively sampled to participate in the study. The sample size suggested by a statistician was 272 in relation to the total population of 926 nurses. The sample size for this study from 23 clinics was 352 nurses. It was suggested that to get better representativeness of the population and to account for non-responses which might be due to staff turnover, the number should be increased to 30% of the population Table 3.1 illustrates the number of nurses from the 23 used clinics.

Table 3.1: Number of nurses allocated in selected clinics

Clinic	Professional nurses	Enrolled Nurses
uMhlathuze Sub-district		
Clinic 1	05	07
Clinic 2	09	08
Clinic 3	09	06
Clinic 4	06	07
Clinic 5	18	09
Clinic 6	05	04
Clinic 7	33	26
Clinic 8	06	05
Clinic 9	06	04
Clinic 10	12	07
Clinic 11	10	05
Clinic 12	06	04
Clinic 13	05	03
Clinic 14	07	05
Clinic 15	12	07
uMfolozi Sub-district		
Clinic 16	05	07
Clinic 17	11	10
Clinic 18	07	05
Clinic 19	05	05
Clinic 20	05	04
Clinic 21	04	06
Clinic 22	05	04
Clinic 23	07	06
Total	**198**	**154**

3.7.1 Recruitment

The respondents were recruited by having posters about the research at strategic areas of the clinics informing them about the study. The recruitment process took place over a period of four to six weeks.

Inclusion criteria

- Professional nurses who are working at the fixed primary health care clinics and the Community Health Centre.
- Professional nurses employed by the district partner, Broad Reach Health Care.
- Enrolled nurses who are working at the fixed primary health care clinics and the Community Health Centre.
- Enrolled nurses employed by the district partner, Broad Reach Health Care.

Exclusion criteria

- All other professional nurses, enrolled nurses and nursing assistants who are working in the hospitals and mobile services.
- All professional nurses who are operational managers working in the hospitals, Community Health Centre, fixed clinics and mobile services.

3.8 Research instrument

The primary consideration of the data collection tool is conceptual relevance, whether the instrument corresponds to the researcher's conceptual definition of a variable (Polit and Beck 2016: 294). The research study was conducted through the survey method using a checklist and a self-administered questionnaire. Grove *et al.* (2013: 224), state that a survey study in a narrower sense is described as a data collection technique in which the researcher uses questionnaires or personal

interviews to gather data about an identified population. The advantage of the checklist is that it includes several questions with the same response format and is relatively efficient and easily understood.

Data collection tools were developed in reference to the NHLS PHC handbook and literature on specimen collection. The checklist was used to gather information on specimen collection.

The checklist was divided into two sections:

- Section one (Appendix 7) gathered information on the availability of specimen collection resources such as blood tubes, request forms, specimen jars, vacutainer needles, gloves and storage refrigerators.
- Section two (Appendix 8) gathered information on steps followed by nurses to ensure quality specimens are collected. The Likert scale option of choice used on the checklist included “yes”, “no” and “not applicable“.

Likert scale was chosen because it consists of several declarative items that express a viewpoint on a topic (Polit and Beck 2016: 301).

The questionnaire was accompanied by the information letter (Appendix 6) as well as the consent form (Appendix 5) to the respondents explaining the benefits and purpose of the study.

The questionnaire consisted of two sections:

- The first section dealt with the demographic data of the respondents: information on age, staff category, years of experience, and years of experience in PHC as well as clinic operational hours.
- The second section dealt with knowledge regarding the collection of clinical specimens (participants were required to give the most appropriate answer to

questions about basic rules on specimen handling). The Likert scale options included “true”, “false” and “not sure” and a section for participants to choose the most correct answer from options given.

The research instruments were constructed with the use of literature and in consultation with the statistician. These instruments were also pre-tested for validity and reliability through conducting a pilot study.

3.9 Pretesting of data collection instruments

A pre-test of the data collection tools was conducted before the actual commencement of data collection. Pretesting of the questionnaire was done to determine whether the questionnaire was understood by the respondents and whether the checklists will be able to capture the desired information.

Pre-testing is referred to as a ‘preliminary study’, a small scale study conducted before the main study with a limited number of participants from the population at hand (Brink *et al.* 2017: 167). The validity of the tool could be achieved by using respondents relevant to the study. Due to a large number of samples, the pretesting was done on 10 sampled enrolled and professional nurses. This was done to achieve more desirable results of the pre-test. The results for the pilot study were not included in the main study. There were no changes required on the questionnaires as pre-test participants did not report any misunderstandings or ambiguity in the questions.

3.10 Data collection process

Prior to conducting the research, permission was requested from the King Cetshwayo Health District Director (Appendix 10) and gate keeper permission was sought from the King Cetshwayo Health District Director (Appendix 2). The

researcher also requested permission from the PHC Managers of uMhlathuze and uMfolozi sub-district (Appendix 11) and sought the permission from the Ngwelezana Hospital Research Committee (Appendix 3) to which the PHC facilities of uMhlathuze and uMfolozi sub-districts report. The purpose of the study was explained and consent obtained from the respondents. The data collection process commenced from May to July 2019. The data collection was done in two phases: phase one: observation by researcher and completion of checklist (Appendix 7 and 8) and phase two: completion of questionnaires (Appendix 6) by respondents.

3.10.1 Phase one: Observation and Checklist

The researcher visited sampled clinics to simultaneously observe the availability of specimen collection and storage resources, as well as to observe procedures followed on specimen collection, handling and storage. Observation visits were conducted on two separate occasions for the researcher to be able to compare the different times of the week for the availability of specimen collection equipment. Data was captured by conducting non-participant observation of interactions and ticking on the checklists (Appendix 7 and 8). The advantage of using a scaled checklist is that the researcher does not have to take detailed notes and miss any interaction (Polit and Beck 2016: 174). Observation under natural conditions was carried out to prevent change in behaviour for respondents and not to interfere with normal activities of the clinic. Checklists were coded for each clinic visited for data collection.

3.10.2 Phase two: Questionnaire

Data on knowledge of basic principles of specimen collection was collected through conducting a survey where self-administered questionnaires (Appendix 6) were handed to the nurses. The nurses responded to the questionnaires at a convenient time. The nurses were allocated a maximum of two weeks to complete the questionnaires. After two weeks, questionnaires were collected and placed in a

locked cupboard. The advantages of a distributed self-administered questionnaire among others are cost-effectiveness and minimizing bias with a relatively high rate of response (Polit and Beck 2016: 305).

3.11 Data analysis

Data analysis is the process of summarising raw data. This process is determined by the researcher's approach to organising and giving meaning to data (Brink *et al.* 2017: 57). Quantitative researchers analyse their data through statistical analysis (Polit and Beck 2016: 60). It was recommended that a plan be discussed about a way to provide a descriptive analysis of data for all independent and dependent variables in the study (Creswell 2014: 201).Data was analysed statistically using the version 27 of the SPSS program. Descriptive statistics were used to describe the data graphically. Inferential statistics were used to make inferences to the larger population in consultation with a statistician. Different tests were used for analysis and interpretation of data, for example, Binomial test and the Chi-square test of independence.

3.12 Validity

Validity and reliability are closely related and a researcher needs to consider both when selecting a research instrument. There is no point in using an instrument that is not valid and cannot be reliable to collect relevant data (Polit and Beck 2016: 311). The validity of an instrument determines the extent to which it reflects or can measure the construct being examined (Grove *et al.* 2013: 393). Validity ascertains whether an instrument accurately measures what it’s supposed to measure (Polit and Beck 2016: 311). The four criteria of internal validity are discussed as face, content, criterion and construct validity.

3.12.1 Content validity

Polit and Beck (2016: 723) describe content validity as the degree to which the items in an instrument adequately represent the universe of content for the concept being measured. Content validity examines the extent to which the measurement method used includes all the major elements needed for the construct being measured (Grove et al. 2013: 394). This validity type is also relevant for effective measures and cognitive measures. (Polit and Beck 2016: 336). The quantitative researchers construct their questions based on a literature review (Polit and Beck 2016: 337). Content validity was ensured by referring to the literature review on the specimen collection process, rejection criteria and quality improvement measures before the design of a questionnaire. The researcher developed a structured questionnaire and submitted it to the supervisors for evaluation to ensure that the instrument measured the desired variables. The pre-test of the instruments was conducted before the actual research data collection process to improve internal validity.

3.12.2 Construct validity

Construct validity is the key criterion for assessing the quality of the study to answer the question: “what is the study measuring?” (Polit and Beck 2016: 339). Construct validity refers to whether an instrument measures the theoretical construct it is supposed to measure. It examines the correlation between conceptual definitions and operational definitions of variables (Grove *et al*. 2013: 200). The known groups approach for construct validity was used by the researcher to ensure that the population and sample targeted the professional and enrolled nurses who are working at the PHC clinics in the King Cetshwayo District**.**

3.12.3 Criterion validity

A research instrument has criterion-related validity if the scores correlate highly with scores on an external criterion or whether correlating on what an instrument

measures with another measure accepted as being valid (Polit and Beck 2016: 338). After the literature review, the scale of measurement for the data collection instrument was constructed with the guidance of the NHLS PHC handbook. The instrument to be designed was checked if there was any similarity to it.

3.13. Reliability

According to Polit and Beck (2016: 331), the reliability of a quantitative research instrument is a major criterion for assessing its quality and accuracy. A research instrument is reliable to the extent that it measures true scores. Reliability is the consistency of the measures obtained of an attribute, item or situation in a study or clinical practice (Grove *et al.* 2013: 389). The reliability of an instrument is indicated by a correlation measure that varies between 0 and 1 with a measure close to 1 having a higher correlation (Polit and Beck 2016: 331). There are three common types of reliability used in healthcare studies namely:

a) Stability reliability

b) Equivalence reliability

c) Internal consistency

(Grove *et al.* 2013: 389).

Equivalence reliability was not applicable to this study.

3.13.1. Stability reliability

The stability of a research instrument refers to its consistency over time. This can be achieved by giving the same person the same instrument on different occasions and observing responses for similarities (Polit and Beck 2016: 332). According to Polit and Beck (2016: 331) stability focuses on instrument susceptibility to extraneous influences over time. It is a useful tool in quantitative research to give direction on the relationship between the variables. This measure of reliability is commonly used with physical measures, technological measures and paper and pencil scales. The technique requires an assumption that the factor to be measured remains the same

after two testing times and that any change in the score is a result of random error (Grove *et al.* 2013: 389).

Stability reliability was ensured by pretesting the instrument to check whether the questions constructed were able to give evidence of the relationship between structure, process and outcome variables of the specimen collection process. Stability can be achieved by the applying the same measurement at two different times (Polit and Beck (2016: 332)

3.13.2 Internal consistency

In internal consistency, an instrument is said to be homogeneous to the extent that its items measure the same trait. Scales and tests involve summing item scores that are typically evaluated for their internal consistency. The reliability is appropriate only when an instrument is examining one concept or construct at a time, meaning all items should measure what is intended (Polit and Beck 2016: 333). The common method to estimate internal consistency is the split-half of the test. It is primarily used with paper and pencil tests or scales and it addresses the correlation of various items within the instrument. The instrument items are split in odd-even or first-last-half and a correlational procedure will be performed between the two halves. This method is less effective with open-ended questionnaires and interviews (Brink *et al.* 2017: 170).

3.14. Ethical considerations

This section describes the ethical considerations for the study before, during and on completion of the study.

Pera and van Tonder (2015: 326) explain that the primary aim of research into health-related issues, namely the improvement of quality of life of individuals and groups, situates research within the realm of the ethics: doing what is good and right.

Ethics is also a moral obligation for health professionals to participate in research studies because it is essential for the evaluation of acquired scientific and existing knowledge (Pera and van Tonder 2015: 328).

The research proposal was reviewed by the Faculty of Health Sciences Research Committee and ethical clearance was received from the Institutional Research Ethics Committee (Appendix 1). Permission to conduct the study was obtained from King Cetshwayo Health District Office (Appendix 2) as well as sub-districts (Appendix 3) that were sampled for the study. This process was done before the study was conducted.

The researcher explained the research process to the respondents using the Letter of Information (Appendix 4). Written consent (Appendix 5) was obtained from the respondents of the study. The respondents were informed that participation in the study was voluntary and they had a right to withdraw from the study at any time if they did not want to proceed with the study. The researcher respected the staff at the clinics and ensured that there was no disruption of services. The consent to conduct the study was obtained by making an appointment with the clinic Operational Managers. The anonymity of the respondents was respected by ensuring that none of their names appeared on the data collection instrument so as to avoid any linkage to the study by external sources. The respondents were informed that they could ask for clarification about the study. Ethical issues are discussed under the following important principles: autonomy, privacy, anonymity and confidentiality.

3.14.1. Autonomy

Autonomy is the right to self-determination and respected in health research as in clinical practice. Autonomous individuals can control their destiny. They are not prone to coercion or exploitation (Grove *et al.* 2013: 164). The researcher treated the respondents as autonomous agents by informing them about the proposed study and allowing them to participate voluntarily. When obtaining consent for a study, the researcher should not force participants to sign the informed consent form.

Participation in a study should be seen as voluntary, and the researcher should explain the instructions on the consent form so that respondents can decide whether to participate or not to participate in the study.

The researcher attempts to avoid deceiving the respondents as they need to know that they are actively participating in a research study. To counteract this problem, the researcher provided instructions that reminded the respondents about the purpose of the study (Creswell 2014: 136). The respondents have a right to withdraw from the study at any time without consequences. All respondents were required to sign an informed consent form and participation in the research study was voluntary (de Vos *et al.* 2013: 117). The Letter of Information was handed to the respondents for them to understand the nature and the purpose of the study prior to giving consent.

The respondents did not write their names on the questionnaire so they could not be linked to their responses. The questionnaires were numbered. The request for permission to conduct the study and research proposal was reviewed by the Institutional Research Ethics Committee and upon receiving ethical clearance, the collection of data commenced. The ethics committee for the Department of Health KwaZulu-Natal reviewed the proposal and granted permission to proceed with the study after the ethical issues were cleared. Pera and van Tonder (2015: 336), stated that the autonomy of the institution as a controlling body should be respected by ensuring that all the necessary information is provided, that is, data collection instrument, the sample and the perceived ethical issues that might be encountered.

3.14.2. Privacy

Privacy implies personal privacy whereby an individual has a right to decide on the extent of his/her responses and behaviour (de Vos *et al.* 2013: 119). Any research

that involves human beings must respect participants' right to privacy (Leedy and Ormrod 2013: 107). Respect for the staff at the clinics was maintained and any disruptions were avoided in consultation with the Operational Managers. Researchers need to respect research sites so that they are left undisturbed after a research study. Organisations often have guidelines for researchers to conduct their study without disturbing their settings (Creswell 2014: 137). The researcher was guided by the KwaZulu-Natal Standard Operational Procedure on Application Process for Gatekeeper Permission to Conduct Research. The extent of disclosure and personal information on the agreement letter should be maintained at all times (Pera and van Tonder 2015: 335).

3.14.3 Anonymity and Confidentiality

Anonymity and confidentiality usually are used interchangeably. Anonymity ensures the privacy of the respondents (de Vos *et al.* 2012: 120). In survey research, researchers disassociate names from responses during the coding and recording process (Creswell 2014: 138). The anonymity of the respondents was respected by ensuring that none of their names appeared on the data collection instrument to avoid any link to the study by an external source. Although the names were appearing on the consent form, the researcher ensured that the forms were kept in a locked cupboard to avoid jeopardising the anonymity of the respondents. Coding was used to identify respondents and clinics.

