An investigation of rejection rates, sources thereof and methods to reduce specimen rejection

By

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DECLARATION

I, Afsana Ballim, do declare that this dissertation is representative of my own work in both conception and execution (except where acknowledgements indicate to the contrary).

_____ _____ 13/06/2024

Afsana Ballim Date

Approved for final submission

__ _____ 14/06/2024

Supervisor: Dr JN Mbatha Date

DEDICATION

I would like to dedicate this dissertation to the person that kept me motivated when it all seemed too difficult and provided me with the support that I didn't know I needed, my husband. Thank you for always believing in me.

I would also like to dedicate this dissertation to my parents. Thank you for the love and education that you provided to me. Thank you for lifting me up this far. My achievements are yours to share.

"Knowledge is power. Information is liberating. Education is the premise of progress, in every society, in every family." – Kofi Annan

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ABSTRACT

Background

Specimen rejection occurs when specimens are sent to a medical diagnostic laboratory and are deemed unsuitable for analysis based on specimen acceptability criteria. Patient care may be hindered due to rejections. Specimen rejections impact negatively on patients, healthcare workers and the diagnostic laboratory. The aim of this study was to investigate specimen rejection rates, the contributing factors, and methods to reduce the number of rejected specimens, thereby improving healthcare for the patient as well as improving the financial and quality standing of the laboratory.

Materials and methods

Rejection statistics were obtained for King Dinuzulu Hospital Complex (KDL) and RK Khan Hospital (RKK) for a period of six months. An investigation of the rejection rates and common causes for rejection was conducted. The information gathered from the rejection statistics was used to create training material for training workshops. Pre-training and post-training questionnaires were completed to determine the effectiveness of the training. Rejection statistics were re-collected for two months post the training workshop sessions to evaluate the rejection rates for improvement.

Results

The initial rejection rates indicated that KDL and RKK exceeded the allowable limit of rejections (National Health Laboratory Service allowable limit < 3%). The primary reason for specimen rejections was identified as errors that occur in the pre-analytical phase, with haemolysis emerging as the predominant contributing factor. Training workshops were conducted, although the improvement in assessment score for the workshop was 49.6% ($p < 0.001$), the rejection statistics collected post-training workshop showed an insignificant change in overall rejection rates at KDL and RKK (p-value = 0.139 and 0.242 respectively).

Conclusion

Specimen rejection is a growing problem that requires mitigation. Structured training has shown to improve pre-analytical knowledge, however, it was noted that the interventions taken by offering training workshops did not reduce the rate of specimen rejections.

Keywords: Specimen rejection, Haemolysis, Training, Criteria

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LIST OF ACRONYMS

AARMS	Academic Affairs and Research Management System
CDW	Central Data Warehouse
EDTA	Ethylenediaminetetraacetic Acid
ESR	Erythrocyte Sedimentation Rate
FBC	Full Blood Count
GLP	Good Laboratory Practice
HIV	Human Immunodeficiency Virus
HPCSA	Health Professional Council of South Africa
INR	International Normalised Ratio
IREC	Institutional Research Ethics Committee
ISO	International Organization for Standardization
KDL	King Dinuzulu Hospital Complex
NHLS	National Health Laboratory Service
PCR	Polymerase Chain Reaction
RKK	RK Khan hospital
SANAS	South African National Accreditation System
SANC	South African Nursing Council

CHAPTER 1: INTRODUCTION

1.1 Chapter overview

This chapter provides an overview on specimen rejection in a medical laboratory. It discusses the causes of specimen rejection and the effects rejection of specimens can have on patient care. Furthermore, the study's purpose, aim and objectives are described. The background of the existing and growing issue related to specimen rejection is outlined, as well as the importance of laboratory testing and the negative link it has to patient care. The prevalence and the rationale of this study is also provided.

1.2 Background

Specimen rejection occurs when specimens submitted to a medical laboratory do not meet the acceptable criteria for testing (Lippi *et al.* 2019). Laboratory tests have unique requirements based on their method of analysis. Tests are rejected when these requirements are not met, with the purpose of avoiding analysis of poor-quality specimens. Thus, only good-quality specimens, those that meet the specific criteria, are processed. These requirements provide individuals with quality laboratory results. In a nutshell, specimen rejection guarantees that testing of biological specimens can be done with little to no interference from poor specimen quality. The quality of a laboratory result is directly proportional to the quality of the specimen received, provided that all internal quality procedures within the testing laboratory are adhered to.

Bayot, Brannan and Naidoo (2022) describe a medical laboratory as a facility in which professionals or qualified personnel perform diagnostic and monitoring tests on biological specimens. The function of a medical laboratory is to perform testing on specimens submitted by healthcare professionals. The intention is to provide reliable results to the patient as per the International Organization for Standardization (ISO15189:2012) requirements. Reliable results can be achieved by ensuring accuracy and precision. Individuals involved in testing procedures such as specimen collection and analysis are regarded as healthcare professionals. In South Africa

healthcare professionals are required to be registered with a relevant statutory body. It is mandatory that practicing clinicians and medical technologists be registered with the Health Professions Council of South Africa (HPCSA), while it is compulsory for nurses to be registered with the South African Nursing Council (SANC).

Biochemical imbalances occur in most illnesses and are attributable to the body's effort to maintain homeostasis (Asmelash, Worede and Teshome 2020). Diagnostic laboratories analyse bodily fluids such as, but not limited to, blood, urine and cerebrospinal fluid. Quick access to laboratory results can lead to timeous initiation of treatment which is important in minimising patient discomfort. Stoppler (2021) describes a patient as a person under healthcare. According to Vanker and Faull (2017), a clinician assesses the patient's illness or diseased state by using specialised knowledge to evaluate the patient's signs and symptoms so as to provide a preliminary diagnosis. In order to confirm or reject the suggested diagnosis, the clinician may request specific biochemical tests that can be assessed within a medical diagnostic laboratory. The laboratory results assist in guiding the clinician with the appropriate or necessary course of treatment (Vanker and Faull 2017). Laboratory tests are also used to monitor treatment and its effectiveness.

1.2.1 Laboratory specimen rejection based on their method of analysis

In order to achieve reliable results, there are many contributing facets such as specimen collection and quality, instrument maintenance, and quality control procedures that need to be followed. In this study, the focus was on specimen suitability as this poses risks associated with issuing poor quality results if not followed. Laboratory personnel are trained to identify and reject unsuitable specimens. Musabaike *et al.* (2018) state that risks associated with issuing false results include results that can be masked, elevated or decreased by interference factors, therefore, not providing a true reflection of one's biological state. Interference factors are attributable to decreased quality of specimen collection techniques, transport, and storage (Musabaike *et al*. 2018).

Kitchen *et al.* (2021) state that all medical laboratories possess criteria for acceptance and rejection of biological specimens. These criteria comprised detailed descriptions

of specimens that are of good and poor quality and are based on collection procedures, transportation conditions and storage of specimens prior to being submitted to the laboratory for analysis. These factors can hinder the accuracy of results if not followed properly (Asmelash, Worede and Teshome 2020).

1.2.2 Prevalence

Patient care is vital not only within South Africa's healthcare system, but also globally. Tapper *et al.* (2017) noted in a study conducted within Jamaica that the most common cause for rejection was unlabelled specimens. Barbato *et al.* (2020) conducted their study in Brazil and found that haemolysed specimens can yield incorrect laboratory results. Ye *et al.* (2018), Dikmen, Pinar and Akbiyik (2015), and Wan Azman *et al.* (2019), conducted studies in China, Turkey and Malaysia, respectively, and identified the pre-examination phase as being the largest contributor of specimen rejections, with haemolysis being the leading cause. Other studies conducted by South African authors (Govender *et al.* 2016; Mazanderani, Moyo and Sherman 2017; Vanker and Faull 2017) discuss rejections and the related concerns for the patient health, but not many of the articles published in South Africa cover a wide range of tests. Magwai *et al.* (2020) noted that the largest contributor to specimen rejections in the pre-analytical phase was specimen insufficiency. Govender *et al.* (2016) conducted their study in Durban, KwaZulu-Natal, in relation to human immunodeficiency virus polymerase chain reaction (HIV -1 PCR) testing. Similarly, Mazanderani, Moyo and Sherman (2017) provide details of HIV-PCR rejections and the related complications with regards to missed early diagnosis of infants in South Africa.

1.3 Rationale of this study

The researcher noticed that specimen rejections were a rising trend in the laboratory where she worked. Specimen rejections are known to have a negative impact on patient diagnosis, treatment and financial loss for the testing laboratory. A discussion of the impact specimen rejections has on patients, healthcare workers and medical laboratories. The importance of this studies aim will be identified.

1.3.1 Why are patient specimens rejected?

Rejection occurs when specimens sent to medical diagnostic laboratories are deemed unsuitable for analysis based on existing rejection criteria (Kitchen *et al.* 2021; Asmelash, Worede and Teshome 2020). Laboratory guidelines for specimen collection are clear about the specimen requirements related to each test and are readily available to healthcare workers. Rejection occurs when the specimen type does not meet the acceptable criteria, for example, when a sputum specimen is submitted to the laboratory with a request for urine microscopy and culture. Alternatively, specimens can also be rejected if interference factors that can be deduced from the appearance of specimens such as haemolysis, clots or icterus, are noted.

1.3.2 Who is affected by specimen rejections?

Specimen rejections affect mainly three groups; healthcare workers i.e. clinicians and nurses, patients, and the diagnostic laboratory. The healthcare worker is affected by increased workload due to re-bleeding or additional specimen collection and having to offer explanations to the patients with regards to the extended waiting period for the results. The progress of patient care is sometimes hindered when specimens do not meet minimum laboratory criteria and are rejected. Kitchen *et al.* (2021) state that the criteria for rejection are created to prevent incorrect or inaccurate results from being generated. Incorrect or inaccurate results can lead to inefficient or unwarranted treatment offered to patients. Specimen rejection causes delays in the patient's attainment of results, thus leading to delayed treatment and prolonged discomfort (Musabaike *et al.* 2018). Specimen rejections lead to frustration to both the healthcare worker and the patient. This may also result in an unfavourable relationship between the healthcare worker and medical diagnostic laboratory.

The patient is affected by the need to provide an additional specimen which in turn results in added discomfort, a longer waiting period for treatment and possibly an extended hospital stay which can have financial and logistical implications. Hospitals in the public sector are mainly utilised by community members who are unemployed, low income earners, pensioners, or homeless. When blood specimens are collected

from outpatients, the patient is given an appointment at a future date for analysis of results and the adjustment of treatment plans; therefore, rejection of specimens may impact the patients financially as well as create an inconvenience for those who travel by means of public transport. For patients in critical conditions, biochemical imbalances could cause death or serious complications if not identified and acted upon without delay (Asmelash, Worede and Teshome 2020).

Kalaria, Ford and Gama (2022) indicate that diagnostic laboratories are affected financially when specimens are rejected and by the wastage of consumables used during specimen collection. Furthermore, there is wastage of reagents when specimens are processed before being identified as unsuitable. This can happen when specimens with potassium ethylenediaminetetraacetic acid (EDTA) contamination are processed. Potassium EDTA contamination is a result of not following the correct order of draw, thus resulting in additive contamination. Specimen quality may be negatively affected by contamination and cannot be detected macroscopically. Such contamination is detected chemically during analysis and thus not only affecting patients but also having financial implications for the laboratory.

