Cape Peninsula University of Technology

ANALYSIS OF RISKS ASSOCIATED WITH LABORATORY ERROR RATES OF COVID-19 TESTING AT THE NHLS PAARL LABORATORY.

by

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DECLARATION

I, Natasha Singh, declare that the contents of this thesis represent my own unaided work, and that the thesis has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the Cape Peninsula University of Technology.

13/10/2023

Signed **Date**

ABSTRACT

This study was conducted at the National Health Laboratory Services (NHLS) in Paarl, located in the Western Cape region, a renowned diagnostic testing laboratory. In the wake of the COVID-19 pandemic's emergence in 2020, healthcare systems were faced with unprecedented challenges, as laboratory testing was the primary means of diagnosing COVID-19 in patients. The NHLS Paarl laboratory was mandated to test high volumes of samples in a short timeframe (within 12 hours), so patients would receive their results and follow isolation protocols promptly if required. This situation brought to light a multitude of laboratory errors, which impacted the COVID-19 testing and resulting process. The primary objective of this research study was to meticulously analyse and identify root causes of these errors, with the aim of reducing and ultimately eliminating them, thus enhancing the quality of patient healthcare.

The conceptual framework underpinning this research employs the application of quality management tools such as: Pareto analysis, Ishikawa diagrams, the 5 Whys analysis, and the Failure Modes and Effects Analysis (FMEA). These tools are firmly rooted in the recognised quality management cycle known as the Plan Do Check Act (PDCA) model. The objective is to develop an optimised pre-analytic process enriched with preventative measures that ensures reduced laboratory errors in COVID-19 testing.

The research methodology adopted for this research is a mixed methods approach, whereby both quantitative and qualitative data was collected and analysed. The quantitative data was collected by means of TrakCare rejection reports during the period 1st January 2021 until 31st December 2021. The qualitative data was collected by means of conducting semi-structured interviews with key stakeholders in the NHLS, namely, the regional quality assurance manager, the business manager, and the head phlebotomist. The quantitative data was analysed using the quality tools: pareto analysis, Ishikawa diagram, the 5 whys analysis, and FMEA. The qualitative data was analysed by using the ATLAS.ti software.

The study's findings revealed deficiencies in the pre-analytical COVID-19 testing process which needed improvement. This research found that vital processes needed to be implemented at specific steps in the pre-analytical COVID-19 testing process, as well as the appointment of key personnel at specified stages to overcome the errors found in this area. Consequently, this research led to the development of an optimised pre-analytical COVID-19 testing process, aimed to enhance the quality and reliability of test results.

This study advocates for the implementation of pre-analytic process procedures and a structured deployment of training and education to health care professionals. Furthermore, it underscores the necessity of establishing check points at various stages, namely: check points prior to specimen collection, specimen and request form labelling, specimen handling, and specimen transportation to reduce and eliminate pre-analytical errors. Additionally, the study recommends annual performance reviews for nurses and clinicians and annual audits of the pre-analytic testing process. These mechanisms are deemed essential for achieving and sustaining continuous process improvement in healthcare.

Keywords: COVID-19, pandemic, laboratory errors, quality tools, Plan- Do- Check- Act model, optimised pre-analytic process, TrakCare rejection report, phlebotomist, check points, continuous process improvement.

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DEDICATION

This thesis is dedicated to mi amor, my husband.

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ABBREVIATIONS AND ACRONYMS

Abbreviation	Full Name
COVID-19	Coronavirus
EGK	Electronic gatekeeping
FMEA	Failure modes and effects analysis
ISO 15189:2012	International Organization for Standardization
LIS	Laboratory information system
NHLS	National Health Laboratory Services
PDCA Cycle	Plan do check act cycle
PQG	Procedure quick guide
QA	Quality assurance
QI	Quality indicator
QMS	Quality management system
RCA	Root cause analysis
RPN	Risk priority number
SANAS	South African National Accreditation Services
SARS-CoV2	Severe acute respiratory syndrome
TTP	Total testing process
WHO	World Health Organization

GLOSSARY

Term	Definition
5 Whys Analysis	A problem-solving technique that involves asking "why" multiple times (typically five) to determine the root cause of an issue.
Annual Audits	Scheduled examinations or assessments of the laboratory's operations, processes, and quality control measures to ensure compliance with standards.
Annual Performance Reviews	Formal assessments of the job performance and skills of healthcare professionals, often conducted to identify areas for improvement.
Asymptomatic	Refers to individuals who are infected with a disease (e.g., COVID-19) but do not exhibit noticeable symptoms or clinical signs of illness.
ATLAS.ti Software	Qualitative data analysis software used for coding, organising, and analysing qualitative research data, such as interview transcripts.
Biohazards	Substances or materials that pose a risk to human health, often encountered in laboratories working with infectious agents, chemicals, or other potentially harmful substances.
Continuous Process Improvement	The ongoing effort to enhance processes, products, or services by identifying and eliminating inefficiencies, errors, and deviations to achieve better results.
Continuous Process Monitoring	Ongoing surveillance and evaluation of processes to detect deviations and ensure they consistently meet quality standards.
COVID-19	A viral respiratory illness caused by the SARS-CoV-2 virus, leading to a global pandemic in 2020, characterised by symptoms such as fever, cough, and shortness of breath.
Diagnostic Testing	Laboratory tests and procedures used to determine a patient's health status, including COVID-19 diagnostic tests.

Failure Modes and Effects Analysis	FMEA is a systematic approach to identifying potential failure modes in a process or system and evaluating their effects and causes.
Haemolysis	The breakdown of red blood cells and release of haemoglobin into a specimen, which can interfere with laboratory testing and lead to inaccurate results.
Ishikawa Diagram	Also known as a fishbone diagram or cause-and-effect diagram, it is a visual tool used to identify and analyse the possible causes of a problem.
Isolation Protocols	Guidelines and procedures for isolating individuals who have tested positive for COVID-19 to prevent the spread of the virus.
Laboratory Errors	Mistakes, inaccuracies, or deviations from standard procedures that occur during laboratory processes, potentially impacting test results.
National Health Laboratory Services	A diagnostic testing laboratory responsible for healthcare testing services, such as COVID-19 diagnostics, often abbreviated as NHLS.
Pandemic	A global outbreak of a disease, typically occurring when a new infectious agent (e.g., a virus) spreads easily from person to person, affecting a large portion of the population across multiple countries or continents.
Pareto Analysis	A quality management technique that prioritises problems or factors by focusing on the most significant causes based on the 80/20 rule.
Plan Do Check Act (PDCA)	A continuous improvement cycle consisting of four stages: Plan (establish objectives), Do (implement plans), Check (evaluate results), and Act (take corrective actions).
Pre-analytical Process	The phase of laboratory testing that includes specimen collection, labelling, handling, and transportation before actual analysis occurs.
Quality Indicators	Measurable parameters or metrics used to assess the quality, accuracy, and reliability of laboratory processes, including testing and reporting.

Quality Management	A systematic approach to ensuring the quality of products or services, including processes to monitor and improve quality.
Root Cause Analysis	A systematic process for identifying the underlying causes of problems or errors to prevent their recurrence.
Specimen	A sample of material collected from a patient's body, such as blood, tissue, urine, or swabs, used for laboratory analysis and diagnosis.
Specimen Collection	The process of obtaining biological samples (e.g., blood, saliva, swabs) from patients for laboratory testing.
Specimen Handling	Procedures and precautions taken to ensure the integrity and preservation of collected specimens during storage and transportation.
TrakCare Rejection Reports	Reports that document instances where specimens or test requests were rejected or deemed unusable in the TrakCare system, a healthcare information system.
Transmissibility	The ability of a pathogen (e.g., a virus) to spread from one host to another, often quantified through parameters like the basic reproduction number (R0) or the effective reproduction number (Rt).
Zoonotic Disease	An infectious disease that can be transmitted between animals and humans, often originating from animals and potentially leading to outbreaks or pandemics.

CHAPTER ONE: SCOPE OF THE RESEARCH

1.1 Orientation of the study

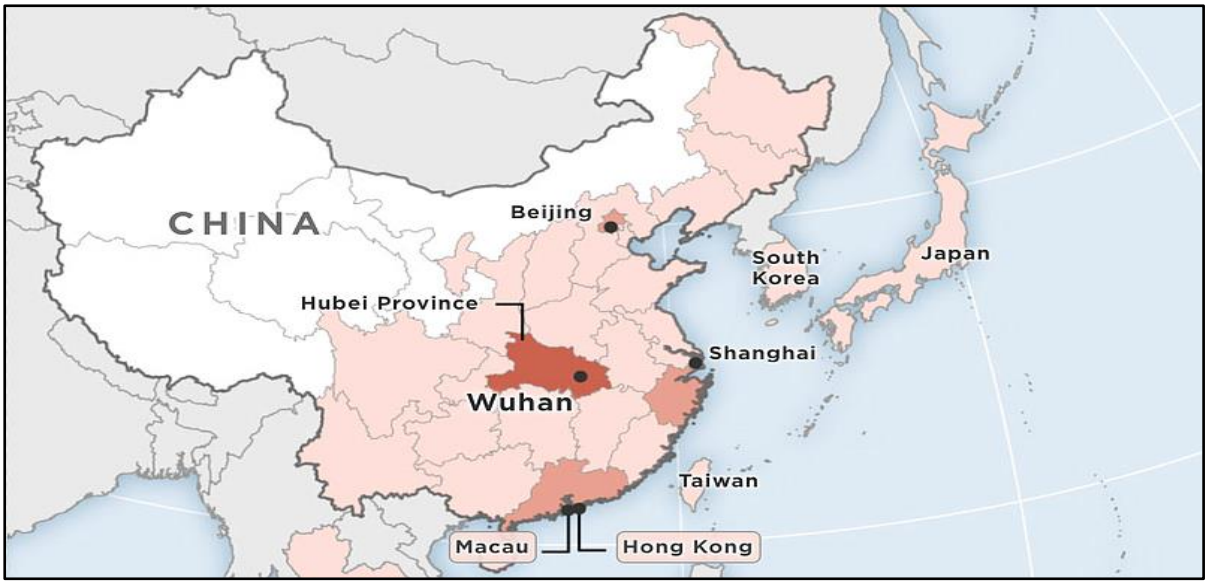
The outbreak of a new disease in 2020, known as Coronavirus (SARS-CoV2 or COVID-19), was a globally significant biological event. At the time of writing this research, 197 million people globally have been infected with the disease and 4.2 million people have lost their lives (Worldometer, 2021). Notably, Lippi and Plebani (2020: 1) describe the disease, which is caused by the novel Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV2), as a biological hazard and an insidious worldwide threat. Therefore, it is important that every country has a strategy to manage the disease. Accurate and timely diagnosis of the disease is a key element of disease management (Plebani, 2020), thus countries across the globe need to have an efficient and effective diagnostic laboratory service to contain the threat to their citizens. This introductory chapter briefly reviews the Coronavirus pandemic and its imminent health threats to society, as well as the role of the medical laboratory in diagnosing the disease in an effort to combat the spread of COVID-19. The chapter defines the research problem, presents the primary research question, followed by the investigative questions, and lastly the research objectives are explained. The chapter describes the conceptual framework adopted, and the ethical considerations that guided the research. The chapter concludes with the rationale for undertaking the research and a brief outline of the research study.

1.2 Background on COVID-19

The highly infectious COVID-19 disease was declared a "*public health emergency of international concern*" by the World Health Organisation (WHO) on the 30th January 2020 (World Health Organisation, 2020). Lippi and Plebani (2020: 1) argue that the COVID-19 disease is more devastating than other viruses as it has proved to be more infectious, with a high mortality rate. DNA analysis revealed that bats, which are classified as mammals, could be the possible reservoir for COVID-19, characterising COVID-19 as a zoonotic disease (Liu, Kuo and Shih, 2020). These authors define a zoonotic disease as a disease that is caused by a virus that can be transmitted from animals to humans or could be referred to as a disease that normally exists in animals, but may infect humans (Lui, Kuo and Shih, 2020). Although the intermediate source of origin of COVID-19 and details of transfer to humans is not known, the rapid human to human transfer of the disease has been widely confirmed (Shereen, Khan, Kazmi, Bashir and Siddique, 2020).

BBC News (2020) reported that COVID-19 initially emerged from the Hubei province in Wuhan, China in December 2019 (see Figure 1). The virus then mutated and rapidly spread to other countries.

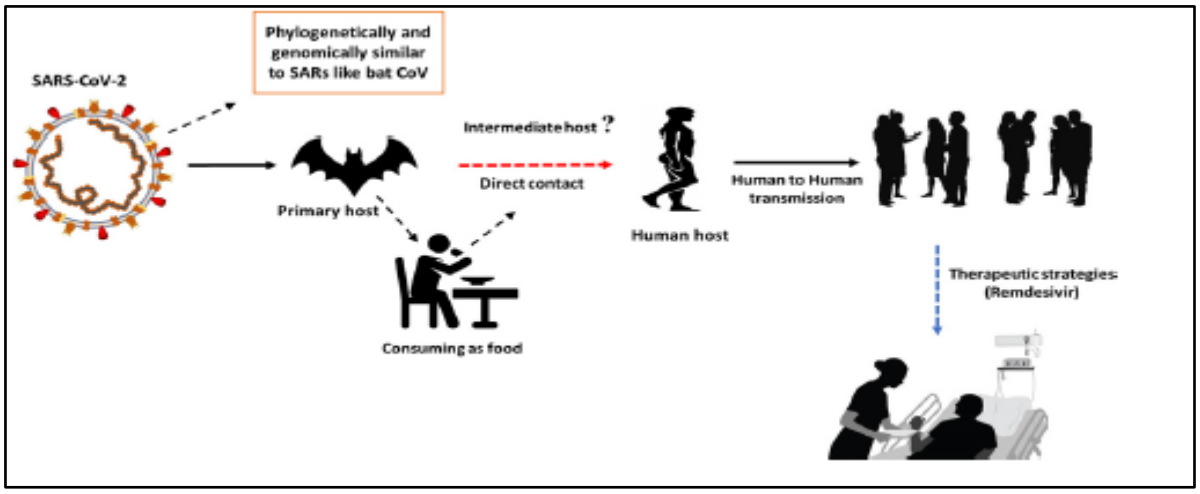
Figure 1: Map of Wuhan, China



Source: WNYC News (2020)

By March 2020, an assessment made by the World Health Organisation on the spread of COVID-19, characterised the outbreak of the disease in 2020 as a pandemic (Lui, Kuo and Shih, 2020). Due to the droplet transmission of the virus, COVID-19 is highly infectious, and it spreads rapidly from person to person (Yao, Zhang, Ma, and Zhou, 2020). The authors explain that tiny particles or respiratory droplets are spread through coughing or sneezing by a COVID-19 infected individual to others, and this promotes the highly infectious nature of the disease. Refer to Figure 2 for the COVID-19 transmission.

Figure 2: Transmission of COVID-19



Source: Shereen et al. (2020)

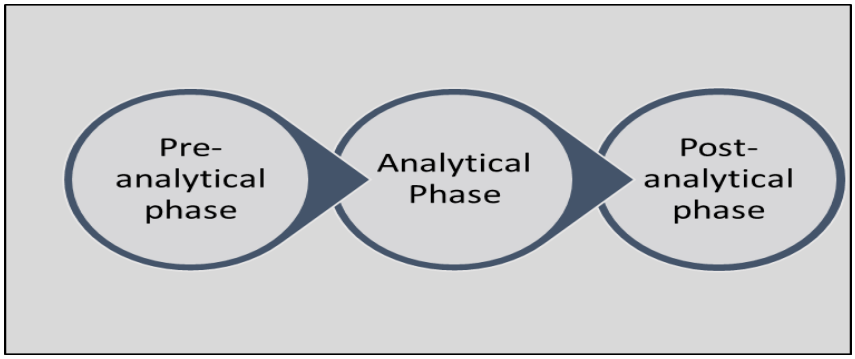
Furthermore, the incubation period of COVID-19 ranges from 1 to 14 days. The patients in the incubation period, also known as pre-symptomatic infected individuals, could potentially transmit the virus to uninfected people, which makes infectivity of COVID-19 disease exceedingly higher than other diseases (Ma, Su, Wang, Wei, Du, and Jiang, 2020: 1).

1.3 Laboratory functions that contribute to disease management

According to Jiang and Jiang (2015: 3) clinical diagnostic laboratories play an indispensable role in diagnosing diseases, since approximately 80-90% of all diagnosis are made based on laboratory results. This foregrounds the important function of laboratory testing during the COVID-19 pandemic, as laboratory testing is the primary mechanism to identify the disease. Lippi and Plebani (2020: 1) confirm that laboratory testing is vital for the diagnosis, care, and maintenance of patients suspected or confirmed with COVID-19. Consequently, laboratory errors may have serious outcomes on patient care and safety.

From a clinical and economic perspective, the consequences of laboratory errors are always significant, however in the case of infectious outbreaks, such as the COVID-19 pandemic, the effects are greatly magnified, as disease prevention and containment strategies are jeopardised (Lippi et al., 2020). Plebani and Carraro (1997: 3) defines laboratory errors as any defect or non-conformity in any of the three phases of the laboratory process, which Miligy (2015) lists as pre-analytic, analytic, and post-analytic phase (see Figure 3). When a laboratory error occurs, the consequence is a rejected test. The test is rejected due to specific predetermined criteria, which is set out by the laboratory (described in further detail in Chapter 2) not being met. When a test is rejected, the patient's sample is not analysed. The dire consequence of a rejected test is that the patient does not receive a diagnostic result to permit treatment and management of disease.

Figure 3: Laboratory phases



Source: Researcher (2021)

The foregoing discussion implies that laboratory errors that lead to specimen rejections may be considered an indicator of the quality of a laboratory service. Plebani and Laura (2011: 10) defines a Quality Indicator (QI) as a measure for assessing a particular process or outcome, and it is a tool for the quantitative measure of quality. Essentially, QIs are one of the Quality Management System (QMS) tools, that are used in laboratories to monitor and control the efficiency of key operational areas. Monitoring and measuring QI's offers the possibility of rapid insight into the level of service quality, so that improvements may be made where deviations are detected (Plebani and Laura, 2011). This underscores the importance of accurately identifying critical QIs during the management of laboratory quality, and the importance of effectively monitoring QIs. Quality Indicators at the NHLS laboratories are discussed in the next section.

1.4 Quality Indicators at the National Health Laboratory Services

Plebani and Sciacovelli (2014) state that QIs are a tool for assessing a particular process or outcome. Moreover, QIs are also known to be a tool for the quantitative measurement of quality. Thus, the NHLS quality division has mandated that NHLS laboratories implement systematic monitoring of QIs as part of its QMS, to assess the laboratory's performance. The NHLS quality manual (2017) indicates that each NHLS laboratory must identify QIs that are the most relevant and appropriate for that laboratory, and each laboratory must develop a schedule to monitor the QI. The QI must be capable of quantitatively reflecting quality in each phase of the laboratory (pre-analytical, analytical, and post-analytical).

A preliminary background survey of the NHLS Paarl laboratory highlighted one critical QI in the pre-analytic phase that requires monitoring: laboratory errors that lead to specimen rejections. Since the pre-analytic phase involves several functions, this QI is concerned with all activities associated with these functions including specimen collection, specimen handling, specimen labelling, specimen storage, and specimen transport. Moreover, there are various role-players and stakeholders such as nurses, clinicians, and administrative personnel, apart from laboratory personnel whose roles and actions all have a lasting impact on the quality of laboratory testing and analysis. Thus, this research study sets out to improve the quality and minimise and reduce errors, to ensure patient safety and well-being, by analysing the functions with associated role-players and stakeholders.

1.5 Research problem

An analysis of laboratory analytics performed in January 2022 indicated that the laboratory error rate for COVID-19 testing at the NHLS Paarl laboratory in the Western Cape is greater than 4%. The effects of errors have a serious impact on the patient, which is why the NHLS'

top management mandates the NHLS Paarl to measure, monitor, and prevent laboratory errors. Accordingly, the NHLS Paarl laboratory manager has set the target for laboratory errors to be 4% or below using baseline data at the Paarl laboratory. Laboratory error rates that exceed 4% are considered to be a cause for concern and should be monitored and improved upon. This research study is an endeavour to reduce the error rate to less than 4%.

1.6 Primary research question

Against this backdrop, the primary research question for this research study is: Can an optimised pre-analytic process be developed, which includes preventative measures, to ensure that laboratory errors remain under 4% during COVID-19 testing?

Four investigative questions were developed to systematically answer the primary research question. The investigative research questions are:

1. What are the critical contributing factors that are responsible for the unacceptable laboratory errors in COVID-19 testing?
2. What are the risks of laboratory errors in COVID-19 test process to patient healthcare?
3. What measures can be put in place to reduce and eliminate the laboratory errors in COVID-19 testing?
4. What are the factors that should be included in developing an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing?

1.7 Research objectives

The following serve as the research objectives:

1. Identify the critical contributing factors that are responsible for the unacceptable laboratory errors in COVID-19 testing.
2. Identify the risks of unacceptable laboratory errors in COVID-19 testing to patient healthcare.
3. Identify the measures that can reduce and eliminate the laboratory errors of COVID-19 testing.
4. Develop an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing.

1.8 Rationale for performing the research

The rationale for performing this research study is to develop an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing. Due to the rapid spread of the COVID-19 disease in the human population

and the high mortality rate, great emphasis has been placed on laboratories by the National Health Department in ensuring the quality of the samples received for laboratory testing. It is anticipated that the results of this research study will be used to benefit healthcare workers in the forefront of dealing with a global health crisis, such as COVID-19, and will ultimately save lives.

1.9 Conceptual framework

In this study, a conceptual framework consisting of a selection of quality tools namely Pareto analysis, Ishikawa diagram, 5 whys analysis, and Failure Modes and Effects Analysis (FMEA) is used. These tools are used in a specified sequence, rooted in a recognised quality management cycle, the Plan Do Check Act (PDCA) cycle (also known as the Deming cycle). It consists of four phases in which specific work is done and is a trusted approach used to manage quality (Plebani, 2020). Thus, it is adopted by this research to provide a scaffold for the abovementioned quality tools, geared towards meeting the research objectives of this study. At the time of writing this research, a search of literature returned a paucity of research on the optimisation of diagnostic laboratory processes. Therefore, a conceptual framework consisting of appropriately aligned quality tools as part of a recognised PDCA quality approach was composed to perform this research. COVID-19 is a newly diagnosed virus which emerged in 2019, hence a novel approach was needed to meet the research objectives. The tools included in the PDCA framework are:

1. Pareto analysis was used in the Plan phase to investigate the potential causes of specimen rejections and assist in prioritising decisions that has the greatest impact on specimen rejections.
2. Ishikawa diagram was used in the Do phase to identify the possible causes and effects of specimen rejections.
3. 5 whys were used in the Do phase to explore the cause-and-effect relationship of specimen rejections.
4. FMEA was used in the Act and Check phase to identify all the possible failures in the process and then develop control measures to prevent failures.

Chapter 4 of this research presents more detailed explanations of the PDCA and the quality tools used within the cycle.

1.10 Research methodology

The methodological approach adopted for this study is a mixed methods approach, where both quantitative and qualitative data are collected and analysed. This approach is adopted to

gain a more meaningful understanding of the research problem than can be secured by using only one method, with the ultimate intention of developing an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing. The methodological approach is discussed in greater detail in Chapter 4.

1.11 Ethics

Stichler (2014: 2) argues that ethics refers to the norms of conduct, or of precautionary action to ensure that research does not have any unintended negative consequences. Research ethics promotes the knowledge, truth, and avoidance of error and protect against fabrication, falsifying, or misrepresenting research data (Stichler, 2014).

In this research study the following ethical considerations have been met:

- The initial step, before conducting the research involved seeking permission from the NHLS in order to conduct the research and to use the data in a safe and ethical manner.
- The researcher had also gained ethical clearance from CPUT for conducting this research study.
- For the purposes of the quantitative component of this research study only laboratory records are used, however the researcher ensured that anonymity and confidentiality are met. This was met by ensuring all names, surnames, ID numbers, race, gender, and socio-economic status were omitted, and only statistical data were used.
- For the purposes of the qualitative part of this research study consent was obtained from research participants prior to data collection, participants were informed that no rewards were given for data and there are no penalties for refusing to provide data and research data was anonymised during transcription.
- The data collected and analysed for the research study was stored safely on an electronic platform on the researchers' laptop, which is under strict access control where only the researcher has full access.

In cognisance of the above, this study ensures there are no breaches of confidentiality, plagiarism, fabrication, and falsification of data. This study maintains a high regard for ethical considerations of all parties and data involved in the study.

1.12 Outline of the research

The following is a brief outline of the chapters that appear in this research study.

Chapter 1: Introduction

This chapter describes the parameters of the study, the background, research problem, primary and investigative research questions, research objectives, conceptual framework, ethical considerations, and the rationale for performing the research.

Chapter 2: Background

The chapter presents the context of the organisation (NHLS) and the COVID-19 pandemic. It clearly outlines quality practices and procedures of the organisation and within the context of this research study.

Chapter 3: Literature review

This chapter reports on other academic studies and articles that have been written on COVID-19 and the risks of laboratory errors during the pandemic. It discusses the conceptual framework of this study and provides a succinct review of literature to the quality tools used in this study.

Chapter 4: Research methodology

This chapter describes the research design and methodology of the study. It explains the vital aspects about the research instrument, data collection and analysis.

Chapter 5: Discussion of quantitative data analysis and research findings

Once data has been collected, and analysis of the quantitative data takes place, the results are presented and discussed in this chapter.

Chapter 6: Discussion of qualitative data analysis and research findings

This chapter discusses the analysis and interpretation of the qualitative data using semi-structured interviews.

Chapter 7: Conclusions and recommendations

Chapter seven explains the overall findings of the research based on the data analysis, and recommendations are provided.

1.13 Chapter summary

This chapter presented a brief introduction of the COVID-19 pandemic and its impact on the health care system. It also showcased the fundamental role of the laboratory during the pandemic as well as the laboratories' measures towards quality improvement. The chapter then presented the research problem, followed by the primary research question, investigative

questions, and the research objectives. The chapter presented the reader with an outline of the conceptual framework for the research and briefly mentioned methodological approach of the study before ethics was discussed. Lastly, an outline of the research chapters was presented.

The next chapter describes the research background such as the organisational context of the NHLS and laboratory processes. Laboratory quality systems are also presented as well as laboratory errors and its impact on the COVID-19 pandemic.

CHAPTER TWO: RESEARCH BACKGROUND

2.1 Introduction

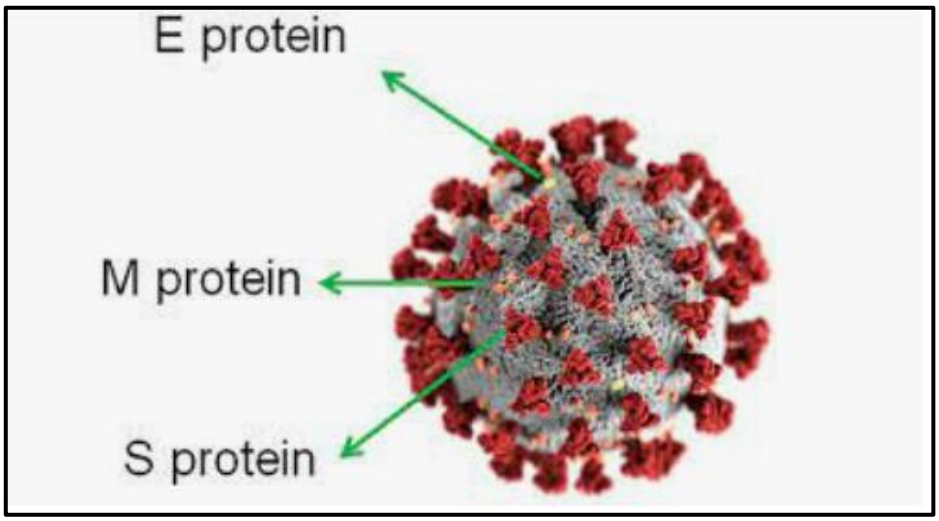
The previous chapter described the emergence of the Coronavirus pandemic and the risk it poses to society and the national and local healthcare systems. It also presented the research problem, primary research questions and research objectives and the ultimate purpose of the study. This chapter expands on Chapter 1 by offering an in-depth description of the research background with respect to: the COVID-19 pandemic, laboratory testing for COVID-19, the organisational context of the NHLS, laboratory processes, quality in the laboratory, laboratory information systems, laboratory errors, and the impact of laboratory errors. This chapter depicts the research environment in its entirety and advances the context of the study. Since the emergence of the COVID-19 pandemic, the role of the medical laboratory has been amplified and its function has garnered considerable significance. Lippi and Plebani (2020) point out that a confirmatory diagnosis of COVID-19 would not be possible without laboratory testing and highlight several systems and procedural factors, which influence the quality of the service laboratories provide in this regard. This chapter probes deep into the NHLS, Paarl laboratory in the Western Cape, to investigate and expose the reasoning behind the COVID-19 error rates in an effort to develop an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing.

2.2 Background to COVID-19 and motivation for the study

COVID-19 is a highly transmissible virus that made its mark on local and international borders on 30th January 2020. It was first diagnosed in Hubei province in Wuhan China in December 2019, and rapidly mutated to other strains, spread widely to several other countries, and attained a catastrophically high mortality rate, characterising the virus as a pandemic (Lui et al., 2020).

COVID-19 originates from the Coronaviridae family, which is a form of respiratory disease which can lead to pneumonia. The COVID-19 structure encompasses a large family of single-stranded positive sense RNA viruses, with a 26-32 kilo base genome, which usually causes mild disease, mostly mimicking influenza, however, some strains are associated with more severe pathology, which can evolve to severe acute respiratory distress syndrome and death (Lippi and Plebani, 2020). Figure 4 depicts the pathological genome of the Coronavirus disease.