Confidentiality, on the other hand, indicates that research information is handled confidentially. It is an agreement between individuals that limits others from accessing information (de Vos *et al.* 2013: 119). Raw data and other materials for example, details of procedures, instruments, once analysed need to be kept for a reasonable period of five years as recommended by the institution. After this period, the researcher should discard the data so that it does not fall into the hands of other researchers who might misappropriate it (Creswell 2014: 140). At the end of the

stipulated period, a record of collected and analysed data will be shredded using a shredder.

Data saved on the computer will be deleted. In quantitative research, the data analysis should reflect the statistical tests and not be under-reported. During the presentation, avoid disclosing results. In research, it is academically dishonest to withhold important results or to cast the results in a favourable light to the respondents' or researchers' inclinations (Creswell 2014: 138). The results on specimen collection and rejection errors for the particular clinic were kept confidential and not shared with any other clinic. The presentation of results avoided bias by not favouring the researcher's point of view or assumption.

3.15 Conclusion

This chapter deliberated on the research methodology which includes research design, setting, population, sampling, sample size, data collection process and ethical considerations. The next chapter presents the data analysis. The results of data collected using data collection instruments are presented.

CHAPTER 4: PRESENTATION OF RESULTS

4.1 Introduction

The previous chapter outlined the methodology adopted in conducting the study. The data collection instruments were based on the knowledge and practice of nurses in the collection of the clinical specimen, and it addressed the objectives of the study. This chapter will present the findings that were gathered from data analysis. The data was analysed and organised in alignment with the research objectives. The objectives of the study were to:

- To identify the available specimen taking and storage resources as per PHC laboratory guideline (handbook):
- To observe the practices applied by nurses before, during and after taking specimens:
- To determine the nurses' knowledge on basic principles of taking different specimens

2 Research instrument

The research instrument consisted of two sections:

The checklist was used to gather information on specimen collection. The checklist was divided into two sections:

- Section one (Appendix 7) gathered information on the availability of specimen collection resources such as blood tubes, request forms, ordering forms and storage facilities

- Section two (Appendix 8) gathered information on steps followed by nurses to ensure that quality specimens are collected. The Likert scale option of choice used on the checklist included "yes", "no" and "not applicable".

The knowledge questionnaire was used to collect information from nurses on specimen collection. The questionnaire (Appendix 6) consisted of two sections:

- The first section dealt with the demographic data of the respondents: information on age, staff category, years of experience as a nurse, and years of experience in PHC as well as hours of operation at the clinic. .
- The second section dealt with the knowledge regarding the collection of clinical specimens (respondents were required to give the most appropriate answer to questions about basic rules on specimen handling). The Likert scale options included “true”, “false” and “not sure” and participants also had to choose the most correct answer from options given.

4.6 Presentation of results

The results are presented in four sections: The questionnaire is presented in section A and B, practices from the checklist in section C and the specimen collection material checklist in section D.

The following statistical tests were used to analyse data from the questionnaire:

- **Descriptive statistics** including standard deviations and mean. Frequencies are also represented in tables and graphs (Grove *et al.* 2013: 538).
- **Chi-square goodness-of-fit-test**: A uni-variate test, used on a categorical variable to test whether any of the response options are selected significantly more/less often that the others. Under the null hypothesis, it is assumed that all responses are equally selected (Grove *et al.* 2013: 587).
- **Binomial test:** Tests whether a significant proportion of participants select one of a possible two responses. This can be extended when data with more than two response options is split into two distinct groups (Grove *et al.* 2013: 582).

4.7 Section A: Demographic data

This section deals with the participant's demographic data of age, nursing category, years of experience as a nurse, years of experience in a PHC clinic and hours of operation at the clinic.

4.7.1 Nursing category

Figure 4.1 indicates the nursing category of 336 respondents of which 27.4% (n=92) are enrolled nurses, 8.0% (n=27) professional nurses undertaking community service, 16.1% (n=54) professional nurses, 47.0% (n=158) professional nurses with PHC speciality and 1.5% (n=5) not specified.

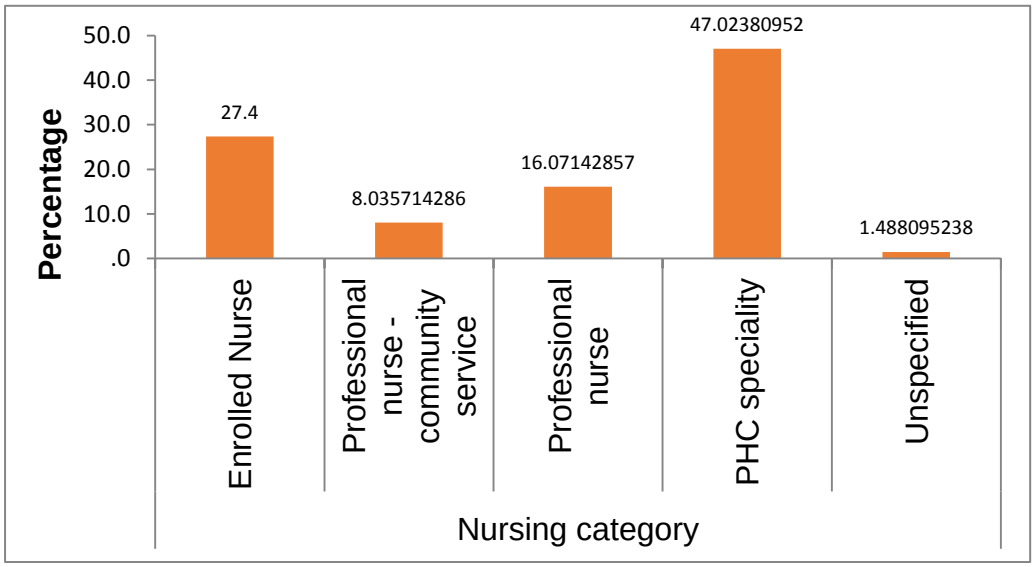

Figure 4.1 Nursing category (n=336)

4.4.2 Clinic operational hours

Figure 4.2 illustrates the clinic operating hours of the 334 respondents of which 33.3% (n=112) worked in the clinics that operate from 07h00 to 16h00 five days a week, 15.2% (n=51) from 07h00 to 16h00 seven days a week, 17.0% (n=57) from 07h00 to 19h00 five days a week, 9.5% (n=32) from 07h00 to 19h00 seven days a week and 24.4% (n=82) 24 hours a day seven days a week.

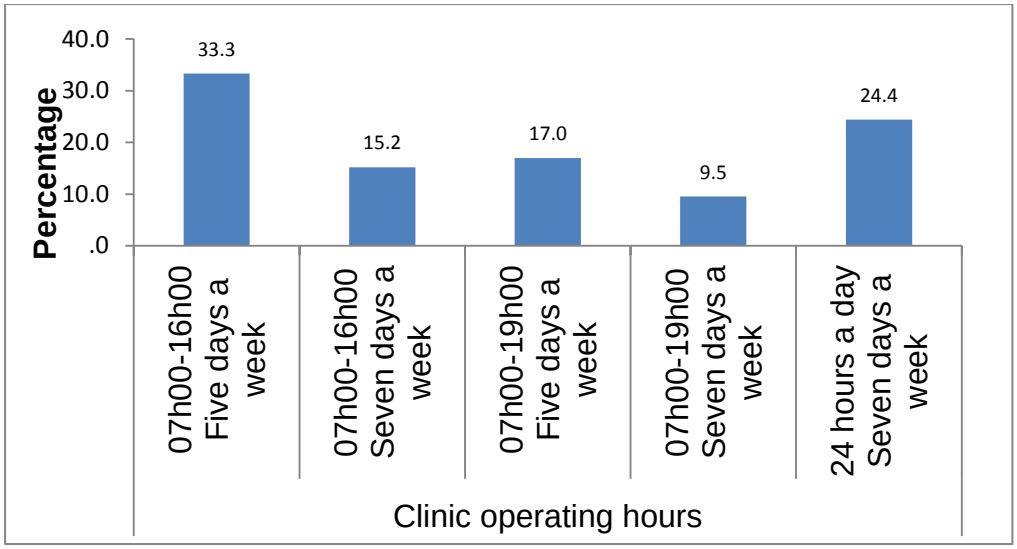

Figure 4.2 Clinic operational hours (n=334)

4.4.3 Descriptive statistics

Table 4.1 showed the age in years of respondents with a minimum of 25 and maximum of 59, the mean is 40.93 and standard deviation 8.021. The standard deviation for age in years is considered high meaning that the age distribution was widely spread and some of the variables were not closer to the mean. The years of experience as a nurse with a minimum of 0 and maximum of 30, the mean is 10.43 and standard deviation 6.684, the standard deviation for experience is considered low, meaning the deviation is closely related to the average. The years of experience in the PHC clinic with a minimum of 0 and maximum of 28, the mean is 8.15 and standard deviation is 5.564. The standard deviation is considered low meaning the deviation is closely related to the average.

Table: 4. 1 **Descriptive Statistics for age in years and years of experience**

	N	Minimum	Maximum	Mean	Standard Deviation
Age in Years	322	25	59	40.93	8.021
Years of experience	331	0	30	10.43	6.684
Years of experience in a PHC clinic	329	0	28	8.15	5.564

4.5 Section B: Knowledge regarding the collection of clinical specimens

The second section dealt with knowledge regarding the collection of clinical specimens. The respondents were required to give the most appropriate answer to questions about basic rules on specimen handling to indicate their knowledge. The questions are based on preparations, requesting a test, specimen collection and handling of results.

4.5.1 Preparation and identification

The analysis of preparation and identification related to the availability of PHC Laboratory handbook at all clinics, weekly checks of equipment needed for specimen collection, N1 form used to order specimen collection equipment, knowledge of the list of tests taken at clinic level is essential and patient identification should be done before taking a specimen.

4.5.1.1 The Primary Health Care laboratory handbook should be available in all clinics

Table 4.2 depicts the results of the availability of the PHC Laboratory handbook in all the clinics. Of the 336 respondents, 98.8% (n=332) was “True” .3% (n=1) “False”,

.3% (n=3) were “Unsure”. The chi-square goodness of fit test showed a significant 332 (98.8%) agreed that the PHC laboratory handbook should be available in all clinics with a *p value* of p<.0005.

Table 4.2 The Primary Health Care laboratory handbook should be available in all clinics (n=336)

Frequency		**Frequency**	**Percent**
Valid	True	332	98.8
	False	1	.3
	Unsure	3	.9
Total		**336**	**100.0**

4.5.1.2 All equipment needed for specimen collection should be checked weekly Table 4.3 depicts the results that all equipment needed for specimen collection should be checked weekly. Of the 336 respondents, 94.6% (n=318) was “True”, 4.2% (n=14) “False”, 1.2% (n=4) were “unsure” whether all equipment needed for specimen collection should be checked weekly or not. The Binomial showed a significant 318 (94.6%) agreed that all equipment needed for specimen collection should be checked weekly p<.0005**.**

Table 4.3 All equipment needed for specimen collection should be checked weekly (n=336)

		Frequency	**Percent**
Valid	True	318	94.6
	False	14	4.2
	Unsure	4	1.2
Total		**336**	**100.0**

4.5.1.3 N1 form is used to order specimen collection equipment

Table 4.4 depicts results that the N1 form is used to order specimen collection equipment. Of the 336 respondents, 21.1% (n=71) was “True” 74.1% (n=249)

"False", 4.8% (n=16) were "unsure". The chi-square goodness of fit test showed that a significant 249 (74.1%) agreed that N1 form is not used to order specimen collection equipment with a *p value* of p<.0005.

Table 4.4: N1 form is used to order specimen collection equipment (n=336)

		Frequency	**Percent**
Valid	True	71	21.1
	False	249	74.1
	Unsure	16	4.8
Total		336	100

4.5.1.4 Knowledge of the list of tests taken at clinic level is essential

Table 4.5 depicts the results that knowledge of the list of tests taken at clinic level is essential or not. Of the 336 respondents, 97.0% (n=326) was "True", .3% (n=1) answered "False", 2.7% (n=9) were "unsure". The chi-square goodness of it test showed that a significant 97.0% (n=326) (responded that knowledge of the list of tests taken at clinic level is essential with a *p value* of p<.0005.

Table 4.5 Knowledge of the list of tests taken at clinic level is essential (n=336)

		Frequency	**Percent**
Valid	True	326	97.0
	False	1	.3
	Unsure	9	2.7
Total		336	100

4.5.1.5 Patient identification should be done before taking a specimen

Table 4.6 depicts the results that patient identification should be done before taking a specimen. Of the 336 respondents, 99.7% (n=335) was "True".3% (n=1) "False". The chi-square goodness of fit test showed that a significant 335 (99.7%) responded

that patient identification should be done before taking a specimen with a *p value* of p<.0005.

Table 4.6: Patient identification should be done before taking a specimen (n=336)

		Frequency	**Percent**
Valid	True	335	99.7
	False	1	.3
Total		**336**	**100**

Table 4.7 summarises the results for preparation and identification and the binomial tests for these results.

Table 4.7 Results for preparation and identification and the binomial tests for these results.

Section	Question	True n (%)	False n (%)	Unsure n (%)	Correct n (%)	p-value#
Preparation and identification	The Primary Health Care laboratory handbook should be available in all clinics	332 (98.8)	1 (0.3)	3 (0.9)	332 (98.8)	<.0005*
	All equipment needed for specimen collection should be checked weekly	318 (94.6)	14 (4.2)	4 (1.2)	14 (4.2)	<.0005*
	N1 form is used to order specimen collection equipment	71 (21.1)	249 (74.1)	16 (4.8)	249 (74.1)	<.0005*
	Knowledge of the list of tests taken at clinic level is essential	326 (97.0)	1 (0.3)	9 (2.7)	326 (97.0)	<.0005*
	Patient identification should be done before taking a specimen	335 (99.7)	1 (0.3)	-	335 (99.7)	<.0005*

Binomial test (correct/incorrect)

* Indicates significance at the 95% level.

4.5.2 Requesting the test

Table 4.8 presents the responses on “requesting the test” and the results of the five questions are the following:

Which of the following groups of tests can a nurse request at the clinic in the absence of the doctor?

Twelve-point five percent (n=42) responded incorrectly and 87.5% (n=294) correctly. The Binomial Test showed that a significant 87.5% responded correctly with a *p value* of p<.0005.

Which of the following forms is used to request specimens in the clinic?

Ninety-two point nine per cent (n=312) responded correctly and 7.1% (n=24) incorrectly. The Binomial test showed a significant 92.9% responded correctly with a p-value of p<.0005.

It is important to fill in the entire patient’s information when requesting a test?

A total of 100% (n=336) responded correctly. The Binomial test showed a significant 100% (n=336) responded correctly with a *p value* of p<.0005.

Clinicians’ practice number is not required on the request form.

Ninety-two-point six percent (n=311) responded incorrectly and 7.4% (n=25) correctly. The Binomial test showed that a significant 92.6% responded incorrectly with a *p value* of p<.0005.

Specimen containers should be clearly labelled.