Laboratories are required to monitor quality indicators to improve the quality management system and set goals to be achieved in order to ensure quality as per the International Organization for Standardization (2012). In the National Health Laboratory Services (NHLS) rejection rates are monitored routinely by assessing the percentage of specimens that were rejected when compared to the total number of specimens received by the laboratory for analysis. An allowable percentage of rejections is established by the laboratories. Bozdemir, Kurutkan and Terzi (2021) state that within the diagnostic laboratory, the chief issue faced is the financial loss and the impact that rejections have on the quality management system.

Rejection of biological specimens have both benefits and risks to the patient. Rejection of patient biological specimens benefit the patient (Barbato *et al*. 2020) by reducing the risk of:

- Falsely high or low results due to analytical errors that occur when specimens are of poor quality;
- Poor or improper treatment; and
- Exposure to side effects of unnecessary or improper drug therapy.

On the other hand, rejection of patient biological specimens increases the risk (Musabaike *et al*. 2018) as follows:

- Delayed treatment;
- Discomfort due to prolonged illness;
- Discomfort with regards to additional specimen collection; and
- The patient remaining undiagnosed due to the lack of an additional or repeat specimen.

Rejection of specimens causes delays in treating the patient, overburdens health workers, and impacts negatively on laboratory analysed specimens, which contributes to the organisation's revenue. The aim of this study was therefore to investigate specimen rejection rates, the contributing factors and methods to reduce the number of rejected specimens, and, by doing so, attempting to improve healthcare for the patient as well as an improved financial and quality standing for the laboratory.

1.4 Objectives

The objectives of this study were to:

1. Determine the rejection rates by collecting data and statistics from different laboratories in the eThekwini business unit at the National Health Laboratory Services.
2. Assess the contributing factors that lead to specimen rejection.
3. Create awareness to stakeholders by presenting methods to reduce the number of rejected specimens established from the findings of this study via a workshop and publication.
4. Monitor rejection rates post workshop and publication to check effectiveness by assessing if the number of rejected specimens have reduced.

1.5 Outline of chapters

A review of literature related to this study is discussed in Chapter 2. Chapter 3 includes details of the methodology used to conduct this study and the statistical tests used in data analysis. In Chapter 4, the results obtained from the data that was collected are provided. Finally, Chapter 5 provides a discussion of results as well as concluding

statements and recommendations drawn from the study. The aim of this study was to use laboratory statistics to identify the most common reasons for laboratory specimen rejections. The rejection statistics were used to create a workshop that disseminated important information and factors extracted from the data that can be implemented by the healthcare workers involved in specimen collection, transportation and storage, in order to minimise rejections. The ultimate goal was to reduce laboratory rejections which may in turn assist with timeous and appropriate treatment for patients.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter presents the importance of diagnostic laboratory testing regarding diagnosis and treatment of patients in the health sector. An explanation is provided for the fundamental need of accurate patient laboratory results and the key role that specimen quality plays. In addition, this chapter outlines the diagnostic laboratory processes and the common reasons for rejected specimens.

2.2 Specimen rejection

Specimen rejections occur when human biological specimens are submitted to a medical diagnostic laboratory but fail to meet the laboratories criteria for suitability. The suitability or rejection criteria are specific for each test offered in a medical diagnostic laboratory (Lippi *et al.* 2019). When a test is rejected due to specimen unsuitability, pathology reports cannot be generated and therefore cannot be accessed by the requesting clinician. When results for specific diagnostic tests cannot be attained, clinicians are required to repeat the process of specimen collection in order to make a justified diagnosis and offer treatment (Musabaike *et al*. 2018).

2.3 Human biological specimens

Human biological specimens are any materials derived from the human body. Biological specimens can be submitted to a laboratory for investigation and testing (Bayot, Brannan and Naidoo 2022). Biological specimens provide key details about the body's functioning and the extent of homeostasis. The term 'homeostasis' refers to the self-regulating process by which biological systems maintain stability while adjusting to changing external conditions (Billman 2020). The human body strives to maintain a balance internally to maintain homeostasis. Any disturbance in the homeostasis can cause disease, illness and injury to the human body thus causing imbalances in vital chemicals, or damage to essential organs that have important roles (Palaparthi 2017). Results from testing can reveal the difference between normal

functioning of the body and malfunctioning. This can be achieved by measuring certain chemicals and anatomical particles present in the human body (Palaparthi 2017).

A comparison of the results is made to the known established reference intervals, which are regarded as expected levels in healthy individuals. Whyte and Kelly (2018) define a reference interval as the interval between and including two reference limits. These limits are values that are obtained from a sample of a reference population. The reference interval is derived from the distribution of results from what is interpreted as a normal or healthy population. If results are out of the specified reference intervals, therapeutic methods are used to assist in re-establishing homeostasis when the human body cannot manage to maintain it naturally (Märtson *et al.* 2020). A diagnostic laboratory assists clinicians with monitoring these imbalances. The laboratory measures vital chemicals and components in the body's fluids to make an informed diagnosis prior to commencement of treatment as well as with monitoring of treatment using analytical methods to note improvements or lack thereof, resulting in dose adjustments or alternative drug therapy (Märtson *et al.* 2020).

2.4 Automation related to diagnostic tests

Over the years, diagnostic methods of testing have developed to provide quick and accurate results with limited room for human error, mainly by replacing manual testing methods with automation (Lippi *et al.* 2019). Some examples of human induced error are pipetting technique errors or visual errors due to colour blindness. Chemical reactions are sensitive to reagent and specimen volume ratios and usually rely on colour changes to detect the presence of chemicals. Manual testing methods are known to be cumbersome whereas automation allows for a quick and manageable workload. Rapid pathology reports are now possible due to automation. As pointed out by Lippi and Da Rin (2019), automation has replaced most manual methods of detection, but there are still some laboratory disciplines that rely on human skills and expertise. These disciplines mostly use microscopy to suggest diagnoses (Bayot, Brannan and Naidoo 2022).

2.5 Diagnostic laboratories role in diagnosis

Diagnostic laboratories play a major role in assessing and confirming imbalances that cause illness in the human body (Bayot, Brannan and Naidoo 2022). Methods used to detect certain analytes within the laboratory can differ and have specific requirements to ascertain precise and reliable results. Most automated diagnostic analysers utilise chemical reactions to achieve results. Poor specimen quality can interfere with the chemical reactions and lead to poor quality results. Maintaining appropriate specimen requirements is imperative to minimise interference factors that may influence results adversely. Barbato *et al.* (2020) state that colorimetric interference factors in a specimen can lead to the generation of incorrect results.

Procedures and processes are necessary in a diagnostic laboratory to maintain specimen integrity and quality when handling patient specimens. For this reason the diagnostic process is usually separated into phases which help to maintain quality by introducing checks at different points. Unfortunately, the pre-analytical phase occurs mainly external to the diagnostic laboratory and the laboratory staff have limited access to perform checks on those outlined procedures. The procedural flow of specimens within a laboratory consists of three main phases (Bilello 2018):

- **Pre-analytical phase**

This phase comprises all procedures that occur prior to testing of patient specimens. This includes the patient preparation, specimen collection, labelling of specimen/s, request form, storage, transport, data capturing and specimen preparation for analysis.

- **Analytical phase**

The analytical phase refers to the specimen preparation, assessment of quality and testing of patient specimen/s. This phase comprised analysis of the patient specimen with the intention of providing a laboratory report.

- **Post-analytical phase**

This phase refers to the procedures related to checking of results and final reporting of results. After analysis of specimens the results are checked by qualified personnel to ensure that there are no analytical or transcription errors. Once results are finalised and accepted, a final laboratory report is generated and made available to the clinician.

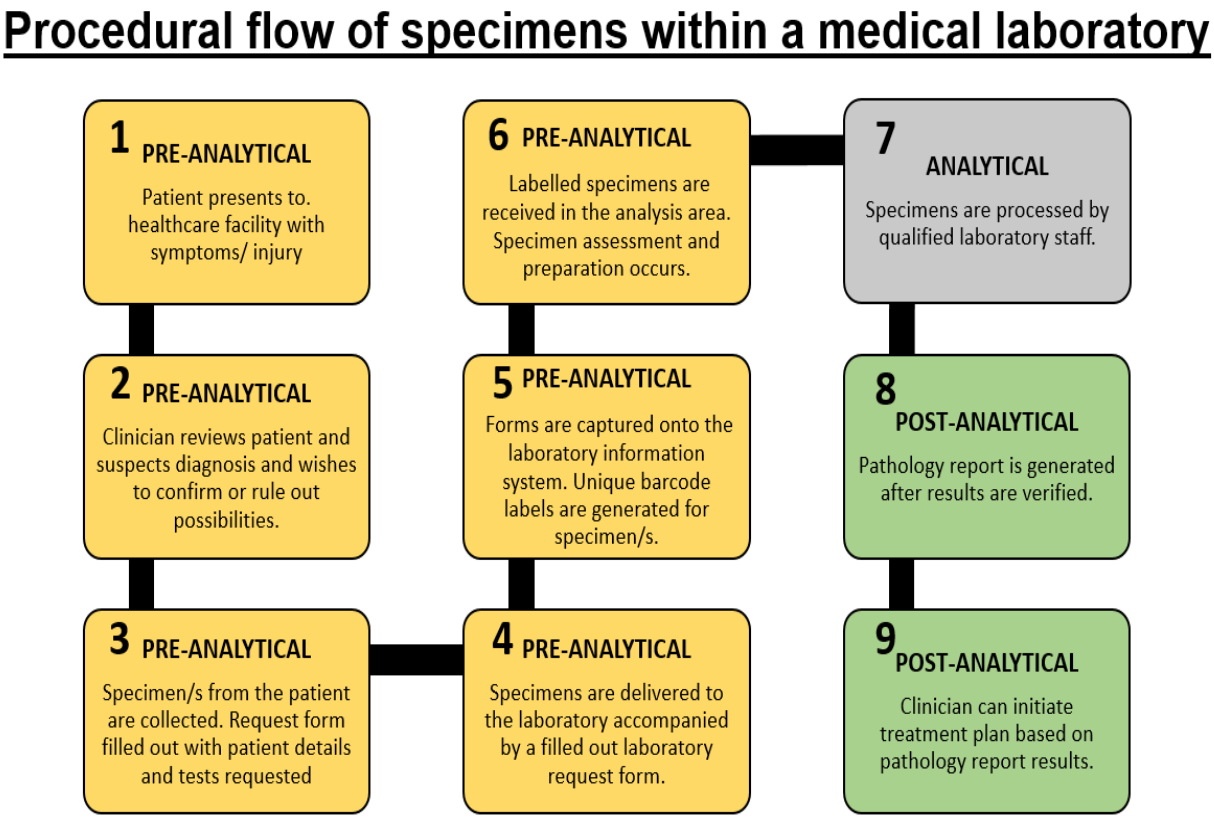

Figure 2.1: Specimen flow in a medical laboratory

Figure 2.1 describes the flow of specimens from specimen collection to the generation of a laboratory report. Errors or shortfalls that hinder the procedures mentioned above can cause specimen rejection (Bilello 2018).