Figure 4: COVID-19 structure

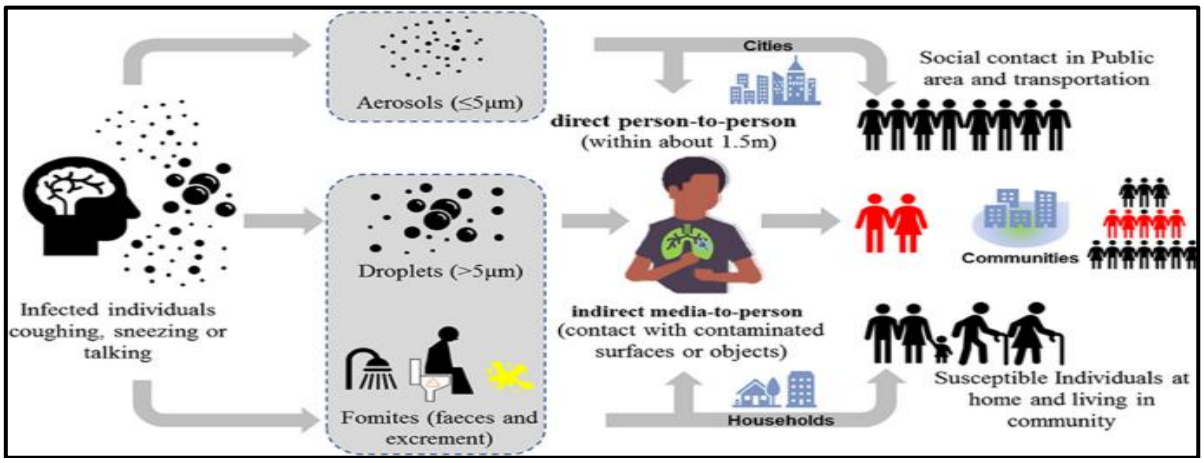


Source: SciELO (2020)

Typical features of the disease as explained by Liu et al. (2020:1), includes flu like symptoms such as fever, malaise, coughing, diarrhoea and dyspnoea. Wu, Wu, Lui, and Yang (2020) confirm that it is also possible for patients to be infected but not display symptoms, classifying them as asymptomatic. In cognisance of the above, COVID-19 usually causes a mild disease mimicking the flu, however, in some cases COVID-19 may cause more adverse health conditions and death.

Wu et al. (2020: 45) reports that the main route of transmission is through respiratory droplet transmission, indicating that the virus is spread by close contact with an infected person, exposed to coughing, sneezing, respiratory droplets or aerosols. Figure 5 demonstrates the routes of transmission of COVID-19.

Figure 5: COVID-19 routes of transmission



Source: Frontiers Online (2022)

The aerosols spread by an infected person can penetrate the human body (lungs) via inhalation through the nose or mouth (Shereen et al., 2020). COVID-19 therefore has the distinct capability of spreading from person to person, thus producing secondary cases among nearby contacts, including relatives and healthcare workers, thereby exponentially increasing the transmission rate. Consequently, the high transmissibility of the COVID-19 virus has triggered an unexpected and unprecedented universal crisis infecting millions of people across the globe. Lippi and Plebani (2020) justly report that stringent measures must be taken to contain and prevent the spread of the disease. In cases of serious biohazards such as the current COVID-19 pandemic, laboratory testing plays a pivotal role in the rapid and accurate identification of the disease by means of molecular diagnostic assays, which represents a cornerstone in diagnostic testing (Lippi and Plebani, 2020: 3). These authors affirm that laboratory testing is the primary mechanism to identify the COVID-19 disease. This foregrounds the vital importance of laboratory testing, as the result of laboratory testing informs crucial healthcare decisions on COVID-19 treatment, management, isolation and quarantine strategies.

2.3 Laboratory testing and COVID-19

Laboratory testing is the backbone of modern healthcare systems (Rana, 2012: 319). The review of literature (Rana, 2012) reveals that laboratory testing plays an essential part of the healthcare system as it leads to results that directly affect clinical aspects regarding the patient's diagnosis, treatment and management. Lillo, Salinas, Garrigos, Santana, Gutierrez, Marin, Miralles, and Uris (2012) argue that laboratory results influence 80% to 90% of the clinical decisions made regarding treatment and disease management. As in the case of the COVID-19 pandemic, the role of laboratory testing has been highlighted once more as the cornerstone of healthcare, as it is the only means of detecting the virus in symptomatic and asymptomatic patients. Plebani (2021: 1036) argues that the COVID-19 pandemic dramatically challenged the testing capacity of laboratories as many laboratories found themselves struggling to cope with the unexpected increase in workload.

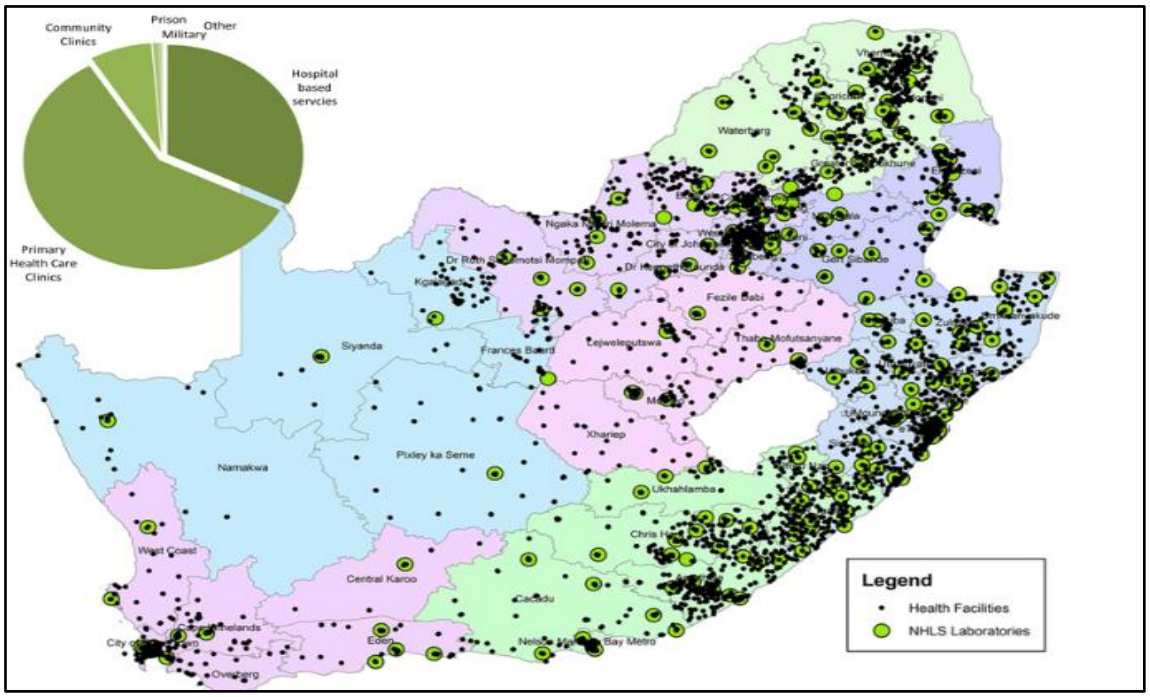
Preceding the COVID-19 pandemic, the importance of laboratory testing was always recognised (Plebani, 2020) however the pandemic raised greater awareness of the essential contribution made by laboratories to diagnostics and the management of cases of suspected or confirmed COVID-19 infections. Apart from the vital stance diagnostic laboratories possess in the healthcare system, timeliness of reporting laboratory results has always been a fundamental attribute that all laboratories needed to secure, as pointed out by Plebani (2021). Since the emergence of the COVID-19 pandemic, this attribute has attained greater magnitude, as timeliness of results directly impact patient isolation and quarantine protocols

(Plebani, 2021). Delays in test reporting as explained by Plebani (2021) due to poor quality of specimen or the inability of the laboratory to perform the test, negatively impacts both the patient outcomes and delays isolation, which is the key to reducing the spread of the COVID-19 virus. Plebani (2021) affirms that the quality of the laboratory service is a major factor, which directly affects the quality of healthcare systems, and in this case national protocols in line with COVID-19 isolation and quarantine strategies. The NHLS is one of the key role players involved in the diagnostic testing of COVID-19 in the African population during the COVID-19 pandemic.

2.4 Organisational context of the NHLS

The NHLS has a well-established quality management system in place to ensure quality diagnostic results are issued to patients (NHLS Quality manual, 2017). National Health Laboratory Service (2020) reports that the NHLS is the largest diagnostic laboratory service in South Africa, which comprises of 349 laboratories across the 9 provinces. The NHLS services 80% of the South African population. In the Western Cape alone, there are 18 diagnostic laboratories that provide diagnostic services to clinics, hospitals, prisons and research centres (National Health Laboratory Service, 2020). Figure 6 presents a geographical depiction of the location of all NHLS laboratories across South Africa.

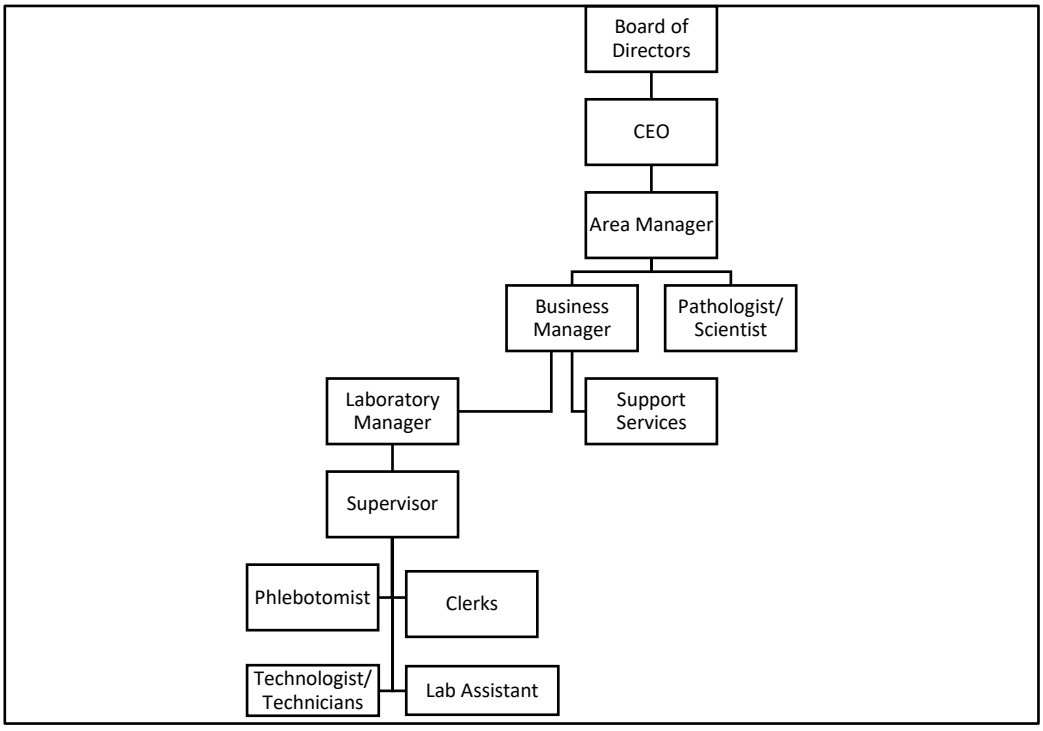
Figure 6: Geographic location of NHLS laboratories in South Africa



Source: ResearchGate (2021)

The NHLS is regarded as a health care provider; which is an institution that provides health services to the population (National Health Laboratory Service, 2020). The primary service provided by the NHLS is to accurately test medical samples and provide diagnostic results to the requesting medical party within a prescribed minimum timeframe, while maintaining high levels of quality in each step of the process. The NHLS is one of the principal health care providers that performs COVID-19 diagnostic testing for the population during the pandemic.
The governance structure of the NHLS includes: a board of directors that are responsible for making fiduciary decisions on behalf of the shareholders of the organisation. The tier below this is composed of the executive members who ensure corporate governance, strategic planning, operational implementation, and financial management. The next managerial tier is the NHLS area and business managers who ensure the business objectives are met and are aligned with the organisation's strategic objectives. The last tier includes the laboratory technologists and technicians, laboratory assistants, laboratory clerks and phlebotomists who ensures patient samples are collected, processed and authorisation of results. Refer to Figure 7 for structure of the NHLS.

Figure 7: NHLS Organogram



Source: Researcher (2021)

Collectively, the NHLS' vision and mission across all tiers is to deliver high quality pathology and laboratory services that are clinically efficient and cost effective. Thus, each level of the NHLS' structure is geared towards maintaining and improving its vision and mission (National

Health Laboratory Service, 2020). The NHLS is a service organisation and laboratory processes form the core of its operation. One of the processes is the COVID-19 testing process, and the errors in this process led to the unacceptable laboratory error rate (greater than 4%). The following section provides a detailed description of the laboratory processes involved in COVID-19 testing.

2.5 NHLS operations

As discussed previously, the NHLS provides a diagnostic service to the public which is delivered through the means of several laboratory processes, one of them being the COVID-19 testing process. A common feature of the laboratory processes (from when the patient first makes contact with the clinician to when the results are issued to the clinician) consists of three main phases. The three phases are pre-analytical, analytic, and post-analytical, which make up the total testing process (TTP) (Plebani and Carraro, 1997).

Plebani (2010) refers to these as the 'classical' laboratory phases. In the recent years, much attention has been drawn to two additional laboratory phases referred to as 'pre-pre-analytical phase' and 'post-post-analytical phase'. The pre-pre-analytic and post-post-analytic phases are usually performed neither in the clinical laboratory, nor under the control of the laboratory personnel (Yusof and Arifin, 2016).

Yusof and Arifin (2016) subdivide the pre-analytical phase into a 'pre-pre-analytical phase' and a 'true' pre-analytical phase as follows:

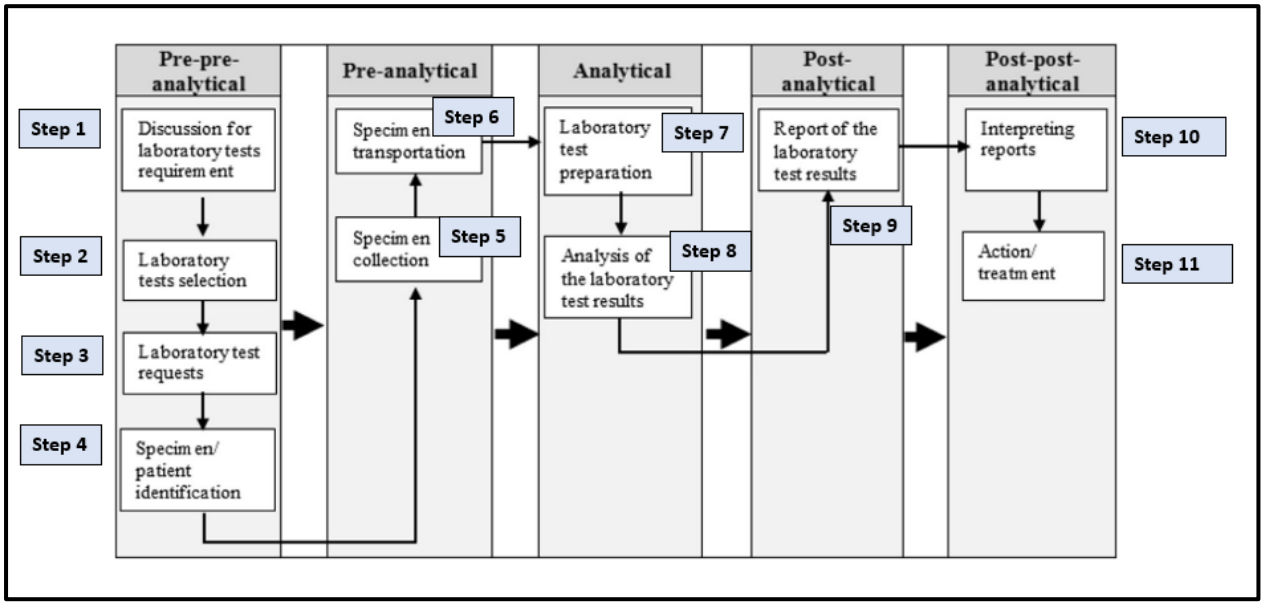
- Pre-pre-analytical phase: comprises of the initial procedures done out of the laboratory setting, such as the doctor rooms, clinic, or hospital bed, and involves test requesting, patient and sample identification and sample collection.
- 'True' pre-analytical phase: includes tasks undertaken within the laboratory walls after specimen reception. This phase involves steps that are required to prepare the sample for analysis such as centrifugation, sorting and aliquoting.

The author also distinguishes between the post-analytical phase and the 'post-post-analytical phase' as follows:

- Post-analytical phase: involves the laboratory providing timeous results to the clinician or nurse either by a hardcopy report or by an electronic report.
- 'Post-post-analytical phase': involves the clinicians' interpretation of the results and immediate delivery and treatment of the patient (Yusof and Arifin, 2016).

In each laboratory phase there are trained personnel who fulfil specific roles and functions. Figure 8 highlights the different phases in the laboratory. For the purposes of this research the pre-pre-analytic and pre-analytic phase, will be amalgamated into one phase and referred to as the 'pre-analytic phase.'

Figure 8: Phases of the laboratory



Source: Yusof and Arifin (2016)

Quality must be maintained in each of the laboratory phases to reduce and prevent errors in patient results. Carraro (1997) posits that any non-conformity or defect found in any phase of the laboratory may result in compromised patient care. All the patient data found in each laboratory phase is captured on the laboratory information system known as TrakCare.

2.5.1 Laboratory information systems

The NHLS utilises a laboratory information system (LIS) known as TrakCare to manage laboratory data in the pre-analytic, analytic, and post-analytic phase. All patient information and laboratory records and results are electronically stored on TrakCare for an unlimited period of time. With the aim of surveillance and monitoring, TrakCare has the capability to electronically generate and store reports linked to laboratory errors resulting in rejected tests. This report on TrakCare is referred to as cancelled test analysis (National Health Laboratory Service TrakCare Lab user manual, 2020). For the purpose of this research the cancelled test analysis report will be referred to as the rejection report, which is drawn from TrakCare and used for data collection and analysis.

2.5.2 Confidentiality and secure access of results

To protect the confidentiality of patient results and laboratory data, only authorised personnel have access to TrakCare. This access is granted as per authorised user application request form, and the level of access is defined by the information technology security group at the NHLS IT department. Additional restrictions may be applied depending on the type of access requested by the user. The laboratory staff requires two unique usernames and passwords in order to log onto TrakCare, thus ensuring confidentiality and protection of patient and laboratory data. User access is confined to laboratory users of the NHLS. For this research, only the researcher has access to the TrakCare rejection report.

2.5.3 Laboratory scope of testing

The NHLS Paarl laboratory performs an array of tests, 172 in total (refer Appendix A for the scope of tests performed at the laboratory). It is worth noting that of the tests offered by the laboratory, only data related to laboratory errors in the COVID-19 testing process are used for analysis in this research study. Details on the data collection and analysis, as well as limitations and delimitations of the study are discussed in Chapter 4 of this study. During the test process of each type of test that can be performed by the NHLS Paarl laboratory, stringent standard quality control measures that form part of its QMS are followed. The next section discusses the laboratory QMS.

2.6 Laboratory Quality Management Systems

“Doing the right thing at the right time, in the right way, for the right person and having the best possible results” is a definition of quality in a laboratory setting suggested by Crema and Verbano (2015) citing Agency for Healthcare Research and Quality. Crema and Verbano (2015) adds that a healthcare system, of which diagnostic laboratories are a part of, is considered of high quality only if it is; accessible, acceptable, safe, effective, timely, efficient, patient- centred, and equitable. The implementation quality standards at any laboratory are verified through the process of accreditation (Gershy-Damet et al*.,* 2010: 394). By definition, accreditation encompasses the formal recognition that the laboratory is competent to carry out specific tests according to Lippi, Plebani and Simundic (2010). The NHLS Paarl laboratory has achieved accreditation status through the South African National Accreditation System (SANAS). The laboratory follows a stringent schedule for accreditation annually to ensure its processes conform with ISO 15189:2012 requirements, and that the results produced by the laboratory are of high quality and is reliable.

Apart from participating in a rigorous accreditation program, the NHLS quality division has implemented that its laboratories incorporate QIs and systematic monitoring of QIs as part of

its QMS, to assess the laboratories performance, as discussed in Chapter 1. Thus, laboratories must continue to strive to improve the quality and minimise and reduce errors, to ensure patient safety and wellbeing. Participating in accreditation programs and rigorous monitoring of QI's ensures patient safety in all NHLS processes including the COVID-19 testing process.

2.7 COVID-19 testing process

The pre-analytic phase COVID-19 testing process consists of eight process steps. It is key for laboratories to manage and maintain quality in these steps which make up the pre-analytic phase, as it is a fundamental phase preceding the analytical and post-analytical laboratory phases (Plebani, 2020). Figure 9 illustrates the pre-analytic COVID-19 testing process.

Figure 9: Pre-analytic COVID-19 testing process

COVID 19 TEST PROCESS STEP
Pre-analytical
1. Discussion on laboratory test requirement
2. Laboratory test selection
3. Capture of the patient data and completion of the request form
4. Patient preparation
5. Specimen collection
6. Labelling of specimen and request form
7. Specimen handling and storage
8. Specimen transportation

Source: Researcher **(**2022)

The pre-analytic COVID-19 testing process begins with the clinician or nurse discussing the need for the laboratory test with the patient, based on symptoms the patient presents with.

Thereafter, the clinician or nurse is responsible for selecting the appropriate laboratory test, that will aid in diagnosis of disease or illness and manage treatment for the patient. Thereafter, the request form is completed by the clinician or nurse with the correct patient details, before patient preparation takes place for specimen collection. The specimen and request form are correctly labelled with the patient details, before the specimen is appropriately stored for transportation to the laboratory for testing. Within these eight steps, potential errors may arise leading to specimens being rejected by the laboratory.

The clinical consequences of laboratory errors are always significant according to Lippi et al. (2020: 1), but in the case of infectious outbreaks such as the COVID-19 pandemic, the consequences are damaging. A review of literature showed that although laboratory errors occur in all phases of the laboratory testing process, the vast majority of errors occur in the pre-analytic phase. Al-Ghaithi et al. (2017) report that up to 70% of laboratory diagnostic errors are due to non-conforming samples, defined as specimens which result from inappropriate sample collection, patient preparation or specimen acquisition, handling, transport and/ or storage, which are all regarded as pre-analytical errors.

2.7.1 Pre-Analytical Errors

Lillo et al. (2012: 4), advances that a possible reason for the pre-analytical phase being the phase where most laboratory errors occur, as ‘activities in this phase are fundamentally manually performed’. Manually performed operations incur numerous errors as there are usually inadequate or a complete lack of control measures for that process (Kang et al., 2020). Unlike the other laboratory phases, the occurrence of pre-analytic errors remains challenging as most activities are not performed under the direct control of clinical laboratories (Kang et al., 2020).

Al-Ghaithi et al. (2017) argues that pre-analytically, the proper collection of an appropriate specimen and its secure transportation to the laboratory prior to analysis is essential to achieve reliable results. Notably, this phase is thought to be the most vulnerable part of the testing process and presents the greatest challenge. Lippi et al. (2020: 1) asserts that in the case of COVID-19, the most common pre-analytical problems that occur are identification problems (transcription), inadequate procedures for collection, handling, transport and storage of the specimen, collection of inappropriate or inadequate material (for quality or volume), presence of interfering substances, and sample contamination. These render the specimen a poor-quality specimen and negatively impacts the quality of the results produced. Poor quality specimens result in the laboratory rejecting the specimen and failing to process the specimen, resulting in a test not being done and a patient not receiving a valid result (Lippi, 2021).

2.7.2 Consequences of Laboratory Errors (Pre-Analytical)

Non-conforming samples are a critical obstacle to the delivery of valid laboratory results, wasting both time and resources, and impeding patient care (Al-Gaithi et al. 2017: 312), when a sample is rejected and testing is halted due to a laboratory error that occurs. Lillo et al. (2012: 6) argue that it is necessary to establish appropriate measures to reduce these errors and improve the quality of the specimen towards improving patient care. In the context of the COVID-19 pandemic the severity of pre-analytical errors is heightened as the errors can have a serious, albeit indirect, impact on public health policies, emergency plans, and restrictive measures established by national authorities for containing the outbreak. This is due to these errors leading to patients not receiving diagnostic results that are necessary for self-isolation and quarantine measures (Lippi et.al, 2020: 1). Hence, it is important that an optimised pre-analytic process be developed to manage pre-analytical activities with the aim of preventing such errors from occurring. In line with this, the NHLS has established a rigorous QMS which incorporates quality indicators which aims to reduce potential errors in the pre-analytic COVID-19 testing process.

2.8 Laboratory errors as an indicator of quality

The consequence of a rejected test is the nurse or clinician not being able to receive a valid result from the laboratory to provide diagnostic or therapeutic care for the patient. The NHLS Paarl laboratory uses laboratory errors as one indicator of quality. This quantitative metric provides the NHLS with evidence of the laboratory's performance against quality targets. The two features of laboratory errors that classifies them as an indicator of quality are, (1) the number of laboratory errors found, and (2) the significant impact of these errors on patient care and safety.

The laboratory has established a standard criterion for accepting and rejecting patient samples based on suitability for analysis during the 'true' pre-analytical phase. Table 1 depicts the laboratories acceptance and rejection criteria for sample analysis. The errors in Table 1 arose from the pre-pre-analytic and pre-analytic phase. As discussed previously in the chapter, both these phases were merged and referred to as the 'pre-analytic phase' for this research study.

Table 1: Specimen acceptance and rejection criteria

SPECIMEN	ERROR	ACCEPT/REJECT	RESPONSIBLE PHASE
All types	Wrong specimen/ container/ Additive	Reject	Pre-Analytic
All types	Patient name and surname does not correspond from sample to request form	Reject	Pre-Analytic
All Types	Specimen and forms incorrectly labelled (Patient stickers don't match)	Reject	Pre-Analytic
All Types	Incorrect site of specimen	Reject	Pre-Analytic
All Types	Collected and transported to lab at incorrect temperature	Reject	Pre-Analytic
All types	Broken specimen containers with specimen	Reject	Pre-Analytic
All Types	Specimen collected in expired containers	Reject	Pre-Analytic
All types	No date and time of collection	Accept with comment	Pre-Analytic
All types	No gender and age	Accept with comment	Pre-Analytic
All types	No clinical information stated	Accept with comment	Pre-Analytic
All types	Leaked out	Reject	Pre-Analytic
All types	Previously requested test 1-3 days prior	Reject	Pre-Analytic
EDTA	Low volume (<2 ml)	Reject	Pre-Analytic
EDTA	Clotted	Reject	Pre-Analytic
Sodium Citrate	Low volume (<4.5 ml)	Reject	Pre-Analytic
Sodium Citrate	Clotted	Reject	Pre-Analytic
Sodium Citrate	Old sample (sent to lab 24 hours after collection)	Reject	Pre-Analytic
Serum	Grossly Haemolysed	Reject	Pre-Analytic
Serum	Low volume (<0.5 ml)	Reject	Pre-Analytic
Heparin	Clotted	Reject	Pre-Analytic
Heparin	Low volume (<1 ml)	Reject	Pre-Analytic

Source: Acceptance and rejection criteria for specimen's manual (2019)

A more detailed explanation of the types of errors listed in Table 1 are provided in the section that follows.

2.8.1 Laboratory errors linked to COVID-19 testing process

Evaluation of Table 1 leads this study to deduce that there are five general types of errors at NHLS Paarl laboratory that results in errors which ultimately leads to rejected samples and a higher error rate. These are: haemolysis, clotted ethylene diamine tetra-acetic acid samples (EDTA), insufficient specimens, cancelled by electronic gatekeeping, Information that does not match, incorrect specimen collected, and specimen too old.

1. Haemolysis, clotted EDTA, and insufficient specimens:

The NHLS handbook (2020), defines haemolysis as the rupture of red cells in the collection tube, clotted EDTA refers to the inappropriate clot formation of blood in the EDTA collection tube, and insufficient specimens refer to any specimen that may be underfilled (<0,5 ml) of blood or fluid. Insufficient specimens also include specimens such as swabs or blood collection containers that arrive at the laboratory empty or without suitable testing material. All the above phenomenon results in an unsuitable specimen for laboratory testing, and subsequently leads to the specimen being rejected. A suitable sample for laboratory testing would be any sample that is free from haemolysis, clots, and one that is sufficiently filled (>0,5ml).

2. Cancelled by electronic gatekeeping

Electronic gatekeeping (EGK) occurs when tests are electronically rejected based on the time that has elapsed since the patient had his/ her last test. This refers to repeat testing on the same patient 1-3 days from the initial test. Electronic gatekeeping also takes into account the interpretation of the previous test results, and whether the test results are within or out of acceptable reference ranges. Reference ranges are a set of values that are deemed normal for a physiological measurement in healthy patients (NHLS handbook, 2020). The purpose of EGK is to avoid duplicate requests for laboratory tests for patients where the same laboratory test was requested between 1-3 days prior. This system is in place to assist hospitals to control unnecessary expenditure and overutilisation of laboratory tests. Refer to Appendix B for list of tests affected by EGK.

3. Information does not match

The NHLS handbook (2020), instructs nurses and clinicians on correctly identifying the patient specimen by the use of a label or sticker so that the details on the specimen corresponds to the request form. Any deviation from the sample to the request form and vice versa results in a specimen being rejected. The details on a sample such as name, surname, date of birth, and hospital number, validates the information on the request form. Similarly, the details on the request form such as the name, surname, date of birth, and hospital number validates the accuracy of the sample taken. The rejection category of information that does not match, will be referred to as mismatched information in this research study.

4. Incorrect specimen collected

The NHLS handbook (2020) advises nurses and clinicians on the correct sample that is required for each test performed in the NHLS. Should the incorrect sample be collected for

the test requested, these will be rendered unsuitable for laboratory testing and rejected as ‘require blood specimen,’ or ‘require separate specimen.’

5. Specimens too old

The NHLS Handbook (2020) recommends that all tests are sent to the laboratory for processing within 2 hours after collection, to ensure reliable patient results. The greater the time delay between collection and processing, the higher the risk of receiving inaccurate and erroneous results. In addition to the critical patient side effects of rejected tests as discussed above Lippi and Plebani (2021) propose that there is irrefutable evidence that laboratory errors on COVID-19 samples, poses a more significant health threat, as patients may go undiagnosed and hence untreated. This may result in the unintentional spread and transmission of the virus. The consequence of this is the disruption of the public health strategies and preventative measures applied for containing the COVID-19 pandemic (Lippi and Plebani, 2021). Thus, it is crucial for the laboratory to manage and maintain laboratory errors, and to develop preventative measure strategies to avert these risks to the patients and the public.

2.9 Chapter summary

This chapter has highlighted the background of COVID-19 and the motivation for this study. The chapter also described the laboratories’ role in COVID-19 testing, together with the role and functions of the NHLS. The crucial role that the laboratory plays due to the emergence of the COVID19 pandemic was also discussed. The chapter then provided a description of laboratory processes and the QMS that the laboratory subscribes to, before discussing errors in laboratory testing. The chapter concluded with a discussion of laboratory errors that are linked to COVID-19 testing as well as the pitfalls in laboratory testing and its repercussions on patients’ healthcare and safety. The next chapter will expand on an in-depth review of literature that was deemed necessary for the research study. It addresses the ideas and interventions of other fellow researchers in the field and provides an extensive background to the research problem.