Ninety-eight-point eight percent (n=332) responded correctly and 1.2% (n=4) responded incorrectly. The Binomial test showed a significant 98.8% responded correctly with a *p value* of p<.0005**.**

Table 4.8 Requesting the test

Section	Question	Cerebro spinal fluid, Pus swab n (%)	CD4 count, Viral load, Gene Expert n (%)	ESR, INR n (%)	Correct n (%)	Incorrect n (%)	p-value#
Requesting the test	Which of the following groups of tests can a nurse request at the clinic in the absence of the doctor?	17 (5.1)	294 (87.8)	24 (7.1)	294 (87.8) (87.8)	42 (12.5)	<.0005*
		N1 n (%)	N2 n (%)	N3 n (%)	Correct n (%)	Incorrect n (%)	p-value#
	Which of the following forms is used to request specimens in the clinic?	312 (92.9)	12 (3.6)	13 (3.6)	312 (92.9)	24 (7.1)	<.0005*
		True n (%)	False n (%)	Unsure n (%)	Correct n (%)	Incorrect n (%)	p-value#
	It is important to fill in the entire patient's information when requesting a test	336 (100)	-	-	336 (100)	-	<.0005*
	Clinicians' practice/practice number is not required on the request form	25 (7.4)	303 (90.2)	8 (2.4)	303 (90.2)	25 (7.4)	<.0005*
	Specimen containers should be clearly labelled	332 (98.8)	1 (.3)	3 (.9)	332 (98.8)	4 (1.2)	<.0005*

4.5.3 Specimen collection and handling

This section looks at colour coding for specimen tubes, volume of the specimen in the container, colour coded blood tube lists and procedure that follow after collecting a blood specimen

4.5.3.1 Colour coding for specimen tubes

Table 4.9 depicts the response that to colour coding for specimen tubes is important. The result of 89.0% (n=299) was "True" and 6.5% (n=22) "False", 3.9% (n=13) were "unsure" and .6% (n=2) was missing data. The Chi-Square goodness of fit test

showed a significant 89.0% responded that colour coding for specimen tubes was important with a *p value* of , p<.0005.

Table 4.9 Colour coding for specimen tubes is important (n=336)

		Frequency	**Percent**
Valid	True	299	89.0
	False	22	6.5
	Unsure	13	3.9
	Total	334	99.4
Missing	System	2	.6
Total		**336**	**100**

4.5.3.2 Volume of the specimen in the container

Table 4.10 depicts the response that the volume of the specimen in the container is not important. The result was12.8% (n=43) “True” and 81.0% (n=272) “False”, 5.7% (n=19) were “unsure” and .6% (n=2) was missing data. The Chi-Square goodness of fit showed a significant 81.0% (n=272) responded that the volume of the specimen in the container is important with a *p value* of p<.0005.

Table 4.10 Volume of the specimen in the container (n=336)

		Frequency	**Percent**
Valid	True	43	12.8
	False	272	81.0
	Unsure	19	5.7
	Total	334	99.4
Missing	System	2	.6
Total		**336**	**100**

4.5.3.3 Colour coded blood tube lists

The response to choose one colour coded blood tube list follows the correct order of the draw when collecting blood was as follows:

Option 1: 14.0% (n=47) purple, yellow, blue, grey,

Option 2: 16.1% (n=54) purple, blue, yellow, grey,

Option 3: 4.5% (n=15) blue, purple, yellow, grey,

Option 4: 64.9% (n=218) yellow, blue, grey, purple and 6% (n=2) was missing.

The Chi-Square goodness of fit showed a significant agreement of 64.9% (n=218) with option 4 and a *p value* of p<.0005. Table 4.10 depicts the results to the colour coded blood tube lists.

Table 4.11 Colour coded blood tube list (n=336)

	Options	**Frequency**	**Percent**
Valid	Purple, yellow, blue, grey	47	14.0
	Purple, blue, yellow, grey	54	16.1
	Blue, purple, yellow, grey	15	4.5
	Yellow, blue, grey, purple	218	64.9
	Total	334	99.4
Missing	System	2	.6
Total		**336**	**100**

4.5.3.4 Procedure to follow after collecting blood specimen in a tube

The responses to the procedure to follow after collecting blood specimen in a tube were the following:

Option 1:19.9% (n=67) mix vigorously at least 8 times;

Option 2: 60.7% (n=204) mix gently 8-10 times;

Option 3: 13.4% (n=45) invert at least once;

Option 4: 5.4% (n=18) shake to ensure adequate mixing and

6% (n=2) were missing.

The Chi-Square goodness of fit showed that a significant 60.7% (n=204) mix gently with a *p value* of p<.0005**.** Table 4.11 presents the results.

Table 4.12 Procedures that follow after collecting blood specimens in a tube (n=336).

	Options	**Frequency**	**Percent**
Valid	Mix vigorously at least 8 times	67	19.9
	Mix gently 8-10 times	204	60.7
	Invert at least once	45	13.4
	Shake to ensure adequate mixing	18	5.4
	Total	334	99.4
Missing	System	2	.6
Total		**336**	**100**

4.5.4 Handling results

4.5.4.1 A nurse should be allocated to sort and action results

The response to a nurse being allocated to sort and action results was 98.2% (n=330) “True” and .9% (n=3) “False”, .6% (n=2) were “unsure” and .3% (n=1) had missing data. The Chi-Square goodness of fit showed that a significant 98.2% (n=330) agreed that a nurse should be allocated to sort and action results with a *p value* of p<.0005. Table 4.12 depicts the results.

Table 4.13 A nurse should be allocated to sort and action results (n=336)

		Frequency	**Percent**
Valid	True	330	98.2
	False	3	.9
	Unsure	2	.6
	Total	335	99.7
Missing	System	1	.3
Total		**336**	**100.0**

4.5.4.2 Gene Expert (Tuberculosis test) results should be available within 24 hrs

Table 4.13 depicts the responses that gene expert (Tuberculosis test) results should be available within 24hrs. The result was 85.7% (n=288) “True” and 10.4% (n=35) “False”, 3.6% (n=12) were “unsure” and .3% (n=1) had missing data. The Chi-Square goodness of fit showed that a significant 85.7% (n=288) responded that gene expert results should be available within 24hrs with a *p value* of p<.0005.

Table 4.14: Gene expert (Tuberculosis test) results should be available within 24hrs (n=336)

		Frequency	**Percent**
Valid	True	288	85.7
	False	35	10.4
	Unsure	12	3.6
	Total	335	99.7
Missing	System	1	.3
Total	**336**	**100.0**	

4.5.4.3 A specimen should be repeated at any time when results are not available.

Table 4.14 showed the results that a specimen should be repeated at any time when results are not available. The response was 36.3% (n=122) “True”, 60.7% (n=204) “False”, 2.7% (n=9) was “unsure” and .3 % (n=1) had missing data. The Chi-Square goodness of fit showed that a significant 60.7% (n=204) disagreed that specimen should be repeated at any time when results are not available with a *p value* of p<.0005.

4.15 A Specimen should be repeated at any time when results are not available (n=336)

		Frequency	Percent
Valid	True	122	36.3
	False	204	60.7
	Unsure	9	2.7
	Total	335	99.7
Missing	System	1	.3
Total		**336**	**100**

4.5.4.4 Results can be traced by calling the laboratory

Table 4.15 depicts that the results can be traced by calling the laboratory. The response was 98.2% (n=330) “True”, 1.5% (n=5) “False” and .3% (n=1) had missing data. The Chi-Square goodness of fit showed a significant 98.2% responded that results can be traced by calling the laboratory with a *p value* of p<.0005.

Table 4.16 Results can be traced by calling the laboratory (n=336)

		Frequency	Percent
Valid	True	330	98.2
	False	5	1.5
	Total	335	99.7
Missing	System	1	.3
Total		**336**	**100**

4.5.4.5 Specimen sticker information is important when tracing results

Table 4.16 depicts the responses that specimen sticker information is important when tracing the results. The response was 96.5% (n=321) “True”, 1.2% (n=4) “False”, 2.7% (n=9) were “unsure” and .6% (n=2) had missing data. The Chi-Square goodness of fit showed a significant 96.5% (n=321) responded that specimen sticker information is important when tracing the results with a *p value* of p<.0005.

Table 4.17 Specimen sticker information is important when tracing the results (n=336).

		Frequency	**Percent**
Valid	True	321	96.5
	False	4	1.2
	Unsure	9	2.7
	Total	334	99.4
Missing	System	2	.6
Total		**336**	**100**

4.6 Descriptive statistics

Table 4.17 depicts the descriptive statistics of overall knowledge, preparation and Identification, requesting test, specimen collection and handling and handling results.

The overall knowledge (n=336) has a mean of 74.68, Standard deviation of 9.263 and Standard error Mean of .505. The standard deviation for knowledge is considered large meaning there was a large variance between the data and the statistical average. Preparation and Identification has a Mean of 74.76, Standard Deviation is 10.189 and Standard Error is .556. Requesting test has Mean which is 77.32 and Standard Deviation is 9.334 and Standard Deviation Error is .509. Specimen collection and handling has mean which is 73.88, Standard Deviation is 27.329 and Standard Deviation Error is 1.491. Handling results has Mean which is 72.62, Standard Deviation is 13.571 and Standard Deviation Error is .740.

Table 4.18 Descriptive statistics for overall knowledge (n=336)

	N	Mean	Std. Deviation	Std. Error Mean
Knowledge_	336	74.68	9.263	.505
Preparation and identification	336	74.76	10.189	.556
Requesting test	336	77.32	9.334	.509
Specimen collection and handling	336	73.88	27.329	1.491
Handling results	336	72.62	13.571	.740

4.7 Chi- Square goodness of fit test

Figure 4.3 illustrates the results of the overall knowledge as follows: 74.76% of respondents displayed knowledge on preparation and identification, 77.32% on requesting the test, 73.88% on specimen collection and handling, 72.62% on handling of results and 74.68% of overall knowledge was displayed. The Chi-Square goodness of fit test showed

a significant 74.68% of the variables agree with each other with a *p value* of p<.0005.

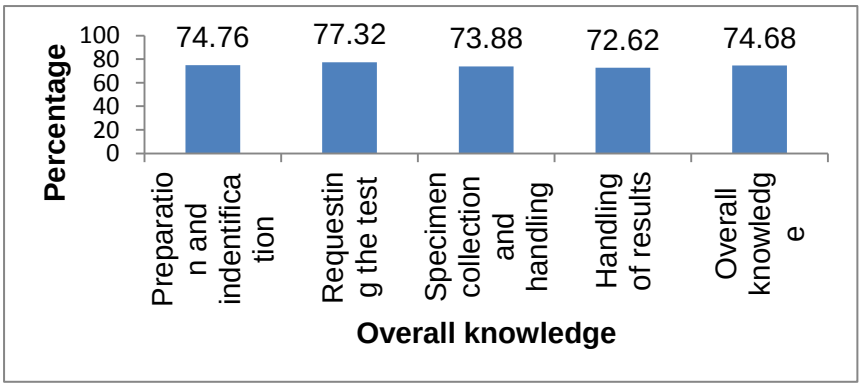

Figure 4.3 Overall knowledge

4.8 Section C Practices

Section C presents results from the checklist on practices during specimen collection. The practices include identification and collection; packaging and storage; courier and management of results.

4.8.1 Identification and collection

The reporting is based on the significant results of performance for group1 and group 2.

Figure 4.4 illustrates the results on the folder being identified against the correct patient; specimens clearly labelled; each laboratory request form is correctly completed; use of correct specimen collection tubes/jars; hands are washed with soap and water/sprayed with alcohol spray; protective clothing are worn, that is, gloves and apron; order of draw is followed correctly when collecting multiple specimens; procedure is explained thoroughly to the patient; specimen is packaged into the provided packaging plastic and specimen is recorded on the specimen register (N4).

The response on the folder being identified against the correct patient was “Yes” that is 100% (n=23). The Binomial Test showed that a significant 100% of group 1 correctly performed the procedure with a *p value* of p<.0005.

The response on specimens clearly labelled was 73.9% (n=17) “Yes” for group 1and 26.1% (n=6) “No” for group 2. The Binomial Test showed that a significant 73.9% (n=17) of group 1 correctly performed the procedure with a *p value* of p<.0005**.**

The response on each laboratory request form is correctly completed (N1) was 78%% (n=18) “Yes” for group 2 and 22% (n=5) “No” for group 1. The Binomial Test showed that a significant 78% (n=18) of group 2 correctly performed the procedure with a *p value* of p<.0005.

The response on use of correct specimen collection tubes/jars was 100% (n=23) “Yes”. The Binomial Test showed that a significant 100% (n=23) of group 1 correctly performed the procedure with a *p value* of p<.0005.

The response on hands is washed with soap and water and sprayed with alcohol was 57% (n=13) “Yes” for group 2 and 43% (n=10) “No” for group 1. The Binomial Test showed that a significant 57% (n=13) of group 1performed the procedure correctly with a *p value* of p<.0005.

The response on protective clothing is worn, that is, gloves and apron was 65% (n=15) “Yes” for group 1 and 35% (n=8) “No” for group 2. The Binomial Test showed that a significant 65% (n=15) of group 1 correctly performed the procedure with a *p value* of p<.0005.

The response on the order of draw is followed correctly when collecting multiple specimens was 56.5% (n=15) “Yes” for group 1, 8.7% (n=2) “No” for group 2 and 26.1% (n=6) not applicable. The Binomial Test showed that a significant 56.5% (n=15) of group 1 correctly performed the procedure with a *p value* of p<.0005.

The response on procedure is explained thoroughly to the patient was 87% (n=20) “Yes” for group 1 and 13% (n=3) “No” for group 2. The Binomial Test showed that a significant 87% (n=20) of group 1 correctly performed the procedure with a *p value* of p<.0005**.**

The response on specimen is packaged into the provided packaging plastic was 100% (n=23) “Yes” for group 1. The Binomial Test showed that a significant 100% (n=23) of group 1 correctly performed the procedure with a *p value* of p<.0005.

The response on specimen is recorded in the specimen register (N4) was 100% (n=23) for group 1. The Binomial Test showed that a significant 100% (n=23) of group 1 correctly performed the procedure with a *p value* of p<.0005.

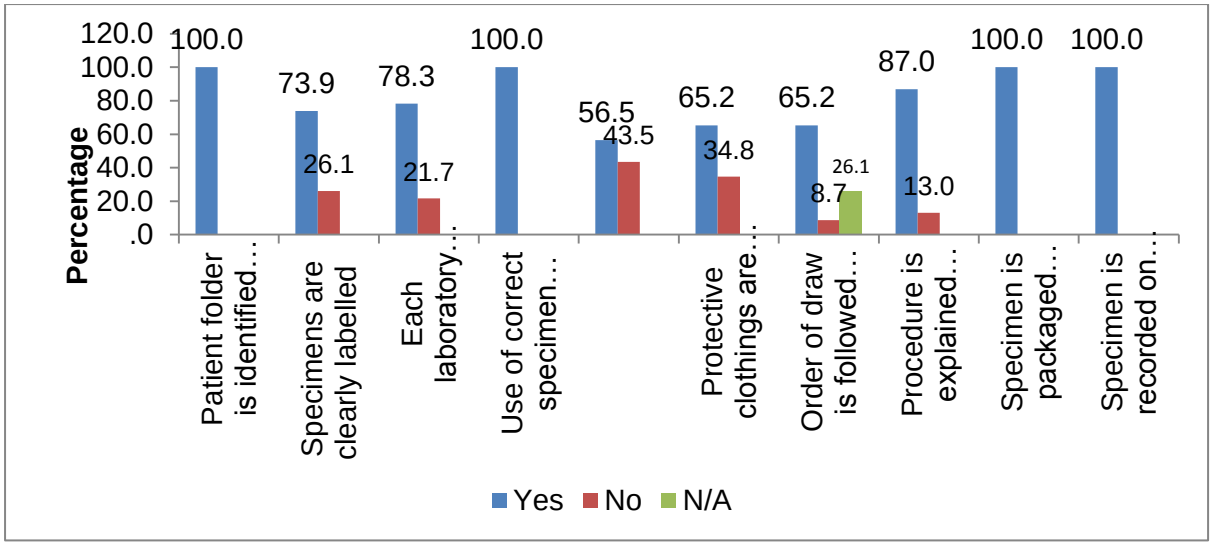

Figure 4.4 Identification and Collection (n=23).