Lippi *et al.* (2019) and Aggarwal *et al*. (2022) agree that the pre-analytical phase is the main area for concern. Literature points to the pre-analytical phase as the largest contributor to laboratory specimen rejections. The study conducted by Tapper *et al.* (2017) in Jamaica revealed that unlabelled specimens were the primary contributing cause for specimen rejection, which sets it apart from other studies where haemolysis was the predominant reason.

Crous and Armstrong (2016) state that within the academic structures of nurses and medical doctors, phlebotomy is not a main focus in the academic syllabus, instead, blood collection skills are learned during on-the-job training. Aggarwal *et al.* (2022) suggest that the lack of standardised phlebotomy procedures and consistent training creates room for inaccuracies and offers a formidable obstacle in monitoring processes related to phlebotomy. The lack of phlebotomy training may emerge as the principal determinant of pre-analytical errors (Abbas, Mukinda and Namane 2017). There are many factors during the blood collection procedure that can affect the quality of a specimen. The common consequences of poor phlebotomy techniques are haemolysis, incorrect patient identification, clotted specimens, and insufficient specimen volume (Aggarwal *et al*. 2022).

2.6 Specimen collection and labelling

Errors related to specimen collection refers to incorrect collection techniques, phlebotomy procedures, and incomplete laboratory requisition forms. At this initial stage, a suspected diagnosis and patient history could indicate what diagnostic tests are required. The identified tests have specific requirements for collection (Morrison, Potgieter and Naicker 2019). The specimen/s should be accompanied by a laboratory requisition form. Details such as patient identifiers, patient history, requesting clinician's name, practice number and contact details are entered on the laboratory requisition form along with the specific tests that are requested. It is essential that accurate information is provided on the completed form. Accurate patient information on laboratory request forms is fundamental for ensuring patient safety, maintaining quality standards, facilitating effective communication, and complying with legal and ethical requirements in the healthcare system. Aggarwal *et al*. (2022) emphasise that specimen/s are required to be labelled with patient information and this information must correspond to the information on the form. Specimen labelling ought to occur during collection to avoid mislabeling and mixing up of blood specimens. Mismatches are easily noticed by checking for correlation of the patient information between the requisition form and the specimen (Aggarwal *et al*. 2022). The danger of unlabelled specimens of different patients is that these can be swapped erroneously during collection and later be labelled with corresponding information on the requisition form

regardless of the fact that the specimen is from a different patient. Therefore, it is essential that specimen collection occur from one patient at a time at organised workstations in order to avoid such undetectable mismatches.

Knowledge of laboratory guidelines is beneficial to clinicians or nurses collecting specimens. The laboratory guidelines are specific to each testing laboratory and provide details of specimen type such as blood, fluid or urine along with specimen containers and tube additives that are used by the laboratory to analyse the specimen for the requested tests (Lippi *et al.* 2019). Blood collection tubes contain additives to ensure good specimen quality for specified tests. The order of draw refers to the order in which blood specimens are drawn from the patient into blood collection tubes. The order of draw plays an important role as the different additives may adversely affect the quality of specimens when incorrectly contaminating other tubes (Bazzano *et al.* 2021). Blood is collected by using a needle, the needle is then pushed into vacutainer tubes that contain additives to release blood into the tubes. Each tube contains additives that have different mode of actions which are unique to the type of test that is required, if there is carry-over of chemical additives into tubes and the order of draw is not followed correctly, it may institute pre-analytical errors. The order of draw exists to prevent cross contamination of additives between tubes such as EDTA contamination which can result in falsely elevated potassium levels in blood, therefore the poor adherence to the order of draw procedure leads to incorrect results (Bazzano *et al.* 2021).

2.7 Specimen transport

Hedayati *et al.* (2020) emphasise that specimens be transported to the laboratory swiftly to provide quick and accurate results. However, in the current NHLS and Department of Health facility situations, specimens are required to stay in the ward or department for a period of time before being batched and transported to the laboratory. Hedayati *et al.* (2020) advocates that specimens should be centrifuged promptly after collection. Plasma or serum specimens must be separated from cells soon after blood is drawn to prevent cellular metabolism and leakage of intracellular analytes into serum in unspun specimens because such an occurrence will give rise to false or inaccurate test results (Hedayati *et al.* 2020). With regards to whole blood specimens,

low temperatures assist in preserving analytes and cells in specimens that cannot be tested immediately. It is suggested by Lippi *et al*. (2019) and Hedayati *et al.* (2020) that low temperatures also slow down metabolic reactions within cells thus allowing for increased stability of analytes being tested in the serum. In view of that, timeous receipt of specimens in the laboratory is imperative.

2.8 Specimen registration

Registration of specimens on the laboratory information system occurs to keep track of patient specimens due to the high volumes of work passing through the laboratories. Information regarding tests requested, patient personal information and contact details as well as the clinician's contact details are captured onto the laboratory server. A properly filled out request form is essential for specimen registration (Nasir *et al.* 2020). Specimen type, collection tube or containers and requisition forms are checked during registration. Mismatched specimens and forms can be detected during specimen registration. Specimens are given internal laboratory tracking numbers that are unique to each patient. Barcoded labels are placed on specimen tubes and containers to allow for automated analysis.

2.9 Specimen suitability

Specimens are assessed for suitability during the process of specimen preparation. Here, depending on the test requested, specimens are either checked for clots with regards to whole blood specimens, for example, EDTA (purple or lavender top) and citrate (blue top) tubes and those that require serum or plasma (yellow top) are spun in a centrifuge to separate components of blood into the three layers: red blood cells at the bottom, the buffy layer in the middle (which contains white blood cells and platelets), and plasma at the top (Anon. 2022). Once spun, the serum or plasma is assessed for colour, with a straw colour serum being considered as normal. Depending on the test requested, specimens are rejected for having variations in colour. The colour variations are caused by haemolysis, icterus and lipaemia (Lippi *et al*. 2019). In addition, specimens are assessed for volume to determine sufficiency for

the tests requested. Specimens with insufficient volume are rejected due to the required volume of specimen not meeting the test requirements (Lippi *et al*. 2019).

2.9.1 Clotted specimens

During clot formation several blood components are used up, hence yielding incorrect results. For example, platelet counts will be falsely decreased due to platelets playing a key role in clot formation. When processing the international normalised ratio (INR) test, the method of testing is to check the time it takes for a clot to form (Kitchen *et al.* 2021). If a specimen is clotted, essential factors and components are depleted, leading to a delayed clot formation, resulting in a falsely prolonged result. Hence, the rejection of clotted specimens is paramount to patient safety (Kitchen *et al*. 2021). This type of rejection commonly affects the tests that require the use of whole blood and plasma. Examples of such tests include full blood count (FBC), erythrocyte sedimentation rate (ESR) and INR.

2.9.2 Haemolysis

Haemolysis is caused by the rupture of red blood cells either in vitro or in vivo leading to the release of intracellular components into the surrounding plasma (Wan Azman *et al*. 2019). In vitro haemolysis occurs during specimen collection and is dependent on phlebotomy technique (Crous and Armstrong 2016). Haemolysis can be detected by the observation of a red tinge or discolouration in the serum or plasma after centrifugation. Errors that result when analysing a haemolysed specimen can cause more harm to a patient than care (Heireman *et al.* 2017). Wan Azman *et al.* (2019) state that less than two percent of all haemolysed specimens are as a result of in vivo haemolysis which is haemolysis due to disease or illness. When red cells lyse, potassium from within the cell is released into the serum, consequently giving a falsely elevated potassium result also referred to as pseudohyperkalaemia (Barbato *et al*. 2020). Similarly, this can mask a true hypokalaemia, as the potassium result can appear within range. Hypokalaemia can affect the respiratory muscles by causing weakness resulting in respiratory failure which can lead to death (Castro and Sharma 2023). Falsely elevated results can lead to misdiagnosis and inappropriate treatment,

which can cause harm to the patient (Barbato *et al*. 2020). Specimen transport and prolonged storage of specimens with delayed processing can affect specimen quality.

2.9.3 Icterus and lipaemia

Icterus is caused by the increased levels of bilirubin present in serum or plasma giving it a difference in colour ranging from bright yellow, green to brown. Unlike haemolysis, icterus cannot be caused by pre-analytical errors but is rather as a result of disease or illness. Similarly, lipaemia occurs as a result of high levels of lipoproteins in serum or plasma (Krasowski 2019). An observation of lipaemia is noted by visible turbidity. Icterus and lipaemia affects certain tests due to chemical and light interferences within the instruments used to analyse blood specimens. Spectrophotometry is a standard method that is utilised by analysers to determine the concentration of chemicals within a solution by means of the absorbance of light. According to the Beer-Lambert law, the absorbance of a solution is directly proportional to the concentration of the absorbing particles in the solution. Lippi *et al*. (2019) confirms that icterus, lipaemia and haemolysis cause interferences during spectrophotometry due to unwanted particles being present. Colorimetric interferences within analysers can lead to false results (Vera and El-Khoury 2022).

2.9.4 Insufficient volume, anticoagulant or additive ratios, mixing and tube expiry

According to Lippi *et al*. (2019), anticoagulants in tubes have a very important function. Anticoagulants are present in blood collection devices to preserve cells and stabilise chemicals by inhibiting or slowing down metabolic reactions, and prevent clotting. Poor quality specimens can be due to the following:

- **Expired tubes** which means that the anticoagulant is expired and not optimally functional.
- **Delayed or inadequate mixing** of blood with anticoagulant which can result in clotting of the specimen and poor preservation of cells.
- **Incorrect volume** of blood which can cause over dilution or under-dilution of the anticoagulant thus affecting the quality of test results.

Unique additive tubes are required for specific tests. The mode of action of each additive is specific for the type of test. Lippi *et al*. (2019) explain the reasons for coupling the correct additive tube with the appropriate test request. A good example is the tubes used for coagulation studies and haematological studies. Both additives are used to prevent clotting, but their mode of actions differ. Coagulation studies require sodium citrate as the anticoagulant. Sodium citrate can be reversibly anticoagulated as the calcium is isolated, which means it stops clotting until calcium is introduced during testing to assess clot formation time. The addition of calcium is called plasma re-calcification. In haematological studies, on the other hand, potassium EDTA is utilised as the anticoagulant. Potassium EDTA functions by chelating calcium and causing irreversible clotting. Therefore, Lippi *et al.* (2019) emphasise that potassium EDTA cannot be used to perform coagulation tests.

With specimens that do not contain additives, it is important for the specimen to meet the criteria of the testing laboratory with respect to volumes required by analysers to ensure testing occurs. This will avoid the specimens from being rejected due to insufficient volume for testing (Aggarwal *et al*. 2022). Most analysers do not require a large amount of whole blood or serum. High volume of blood in collection tubes are mainly required for anticoagulant ratios (Bazzano *et al.* 2021). Paediatric cases are a common contributor to insufficient specimens. Paediatric specimens are usually short volumes and tend to be difficult to obtain as neonates have small delicate veins (Riddick 2023).