CHAPTER THREE: LITERATURE REVIEW

3.1 Introduction

This chapter provides the reader with comprehensive theoretical insight into the main purpose of this study; 'analysis of risks associated with laboratory error rates of COVID-19 testing', through the evaluation of literature. Fink (2019) describes literature review as the systematic, explicit, and reproducible method for identifying, evaluating, and synthesising the existing body of completed and recorded work produced by researchers. Snyder (2019), citing Webster and Watson, propounds that an effective and well-conducted literature review creates a firm foundation for advancing knowledge and is key to any academic research. Guided by the above, the theoretical framework for this study discusses the laboratory Quality Management System (QMS) which encompasses accreditation, quality indicators, and the quality tools. Thereafter, the application of the quality tools used in this research is expanded upon. The discussions that make up this literature review are presented in a manner that sets out to achieve the main research objective of the study, which is; developing an optimised pre-analytic process that includes preventative measures that ensure reduced laboratory errors in COVID-19 testing.

3.2 Modern management of quality in diagnostic laboratories

Laboratory services are the backbone of healthcare (Rana, 2012). Thus, high-quality laboratory testing is critical for patient care, prevention, disease surveillance, and outbreak investigations (Gershy-Damet et al., 2010). The definition of quality in a laboratory setting as stated by Crema and Verbano (2015) citing Agency for Healthcare Research and Quality, is "*doing the right thing at the right time, in the right way, for the right person and having the best possible results*". Lippi (2021) acknowledges this definition and offers a more comprehensive definition, by stating that a healthcare system is considered of high quality only if it is; accessible, acceptable, safe, effective, timely, efficient, patient-centred, and equitable. Since the emergence of the COVID-19 pandemic the laboratories' quality standards are under a greater spotlight (Lippi, 2021), as inadequacies in the quality of results produced by the laboratory could be detrimental to COVID-19 disease surveillance and management and has potential to impact the spread of the disease. Thus, quality management in diagnostic laboratories became significant.

The field of quality management has evolved significantly over the years thanks to the contributions of many quality gurus who have shaped and influenced the field. These 'quality gurus,' have developed and introduced new ideas, theories, quality tools and methods that have helped organisations improve their performance and achieve their goals (Westgard,

2016). Edward Deming, was one such quality guru who introduced the Deming PDCA cycle. This quality tool is widely used in diagnostic laboratories today to identify process gaps and make improvements on service delivery (Westgard, 2016).

With the intention of meeting high quality laboratory standards, the NHLS laboratories utilises this quality tool and others that are linked to Demings PDCA cycle for evaluation of QI's which are embedded in the QMS for root cause analysis, risk assessments, and continual quality improvement strategies, which are assessed during the accreditation process.

3.3 Application of the PDCA cycle in managing quality in a diagnostic laboratory

The PDCA cycle, also known as the quality loop, and consists of four processes: Plan, Do, Check, and Act, that has the ability to fix any problem or improve any process in a system (Zhou, Yao, and Wu, 2023). The four processes include: (1) Plan: consists of setting goals and processes to achieve specific results, (2) Do: providing the resources and tools to conduct the changes, (3) Check: the analysis stage where monitoring and evaluation take place, (4) Act: where actions are taken to improve results and meet or exceed specifications. Thus, in an endeavour to reduce failures and improve quality in the pre-analytic process, this research study adopts the PDCA cycle as a point of departure.

The inference drawn from literature when used together with other quality tools, the PDCA enhances the intended outcome by improving quality in a specific area (Isniah, Purba, and Debora, 2020). Although no literature was found at the time of conducting this research, linking the PDCA cycle with the four quality tools selected to constitute the conceptual framework of this study, in the manner this study does, a conclusion derived from literary analysis is that when the four tools (Pareto analysis, Ishikawa diagram, 5 whys analysis, and FMEA) are used in the PDCA cycle, they have great potential in improving the quality in the laboratory.

3.3.1 Quality Tools used in diagnostic laboratories

Based on the aforementioned, the NHLS has quality tools rooted in the QMS for quality improvement. Westgard (2014) posits that several quality tools can be implemented by laboratories to improve quality standards. Conventional quality tools according to Westgard (2014) include; cause and effect diagram, check sheets, control charts, histograms, pareto chart, scatter diagram, and stratification. Rotich (2022) claims that there are risk management and project management tools that may also be used to improve quality standards such as Ishikawa diagram, 5 whys analysis, and FMEA.

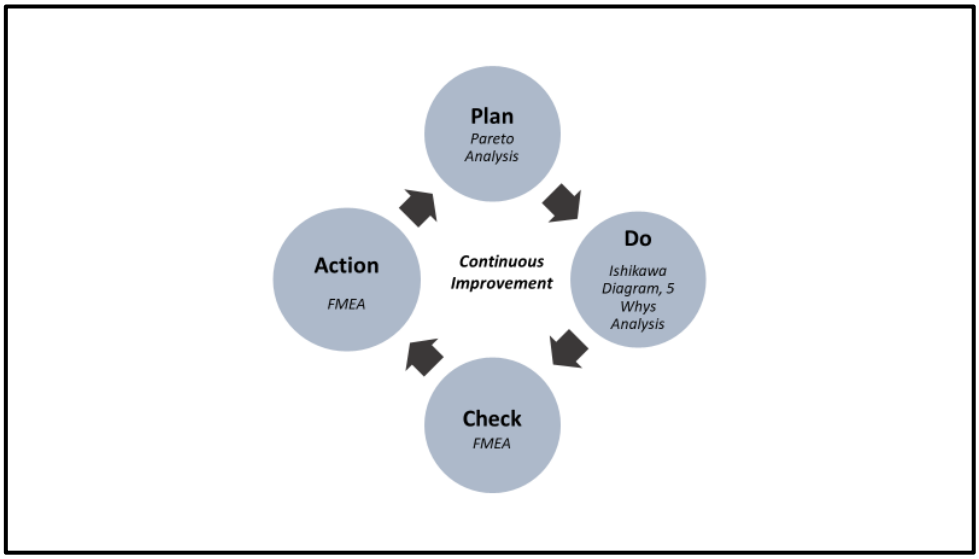
As discussed in Chapter 1, the conceptual framework adopted for this research consisted of four quality tools which are: Pareto analysis, Ishikawa diagram, 5 whys analysis, and FMEA in this exact sequence as it aligns to the four processes of the PDCA cycle. These quality tools were selected as they appear to be the most appropriate tools for meeting the research objectives in this study. This research study requires an identification of the most crucial areas in the QI of rejected specimens to be identified as well as an in-depth RCA and risk assessment to be conducted.

The quality tools selected for this research study are linked to the PDCA cycle as follows:

- Plan stage: Pareto analysis is used in the Plan stage to investigate the potential causes of specimen rejections and assist in prioritising decisions that have the greatest impact on specimen rejections.
- Do stage: Ishikawa diagram is used in the Do stage to identify the possible causes and effects of specimen rejections.
- Do stage: 5 whys are used in the Do stage to explore the cause-and-effect relationship of specimen rejections.
- Check and Act stage: FMEA is used in the Check and Act stage to identify all the possible failures in the process and then develop control measures to prevent failures. Due to the PCDA being a continuous cycle for improvements, after the action stage, and new cycle can start proceeding with the plan stage.

Refer to Figure 10 for a graphic illustration the Quality tools and its linkage to the PDCA cycle in this research study.

Figure 10: PDCA cycle linked to quality tools



Source: Researcher (2022)

3.3.2 Pareto analysis in the 'Plan' Stage

Pareto analysis is also referred to as the "80/20 rule," according to Powell and Sammut-Bonnici (2014), and was introduced by an Italian economist; Vilfredo Pareto. Brooks (2014) explains that the Pareto principle is based on the idea that 80 percent of an organisation's problems can be traced to 20 percent of the causes. Powell and Sammut- Bonnici (2014) argue that a caveat when applying the concept of the Pareto principle is that the 80/20 ratio is not to be taken literally, however it is just an indication that the majority of results are often derived from a minority of inputs.

Pareto analysis is used when there are numerous problems or defects in an area, and where the user wants to focus on the most significant ones to bring about improvements (Brooks, 2014). A review of literature stated that when Pareto analysis is conducted, all the possible problems or defects are tabulated together with their occurrence, to which they are then graded as percentages and cumulative percentages of the total number of problems or defects. This data is then used to construct a Pareto chart so that the significant few problems emerge from the general background (Brooks, 2014). Pareto analysis according to Brooks (2014), cannot be used with measurements such as temperature readings or pH values, it can only be used with nominal data. Hence, in this study is performed using the specimen rejection data.

Pareto analysis is useful in identifying the minor (few) causes that affect the majority of the results, as the tool highlights the most important factors that lead to problems (or result in errors). Pareto analysis is a useful tool to be used in the planning stage of this research study, as it is crucial for prioritisation of the most significant errors that need corrective action. In essence, prioritisation is part of planning. Brooks (2014) posits that prioritisation is pivotal step in planning when there is a need for investigative analysis and corrective measures in problem areas. From the review of this literature is can be gleaned that Pareto analysis is a quality tool that is capable of identifying the most critical contributing factors from a list of several factors that are responsible for the unacceptable laboratory errors in COVID-19 testing. It will assist the user of the tool with not only the identification but also the prioritisation of factors that require corrective action.

3.3.3 Root Cause Analysis in the 'Do' stage

Authors Schmidt, Messinger, and Layfield (2013), posits that RCA involves a detailed investigation into the circumstances that contribute to a specific error or trend. The purpose of RCA is to identify the possible root cause/s of the problem, which is significant in attempting to solve the problem. These authors state that by performing suitable RCA on a problem, the

user not only gains a richer understanding of the problem, but also gains significant insight on finding methods to solve the problem (Schmidt, Messinger, and Layfield, 2013). The Ishikawa diagram and the 5 whys analysis are RCA tools and they may be used independently, however, in literature presented by these authors the Ishikawa diagram and the 5 whys analysis were used in conjunction to identify the root cause of errors in their study, and these tools work well together (Schmidt, Messinger, and Layfield, 2013). Similarly, this research study employed the use of the Ishikawa diagram and the 5 whys analysis in conjunction to determine the root cause/s for the QI resulting in increased specimen rejections. The review of literature returned that Pareto analysis is not inherently linked to RCA, however in this research study the results of Pareto analysis was used as part of the troubleshooting process. Schmidt, Messinger, and Layfield (2013) stated that Pareto analysis and RCA if used together may be beneficial to the user, as it prioritises the defect/s or non-conforming area/s where focus on troubleshooting and corrective measure strategies should be targeted. Thereby, this research study used the results of Pareto analysis for RCA, so that a more targeted approach on prioritising the areas of highest concern was isolated for determining the root cause/s and implementing corrective action strategies.

3.3.3.1 Ishikawa diagram in the 'Do' stage

The Ishikawa diagram is a casual diagram that was created by Karou Ishikawa (Loredana, 2017). The diagram is a graphic representation, which helps with mental processing and organisation of ideas. Loredana (2017) asserts that this diagram was originally developed as a quality tool that could assist with the logical and systematic processing of the causes of certain problems or effects. Coccia (2016) points out that the Ishikawa diagram is a graphical technique to show the several causes of a specific event or phenomenon. She explains that the Ishikawa diagram is also known as the 'fishbone' diagram, as its structure resembles that of the skeleton of a fish, where the main effect is illustrated as a box at the right-hand side representing the head of the fish, and the causes are illustrated by major and minor branches at the left of the diagram representing the body of the fish. Loredana (2017: 99) states that the Ishikawa diagram is a successful technique as it is a visual representation that is simple and human-readable. It helps to identify possible causes of variation that allows for the determination of the fundamental cause to find solutions for improvement. The author points out that each cause or 'reason for imperfection' is a source of variation. The causes of variation are grouped into major categories such as man, method, material, machine, measurement, and environment to identify the overall sources of variation that lead to the main effect. Loredana (2017: 98) describes the categories as:

- Man: anyone involved in the process.

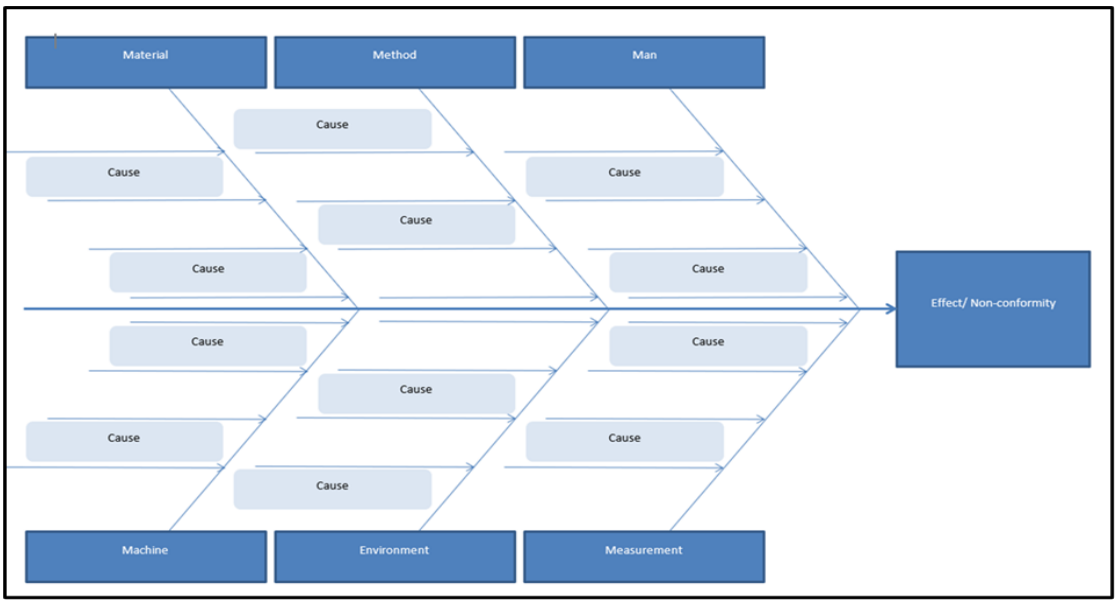
- Method: how the process is performed and specific requirements for doing it, such as policies and procedures.
- Material: raw materials used to produce the final products.
- Machine: any equipment, computers, or tools used to accomplish the job.
- Measurement: data generated from the process that is used to evaluate its quality.
- Environment: the conditions, such as location, temperature, and culture in which the process operates.

Loredana (2017) argues that it is possible that more than one source of variation can be present at the same time. Notably, many sources of variation may occur as an individual category or multiple categories occurring simultaneously resulting in the same problem. In this research it is shown in some cases there are multiple sources of variation presented in a single category.

The Ishikawa diagram is an insightful quality tool as it has the potential in assisting the researcher in identifying all the sources of variation that results in specimen rejections that were highlighted in the Pareto analysis. Based on the literature that was examined, this study deduces that the Ishikawa diagram is appropriate for use during the identification of factors that require correction to optimise the COVID19 testing process in this research study.

Figure 11 illustrates a typical example of how an Ishikawa diagram is constructed.

Figure 11: Ishikawa diagram template



Source: Luca (2016)

3.3.3.2 The 5 Whys analysis in the 'Do' stage

Dziuba, Jorossova, and Golebiecka (2014; 17) describes the 5 Whys Analysis as a tool that detects causes of quality problems or failures by asking the question 'why?' five times or more. Serrat (2017: 307) states that this technique was developed by Sakichi Toyoda for Toyota Industries Corporation. It was reported that by asking 'why?' five times, one can peel away the layers of symptoms that hide the cause of a problem, but it is also noted that fewer than five 'whys?' may also get to the root of the problem (Serrat, 2017). The 5 Whys method allows one to get to the root of the problem, by thoroughly analysing the cause. Dziuba et al. (2014) confirm that the 5 Whys technique is valuable in getting to the root of the problem as this method allows for the problem to be more understandable so that remedial measures can be applied to eliminate the problem. A review of literature found that there are some challenges with using the 5 whys tool. Serrat (2017: 310) reports that the 5 whys tools has been criticised as too basic a tool to analyse root causes to the depth required to ensure that the causes are fixed. This is mostly due to the investigators stopping at the symptoms, and not proceeding to lower-level root causes, as well as the lack of facilitation and support to help investigators ask the right questions. Thus, the 5 Whys tool is not recommended to be used as a standalone tool. Instead, Serrat (2017) suggests it be used with other tools such as the Ishikawa for a comprehensive RCA to be performed. Serrat (2017) specifically recommends that the Ishikawa tool be used with the 5 whys tool to identify the root causes that need to be corrected as part of the RCA during the optimisation of a process, such as the pre-analytic COVID-19 testing process. It must be noted that the results of the RCA only identify the problem, a further step, namely corrective action still needs to be applied to remove the root cause of the problem and an impact analysis to be performed. Based on this, this study is able to deduce that this is a potential approach that can be used to optimise the pre-analytic COVID-19 testing process.

Based on the preceding discussion, and the views of Serrat (2017), it is clear to this study that corrective action is a key step to fix the problems in the processes that are being optimised. Moreover, further steps are required to prevent recurrence. According to Ahsen et al. (2021) FMEA is an example of one such quality tool which plays this critical role.

3.3.4 FMEA in the 'Check' and 'Act' stage

Mascia et al. (2020: 312) posit that FMEA was first developed by the US military in the 1940s, and is a revered quality tool as it is used to examine potential causes of failures in processes. It is an essential risk management tool that is used to evaluate the risks in a process and identify specific actions to mitigate the risks identified. Ahsen et al. (2021) concede that FMEA is a powerful risk management tool for assessing the performance of systems or processes,

and adds that it is a systematic process where potential errors are identified, evaluated, and improved upon. Rostich (2022) states that risk management is vital as it assists organisations to develop solutions to potential process challenges or defects before they arise. Based on literature, FMEA aids users in managing risks associated with processes, and thereby can potentially optimise processes (Rostich, 2022). A review of literature returned that the purpose of conducting FMEA is to prevent specified requirements from not being met. For the purpose of this research, in order for the pre-analytic process to be optimised, it is vital to improve on the poor QIs. The specific QI for this research that requires improvement is rejected specimens. The process of FMEA involves determining all the steps in a process that have the potential for failure and then calculating the risk of each step. Mascia et al. (2020: 314) explain that for each process step or potential failure mode a risk priority number (RPN) is calculated by multiplying the severity, frequency of occurrence, and its level of detection. These authors further explain that the RPN is then compared with a predefined RPN matrix, to identify the opportunities for improvement. Each organisation is responsible for establishing an RPN matrix based on the organisation's risk evaluation criteria, and the highest RPNs (greater than 300) indicate prioritisation for mitigation (Mascia et al., 2020). In a FMEA study conducted by Ahsen et al. (2022), a 1-10 ranking matrix was compiled where a score of 1= low, and 10= high, for the severity, frequency, and detectability. All RPNs greater than 300 required immediate action for improvement. Based on the aforementioned literature this FMEA ranking matrix seems suitable and has potential to be adopted for this study. Refer to Appendix C for the ranking matrix. Ahsen et al. (2022) states that FMEA can be conducted in two phases, where the first phase lists all the processes that require investigation and the RPNs are calculated. The second phase is where the processes with the highest RPNs are identified (from phase one) for process improvements. After adjustments are made to the processes, the RPNs are recalculated and evaluated to see if improvements were presented.

It must be noted that there are some drawbacks when using FMEA which are evident in literature. Ahsen et al. (2022) explains that in order for FMEA to be successfully conducted, there must be sufficient resources, time, and personnel that are committed to identifying risks in an organisation and making unbiased process improvements that are geared towards optimising a particular process. These authors state that this quality tool is not always effective as many organisations are unable to schedule the time to conduct this process and are incapable of providing the resources to complete the process (Ahsen et al., 2022).

Based on the literature reviewed, this study deduces that FMEA may be a suitable tool to be used in this research as it lends itself to performing proficient risk management on the

laboratories' pre-analytic process which may show improvement on the poor QI of rejected specimens.

3.4 Chapter summary

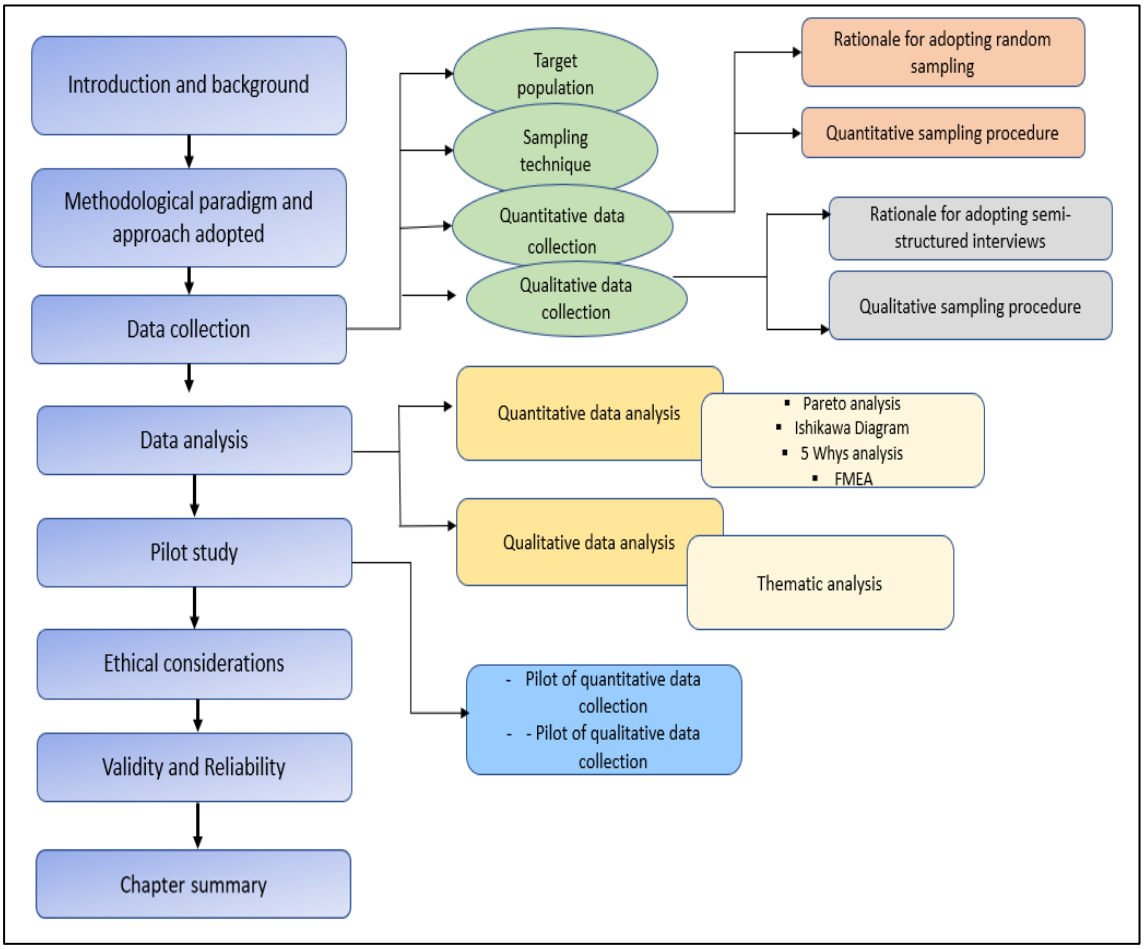
This chapter presented the reader with a succinct review of literature for this research study, which commenced with an introduction of the laboratory QMS, followed by the management of quality in a diagnostic laboratory. Thereafter, the application of the PDCA cycle was discussed, before expanding on the potential quality tools that may be used for this research. Theory evaluated in this chapter provides support for the research design which is presented in the next chapter and ultimately the intent of this research which is to optimise the pre-analytic process of the NHLS Paarl laboratory. The review of literature highlighted that it is possible to use four quality tools (Pareto analysis, Ishikawa diagram, 5 Whys analysis, and FMEA) in this distinct order as part of a PDCA cycle in this study to develop an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing.

The next chapter describes the research design and methods used by this study, which includes the quality tools identified by literature review within a strategy to meet the objectives of this research study.

CHAPTER FOUR: RESEARCH DESIGN AND METHODOLOGY

This chapter offers the reader insight into the research design and methodology. The chapter commences with a reminder of the research problem. Following this, the research methods used to solve the problem are described. Thereafter, the data collection and sampling methods are discussed, and the data analysis strategy is explained. The chapter presents the pilot study performed, followed by the ethical considerations observed during the research study. The chapter concludes with considerations for data validity and reliability and the chapter summary. Figure 12 represents a visual depiction of the flow of the research design and methodology as presented by this chapter for this study:

Figure 12: Graphic depiction of research design and methodology flow



Source: Researcher (2021)

4.1 Introduction and background to the research methodology

Chapter 1 reports that the laboratory error rate for the COVID-19 testing at the NHLS Paarl laboratory in the Western Cape is greater than 4%. This was determined during the routine monthly analysis of the laboratory rejection report. Thus, this research study set out to

investigate all the contributing factors that rendered laboratory errors and to identify and implement practical measures to improve the error rate at the NHLS Paarl laboratory. Due to the complexity of this study, multiple data collection tools are required to collect data to perform a comprehensive analysis to reach the ultimate goal of the study, which is to develop an optimised pre-analytic process that includes preventative measures that ensure reduced laboratory errors in COVID-19 testing. In light of the complexity of the goal of this study, Creswell (2019: 10) asserts that applying a mixed methods approach allows multiple types of data to be collected and analysed, permitting a more comprehensive understanding of the research problem. Hence, to accomplish the research objectives in this multifaceted study, it is deemed appropriate to employ a sequential mixed methods approach, which includes both quantitative and qualitative data. Literature by Creswell (2019) returned that the sequential mixed methods approach is where the researcher seeks to elaborate on or expand the findings of one method with another method. This is in keeping with the approach adopted for this research study, where the researcher begins with the collection and analysis of quantitative data, followed by the collection and analysis of qualitative data which is used to verify the findings of the quantitative data.

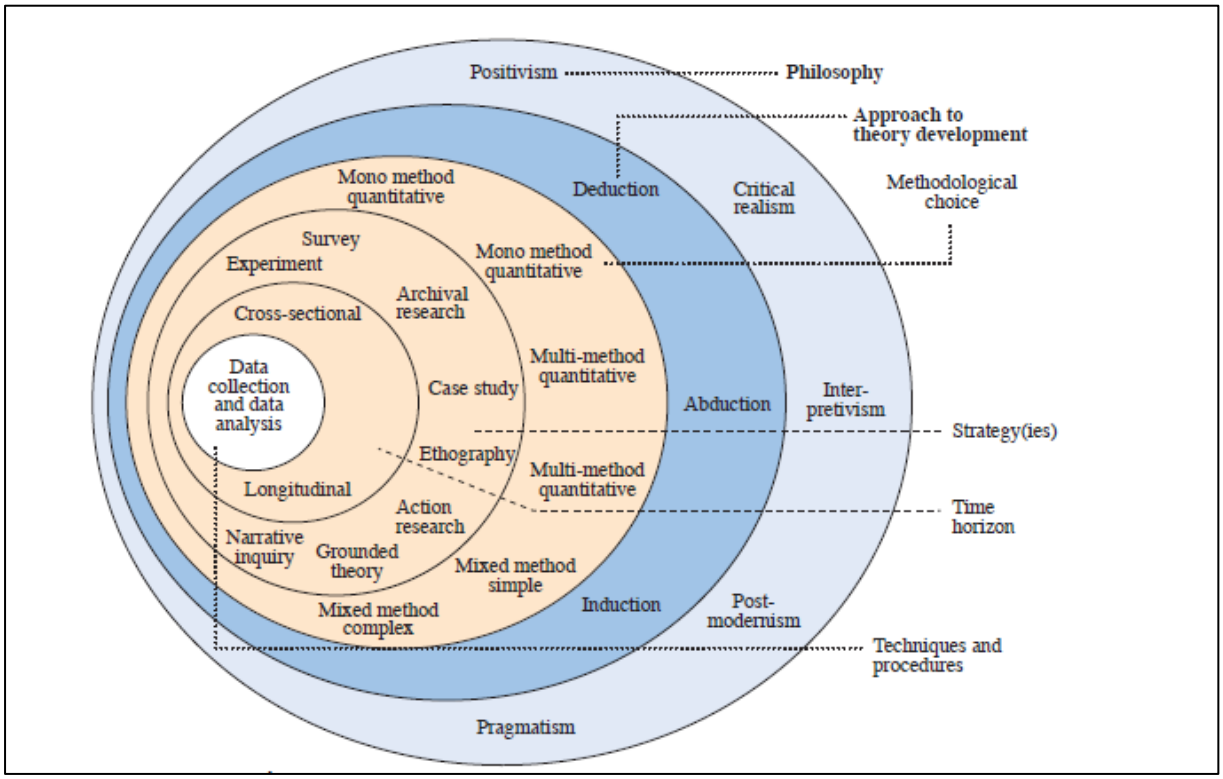
A literature search showed a paucity of studies reporting on the optimisation of laboratory methods using quality management tools. Consequently, it was not possible to identify a pre-existing methodological approach for this study. Therefore, an original approach is developed utilising a combination of quality management techniques to collect quantitative data, in addition to a traditional qualitative research approach (semi-structured interviews) to collect qualitative data. As discussed above, a mixed method approach is adopted, which combined two distinct methods in which data were sequentially collected and analysed: first quantitative, and then qualitative data. This approach aided the researcher in acquiring a richer understanding of the research problem, with the ultimate purpose of developing an optimised pre-analytic process that includes preventative measures that ensure reduced laboratory errors in COVID-19 testing.

4.2 Methodological paradigm of the research study

A research paradigm refers to the philosophical way of thinking (Kivunja and Kuyini, 2017) and is used to describe the researcher's worldview. A worldview is a perspective way of thinking or set of shared beliefs that inform the meaning or interpretation of research data (Mackenzie and Knipe, 2006). Citing Lather (1986), Kivunja and Kuyini (2017: 26) explain that a research paradigm inherently reflects the researcher's beliefs about the world that s/he lives in. The author elaborates by adding that it constitutes the abstract beliefs and principles that shape how a researcher sees the world, and how she or he interprets and acts within that

world. A paradigm is a conceptual lens through which the researcher examines the methodological aspects of the research study to determine the research methods that will be used and how the data will be analysed (Lather, 1986). Paradigms are important as they define the researcher's philosophical orientation which has significant implications for every decision made in the research process, including the choice of methodology and methods (Kivunja and Kuyini, 2017: 26). Methodology is a general strategy that depicts the way research should be undertaken (Melnikovas, 2018: 33) and it includes a system of beliefs and philosophical assumptions which shape the understanding of the research questions and underpin the choice of research methods. Melnikovas (2018: 30) proposes that one of the most common models for methodology development in research is the "research onion", developed by Saunders, Lewis and Thornhill (2016) (see Figure 13). The author asserts that the research onion concept creates a firm basis for the development of coherent and justifiable research design.