4.8.2 Packaging and storage

Figure 4.5 illustrates the results on samples are kept away from direct sunlight; there is at least one functional wall mounted thermometer in area for laboratory specimens which are stored for courier collection; the temperature of the storage area for laboratory specimens is recorded daily; there is a refrigerator dedicated for specimens; when the room temperature exceeds 25°C, samples are stored in the fridge (at +- 5°C); and length of storage does not exceed 24 hours, stored at room temperature (+- 20-25°C).

The response on samples are kept away from direct sunlight was a 100% (n=23) “Yes” from group 1 and 2. The Binomial Test showed that a significant 100% (n=23) performed the procedure correctly with a p-value of p<.0005.

The response on there is at least one functional wall mounted thermometer in area for laboratory specimens are stored for courier collection was 73.9% (n=17) “Yes” and 26.1% (n=6) “No”. The Binomial Test showed that a significant 73.9% (n=20) of group 1 performed the procedure correctly with a *p value* of p<.0005.

The response on the temperature of the storage area for laboratory specimens is recorded daily was 73.9% (n=17) “Yes” and 26.1% (n=6) “No”. The Binomial Test showed that a significant 73.9% (n=20) of group 1 performed the procedure correctly with a *p value* of p<.0005**.**

The response on there is a refrigerator dedicated for specimens was 73.9% (n=17) “Yes” and 26.1% (n=6) “No”. The Binomial Test showed that a significant 73.9% (n=20) of group 1 and 2 performed the procedure correctly with a *p value* of p<.0005.

The response on where the room temperature exceeds 25°C, samples are stored in the fridge (at +- 5°C) was 73.9% (n=17) “Yes” and 26.1% (n=6) “No”. The Binomial Test showed that a significant 73.9% (n=20) of group 1 performed the procedure correctly with a *p value* of p<.0005.

The response on length of storage does not exceed 24 hours, stored at room temperature (+- 20-25°C) was 100% (n=23) “Yes”. The Binomial Test showed that a significant 100% (n=23) of group 1performed the procedure correctly with a *p value* of p<.0005.

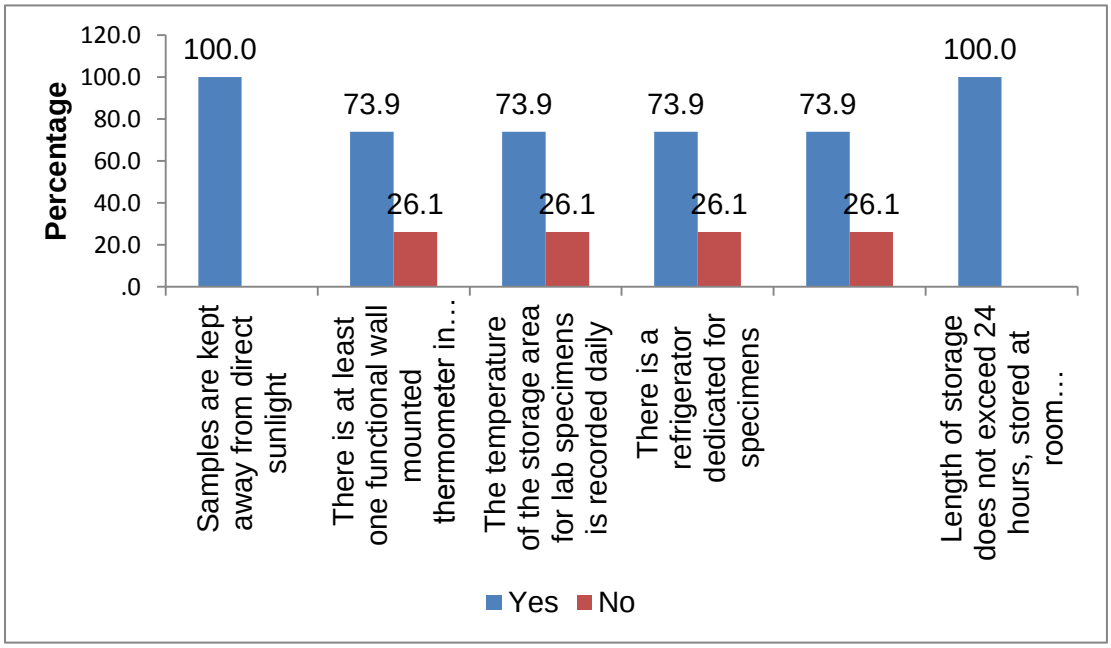

Figure 4.5 Packaging and Storage (n=23).

4.8.3 Courier and management of results

Figure 4.6 illustrates the results on the specimens are stored at room temperature before transit; courier personnel signs specimen register; results are recorded on the specimen register and turnaround time is recorded on the register.

The response on the specimens are stored at room temperature before transit was 100% (n=23) “Yes” for group 1 and 2. The Chi-Square goodness of fit test showed that a significant 100% (n=23) performed the procedure correctly with a *p value* of p<.0005.

The response on courier personnel signs specimen register was 87% (n=20) “Yes” and 13%% (n=3) “No”. The Chi-Square goodness of fit test showed that a significant 87% (n=20) performed the procedure correctly with a *p value* of p<.0005.

The response on results are recorded on the specimen register was 21.7% (n=5) “Yes and 78.3% (n=18) “No”. The Chi-Square goodness of fit test showed that a significant 78.3% (n=18) performed the procedure incorrectly with a *p value* of p<.0005.

The response on turnaround time is recorded on the register was 13% (n=3) “Yes” and 87% (n=20) “No”. The Chi-Square goodness of fit test showed that a significant 78.3% (n=18) performed the procedure incorrectly with a *p value* of p<.0005.

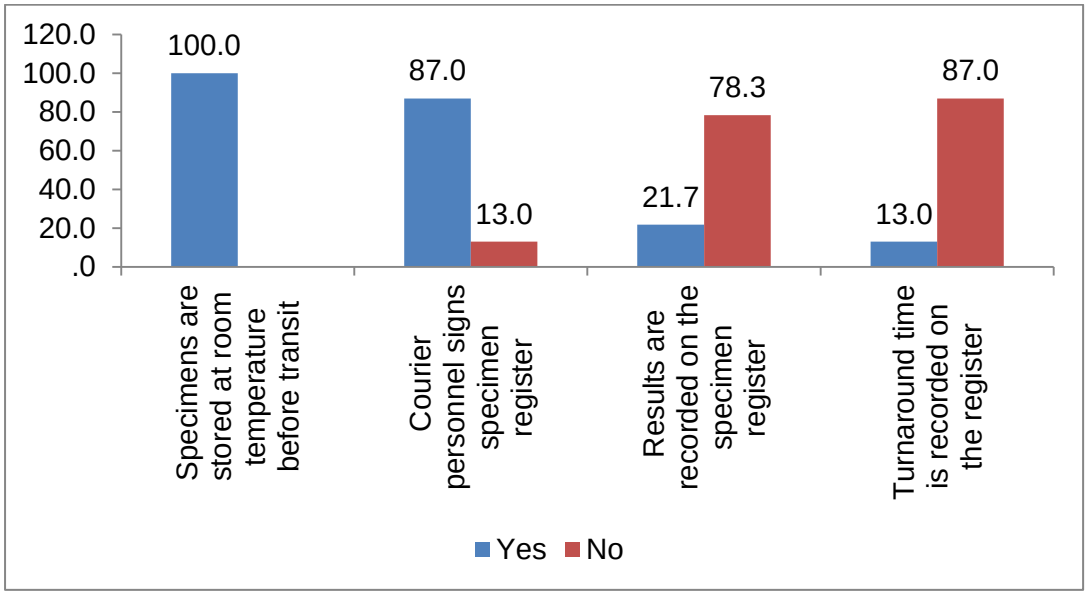

Figure 4.6: Courier and management of results (n=23).

4.9 Section D: Specimen Checklist

Section D includes facility specimen collection consumables; specimen collection material; PAP smear collection material; EAD collection materials and displays the results on availability of specimen collection equipment checklist for visit 1 and visit 2 of sampled clinics.

4.9.1 Facility specimen collection consumables

Figure 4.7 depicts the results on facility specimen collection consumables:

(i) Haemoglobinometer (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of a Haemoglobinometer with a *p value* of p<.0005**.**

(ii) Blood glucometer (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of a blood glucometer with a *p value* of p<.0005.

(iii) Blood Lancets (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of blood lancets with a *p value* of p<.0005.

(iv) Blood glucose strips (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2.The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of blood glucose strips with a *p value* of p<.0005.

(v) Urine dipsticks (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of **urine** dipsticks with a *p value* of p<.0005.

(vi) Urine specimen jar or flask (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of urine specimen jar or flask with a *p value* of p<.0005.

(vii) Malaria rapid test (malaria risk areas) (n=23): The response was 73.9% (n=17) “Available” on visit 1, 82.6% (n=19) on visit 2 and 8.7% (n=2) “not available” on visit 1. On visit 1and 2 the response was17.4% (n=4) “not applicable” The Chi-Square goodness of fit test showed a significant 73.9% (n=17) and 82.6% (n=19) availability regarding malaria rapid test on visit 1 and 2 respectively with a *p value* of p<.0005.

(viii) Rapid HIV test: The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) of availability of rapid HIV test with a *p value* of p<.0005.

(ix) Rh ‘D’ (Rhesus factor) test (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of Rh ‘D’ (Rhesus factor) test with a *p value* of p<.0005.

(x) Brushes for cervical smears (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of brushes for cervical smears with a *p value* of p<.0005.

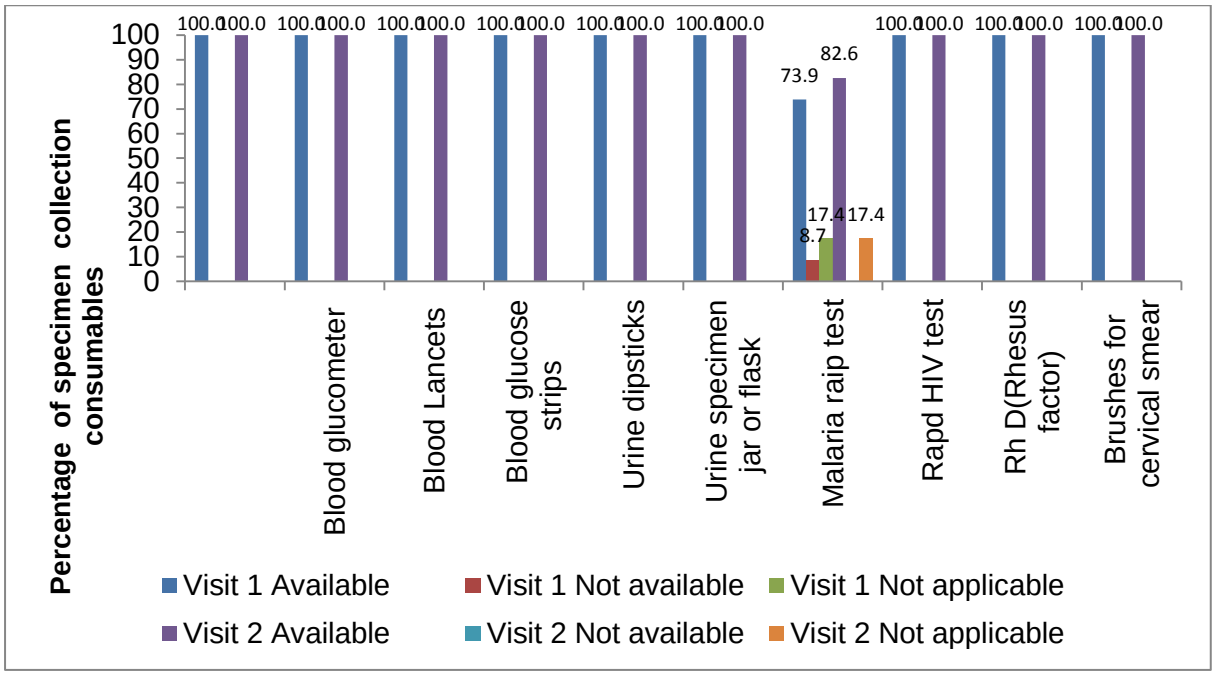

Figure 4.7 Facility Specimen collection consumables (n=23).

4.9.2 Specimen collection material

Figure 4.8 illustrates the responses on the availability of specimen collection material for visit 1 and visit 2 as follows:

(i) Vacutainer tube: Blue Top (Sodium Citrate) (n=23): The response was 69.6% (n=16) “Available” on visit 1and 73.9% (n=17) on visit 2, 30.4% (n=16) “not available” on visit 1and 26.1% (n=6) on visit 2. The Chi-Square goodness of fit test showed a significant 69.6% (n=16) and 73.9% (n=17) availability on visit 1 and 2 respectively regarding vacutainer tube: blue top with a *p value* of p<.0005

(ii) Vacutainer tube: Red OR Yellow Top (SST) Blue Top (Sodium Citrate) (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of vacutainer tube: red or yellow top with a *p value* of p<.0005.

(iii) Vacutainer tube: Grey Top (Sodium Fluoride) (n=23): The response was 100% (n=23) “Available” on visit 1, 91.3% (n=21) on visit 2 and 8.7% (n=2) “Not Available”. The Chi-Square goodness of fit test showed a significant 100% (n=23) and 91.3% (n=21) availability on visit 1 and 2 respectively regarding vacutainer tube: grey top with a *p value* of p<.0005.

(iv) Vacutainer tube: White Top (PPT) (n=23): The response was 100% (n=23) “Available” on visit 1 and 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of vacutainer tube: white top with a *p value* of p<.0005.

(v) Vacutainer tube: Purple Top (EDTA) (n=23): The response was 100% (n=23) “Available” on visit 1 and 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of vacutainer tube: purple top with a *p value* of p<.0005.

(vi) Microtainer tube: Purple Top (EDTA Paeds) (n=23): The response was 78.3% (n=18) “Available”, on visit 1, 87% (n=20) on visit 2, 21.7% (n=5) “not available” on visit 1 and 13% (n=3) on visit 2. The Chi-Square goodness of fit test

showed a significant 78.3% (n=18) and 87% (n=20) availability of microtainer tube: purple top with a *p value* of p<.0005.

(vii) Microtainer tube: Yellow Top (SST-Paeds) (n=23): The response was 69.6% (n=18) “Available” on visit 1, 73.9% (n=17) on visit 2, 30.4% (n=7) “not available” on visit 1 and 26.1% (n=6) on visit 2. The Chi-Square goodness of fit test showed a significant 69.6% (n=18) and 73.9% (n=17) availability of microtainer tube: yellow top with a *p value* of p<.0005.

(viii) Venepuncture needles (Green OR Black) (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of venepuncture needles with a *p value* of p<.0005.

(ix) Specimen Plastic Bags (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of specimen plastic bags with a *p value* of p<.0005.

(x) Tourniquet (n=23): The response was 73.9% (n=17) “Available” on visit 1 and visit 2 and 26.1% (n=6) “not available”. The Chi-Square goodness of fit test showed a significant 73.9% (n=17) availability of tourniquet (n=23) with a *p value* of p<.0005.