2.10 The importance of rejecting specimens

The progress of patient care is sometimes hindered when specimens do not meet minimum laboratory criteria and are rejected (Alavi *et al.* 2020). The criteria for rejection exist in order to prevent incorrect or inaccurate results from being generated. Musabaike *et al.* (2018) indicate that incorrect or inaccurate results can lead to inefficient or unwarranted treatment of patients. Furthermore, Asmelash, Worede and Teshome (2020) note that specimen rejection is known to cause delayed treatment due to delays in the generation of pathology reports. The negative impact delays have on patients with critical conditions can cause serious complications or death. In addition, misdiagnosis due to specimen mix up or incorrect pre-analytical procedures

can cause further harm to a patient due to an incorrect treatment plan which is based on improper blood results (Musabaike *et al.* 2018).

The goal is to work together with the hospital facilities to close the gaps that exist and ensure that patient safety and care is a combined focus. Providing timeous and accurate results is one of the essential factors by which pathology can improve healthcare. The improvement can be beneficial to the patient, clinician and laboratory organization. The benefits of receiving timeous and accurate laboratory results for the patient include (Alavi *et al.* 2020):

- Quick and appropriate treatment,
- Improved health in patients,
- Effective management of illness or disease.

The benefits of receiving timeous and accurate laboratory results for the healthcare workers include (Bodansky *et al.* 2017):

- A more efficient work-flow,
- Fewer frustrated patients related to re-bleeding,
- Fewer frustrated patients related to waiting time.

The benefits to the laboratory that sends timeous and accurate test results include (Gupta *et al*. 2021):

- A good customer relationship and satisfaction,
- Less stigma associated with the laboratory and waiting time,
- Less financial loss due to rejections.

2.11 Monitoring of specimen rejections within the laboratory

The laboratory monitors rejections as part of their quality indicators. According to Gupta *et al*. (2021), monitoring of rejections is regarded as a quality indicator in relation to the effects a rejected specimen has on the patient. A rejected specimen can cause a delay in diagnosis, thus causing delayed treatment (Musabaike *et al.* 2018). Laboratories are required to monitor quality indicators with the intention of improving the quality management system. This involves setting goals that ensure quality as per the ISO standard (2012).

The South African National Accreditation System (SANAS) is a body that monitors a laboratory's performance related to the ISO 15189:2012. The monitoring of rejection rates is practised as part of the ISO requirements within the NHLS. This is achieved by establishing a target limit per laboratory with an allowable percentage of rejections (GPQ0044 – Standard operating procedure for quality indicators within the NHLS). When the laboratory fails to stay within the allowable target, further investigations are expected from the laboratory management to assess the root cause of the problem and take actions to mitigate them (Gupta *et al.* 2021). Actions such as communicating rejection statistics to the hospital management, meeting with medical managers and nursing managers in an attempt to arrange pre-analytical training sessions with staff that are involved in phlebotomy. Considering the actions currently being taken by the NHLS, a high rejection rate still exists, hence this research study was taken on to further identify gaps and actions that need to be addressed in order to reduce rejection rates. Overall, the financial loss incurred by the laboratory, and the impact rejections have on the improvement of the quality management system with regards to patient care, are the chief issues.

Specimen rejection is a serious cause for concern as delayed treatment and re-collection of specimens increases patient discomfort. Patients that attend clinics carry the risk of returning to a facility for follow up treatment with no laboratory results available to them, which can cause frustration over and above the original discomfort that caused them to seek treatment in the first place. Rejections can cause delayed treatment, monitoring, and dose adjustments. In patients with life threatening illnesses a delayed result can lead to severe damage to vital organs or death (Musabaike *et al.* 2018). As a result, this study was aligned to quality management with the aim of targeting the common reasons for rejections and finding ways in which these rejections can be reduced. A reduction in rejections can ultimately lead to better healthcare.

2.12 Conclusion

Specimen rejection is an international challenge that all laboratories face. Literature indicates that the pre-analytical phase is the largest contributor to specimen rejections with haemolysis being the leading cause of rejections. Improper phlebotomy techniques and improper use of specimen collection tools are the key causes of

specimen rejection in the pre-analytical phase. This could be due to the lack of standardised procedures and training with regards to phlebotomy techniques and the use of blood collection tools. Rejections can lead to patient discomfort and prolonged waiting periods for treatment of patients. The importance of rejecting unsuitable specimens was covered in this chapter and suggests that poor quality specimens can yield false results that can be detrimental to patient care.

CHAPTER 3: METHODOLOGY AND MATERIALS

3.1 Introduction

Specimen rejections are known to have a negative impact on patient diagnosis, treatment and financial loss for the testing laboratory. Hence, the aim of this study was to investigate specimen rejection rates, the contributing factors to rejection, and methods to reduce the number of rejected specimens. This chapter describes the study design, research procedure, data collection criteria and ethical considerations undertaken during the course of this study.

3.2 Study design

This study used a quantitative and descriptive research design as rejection rates are quantified and expressed in numbers. The types of rejections were described and methods to reduce them were discussed in training workshop sessions.

3.3 Study setting

This study was conducted in two NHLS laboratories, namely, King Dinuzulu Hospital Complex and RK Khan Hospital, which are situated in eThekwini, KwaZulu-Natal. The study had originally planned to utilise three facilities to conduct research but one facility opted out due to a staff shortage therefore staff could not be released to attend the training sessions.

3.4 Ethical considerations

The researcher successfully completed ethics training certification and permission was sought from the business unit manager to conduct the study within the NHLS eThekwini district. Being able to conduct research within the NHLS also required permission from the Academic Affairs and Research Management System (AARMS). Once ethical approval was received from the Durban University of Technology Institutional Ethics Committee (IREC), ethics approval number IREC 123/21, data

collection commenced. Upon completing data collection, training sessions were planned after obtaining permission to conduct the study from the KwaZulu-Natal Department of Health, National Health Research Database. Before commencement of the training sessions, gatekeeper permissions were also obtained from the ethics committees located at King Dinuzulu Hospital Complex and RK Khan Hospital. Henceforth, they will be denoted as KDL and RKK respectively. During the training sessions, informed consent was obtained from the participants. Each participant was given an information letter about the study and was requested to participate. Participation in this study was voluntary. A pre-training and post-training questionnaire were completed during the workshop to evaluate the effectiveness of the workshop. Confidentiality and anonymity of the participants who attended the workshop was maintained. This study did not require the use of personal identification when reporting of results. The letter of information and consent form did not need to be translated to isiZulu as the target audience were all fluent in English.

3.5 Inclusion and exclusion criteria

This criterion is put in place to determine if participants and data are eligible to be included in the study. It ensures that the participants and data are relevant and representative of the factors that are being investigated.

3.5.1 Inclusion criteria

Specimens were considered for analysis if the diagnostic laboratory conducted clinical pathology tests within the fields of chemical pathology, haematology, or microbiology. Workshop participants encompassed all personnel engaged in the specimen collection process, comprising both nursing staff and doctors.

Table 3.1: List of tests included in the analysis of rejection rates

CHEMISTRY	HAEMATOLOGY	MICROBIOLOGY
• Urea and electrolytes • Liver function tests (including Neonatal total bilirubin) • Calcium, magnesium and phosphate • Creatinine kinase • Glucose (Random and Glucose Tolerance Test) • Uric acid	• Full blood count and differential • International normalised ratio • Erythrocyte sedimentation rate	• Urine • Stool • Sputum • Blood cultures

Laboratory diagnostic tests include tests that are commonly requested in chemistry, haematology and microbiology. Table 3.1 contains a detailed list of tests in each department that are affected by rejection.

3.5.2 Exclusion criteria

Specimens were omitted from analysis if the laboratory did not perform clinical pathology tests, specifically in chemistry, haematology and microbiology. Similarly, individuals were excluded from the research if they were not engaged in specimen collection processes.

3.6 Research procedure

A step by step outline of the study's flow with regard to all aspects of the research procedure.

3.6.1 Collection of specimen rejection data

Specimen rejection data for KDL and RKK was extracted from the NHLS Central Data Warehouse (CDW) for a period of 6 months. Permission was obtained from the NHLS AARMS prior to data collection and the data was captured onto Microsoft excel. Common reasons for specimen rejections were analysed and determined from the data extracted. After data collection and the analysis of the laboratory rejection rates were complete, training material for the workshop was created. The training material

was used to inform and educate nurses and clinicians on the causes of specimen rejections and the different ways these rejections can be mitigated.

3.6.2 Pre- training and post-training assessment procedure

The pre- and post-training assessments contained identical questions related to pre-analytical knowledge. Participants were expected to answer the assessment at the beginning of the training session and then again at the end of the session. The assessments were completed to assess effectiveness of the training workshop. A comparison of the scores between the pre-assessment and post assessment was made for each participant using Microsoft excel.

3.6.2.1 Validity and reliability

The questionnaires were created after consulting the existing literature as well as knowledge from on-the-job experience. Hence, a questionnaire that consists of relevant content was generated. The questionnaire contained pre-analytical related questions to assess participants' pre-analytical knowledge. The questionnaires were piloted with a group of clinicians to check that the questions were unambiguous and clear to understand.

3.7 Data storage

According to the Durban University of Technology standard operating procedure of the IREC (2020) and in keeping with the Good Clinical Practice (GCP) guidelines, all data collected are stored electronically for a period of five years with password protection and will subsequently be deleted. This includes confidential information such as the attendance registers and questionnaires for the workshop.

3.8 Data analysis

Data was analysed by means of graphs and tables on Microsoft Excel. P-values were calculated using Microsoft excel t-Test. A p-value of <0.05 was considered statistically significant. Comparisons were made between the rejection rates from the two laboratories before the intervention in the form of pre-analytical training. In addition, a comparison was made between the pre- and post-training assessments to evaluate effectiveness of the training sessions.

Results obtained from the data analysis will be presented as narrative, figures, graphs and tables in Chapter 4.

CHAPTER 4: RESULTS

4.1 Introduction

In this chapter, the results of the study conducted are presented and outlined in relation to the study objectives. Initially, the baseline data was collected for specimen rejection statistics and rejection rates were examined for two NHLS laboratories located in KDL and RKK. Then, the common reasons for rejections were detailed for each laboratory as well as the magnitude of its contribution to the total rejection rate. Subsequently, training material was compiled based on the common reasons for rejection and training workshops were held for clinicians and nurses in the two participating hospitals The training material detailed the causes of the listed rejections and methods in which they can be avoided.

A total of 74 healthcare workers attended the training workshops. Only 65 healthcare workers participated by completing the pre-training and post-training questionnaire. The questionnaire was used to determine the effectiveness of the training workshop for the 65 participants. Lastly, overall rejection statistics were collected post-intervention (the training workshops) and were compared to the baseline rejection statistics. This comparison was done to evaluate whether there was a reduction in the number of tests rejected. This chapter will allow a statistical view on an intensifying problem which is specimen rejection.

4.2 Analysis of data collected

Research data that was collected is presented in the form of tables, figures and graphs. Statistical tests were used to determine p values.

4.2.1 Analysis of baseline rejection statistics

Data for specimen rejection statistics was obtained from the NHLS Central Data Warehouse. The data collected represented the NHLS laboratories located in KDL and RKK for a period of six months. The acceptable limit for rejection rates as per NHLS policy, GPQ0044 is less than three percent of the total number of tests requested. The

rejection statistics are detailed using the total tests requested, total tests rejected and the rejection percentage for KDL (Table 4.1) and RKK (Table 4.2).