Figure 13: Research Onion



Source: Saunders et al. (2016)

In cognizance of Figure 13, Table 2 consists of descriptions of each of the layers of the "Research Onion" in the context of this study, based on the views of Melnikovas (2018: 33) citing Saunders (2016).

Table 2: Layers of the research onion in the context of this study

Layers	Description
Research Philosophy	This outer layer of the onion forms the basis of the research by delineation of *ontology*- nature of reality*, epistemology*-nature, sources of knowledge or facts, and *axiology*- values, beliefs, and ethics of the research. The philosophy adopted for this research study is post-positivistic, as this study employs a mixed methodology approach due to the nature of the research objectives, and to gain an enhanced understanding of the research problem.
Approach to theory development	The second outermost layer of the research onion is directed by research philosophy and facilitates the consideration of whether the research will be deductive, inductive, or adductive. This mixed method research study follows both deductive and an inductive approach, as the study is initiated by the observation of the unacceptable error rate (>4%) of COVID-19 samples at the NHLS Paarl laboratory, then proceeds with data collection, and an initial deductive quantitative data analysis, followed by inductive qualitative data analysis which leads to the formation of a theory.
Methodological choice	This layer facilitates the researcher with the determination of whether to use quantitative or qualitative methods or various mixtures of both. This research study employs a mixed methodology approach which encompassed both quantitative and qualitative methods.
Strategy	This layer facilitates the researcher in shaping which data collection and analysis approach to employ experiments, surveys, case studies, action research, grounded theory. This research study follows a sequential mixed methods strategy as it commences with the collection and analysis of the quantitative data, followed by the collection and analysis of qualitative data.
Time horizons	This layer defines the time frame for the research- cross-sectional or short-term study, involving the collection of data at a specific point of time; longitudinal- collection of data repeatedly over a long period of time in order to compare data. The time frame for this research study is short-term as it involves the collection and analysing data over a 12-month period.
Techniques and procedures	This layer facilitates the researcher in defining techniques used for data collection and analysis- the use of primary/ secondary data, choosing sampling groups, developing questionnaire content, preparing interviews, etc. This research study employs quantitative data collection and analysis followed by qualitative data collection and analysis. For the quantitative phase, random sampling techniques are used and data is analysed using; Pareto analysis, Ishikawa diagram, 5 Why's analysis, and Failure Modes and Effects Analysis (FMEA). For the qualitative phase, semi-structured interviews are employed which grounded the research and assisted the researcher in gaining a deeper understanding of the research problem.

Source: Saunders et al. (2016)

Citing Candy (1989), Kivunja and Kuyini (2017: 30) argue that research paradigms can be grouped into three main taxonomies, namely, positivist, interpretivist or critical. In addition, these authors mention that a post-positivist paradigm also exists and is considered to be a

derivative of the positivist paradigm. The positivist paradigm involves a process of experimentation that is used to make observations and answer questions. Kivunja and Kuyini (2017: 30) propose that this paradigm is used to search for cause-and-effect relationships in nature, where the aim is to find an explanation of a phenomenon and to make predictions on measurable outcomes. Conversely, the post-positivist paradigm allows for observations without experimentation or the formulation of hypotheses to be tested.

For this reason, this study adopted a post-positivistic approach as it lends itself to validating research findings through the use of multiple methods. This research study commences with the quantitative phase, which is followed by the qualitative phase in which findings of the preceding phase are emphasised, validated, and strengthened. The use of a post-positivistic approach also ensures that the research problem is studied from more than one dimension, with the purpose of gaining greater knowledge into the research which renders a more valuable research outcome.

4.3 Methodological approach of the research study

The overall premise of this study is to explore the error rates of COVID-19 and to ultimately develop an optimised pre-analytic process to serve as a preventative tool for reducing and eliminating these errors. As discussed above, both quantitative and qualitative data are collected and analysed for this research. The convergence of the two methods reinforced the study's conclusions. This approach is aligned with the view of Hesse-Biber (2010: 3), who advances the use of a mixed method approach to enhance the credibility of the research findings, as using both quantitative and qualitative data ultimately fortifies a study's conclusions.

The quantitative phase of the study encompasses the collection and analysis of data obtained from TrakCare rejection reports. The subsequent qualitative phase of the study involves conducting semi-structured interviews and analysing the interview data which assists in validating and confirming the quantitative data findings. Both these phases are crucial for developing a solution to the research problem. Creswell (2009: 12) refers to a strategy such as the one described above as a 'sequential explanatory' design. He explains that it is characterised by the collection and analysis of quantitative data followed by the collection and analysis of qualitative data. This approach allows for diverse types of data to be collected and analysed, which provides a more comprehensive understanding of the research problem that would not be possible with just one method. Creswell (2009: 12) advised that when utilising this approach, the research study begins with a broad sampling technique to generalise results to a population, and then focuses on the second phase where a detailed qualitative semi-

structured interview occurs, to collect detailed contextual views from participants. A sequential explanatory strategy is practical to implement as the steps fall into clear and separate stages as illustrated below:

Step 1: Collect quantitative data. In the context of this research, information is obtained from TrakCare rejection reports.
Step 2: Analyse quantitative data. For this research quality tools such as Pareto analysis, Ishikawa diagram,5 Whys analysis, and Failure Mode and Effects Analysis (FMEA) is used for quantitative data analysis.
Step 3: Collect qualitative data. In this study qualitative data is collected through semi-structured interviews with key stakeholders in the local healthcare system.
Step 4: Analyse qualitative data. Data obtained from the interview transcripts follow thematic analysis.
Step 5: Report on findings after analysing quantitative and qualitative data.

4.4 Data collection

A review of literature by Wilcox, Gallagher, Boden, and Bakken (2012) showed that data collection is a critical mandatory step in every research process. Thus, this research study employs a precise data collection strategy which is discussed in the section below.

Trochim (2012) posits that it is fundamental to determine the unit of analysis for the study. A unit of analysis is defined as the major entity that is being analysed in a study. It is the 'what' or 'who' that is being studied (Trochim, 2012). For this research study, two units of analyses have been identified: laboratory reports (TrakCare rejection reports) for the quantitative phase of this research and interview participants for the qualitative phase of this research, as these will serve as the vehicles of analysis to resolve the research problem.

4.4.1 Target population

There are two target populations identified for this research, one for the quantitative phase and one for the qualitative phase. The target population for the quantitative component of this research study are records of all laboratory specimens that were rejected from January 2021 to December 2021, thus allowing a total of twelve months' data to be analysed for the research study. Records of all the rejected samples are obtained by drawing a TrakCare rejection report from the NHLS Paarl data management system repository for this period. This report is referred to as the master TrakCare rejection report. The master TrakCare rejection report contains information on all the rejected samples (n=32000 which were collected between 1st

January 2021 until 31st December 2021. After further refinement, this report is then used for the quantitative data analysis which will be discussed further in the chapter.

The target population for the qualitative phase of the study is identified as the three key stakeholders at NHLS Western Cape, namely the business manager, the regional quality manager, and the head phlebotomist. NHLS employees who are appointed in these three key roles (n=3) are selected as qualitative research participants as they are the key knowledge holders, and they share a vested interest in improving specimen rejections relating to COVID-19 and are able to provide valuable insight into the research problem.

4.4.2 Sampling technique

Sharma (2017) defines sampling as a technique employed by the researcher to systematically select a relatively smaller number of representative items or individuals from a pre-defined population to serve as the subject for observation or experimentation. For the quantitative phase of this research study, it was deemed appropriate to use a census sampling technique. Daniel (2012) explains that a census sample is one that includes all of the elements in a target population. This research study employed a census sampling technique by applying specified inclusion and exclusion criteria on the master TrakCare rejection report (as discussed below), and thereafter using the entire population to perform the quantitative data analysis.

Census sampling was also used for the qualitative phase of the study as there is only one person in each of these key roles and all three key individuals are selected to participate in the semi-structured interviews, as they share a valued perception of the research problem.

4.4.3 Rationale for employing census sampling

The rationale for using census sampling is that the scope of this research study is to eliminate sample error, as the entire COVID-19 rejected test dataset is used. The main advantage of census sampling as stated by Daniel (2012), is that it adds to the validity and trustworthiness of the results of the study, as each sample in the target population is used.

4.4.4 Quantitative sampling procedure

As discussed earlier, the data collected for the quantitative phase of the study is an electronic record of n= 32000 TrakCare sample rejections from January 2021 to December 2021. Thereafter, the master TrakCare rejection report is filtered to include and exclude certain parameters. This allows the researcher to identify and analyse the contributing factors resulting in the rejection, as well as identify the risk to patient healthcare.

The inclusion criteria were:

- Samples collected from Paarl State Hospital only.

The exclusion criteria were:

- Non-COVID-19 related samples, such as blood submitted for routine testing.

Once the laboratory rejection reports are collected and filtered, it is saved on an access-controlled computer. No one else has access to this data, except the researcher. The filtered TrakCare rejection report now contains (n= 9600) records for quantitative data analysis.

4.4.5 Qualitative data collection

In this sequential explanatory research study, the qualitative data collection is performed after quantitative data collection and analysis. Qualitative data is collected through semi-structured interviews which are used to validate the findings of the quantitative data. The three key interviewees who occupy roles that are significant to the service quality of the organisation are: the regional quality assurance (QA) manager: the regional QA manager is selected as a research participant as they undertake the role of ensuring the Western Cape regional laboratories complies with the national quality policy objectives. The QA manager also assists laboratories with QI monitoring, and mitigating risks identified by laboratories that may affect patient care. The second research participant is the business manager: whose role is to oversee all the Western cape NHLS laboratories, with regards to the alignment of strategic objectives of the NHLS with quality patient care, as well as mitigating high-risk areas from the laboratory perspective that affect patient care and safety. The third research participant selected is the head phlebotomist: whose role is to oversee the phlebotomy training for the NHLS and mentoring other healthcare professionals in the Western Cape, as well as mitigating high-risk areas from a phlebotomy and specimen collection aspects, that affect patient care and safety.

The Interviews took place through the online Zoom application platform. The interviews were conducted separately with each participant and were between 30 to 45 minutes in duration. The researcher allowed a five-minute time slot at the end of the interview for closing comments and feedback from the participants. The interviews were recorded using Zoom software and automatic transcripts were created using Microsoft Word software. The researcher made notes during the interview to clarify points made by the participants. Refer to Appendix D for the questionnaire used for the semi-structured interview.

4.4.5.1 Rationale for utilising semi-structured interviews

A review of literature by Adeoye-Olatunde and Olenik (2021) claimed that the primary benefit of a semi-structured interview is to allow the interview to be focused, while still permitting the exploration of pertinent ideas that may come up in the course of the interview. In a mixed-method study, contextual exploration is not something that can be derived from quantitative data, hence a semi-structured interview can be used to enhance the depth of the quantitative data (Adeoye-Olatunde and Olenik, 2021). In addition to this, the rationale for adopting semi-structured interviews in this research is to ensure the research participants are comfortable during the interview process, due to its typical informal tone and flexibility in nature. Longhurst (2003: 144) citing Kreuger and Casey (2000) states that semi-structured interviews are also referred to as 'soft' interviews and are centered around not only talking with people but also about listening and paying attention to open responses and body language of participants. This allows the researcher to gain a clearer understanding of the research problem, which simply would not be observed in a structured interview relying on yes or no responses. Longhurst (2003) further advances that semi-structured interviews are a blend of open and closed-ended questions, where the participants are given the opportunity to expand on their responses while being guided by the interviewer. In this study, semi-structured interviews are performed to validate and expand on the findings of the quantitative data analysis. Consequently, this facilitates a richer understanding of the research problem, which supports the researcher in developing a robust solution.

4.4.5.2 Qualitative sampling procedure

Longhurst (2003) explains that a semi-structured interview is a verbal interchange where one person, the interviewer, attempts to elicit information from another person by asking questions. The interviewer prepares a list of predetermined questions however, semi-structured interviews unfold in a more conversational manner allowing the participants to explore and address issues they feel are important (Longhurst, 2003). In keeping with this, for this research, interviews commence with the interviewer thanking the interviewee for participating in the research study. This is followed by the interviewer briefly explaining the context of the research study and the research objectives. The interviewer also informed each of the participants that participation in the interview is voluntary, and if the interviewee wanted to discontinue the interview at any point, they could do so. Finally, the interviewer expanded on the confidentiality and anonymity of the interview and gave the interviewee a consent form to complete. The audio recordings of the interview were transcribed. During the transcriptions, the recordings were anonymised and returned to the Participants to confirm accuracy. Anonymity was maintained by ensuring that the interview transcripts referred to the research participants as Participant 1, Participant 2 and Participant 3. Recordings of the interview were

permanently deleted after the transcripts are made. Refer to Appendix E for the consent form used in the semi-structured interview.

4.5 Data analysis

This research study follows a strategic data analysis plan as described below, with the intent of gaining an enhanced understanding and interpretation of data. Interpretation of data is the heart of any research (Willig, 2014). The author concedes that without interpretation one cannot make sense of data and hence is unable to reach viable research conclusions.

4.5.1 Quantitative data analysis

A project team is assembled to perform the quantitative data analysis. The team consisted of the researcher, a laboratory technologist, and a laboratory quality control officer. Choi and Oh (2019) posit that a research team (referred to as the project team in this study) increases the productivity and quality of the research, as teams can integrate diverse ideas and research resources. Moreover, the quality tools selected for the quantitative phase of this research are designed to be performed and interpreted as a team. The rationale for this is the nature of the brainstorming of ideas and possible solutions are inherent characteristics of the design of the quality tools. Thus, enabling the generation of findings during data analysis and providing a mechanism to cross-check and peer review, which supplemented the validity of the research. Subsequent to filtering (applying inclusion and exclusion criteria) the TrakCare rejection report, the data is chronologically organised for analysis using the quality tools. The quality tools that are used in this study are: Pareto analysis, Ishikawa diagram, 5 Whys analysis, and FMEA. A brief description of each of the tools and how they were used are presented below. As discussed in the previous chapters the quality tools are strategically used in this sequence as they are linked to the PDCA cycle, which is a cyclic problem-solving tool aimed to achieve process improvement. Furthermore, the results from the preceding tool are used to provide input for the subsequent tool.

4.5.1.1 Pareto Analysis

Pareto analysis initiates the data analysis in this research, as it constitutes the primary investigation of the main sources of specimen rejections. Pareto analysis correlates to the PDCA cycle, as it represents the ‘Plan’ stage. In this study, the Pareto principle is applied based on the belief that 80% of laboratory errors encountered arise from 20% of the causes. The master TrakCare rejection report provides the data for Pareto analysis. The project team first reviews all the rejected specimens and then evaluates why they are rejected and reports the findings in a table. The project team then calculates the cumulative percentage of rejections and then uses this data to construct a Pareto chart. Pareto analysis assists in

prioritising decisions that have the greatest impact on specimen rejections, thereby facilitating in meeting the first research objective; “to identify the critical contributing factors that are responsible for the errors in COVID-19 testing.” The research findings of the Pareto analysis are then used for the next quality tool: the Ishikawa diagram.

4.5.1.2 Ishikawa diagram

The Ishikawa diagram is a graphic representation that helps with mental processing and organisation of ideas (Loredana, 2017). The Ishikawa diagram is an ideal quality tool for facilitating brainstorming when the root causes of problem areas are unknown (Luca, 2016). In this research the main causes of specimen rejections that are highlighted in the Pareto analysis, provide the input for the Ishikawa diagram. The project team graphically illustrates all the possible causes and sub-causes of specimen rejections. Individual Ishikawa diagrams are created for each rejection category, where the effect and all its possible causes are listed. The project team constructs the Ishikawa diagram in two phases: the first phase is where the project team reviews each non-conformity and classifies them according to one or more of the five categories (man, method, machine, material, measurement, and environment). The second phase involves the project team reflecting on each non-conformity and removing redundant causes. Although the Ishikawa analysis is traditionally performed by constructing diagrams as seen by the attached appendices (Appendix F to L), for this study, to simplify the presentation of analysed research data in the ambit of this research report, the results of the analysis are presented in a table format in the data analysis chapter as opposed to the traditional presentation.

Significantly, however, the benefit of constructing Ishikawa diagrams in this study is to allow for the graphical representation of the causes and the effect of a problem (Luca, 2016). The use of an Ishikawa diagram tool enables the researcher in meeting the first and second research objectives; “Identifying the critical contributing factors that are responsible for the unacceptable laboratory errors in COVID-19 testing and identifying the risks to patient healthcare.” The research findings of the Ishikawa diagram provide the input for the next quality tool: 5 whys analysis.

4.5.1.3 The 5 Whys Analysis

While the Ishikawa diagram graphically depicts the overall main high-level causes of specimen rejections, the 5 Whys analysis ultimately showcases the root causes of specimen rejections. The 5 Whys analysis differs from the Ishikawa diagram as this tool is designed as a ‘drilling down’ technique to identify the root of the problem, as opposed to the Ishikawa which identifies the higher-level problem source (Voehl, 2016).

A detailed questioning process is used during the 5 Whys technique to uncover the root causes of specimen rejections. The primary goal of using this technique is to drill down and expose the root cause of the problem by repeating the question “why?” five times. To simplify the presentation of the analysed research data the 5 whys analysis is illustrated in the form of separate tables for each cause category that was identified by the Ishikawa diagram. Thereby, the 5 whys analysis aids the researcher in meeting the second and third research objective which was to “identify the risks to patient healthcare and Identify measures that can reduce and eliminate the laboratory errors of COVID-19 testing.” The Ishikawa diagram and the 5 whys analysis are considered to the be ‘Do’ stage of the in this study.

4.5.1.4 Failure Modes and Effects Analysis (FMEA)

Failure modes and effects analysis is performed after the 5 Whys analysis, as the outcome of the 5 Whys analysis serves as input for the FMEA. Lee (2019: 27) opined that FMEA is a powerful quality tool that is used to identify errors in a system or process and assist in developing suitable risk management strategies that can be implemented to achieve quality improvement. FMEA represents the ‘Check and Act’ stage of PDCA cycle. Mascia, Cirafici and Bongiovanni (2020) advance that FMEA focuses on process development and on the control of opportunities for error and represents formal documentation that includes detailed descriptions of the process and risk assessments. Guided by the aforementioned, in this research study, FMEA is conducted by identifying potential failure risks within the pre-analytical system that led to the highest specimen rejections and analysing them.

Drawing from literature, the project team for this part of the study adopted the 1-10 ranking matrix compiled by Ahsen et al. (2022) where a score of 1= low, and 10= high, for the severity, frequency, and detectability. The ranking matrix can be seen in Appendix C. FMEA seeks to alleviate risk at all levels in a process with resulting prioritised actions that prevent failures or at least reduce their severity and/ or probability of occurrence (Siemens, 2016). The risk priority number (RPN) is calculated by the following formula as stated by Siemens (2016) and seen below:

RPN= Severity x Frequency x Detection

Ultimately the FMEA tool is used in this research study to assess the entire pre-analytic laboratory process, and then isolate the areas where process adjustments are needed in an effort to reduce the risks and improve the outcome. The project team first identifies the pre-analytical process steps that results in specimen rejections and determines the risk by gauging the severity, likelihood of occurrence, and failure detection. The RPN is then calculated.

Thereafter, the project team reviews the process steps with the highest risks and attempts to modify the process in an effort to improve the quality, by reducing and eliminating the causes of specimen rejections. This supports the endeavour towards the last research objective which is “developing an optimized pre-analytic process which includes preventative measures that ensure reduced laboratory errors in COVID-19 testing”. The qualitative data analysis is discussed in the next section, and this is used to validate the findings of the quantitative data analysis.

4.5.2 Qualitative data analysis

The qualitative data analysis is performed solely by the researcher. Semi-structured interviews are conducted with three key stakeholders who hold key knowledge of the research study and share a vested interest in improving and reducing specimen rejections. The use of semi-structured interviews requires a certain level of the previous study in the research area, claims Kallio et al. (2016) as the interview questions are based on previous knowledge. To this end, this research study uses findings of the quantitative data analysis phase and previous knowledge of specimen rejections to inform the qualitative data collection instrument. The transcripts from the interviews are then analysed using thematic analysis by utilising a web-based coding program known as ATLAS.ti.

4.5.2.1 Thematic analysis

Citing Boyatzis (1998), Alhojailan (2012) defines thematic analysis as a type of qualitative analysis used to analyse and present themes that relate to the data. Maguire and Delahunt (2017) concur with Alhojailan (2012) and point out that the goal of thematic analysis is to identify themes that are important or interesting and go on to explain that these themes may be instrumental in addressing the research problem. Alhojailan (2012: 40) believes that through interpretation, thematic analysis permits the researcher to determine the relationship between concepts and compare them with replicated data. In this study, thematic analysis is performed to determine the relationship between concepts and compares them to the quantitative findings that are derived from the project team’s analysis of the TrakCare rejection reports. Thematic analysis is used by the researcher to gain a richer understanding of the research problem and to confirm the quantitative analysis findings. The application ATLAS.ti is used for the electronic coding of the interview transcripts, from which themes and concepts pertaining to the research problem are derived.

The researcher employs a six-phase approach as described by Braun and Clarke (2006) as a framework for conducting thematic analysis. See Table 3 for the six-phase thematic analysis framework.

Table 3: Thematic analysis framework

Step	Description
Step 1	Become familiar with the data
Step 2	Generate initial codes
Step 3	Search for themes
Step 4	Review themes
Step 5	Define themes
Step 6	Write up

Source: Braun and Clarke (2006)

The next section describes each step highlighted by Table 3 and illustrates how thematic analysis is conducted in this research.

4.5.2.1.1 Become familiar with the data

After the semi-structured interviews were conducted with the three participants, the interview records were transcribed using Microsoft Word. The researcher commenced with Step 1 in Table 3 by becoming familiar with the data by reading and re-reading the data to gain a fuller understanding of the research problem and to gain a high-level understanding of the main concepts that confirm the quantitative data analysis that is presented in Chapter 5.

4.5.2.1.2 Generate initial codes

During Step 2 of thematic data analysis the researcher re-read the interview transcripts and began organising the data in a meaningful way, by generating codes with ATLAS.ti software. Codes are created to label the text in an effort to reduce data into smaller chunks of meaning (Maguire and Delahunt, 2017). This research employed inductive coding, which involves using the data from the interviews to inform the codes that are generated. Refer to Table 4 for codes generated for this research, along with the description of each code.

Table 4: Codebook

Code	Description
Confirming research problem	Aspects that confirms the research problem
Correct Pre-analytic procedure	Processes done correctly (according to SOP) in the pre-analytic process resulting in acceptable results
Effects of Errors	Outcomes of errors, that lead to failures
Effects of mitigation factors	Potential effects of mitigation measures on the failures that lead to pre-analytic errors
Failure	Process where non-conformity occurs, leading to specimen rejection
Finance strategy	Financial impact and viability of solution
New mitigating factor	New mitigating factor to reduce the rejection rate
Pre-analytic checks	Checks done during collection and labelling process prior to specimen being sent to lab
Pre-analytic errors	The factors lead to errors in pre-analytic specimen collection
Process Improvement	Steps or phases that show advancement, progression and improvement
Process step	Process of specimen collection
Quality Factors	Quality management strategies towards making improvements
Relationship of NHLS and DOH	Joint partnership between NHLS and DOH
Research Relevance	The use of this research in a real world setting and the benefits of the research
Risks of errors	Potential risks of rejections
Significant event	Known problem or occurance
Solution	Potential solution to reduce pre-analytic errors
System Failure	Failures in the system that caused pre-analytic errors
Variables	The different factors involved in pre-analytic process

Source: Researcher (2022)

4.5.2.1.3 Search for themes

A theme is defined as a pattern that captures something significant or interesting about the data and the research question, as stated by Maguire and Delahunt (2017), and is central to thematic analysis. After generating initial codes as previously discussed, the researcher commenced with Step 3 by developing themes by categorising closely related codes into themes. Refer to Table 5 for an illustration of the themes generated.

Table 5: Theme identification

Code	Description	Themes
Confirming research problem	Aspects that confirms the research problem	Research problem
Correct Pre-analytic procedure	Processes done correctly (according to SOP) in the pre-analytic process resulting in acceptable results	Pre-analytic procedure
Effects of Errors	Outcomes of errors, that lead to failures	Risk of rejections
Effects of mitigation factors	Potential effects of mitigation measures on the failures that lead to pre-analytic errors	Consequence of solution
Failure	Process where non-conformity occurs, leading to specimen rejection	Failures
Finance strategy	Financial impact and viability of solution	Financial opportunity
New mitigating factor	New mitigating factor to reduce the rejection rate	Process improvement
Pre-analytic checks	Checks done during collection and labelling process prior to specimen being sent to lab	Process improvement
Pre-analytic errors	The factors lead to errors in pre-analytic specimen collection	Failures
Process Improvement	Steps or phases that show advancement, progression and improvement	Process improvement
Process step	Process of specimen collection	Pre-analytic procedure
Quality Factors	Quality management strategies towards making improvements	Process improvement
Relationship of NHLS and DOH	Joint partnership between NHLS and DOH	Joint partnership
Research Relevance	The use of this research in a real world setting and the benefits of the research	Research benefits
Risks of errors	Potential risks of rejections	Risk of rejections
Significant event	Known problem or occurance	Important occurrance
Solution	Potential solution to reduce pre-analytic errors	Process improvement
System Failure	Failures in the system that caused pre-analytic errors	Failures
Variables	The different factors involved in pre-analytic process	Failures

Source: Researcher (2022)

4.5.2.1.4 Review themes

This stage of the research study involves reviewing and modifying themes that are identified in step 3 above. The themes are reviewed to ensure coherence with the research problem.

4.5.2.1.5 Define themes

In this step the final refinement of the themes takes place. Maguire and Delahunt (2017) citing Braun and Clarke (2006), stated that the aim of this phase is to identify the essence of what each theme is about. This step encompasses doing an in-depth investigation of what the theme was saying, identifying subthemes, how they interact with the main theme, and finally how the themes relate to each other.

4.5.2.1.6 Write up

This is the last step of thematic analysis, where the results from steps 1 to step 5 are reported. This step involves reviewing the outcomes of the four quality tools and performing confirmatory analysis to assess the participants' responses in conjunction with the research findings of the quantitative data analysis.

4.6 Pilot study

The term ‘pilot study’ refers to a mini version of a full-scale study (Teijlingen and Hundley 2001). It can also be referred to as a feasibility study or trial run, done in preparation for the major study. Citing Baker (1994), Teijlingen and Hundley (2001) explain that a pilot study can be the pre-testing or trying out of the research instruments. A pilot study is conducted for this research to determine if the research instruments are adequate and to assess the feasibility of the study. A pilot of the quantitative and qualitative data collection methods is conducted to assess whether the design and methodology are realistic and practicable.

4.6.1 Pilot study for quantitative data collection

A pilot of the quantitative data collection instrument was conducted by the researcher in June 2021. The research instrument is tested by collecting data for a period of one month (from 1st December 2019 to 31st December 2019) from the TrakCare reporting system, to determine the appropriateness and effectiveness of the research design. After the pilot study was conducted, results revealed that the research instrument is appropriate for the research study. It is noted that all the elements that are required from the quantitative data are available and accessible. The research instrument is deemed appropriate, and no amendments are needed for the main research study.

4.6.2 Pilot study for qualitative data collection

A pilot of the qualitative phase of the research study was conducted in August 2021 to assess the appropriateness of the interview style and questions. Two staff members from the NHLS Paarl laboratory who were not part of the target population were asked to participate in the pilot study. The two pilot participants were issued with a consent form (see Appendix E). The same consent form that was used for the pilot study, was also used for the main study. The participants were assured that confidentiality and anonymity will be maintained throughout the pilot study. The research aims and objectives were explained to the participants prior to their participation.

The first pilot participant is requested to inspect the interview design and format and to assess if the questions are relevant to the study. The second pilot participant is requested to partake in an interview so that the researcher could assess the time taken to perform the interview and address any shortcomings in the layout of the questions as well as the interview process. After completion of the pilot study for the qualitative phase of the study, results revealed that the semi-structured interviews are conducted in a suitable manner.

Feedback from the first participant revealed that the design, format, and relevance of the questions are adequate and succinct. The results also revealed minor limitations of the study such as the second participant was not prompted to give their personal and professional opinions on the research problem at the end of the interview. The researcher adapted the interview process due to these findings and included a section towards the end of the questionnaire, where the participant is asked to give their professional views on the research problem. The shortcomings highlighted in the pilot qualitative study guided the researcher in making the necessary changes to the main study to enable this research study to meet all the research objectives.

4.7 Ethical considerations

Ethical clearance for this study was granted by the Faculty of Engineering and the Built Environment Ethics Committee. The researcher also acquired written permission from the NHLS Western Cape business unit manager for the collection of NHLS data prior to the commencement of data collection. Ethical consideration was given to aspects such as confidentiality and anonymity, and informed consent was used throughout the study to fulfil ethical requirements. The participants were informed that all the data collected will be stored electronically on a password-protected laptop, which may only be accessed by the researcher. They were informed that the participants will remain anonymous and that they had the right to withdraw from the research at any time if they felt the need to.

4.8 Data validity and reliability

Data validity and reliability refer to the integrity in which a study is conducted (Noble and Smith, 2015). Validity specifically refers to the integrity and application of the methods used, while reliability describes the consistency of the analytical procedures used that may have influenced the findings of a study (Noble and Smith, 2015).

4.8.1 Validity

Noble and Smith (2015) opine validity is a matter of trustworthiness and is concerned with whether the research is believable and true. In this research study, a pilot study was conducted to ensure data validity is maintained. Conducting a pilot study on both the quantitative and qualitative data collection instruments allowed for the identification of errors, which were remedied before the main study commenced. Thereby, the pilot of the quantitative data collection ensures the validity of the content of the TrakCare rejection reports, and the pilot of the qualitative data collection phase allows the validity of the interview process and questions posed to the participants prior to the main interview.

The pilot study confirmed that the research instruments were adequate in measuring the research outcomes.

Zohrabi (2013) points out that internal validity also exists for quantitative and qualitative data collection instruments and is concerned with the compatibility of the research findings with reality. Noble and Smith (2015), agree with Zohrabi (2013) and added that there are many strategies that can be adopted to ensure the internal validity of a study's findings, such as:

- Accounting for personal bias which may have influenced findings.
- Meticulous record keeping, demonstrating a clear decision trail, and ensuring interpretations of data are consistent and transparent.
- Data triangulation, whereby different methods and perspectives help produce a more comprehensive set of findings.

Strategies such as the above are applied to this research study. Refer to Table 6 to view details of the application of the strategies.