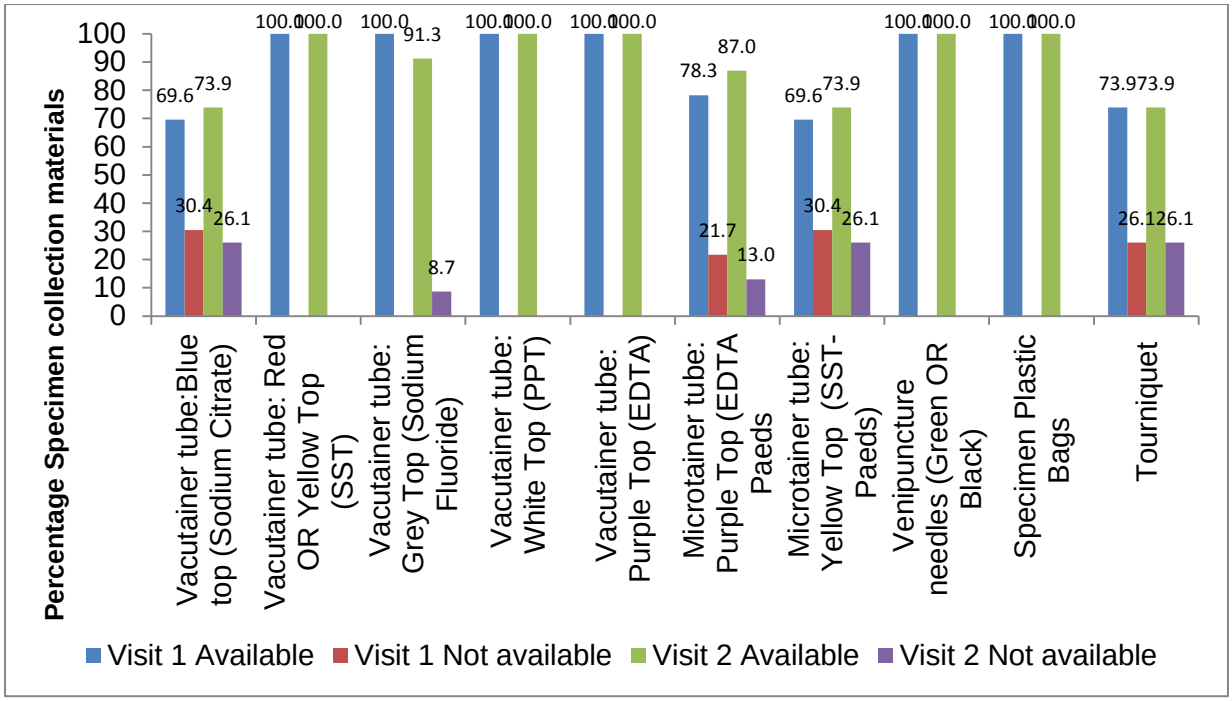

Figure 4.8 Specimen collection materials

4.9.3 PAP Smear collection materials

Figure 4.9 illustrates the responses on the availability of PAP smear collection material for visit 1 and visit 2 as follows:

(i) Liquid - based Cytology (LBC) vials (N/A if facility uses traditional PAP smear method) (n=23): The response was 100% (n=23) on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of liquid - based cytology (LBC) vials with a *p value* of p<.0005.

(ii) **Combi - brush (N/A if facility uses traditional PAP smear method) (n=23):** The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of combi - brush with a *p value* of p<.0005.

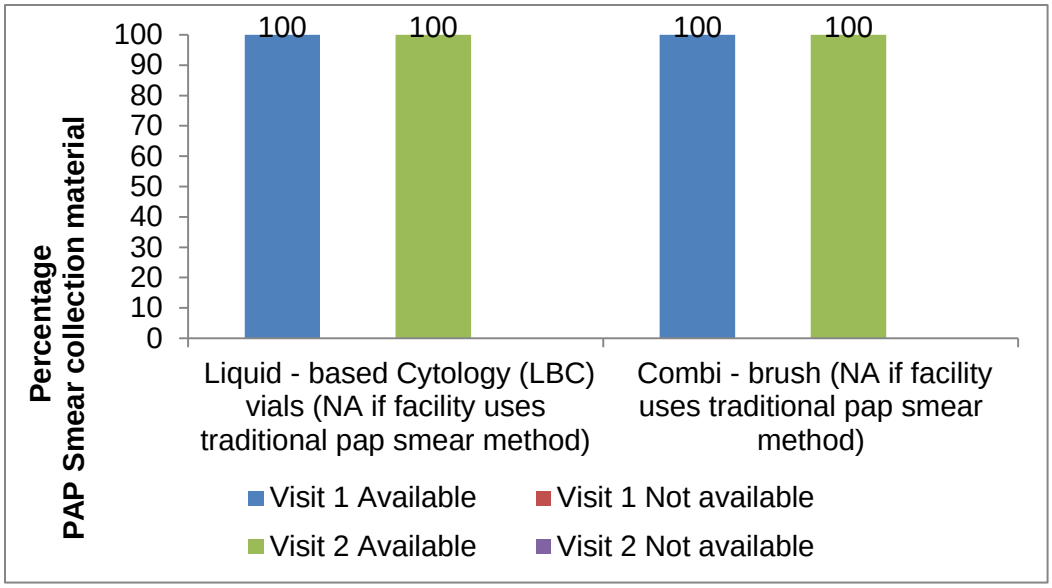

Figure 4.9 PAP smear collection materials (n=23)

4.9.4 EAD Collection materials

Table 4.18 illustrate responses on availability of EAD collection materials for visit 1 and 2.

The response on the availability DBS PCR Kit or EDTA microtainer tube: was 100% (n=23) on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of DBS PCR Kit or EDTA microtainer tube with a *p value* of p<.0005.

4.9.5 NHLS Stationery

Figure 4.10 illustrates responses on availability of NHLS Stationery for visit 1 and 2 as follows:

(i) N1 - PHC Request Forms (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of PHC request forms with a *p value* of p<.0005.

(i) N2 - Cytology Request Form (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a

significant 100% (n=23) availability of cytology request form with a *p value* of p<.0005.

(iii) N3 - PHC Order Book Material for specimen collection (n=23): The response was 95.7% (n=22) “Available on visit 1, 100% (n=23) on visit 2 4.3% (n=1) was “Not Available” on visit 1. The Chi-Square goodness of fit test a significant 100% (n=23) availability of PHC order book material for specimen collection with a *p value* of p<.0005.

(iv) N4 - PHC Facility Specimen Register (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of PHC facility specimen register with a *p value* of p<.0005.

(v) PHC laboratory handbook (n=23): The response was 100% (n=23) “Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 100% (n=23) availability of PHC laboratory handbook with a *p value* of p<.0005.

(vi) SMS printer (N/A) for facilities with Track care Laboratory system. (n=23): The response was 13% (n=3) “Available” and 73.9% (n=17) “Not Available” on visit 1 and visit 2. The Chi-Square goodness of fit test showed a significant 73.9% (n=17) non- availability of SMS printer (N/A) for facilities with track care laboratory system with a *p value* of p<.0005.

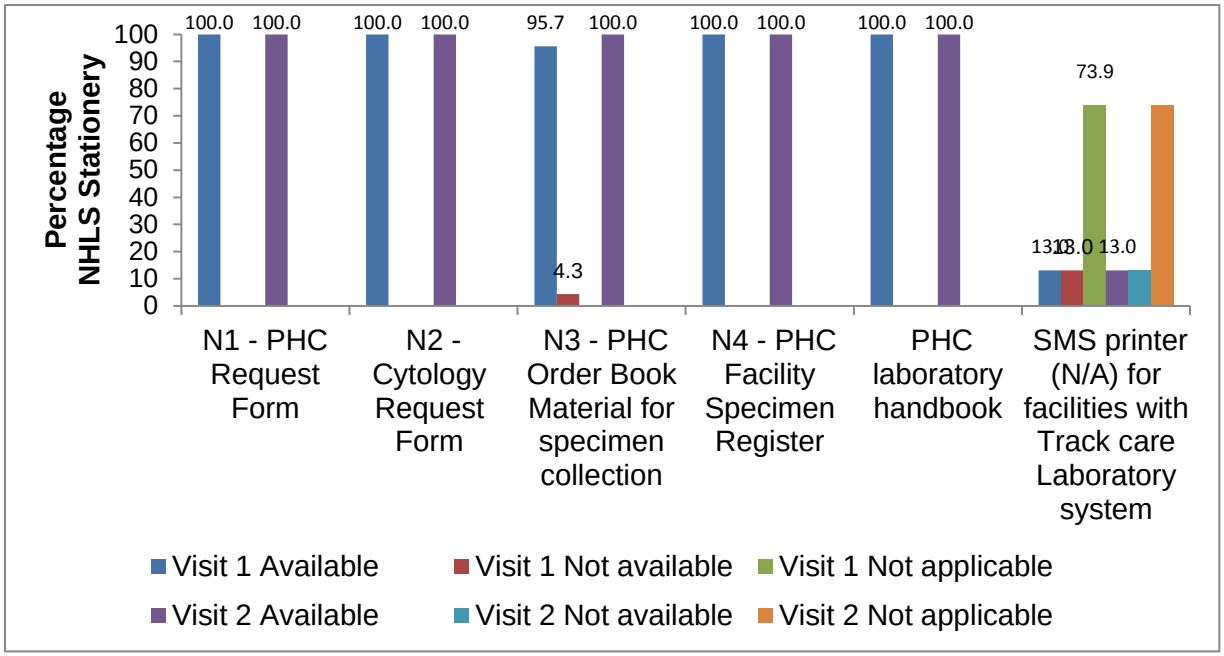

Figure 4.10 NHLS Stationery

4.10 CONCLUSION

Chapter 4 dealt with presentation of findings of data that was collected from the sampled clinics, Professional and Enrolled nurses. The chapter presented the analysis of data using statistical tests such as descriptive statistics, Binomial test and Chi-square goodness-of-fit test. The analysis was based on the demographical data of the respondents which is age in years, nursing category as well as the clinic operational hours. The data analysed on knowledge and a practice of nurses was based on the steps of specimen collection process which are: preparation and identification; requesting the test, specimen collection and handling as well as the handling of results. Chapter 5 will present the discussion of findings; relevant literature will support the findings. The conclusion and recommendations based on the findings will be drawn.

Chapter 5: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the results that were presented in the previous chapter. The discussion of the results is based on the research which describes the knowledge and practices of nurses in the collection of clinical specimens. Relevant literature was reviewed where necessary as it relates to the findings. The conclusion was drawn and recommendations outlined.

The discussion is centred on the three elements of Donabedian's theory of quality in health care. These dimensions are important in ensuring quality in the identification of the practices and knowledge of nurses in the collection of clinical specimens. It is essential that the structures in healthcare be put in place to allow processes of care to be carried out, therefore, giving better results to care (Weisemann-Brenner *et al.* 2014:180).

5.2 Section A: Demographic data

The discussion on the demographic data relate to nursing category, clinic operational hours, age in years and years of experience.

5.2.1 Nursing category

The nurses who were allocated in the clinics were professional nurses and enrolled nurses. The allocation of nurses was accepted because it was according to the Nursing Act No. 33 of 2005 regulation regarding the Scope of Practice of Nurses and Midwives (South Africa, Department of Health 2020: 4). There was a combination of nurses concerning years of training and experience. There was 8.0% (n=27) nurses who were professional nurses doing community service and 47.0% (n=158) were professional nurses with primary health care (PHC) as a specialty. The professional nurses with PHC specialisation which showed that most of the nurses did have a high level of expertise and were expected to display sufficient knowledge of

specimen collection. Evripidou, Charalambous and Papastavrou (2019: 56) proved that well-trained and experienced nurses have improved knowledge and skills.

5.2.2 Clinic operational hours

The clinical operational hours of nurses varied between 33.3%(n=112) who worked in clinics that operate from 07h00 to 16h00 five days a week and 24.4%(n=82) who worked 24hours seven days a week. The clinic operational hours play an important role in storage and transportation time which in turn has a major contribution to specimen rejection. Thirty-three-point three percent of the clinics that operate from 07h00 to 16h00 are in rural areas. The specimens collected in rural areas are more likely to be rejected than those collected in hospitals or areas near the laboratory (Rooper *et al.* 2017: 2). The rejection is due to the delay caused by the distance travelled by the courier from the clinics to the laboratory which might increase the turnaround time of specimens.

The clinics that operate between 07h00 to 16h00 often have the specimens collected in the morning because courier routes are allocated by NHLS and the specimens which are collected after the courier has left are kept in the refrigerator until the next collection time to avoid them being compromised by excessive heat. The storage of specimens in rooms and refrigerators were not monitored by 26.6% of the clinics. According to Kiros *et al*. (2020: 852), extreme temperature–either hot or cold compromises the quality of the specimens.

The specimens that are collected early in the morning tend to have a longer TAT because of the waiting period for all orders from the other clinics before they are processed (Mwogi *et al.* 2020: 11). Specimens that are too old to be processed, for example, potassium received more than 24 hours after collection will not be processed (South African Department of Health 2020 and National Health Laboratory Services 2016: 39)

5.2.3 Age in years and years of experience.

The minimum age of the respondents was 25 years old and the maximum 55 years old and with a mean age of 40.93. The mean age of 40.93 was significant concerning the years of experience in the nursing field. The professional nurses (47%) with a Primary Health Care (PHC) specialisation have an average of 8.15 years of experience in PHC settings and have acquired specimen collection skills. The experienced nurses have acquired skills through continuous in-service training and mentoring, therefore Atalla and Henedy (2018: 21) recommended that the junior, less experienced nurses and nurses doing community service be offered the same. The PHC nurses work independently by identifying the need for ordering and collecting the specimen for prompt diagnosis (South African Department of Health 2020: 19). The newly qualified nurses who have undertaken their community service (16.1%) are less experienced within PHC services since most of their training is hospital oriented. Rizany, Hariyati and Handayani (2018: 156) stated that there is a significant relationship between work experience and age in years, through training and continuous mentoring in the working environment. Sharma, Gupta and Tripathi (2019: 358) found that majority of nurses (49.4%) had between 6 -10 years' experience and there was a significant correlation between experience and knowledge.

The Nursing Act No. 33 of 2005 regulation regarding the Scope of Practice of Nurses and Midwives addresses the role and boundaries for nursing practice and states that competencies for a Primary Health Care Specialist (SANC Regulation 212) are that a nurse is an independent nurse specialist who focuses on individuals with health problems and needs (South African Department of Health 2020: 19). According to Sareen and Dutt (2018: 1), the rejection of the samples especially due to pre-analytical errors generally occurs among nurses whose training and experience is limited in the clinical setting.

5.3 Section B: Knowledge regarding the collection of clinic specimens

The knowledge regarding the collection of clinic specimens targeted preparations, requesting a test, specimen collection and handling of results.

5.3.1 Preparation and identification

The study findings revealed that the respondents showed a mean of 74.68% for overall knowledge and a mean of 74, 76 for patient preparation and identification. A significant 98.8% of the respondents agreed that the primary healthcare laboratory handbook should be available in all clinics. (Cornes *et al.* 2017: 29) recommended the use of clinical guidelines and standards to ensure safe practice for nurses and patients.

Insufficient knowledge was displayed by 4.2% of the respondents that all the equipment needed for specimen collection should be checked weekly. 94.6% of nurses responded that all the equipment needed for specimen collection should be checked weekly. The specimen collection tubes should also be checked for expiration dates before use as it may cause loss of vacuum resulting in inappropriate volume and changes in the blood to the additive ratio (South African Department of Health 2015: 93). Checking the equipment ensures constant availability and that the specimens are collected using the tubes, swabs, brushes and vacutainer needles that have not expired. Using expired tubes compromises the specimen suitability for analysis, leading to rejection or incorrect interpretation of results (Sareen and Dutt 2018: 3).

The study showed that 74.1% of the respondents had sufficient knowledge and stated that the N1 form is not used to order specimen collection equipment. Knowledge of different forms is vital for specimen collection. Using the incorrect form will lead to specimens being rejected by the laboratory. The forms serve as a communication tool between the nurses and the laboratory (Kipkulei and Lotodo 2019: 863). South African Department of Health (2020) and National Health Laboratory Services (2016: 23) stated that PHC Request Form (N1) is for general

routine tests and that specimen collection material is ordered with PHC Order Book: Materials for Specimen Collection with the (N3) form. Equipment can also be ordered at any given time using the N3 form. It is primarily the nurses' role to check the equipment and consumables daily. The availability of specimen collection material should be checked to avoid sending patients away which delays their diagnosis and initiation of treatment. Supplies must also be checked for defects and be used within expiry date (Atef and Faraj 2020: 24).