Table 4.1 represents six months of rejection rate statistics for KDL. It is noted that the NHLS limit for rejections of less than three percent was exceeded in all six months with January 2021 being the month with the highest rejected rate (5.1%) and March 2021 had the lowest rejected rate (3.0%). The number of rejected tests ranged from 1 814 to 2 995.

Table 4.2 represents six months of rejection rate statistics for RKK. The NHLS limit for rejections was also exceeded in all six months, with January 2021 being the month with the highest rejected rate (7.7%). March and June 2021 had the lowest rejected rate (6.5%). The number of rejected tests within RKK ranged from 9 884 to 10 492.

Table 4.1: Baseline rejection statistics collected from King Dinuzulu Hospital Complex

LABORATORY	MONTH	TOTAL TESTS	TOTAL REJECTED	REJECTION PERCENTAGE
King Dinuzulu	Jan 2021	59 161	2 995	5.1%
King Dinuzulu	Feb 2021	57 552	1 814	3.2%
King Dinuzulu	Mar 2021	65 198	1 953	3.0%
King Dinuzulu	Apr 2021	54 113	1 739	3.2%
King Dinuzulu	May 2021	59 017	2 150	3.6%
King Dinuzulu	Jun 2021	54 789	1 983	3.6%

Table 4.2: Baseline rejection statistics collected from RK Khan hospital

LABORATORY	MONTH	TOTAL TESTS	TOTAL REJECTED	REJECTION PERCENTAGE
RK Khan	Jan 2021	136 534	10 492	7.7%
RK Khan	Feb 2021	135 225	9 530	7.0%
RK Khan	Mar 2021	159 348	10 372	6.5%
RK Khan	Apr 2021	147 667	9 777	6.6%
RK Khan	May 2021	160 518	10 541	6.6%
RK Khan	Jun 2021	151 215	9 884	6.5%

4.2.2 Common reasons that contribute to the rejection rates

Reasons for rejections that contributed to the rejection rates during the six-month period were extracted in order to establish two factors: the common reasons for

rejection and the frequency of that reason. Rejection reasons that were not related to the pre-analytical errors and reasons for rejections that were not specific enough to identify the problem with the intention to mitigate the cause were referred to as “other”. The rejection reasons and the frequencies of their occurrence are shown for KDL (Table 4.3) and RKK (Table 4.4).

Table 4.3 (KDL) shows that haemolysis was the main reason for the rejection specimens, with 6 762 (53.92%) specimens rejected. Table 4.4 (RKK) also shows that haemolysis was the main reason for the rejection of specimens, with 35 949 (59.60%) specimens rejected.

Table 4.3: Rejection reasons and frequency at King Dinuzulu Hospital Complex

REJECTION REASON	FREQUENCY (%)
Unsuitable: haemolysed	6 762 (53.92)
Incorrect specimen received	985 (7.85)
Specimen not labelled	896 (7.15)
Specimen insufficient	651 (5.19)
Specimen not received	532 (4.24)
Info does not match	404 (3.22)
Unsuitable: clotted	343 (2.74)
Unsuitable: leaked	313 (2.50)
Unsuitable: too old	80 (0.64)
Invalid: EDTA contamination	67 (0.53)
Incorrect volume	29 (0.23)
Unsuitable: expired tube	28 (0.22)
Other	1 450 (11.56)

Table 4.4: Rejection reasons and frequency at RK Khan hospital

REJECTION REASON	FREQUENCY (%)
Unsuitable: haemolysed	35 949 (59.60)
Incorrect specimen received	5 484 (9.09)
Specimen not received	3 239 (5.37)
Specimen insufficient	3 139 (5.20)
Unsuitable: clotted	2 070 (3.43)
Unsuitable: leaked	1 769 (2.93)
Request form inadequacy	1 486 (2.46)
Specimen not labelled	1 035 (1.72)
Invalid: EDTA contamination	823 (1.36)
Info does not match	635 (1.05)
Incorrect volume	420 (0.70)
Unsuitable: too old	292 (0.48)
Unsuitable: expired tube	161 (0.27)
Other	3 816 (6.33)

4.2.3 Analysis of pre-training and post-training questionnaire results

The analysis of test results was completed by inspection of the pre-training and post-training assessment score comparison. Figure 4.1 shows the test scores for each participant. The purpose of the training sessions was to increase the pre-analytical knowledge of clinicians and nurses that are involved in the specimen collection processes. The average score for the pre-training assessment was 3.8/12 (32%) while the post-training assessment average score was 9.8/12 (82%). There was an average increase in test scores post-training of 5.95 points, thus indicating a 49.6% increase of pre-analytical knowledge. The p-value of the comparison of scores was < 0.001, indicating that the improvement in knowledge after training was statistically significant.

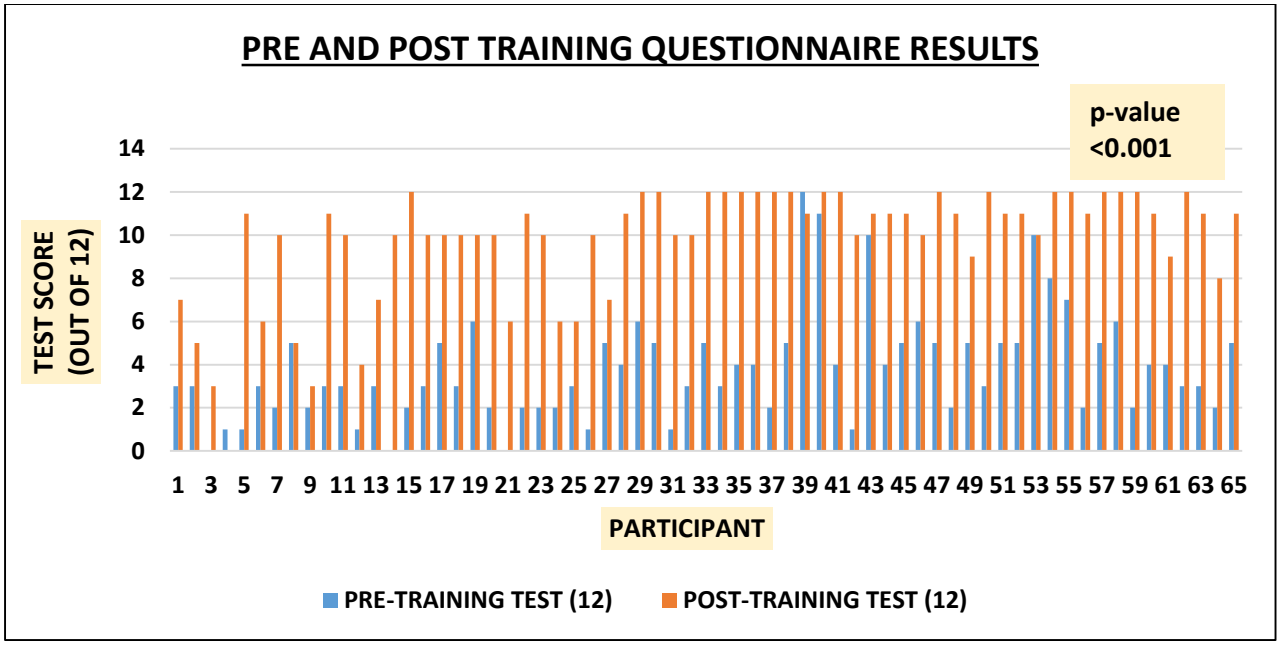

Figure 4.1: Pre-training and post-training test results

4.2.4 Analysis of rejection statistics after training sessions were concluded

Data for specimen rejection statistics post the training workshop was obtained from the NHLS Central Data Warehouse, specifically using the business unit rejection dashboard reports that were generated monthly and disseminated to the respective laboratories. This data was collected for a period of two months. The allowable rejection rate as per NHLS policy, GPQ0044 is a limit of < 3% rejections.

Table 4.5 shows the comparison of rejection rates for KDL before and after the training workshop. The allowable limit for rejections was still exceeded in both May and June 2022. Although, a slight decrease in rejection rates was noted, 0.3% and 0.2%, respectively, the p-value suggested that the decrease in rejections was not statistically significant ($p = 0.139$).

Table 4.6 shows the comparison of RKK rejections, indicating that there was an increase in the rejection rate during the months of May and June 2022 of 0.1% and one percent, respectively. The p-value indicates a statistically insignificant change in rejection rates ($p = 0.242$).

Table 4.5: A summary of rejection statistics collected from King Dinuzulu Hospital Complex post-training sessions

LABORATORY	MONTH	TOTAL TESTS	TOTAL REJECTED	REJECTION (%)	MONTH	TOTAL TESTS	TOTAL REJECTED	REJECTION (%)	p-value
King Dinuzulu	May 2021	59017	2150	3.6%	May 2022	65497	2192	3.3%	0.139
King Dinuzulu	Jun 2021	54789	1983	3.6%	Jun 2022	62466	2099	3.4%	

Table 4.6: A summary of rejection statistics collected from RK Khan hospital post-training sessions

LABORATORY	MONTH	TOTAL TESTS	TOTAL REJECTED	REJECTION (%)	MONTH	TOTAL TESTS	TOTAL REJECTED	REJECTION (%)	p-value
RK Khan	May 2021	160518	10541	6.6%	May 2022	158727	10584	6.7%	0.242
RK Khan	Jun 2021	151215	9884	6.5%	Jun 2022	155286	11596	7.5%	

4.3 Conclusion

The results of this study was depicted in the form of tables and graphs. A discussion of the results presented above will be provided in the next chapter.

CHAPTER 5: DISCUSSION

5.1 Chapter overview

This chapter will reiterate the research problem and summarise the study findings; it will detail the interpretation of results and contextualise the findings with the objectives and existing literature. The relevance of this study will be displayed and the link of the study's results to previously discussed literature will be made apparent. The limitations that were faced are acknowledged and recommendations put forward.

5.2 The research problem

This section will offer insights to the study's research problem and discuss the significance of attempting to reduce specimen rejection.

5.2.1 The effects specimen rejection has on stakeholders

When specimens are rejected, healthcare workers may experience an increased workload due to repeated specimen collection. Moreover, they may face frustration from repeating tasks and explaining prolonged waiting periods to patients resulting from specimen rejections. This frustration can create an unfavourable relationship between healthcare workers and the medical diagnostic laboratory. The progress of patient care can be hindered when specimens fail to meet minimum laboratory criteria, leading to delays in obtaining results and prolonged discomfort (Musabaike *et al.* 2018). Kitchen *et al.* (2021) confirm the point that rejection criteria are designed to prevent the generation of inaccurate results and acknowledge that rejections can lead to inefficient or unnecessary treatment for patients.

Patients are affected by the necessity to provide additional specimens, resulting in increased discomfort, longer waiting periods for treatment, and the possibility of an extended hospital stay. Public sector hospitals primarily serve community members

who are unemployed, pensioners, homeless, and low-income earners. Specimen rejections can impact patients financially and create an inconvenience for those reliant on public transportation. For patients in critical conditions, the failure to promptly identify and address biochemical imbalances can lead to severe complications or death (Asmelash, Worede, and Teshome 2020).

Financially, diagnostic laboratories are impacted by specimen rejections through the wastage of consumables used during specimen collection and the additional wastage of reagents when processing specimens identified as unsuitable. Laboratories monitor quality indicators to enhance their quality management systems which are aligned with the International Organization for Standardization (2012) requirements (Bozdemir, Kurutkan, and Terzi 2021). The laboratory strives to offer quality laboratory results to the patients in order to assist clinicians with providing appropriate and effective treatment.