Table 6: Strategies for ensuring credibility in the research study

Strategies adopted to ensure credibility: Noble and Smith (2015) and Zohrabi (2013)	**Strategies adopted to ensure credibility in this Research Study**
• Accounting for personal bias	Interviews were conducted independently with participants, where leading questions were avoided. Follow-up questions were asked and special care was taken to ensure leading the participant was avoided. The researcher remained impartial and non-judgmental.
• Meticulous record keeping	The researcher acquired the assistance of the project team which cross-checked all the quantitative data and assisted the researcher in performing and recording the results of the quantitative data analysis.
• Data triangulation	The research study followed a mixed methods approach which allowed for two types of data (quantitative and qualitative) to be triangulated, allowing a robust understanding of the research problem.

Source: Researcher (2022)

4.8.2 Reliability

Reliability is concerned with the consistency, dependability, and replicability of results obtained from any research, as pointed out by Zohrabi (2013). For the quantitative phase of the study, reliability is achieved through a peer review of the data. This is achieved by the project team checking and cross-checking all the data and assisting the researcher with the

quantitative data analysis. For the qualitative phase of the study, data saturation is used in the study as a technique to ensure reliability. Fofana, Bazeley, and Regnault (2020) state that data saturation is a core concept in qualitative research and is achieved when no new relevant information emerges with additional interviews. Data saturation is reached when the data collected is sufficient to cover the themes of interest and where collecting further data will not bring new relevant information (Fofana, Bazeley, and Regnault, 2020). For this study data saturation is achieved by asking questions to the participants in alternate ways, until no new information relating to specimen rejections in COVID-19 is returned.

4.9 Chapter summary

This chapter commenced with an introduction to the research design and methodological approach applied to this research, prior to the reasons for following a post-positivistic approach being presented. This is followed by a discussion of the mixed methodological approach adopted for the research, along with the rationale for using this strategy. The reader is then given a detailed account of the target population, the sampling technique for both quantitative and qualitative data, and the inclusion and exclusion criteria that are adopted specifically for the quantitative data. The quantitative and qualitative data collection strategy is explained before the methods employed for quantitative and then qualitative data analysis are discussed. The ethical considerations for the research are then presented, before the chapter concludes with discussions on validity and reliability, including a description of the pilot study that was performed.

The next chapter presents the reader with a comprehensive view of the quantitative data analysis plan that is executed in this research study, conducive to meeting the research objectives.

CHAPTER FIVE: QUANTITATIVE DATA ANALYSIS

The previous chapter outlined the research design and methodology. It expanded on the plan for collecting and analysing the data. It also discussed the mixed methods approach that was adopted and how the use of both quantitative and qualitative data fortifies this study. This chapter is a progression from that as it sets out to demonstrate how the research plan is executed and how the data is analysed to meet the research objectives. This chapter will solely explore the quantitative data analysis.

5.1 Quantitative data analysis

An extract of the master TrakCare rejection report is used to conduct quantitative data analysis. Refer to Appendix M for an extract of the TrakCare rejection report that is used for this study. As discussed in the previous chapter, the plan for analysing the quantitative data entails filtering down the TrakCare rejection report before performing the data analysis. Inclusion and exclusion criteria are applied. The inclusion criteria are samples that are collected only from Paarl Hospital that are selected for this study, and the exclusion criteria are all non- COVID-19 related samples. Thereafter, the data is arranged in chronological order for it to be analysed using quality tools.

The quality tools selected for this study, namely Pareto analysis, Ishikawa diagram, 5 Whys analysis and FMEA are selected for the unique level of enquiry they provide to enable this study to meet each of the research objectives. As discussed in Chapter 3, these quality tools are optimally used in a PDCA cycle and are intentionally used in this specific order to perform the four stages of the Plan-Do-Check-Act model. Furthermore, these quality tools are conducted in this sequence as the outcomes derived from each preceding tool are used as the basis of analysis of the tool that follows. Following this strategy yielded the main causes of specimen rejections and enables a sequential detailed root cause analysis to be performed on the crucial areas only.

5.1.1 Pareto Analysis

Data analysis commences with a Pareto Analysis. The extract of the master TrakCare rejection report contains data on all the rejected samples, and by applying the Pareto principle, the crucial 20% of the causes of rejections that led to 80% of the rejected samples are highlighted. Utilising Pareto analysis enables this study to meet the first research objective which is to ‘identify the critical contributing factors that are responsible for the errors in COVID-19 testing’.

The Pareto analysis is performed in the following five steps by the project team to identify the critical factors:

Step 1: The rejection descriptions are listed;

Step 2: Rejected samples are categorised according to a reason for descriptive designation for the rejection and the number of samples in each category is counted;

Step 3: Categories are arranged in descending order;

Step 4: The percentage for each category and the cumulative percentage of rejections are calculated;

Step 5: The Pareto chart is constructed.

Table 7 illustrates Steps 1 to Step 4 of the Pareto analysis and Figure 14 depicts Step 5 of the process followed by the laboratory project team when performing the Pareto analysis.

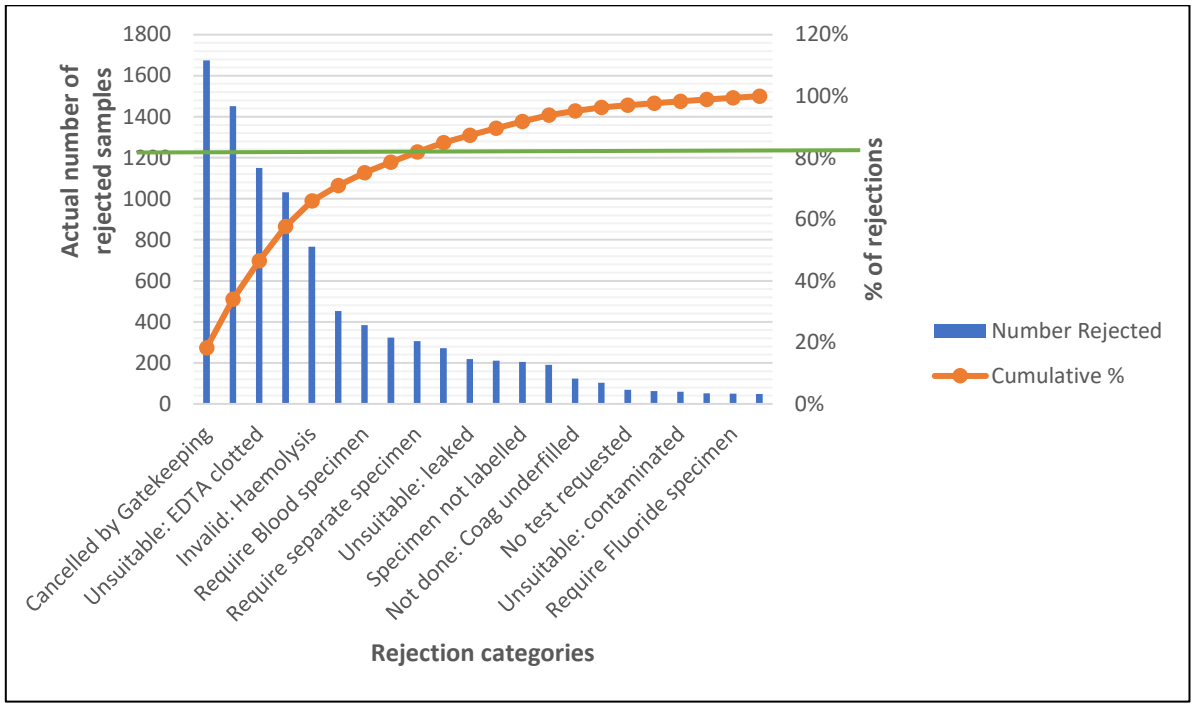
Table 7: Pareto analysis data

Rejection Description	Number Rejected	Cumulative	%	Cumulative%
Cancelled by Gatekeeping	1675	1675	18%	18%
Unsuitable: Haemolysed	1452	3127	16%	34%
Unsuitable: EDTA clotted	1150	4277	12%	46%
Specimen insufficient	1032	5309	11%	58%
Invalid: Haemolysis	766	6075	8%	66%
Info does not match	452	6527	5%	71%
Require blood specimen	384	6911	4%	75%
Unsuitable: too old	323	7234	4%	79%
Require separate specimen	306	7540	3%	82%
Require EDTA Specimen	272	7812	3%	85%
Unsuitable: leaked	219	8031	2%	87%
Specimen not received	210	8241	2%	90%
Specimen not labelled	204	8445	2%	92%
Unsuitable: clotted	191	8636	2%	94%
Not done: Coag underfilled	123	8759	1%	95%
Cancelled by Dr	103	8862	1%	96%
No test requested	68	8930	1%	97%
Require PPT specimen	63	8993	1%	98%
Unsuitable: contaminated	60	9053	1%	98%
Not done: unsuitable	52	9105	1%	99%
Require Fluoride specimen	50	9155	1%	99%
Unsuitable: Bloodstained	48	9203	1%	100%
Total	**9203**			

Source: Researcher (2022)

Figure 14 illustrates the Pareto chart that the project team constructed.

Figure 14: Pareto chart of specimen rejections



Source: Researcher (2022)

The Pareto chart in Figure 14 displays 11 rejection categories that are identified as problem sources. It also illustrates the actual value and the calculated percentages of the specimen rejections. Pareto analysis allows this study to categorise the errors that gave rise to specimen rejections by graphically illustrating the results in a Pareto diagram, so the 'significant few' problems could be isolated from the general background of laboratory errors. Eight "significant few" problem sources were identified by the Pareto analysis. These are:

- Problem source 1: Cancelled by electronic gatekeeping (EGK)
- Problem source 2: Unsuitable: Haemolysis
- Problem source 3: Unsuitable: EDTA clotted
- Problem source 4: Specimen insufficient
- Problem source 5: Invalid: Haemolysis
- Problem source 6: Information does not match
- Problem source 7: Require blood specimen (incorrect specimen taken)
- Problem source 8: Unsuitable too old

The categories listed above are then examined using Ishikawa diagrams, which is the next phase of the quantitative data analysis plan. It must be noted that problem source 2 and

problem source 5 have been amalgamated into one problem in this research study as their outcomes are identical, thereby identifying a total of seven problem sources.

5.1.2 Ishikawa diagram

The Ishikawa diagram enables the researcher to explore the problems identified by Pareto analysis by generating a systematic graphic depiction of both the problem and the sources. This type of analysis facilitates the schematic identification of the relationship between the problem and all its causes by drawing and mapping out the main non-conformity, which is represented by the head of the diagram, and linking all the possible causes, which are represented as the body of the diagram (Luca, 2016; Loredana, 2017). A template for an Ishikawa diagram can be seen in Figure 11 of Chapter 3.

The following steps are performed by the project team during the construction of the Ishikawa diagram for each of the seven problems highlighted by Pareto analysis:

Step 1: The problem identified is first placed in the box on the right-hand side of the diagram. This represents the 'head of the fish.' Thereafter, a horizontal line is drawn directed towards the problem which represents the backbone;

Step 2: Contributory factors linked to the problem are identified by the project team;

Step 3: Contributory factors identified in Step 2 are categorised into: Man, Methods, Machine, Material, Measurement, and Environment. These main categories are placed in boxes on either side of the 'body of the fish,' and slanting arrows connected them to the main diagram. The possible causes that are identified in each category, are indicated as smaller arrows on the diagram or the 'fish bones' related to that category;

Step 4: The project team performs a brainstorming session where thoughts and concerns regarding each cause are documented. Notably, the project team in this research study found no causes responsible for problems under the measurement category.

Step 5: The project team then reviews and reflects on the Ishikawa diagram for accuracy and completeness. In this study, the project team identified only two categories of concern: method and material.

Step 6: Guided by the results of the reflection performed in Step 5, the project team simplifies the Ishikawa diagram by confirming that validity of causes, moving causes from one category to another where relevant, and removing redundancies in the diagram.

Although seven traditional Ishikawa diagrams were constructed as part of this study for the seven problems highlighted by the Pareto Analysis, the results of the Ishikawa analysis are presented in the form of a table instead of a diagram, due to the amount of data being

presented and to simplify the presentation and discussion of results in the ambit of this dissertation. Thus, Table 8 presents the summary of the results of the Ishikawa diagram on rejected specimens. The effect, or nonconformity, is placed on the vertical axis and the causes for each category are listed on the horizontal axis.

To view the traditional format of the Ishikawa diagrams for each nonconformity raised from Pareto analysis, refer to Appendices F to L.

Table 8: Ishikawa diagram for rejected specimens (Source: Researcher, 2022)

Effect/ Nonconformity	Causes: Man	Method	Material	Machine	Measurement	Environment
Problem source 1 Test Cancelled by EGK	Nurse/ clinician requested duplicate test on patient too soon after last test request	1. Lab reception procedures not available 2.TrakCare LIS guidelines not available	none	none	none	none
Problem source 2 Unsuitable haemolysed samples	1. Nurse/ clinician used incorrect technique to collect sample 2. Courier incorrectly handled and stored sample during transportation	1. Patient preparation guidelines not available 2. Specimen collection guidelines not available	Specimen collection containers and blood collection needles not available	none	none	1. Specimens stored at incorrect temperature 2. Specimens transported at incorrect temperature
Problem source 3 EDTA clotted	1. Nurse/ clinician used incorrect technique to collect sample 2. Courier incorrectly handled and stored sample during transportation	1. Patient preparation guidelines not available 2. Specimen collection guidelines not available 3. Transport guidelines not available.	Specimen collection and blood collection containers not available	none	none	1. Specimens stored at incorrect temperature 2. Specimens transported at incorrect temperature
Problem source 4 Specimen insufficient	1. Nurse/ clinician failed to collect sufficient specimen for testing. 2. Courier mishandled sample during transport, resulting in samples being opened and leaking out.	1.Patient preparation and specimen collection guidelines not available. 2. Lab receiving guidelines not available.	Specimen collection containers not available	none	none	none
Problem source 5 Information does not match	1. Nurse/ clinician incorrectly labelled specimen and request from 2. Patient submitted incorrect information	Patient preparation guidelines not available	1. Incorrect/ no Patient ID sticker used on specimen. 2. Incorrect/ no Patient ID sticker used on request form.	Incorrect patient information registered on Hospital database	none	none
Problem source 6 Require blood specimen	Nurse/ clinician collected incorrect sample type	Specimen collection guidelines not available	Specimen collection containers not available	none	none	none
Problem source 7 Sample too old	1.Nurse/ clinician failed to send sample to lab after collection. 2.Courier delayed in transporting sample to lab. 3.Lab technologist failed to process sample timeously upon receipt in lab.	None	none	none	none	none

Table 8 depicts the results of the first draft of the Ishikawa analysis (Step 4) performed by the project team. After reviewing the Ishikawa diagram the project team discusses and reflects on the causes of each non-conformity to remove the redundant causes (Steps 5 and 6). Thus, a second Ishikawa diagram is then constructed by the project team after reflecting on the initial Ishikawa diagram in Table 8. The modified Ishikawa diagram can be seen in Table 9.

Table 9: Modified Ishikawa diagram (Source: Researcher, 2022)

Effect/ Nonconformity	Causes: Man	Method	Material	Machine	Measurement	Environment
Problem source 1 Test Cancelled by EGK	None	Guidelines not available for: Tests affected by EGK	none	none	none	none
Problem source 2 Unsuitable haemolysed samples	None	1. Guidelines not available for: Patient preparation, specimen collection, transport, and storage 2. Inadequate measuring method for: Specimen collection, availability of suitable blood collection material	none	none	none	none
Problem source 3 EDTA clotted	None	1. Guidelines not available for: Patient preparation, specimen collection, transport, and storage 2. Inadequate measuring method for: Specimen collection, availability of suitable blood collection material	none	none	none	none
Problem source 4 Specimen insufficient	None	1. Guidelines not available for: Patient preparation, specimen collection, and transport 2. Inadequate measuring method for: Specimen collection and courier handling and transport	none	none	none	none
Problem source 5 Information does not match	None	1. Guidelines not available for: Patient administration and data capturing 2. Inadequate measuring method for confirmation of patient details	Flawed/ omission of Patient ID sticker on: specimen and request form.	none	none	none
Problem source 6 Require blood specimen	None	1.Guidelines not available for: Specimen collection 2. Inadequate measuring method for confirmation of suitable sample collected	Specimen collection containers not available	none	none	none
Problem source 7 Sample too old	None	1.Inadequate measuring method for ensuring timeous transport of specimen to lab 2.Guidelines not available for lab contingency plan	none	none	none	none

The modified Ishikawa diagram (Table 9) is created after the project team reached a consensus decision on the key sources of each of the seven rejection types. Through discussion among the project team, each cause is thoroughly examined and evaluated. Thereafter, the project team eliminated the redundant sources that lead to the specimen rejections and decided on the probable cause for the rejection. In some cases, the laboratory project team identified multiple causal sources for the rejection, which is further analysed. Review of the completed Table 9 allowed the project team to deduce that the likely causes of specimen rejections are system failures for all seven problems emanated from only two causal categories, which are method and material. Under the category 'method' the lack of appropriate guidelines for procedures was indicated as a cause for rejection in all seven problem types. Moreover, under the category 'material', inadequate supplies available to perform the process was highlighted as a cause for the problem source 'information does not match' and 'require blood specimen'. Each one of these findings are further investigated in the 5 Whys analysis which is the next phase of quantitative data analysis.

Ultimately, together with Pareto analysis, the Ishikawa diagram permitted this study to meet the first research objective; 'to identify the critical contributing factors that are responsible for the unacceptable laboratory errors in COVID-19 testing'.

5.1.3 The 5 Whys analysis

Voehl (2016) explains that the 5 Whys technique is the practice of asking "why" five or more times, to get to the root cause of the problem. With this practice, the quality tool attempts to peel away the layers of a problem, making it more understandable and thereby allowing the root cause to be identified. In doing so, it facilitates the creation of possible solutions.

Isixsigma (2022) states that in some situations fewer than 5 whys may be sufficient to establish the root cause, as long as the analysis is rigorously performed. Significantly, during this part of the quantitative data analysis, it was noted that although Pareto analysis returned seven problem sources, three of those sources identified, namely: Problem source 2: Unsuitable haemolysed samples, Problem source 3: EDTA clotted, and Problem source 4: Specimen insufficient, the procedure followed to collect specimens (which were later rejected) are identical. Thus, these three categories of specimen rejections are combined in this study.

Tables 10 to 14 are detailed illustrations in table form of the 5 Whys analysis that is performed on the five critical problems that were identified by the Ishikawa diagram analysis.

5.1.3.1 The 5 Whys analysis on specimens rejected due to cancellation by EGK

Electronic gatekeeping is a system for preventing the duplication of patient testing that may be ordered by the nurse or clinician. The principle of EGK is based on systematic rules that are set up on TrakCare to automatically reject tests that are duplicated on the same patient. The root cause of specimens being rejected due to cancellation by EGK returned that clinicians and nurses ordered repeat tests on the same patient, as there are no procedures on EGK rules available. Table 10 presents the findings of the 5 Whys analysis performed on specimens rejected as a result of EGK. This study thereby deduces that the root cause for specimens being rejected by EGK are due to ineffective processes in place for ensuring clinicians are up to date with TrakCare EGK procedures.

Table 10: 5 Whys analysis on specimens rejected due to cancellation by EGK

Problem Category	Why 1	Why 2	Why 3	Why 4	Why 5	Root Cause
Method TrakCare procedures not available for tests affected by EGK	TrakCare procedures set up electronically on LIS to prevent repeat testing	Clinician orders repeat test on patient	Clinician not aware of repeat testing procedures and rules for ordering tests	TrakCare procedures on repeat testing was not made available to nurse/ clinician	No checkpoint in place to ensure TrakCare procedures are available for nurses/ clinicians	Ineffective process for ensuring clinicians are up to date with TrakCare EGK procedures

Source: Researcher (2022)

5.1.3.2 The 5 Whys analysis on specimens rejected due to haemolysis, clotted EDTA, and insufficient specimens

Analysis of the Ishikawa diagrams for Problem source 2, Problem source 3, and Problem source 4 indicated that these rejections occurred due to incorrect techniques used to collect the specimens. The 5 Whys analysis, as seen in Table 11, shows that there are three root causes that led to haemolysed, clotted, and insufficient specimens which resulted in the specimen being rejected. Data analysis allowed this study to deduce that the root causes are: (1) a lack of suitable control measures to assess the competency of nurses and clinicians during patient preparation and specimen collection, (2) procedures for specimen handling, transport, and storage for newly appointed couriers are not available and (3) training programs for stores clerks on effective stock management procedures are not available.

Table 11: 5 Whys analysis on specimens rejected due to haemolysis, clotted EDTA, and insufficient specimens (Source: Researcher, 2022)

Problem Category	Why 1	Why 2	Why 3	Why 4	Why 5	Root Cause
1.Method Patient preparation and specimen collection procedures not available	Nurse/ clinician inadequately prepared patient for specimen collection, and incorrect technique used to collect specimen	Nurse/ clinician did not follow suitable patient preparation and specimen collection procedures	Procedures for patient preparation and specimen collection not available in ward	No checkpoint in place to ensure nurse/ clinician adequately prepared patient for specimen collection	Inadequate control measures in place for ensuring correct procedure followed during patient preparation and specimen collection	Lack of suitable control measures to assess competency of nurses/ clinicians during patient preparation and specimen collection, and absence of patient preparation and specimen collection procedures
2.Method Specimen handling, transport, and storage guidelines not available	Courier failed to correctly handle specimens, as well as correctly store and transport specimens to the lab at 2-8 C	Courier not aware of correct handling procedures, and correct temperature to store samples during transportation	Due to COVID-19 pandemic, increased courier appointments. Newly contracted couriers not inducted on specimen storage and transport	Procedures not available to address suitable handling, transport and storage conditions of specimens with newly appointed couriers	No checkpoint in place to ensure availability of specimen handling, transport, and storage procedures with newly appointed couriers	Absence of specimen handling, transport, and storage procedures for newly appointed couriers
3.Method Incorrect technique used by nurse/ clinician to collect sample	Nurse/ clinician not adequately trained to collect blood specimens	Specimen collection training not identified as critical need for nurses/ clinicians	Department of Health not mandated to provide training as part of curriculum on blood collection procedures. Responsibility falls under local facility to provide training	No checkpoint in place to ensure nurses/ clinicians are adequately trained and signed off as competent before collecting specimens from patients	No SOP in place for ensuring nurses/ clinicians are first competent before collecting patient specimens	Absence of suitable SOP to address competency of nurses/ clinicians before they can collect patient specimens.
4.Method Unavailability of suitable specimen collection containers	Ward has incorrect stock / no stock of suitable blood collection supplies	Stores clerk failed to restock ward with blood collection supplies	Stores clerk failed to place stock order from supplier for blood collection supplies	Ineffective training supplied to stores clerk on effective stock management procedures	No checkpoint in place to ensure stores clerk received training to effectively manage stock ordering processes	Ineffective training programme on stock management procedures for blood collection supplies

5.1.3.3 The 5 Whys analysis on specimens rejected due to information does not match

As discussed in Chapter 2, 'information does not match or mismatched information,' is a cause for specimens being rejected as the information on the specimen does not correlate to the information on the request form, or vice versa. The 5 Whys analysis in Table 12 allowed this study to deduce that the three root causes for specimens being rejected due to mismatched information is a result of (1) the absence of adequate patient administration and data capturing procedure, (2) the absence of guidelines addressing the confirmation of patient details, and (3) an inadequate procedure in place to ensure correct ID stickers are placed in patient folders.

Table 12: 5 Whys analysis on specimens rejected due to mismatched information (Source: Researcher, 2022)

Problem Category	Why 1	Why 2	Why 3	Why 4	Why 5	Root Cause
1.Method Patient administration and data capturing procedures not available	Admin personnel are responsible for patient admin and data capturing of patient details on hospital system	Admin staff did not follow procedures for correctly capturing patient details on hospital system	Admin staff not adequately trained on correct procedures for data capturing	Procedures not available to address data capturing of patient information on hospital system	No checkpoint in place to address availability of appropriate procedures for data capturing patient information of hospital system	Absence of patient administration and data capturing procedures for admin staff
2.Method Incorrect patient details on hospital computer systems	Incorrect Patient details were captured on hospital computer system	Admin staff failed to confirm correctness of patient details prior to capturing on hospital computer system	Admin staff were not adequately trained on correctly capturing patient information on hospital computer system	Procedures not available for confirming correct information is captured onto hospital computer system	No checkpoint in place to confirm correctness of patient details captured onto hospital computer system	Absence of procedures for confirmation of correctness of patient details
3.Material Incorrect/ no patient ID Sticker on specimen and request form	Incorrect / no patient ID sticker was used on specimen and request form	1. Nurse/ clinician failed to attach patient ID sticker on specimen and request form 2.Nurse/ clinician attached incorrect patient ID sticker on specimen and request form	Admin staff failed to place patient ID sticker/ correct patient ID sticker in patient folder for nurse/ clinician to use	Admin staff failed to verify contents of patient folder when patient was admitted into hospital	No checkpoint in place to ensure patient ID stickers/ correct patient ID stickers are contained in patient folder	Inadequate procedures in place to ensure patient ID stickers/ correct patient ID stickers contained in patient folders

5.1.3.4 The 5 Whys analysis on specimens rejections due to incorrect specimens collected

Evaluation of the incorrect specimen problem revealed that the incorrect procedures are followed by the nurse or clinician in collecting the correct specimen type for the test requested. The 5 Whys investigations highlighted the lack of correct specimen collection containers at the ward which led to the collection of specimens in the incorrect containers. From data analysis, this study deduced three root causes for specimen rejections due to the incorrect samples being collected. These were: (1) the absence of a specimen collection procedure, (2) inadequate measuring methods for ensuring correct specimen types are being collected, and (3) an ineffective training programme for stock management procedures. Table 13 presents the 5 Whys analysis on rejections due to incorrect specimens collected.

Table 13: 5 Whys analysis on specimens rejected due to incorrect specimen collected (Source: Researcher, 2022)

Problem Category	Why 1	Why 2	Why 3	Why 4	Why 5	Root Cause
1.Method Incorrect specimen collection procedures followed	Nurse/ clinician collected incorrect specimen for tests requested.	Nurse/ clinician did not follow specimen collection procedures	Nurse/ clinician not adequately trained on correct blood collection procedures	procedures not available for correct blood collection techniques	No Checkpoint to ensure correct sample is being collected to the test requested	Absence of specimen collection procedures
2.Method Incorrect sample type collected by nurse/ clinician for test	Nurse/ clinician collected incorrect sample type	Nurse/ clinician unaware of appropriate sample types for tests	Nurse/clinician not adequately trained on appropriate sample types	Hospital failed to adequately sign off competency for staff on collecting blood samples	No measuring method for ensuring correct sample types are being collected	Inadequate control measures for ensuring correct sample types are being collected for tests requested
3.Material Incorrect specimen collection containers used	Ward has incorrect/ no stock of different blood collection supplies	Stores clerk failed to restock ward with correct blood collection supplies	Stores clerk did not place order from supplier for blood collection supplies	Ineffective training supplied to stores clerk on effective stock management procedures	No checkpoint in place to ensure stores clerk received training to effectively manage stock ordering processes	Ineffective training programme on stock management procedures for blood collection supplies

5.1.3.5 The 5 Whys analysis on specimens rejected due to samples being too old

The 5 Whys analysis of the research data on ‘specimens rejected due to samples being too old’, revealed that there are three possible causes for a time delay from when the sample was taken to when it was processed. These were: (1) a delay resulting from the lack of control measures in the process performed by the clinician or nurse when sending the specimen to the laboratory, (2) courier delays in delivering the sample to the lab, and (3) delays at the laboratory while processing of the sample. Refer to Table 14 for the 5 Whys analysis for specimens rejected due to samples being too old.

Table 14: 5 Whys analysis on specimens rejected due to samples being too old (Source: Researcher, 2022)

Problem Category	Why 1	Why 2	Why 3	Why 4	Why 5	Root Cause
1.Method Nurse/ Clinician did not send sample timeously to the lab for testing	Nurse/ Clinician did not send specimen to the lab immediately after collection	Nurse/ clinician batched specimens after collection for single delivery of samples to the lab.	Nurse/ clinician unaware of risks of delaying sample delivery to the lab after specimen collection.	Procedures not available to address timeous transporting of samples to lab after collection	No checkpoint in place to ensure samples sent to lab immediately after collection	Inadequate control measures to ensure timeous transportation of specimens to the lab
2.Method Courier did not deliver specimens to the lab timeously for testing	Courier collected specimens, but did not deliver immediately to the lab for testing	Courier batched specimens and opted to deliver specimens to the lab at the end of day	Courier unaware of risks of delaying sample delivery to the lab after specimen collection.	Procedures not available to address timeous transporting of samples to lab after collection	No checkpoint in place to ensure courier delivers samples to lab immediately after collection	Inadequate control measures to ensure timeous transportation of specimens to the lab
3.Method Lab technologist delayed the processing of the specimen	Lab had backlog of work and technologist was unable to process all specimens timeously	Lab did not have sufficient staff to process specimens	Procedures not available for contingency plan whereby samples must be sent to the neighbouring lab for processing when there is not enough staff	Lab staff did not follow contingency plan	No checkpoint in place to ensure lab follows contingency plan	Procedures not available on contingency plans for staff to follow when there are not enough staff on duty

5.1.4 Summary of the 5 Whys analysis

The 5 Whys analysis highlighted all the root causes of specimen rejections. Table 15 presents a summary of the root causes with the corresponding process steps of the pre-analytical COVID-19 testing process as it was illustrated by Figure 9 in Chapter 2. Table 15 is an extended version of Figure 9 found in Chapter 2. Table 15 allows this research to see what pre-analytic process steps of the COVID-19 testing process needs interventions so that optimisation of the process can take place.

Table 15: Summary of root cause analysis for specimen rejections (Source: Researcher, 2022)

COVID 19 TEST PROCESS STEP	ROOT CAUSE
Pre-analytical	
1. Discussion for laboratory test requirement	● None
2. Laboratory test selection	● Inadequate control measures to ensure clinicians are up to date with EGK procedures
3. Identification of the patient and completion of the request form (Specimen collection)	● Lack of suitable control measures to assess the competency of nurses/ clinicians during patient identification and completion of the request form. ● Inadequate patient administrative procedures
4. Patient preparation (Specimen collection)	● Lack of suitable control measures to assess the competency of nurses/ clinicians during patient preparation. ● Lack of patient preparation procedures
5. Specimen collection	● Lack of suitable control measures to assess the competency of nurses/ clinicians during patient collection. ● Lack of specimen collection procedures ● Lack of suitable control measures to ensure correct sample types are being collected for the test requested ● Inadequate training programs for stores clerks on stock management procedures for specimen collection supplies
6. Labelling of specimen and request form (Specimen labelling)	● Lack of suitable control measures to assess the competency of nurses/ clinicians during labelling. ● Lack of procedures for the confirmation of the correctness of patient details ● Inadequate procedures in place to ensure patient ID stickers/ correct ID stickers are in patient folders
7. Specimen handling and storage (Specimen labelling)	● Lack of specimen handling and storage procedures
8. Specimen transportation	● Lack of specimen transportation procedures ● Inadequate measuring method to ensure timeous transportation of specimens to the lab

The research findings of the 5 Whys analysis provided the data for the next phase of data analysis, the FMEA. During the FMEA, failure modes in each of the pre-analytical COVID-19 test process steps listed in Table 15 are analysed to identify corrective actions and improvement measures that may reduce or eliminate the risk of rejected specimens in these areas.