The majority (97%) of nurses responded that knowledge of the list of tests taken at the clinic level is essential. In support of this finding, Mazanderani *et al.* (2017: 3) stated that knowledge of standardised practice minimises pre-analytic errors that lead to specimen rejection. The knowledge of the list of tests that can be requested at the clinic level prevents nurses in general from taking specimens that should not be taken at the clinic level. South African Department of Health (2020) and National Health Laboratory Services (2016:18) provide clear guidance on the list of tests that can be requested by a nurse at the clinic level. The list is known as the PHC essential laboratory list. The study conducted by Sharma *et al.* (2019: 358) found that the knowledge of nurses in specimen collection processes improved by 70%.

The majority (99.7%) of the respondents displayed knowledge that patient identification should be done before taking the specimen. Patient identification is a critical element in specimen collection (Kumar *et al.* 2020: 31). Saffar *et al* (2020: 62) stated that insufficient knowledge on patient identification makes healthcare providers prone to inappropriate ordering as well as making mistakes in the interpretation of the results. Sandhu *et al.* (2017: 248) stated that improved communication and collaboration between laboratory and healthcare professionals is effective to decrease specimen identification errors.

- **Structure element of quality**

The structure element defines the physical environment where healthcare is provided, as well as the human and material resources that are put in place for the

quality procedure to take place. The structure looks at the availability of equipment, consumables, financial resources, guidelines/standards, personnel and their training (Polsa *et al.* 2013: 55). The researcher considered that structure is applicable to ensure quality in the collection of clinical specimens by nurses, to establish whether the availability of all the supplies that are needed for specimen collection can contribute to the improvement of the specimen rejection criterion. Mrazek *et al.* (2020: 7) found that the use of inappropriate specimen collection material contributed to 0.03% to 3.6% of overall samples, or 2.6% to 8.1% of all errors analysed.

The preparation and identification of specimen collection consumables are also essential for the structure element. The researcher used a checklist to determine the availability of the specimen collection resources and found out that eight of the specimen collection resources were not available in five clinics. These resources form the basis of the structural element in Donabedian's theory of quality. The study found that most of the experienced nurses displayed knowledge of specimen collection consumables; however, the less experienced nurses had insufficient knowledge of these consumables and most of them were unsure. Preparation and identification of the patient is also a crucial step in preventing pre-analytical errors. The steps include ensuring that the specimen is collected from the correct patient. The study by Matlala *et al.* (2021: 6) discovered that most nurses including less experienced nurses displayed sufficient knowledge in patient identification.

The experience in PHC clinics and the level of training for nurses is also essential to determine their knowledge of the specimen collection process. The researcher used a self-administered questionnaire to measure the knowledge of nurses on specimen collection and awareness of pre-analytical errors. The researcher found that most of the nurses had a PHC qualification which rendered them more experienced than others. The nurses who were doing their one-year community service were less experienced and lacked knowledge in the clinical specimen collection process. The study also noted that enrolled nurses displayed sufficient knowledge of the PHC laboratory handbook than nurses who were doing community service, which might

be due to a lack of proper training and mentorship. Nurses need to have sufficient knowledge of the PHC handbook and specimen collection skills to provide quality laboratory services (Köse *et al.* 2016: 678). It is for the same reason that emphasis is made that measures should be implemented for the nurses to be provided with adequate skills for the clinical specimen collection process for quality clinical outcomes. Donabedian's theory regards training as the structural element (Satchi and Venkatesan 2018: 1741).

5.3.2 Requesting the test

The study results revealed that the respondents displayed a 77.32% overall knowledge on the processes followed when requesting a test/specimen. Most of the respondents (87.5%) displayed sufficient knowledge of groups of tests that a nurse can request at the clinic in the absence of the doctor. Appropriate and accurate results may be achieved by addressing nurses' knowledge of the specimen collection processes and requirements (Jones *et al.* 2015: 173).

Most respondents (92.9%) were knowledgeable that the N1 form is used to request for specimen collection and N2 (Cytology Request Form) for Pap smears and other cytology tests. The testing process in a clinical laboratory starts with a test requisition form filled by the clinician followed by the sample sent to the laboratory (Kumar *et al.* 2020: 30). The ELL identifies all laboratory tests that can be requested by PHC facilities and details the turnaround times, specimen collection tubes, specimen types, specimen storage conditions and special instructions for each test (South Africa, Department of Health 2000 and National Health Laboratory Services 2016: 30). Laboratory investigations do not replace the need for a clinical examination of the patient by PHC nurses (South Africa, Department of Health and National Health Laboratory Services 2016: 6).

There was 100% response that the patients' entire information should be filled in and specimen containers should be clearly labeled. All tubes must be labeled in the presence of the patient with the correct patient's information. The patient information is important to ensure that the laboratory data is matched to the correct patient and that appropriate age and gender-adjusted reference intervals are supplied (South Africa, Department of Health and National Health Laboratory Services 2016: 23). Labeling must be done before collecting the specimen to minimise handling after collection (Sareen and Dutt 2018: 2).

Most of the respondents (92.6%) showed insufficient knowledge that the practice number for the clinician is required on the form. The request form should be completed in full with the details of the requesting practitioner including the practice number of the registering body (SANC) to authenticate the request and so that the laboratory can process the specimens efficiently. This is also to ensure that the laboratory can contact the healthcare worker if the need arises (South Africa, Department of Health 2017b: 61).

A significant 98.8% of the respondents agreed that the specimen containers should be clearly labeled. According to South African Department of Health (2018: 5), the request form identifiers must match the specimen and healthcare record identifiers. Tóth *et al.* (2020: 9) proved that 0.8% of specimens were rejected due to labeling errors and recommended that specimens should be accurately and legibly labeled at each step of the process. Nurses requesting the test should be responsible for ensuring that the requested tests are clinically justified to prevent testing not being repeated unnecessarily so that test results can be acted upon and patient safety is not compromised (South Africa, Department of Health 2017b: 6).

- **Process element of quality**

The process element investigates the process in which the specimen collection procedures are performed. The researcher considered the process to investigate the practices of nurses in the collection of clinical specimens by observing the procedure

of specimen collection that might result in specimens being processed or rejected by the laboratory. The specimen collection and handling in this study closely examined the practices of nurses. The use of standards prescribed by the Department of Health on laboratory practices for this dimension is important. The researcher found that 8.0% (n=27) of nurses especially the less experienced nurses did not know about the PHC laboratory handbook which serves as the day to day guide for the collection of different specimens. That in return resulted in errors being committed when collecting specimens. The use of correct clinical guidelines and knowledge of contributory factors to pre-analytic errors can reduce specimen rejection (Arul, Pushparaj and Masilaman 2018: 237).

The study also found out that 12.5% (n=42) of nurses were not sure of the different specimen tubes and how to follow the correct order of draw when collecting blood specimen to prevent haemolysis error. The pre-analytical errors result in specimens being rejected by the laboratory thus delaying patient care. Some of the nurses were not following the precautionary measures for infection prevention and control such as wearing gloves to prevent cross-infection when handling the specimens. The nurse in diagnostics are required to wear personal protective clothing due to challenges in a hospital environment when handling infectious samples for diagnostics to prevent cross infection (Loibner *et. al* 2019: 1). The availability of all the resources alone cannot guarantee quality results if the correct processes are not applied. The effective process of specimen collection is achieved through paying attention to operational procedures and standards (Dakappagari *et al.* 2017: 644). A similar study by Bölenius (2014: 8) recommended that, for an accurate specimen collection process to take place, there was a need for quality monitoring programmes to be developed and implemented in PHC clinics.

5.3.3 Specimen collection and handling

The research results showed that respondents displayed an overall 73% knowledge in the specimen collection and handling section. Eighty-nine per cent of the

respondents had sufficient knowledge that colour coding of specimen tubes is important especially when taking blood specimens. Nurses need to know the colour codes of blood tubes because the colours differentiate the types of blood specimens that should be taken in a particular tube, and it is essential to minimize the effects of platelet clumping (Cadman 2014: 42).

The study results revealed that the respondents (81%) were aware of the importance of the volume of the specimen in the container. The specimen volume determines whether the specimen will be suitable for analysis or not. The incorrect specimen volume particularly the insufficient volume has been reported to amount to at least 40% of rejection errors (Wadhwa 2020: 354). Most tests require a minimum volume of 1 ml and had to be collected in appropriate sample collection tubes (Rooper *et al.* 2017: 2). In the case of children, a minimum of at least 250µl from the pricked site is sufficient and a minimum of 1ml of venipuncture blood. Sputum specimens with sub-optimal volume (less than 5ml) will not be processed as this may produce a false-positive result (South Africa, Department of Health and National Health Laboratory Services 2016: 43).

The majority (64.9%) of respondents had sufficient knowledge on the choice of colour coded blood tube and followed the correct order of draw when collecting blood. The techniques used by clinicians to collect the specimens are often neglected but they have a major impact on the specimen results (Crous and Armstrong 2016: 339). Thimesch (2018: 09) in support stated that it is also equally important to ensure that the correct order of draw is according to the list when collecting multiple blood specimens. Test tubes have anticoagulants and preservatives in them therefore there should be no cross- contamination.

The results showed that majority (60.7%) of the respondents indicated that blood tubes containing additives should be mixed gently by inverting tubes at least 8-10 times for proper uniform mixing of the anticoagulant with patient's blood. The vigorous mixing of the blood specimen should be avoided as it causes haemolysis

and compromise the analysis, resulting in the specimen being rejected (Atef and Faraj 2017: 10).

5.3.4 Handling Results

The study findings revealed that most respondents (98.2%) had agreed that a nurse should be allocated to sort and action results. The facility manager must designate a competent professional nurse to review the printed laboratory results. The nurse should be able to interpret and action abnormal results. The results should be updated on the PHC Facility Specimen Register (N4) (South Africa, Department of Health and National Health Laboratory Services 2016: 82).

The results of the study showed that 85.7% of the respondents agreed that Gene-Expert (tuberculosis test) results should be available within 24hrs, according to South Africa, Department of Health and National Health Laboratory Services. (2016: 34) sputum results for the Gene-Expert test. The sputum results should be entered on the N4 register as well as the TB case identification register for monitoring of the turn-around time which is an important measure of quality and should be recorded on the patient's file.

The results of the study also showed that 60.7% of respondents disagreed that specimens should be repeated at any time when results are not available. Foong *et al.* (2019: 3) states that to avoid repeating specimens unnecessarily, there are several mechanisms for health facilities to access laboratory results including receiving printed laboratory copies and electronic versions are printed automatically at the facility. If the results are misplaced or not received within 24hrs before repeating the specimen, results can be accessed through the NHLS web view portal. 98.2% of the respondents telephonically traced the patient's results using the bar code sticker by directly communicating with the local laboratory.

The study results showed that 96.5% of respondents agreed that specimen sticker information is important when tracing the results. Tests should not be repeated because results are not available unless the laboratory confirms that the specimen was not received by the laboratory for example, lost in transit or rejected for a specific reason such as insufficient specimen. Quick turnaround time assists the nurses to make timely decisions concerning patient diagnosis (Low *et al.* 2020: 35-38). It is the primary duty of the nurses to ensure that tests which are requested are clinically justified, tests are not repeated unnecessarily, test results are acted upon and patient safety is not compromised (South Africa, Department of Health 2017b: 6).

Specimen rejection leads to inconvenience and discomfort of repeat collection and leads to delayed reporting of test results. Hence, monitoring of acceptability of specimens is an important quality assurance measure for clinical laboratories (Wadhwa 2020: 354). Turnaround time is one of the most important measures when judging the efficiency of any laboratory care system (Mwogi *et al.* 2020: 1). Turnaround time is a proven benchmark of efficient laboratory service and yet often overlooked by most of the laboratories (Bhattarai and Manandhar 2018: 29).

- **Outcome element**

The quality of health is achieved when the set standards meets the expectation and results in client satisfaction. The outcome element is an extension of structure and process elements whereby the desired results of healthcare are achieved. The researcher considered that the availability of specimen collection resources and application of correct procedures that yield good outcomes for patients. The desired outcomes among others are correct results generated by the technicians and timorously available to clinicians. This leads to correct patient diagnosis, prompt treatment and management (Mwogi *et al.* 2020: 11).

To shorten the turn-around time, validated results shall be printed in the laboratory and delivered to the healthcare facility via messengers or couriers. Results can also

be made available electronically via Trak Care web view, short message service printers or email. Maintenance of confidentiality of patient information is critical. Nurses must use laboratory information to make appropriate medical decisions. The researcher also considered the outcome of collected specimens by observing the process of how results of specimens were handled. Monitoring of quality performance on specimen collection at PHC level will be achieved by intensifying Ideal Clinic Realization program. Evidence- based measures are required to boost staff knowledge on pre-analytical errors through standardised monitoring and evaluation (Makhumula-Nkhoma, Whittaker and McSherry 2015: 370).

5.4 Section C: Practices

The data was gathered from a checklist. The practices include identification and collection; packaging and storage; courier and management of results.

5.4.1 Identification and collection

The study findings showed that the nurses displayed knowledge in identification and collection of specimens; specimens were clearly labeled; each laboratory request form was correctly completed; the correct specimen collection tubes/jars was used; hands were washed with soap and water and sprayed with alcohol spray; personal protective clothing such as gloves and apron are worn; order of draw was followed correctly when collecting multiple specimens; the procedure was explained thoroughly to the patient; specimens were packaged into the provided packaging plastic and the specimen was recorded on the specimen register (N4). 100% of respondents identified patients correctly. Atef and Faraj (2020: 3) agree by stating that patients should be actively involved in the identification process and shall be educated on the importance of correct patient identification if he/she is conscious and oriented. The specimen collector must ensure that the blood specimen is drawn from the right patients. The two main identifiers shall be the patient's full name and registered number. Misidentification of patients is an avoidable error.

73.9% of the respondents labeled the specimens correctly. It is imperative that the specimens are accurately labeled (Thimesch 2018: 43). The sample labeling

requirements included the patient's full name, medical record number or date of birth and initials of the person who drew the blood. If the sample did not contain the mandatory information, it was rejected (Forest *et al.* 2017: 106).

In this study, 78.3% of respondents filled the requisition form correctly. Nurses should be aware that the test requisition is the communication between the clinician and the laboratory technicians therefore correct patient information on the request form is important as it impacts on quality of health provided (Jegede *et al.* 2016: 11). 100% of respondents used correct tubes/jars to collect different specimens. Correct specimen collection tubes/jars must be selected according to the test requested and a laboratory requirement (Atef and Faraj 2020: 7).

The study findings showed that only 57% of respondents washed their hands before and after specimen collection and 65% of the respondents wore the personal protective clothing. It is also important that infection prevention and control practices are always observed before and after touching the patient, such as hand washing, wearing personal protective gear such as gloves and aprons. Wearing of personal protective clothing prevents cross-infection and occupational injuries when collecting the specimens (Thimesch 2018: 62).

In this study 56.5% of the respondents followed the correct order of draw when collecting multiple blood specimens. The correct order of draw should be followed when collecting multiple specimens to avoid contaminating other tubes with 87% of respondents explained the procedure thoroughly to the patient before collecting the specimen. The specimens were packaged into the provided plastic packaging by 100% of respondents and 100% of respondents recorded the specimens on the specimen register (N4).