5.2.2 Why it is important to reject unsuitable specimens

Specimen rejections have been demonstrated to be a prevalent burden. The pre-analytical phase is the main area for concern (Aggarwal et al. 2022; Lippi et al. 2019). The apprehensions about specimen rejections are shared by South African authors such as Govender et al. (2016), Mazanderani, Moyo, and Sherman (2017), and Magwai et al. (2020). While rejections and the concern for patients are discussed, articles published in South Africa often do not cover a broad range of tests. A local article that shares similarities to this study was conducted by Magwai et al. (2020) in Durban, KwaZulu-Natal, regarding specimen rejections and found that although the pre-analytical phase was the problem, specimen insufficiency was the largest contributor to rejections and the authors noted that a large number of insufficient specimens came from the neonatal and paediatric units. Govender et al. (2016) in Durban, KwaZulu-Natal, noted the significance of laboratory rejections for ensuring quality and reliable results, specifically in the context of HIV-1 PCR testing. Similarly, Mazanderani, Moyo, and Sherman (2017) provide details on HIV-PCR rejections and the associated complications related to missed early diagnosis of infants in South Africa.

Specimen rejections occur when human biological specimens are submitted to a medical diagnostic laboratory but do not meet the laboratory's suitability criteria. These criteria are tailored to the specific requirements of diagnostic tests offered in the laboratory (Lippi et al. 2019).

Specimens that do not meet the quality standards as per the acceptance criteria are rejected on the premise that poor quality specimens cause poor quality and inaccurate results. Ensuring that proper specimen requirements are adhered to is crucial to reduce interference factors that could negatively impact patient pathology results. Poor quality specimens are known to introduce interference factors during the analysis of results. This study investigates specimen rejections and its causes therefore it is crucial to explore and understand the importance of rejecting unsuitable specimens. When a test is rejected due to unsuitable specimens, pathology reports cannot be generated, preventing access to results by the requesting clinician. In cases where results for specific diagnostic tests cannot be obtained, clinicians are required to repeat the specimen collection process to ensure a valid diagnosis is made and provide appropriate treatment (Musabaike *et al.* 2018). Specimen rejections have a significant impact on three primary groups: healthcare workers (including clinicians and nurses); patients; and the diagnostic laboratory.

5.2.3 The lack of phlebotomy training and standardisation; the effects it has on specimen rejection

According to Aggarwal *et al.* (2022), the absence of standardised phlebotomy procedures and consistent training introduces the potential for inaccuracies. This poses a significant challenge in overseeing phlebotomy-related processes (Abbas, Mukinda and Namane 2017). The lack of formal phlebotomy training may emerge as the primary factor contributing to pre-analytical errors. Numerous factors during the blood collection process can impact specimen quality. Common outcomes of inadequate phlebotomy techniques include haemolysis, incorrect patient identification, incorrect additive tubes, clotted specimens, and insufficient specimen volume (Aggarwal *et al.* 2022).

This study aimed to investigate specimen rejection rates, the contributing factors and methods to reduce the number of rejected specimens. The goal was to collect and analyse the rejection statistics from the participating laboratories and identify common reasons for rejections. Once the common reasons for rejections were made apparent, the causes of rejections and the methods to reduce rejections through spreading knowledge of appropriate phlebotomy techniques as well as adherence to proper pre-analytical procedures were used to create and disseminate knowledge by means of training workshops in an attempt to reduce specimen rejections.

In order to meet the set objectives, the following questions were required to be answered during data analysis:

- Did the laboratory stay within the NHLS limit for rejections of less than 3%?
- Which phase in the diagnostic process in this study contributes the most to specimen rejections between the pre-analytical, analytical or post-analytical phase?
- What is the specific rejection reasons and which reason is the largest contributor to the total specimen rejection?
- Were the training sessions effective when comparing pre- training and post-training workshop knowledge?
- Long term, was the training workshop sessions effective in the reduction of specimen rejection rates?

5.3 Discussion of findings

This section analyses and interprets the results of the research that was conducted. The significance of the results is discussed and related to the research problem.

5.3.1 Baseline rejection data statistics and rejection rates

Laboratories routinely, monitor quality indicators in order to enhance their quality management systems. The procedures followed in the laboratories are aligned with ISO 15189 (2012) requirements. The NHLS policy, GPQ0044 contains an allowable target of less than three percent for rejections. In this study it was noted that both KDL

and RKK exceeded the allowable limit for rejections with an average rejection rate of 3.6% and 6.8%, respectively. As observed, the rejection rate at RKK is higher than that of KDL, this is possibly due to RKK having a higher number of specimens being processed at the laboratory when compared to KDL as seen in tables 4.5 and 4.6. Specimens are submitted to the diagnostic laboratory in order to confirm or rule out a diagnosis. Providing a pathology report to the clinician aids in accurate diagnosis of patients which in turn results in appropriate treatment. Rejections limit the information on the pathology report and this can lead to delayed diagnosis and treatment of patients (Musabaike *et al*. 2018). Patients with critical conditions may suffer unnecessary complications and possibly death due to delayed treatment (Asmelash, Worede, and Teshome 2020). Therefore, it is essential to reduce the rejection rates that are experienced by KDL and RKK.

5.3.2 The diagnostic process phases that contribute to exceeded rejection rates

The rejection reasons that were extracted suggest that the pre-analytical phase is the largest contributor to specimen rejections with haemolysis being the most frequent reason for rejections, making up more than 50% of all rejected specimens. This is in keeping with international studies conducted by Ye *et al.* (2018), Dikmen, Pinar and Akbiyik (2015) and Wan Azman *et al.* (2019) which identified the pre-analytical phase as the principal contributor of specimen rejections, with haemolysis being the leading cause. However, Magwai *et al.* (2020) conducted a study in Durban, South Africa, with an attempt to reduce specimen rejections had suggested that although, the pre-analytical phase was the problem, specimen insufficiency was the largest contributor to rejections.

5.3.3 Common causes that contribute to specimen rejection

Haemolysis accounted for 53.92% of all rejections at KDL and 59.60% of all rejections at RKK. Haemolysis is mainly caused by poor phlebotomy techniques (Crous and Armstrong 2016). Studies conducted in Italy and Brazil confirmed the justification for rejecting haemolysed specimens as they can yield incorrect laboratory results

(Barbato *et al.* 2020). In China, Turkey and Malaysia, Ye *et al.* (2018), Dikmen, Pinar and Akbiyik (2015) and Wan Azman *et al.* (2019) identified haemolysis as the leading cause of specimen rejections which is in keeping with this study's findings. Many chemistry and coagulation tests cannot be carried out when a haemolysed specimen is obtained. In cases where patients have electrolyte imbalances and those that are on anticoagulant therapy such as warfarin, such delays in receiving laboratory results and treatment can cause severe harm and possible death.

Incorrect specimen received was the second largest contributor to specimen rejections with 7.85% (KDL) and 9.09% (RKK) and specimen not received was among the common reasons for rejections (KDL 4.24% and RKK 5.37%). The laboratories possess and distribute laboratory guidelines to hospital staff that entails information on specimen requirements for all tests offered at the laboratory. Information such as specimen type, tube, specimen volume and transport conditions are described in the laboratory guidelines (Lippi *et al.* 2019). The receipt of incorrect specimens and specimens not being received indicates that these guidelines are not adhered to. Patients may be inconvenienced by unnecessary specimen collection procedures and delayed treatment due to delayed pathology reports.

Specimen insufficiency was also a common cause of rejections (KDL: 5.19% and RKK:5.20%). This occurs when there is an inadequate amount of specimen to complete the required tests. This often occurs for neonatal and paediatric specimens as neonates have small, delicate veins and are difficult to bleed.

Specimen clotted (unsuitable clotted) had made a large contribution to the rejection rates (KDL: 2.74% and RKK: 3.43%). Clotted specimens occur when blood samples are not properly mixed by inversion in order to dissolve the anticoagulant with blood. This type of rejection predominantly effects tests such as, but not limited to, FBC, coagulation studies and ESR. Delays in FBC results can jeopardize a patient's life when the haemoglobin and platelet counts are required by the clinician to commence with surgery.

In summary, it was observed that inadequate phlebotomy methods and a lack of pre-analytical understanding may result in hemolysis, clotting of specimens, insufficient specimen volume, and the receipt of incorrect specimens or no specimens at all. The

negative impact and implications that specimen rejections have on patient care is sufficient to ensure that appropriate efforts are made to reduce specimen rejections.

5.3.4 Pre- and post-training assessment results

Test scores were compared and effectiveness of training was determined. There was an average increase in test scores post-training of 5.95, thus indicating a 49.6% increase of pre-analytical knowledge. The improvement was statistically significant ($p < 0.001$). The assessments were identical and were piloted prior to conducting the training workshops. The study conducted by Abbas, Mukinda and Namane (2017) indicated similar findings after training sessions with a significant increase in pre-analytical knowledge, specifically phlebotomy training.

5.3.5 Rejection data statistics post-training workshop

The general rejection rates did not decline for the two months following the pre-analytical training workshop, with both KDL and RKK still exceeding the limit for rejections of less than three percent. Abbas, Mukinda and Namane (2017) indicated in their study that there was no significant decrease in rejections after phlebotomy training was completed, as seen in this study. KDL showed a slight decrease in rejections while RKK showed an increase in rejection rates. The difference observed may be attributed to KDL attendees being permanently employed clinicians and nurses while RKK had only intern doctors attend the training sessions. It is known that interns rotate to different departments and eventually leave due to community service placements.

The lack of significant change in rejections related to the pre-analytical phase was linked to the low attendance numbers due to the high volume of patients to tend to, leading to insufficient time allocated to attending a training session. Similarly, with the current study conducted, not all staff involved in specimen collection procedures attended the training workshops. There were also limited time slots allocated for training as the staff were required to get back to work due to the high volumes of patients that needed consultation as well as staff shortages. It is understandable that

there are chronic issues faced by the public sector hospitals such as understaffing and poor facility conditions (Maphumulo and Bhengu 2019) but, training and continuous development is essential in all professional fields of study. It was disappointing to note how little importance was given to the training sessions with regards to allocated time and attendance.

In summary, the analysis of data in this study suggests that the pre-analytical phase is the largest contributor to the overall rejection rates experienced by both laboratories. This is in keeping with literature reviewed, where it is noted that the highest number of rejections occur in the pre-analytical phase, therefore this is the main area of concern. The majority of rejections are due to phlebotomy errors, the lack of pre-analytical knowledge, and the lack of following laboratory guidelines. The journey embarked on to carry out training workshops with clinicians and nurses. The data suggests that adequate pre-analytical training methods can improve the pre-analytical knowledge of healthcare workers.

Although the improvement in knowledge after the training sessions was significant, there was no overall improvement of rejection rates in the months after the training sessions were completed. The lack of improvement in rejection rates could be attributable to factors such as the number of participants that attended the training sessions. There was a total of 65 participants which included participants from both KDL and RKK. The number of participants made up only a small percentage of the total number of staff actively involved in the blood collection procedures.