5.1.5 Failure Modes and Effects Analysis (FMEA)

In this research study, the FMEA starts with a high-level examination of each step in the current COVID-19 testing process to determine the severeness of the impact of failure modes that could potentially occur in that step. Each finding derived from the 5 Whys analysis (shown in Table 16) represents a failure mode in one of the seven pre-analytical COVID-19 test process steps (COVID-19 pre-analytical process step 1 ‘discussion for laboratory test requirement,’ has no potential errors and will not be part of the FMEA).

Table 16: FMEA failure modes (Source: Researcher, 2022)

Pre-analytical COVID-19 Test Process Step	Potential failures in a specific step of the process
1. Laboratory test selection (Laboratory test selection failure) — Failure Mode 1	• Laboratory test selection failure • Test order duplicated
2. Identification of the patient and completion of the request form (Specimen collection failure) — Failure Mode 2	• Specimen collection failure • Patient incorrectly identified, where incorrect/ mismatched details are on specimen and request form
3. Patient preparation (Specimen collection failure)	• Specimen collection failure • Incorrect procedures followed for patient preparation prior to specimen collection
4. Specimen collection (Specimen collection failure)	• Specimen collection failure • Incorrect technique used to collect specimen
5. Labelling of specimen and request form (Specimen labelling failure) — Failure Mode 3	• Specimen labelling failure • Incorrect/ mismatched information used on specimen and request form
6. Specimen handling and storage (Specimen transportation failure) — Failure Mode 4	• Specimen transportation failure • Specimens handled incorrectly during transportation • Specimens stored at incorrect temperatures during transportation
7. Specimen transportation (Specimen transportation failure)	• Specimen transportation failure • Delay in specimen transportation to the laboratory

Table 16 illustrates the four failure modes that were identified by the project team, namely: (1) laboratory test selection failure, (2) specimen collection failure, (3) specimen labelling failure, and (4) specimen transportation failure.

A risk priority number (RPN) is tabulated for each failure mode identified, by calculating the product of the values assigned for the severity of the failure mode, the likelihood of occurrence and the effectiveness of detection mechanisms for that failure mode. This research adopted a 1-10 ranking matrix complied by Ahsen et al. (2022) (Appendix C), where a score of 1= low, and 10= high, for the severity, frequency, and detectability. Informed by literature, in a study conducted by Ahsen et al. (2022) all RPN's greater than 300 required mitigation for improvement, similarly in this study the failure modes with a RPN of greater than 300 are re-examined and recommendations are made to modify these steps. Thereafter, RPNs are recalculated to determine if further improvement is needed. The risk is accepted if the RPN is 300 or less.

5.1.5.1 FMEA investigations

Table 16 is a summary depiction of each of the steps in the pre-analytical COVID-19 testing process and highlights which failure modes can occur in each step of the pre-analytical COVID-19 testing process. Table 16 demonstrates that laboratory tests selection failure is the failure mode which can occur in Step 1. Identification of the patient and completion of the request form, patient preparation and specimen collection is the failure mode which can occur in Step 2, 3, and 4. Labelling of specimen and request form is the failure mode which can occur in Step 5. Specimen handling and storage and specimen transportation is the failure mode which can occur in Step 6 and 7. Thus, a total of four failure modes are identified in the pre-analytical COVID-19 testing process. A brief description of the findings of the investigation performed by the laboratory project team on each of the failure modes with an RPN greater than 300 is discussed below. The pre-analytic COVID-19 process steps that achieved RPN greater than 300 and required mitigation are Step 4: specimen collection, and Step 5: specimen labelling.

5.1.5.1.1 Pre-analytical COVID-19 test process Step 4: specimen collection

The RPN is calculated for this failure mode and achieved an overall score of 720. This was a result of the product of the severity, the frequency, and the detection level. The severity score achieved is 10 which presented a high risk to the patient. Due to the rejection, there are no results received by the clinician to treat the patient. Research findings revealed that the frequency score is 9, due to its very high occurrence, and the detection score is 8, indicating that these errors have a very low probability of being detected prior to being sent to the

laboratory for testing. Due to the RPN being greater than 300 this is indicative that this process requires immediate mitigation.

5.1.5.1.2 Pre-analytical COVID-19 test process Step 5: specimen *labelling*

The RPN is calculated for this failure mode and achieved an overall score of 648. This was a result of the product of the severity, frequency, and detection. A severity score of 9 is received as it presents a very high risk to the patient as no results and treatment are received. A frequency score of 9 is assigned to this failure mode, indicating a very high occurrence. A detection score of 8 is assigned, indicating this process has a low probability of being detected and corrected prior to being sent to the laboratory for testing. Due to the RPN being greater than 300 this is indicative that this process requires immediate mitigation.

The illustration of the FMEA process discussed can be seen in Appendix N. Data analysis deduced that the pre-analytical COVID-19 test process Step 4: specimen collection and pre-analytical COVID-19 test process Step 5: specimen labelling, are to be re- examined and recommendations are to be made by the project team to modify these pre-analytical process steps.

5.1.5.2 Review of the FMEA

Guided by literature (Ahsen et al., 2022) during the review of the FMEA the project team identified the process steps with the highest risk failure modes and brainstormed process improvements such as modifying the specimen collection and labelling processes, to overcome the high risk (prevent specimen rejections) and essentially optimise the process. Thereafter, the RPNs are recalculated to assess if any further process improvements were needed, or if the process risk could be accepted. An updated FMEA was the outcome of the FMEA review and can be seen in Appendix O.

The interventions listed below are the findings of data analysis:

5.1.5.2.1 Interventions for the pre-analytical COVID-19 test process Step 4: specimen collection

The project team proposed five recommendations for modifying the specimen collection process step to reduce specimen rejections. These are:

1. Implementing quarterly induction and training sessions: Lee (2019) explains that induction and training programs organized by health institutions would benefit nurses and clinicians by exposing them at an early stage to the correct techniques of patient preparation and specimen collection. This enables practical mentorship for nurses and

clinicians so that specimen collection techniques are mastered before they can be performed on patients. The project team deduced that a well-structured induction program, facilitated by the NHLS and Department of Health for all newly appointed nurses and clinicians would address the requirements for specimen collection and labelling. Thereafter, follow up trainings should be made available at three to six months after the induction session to ensure that nurses and clinicians continue to perform specimen collection and labelling in an acceptable manner in which reduces the risk of specimen rejections. If a nurse or clinician fails to perform acceptable specimen collection and labelling after the follow-up training sessions, re-training or working under supervision should be implemented by the health care facility.

2. The development and display of posters and visual aids on blood collection techniques in areas where blood collection takes place. This form of visual management would be a method of continuously and subconsciously alerting nurses and clinicians on correct specimen collection techniques when they are actively collecting specimens (Lee, 2019). Additionally, by distributing hardcopy and PDF copies of the procedure quick guide (PQG) to healthcare facilities, nurses and clinicians would have immediate access to specimen collection techniques that would provide additional support when needed. Thus, reducing the number of errors in specimen collection, and subsequently reducing the effects of haemolysis, clotted EDTA, insufficient specimens, and incorrect specimens taken, ultimately reducing specimen rejections.
3. The use of a stock template vessel in each blood collection trolley would ensure that the stock clerk has a visual guide when restocking blood collection trolleys. This would ensure the correct consumables are restocked for nurses and clinicians to use when collecting specimens (Kang, Li, Xia, and Shan, 2020).
4. The appointment of an admin clerk as a control check to verify if the correct specimen tubes are collected and if the details on the specimen and request form correspond would be valuable. Only specimens that pass the control check will be sent through the following pre-analytic process step by the admin clerk. All erroneous specimens and forms that failed the control check will be sent back to the nurse or clinician to rectify prior to being sent to the laboratory for testing.
5. Outsourcing and appointing a phlebotomy service in high-rejection areas, may alleviate or eliminate the risk of specimen rejections. A phlebotomy service by profession would be responsible for correctly collecting, labelling, and transporting the specimen in strict accordance with ISO 15189:2012 guidelines to the laboratory for testing, thereby reducing and eliminating all pre-analytical errors. Phlebotomy services are widely used by the private sector, however, due to financial constraints and national policies by the state sector, this recommendation is not always viable. Should

there be a financial allocation and a change in policy guidelines for this resource, it would be valuable in optimizing the pre-analytical process and eliminating the burden of rejected specimens.

With the implementation of the above-mentioned, the RPN of the pre-analytical COVID-19 process Step 4: specimen collection, is recalculated. During the final review of this failure mode, the project team determined that the rating of the severity, the frequency, and the detection level is 2. By calculating the product of these three, the new RPN is 8. Since the new RPN is less than 300, the risk is accepted.

5.1.5.2.2 Interventions for the pre-analytical COVID-19 test process Step 5: specimen Labelling

The project team identified two interventions for the pre-analytical COVID-19 test process Step 5: specimen labelling, to reduce specimen rejections. These are:

1. Liaise with the hospital to create and distribute patient admissions and data-capturing procedures that would be beneficial to the hospital admin staff. This would serve as the official procedure for the correct identification of patients when they are initially admitted to the Hospital (Kang et al., 2020). A standard operating procedure for patient admissions and data capturing is believed to be capable of reducing and possibly eliminating the number of labelling errors that results in specimens being rejected.

2. The appointment of an administration clerk to serve as a control check. The job of this person is to verify the accuracy of the specimen label and request form. This intervention serves as a checkpoint before the specimen is sent to the laboratory. All erroneous specimens and forms that failed the control check will be sent back to the nurse or clinician to rectify prior to being sent to the laboratory for testing. This intervention is capable of eliminating all specimen labelling errors and significantly reduce specimen rejections.

With the implementation of the afore-mentioned interventions, the RPN is recalculated by the project team. During the final review of this failure mode, the project team determined that the rating of the severity is 1, the frequency is 2, and the detection level is 1. By calculating the product of these three, the new RPN is 2. Since the new RPN is less than 300, the risk is accepted.

Guided by the above recommendations and improvement measures made by the project team, the results reveal an optimised pre-analytical process with reduced specimen rejections. Data analysis deduced that the findings of FMEA confirm the accomplishment of the 4th research objective in this study, “developing an optimised pre-analytic process which includes preventative measures that ensure reduced laboratory errors in COVID-19 testing.”

5.2 Chapter summary

This chapter presented the quantitative data analysis that was performed by a project team, led by the researcher of this research study. Four quality tools were used namely Pareto analysis, Ishikawa diagram, the 5 whys analysis, and FMEA. The Pareto analysis highlighted the 20% of the causes of rejections that led to 80% of rejected specimens. It identified the crucial categories of rejections as; cancelled by gatekeeping, haemolysis, EDTA clotted, specimen insufficient, information does not match, require blood specimen, and specimen too old. The root causes were identified by the Ishikawa diagram and the 5 whys analysis, thereafter FMEA was conducted to prioritise the process steps that required modification to improvement. The chapter concludes with recommendations made by the project team to reduce specimen rejections and improve the pre-analytic process phase. The next chapter reports the research findings of the qualitative data analysis phase.

CHAPTER SIX: QUALITATIVE DATA ANALYSIS

The previous chapter presented the findings of quantitative data analysis of this study. This chapter presents the qualitative data analysis findings which involved the analysis and interpretation of data from the semi-structured interviews. When used on sequence as in this study, the purpose of the qualitative data analysis phase is to enhance and validate the findings of the quantitative data (Adeoye-Olatunde and Olenik, 2021). This chapter consists of three sections. The first section provides a summarised reflection of the research findings. The second section presents an overview of semi-structured interviews that were conducted, and the last section provides the confirmatory analysis of the qualitative data.

6.1 Reflection of the research findings

During quantitative data analysis, four quality tools (Pareto analysis, Ishikawa diagram, 5 whys analysis, and FMEA) that are linked to the PDCA cycle were used to identify the root causes of specimen rejections and make recommendations to improve pre-analytical COVID19 test process. A summary of these findings can be seen in Appendix P. There were two pre-analytical COVID-19 test process steps that were identified by FMEA, that required significant improvement. These are: (1) Pre-analytical COVID-19 test process step 4: specimen collection and (2) Pre-analytical COVID-19 test process step 5: specimen labelling. The five key recommendations derived from FMEA to improve pre-analytical COVID-19 test process step four: specimen collection, are: (1) implement quarterly induction and training sessions for nurses and clinicians, (2) develop and distribute specimen collection and labelling procedures and visual aids on blood collection techniques, (3) use a stock template vessel in blood collection rooms, (4) appoint an administration clerk to verify specimen collection and labelling, and (5) outsource a phlebotomist to collect specimens in high rejection areas.

Moreover, the two key recommendations derived from FMEA to improve pre-analytical COVID-19 test process step five: specimen labelling, are: (1) develop and distribute patient admissions and data capturing procedures and (2) appoint an administration clerk to manually verify correctness of the specimen collected for the test requested and to verify corresponding details on specimen and request form. These recommendations provided the basis for the semi-structed interviews that are conducted.

6.2 Semi-structured interviews

This section of the chapter reports on the analysis of data collected by means of semi-structured interviews. Three research participants are selected for the interviews and comprise of the key stakeholders in the NHLS diagnostic environment. The research participants are:

the regional quality assurance manager, the business manager, and the head phlebotomist. The selection of each of the research participant is rooted in the significant roles they hold in the NHLS and because each has a vested interest in the research problem.

The interviews took place through the Zoom software application, which is an online platform. The interviews are conducted separately with each participant and lasted between 30 to 45 minutes in duration. The interviews are recorded on Zoom and automatic transcripts were made during the interviews. After each interview, the transcript is anonymised, and any information that could identify the research participant was removed. The research participants are referred to as 'participant 1,' 'participant 2,' and 'participant 3' on the interview transcripts. The researcher made notes to clarify points made by the research participants during the interview.

Following transcription, thematic analysis is used to analyse the data using ATLAS.ti software. Thematic analysis involved extracting codes and themes from the data, aimed at enhancing the understanding of the perceptions, attitudes and feelings of the research participants in the study (Maguire and Delahunt, 2017). Thematic analysis is used in this study to verify the validity of the findings of the quantitative data analysis. This provided the basis for the confirmatory analysis of the qualitative data.

6.3 Confirmatory analysis of qualitative data

This section of the chapter presents the interpretation of the qualitative data, which involved the researcher examining each interview transcript to identify themes and report the findings that confirmed the research findings of the Pareto analysis, Ishikawa diagram, 5 whys analysis and FMEA.

6.3.1 Qualitative data that supports the findings of Pareto analysis

Consistent with the findings of study by Brooks (2014), in this study, Pareto analysis quantitatively prioritised the specimen rejections that required urgent mitigation. It was shown that pre-analytical errors account for majority (up to 70%) of laboratory errors (Al-Ghaithi et al., 2017) and are due to factors that are usually out of the laboratory control. The response from participant 1 confirms the results of the Pareto analysis performed in the quantitative phase of this study stating "(The) majority of the errors are the preanalytical errors, in terms of when the specimens are being collected and labelled." Literature returned that common pre-analytical errors that required urgent attention included mismatched information, haemolysis, clotted and insufficient samples (Plebani, 2010). This is consistent with the view of participant 1, who states "The highest errors relate to mismatch in the name on the swab and the request

form, the person who took the swab has filled in the form incorrectly as well as labeled the specimen incorrectly. Also hemolyzed specimens, and insufficient specimens for testing".

Participant 3 agrees with the response of Participant 1, and states "Incorrect specimen collection and handling has consequences such as, hemolysis, EDTA, clotted, insufficient samples, and mismatched specimen and request forms. These account for the highest specimen rejections in the NHLS".

Literature returned that errors of the pre-analytic phase are not usually under the control of the laboratory, however due to the high risk of pre-analytic errors on patient healthcare, laboratories are tasked with assisting nurses and clinicians in making improvements to this phase of the laboratory (Plebani, 2010). Participant 1 verified that this is also the case at the NHLS, stating "It's relatively challenging to control these pre-analytic errors from a lab perspective because lab personnel weren't there on site during specimen collection to see how the specimen was collected and labelled. However, laboratories must aim to assist nurses and clinicians in reducing pre-analytic errors as they pose a major risk to patient healthcare". The aforementioned research findings confirms that the highest specimen rejections are from the pre-analytic laboratory phase. Thus, this qualitative phase of the study is able to confirm the findings of the Pareto analysis performed in the quantitative phase of this study.

6.3.2 Qualitative data that supports the findings of the Ishikawa diagram and the 5 whys analysis

Literature by Voehl (2016) demonstrated that the 5 whys analysis is a quality tool that can be used in conjunction with the Ishikawa diagram. This technique of using the two quality tools in conjunction enables the user to drill down to get to the origin of a problem in root cause analysis. In this qualitative phase of this research study, interview data is analysed to determine if the collective result of the Ishikawa diagram analysis and 5 whys analysis is accurate.

When asked about suitable procedures in place for healthcare professionals to correctly collect and transport patient samples, participant 1 stated "There are incorrect systems are in place or lack of systems and proper procedures. The nurse and doctor are not using the proper systems and procedures, resulting in specimen rejections and errors". Significantly, consensus was noted between the views of participant 2, and participant 1, as participant 2 stated "I think the cause of most pre-analytic errors with regards to specimen collecting and transport are linked to the lack of procedures in place. There are also important systems either being overlooked, or it's not being valued enough. This is then causing most of the errors we

see in specimen rejections". Moreover, participant 3 was also in agreement, stating "The main cause for concern is the lack of procedures and policies at the level where specimens are being collected, and the lack of systems to ensure the correct procedures are being followed. There are inadequate control mechanisms to ensure the correct processes are being followed. The consequence is critical, especially during the pandemic, in that there are high laboratory rejections, which has a negative impact on the patient and their effective treatment."

Thereby, from the qualitative findings it is deduced that there is a lack of adequate procedures and inadequate control measures to address the pre-analytic processes. Thus, the deduction of this study is consistent with literature (Ghaithi et al., 2017; Lee, 2019) which advances that adequate pre-analytic procedures and systems are required to achieve acceptable sample collection from nurses and clinicians.

6.3.3 Qualitative data that supports the findings of FMEA

An FMEA was performed to identify process errors and to create opportunities for improvement in the quantitative phase of this research. Two of the seven COVID- 19 test process steps were highlighted as steps in need of improvement. These were: (1) Pre-analytical COVID-19 test process step 4: specimen collection and (2) Pre-analytical COVID-19 test process step 5: specimen labelling.

With reference to specimen collection and labelling, the findings of FMEA were that regular training and induction sessions would assist in reducing pre-analytic errors. Similarly, literature (Al-Gaithi et al., 2017) indicates that continuous training and educating of health personnel are necessary to eliminate common causes of non-conforming samples and thereby reducing pre-analytic errors. This is consistent with the views expressed by participant 2 *"The best thing we can do with minimal cost impact is training and educating nurses and clinicians. In my opinion, if we if we reach enough people (healthcare professionals) in training and education sessions to where the origin of the problem is, that is where the rectification should happen earlier on in the learning and training phase. We need to train on correct specimen collection, labelling, handling, and transportation processes."* This view is also shared by participant 1 who said: *"We need to train and educate the staff on the correct processes. We need to get involved with where the professionals are being trained currently before they go into hospital and clinic settings."*

With reference to specimen collection and labelling a crucial factor that is highlighted during the analysis of interview data, is the importance of training of healthcare professionals before they can practice in the work environment. Participant 2 stated *"The training that we are*

referring to should have been implemented at a much earlier stage in the professional curriculum for nurses and clinicians. They should have been part of a standardised program, some pre graduate training, where they are trained and assessed, and only when deemed competent can they be involved in collecting and handling patient samples." Parallels with literature review were noted as Al-Gaithi et al. (2017) stated that healthcare professionals must be trained and certified as competent before working with patients and collecting samples.

The availability of adequate specimen collection procedures for healthcare staff to follow was a crucial aspect highlighted during quantitative analysis (the FMEA) to reduce pre-analytic errors. Findings of FMEA, revealed that adequate procedures for specimen collection, labelling, handling, and transport, must be made available for nurses and clinicians to use. With reference to this, participant 1 stated, *"Specimen collection procedures must be made available to all healthcare staff. This should provide all the details which shows you how to take every sample. Shows you exactly which the consumables are required for the blood taking and sample taking. It also has information on how to store, handle and transport the sample. This procedure needs to be followed by nurses and clinicians so that we can get uniformity across the board and improve specimen rejections."* A similar view was expressed by participant 2, *"Hospital procedures need to be reviewed and made available and put into practice for all healthcare staff to follow."*

Thus, a congruence with literature (Al-Gaithi et al., 2017; Plebani, 2010) was noted and the key recommendation derived from FMEA, which was to appoint a phlebotomy service in high specimen rejection areas, to reduce specimen rejections. This recommendation is aligned with recommendation of Plebani (2010) that phlebotomists be deployed in healthcare facilities where there are high rejections, to significantly reduced error rates and improve patient care. The opinions expressed by participant 2 are:

"I think having an individual phlebotomist will reduce specimen rejections. The phlebotomist should be situated in high rejection zones in the hospital. This will ensure that there will be a dedicated person only taking bloods and other samples, knowing exactly what it is that we need to focus on. So that's what I think, an independent phlebotomy service and that'll be the link between patient and lab." Similar to these views expressed by participant 2, participant 3 states:

"So, I think the biggest action to reduce pre-analytic errors is to appoint a phlebotomy service at the hospital."

The qualitative findings deduced that continuous training and educating of nurses and clinicians, availability of adequate specimen collection and labelling procedures, and appointing a phlebotomist in high specimen rejection areas are key to reducing pre-analytic errors.

6.3.4 Qualitative data that supports unanticipated inductive research findings

Results from the semi-structured interviews revealed some unanticipated research findings that are beneficial to this research. These findings are regarded important, as they are instrumental in the development of an optimised pre-analytic process which includes preventative measures that ensure laboratory error rates remain under 4% thereby allowing this study to meet research objective 4 which is to 'identify factors that should be included in the development of an optimised pre-analytic process which includes preventative measures to reduce laboratory errors in COVID-19 testing'.

6.3.4.1 Findings relating to identifying factors that should be included in the development of an optimised pre-analytic process which includes preventative measures to reduce laboratory errors in COVID-19 testing

A finding derived from the analysis of qualitative data was that continuous monitoring of pre-analytic process systems and regular periodic review of quality indicators are necessary to reduce pre-analytic errors. Participant 3 stated *"There needs to be regular monitoring of systems. Reviewing quality indicators quarterly or annually for improvements. Reviewing their admin section in terms of procedures, ensuring stock in blood rooms sufficient and up to standard. Review these quality indicators, and then they need to take action in terms of whether it is training, if it's lack of procedures or policies or documentation. And they need to put interventions and to ensure that those rejection rates come down."* Agreement was noted with participant 2, who states that monitoring of pre-analytic systems should be introduced as a quality improvement project, and added, that it should form part on a regular auditing system for the Hospital.

"They (Hospital) should review their systems, It should be one of the quality improvement projects that they can run that's part of an audit for them that becomes part of their annual activities."

Results of the qualitative data analysis also suggest that regular performance reviews of nurses and clinicians be implemented for a targeted approach to addressing errors in specimen collection. Participant 2 proposed:

“There needs to be a review of their performance and evaluation to assess if nurses and clinicians are performing their duties in accordance with the relevant procedures. Then if you take rejected samples, you look at all the rejections that affects you and your area, if the performance is poor, there must be corrective measures in place for improvement.”

Consistent with research findings, Lee (2019) stated that performance of individuals in the health sector should be reviewed annually, through a structured performance plan. Thus, this study deduced that continuous monitoring of pre-analytic process systems and reviewing of quality indicators as well as annual performance reviews of nurses and clinicians should be used in developing an optimised pre-analytic process which includes preventative measures to reduce laboratory errors in COVID-19 testing. This will be discussed in the next chapter.

6.4 Chapter summary

This chapter offered the reader insight into the qualitative data analysis phase. A summary of the research findings was presented and discussed. The chapter concluded with the confirmatory analysis of the qualitative data. This section presented the qualitative data that supported the research findings of each of the four quality tools used in the quantitative data analysis. It also reported on unanticipated findings from the interviews, before concluding that the qualitative data verified and reinforced the quantitative data. The next chapter provides the reader with the conclusions and recommendations for this study.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATIONS

The previous chapter informed the reader of the qualitative data analysis conducted and the research findings. This chapter presents a summary of the previous chapters, and revisits the research question, objectives, and findings. The chapter explains the limitations of this research before expanding on the discussion of the optimised pre-analytic process that was developed. Lastly, the chapter highlights the recommendations and final conclusions of this research. This study analyses the risks associated with pre-analytical laboratory error rates of COVID-19 testing at the NHLS Paarl laboratory. The purpose of this final chapter is to deliver a conclusive summary of all the key findings related to each of the four research objectives that were identified in chapter one of this study. This chapter makes recommendations and identifies opportunities for future research in the field.

7.1 Summary of previous chapters

7.1.1 Summary of Chapter 1

Chapter 1 presented an introduction of the research and discusses the emergence of the COVID-19 pandemic. The main research questions and subsequent investigative questions were stated, before addressing the research objectives. Then, the rationale for performing the research was explained. Thereafter, the conceptual framework and a brief overview of the research methodology was explained.

7.1.2 Summary of Chapter 2

Chapter 2 discussed the research background and explained the organisational context of the NHLS, laboratory processes, and laboratory quality management systems in detail. Thereafter, laboratory errors are discussed, before concluding the chapter with the laboratory information systems and the laboratory scope of testing.

7.1.3 Summary of Chapter 3

Chapter 3 presented a current review literature pertaining to the research problem. This chapter discussed the laboratory QMS, and explained accreditation, quality indicators and quality tools. Thereafter, the chapter discussed the application of the quality tools in meeting the research objectives, and the chapter concluded with the possible existing solutions to the research problem.

7.1.4 Summary of Chapter 4

Chapter 4 presented the research methodology adopted for the study. The methodological paradigm was first discussed before explaining the methodological approach that was implemented. Thereafter, the mixed methods approach that was employed for the research utilising both quantitative and qualitative data were expanded upon. The data collection strategy such as the target population and sampling techniques were explained. The chapter then expanded on the quantitative data collection and the qualitative data collection method. Thereafter, the data analysis of the quantitative and qualitative phases were discussed. The chapter concluded with a presentation of the pilot study, before the ethical considerations, and data validity and reliability were explained.

7.1.5 Summary of Chapter 5

Chapter 5 presents the findings of the quantitative data analysis phase. Results of the four quality tools; Pareto analysis, Ishikawa diagram, 5 whys analysis, and FMEA were discussed.

7.1.6 Summary of Chapter 6

Chapter 6 offers the findings of the qualitative data analysis phase, where the transcripts of the semi-structured interviews were analysed using thematic analysis and ATLAS.ti for encoding the data.

7.2 Revisited research question, objectives, and findings

This section reviews the research questions, objectives, and findings that were presented in earlier chapters to determine if the main aim and objectives of the study have been accomplished. Moreover, an optimised pre-analytic process which includes preventative measures that ensures reduced laboratory errors in COVID-19 testing.

7.2.1 Research problem statement revisited

The research problem statement for this research study is: “The laboratory error rate for COVID-19 testing at the NHLS Paarl laboratory in the Western Cape is greater than 4%.” The research problem has a significant impact on the health and safety of patients and the general population due to the highly transmissible and infectious COVID-19 virus. Accordingly, the primary research question is revisited in the next section.

7.2.2 Primary research question revisited

The research question for this research study is: “Can an optimised pre-analytic process be developed which includes preventative measures that ensure laboratory error rates remain

under 4% during COVID-19 testing?" Towards answering this question, this research set out to achieve the objectives listed below.

7.2.3 Research objectives revisited

Below is a discussion of the research objectives of this study.

7.2.3.1 Findings related to Research Objective 1 on critical contributing factors that are responsible for the unacceptable laboratory errors in COVID-19 testing

7.2.3.1.1 Analogies drawn from literature

According to Al-Ghaithi et al*.* (2017) up to 70% of laboratory errors are linked to pre-analytic errors, where the specimen is incorrectly collected and handled, resulting in unacceptable samples by laboratory standards. Plebani (2010) advances with this and posits that pre-analytic errors are predominantly due to the incorrect specimen collection techniques applied by the nurse or clinician. This results in specimens that are: haemolysed, clotted, insufficient, and/or have mismatched information. A review of literature by Lee (2019) revealed that adequate pre-analytic procedures and systems are essential to achieve acceptable specimen collection form nurses and clinicians.

7.2.3.1.2 Analogies drawn from quantitative and qualitative data analysis

Quantitative data analysis of the Pareto chart revealed that the most significant contributory factors responsible for the unacceptable pre-analytic laboratory errors in COVID-19 testing are: test cancelled by EGK, haemolysed specimens, clotted specimens, insufficient specimens, specimens too old, correct blood specimen required, and information does not match. This is confirmed by participant 1 and participant 3 during the semi-structured interview.

Data analysis with the Ishikawa diagram and 5 Whys analysis showed that contributing factors that are responsible for the unacceptable laboratory errors in COVID-19 testing are due to system failures. The system failures are: inadequate pre-analytic procedures in place (specimen collection, handling, labelling, transportation and administration), inadequate measuring methods available for ensuring sufficient supplies were available to perform the process, inadequate training programs for stores clerks on stock management procedures, lack of suitable control measures to assess competency of nurses and clinicians during entire specimen collection process, lack of suitable control measures to ensure correct specimens

are being collected for the test requested, and for ensuring correctness of patient identity stickers used, and lack of contingency plan procedures.

The aforementioned quantitative findings are confirmed by the qualitative data analysis phase where all three research participants verified that these are the contributing factors that are responsible for the unacceptable error rates in the COVID-19 testing process.

7.2.3.1.3 Conclusion to Research Objective 1

The conclusion derived from quantitatively analysing the first three quality tools (Pareto analysis, Ishikawa diagram, and 5 whys analysis) and qualitatively analysing the responses from the semi-structured interviews, is that pre-analytic errors are linked to specimen collection, handling, labelling, transportation and administration. The use of the afore-mentioned quality tools enabled the completion of the 'Plan' and 'Do' stages of the PDCA cycle. The critical contributing factors found responsible for the unacceptable laboratory errors in COVID-19 testing are: test cancelled by EGK, haemolysed specimens, clotted specimens, insufficient specimens, specimens too old, correct blood specimen required, and information does not match.