5.4.2 Packaging and Storage

The results of the study revealed that in 73.9% of clinic samples were kept away from direct sunlight. There was at least one functional wall-mounted thermometer in the area where laboratory specimens were stored for courier collection and the temperature of the storage area for laboratory specimens was recorded daily. There was a refrigerator dedicated for specimens and where the room temperature exceeds 25°C, the samples are stored in the refrigerator (at +- 5°C); and length of storage did not exceed 24 hours. According to South Africa, Department of Health and National Health Laboratory Services (2016: 69), samples are kept away from direct sunlight and there is at least one functional wall-mounted thermometer in the area for lab specimens stored for a courier collection.

The temperature of the storage area for lab specimens is recorded daily. Where the room temperature exceeds 25°C, samples are stored in the refrigerator dedicated for specimens are at (+- 5°C). Length of storage should not exceed 24 hours, when stored at room temperature (+- 20-25°C) All samples should be processed promptly after collection and the nursing staff is entrusted with the responsibility of transport of specimen at the desired temperature (Sareen and Dutt 2018: 3). The study results showed that 26.1% (n=3) of the clinics were not monitoring the temperature of the rooms where specimens were kept and that 26.1% (n=3) of clinics did not have room thermometers. The specimens should be collected at least twice daily by a courier to give an allowance of specimens taken later in the day to also be transported on the same day. This will minimise rejection errors associated with storage. In case there are delays in transportation, the specimens should be kept at 2-8°C (Kiros *et al.* 2020: 849). Mrazek *et al.* (2020: 6) also stated that to ensure that specimen analysis stability is maintained, specimens should be collected in the morning and time of collection should always be documented on the request form.

The reasons associated with packaging and storage for specimens to be rejected by the laboratory included specimens not being labeled or improperly labeled and unsealed specimens resulting in contamination. Specimens received in leaking, cracked or broken containers are not appropriate for a particular test are also

rejected (South Africa, Department of Health and National Health Laboratory Services 2016: 66). It is essential to store specimens in temperatures between 4°C-8°C when delayed transportation of more than 12 hours is anticipated (Bezuidenhout *et al.* 2016: 454).

5.4.3 Courier and management of results

The results of the study revealed that 100% of clinics stored their specimens at room temperature before transit, and it was found that the courier personnel signed the specimen register in 87% of the clinics. The study also revealed that only 27% of clinics recorded their results on the specimen register (N4) and 13% of clinics recorded and monitored the turnaround time of specimens on the register. The turnaround time that is not recorded and monitored makes it difficult to measure the quality of care rendered and the specimens cannot be traced successfully (Saathoff *et al.* 2018: 134) The designated staff in each facility should ensure that the number of specimen packages from the specimen collection box/fridge/cooler box corresponds with the number of entries in the facility specimen register (Mwogi *et al.* 2020: 6). Recording of the results ensures that turnaround time is monitored, as Bhatt, Shrestha and Risal (2019: 19) found that specimen registration in laboratory delayed 26.9% of specimens from being reported on time.

The study found that the courier personnel were signing the register in 87% of the clinics. The courier personnel should sign the specimen register to ensure that all the specimens were taken and be able to trace any lost specimens. The vehicle should be suitable for specimen transportation to avoid specimen quality being compromised resulting in rejection. The study also found that 74.3% of the clinics were not recording the specimen results on the register, the consequence of which was poor result tracing and unnecessary repetition of the specimen collection. The results should be recorded in the specimen register and turnaround time to be recorded and monitored on the register (South Africa, Department of Health and National Health Laboratory Services 2016: 77).

5.5 Section D: Specimen Checklist

The checklist comprised of facility specimen collection consumables and materials.

5.5.1 Facility specimen collection consumables and materials

This section discusses the results of the study on the availability of facility specimen collection consumables; specimen collection material; PAP smear collection material; EAD collection materials and displayed results on the availability of specimen collection equipment checklist for visit one and visit two of sampled clinics. In this section, the researcher evaluated and described all the equipment, materials and consumables needed for quality specimen collection as laid down in the PHC laboratory handbook. The unavailability of some of the specimen collection consumables has an impact on the study in the sense that, the practices of nurses in the collection of specimens may be altered or compromised for example, the use of incorrect tubes resulting in specimens being rejected due to unsuitability for analysis in the laboratory.

The visits by the researcher were conducted on two separate occasions so as to compare different times of the month, whether the unavailable items were due to the laboratory not providing the clinics or the clinics were not ordering on time. The study findings has shown that there is a significant relationship between the three elements of Donabedian's theory of quality, that when there is insufficient equipment, staff education (structure) there will be incorrect execution of procedures (process) leading to poor health outcomes like mortality and delayed patient management (outcome). The nurses' role is to ensure that all specimen collection consumables are available by ordering them using an N3 form and checking for quantities daily as well as for expiration dates (Gaskin and Yahaya 2019: 75). The insufficient knowledge of the N3 ordering form results in poor ordering of consumables.

The study results revealed that on the first visit, 100% of clinics had the following consumables available: Haemoglobinometer for checking blood haemoglobin; blood glucometer for measuring blood glucose; blood lancets for pricking patients and children when collecting blood drops for dried blood spots, blood glucose strips for manual measurement of blood glucose; urine dipsticks for testing urine specimen; urine specimen jar or flask for collection of urine and sputum specimens. The availability of sputum specimen jars ensures the early diagnosis of TB, pneumonia and lung diseases; and that treatment is initiated effectively before complications arise (Myatt 2017: 42).

The rapid HIV test for HIV testing was also available in 100% of the clinics; as well as the Rh 'D' (Rhesus factor) test which is used to test the Rhesus factor in pregnant women; brushes for cervical smears used for cervical cancer screening. However, 73.9% clinics had malaria rapid test (malaria risk areas) on the first visit and 82.6% improvement was noted on the second visit, this could mean that the clinics were ordering test kits using the N3 form. Some facilities were not allocated Malaria test kits due to their location which is not a malaria-risk area. The unavailability of malaria equipment in certain areas that are not indicated as high-risk areas may result in missed opportunities to diagnose malaria which is common in sub-Saharan region (Makanjuola and Taylor-Robinson 2020: 3). Shittu-Koiki 2018: S137) stated that malaria is rated among the deadliest diseases in African countries.

The findings on the availability of specimen collection material showed that, the material included vacutainer tube: blue top (Sodium Citrate); vacutainer tube: red or yellow top (SST); vacutainer tube: grey top (Sodium Fluoride); vacutainer tube: white top (PPT); vacutainer tube: purple top (EDTA); microtainer tube: purple top (EDTA-Paeds; Microtainer tube: yellow top (SST-Paeds); venipuncture needles (green or black); specimen plastic bags; tourniquet; vacutainer tube: blue top (Sodium Citrate); vacutainer tube: red or yellow top (SST); vacutainer tube: grey top (Sodium Fluoride); vacutainer tube: white top (PPT); vacutainer tube: purple top (EDTA); Microtainer tube: purple top (EDTA- Paeds); microtainer tube: yellow top (SST-

Paeds); venipuncture needles (green or black); specimen plastic bags and tourniquet (Thimesch 2018: 56).

The results of the study also revealed that 100% of clinics had the red or yellow top (SST) which is used to collect blood for hypertension monitoring; white top (PPT) vacutainer tube which is used to collect blood for viral load monitoring; purple top (EDTA) is used to collect haematology; venipuncture needles (green or black) and specimen plastic bags because these items are used frequently. The availability of these tubes ensures proper monitoring of HIV and non-communicable diseases progression for patients. The research results revealed that 73.9% of clinics were having vacutainer tube: blue top on the first visit as well as on the second visit. The tube is only used to collect blood for INR (International Normalized Ratio), and the specimen is collected by the visiting doctor and the tube is rarely used. The study also revealed that 91.3% of clinics had a vacutainer tube: grey top (Sodium Fluoride) which is used for blood glucose monitoring (Thimesch 2018: 56).

87% of clinics had microtainer tube: purple top (EDTA- Paeds), which is used for the collection of blood from babies under the age of five years; microtainer tube: yellow top (SST-Paeds); 73.9% of clinics had tourniquet which is used to create ligation of the vein when collecting blood specimen. The unavailability of the tourniquet poses a risk for nurses using non prescribed material like rubber gloves; this in turn compromises the quality of the specimen rendering it unsuitable for analysis due to haemolysis. The incorrect and prolonged application of the tourniquet could be one of the causes of haemolysis (Heireman *et al.* 2017: 1317). The researcher on both visits found that 87% of clinics had micro trainer tube: purple top (EDTA-Paeds) and 73.9% of clinics had the microtainer tube: yellow top (SST-Paeds) which is used for the collection of blood from babies. The study also noted that some specimen collection materials were unavailable for two consecutive visits to the clinics, which are yellow vacutainer tubes for paediatrics (30.4% on visit 1 and 26.1% on visit 2); purple vacutainer tubes for paediatrics (21.7% on visit 1 and 13% on visit 2), vacutainer: blue top (26.1%), tourniquet as well as malaria kit. The availability of the

paediatric consumables depends on the doctors as most of the tests are requested by the doctor and specimens collected by nurses (Duddy and Wong 2018: 3).

The results of the study revealed that 100% of clinics had liquid-based cytology vials as well as a combi–brush; this material is used to collect cervical cancer smears. The availability of these materials ensures that the cervical cancer screening programs are not compromised; patients will be diagnosed early, and cervical cancer treatment will be initiated early before complications (Getachew *et al.* 2019: 8). The study conducted by Fontham *et al.* (2020: 344) indicates that there is evidence of the benefit of cervical screening done at the early age of about 25 years to exclude abnormalities. The results of the study revealed that 100% of the clinics had dried blood spot Polymerase CR Kit or EDTA microtainer tubes which are used to collect blood specimen for HIV testing for babies. The significance of HIV testing for babies is that early identification of newly infected babies permits the timely initiation of anti-retro viral therapy to reduce transmission rates and improve health outcomes (Tsai *et al.* 2017: 1250).

5.6 Gaps related to the knowledge and practices regarding the collection of clinical specimens.

The study results showed the four main areas of specimen collection which are: preparation and identification; collection and handling; courier and results handling as well as the availability of specimen collection material. From the researcher's findings, experience plays an important role in increasing the level of competency. The findings of the study revealed that 8% of nurses undertaking community service were inexperienced in PHC clinics and had insufficient knowledge of the basic principles of specimen collection. These nurses undertaking community service (8%) were unsure about most of the principles of the specimen collection. This lack of knowledge in return compromises the service as they are qualified professional nurses but expected to work under supervision of qualified nurses at the clinic (Yahya and Nasir 2020: 36).

The nurses (7.1%) who were uncertain as to which form was used when requesting the laboratory test for different specimens, were part of the 47% nurses undertaking community service. Some lacked knowledge on which group of tests can be requested by the nurse at the clinic level. Some nurses (34.6%) who were enrolled nurses and professional nurses undertaking community service, were lacking the knowledge of the correct order of draw to be followed when collecting multiple specimens, which is a major cause of clotted specimens (Sheferaw, Yismaw and Getachew 2018: 3). Slaven and Peters (2019: 2) in their study concluded that there is a great need for continuing education for nurses to improve their skills and practices.

The study also revealed that when it came to practices, 73.88% of nurses were applying correct practices like completing the form correctly; packaging and storing correctly. However, some incorrect practices were observed by the researcher as not applying infection prevention and control practices by not wearing aprons and gloves. The correct order of draw was also not followed by 8.7 % of nurses when collecting multiple specimens. Incorrect practices by 78.3% of nurses were observed especially with results handling; the specimen results were not handled according to NHLS guideline (handbook) where they were not recording results on the N4 register and the turn-around time was not monitored accurately. Compliance with step-by-step guidelines is directly linked to improved clinical practice for nurses (Bölenius *et al.* 2014: 6). West *et al.* (2016: 17) recommended standardisation of the specimen collection process to minimise errors associated with collection and handling.

5.7. Recommendations

The following recommendations are made as result of the study findings:

5.7.1 Nursing practice

To provide continuous in-service education for nurses on specimen collection, monitoring and rejection of specimens; and to increase their knowledge in the

prevention of pre-analytical errors. Clinics within certain proximity should be clustered to allow for specimen collection at least twice a day by courier services.

5.7.2 Nursing education

There is a need for specimen collection procedures to be included as a module in the basic nursing curriculum. The student nurses should be allocated at least six months for their clinical training at the PHC clinics before they qualify, this exposure will assist them to become familiar with the PHC setting.

5.7.3 Future Research

This study forms the basis of future studies on the causes of specimen rejection in the PHC setting. Future studies can be conducted on in-depth reviews of factors affecting pre-analytic phase and measures to revise the methods used for gathering data on specimen collection.

5.8 Study limitations

The following limitations are acknowledged:

- **Access**

The study was dependent on having access to clinics, access was otherwise limited, due to the unique PHC settings; permission to access the sampled clinics had to be sought from three different levels namely: the regional hospitals, the district hospitals and community health centres at the local level.

- **Longitudinal effect**

The excessive amount of time that was required to complete the literature review as there was limited literature on specimen rejection at PHC level and to apply the methodology which had three sets of data collection tools, to gather data and interpret the results.

The scope and depth of discussions of results for the study was compromised at many levels compared to the work of experienced researchers. This was due to the

researcher's lack of experience of conducting research. In-depth training on research methods is recommended for the future research studies.

5.9 Conclusion

This chapter discussed the results that were presented in the previous chapter. The discussion of the results was based on the research which described the knowledge and practices of nurses in the collection of clinical specimens. The discussion was based on the main areas of the specimen collection: preparation and identification; requesting the test; specimen collection and handling and handling of results. Relevant literature was reviewed where necessary as it related to the findings. This section will then give a conclusion to the finding of the study.

The study showed that three phases of specimen collection which are: specimen and patient preparation (pre-analytical), collection and analysis (analytical) as well as results handling (post-analytical) can influence each other negatively or positively. The positive influence is when the availability of all specimen collection consumables, proper nurses training (structure) and use of correct procedures(process) enables nurses to collect the specimens correctly; therefore, accurate results will be produced (outcome). The negative influence is when the unavailability of some specimen collection consumables, inadequate training results in nurses using incorrect procedures to collect specimens; therefore, inaccurate results will be produced by the laboratory delaying patients' diagnosis and treatment.

Due to the burden of diseases like TB, HIV and non-communicable diseases in South Africa, there is an increasing need for specimen collection. In trying to meet the demands of the priority programs of the Department of Health, the nurses are collecting a lot of clinical specimens at clinic level. The findings of the study showed that nurses have necessary knowledge and equipment required for specimen collection and the process of specimen collection is correctly followed. According to the findings of the study, nurses displayed an average of 74.68% in knowledge of specimen collection. The study showed that nurses have sufficient knowledge

(74.76%) on preparation and patient identification and 77.32% on requesting the test.

Several efforts for increasing patient safety and positive outcomes were in place during collection and handling of specimens (73.88%). The knowledge on steps of handling the results are known (72.62%) but more improvement is needed on recording of results. 100% of clinics had the guidelines (PHC laboratory handbook) that serves as the guide in specimen collection and had enough equipment/consumables required for specimen collection. The several studies have shown that to facilitate clinical decision-making, clinical laboratory processes are important. The study conducted by Theel and Schuetz (2021: 12) found that the accuracy and relevance of the laboratory results, is dependent not on one but multiple factors.

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Appendix 1: Ethical approval

Institutional Research Ethics Committee
Research and Postgraduate Support Directorate
2nd Floor, Berwyn Court
Gate 1, Steve Biko Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2375
Email: [illegible]
http://www.dut.ac.za/research/ethics/editorial_research_ethics

www.dut.ac.za

25 March 2020

Mrs B T Mchethwa
P O Box 7143
Empangeni Rail
3910

Dear Mrs Mchethwa

An evaluation of the knowledge and practices of primary health care nurses in the collection of clinical specimens at the King Cetshwayo District, KwaZulu-Natal, South Africa.
Ethical Clearance number IREC 006/19

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

We are pleased to inform you that the data collection tool has been approved. Kindly ensure that participants used for the pilot study are not part of the main study.