5.4 Challenges and limitations

The main challenge that caused delays to the progress of this study was obtaining gatekeeper permissions and approvals to conduct the study. Additionally, after data collection was allowed to commence, gaining access to the facilities to organise and commence with the training sessions was difficult.

There were delayed responses and the lack of willingness to attend sessions due to staffing and time constraints as reiterated by Maphumulo and Bhengu (2019). The wards that make a large contribution to specimen rejections such as casualty could not attend the training sessions due to staffing constraints. In an article published by

Maphumulo and Bhengu (2019), it was also noted that only 16% of South Africa's population have access to private healthcare, which indicates that 84% of the population have limited access to private healthcare due to affordability and rely merely on public healthcare.

Not all clinicians and nurses that are responsible for specimen collection attended the training sessions. There was a total of 65 participants who attended the training sessions which is an insignificant number when compared to the total number of clinicians and nurses employed within these public sector hospitals. As an example, the staff complement of healthcare workers at RKK is approximately 541. This number includes medical doctors (115), intern doctors (84) as well as nurses (341), yet only 26 intern doctors attended the training session therefore 95.19% of the healthcare workers were not trained. In addition, time constraints due to being a part time researcher did not allow for flexibility. This also hindered the opportunity to conduct more frequent training sessions in order to gain more participants which possibly could have made a larger difference in rejection rates.

The specimen rejection statistics included specimens rejected from all the wards and clinics that were serviced by KDL and RKK. It is noted that the training sessions were not attended by all wards and clinic staff that are involved in specimen collection processes. An improvement in rejections for the specific departments that did attend the training sessions may have been masked by the large amount of errors being made by the staff that did not attend the sessions.

5.5 Conclusion

In conclusion, the initial rejection rates indicated that KDL and RKK did not meet the allowable limit of rejections. The errors in the pre-analytical phase proved to be the largest cause of specimen rejections, with haemolysis being the leading cause for rejections. Training workshops were conducted to attempt to reduce specimen rejections via disseminating pre-analytical knowledge. However, the statistics collected post-training workshop showed an insignificant change in overall rejection rates.

5.6 Recommendations

This study has shown that the current method of on-the-job training does not cover the theory that is necessary to follow the appropriate pre-analytical procedures. Before commencing with a task, one should be trained and deemed competent in order to carry out tasks with appropriate knowledge, skill and confidence. Continuous education, training and competency should not be abandoned due to staffing constraints. It is recommended that the following be considered to reduce specimen rejection rates:

- A structured training programme for pre-analytical procedures and phlebotomy techniques should be implemented as part of a fundamental module in the nursing and medical curricula within the universities and training institutions in KwaZulu-Natal.
- An agreement between the Department of Health and the laboratory facilities to conduct a mandatory laboratory-based orientation programme for all existing and new staff.
- Existing nurses and clinicians be trained in pre-analytical procedures in well-structured training sessions that can be suited to accommodate staff shortages by scheduling multiple training sessions.
- There should be more consistent training sessions like the one conducted during this study so that all staff involved in the pre-analytical phase of specimen collection is offered a chance to attend.
- Once training is completed there should be a qualified phlebotomist conducting regular observations in bleeding rooms within the hospital to ensure compliance of correct procedures.
- An agreement with NHLS and DOH to offer a phlebotomy training programme or learnerships similarly to some private sector laboratories.

Future studies should focus more narrowly on specific departments and extract data that is specific for the departments that are represented during the training sessions. When focusing the study in a specified area, more detailed rejection reports can be extracted to scrutinise the root causes within a smaller group of participants and more frequent training sessions should be conducted.

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APPENDICES

Appendix 1: Ethics training certificate (Introduction to Research Ethics)

Zertifikat Certificado
Certificat Certificate
TRREE
Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants
Clinical Trials Centre
The University of Hong Kong
Certificat de formation - Training Certificate
Ce document atteste que - this document certifies that
Afsana Ballim
a complété avec succès - has successfully completed
Introduction to Research Ethics
du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation
Release Date: 2020/06/20
CID : GLDWSSLcC
Professeur Dominique Sprumont
Coordinateur TRREE Coordinator
FMH
Continuing Education Program (5 Credits)
Programme de formation continue (5 Crédits)
Fachverband Pharmazeutica Schweiz
FPH
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[REV : 20170310]

Appendix 2: Ethics training certificate (Research Ethics Evaluation)

Zertifikat Certificado
Certificat Certificate

TRREE

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants

Clinical Trials Centre
The University of Hong Kong

Certificat de formation - Training Certificate

Ce document atteste que - this document certifies that

Afsana Ballim

a complété avec succès - has successfully completed

Research Ethics Evaluation

du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2020/06/24

CID : FVFBAOkp7c

Professeur Dominique Sprumont
Coordinateur TRREE Coordinator

FMH Continuing Education Program (5 Credits)
Programme de formation continue (5 Crédits)

Fondazione Pharmaceutica Helvetiae

FPH Programmes de formation continue

Continuing Education Programs
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[REV : 20170310]

Appendix 3: Permission letter from NHLS eThekwini Business Unit Manager

NATIONAL HEALTH LABORATORY SERVICE

Oakford Road, Verula

Tel: 032 541 92:

Cell:07385531

The Business Manager
National Health Laboratory Service
eThekwini
Durban

04/02/2021

Dear Mrs. Dlamini,

I would like to carry out a study for my Masters research project titled "An investigation of rejection rates, sources thereof and methods to reduce specimen rejection.". It requires me to study rejection statistics within our business unit. I will be assessing the major contributing factors that cause rejections and with success hopefully implement actions that can be used to mitigate these factors thus reducing our rejections.

From research and reading I have noticed that it is a major issue not only within our business unit but nationally and internationally as well. Having to reject patient samples not only affects the lab financially due to wastage but also results in delayed patient treatment. I aim to determine our problem areas, create an action plan, implement the actions and monitor for progress.

I write this letter to ask for permission to access and use the business unit's data with regards to rejection statistics. I will ensure that Laboratory related business will remain confidential.

I would appreciate your assistance in granting me permission to use the Laboratories within the business unit for my research. I would also appreciate your guidance and expertise along the research I have undertaken going forward.

Yours sincerely,

Afsana Ballim

I, D. Hlengiwe Dlamini hereby grant permission to Mrs Afsana Ballim to collect and use data required for the above mentioned research study.

3-02-2021

Hlengiwe Dlamini

Appendix 4: Approval letter NHLS Academic Affairs and Research Management System

NATIONAL HEALTH LABORATORY SERVICE

Academic Affairs and Research
1 Modderfontein Road, Sandringham, 2031
Tel: +27 (0)11 555 0367/0406
Email: babatyi.kgokong@nhls.ac.za
academic.research@nhls.ac.za
Web: www.nhls.ac.za

27 September 2022

Applicant: Afsana Ballim
Institution: NHLS
E-mail Address: afsana0211@gmail.com
Tel: 032 541 9236 **Cell:** 073 855 3152

Project Title: An Investigation of rejection rates, sources thereof and methods to reduce specimen rejection
Reference Number: PR2119009

Research Application Type(s):
1. Request for Data

RE: APPROVAL LETTER: REQUEST TO ACCESS NHLS RESOURCES FOR RESEARCH PURPOSES

This letter serves to advise that the application requesting permission to conduct the above-mentioned research using the listed NHLS resources has been reviewed and **"Approved"**. Please note that the approval is granted on the condition that you comply with the NHLS Research Material and Data Access Policy and requirements stated below.

1. All material and data requested shall be used as per the research protocol submitted to the NHLS and as approved by the relevant Health Research Ethics Committee (HREC) in South Africa.
2. Access to the NHLS material and/or data shall be limited to the minimum required for successful completion of the approved study and shall be made available ***without patient names and other patient identifiers (including, but not limited to, national identity numbers, hospital/clinic file numbers, addresses and telephone numbers)***.
3. Confidentiality shall be maintained at the participant and institutional level and there shall be no disclosure of personal information or confidential information.
4. Data and/or material shall not be shared with other parties unless approved by the NHLS
5. The material and/or data obtained from the NHLS shall be anonymised and not, for any reason, be used to track or recruit patients as no pre-approval/consent is obtained from patients.
6. Processes shall be discussed with the relevant NHLS departments (i.e. Corporate Data Warehouse (CDW), NHLS Laboratory Management, Operations Office, etc.) and agreed upon.
7. Any amendments to the study requirements, including the use of the material and/or data for purposes not initially disclosed to the NHLS) shall be cleared by an approved HREC and submitted to the NHLS for approval via the AARMS system – https://aarms.nhls.ac.za.
8. The NHLS shall be acknowledged as a source of material and/or data in any output, such as abstracts and journal articles, emanating from the project.
9. A final report of the research study and any published output resulting from this study shall be submitted to the NHLS via AARMS

Please note that this letter constitutes approval by the NHLS Academic Affairs and Research Office. The NHLS entities tasked with providing the material and/data may have additional requirements for access. Data related queries may be directed to NHLS CDW, email: zarina.sabat@nhls.ac.za; contact number: 011 386 6074 and sample related queries (if applicable) shall be directed to the relevant business manager.

Dr Babatyi Malope-Kgokong
National Manager: Academic Affairs and Research

Appendix 5: IREC Ethical Clearance (Full approval)

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

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2375
Email: lawlahad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

19 September 2022

Mrs A Ballim
P O Box 763
Pietermaritzburg
3200

Dear Mrs Ballim

An investigation of rejection rates, sources thereof and methods to reduce specimen rejection
Ethical Clearance number IREC 123/21

The DUT-Institutional Research Ethics Committee acknowledges receipt of your notification regarding the piloting of your data collection tool.

Kindly ensure that participants used for the pilot study are not part of the main study.

In addition, the DUT-IREC acknowledges receipt of your gatekeeper permission letters.

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 DUT-IREC according to the DUT-IREC SOP's.

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

Yours Sincerely

Prof J K Adam
Chairperson: DUT-IREC

Appendix 6: Approval letter for NHRD (Department of Health)

KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DIRECTORATE:
Health Research & Knowledge Management Unit

Postal Address: Private Bag X9051
Physical Address: 330 Langalibalele Str, PM Burg, 3201
Tel: 0333953189/3123/2805 Fax: 033-3943782
Email address: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

NHRD Ref: KZ_202109_029

Dear Mrs A Ballim
(DUT)

Approval of research

1. The research proposal titled **'An investigation of rejection rates, sources thereof and methods to reduce specimen rejection'** was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

   The proposal is hereby **approved** for research to be undertaken at King Dinuzulu Hospital Complex and RK Khan Hospitals.