7.2.3.2 Findings related to Research Objective 2 on identification of risks to patient healthcare

7.2.3.2.1 Analogies drawn from literature

Lippi et al. (2020) argues the consequences of laboratory errors on patients are harmful and poses a high risk, as treatment and disease management are delayed and often not administered. The risk to patient care is high when healthcare staff fail to follow procedures. The risks to patient care are magnified in the case of the COVID-19 pandemic, as disease prevention and containment efforts are jeopardised (Lippi et al., 2020). Plebani (2020) stated that it is crucial for patients to receive their COVID-19 test results timeously (within 24 hours after testing) so they may self- isolate and curb the spread of the disease.

7.2.3.2.2 Analogies drawn from quantitative and qualitative data analysis

Data illustrated by Pareto analysis showed that a total of 9000 specimens were rejected for the period 1st January to 31st December 2021, due to pre-analytic errors. Thus, 9000 patient results were not completed, resulting in patients not receiving adequate treatment for their illness. Data analysis of FMEA revealed that there is an unacceptable high risk of samples not being collected and labelled appropriately from the pre-analytical process step 4 and 5 respectively of the pre-analytical COVID-19 testing process, that results in the high specimen rejection rate. The consequence of this is patients are at high risk for exacerbating their illness,

as well as unknowingly contributing towards the spread of COVID-19 disease to close relatives, friends and work colleagues, thus worsening the health care strategies already in place by national government for containing the spread of the disease.

From the qualitative data analysis, the response from participant 3 confirmed the risks to patient care.

7.2.3.2.3 Conclusion to Research Objective 2

Pareto analysis and responses from the research participants in the semi-structured interviews, revealed the risks to patient healthcare. Data analysis highlighted the negative impact laboratory errors have on patients in the ambit of the COVID-19 pandemic, and the burden it places on national isolation and disease containment strategies.

7.2.3.3 Findings related to Research Objective 3 on measures that can be put in place to reduce and eliminate the laboratory errors in COVID-19 testing

7.2.3.3.1 Analogies drawn from literature

Lee (2019) stated that continuous education and training are crucial for nurses and clinicians in reducing the errors found in the pre-analytical phase of the laboratory. Appropriate procedures and systems around specimen collection, handling, labelling and transportation must be available for healthcare workers to use to minimise and eliminate non-conformities in specimen collection (Lee, 2019). Furthermore, Plebani (2020) posits that appointing a phlebotomy service in high rejection areas, proved to significantly reduce specimen rejections, and is a valuable opportunity that health institutions should invest in.

7.2.3.3.2 Analogies drawn from quantitative and qualitative data analysis

The data illustrated by FMEA showed the gaps in the pre-analytic COVID-19 testing process that required urgent mitigation. Some measures were put in place to address these gaps, and they showed improvement in the pre-analytic process when implemented. These measures are: developing and distributing specimen collection and handling. Labelling, transportation and administration procedures, developing and implementing training management program for nurses and clinicians, development and distribution of quick access specimen collection guide, creation of manual system for verifying correct patient details on specimen and form as well as verifying that the correct specimen was collected, and appointing a phlebotomist in high specimen rejection zones.

The responses from all three research participants from the qualitative data analysis confirmed that the above mitigation measures are key to reducing and eliminating laboratory errors in COVID-19 testing.

7.2.3.3.3 Conclusion to Research Objective 3

The conclusion to the third research objective was identifying control measures that would reduce and eliminate laboratory errors in COVID-19 testing. Data analysis allowed this study to deduce that two control measures are needed: (1) a check point to ensure that specimens are collected correctly, and (2) a check point to ensure that specimens are labelled correctly. Completion of FMEA signified the finalisation of the 'Check' and 'Action' stages of the PDCA cycle.

7.2.3.4 Findings related to Research Objective 4 on the factors that should be included in the development of an optimised pre-analytic process which includes preventative measures to reduce laboratory errors in COVID-19 testing

7.2.3.4.1 Analogies drawn from literature

Lee (2019) argued that a targeted quality improvement intervention and its continuous maintenance is needed to reduce pre-analytic errors and improve patient safety. The quality improvement intervention should include detailed specimen collection process procedures, continuous education and training of healthcare workers, and adequate control measures at each step in the pre-analytic phase where specimen collection occurs (Lee, 2019).

7.2.3.4.2 Analogies drawn from quantitative and qualitative data analysis

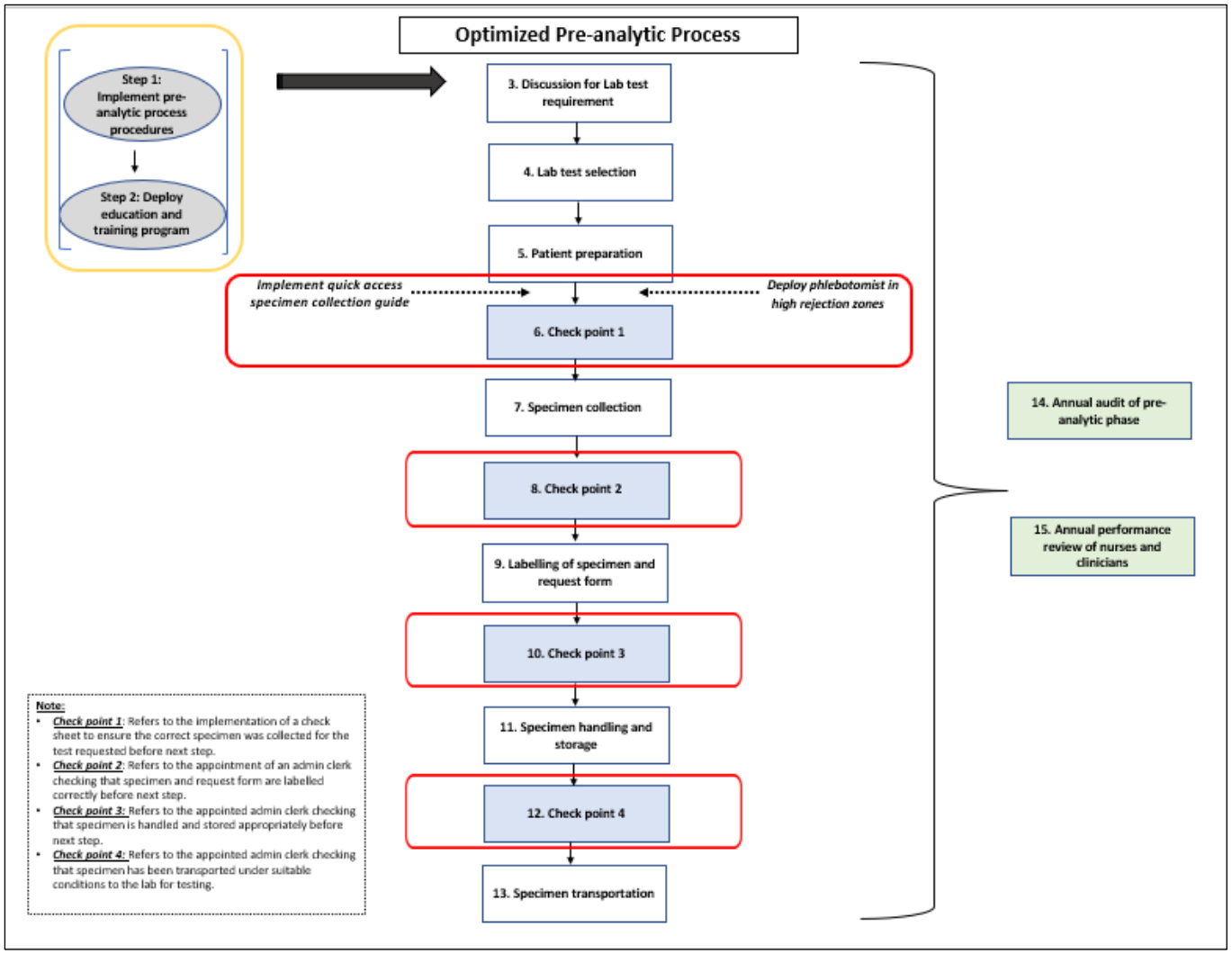
The control measures identified to reduce and eliminate laboratory errors in COVID-19 testing as discussed at the conclusion of Research Objective 3, will be considered to optimise the old pre-analytic COVID-19 testing process to create a new process.

7.2.3.4.3 Conclusion to Research Object 4

The conclusion to the fourth research objective is to develop an optimised pre-analytic process which includes preventative measures for reducing laboratory errors in COVID-19 testing. From the qualitative data analysis this research deduces that check points will be added to the pre-analytic process. These check points were identified as the output of research objective three and include: check point 1 to ensure specimens are collected correctly, and check point 2 to ensure that specimens are labelled correctly. These check points are strategically arranged in key places to serve as preventative measures to reduce the cause of

the highest specimen rejection errors. The qualitative data analysis also deduced that a pre-analytic process guide be made available, and more training is required, thus a recommendation is to develop a pre-analytic process guide and specialised training be conducted. Additionally, the quantitative and qualitative data analysis also highlighted other measures that would optimise the pre-analytic process in an effort to reduce pre-analytic errors and these involved implementation of: check point 3 which requires a check sheet to be completed for the correct handling and storage of specimens and check point 4 which requires a check sheet to be completed for the correct transportation of specimens. After careful consideration of all the outputs from the quantitative and qualitative data analysis the researcher developed and optimised pre-analytic COVID-19 process. Figure 15 depicts the optimised pre-analytic process with the highlighted (red and yellow) check points for reducing pre-analytic errors.

Figure 15: Optimised pre-analytic process



Source: Researcher (2022)

Thus, the research objectives have been accomplished and the aim of this study was fully achieved. Based on the conclusions derived above, the pre-analytic process was optimised by including preventative measures that ensure reduced laboratory errors in COVID-19 testing.

7.3 Discussion of optimised pre-analytic process

The optimised pre-analytic process was developed by modifying the original pre-analytic process (Figure 9 seen in Chapter 2). With the addition of check points (1-4, the pre-analytic process is now optimised and designed to reduce non-nonconformities in specimen collection and reduce rejected specimens. The following check points are added to create an optimised pre-analytic process:

- Implementation of pre-analytic process procedures

With adequate process procedures on specimen collection, handling, labelling, administration and transportation, nurses and clinicians would have access to an established standard to refer to. The purpose of these procedures is to guide nurses and clinicians on what acceptable specimens are and directs the manner in which specimens need to be collected, handled, labelled and transported for laboratory testing. Additionally, it is recommended that these procedures be reviewed annually for any changes or updates to the process.

- Development of education and training programs

Quarterly education and training sessions on pre-analytic processes shall be offered to nurses and clinicians. This is to ensure nurses and clinicians are given the right information and made aware of the correct techniques used to collect and handle patient specimens. It is recommended that these sessions be held on a quarterly basis so that new nurses and clinicians are trained and deemed competent prior to working with patients and collecting specimens. This would assist in building the theoretical and practical skillset of nurses and clinicians that are required for collecting and handling patient specimens.

- Check point 1

Check point 1 is positioned ahead of the specimen collection step to ensure that the correct specimen type is collected for the test requested. This involved the implementation of a check sheet for the nurse or clinician to use prior to specimen collection taking place. The check sheet as seen in Appendix Q includes (1) ensuring the patient is prepared appropriately for the blood collection procedure, (2) lists the specimen collection tubes for the test requested, (3) lists the number of times each tube should be mixed after collection, and (4) includes a

section for correctly labelling the specimen and request form after specimen collection. This check point which includes a check sheet must be completed and signed off by the nurse or clinician prior to leaving the patient. Should any item on the check sheet not be completed, the specimen will not be sent to the next pre-analytic process step, the nurse or clinician will reassess the check sheet and ensure the incomplete items are complete. Should the check sheet be complete, the specimens will be sent to the next pre-analytic process step.

- Check point 2

Check point 2 involves appointing an admin clerk to manually verify the patient details on the specimen and request form. Corresponding details on the specimen and request form will be sent to the next step of the pre-analytic process. Mismatched specimen and request form details will be held back in the pre-analytic process for the nurse and clinician to rectify before the specimen can be sent to the lab for testing.

- Check point 3

Check point 3 is where the admin clerk ensures that the specimen is handled and stored at the correct temperature before being sent to the lab. The use of a check sheet (Appendix R) is implemented, where the nurse and clinician sign and acknowledges for the correct handling and storage of the specimen under the appropriate conditions. The purpose of this check point is for the admin clerk to verify that the specimens are handled and stored under the appropriate conditions. This will be done by completing the check sheet. Should the requirements of the check sheet not be met, the specimens will be held back from storage until the appropriate conditions have been met for specimen storage and handling.

- Check point 4

Check point 4 is where the admin clerk ensures that the specimen is transported to the lab under the appropriate conditions by the courier. The use of a check sheet (Appendix S) is implemented, where the admin clerk checks for the correct temperature of the cooler box used to transport the specimen. Should this control check pass, the specimen is transported immediately to the lab for testing. Should the control check fail, the admin clerk and courier would need to source an alternate cooler box with the appropriate temperature for the specimens to be transported to the lab.

- Annual audit of pre-analytic process

It is recommended that the hospital performs annual audit checks on the complete pre-analytic process as part of a quality improvement plan. The audit should be guided by ISO:15189

guidelines. Any non-conformities raised during the audit, should undergo corrective actions to demonstrate improvement in that area.

- Annual performance review of nurses and clinicians

An annual performance review of the pre-analytic duties performed by nurses and clinicians was recommended. All personnel with acceptable performance will be certified as competent and will continue to collect patient specimens. Personnel with unacceptable performance will need to be retrained and their competencies be reassessed before continuing to collect patient specimens. These personnel may work under supervision until deemed competent for collecting patient specimens.

Additional steps that are included in the optimised pre-analytic process: deploying a phlebotomist in high rejection zones: this would prevent pre-analytic errors in specimen collection and reduce rejected specimens, implementing a procedure quick guide for specimen collection in blood collection rooms: this would ensure nurses and clinicians have unlimited access to specimen collection procedures at their disposal at any point during collection, handling, labelling, and transporting of the specimen.

7.4 Recommendations

The final recommendation for future research is to implement the optimised pre-analytic process developed in this study at the Paarl Provincial Hospital in the Western Cape. This process should be implemented for a period of two years with bi-annual reviews to improve on challenges and faults experienced by the users. Thereafter, the optimised pre-analytic process should be implemented for other testing processes (not just COVID-19) that are often a burden to healthcare systems such as TB and HIV monitoring. Lastly, the recommendation is to roll out this optimised pre-analytic process to all public hospitals in the Western Cape for a reduced rejection rate, and improved patient care.

7.5 Limitations of this research study

This research study was conducted at the NHLS Paarl laboratory in the Western Cape thus these findings cannot be applied to other laboratories in the Western Cape region.

7.6 Study conclusion

This research took place at the NHLS Paarl laboratory in the Western Cape. The purpose of this study was to develop an optimised pre-analytic process that includes preventative measures that ensures reduced laboratory errors in COVID-19 testing. The reviewed literature guided the quantitative and qualitative data collection, analysis and interpretation, which

yielded the conclusions and recommendations of this study. Research questions were answered and objectives achieved.

The aim of this research was to develop an optimised pre-analytic process that includes preventative measures that ensures reduced laboratory errors in COVID-19 testing. An optimised pre-analytic process designed for reducing laboratory errors in COVID-19 testing was developed, that has the potential to overcome the challenges associated with pre-analytic errors.

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APPENDICES

Appendix A: List of Laboratory tests

Discipline and Sample Type	Type of Tests	Discipline and Sample Type	Type of Tests
Chemistry		**Chemistry**	
Serum	Alanine Aminotransferase (ALT)	Serum	Phenobarbitone
Serum	Albumin	Serum	Phenytoin
Serum	Alkaline Phosphatase (ALP)	Serum	Lithium
Serum	Aspartate Aminotransferase (AST)	**Serology**	RPR
Serum	Bilirubin Direct		
Serum	Bilirubin Total	Dry Swab	COVID-19 PCR
Serum	C- Reactive Protein	**Endocrinology**	
Serum	Calcium	Serum	TSH
Serum	Chloride	Serum	Free T4
Serum	Cholesterol - Total	Serum	Total PSA
Serum	Creatine Kinase (CK)	Serum	Free PSA
Serum/ Urine	Creatinine	Serum	Beta HCG
Serum	Gamma Glutamyl Transferase (GGT)	Serum	Free T3
Serum/CSF	Glucose	Serum	Vitamin B12
Serum	High Density Lipoprotein (HDL)	Serum	Folate
Serum/ Fluids	Lactate Dehydrogenase (LDH)	**Hematology**	
Serum	Lipase	Whole blood	Differential Count (Automated)
Serum	Magnesium	Whole blood	WBC
Serum	Phosphate Inorganic	Whole blood	RBC
Serum	Potassium	Whole blood	Hemoglobin
Serum	Protein - Total	Whole blood	HCT
CSF/Fluid/Urine	Protein-Micro (MTP)	Whole blood	MCH
Serum	Sodium	Whole blood	MCHC
Serum	Triglycerides	Whole blood	MCV
Plasma	Troponin T	Whole blood	RDW (Red Cell Distribution Width)
Serum	Urea	Whole blood	Platelet Count
Serum	Uric Acid	Whole blood	Erythrocyte Sedimentation Rate
Serum	HIV	Whole blood	Reticulocytes
Serum	Syphilis	Whole blood	Malaria Antigen
Whole Blood	HbA1C	**Coagulation**	
Citrate Plasma	D-Dimer	Plasma	Activated Partial Thromboplastin Time (aPTT)

Appendix B: List of tests affected by Electronic Gate Keeping (EGK)

Test Name	EGK Rule
Glycated haemoglobin (HbA1c)	Female: 1 month, Male: 3 months
Uric acid	Female: 1 day, Male: 1 month
Total protein	1 month
Albumin	1 day
Total bilirubin	1 day
Conjugated bilirubin	1 day
Alanine transaminase (ALT)	1 day
Aspartate transaminase (AST)	1 day
Alkaline Phosphatase (ALP)	1 day
Gamma- glutamyl transferase (GGT)	1 day
Lactate dehydrogenase (LD)	1 day
Amylase	1 day
Lipase	1 day
Lipid profile	3 months
Total cholesterol	3 months
Triglyceride	1 day
HDL cholesterol	3 months
LDL cholesterol	3 months
C-reactive protein	1 day
Iron	3 months
Transferrin	3 months
Ferritin	1 month
Vitamin B12	3 months
Serum folate	3 months
Beta-HCG	1 day
CD4	3 months
Hepatitis Ag + Ab	1 month
FBC	None
COVID-19 PCR	None

Appendix C: FMEA ranking matrix

(Ahsen et al., 2021)

SEVERITY	RANKING	FREQUENCY (Per day)	RANKING	DETECTION	RANKING
No Effect to patient	1	No Rejections	1	Potential Error undetected	10
Mild risk >95% results received for treatment	2	Low rejections </=2 Specimen repeated	2-3	Potential error has a low probability of being detected and corrected before sent to lab	8-9
Mild risk 80-94% results received for treatment	3	Moderate (3-5 rejections) Specimen repeated	4-6	Potential error has a moderate probability of being detected	7-6
Moderate risk 75-79% results received for treatment; inconvenience caused to patient for retesting	4-6	High (6-10 rejections) Specimen not repeated	7-8	High probability the potential error is detected and corrected before sent to lab	5-3
High risk <50% results received for patient treatment. 50% tests not done due to specimen rejection	7-8	Very high (10-20 rejections) Specimen not repeated	9-10	Almost certain potential error found and corrected before sent to lab	2
Very high-risk specimen rejected, no results received for treatment	9-10	Very high (>20 rejections) No results received Patient not treated	9-10	Potential error found	1

Appendix D: Questionnaire for semi-structured interviews

Interview Questionnaire

Title of Research Study:

Analysis of risks associated with laboratory error rates of COVID-19 testing at the NHLS Paarl laboratory.

Principal researcher: *Ms. N Singh*

You have been selected to participate in the research study titled *"Analysis of the risks associated with laboratory error rates of COVID-19 testing at the NHLS Paarl laboratory."* The study is being conducted by Ms. N Singh, a postgraduate research student from Cape Peninsula University of Technology (CPUT), from the Department of Engineering and the built environment, with a Master's degree in Quality management.

CPUT and the principal researcher subscribe to strict principles of ethical conduct in order to protect the interests, integrity, and safety of the research participants and the environment.

Question 1: Thoughts and opinions on the high rejection rate.

Question 2: From a Registered professional perspective can you highlight the risks of high rejection rate to patient healthcare?

Question 3: What impact does this have on the lab QMS?

Question 4: From RCA on quantitative data, it was shown that at the point of specimen collection, there are systems lacking, as well as inadequate SOPs, and training. Do you agree? Explain.

Question 5: In your opinion, what measures can be implemented by NHLS to mitigate any risks identified?

Question 6: In your opinion, what measures can be implemented by DoH to mitigate any risks identified?

Question 7: In your opinion do you think this research is adding value to society? Explain.

Any further comments?

Thank you for participating in this research study.

Appendix E: Consent form for interview

Individual Consent for Research Participation

Title of Research study:

Analysis of risks associated with laboratory error rates of COVID-19 testing at the NHLS Paarl laboratory.

Principal researcher: *Ms N Singh*

You have been selected to participate in the research study titled *"Analysis of the risks associated with laboratory error rates of COVID-19 testing at the NHLS Paarl laboratory."* The study is being conducted by Ms N Singh, a post graduate research student from Cape Peninsula University of Technology (CPUT), from the department of Engineering and the built environment, under the Master's degree in Quality management.

CPUT and the principal researcher subscribe to strict principles of ethical conduct in order to protect the interests, integrity and safety of the research participants and the environment. By signing this consent form, you agree to the following;

- ***Confidentiality***: you have received assurance from the researcher that the information you share will remain strictly confidential, and the contents will only be used for the qualitative analysis in this research study.
- ***Anonymity***: will be protected. No names and surnames will be used for this research study.
- ***Conservation of data***: you have been assured by the researcher that data collected for this research study will be securely stored on the researchers' laptop, where only the principal researcher has access.
- ***Voluntary participation***: you have been informed that you are under no obligation to participate in this research study. You are able to withdraw from the interview at any time.

Acceptance: I, _____

agree to participate in the above research study conducted by N Singh of the Faculty of Engineering and the Built Environment, Quality Management Department, at CPUT, which research is under the supervision of Dr B Swartz.

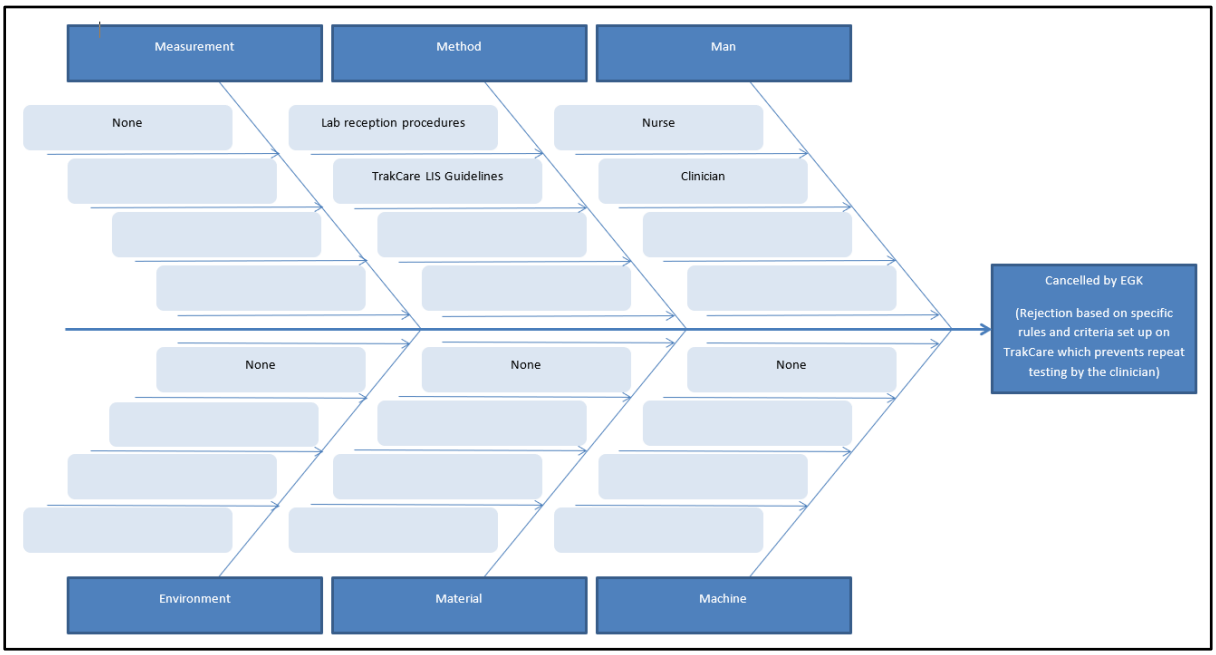
For any further questions on the research study, you may contact the researcher or the supervisor via email;

Principal researcher: natashans.singh@gmail.com, Supervisor: swartzb@cput.ac.za

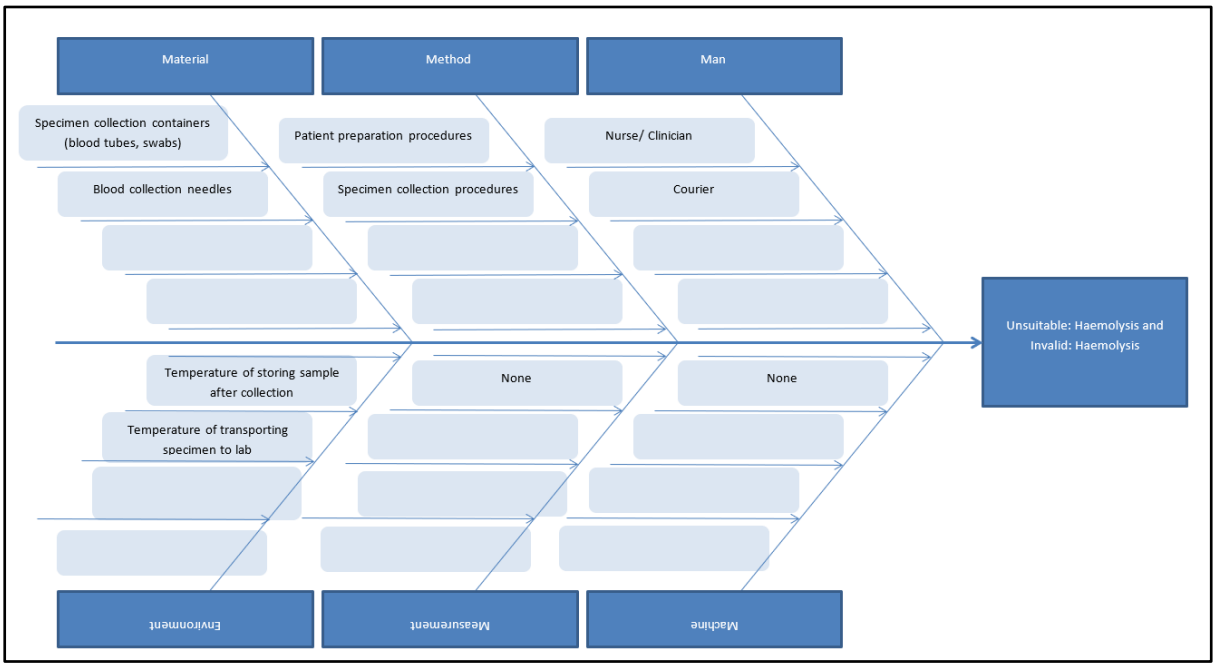
Participant's Signature: _____ Date: _____

Researcher's Signature: _____ Date: _____

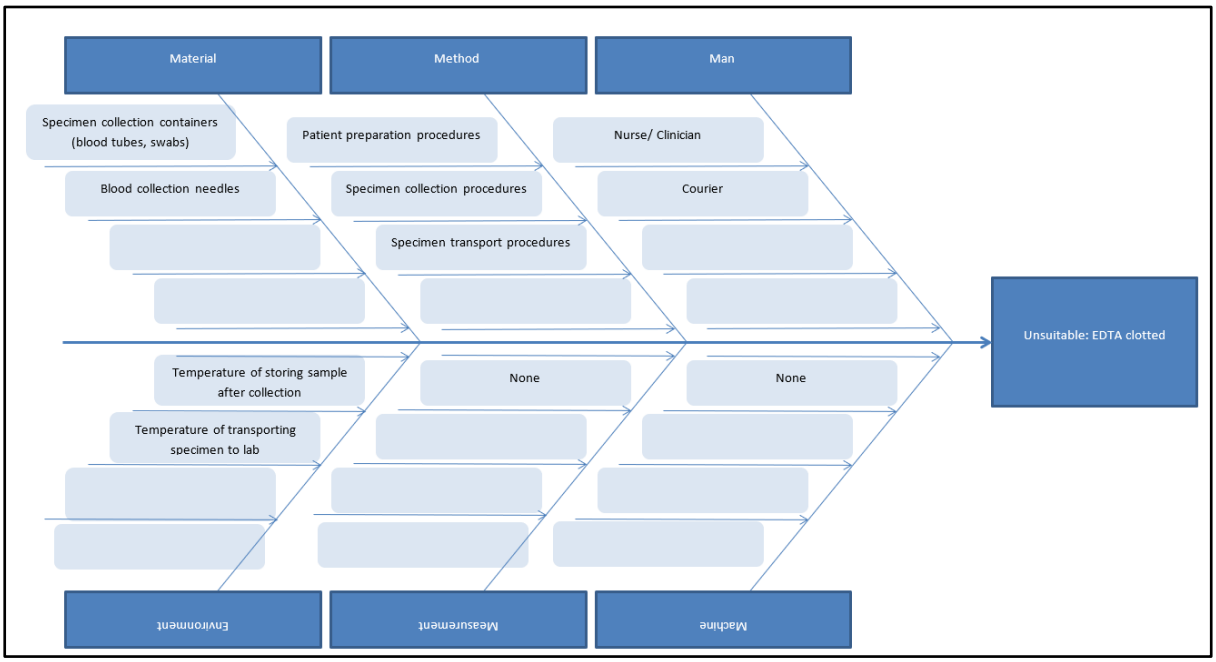
Appendix F: Ishikawa diagram of Rejections due to EGK Cancellation