In addition, the IREC acknowledges receipt of your gatekeeper permission letter.

Please note that FULL APPROVAL is granted to your research proposal. You may proceed with data collection.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC Standard Operating Procedures (SOP's).

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Yours Sincerely,

Professor J K Adam
Chairperson: IREC

Appendix 2: Gatekeeping permission

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

DIRECTORATE

Physical Address: Kwa Love Avenue Corner of Chronje & Crescent Empangeni
Postal Address: Private x20044 Empangeni Ref 3810
Tel: 035-787 0201 Fax: 035-7870644 Email: kla.wa.hlophe@kznhealth.gov.za
www.kznhealth.gov.za

Reference: Research Study

Date: 06 March 2020

To: Principal investigator: Mrs Bhekisiwe Thobekile Mthethwa
Student Number: **20100579**
Heath Science
Nursing
Durban University of Technology
Email: mthethwabhekisiwe@gmail.com

Supervisor: Dr A Razak
Co-Supervisor: Mrs P Pillay

CC: Dr. E Lugie: Manager Research Unit ZN DOH
CC: Dr. SNT Vilakazi: CEO Nselen CHC & Dr. BS Maclala: CEO Ngwelezana Hospital

RE: PERMISSION TO CONDUCT RESEARCH "AN EVALUATION OF THE KNOWLEDGE AND PRACTICES OF PRIMARY HEALTH CARE NURSES IN THE COLLECTION OF CLINICAL SPECIMENS AT THE KING CETSHWAYO DISTRICT, KWAZULU-NATAL, SOUTH AFRICA."

I have pleasure in informing you that permission has been granted to you by the King Cetshwayo District Director to conduct research on **"An evaluation of the knowledge and practices of primary health care nurses in the collection of clinical specimens at the King Cetshwayo District, KwaZulu-Natal, South Africa."**

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 approval of your study from the Provincial Health Research and Ethics Committee (PHREC) in the KZN Department of Health.
3) Please ensure this office is informed before you commence your research.
4) The District office/facility will not provide any resources for this research.
5) You will be expected to provide feedback on your findings to the District Office/Facility.
6) You are required to contact this office regarding dates for providing feedback when the research has been completed.

Sincerely,

Mrs. NE Hlophe
District Director:
King Cetshwayo District

Fighting Disease, Fighting Poverty, Giving Hope

Appendix 3: Letter of approval

KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Postal Address: Private Bag x 20021 Empangeni 3880
Physical Address: Thandoyise Road Empangeni 3880
Tel 035 9017273 Fax: 0865136873 Email address : tobias.gumede@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
MEDICAL SERVICES
SENIOR MANAGER : MEDICAL SERVICES

Enquiries: Dr RS Moeketsi
Date: 03.07.2020

To : Mrs B.T. Mtholhwa
P.O. Box 7785
Empangeni Rail
3910

Dear Sir / Madam

RE: APPROVAL TO CONDUCT RESEARCH STUDY AT NGWELEZANA TERTIARY HOSPITAL

Your request to conduct research study at Ngwelezana Tertiary Hospital refers,
Please be advised that permission to conduct research study is hereby granted under the following conditions:-

- Confidentiality of hospital information, including staff and patients or contact information must be kept confidential at all times. Patient records are **not** to be removed from the hospital premises nor you are not allowed to photocopy/ photograph them.
- You are to ensure that your data collection process will not interfere with the routine services of the hospital.
- You are to ensure that hospital resources are **not** used to manage your data collection, e.g. Hospital staff collating data, photocopying, telephone etc.
- Informed consent is to be obtained from participants in your study if applicable.
- Policies, guidelines and protocols of the Department of Health and Ngwelezana Hospital must be adhered to at all times.
- Professional attitude and behaviour whilst dealing with research participants must be exhibited.
- The Department of Health and hospital's staff will not be held responsible for any negative incidents and or consequences including injuries and illness that may be contracted on site.
- You are required to submit to this office a summary of study findings upon completion of your research.
- You are requested to make contact with **Dr RS Moeketsi, Senior Manager: Medical Services** at Ngwelezana Tertiary Hospital once you are ready to commence your study.

Regards,

Recommended/ ~~not recommended~~ by:

Dr RS Moeketsi
Senior Manager: Medical Services
Ngwelezana Tertiary Hospital
Date 6/7/2020

Approved/ ~~disapproved~~ by:

Mrs IJ Nene
Acting Chief Executive Officer
Ngwelezana Tertiary Hospital
Date 06.07.20

Appendix 4: Letter of information

LETTER OF INFORMATION

Dear Colleague

Greeting, thank you for agreeing to participate in the study. Please receive the letter of information concerning the study:

Title of the Research Study: An evaluation of the knowledge and practices of primary health care nurses in the collection of clinical specimens at the King Cetshwayo District, KwaZulu-Natal, South Africa.

Principal Investigator/s/researcher: Mrs BT Mthethwa (MTech: Nursing candidate)

Co-Investigator/s/supervisor/s: Dr A Razak, (PHD: Nursing) and Mrs P Pillay (M: Nursing)

Brief Introduction and Purpose of the Study: I will be conducting an evaluation of the knowledge and practices of nurses in the collection of clinical specimens at clinics in the King Cetshwayo district.

Outline of the Procedures: If you agree to participate in this study, the questionnaire will be hand delivered to you to respond on your most convenient time without interrupting your duties, observation during specimen collection will also be conducted.

Risks or Discomforts to the Participant: There is no risk or discomfort that will be inflicted to you.

Benefits: The study findings will be used to make recommendations on practices applied during specimen collection. This will benefit the facility by decreasing rejections and costs thus improving patient satisfaction.

Reason/s why the Participant May Be Withdrawn from the Study: You will be allowed to opt out from the study or withdraw at any time should you wish to do so.

Remuneration: You will not be expected to pay anything for taking part in the study, and also no payment will be given to you for taking part in the study.

Costs of the Study: You will not be expected to cover any costs towards the study.

Confidentiality: All the information will be kept in strict privacy. Your name will not be written on any of the data collection tools except on the consent form which will be kept in strict privacy and separate from the questionnaire. The information gathered will only be used for the purpose of this study.

Research-related Injury: No compensation, however the nature of the study does not pose any risk of injury to you.

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

Researcher: Mrs BT Mthethwa Tel no. 0829363567, Supervisor: Dr A Razak Durban University of Technology cell no. 0837867282 or the Institutional Research Ethics Administrator on 031 373 2375. Complaints can be reported to the Director: Research and Postgraduate Support, Prof C Napier on 031 373 2577 or carinn@dut.ac.za

Appendix 5: Consent

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, _____(Name Researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,
- 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 computerized 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, _____ (name of researcher) 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: Questionnaire

SURVEY QUESTIONNAIRE ON KNOWLEDGE IN COLLECTION OF CLINICAL SPECIMEN

Thank you for agreeing to participate in the study. Please answer questions as honestly as possible by [√] ticking the box most relevant to you.

SECTION A

Demographic Data

1. Age in years:

2. Nursing Category (Select ONE option only)

Enrolled Nurse	
Professional nurse –community service	
Professional Nurse	
PHC speciality	

3. Years of experience as a nurse:

4. Years of experience in a Primary Health Care clinic:

5. Hours of operation at the clinic in which you are currently working (Select ONE option only)

07h00-16h00	Five days a week	
07h00-16h00	Seven days a week	
07h00-19h00	Five days a week	
07h00-19h00	Seven days a week	
24 hours a day	Seven days a week	

SECTION B: KNOWLEDGE REGARDING COLLECTION OF CLINICAL SPECIMENS

1. Preparation and identification

Please select one of the options true/ false/ unsure for each of the following statements.

	True	False	Unsure
1.1. The Primary Health Care laboratory handbook should be available in all clinics.			
1.2. All equipment needed for specimen collection should be checked weekly.			
1.3. N1 form is used to order specimen collection equipment.			
1.4. Knowledge of the list of tests taken at clinic level is essential.			
1.5. Patient identification should be done before taking a specimen.			

2. Requesting the test

2.1. Which of the following groups of tests can a nurse request at the clinic in the absence of the doctor? (Select <u>ONE</u> option only)

Cerebrospinal fluid, Pus swab	CD4 count, Viral load, Gene Expert	ESR, INR

2.2. Which of the following forms is used to request specimens in the clinic? (Select <u>ONE</u> option only)

N1	N2	N3

Please select one of the options true/ false/ unsure for each of the following statements

	True	False	Unsure
2.3. It is important to fill in the entire patient's information when requesting a test.			
2.4. Clinicians' practice/practice number is not required on the request form.			
2.5. Specimen containers should be clearly labelled.			

3. Specimen collection and handling

Please select one of the options true/ false/ unsure for each of the following statements

	True	False	Unsure
3.1.Colour coding for specimen tubes is important:			
3.2.Volume of the specimen in the container is not important			

3.3. Which ONE of the following colour coded blood tube list follows the correct order of draw when collecting blood?

Purple, yellow, blue, grey	Purple, blue, yellow, grey	Blue, purple, yellow, grey	Yellow, blue, grey, purple

3.4 Which ONE of the following procedures should be followed after collecting blood specimens in a tube?

Mix vigorously at least 8 times	Mix gently 8-10 times	Invert at least once	Shake to ensure adequate mixing

4. Handling of results

Please select one of the options true/ false/ unsure for each of the following statements

	True	False	Unsure
4.1. A nurse should be allocated to sort and action results.			
4.2. Gene expert (Tuberculosis test) results should be available within 24hrs.			
4.3. A Specimen should be repeated at any time when results are not available.			
4.4. Results can be traced by calling the Laboratory:			
4.5. Specimen sticker information is important when tracing the results.			

Appendix 7: Checklist

CHECKLIST: SPECIMEN COLLECTION EQUIPMENT

Check for the availability and expiry of specimen collection/storage consumables. Tick the appropriate answer: Yes for availability and No for non-availability or not applicable.

ITEM	Available		
	Yes	No	Not applicable
1. **Facility Specimen collection consumables**			
1.1. **Haemoglobinometer**			
1.2. **Blood glucometer**			
1.3. **Blood Lancets**			
1.4. **Blood glucose strips**			
1.5. **Urine dipsticks**			
1.6. **Urine specimen jar OR flask**			
1.7. **Malaria rapid test (malaria risk areas)**			
1.8. **Rapid HIV test**			
1.9. **Rh 'D' (Rhesus factor) test**			
1.10. **Brushes for cervical smears**			
2. **Specimen collection material**			
2.1. **Vacutainer tube: Blue Top (Sodium Citrate)**			
2.2. **Vacutainer tube: Red OR Yellow Top (SST)**			
2.3. **Vacutainer tube: Grey Top (Sodium Fluoride)**			
2.4. **Vacutainer tube: White Top (PPT)**			
2.5. **Vacutainer tube: Purple Top (EDTA)**			
2.6. **Microtainer tube: Purple Top (EDTA Paeds)**			
2.7. **Microtainer tube: Yellow Top (SST-Paeds)**			
2.8. **Venipuncture needles (Green OR Black)**			
2.9. **Specimen Plastic Bags**			
2.10. **Tourniquet**			
3. **Pap smear collection materials**			
3.1. **Liquid - based Cytology (LBC) vials (NA if facility uses traditional pap smear method)**			
3.2. **Combi - brush (NA if facility uses traditional pap smear method)**			
4. **Early Infant diagnosis (EID) collection material**			
4.1. **DBS PCR Kit OR EDTA Microtainer tube**			

5. **NHLS stationery**			
5.1. **N1 - PHC Request Form**			
5.2. **N2 - Cytology Request Form**			
5.3. **N3 - PHC Order Book Material for specimen collection**			
5.4. **N4 - PHC Facility Specimen Register**			
5.5. **PHC laboratory handbook**			
6. **SMS printer (N/A) for facilities with Track care Laboratory system.**			

Appendix 9

PAMPHLET FOR RECRUITING PARTICIPANTS FOR A RESEARCH STUDY AT THE CLINIC

TOPIC: EVALUATION OF KNOWLEDGE AND PRACTICES OF NURSES IN COLLECTION OF CLINICAL SPECIMEN AT KING CETSHWAYO DISTRICT.

Objectives of the study

-To identify the available specimen taking and storage resources as per PHC laboratory guideline.

-To observe the practices applied by nurses before, during and after taking specimens.

-To determine the nurses' knowledge on basic principles of taking different specimens.

Inclusion criteria

-Professional nurses who are working at the fixed primary health care clinics.

-Enrolled nurses who are working at the fixed primary health care clinics**.**

Exclusion criteria

-All other professional nurses, enrolled nurses and nursing assistants who are working in the hospitals, community health centre and mobile services.

-All professional nurses who are operational managers working in the hospitals, community health centre, fixed clinics and mobile services.

Contact person

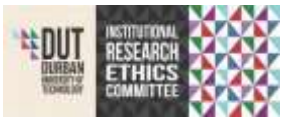
Researcher: Bhekisiwe Thobekile Mthethwa

0829363567

035 7951124

Email: mthethwabhekisiwe@gmail.com

Appendix 10



PO Box 7785

Empangeni Rail

3910

Mrs Hlophe

District Director

King Cetshwayo Health District

2 Lood Avenue

Empangeni Rail

3910

06 MARCH 2019

Dear Sir/Madam

REQUEST FOR PERMISSION TO CONDUCT RESEARCH

I am a registered Master of Health Sciences: Nursing student in the Department of Nursing at the Durban University of Technology.

The proposed topic of my research is: *Evaluation of knowledge and practices of nurses in collection of clinical specimens at King Cetshwayo District.*

The aim of the study is to evaluate knowledge and practices of nurses in collection of clinical specimens in Primary Health Care clinics that may lead to the rejection of the specimens.

The objectives of the study are:

a) To identify the available specimen taking and storage resources according to the guidelines;
b) To observe the practices applied by nurses before, during and after taking specimen;
c) To determine the knowledge of nurses about taking different clinical specimens.

I am hereby seeking your consent to collect data from professional and enrolled nurses in the Primary Health Care clinics and specimen registers. To assist you in reaching a decision, I have attached to this letter:

(a) A copy of an ethical clearance certificate issued by the university;

(b) A permission letter from the provincial office.

Should you require any further information, please do not hesitate to contact me or my supervisor. Our contact details are as follows:

Tel: 0829363567 mthethwabhekisiwe@gmail.com, Dr A Razak (Supervisor) Tel: 0837867282 razaka@dut.ac.za.

Upon completion of the study, I undertake to provide you with a bound copy of the dissertation.

Your permission to conduct this study will be greatly appreciated.

Sincerely yours

……..

Mrs Bhekisiwe Thobekile Mthethwa

Appendix 11

PO Box 7785

Empangeni Rail

3910

The Operational Manager

UMhlathuze and uMfolozi Clinics

Private Bag X 20021

Empangeni

3880.

06 March 2019

Dear Sir/Madam

REQUEST FOR PERMISSION TO CONDUCT RESEARCH

I am a registered Master of Health Sciences: Nursing student in the Department of Nursing at the Durban University of Technology.

The proposed topic of my research is: Evaluation of knowledge and practices of nurses in collection of clinical specimens at King Cetshwayo District.

The aim of the study is to evaluate knowledge and practices of nurses in collection of clinical specimens in Primary Health Care clinics that may lead to the rejection of the specimens.

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Tel: 0829363567 mthethwabhekisiwe@gmail.com, Dr A Razak (supervisor) Tel: 0837867282 razaka@dut.ac.za

Upon completion of the study, I undertake to provide you with a bound copy of the dissertation.

Your permission to conduct this study will be greatly appreciated.

Sincerely yours

……

Mrs Bhekisiwe Thobekile Mthethwa