2. You are requested to take note of the following:

   a. *All research conducted in KwaZulu-Natal must comply with government regulations relating to Covid-19. These include but are not limited to: regulations concerning social distancing, the wearing of personal protective equipment, and limitations on meetings and social gatherings.*
   b. *Kindly liaise with the facility manager BEFORE your research begins in order to ensure that conditions in the facility are conducive to the conduct of your research. These include, but are not limited to, an assurance that the numbers of patients attending the facility are sufficient to support your sample size requirements, and that the space and physical infrastructure of the facility can accommodate the research team and any additional equipment required for the research.*
   c. *Please ensure that you provide your letter of ethics re-certification to this unit, when the current approval expires.*
   d. *Provide an interim progress report and final report (electronic and hard copies) when your research is complete to* ***HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200*** *and e-mail an electronic copy to hrkm@kznhealth.gov.za*
   e. *Please note that the Department of Health shall not be held liable for any injury that occurs as a result of this study.*

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

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee
Date: 21/09/2021

GROWING KWAZULU-NATAL TOGETHER

Appendix 7: Permission letter from KDL

KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DIRECTORATE:
King Dinuzulu Hospital Complex

P.O. Dormerton, Sydenham, 4015
75 R.D. Naidu Drive, Sydenham, 4015
Tel: 031 2426000 Fax: 031 2099586

Enquires: Dr Z. Dlamini

Reference: RES 24/2021

02/12/2021

Dear Ms Ballim

RE : AN INVESTIGATION OF REJECTION RATES, SOURCES THEREOF AND METHODS TO REDUCE SPECIMEN REJECTION.

I have pleasure in informing you that permission to conduct the above study has been supported by King Dinuzulu Hospital Complex.

Please note the following:

1. Please ensure that you adhere to all policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. Neither the District Office nor KDHC will provide any resources for this research.
3. Your attention is drawn to the maintenance of confidentiality with respect to staff records/files and may not be removed from this Institution.
4. You will be expected to provide feedback on your findings to KDHC.

Yours faithfully

Dr Z. Dlamini
Acting C.E.O.

GROWING KWAZULU-NATAL TOGETHER

Appendix 8: Permission letter from RKK

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address : R.K. Khan Circle
Physical Address : CHATSWORTH
Tel: [031] 4596001 Fax:[031] 401 1247 Email:Dianne.naicker@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
R.K. KHAN HOSPITAL
OFFICE OF THE SENIOR
MANAGER: MEDICAL SERVICES

ENQUIRIES: DR G.M. GOVENDER

25 OCTOBER 2021

Ms. Afsana Ballim
NHLS
Medical Technologist
Osindisweni Laboratory

Dear Ms Ballim

RE: PERMISSION TO UTILIZE FACILITY TO CONDUCT A TRAINING SESSION WITH CLINICIANS AND NURSES INVOLVED IN THE PRE-ANALYTICAL PHASE I.E. PATIENT PREPARATION AND SPECIMEN COLLECTION PROCEDURES.

"AN INVESTIGATION OF REJECTION RATES, SOURCES THEREOF AND METHODS TO REDUCE SPECIMEN REJECTION."

Permission is granted to conduct the above investigation at this institution.

Please note the following:

1. Please ensure that you adhere to all the policies, procedures protocols and guidelines of the Institution with regards to this process.

2. **You will be expected to provide feedback on your findings to this institution.**

3. You will be liaising with: Dr G.M. Govender – Clinical Manager and
Mrs C.Z.L. Simelane - Deputy Manager: Nursing
Tel: 031- 4596030 / 4596384 / 4596208

Yours faithfully

DR G.M. GOVENDER
ACTING SENIOR MANAGER: MEDICAL SERVICES

Appendix 9: Participant letter of information and request to participate

LETTER OF INFORMATION

Title of the Research Study:
An investigation of rejection rates, sources thereof and methods to reduce specimen rejection

Principal Investigator/s/researcher:
Afsana Ballim, BTech in Biomedical Technology

Co-Investigator/s/supervisor/s:
Dr JN Mbatha, PhD in Med Sc: Medical Microbiology

Brief Introduction and Purpose of the Study:

Good day

I am a student at DUT doing research for my Master's degree in Medical Laboratory Science.

I would like to invite you to participate in the research that I have undertaken.

What is Research
Research is a systematic search or enquiry for generalized new knowledge. The Research that you will be partaking in will attempt to address the concerns around rejection of patient specimens.

Rejection occurs when specimens are sent to medical diagnostic laboratories and are deemed unsuitable for analysis based on rejection criteria. The criteria are put in place to ensure patients get a result that is of the highest quality to assist in yielding appropriate patient care. The purpose of this study is to identify the reasons for specimen rejections within a medical diagnostic laboratory. The factors contributing to rejection will be investigated and documented. These factors will be assessed and potential causes of specimen rejections will be gathered. This information can create awareness for you as healthcare workers on how rejection of specimens can be avoided.

Outline of the Procedures:
Those of you involved in the pre-analytical phase of laboratory procedures will be included e.g. Medical practitioners, nurses, phlebotomists, clinical associates, laboratory personnel etc. individuals that do not meet the above mentioned criteria will be excluded.
You are required to complete the pre-assessment and post-assessment.
The requirement exists to assess the effectiveness of the workshop/training session.
The session will take approximately 2 hours and will include:

- Introduction of the topic: The question "What is specimen rejections?" will be answered.
- A list of criteria for specimen requirements (for the specific tests covered in this study).
- An explanation of why it is necessary for samples to meet the criteria and the importance of quality and
- reliable results for the patient.
- Order of draw will we discussed.
- A criteria checklist for correct phlebotomy technique – 18 step guide (Crous and Armstrong, 2016) will be discussed.

The most favourable outcome for your participation would be the attainment of additional and useful knowledge to improve the quality of patient care.

Risks or Discomforts to the Participant:
Due to the nature of the study there will be no risk or discomfort to you.

Explain to the participant the reasons he/she may be withdraw from the Study:
You can withdraw from the study as you wish for whatever reason.

Benefits:

To the patient

- Improved quality of test results thus may assist in more accurate treatment.
- Minimized re-bleeds for tests requested hence decreased patient discomfort.
- Reduced waiting time for laboratory results.

To you:

- Improved awareness of laboratory rejection and why it is necessary for quality results.
- Improved quality of patient care with regard to laboratory diagnosis and monitoring.
- Effective management of illness or disease with the assistance of improved quality results.

To the researcher:

- Publication
- Improved knowledge
- Improved quality indicators to improve the laboratories quality management system.
- Improved client awareness of laboratory rejection and why it is necessary for quality results.

Remuneration:
Participation in this study is voluntary hence there is no remuneration attached to this study.

Costs of the Study:
There are no costs of the study.

Confidentiality:
The assessments and questionnaire will maintain your confidentiality and anonymity as the research does not require personal identification or information to be used in the data processing. You will be allocated a number i.e. as a method of identification with regard to the assessment.

Results:
Results of this study will be communicated to you via publication and will be made available to the public.

Research-related Injury:
Due to the nature of the study you are at no risk of injury.

Storage of all electronic and hard copies including tape recordings
All confidential information including the attendance registers and assessments for the workshop will be stored electronically with password protection for a period of five years and will subsequently be deleted.

Appendix 10: Pre-training Questionnaire (Identical to Post- Training Questionnaire)

Appendix D-1 Pre-assessment of knowledge prior to workshop/training.

Institution/facility: _____

Name: _____ **Surname:** _____

Seat No.

Question 1

All 7 words listed in the box are related to the order of draw that should be used when drawing blood into tubes for laboratory testing. List them in the correct order. (7)

Green (Heparin) (A)	Yellow (SST) (B)	Blood culture (C)	Blue (Sodium citrate) (D)	Purple (EDTA) (E)	Grey (Sodium fluoride) (F)	Brown (Plain/Sterile) (G)

Answer:

	Correct order of draw. Indicate the corresponding letter e.g.; 1 – C, 2 - A
1	
2	
3	
4	
5	
6	
7	

Question 2 – Circle the letter of the most correct answer.

2.1) What is your understanding of the term anti-coagulant ratio? (1)

a) The ratio between preservative or anticoagulant to blood in a tube.
b) The ratio of coagulants in the patient's blood sample.
c) The amount of antibodies in the patient's samples.

2.2) The laboratory rejects **clotted** specimens for haematology requests (FBC, ESR and INR) because: (1)

a) The staff do not want to perform the test.
b) The clot formation uses up platelets, red cells and clotting factors which can yield an incorrect patient result.
c) The sample becomes insufficient for analysis.

2.3) Why is it important for the laboratory to receive and analyze specimens within a short period from being drawn? (1)

a) Anticoagulants can have effects on blood cells when exposed for long periods of time e.g. EDTA changes.
b) Potassium leaks from red cells into the serum when left standing for a long time without being spun down and separated e.g. Yellow top SST for UE analysis.

c) Specimens for microscopy culture and sensitivity have bacteria that can either die or multiply yielding a falsely elevated result with samples like urine and stool and a false negative result with samples such as CSF and sterile fluids.
d) All of the above.

Question 3- Circle the letter of the most correct answer.

3.1 Haemolysis due to phlebotomy is related to: (1)
a) The tourniquet is too tight
b) Tourniquet not being loosened once blood flows
c) Both A and B.
d) None of the above.

3.2 EDTA contamination occurs when the incorrect order of draw is followed. This occurs when blood is drawn into the purple top tube and then into the yellow top tube. (1)
a) True
b) False

Score:	/12

Appendix 11: Questionnaire Pilot Study Outcome

Research Ethics Clearance number: IREC 123/21

To whom it may concern:

Pilot study and outcome

Date of pilot study: 13/04/2022

Location: Orthopedic department

Number of participants: 8

Target audience: Clinicians

The Pre and Post assessment questionnaire are the same. Hence, only the Pre assessment questionnaire was piloted to ensure there was no ambiguity and if the questionnaire was easy to understand.

Consent was granted by all 8 participants and feedback was given. It is also noted that the participants used in this pilot study will not be participating in the main study.

All the participants felt that the questionnaire was easy to understand and found that there was no ambiguity in the line of questioning.

No changes will be made to the questionnaire.

The session was a face to face session. All participants wore masks and Covid-19 protocols were followed.

Regards ,

Afsana Ballim

Appendix 12: Turnitin report

Masters Dissertation initial

ORIGINALITY REPORT

2%	2%	1%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Ngugi, Richard M.. "Impacting the Knowledge of Equipping Church Leaders in a Select Group of Pastors from Rural Regions of Kenya", Ashland Theological Seminary, 2023 Publication	<1%
2	jcmad.com Internet Source	<1%
3	Submitted to Middlesex University Student Paper	<1%
4	Submitted to Universiti Teknologi Petronas Student Paper	<1%
5	aff.org.au Internet Source	<1%
6	www.nice.org.uk Internet Source	<1%
7	Submitted to Glasgow Caledonian University Student Paper	<1%
8	Submitted to Purdue University Student Paper	<1%

Appendix 13: Editing certificate

DR RICHARD STEELE
BA HDE MTech(Hom)
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Practice No. 0807524
Freelance academic editor
Associate member: Professional Editors' Guild, South Africa

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5292
Eastern Cape

082-928-6208
rsteele@vodamail.co.za

EDITING CERTIFICATE

Re: **Afsana Ballim**
DUT master's dissertation: **An investigation of rejection rates, sources thereof and methods to reduce specimen rejection**

I confirm that I have edited this dissertation and the references for clarity and language. I returned the document to the author with track changes so correct implementation of the changes and clarifications requested in the text and references is the responsibility of the author. I am a freelance editor specialising in proofreading and editing academic documents. My original tertiary degree which I obtained at the University of Cape Town was a B.A. with English as a major and I went on to complete an H.D.E. (P.G.) Sec. with English as my teaching subject. I was a part-time lecturer in the Department of Homoeopathy at the Durban University of Technology for 13 years and supervised many master's degree dissertations during that period.

Dr Richard Steele
25 November 2023
per email