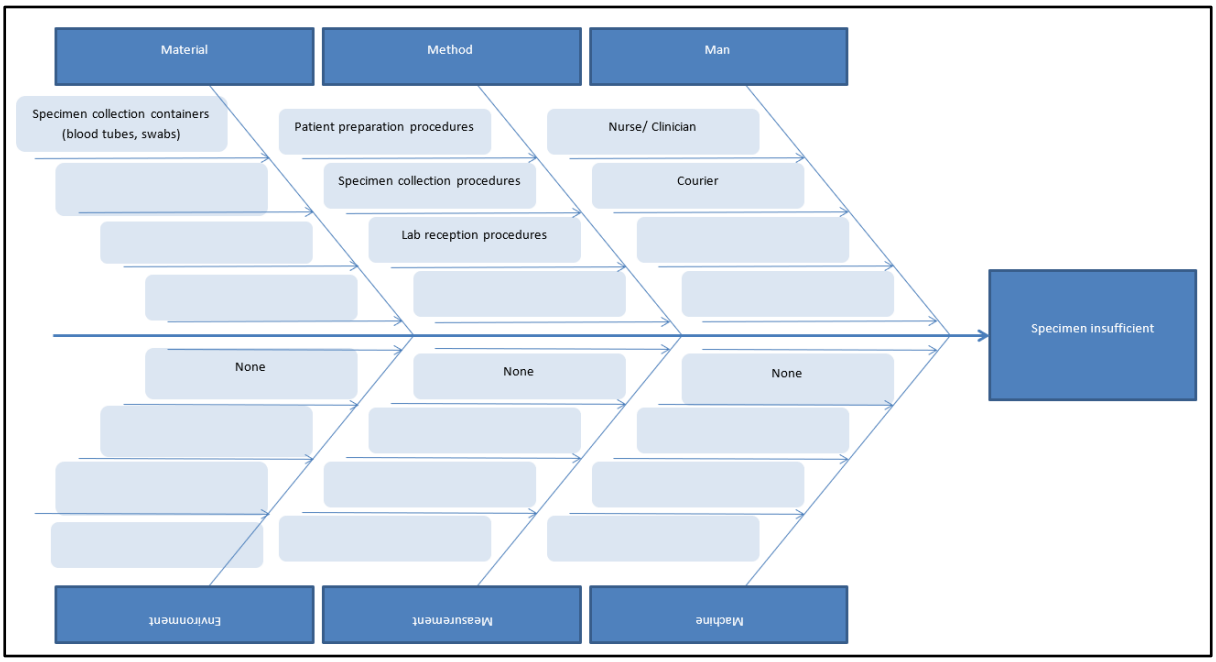
Appendix G: Ishikawa diagram of Rejections due to Haemolysis



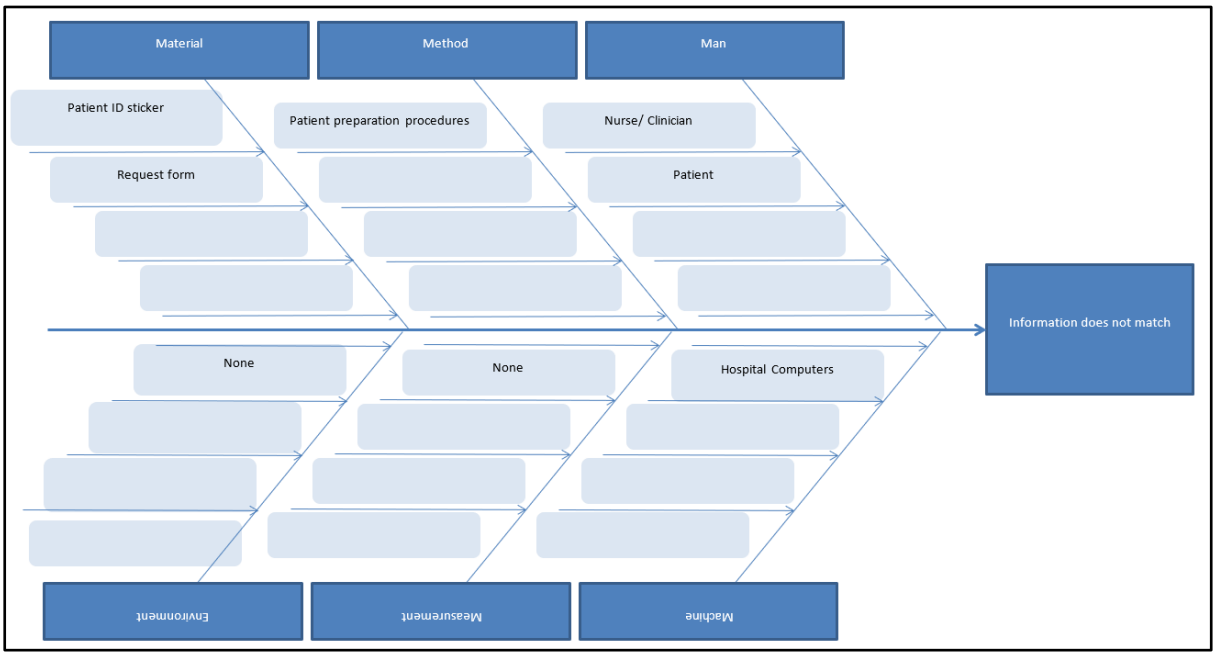
Appendix H: Ishikawa diagram of Rejections due to Clotted EDTA



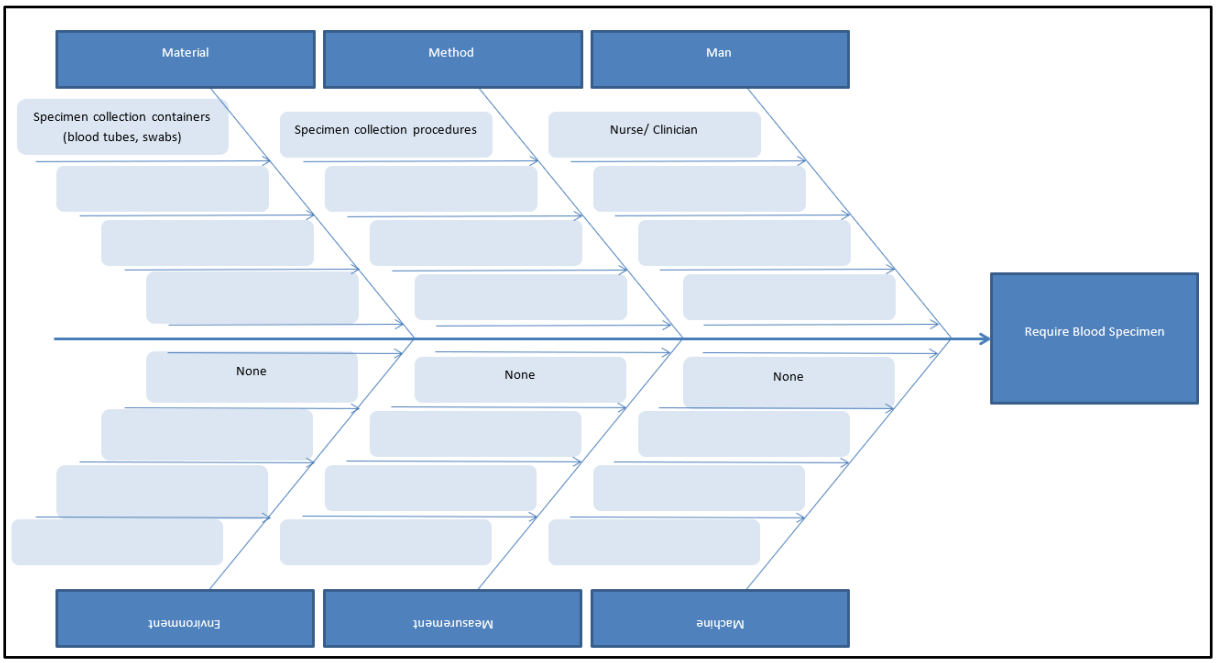
Appendix I: Ishikawa diagram of Rejections due to Insufficient Specimens



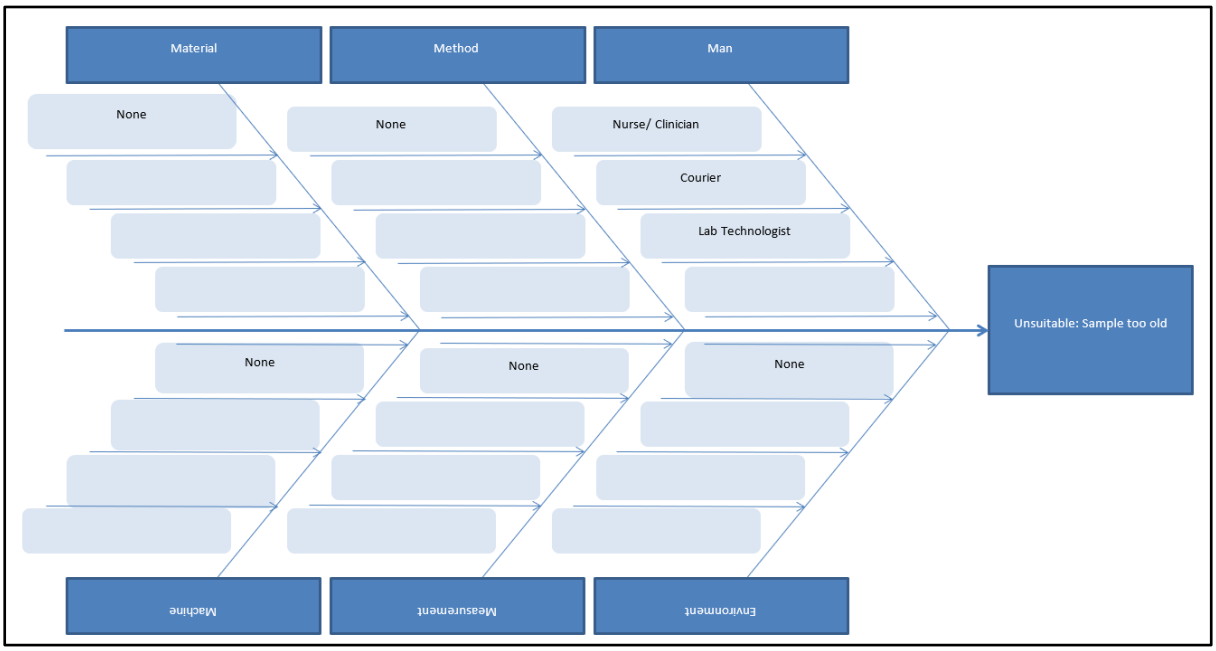
Appendix J: Ishikawa diagram of Rejections due to Information does not match



Appendix K: Ishikawa diagram of Rejections due to Incorrect specimen collected



Appendix L: Ishikawa diagram of Rejections due to Specimens too old



Appendix M: Extract of TrakCare rejection report

TrakCare Rejection Report
Parameters:
From Date 2021-01-01
To Date 2021-12-31
Region WN
Branch WNWC
Usersite XK
Department
Referral All

User Site	Reason	Patient Location	Test Set	Sample
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	1
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	2
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	3
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	4
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	5
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	6
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	7
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	8
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	9
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	10
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	11
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	12
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	13
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	14
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	15
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	16
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	17
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	18
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	19
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	20
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	21
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	22
Paarl Laboratory	Info does not match	Paarl Hospital wc PAH - Emergency Unit	C002 - Creatinine (plus eGFR)	23

Appendix N: FMEA Table

Process Step	Potential Failure Mode	Potential Failure Effect	Severity	Potential Cause	Frequency	Detection	RPN	Recommendation
Test Requested by clinician/ nurse	Clinician/ nurse ordering duplicate testing on patient	Duplicate testing will be rejected by EGK. Specimen rejected	5	No checkpoint in place for ensuring TrakCare guidelines are available for nurses and clinicians	5	8	200	Implement a document managemet system (DMS) and communication strategy for the hospital regarding TrakCare guidelines and EGK updates.
Specimen collection	Incorrect technique/ procedure used to collect specimen	Unsuitable samples for analysis (Haemolysed, EDTA clotted, insufficient and incorrect specimen taken). Lab rejects specimen	10	Lack of suitable control measures to assess competency of nurses/ clinicians during patient preparation and specimen collection. Absence of patient preparation and specimen collection guidelines. Absence of specimen handling, transport, and storage guidelines for newly appointed couriers. No measuring method for ensuring correct sample types are being collected for the test requested. Inadequate training programme for stock management of blood collection supplies.	9	8	**720**	Develop and implement training management programme to address: patient preparation, specimen collection, specimen handling, specimen transport, specimen storage, and stock management of blood collection supplies. Training strategy to be deployed every quarter as part of an induction and orientation programme for nurses/ clinicians/couriers/ stores clerks. Develop and distribute quick access patient preparation and specimen collection guides to nurses and clinicians. Create a manual system for checking the correct sample tubes are collected from the patient for the tests required. Outsource phlebotomy service for emergency departments or areas with high rejections.
Specimen labelling	Incorrect patient folder retrieved, or absence of correct patient ID in folder	Incorrect patient details used on request form and specimen, lab rejects sample, no results received	9	Absence of patient administration and data capturing guidelines for admin staff. Absence of guidelines to address confirmation of patient details.Inadequate systems in place to ensure correct patient ID stickers are contained in the patient folder.	9	8	**648**	Liase with hospital to create and implement patient administration and data capturing guidelines. Implement manual system for confirmation of patient details and for ensuring correct patient ID stickers are placed in patient folders.
Transportation of specimen to lab	Delayed specimen transport to lab after collection	Specimen unsuitable for testing when arrives at lab, as it is too old. Specimens rejected, no results received	5	Inadequate measuring method to ensure timeous transportation of specimens to the lab. Guidelines not available for lab contingency plan when there are insufficinet staff on duty.	7	8	**280**	Implement system where couriers collect samples every hour from hospital wards and deliver to lab. Create contingency plan for lab staff to follow in cases when there are insufficient staff.

Appendix O: FMEA Modified

Process Step	Potential Failure Mode	Potential Failure Effect	Recommendation	Action Taken	Severity	Frequency	Detection	RPN
Specimen collection	Incorrect technique/ procedure used to collect sample	Unsuitable samples for analysis (Haemolysed, EDTA clotted, insufficient and incorrect specimen taken). Lab rejects specimen	1. Develop and implement training management programme	1.1 Develop and implement training programme for: patient preparation, specimen collection, specimen handling, specimen transport, specimen storage, and stock management of blood collection supplies.	2	2	2	**8**
				1.2 Deploy training strategy as a pre-recorded video or in person session quarterly as part of an induction and orientation programme to nurses, clinicians, couriers, and stores clerks.				
			2. Develop quick access specimen collection guide for nurses and clinicians	2.1 Distribute specimen collection guidelines as pocket guide to all nurses and clinicians				
				2.2 Distribute specimen collection posters in ward for easy and instant access to specimen collection tecniques.				
			3. Create manual system for checking correct sample tubes are collected for test requested	3.1 Create and distribute stock template vessel for all blood collection trolleys				
				3.2 Create post for admin clerk to check if correct tubes are collected for the tests required				
			4. Outsource Phlebotomy service for blood collection	4. Outsource and position phlebotomy service in areas of highest rejections				
Specimen labelling	Incorrect patient folder retrieved, or absence of correct patient ID in folder	Incorrect patient details used on request form and specimen, lab rejects sample, no results received	1. Liase with hospital to create and implement patient administration and data capturing guidelines	1. Create and distribute patient administration and data capturing guidelines for admin clerks	1	2	1	**2**
			2. implement checkpoint for verifying patient details on specimen and request form.	2.Position admin clerk appointed in 3.2 above to verify labelling of specimen and request form prior to sample being sent to lab				
			3. Implement checkpoint for verifying correct patient stickers are contained in patient folders.	3. Admin staff to verify correct patient stickers are reprinted and placed in patient folder upon patient administration.				

Appendix P: Summary of Findings

Pareto Analysis	Ishikawa Diagram		5 Whys Analysis	FMEA
	Category	Cause	RCA	Failure modes
Cancelled by EGK	*Method*	Guidelines not available for tests affected by EGK.	Ineffective system for ensuring clinicians are up to date with TrakCare EGK guidelines	1. No Checkpoint in place for ensuring TrakCare guidelines are available for nurses and clinicians
Haemolysis, clotted EDTA, insufficient specimens	*Method*	1.Guidelines not available for: patient preparation, specimen collection, transport, and storage.	Lack of suitable control measures to assess competency of nurses/ clinicians during patient preparation and specimen collection, and absence of patient preparation and specimen collection guidelines	1. Lack of control measures to assess competency of nurses/ clinicians. 2. Absence of procedure guidelines that address: patient preparation, specimen collection, specimen handling, transport, and specimen storage. 3. No measuring method for ensuring correct sample types are being collected for the test requested. 4. Lack of suitable training programme for stock management of blood collection supplies.
		2. Inadequate measuring method for: Specimen collection, availability of suitable blood collection material.	Absence of specimen handling, transport, and storage guidelines for newly appointed couriers	
		3. Inadequate measuring method for: Specimen collection and courier handling during transport	Absence of suitable SOP to address competency of nurses/ clinicians before they can collect patient specimens.	
			Ineffective training programme on stock management procedures for blood collection supplies	
Mismatched Information	*Method*	1. Guidelines not available for: Patient administration and data capturing	Absence of patient administration and data capturing guidelines for admin staff	1. Absence of patient administration and data capturing guidelines for admin staff. 2. Inadequate systems in place to ensure correct patient ID stickers are contained in the patient folder.
		2. Inadequate measuring method for confirmation of patient details	Absence of guidelines for confirmation of correctness of patient details	
	Material	1.Flawed/ omission of Patient ID sticker on: specimen and request form.	Inadequate systems in place to ensure patient ID stickers/ correct patient ID stickers contained in patient folders	
Require blood specimen	*Method*	1.Guidelines not available for: Specimen collection	Absence of specimen collection guidelines	1. Absence of specimen collection guidelines 2. No checkpoint for ensuring correct specimens are collected and sent to laboratory 3. Lack of suitable training programme for stock management of blood collection supplies
		2. Inadequate measuring method for confirmation of suitable sample collected	No measuring method for ensuring correct sample types are being collected for tests requested	
	Material	Specimen collection containers not available	Ineffective training programme on stock management procedures for blood collection supplies	
Specimen too old	*Method*	1.Inadequate measuring method for ensuring timeous transport of specimen to lab	Inadequate measuring method to ensure timeous transportation of specimens to the lab	1. No checkpoint in place to ensure timeous transport of specimens to laboratory 2. Lack of suitable laboratory contingency plan
		2.Guidelines not available for lab contingency plan	Guidelines not available on contingency plans for staff to follow when there are not enough staff on duty	

Appendix Q: Check Sheet for Specimen Collection

Check Sheet for Specimen Collection			
Patient Name		Patient Preparation Complete	☐
Patient Surname		Specimen Tubes collected	
Patient ID		▪ EDTA	☐
Hospital Number		▪ Serum	☐
Medical Aid		▪ CSF	☐
Medical Aid Number		▪ Urine	☐
		▪ Swab	☐
Date of Specimen collection		Mixing of Specimens complete	☐
Name of Nurse/ Dr		Label Specimen and Request form	☐
Signature of Nurse/ Dr		***Comments:***	

Appendix R: Check Sheet for Specimen Handling and Storage

Check Sheet for Handling and Storage of Specimen			
Confirm Patient Name		Specimens Stored upright in rack	☐
Confirm Patient Surname		Specimens Stored at 2-8 ^{o}C	☐
Hospital Number		Fridge Daily Temperature checked	☐
Labeling of Specimen and Request Form Correct	Yes ☐ No ☐	***Comments:***	
		Batch Number	
Additional Information:			
Date of Specimen collection		Name of Clerk	
Time Specimen Received		Signature of Clerk	

.

Appendix S: Check Sheet for Specimen Transportation

Check Sheet for Specimen Transportation			
Batch Number		Specimens Stored upright in Cooler Box	□
Cooler Box Number		Thermometer Present in Cooler Box	Yes □
Temperature of Cooler Box			No □
Ice Packs present in Cooler Box	Yes □ No □	Courier Name and Signature:	
		Time of Collection	
Additional Information:			
Date of Specimen Receipt in Lab		Name of Clerk	
Time Specimen Receipt in Lab		Signature of Clerk	

Appendix T: Editor's Report

NERESHNEE GOVENDER COMMUNICATIONS (PTY) LTD

REGISTRATION NUMBER: 2016/369223/07
DR NERESHNEE GOVENDER (PhD)
neresh@ngcommunications.co.za
0847022553
WRITING PRACTITIONER • EDITOR • COPYWRITER • TRAINER

PhD-Management Sciences: Marketing (gender and media); *PG DIP - Higher Education - Academic Developers (Cum laude;)* M-Tech Public Relations; B-Tech Public Relations *(Cum laude)*; B-Tech Journalism *(Cum laude)*; *N-Dip Journalism*

17/09/2023

NATASHA SINGH
Student No. 214290093
Cape Peninsula University of Technology

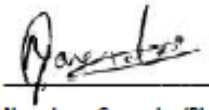
RE: EDITING CERTIFICATE

FOCUS AREA: ANALYSIS OF RISKS ASSOCIATED WITH LABORATORY ERROR RATES OF COVID-19 TESTING AT THE NHLS PAARL LABORATORY.

Thesis submitted in fulfilment of the requirements for the degree MASTER OF ENGINEERING IN QUALITY In the Faculty of Engineering and Built Environment at the Cape Peninsula University of Technology

This serves to confirm that this research has been edited for clarity, language and layout.

Kind regards,



Nereshnee Govender (PhD)

Appendix U - NHLS Ethical Clearance Request

c/o Business
Manager:
Mr Francois
Barton

Dear Mr Barton

20 July 2020

Re: Request for the use of NHLS Paarl Laboratory Data and the use of the term 'NHLS Paarl Laboratory'

This letter serves to ask for permission to use NHLS Paarl Laboratory Data and the use of the term 'NHLS Paarl Laboratory' in my Masters Thesis: "Analysis of risks associated with laboratory error rates of SARS- CoV2 within the medical diagnostic laboratory: A case study of the NHLS Paarl Laboratory in the Western Cape."

The request for permission is a requirement of my ethical clearance. I hereby assure, that should data be derived from patient samples, I will ensure that they will remain anonymous. Further, all raw data and Laboratory Information System reports will be kept strictly confidential and within the confines of the research.

Should you need to speak to my supervisor her details are as follows:

Dr B Swartz
Department of Industrial Engineering
Faculty of Engineering and Built Environment
email: swartzb@cput.ac.za
Tel No.: 021 959 6357

I look forwards to a favorable response.

Regards,
Ms N Singh

Masters Student
214290093
Department of Industrial
Engineering
Faculty of Engineering and
Built Environment

Appendix V - NHLS Ethical Clearance Approval

NATIONAL HEALTH LABORATORY SERVICE

Dear Natasha,

Re: Permission to use NHLS Paarl Laboratory Data and the use of the term 'NHLS Paarl Laboratory'

This letter is in response to your letter dated 20 July 2020, titled: *Request for the use of NHLS Data and the use of the term 'NHLS Paarl Laboratory'.*

In reply to your request; I, Mr F Barton, Business Manager: National Health Laboratory Services, Western Cape hereby give permission to use NHLS Paarl Laboratory Data and use the term NHLS Paarl laboratory in your Masters Thesis: "Analysis of risks associated with laboratory error rates of SARS- CoV2 within the medical diagnostic laboratory: A case study of the NHLS Paarl Laboratory in the Western Cape."

Francois Barton

21/07/2020

Business Manager

Western Cape Regional Laboratories

Tel: 021 417 9374 | Cell: 082 880 9878

francois.barton@nhls.ac.za | www.nhls.ac.za

c/o Business
Manager:
Mr Francois
Barton

Dear Mr Barton

20 July 2020

Re: Request for the use of NHLS Paarl Laboratory Data and the use of the term 'NHLS Paarl Laboratory'

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Should you need to speak to my supervisor her details are as follows:

Dr B Swartz
Department of Industrial Engineering
Faculty of Engineering and Built Environment
email: swartzb@cput.ac.za
Tel No.: 021 959 6357

I look forwards to a favorable response.

Regards,
Ms N Singh

Masters Student
214290093
Department of Industrial Engineering
Faculty of Engineering and Built Environment

21/7/2020

Appendix W - CPUT Ethical Compliance Approval

Cape Peninsula University of Technology

MAY 2014

FREC 1.1 - Ethical compliance for engineering students

Student's surname	Singh	**Student no.**	214290093
First names	Natasha		
ne: **Cell phone: 0609660627**		**E-mail: Natasha.singh@nhls.ac.za**	
Gender: ~~M~~ / F		**Ethnic group*:** ~~Black / White / Coloured /~~ Indian	
Nationality: South African			
~~**Prior qualifications: BTech: Quality Management**~~		**Status** (f ull-time / part-time):Part time	
Title of dissertation/thesis: Analysis of risks associated with laboratory error rates of COVID-19 testing at the NHLS Paarl Laboratory			
Indicate whether a 50% dissertation or 100% thesis:		**50% dissertation**	**100% thesis**
Faculty	Engineering and the Built Environment		
Department	Industrial and Systems Engineering		
Degree	Masters of Engineering: Quality Management		
Principal supervisor	Dr B Swartz		
Position	~~Lecturer~~	**Qualifications D Phil: Quality**	

Name of Reviewer	
It is recommended that the application for ethics approval be: Approved / Not approved	
Comments:	

Faculty Research Ethics Committee comments:

☐ No data collection is required

☒ Data collection is required and permission letter was obtained.

Date of FEC minutes in which recorded:

Approved	Referred back	Chairperson	Date:

ETHICAL COMPLIANCE AGREEMENT:

Explain the potential ethical issues that could arise from this research.	Organizational data will be used for the research, regarding patients that have been screened and tested for COVID19 at the NHLS Paarl Laboratory, Western Cape. Since the research will be conducted using organizational data, which contains sensitive patient information the researcher will ensure anonymity is maintained at all times and that all records used for the research will be treated with the strictest confidentiality. Permission for using the data will be obtained from the Business manager of the NHLS, Western Cape region, prior to data collection. The data collected will be stored electronically on the NHLS database, which is password protected. The researcher will be the sole gatekeeper of the collected data to ensure the data is safely stored and that no other unauthorized personnel have access to this sensitive data.
How will the quality and integrity of the research be ensured	The researcher will ensure the highest quality standards are met whilst performing the research, and that only records pertaining to the research study will be used. In order to ensure high quality standards are met while performing the research, the researcher will use the Ethical Guidelines for Good practice in health care professions as documented by the Health Professions Council of South Africa (HPCSA). The researcher will also use the HPCSA General Ethical guideline for Health Researchers, which encompasses the National Health Act (Act No. 61 of 2003), which protects the best interest of the patient and data containing any patient information during the course of the research. The researcher will also ensure that when other researcher's work areis used, they will be appropriately referenced. The researcher will ensure integrity by ensuring anonymity of patient information on the records used. No patient information such as names, ID numbers, race, gender, social status will be used for the research study.
How will informed consent will be obtained from participants	For the purposes of the research study, only current laboratory records from the Laboratory information system (LIS) are being used, and a letter granting permission to use these records has been obtained from the National Health Laboratory Services.
How will the confidentiality and anonymity of the research respondents will be ensured	The researcher will ensure the strictest confidentiality and anonymity are maintained at all times. The researcher will ensure anonymity by omitting all names, surnames, ID numbers, race, gender, and social status from the records used and only using statistical information from the lab records. The researcher will ensure confidentiality by not divulging any information pertaining to the research study to any personnel except the research supervisor. Only the researcher will have access to the records used for the research study, and these records will be stored electronically and may only be accessed by the researcher who will be the sole gatekeeper.
How will voluntary participation be ensured	No human participation for the purpose of the research, only organizational data will be used and permission has [illegible] collecting and using the data.
How will harm to the participants be prevented	Given that this research study will focus on using laboratory records only, no harm will be done to human participants. All organisational/laboratory records used will be treated with the highest integrity and confidentiality.
How will harm to the environment be prevented	Given that this research study will focus on using laboratory records only, no harm will be done to the environment.

How is it ensured that the research will be independent and impartial?	The researcher will not falsify or fabricate results. The data collection instrument will be the laboratory information system (LIS). The researcher will select data over a period of time from the LIS in order to perform the research and the data will be refined. The researcher will be reporting results honestly and will seek assistance from the NHLS Quality Assurance (QA) Manager to ensure that there are no mistakes and independence of results. The researcher will not make up details for use in the research nor will the researcher falsify final outcomes in order to support a final conclusion. The researcher will not misrepresent the results of the research in order to mislead others to the final outcome of the research. The research will be peer reviewed by a second Master's student, who is unrelated and has an unbiased opinion of the research. The researcher has no incentive from the bursar to perform the research and will be performing the research only to make a scientific contribution for the good of humans.
Explain if there are any other organisations involved in the research, whether the ethics policy of the institution has been explained to them and whether written permission has been obtained from them to participate in the research.	The National ~~health~~Health Laboratory Services are involved in this research as laboratory records will be used for the purposes of the research study. A letter of permission has been granted from the Business Manager in order to use the laboratory records, whilst ensuring integrity and confidentiality are maintained at all times.
Explain any ethics requirements that are set by potential funders and how these will be dealt with.	There are no ethical requirements set by potential funders. This does not apply to the research
Explain what risk scenarios exist (individual, community, environment etc) and how these will be dealt with.	The risk scenario that could be identified pertaining to this research would be if anonymity and confidentiality are breached. An individual would be at risk, however the researcher will make every effort in order to ensure anonymity and confidentiality are met. The researcher will ensure that during data collection, data review, research discussion, results review and conclusions, all information and records pertaining to the research will be kept under strict electronic access control, that may only be retrieved by the researcher. All electronic records will be void of individual names, surnames, identity numbers, race, and gender. The researcher will make use of unique barcodes representing an individual in the data collection for statistical purposes, this will ensure anonymity. Should any risk occur, all avenues will be explored to mitigate and eliminate the risk. The researcher may also seek assistance from the NHLS risk management team.
Explain how authorship issues will be dealt with when publications and conference papers are produced as a result of the research. Indicate what the roles and responsibilities will be and who will be the primary and secondary authors.	The Student is the first author and the Supervisor is the second author.
Explain what will be done to prevent any form of plagiarism in the research publications.	The researcher is aware of plagiarism and will ensure any and all literature used will be appropriately referenced. The researcher will not steal any other authors work. The researcher is also aware that CPUT has a policy on plagiarism. The researcher will also employ turnitin software to check for plagiarism throughout the study.
	There are no conflicts of interest in this research.

Explain if there may be any conflicts of interest relating to the supervisor and the student in the research, whether any other parties will benefit from the research and how this will be dealt with in a fair and transparent way.	
Explain what engineering aspects of the study will be subject to the codes of conduct of the engineering profession and its representative bodies and how these will be complied with.	The research is being conducted in the Faculty of Engineering and the Built Environment, however the professional body for Engineers (ECSA) does not oversee that MEng: Quality qualification. ECSA codes of conduct does not apply to this study, however the FEBE ethical guidelines will be followed.

Signed (Student) 

Date: 22/9/2020

Signed (Supervisor)

Date:

Signed (HOD)

Date: