EVALUATION OF THE PERFORMANCE OF ANALYTICAL QUALITY INDICATORS ON THE QUALITY MANAGEMENT SYSTEM IN A MEDICAL LABORATORY ESTABLISHMENT

Nishani Hirjee

Student Number: 19551895

Dissertation submitted in fulfilment of the requirements for the Degree Masters of Health Sciences in Medical Laboratory Science in the Department of Biomedical and Clinical Technology at Durban University of Technology

Supervisor: Dr B. T. Mkhize

Co-supervisor: Dr P. Pillay

Date: 12 June 2022

DECLARATION

I hereby certify that the work is wholly my own and that no other authors are included, except for those explicitly acknowledged (including references to published and unpublished sources). This work has not been submitted in any form to the Durban University of Technology or any other institution before.

___ _____

Signature of student Date: 12/06/2022

_____

Signature of Supervisor: Dr B. T. Mkhize Date: 12/06/2022

_____

Signature of Co-Supervisor: Dr P. Pillay Date: 12/06/2022

ABSTRACT

Since laboratory results are used to diagnose, monitor, and evaluate patient outcomes, a medical laboratory is an essential component of health care. It is therefore the responsibility of a medical laboratory to maintain the quality of their analytical procedures and to implement a quality management system to improve the effectiveness and efficiency of their tests. Medical laboratories use quality indicators to monitor and control the quality of their laboratories.

Quality indicators identify risks that may lead to errors, which may cause harm to patients. In order to comply with the International Organisation for Standardisation (ISO) quality standard for medical laboratories, quality indicators must be implemented and monitored. To assess a laboratory's competence, medical laboratories use quality indicators from the ISO 15189:2012 checklist. Each year, the laboratory monitors a maximum of three quality indicators covering pre-analysis, analysis, and post-analysis variables.

A study that compared the performance of selected analytical quality indicators between three main laboratories and ten peripheral laboratories over a two-year period was designed to assess the quality management system of a medical establishment. Furthermore, the study evaluated quality reports for the selected analytical quality indicators between January 2017 and January 2019. To determine whether the conventional method of choosing only one out of nine quality indicators is sufficient to maintain quality in the laboratory, analytical quality indicators were compared.

The study consisted of a retrospective component and a prospective component. The retrospective aspect involved the evaluation of laboratory quality reports over a two-year period, from January 2017 to January 2019. The prospective aspect consisted of administering a questionnaire to 80 medical technologists in order to assess their knowledge, attitudes, and practices regarding quality indicators. The Institutional Research and Ethics Committee (IREC) of the Durban University of Technology provided ethical clearance. To analyse the data collected, SPSS 26.0 version was used.

The analysed data depicted a gender composition amongst the participants, with females predominant in the medical laboratory establishment. The overall ratio of males to females was approximately 3:7. The results revealed that more than half of the participant population had working experience of greater than nine years post – qualification. It was deduced that the pre-selected quality indicator is not sufficient to maintain the quality management of the medical establishment. The study identified a suggested list of analytical quality indicators in this medical establishment where the problem areas can be identified and improved by decreasing analytical errors and improving patient care. The correlation of the level of knowledge has a direct impact on the attitudes and practices of medical technologists on the current use of quality indicators ($p<0.001$).

The levels of knowledge practises and attitudes of medical technologists were assessed and further training was suggested to improve the quality management system. The key findings noted were that the medical technologists in this establishment had adequate knowledge on document control and instrument maintenance. Another key finding was that knowledge directly affects the practises and attitudes. The pre-selected quality indicator is not sufficient to maintain the quality management system of this medical establishment.

DEDICATION

Throughout my journey, I have been provided with strength by God, and I dedicate this dissertation to my late father, Mr Jewonlall Seron. I thank my family, my husband, my mother, and my two children for their ongoing support.

ACKNOWLEDGEMENTS

My sincerest thanks goes to Dr B. T. Mkhize, my supervisor, and Dr P. Pillay, my co-supervisor, for their constant guidance, support, encouragement, and valuable feedback. Through their collaboration I have learned a great deal.

Thank you to Mr Deepak Singh, my statistician, the research committee and management for your contributions to this project. I also thank the medical establishment and the participants of the study.

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ACRONYMS

CV	Coefficient of variation
EQA	External quality control
ISO	International standards of organisation
IQC	Internal quality control
QMS	Quality management system
SANAS	South African National Accreditation System
SD	Standard deviation
SOP	Standard operating procedure
TAT	Turnaround time
TEA	Total allowable error
WHO	World Health Organisation
WI	Working Instruction
SA	South Africa

CONTENTS

CHAPTER ONE

1. Introduction

1.1 Introduction and Background

A medical laboratory plays an essential part of the health care sector, with the laboratory results being extremely important in the diagnosis, monitoring, and evaluation of patient outcomes. Patient management is dependent on laboratory data and this highlights the need for ensuring that the patient's results are of excellent quality (Chawla and Singh 2010). Therefore, a medical laboratory handles test results making sure they are fit for their clinical purposes. This is achieved by setting and maintaining the quality of their analytical methods and by having a quality management system in place to improve the effectiveness and efficiency on a continuous basis (Chawla and Singh 2010).

A medical laboratory must have documented standard operating procedures to assist in maintaining a quality management system that is effective and efficient and these procedures may improve continually. When there is no total quality management system in place, then there may be an increase in errors. An error is defined as any defect that occurs in the testing process. Laboratory errors may lead to increased health care costs and decreased patient satisfaction (Plebani 2014). Quality indicators allow medical laboratories to identify risks that may lead to such errors, which in turn may result in patient harm. It is important for a medical laboratory to have a quality management system in place to ensure effectiveness and efficiency of laboratory processes on a continuous basis.

The assessment of quality demands that every step in the analytical process is performed correctly and accurately to ensure important decision-making as any risk or error identified during this process will negatively impact patient care. A study conducted by Plebani (2016) on the quality indicators for the total testing process in a medical laboratory concluded that a standard reporting system as part of the analytical activities must be maintained to achieve consistently higher levels of quality in laboratory medicine.

The International Organisations for Standardisation (ISO) quality standard for medical laboratories requires quality indicators to be implemented and monitored. The International Organisations for Standardisation is an independent non-governmental organisation, which creates standards that provide requirements and guidelines that can be used by medical laboratories to gain competence. Medical laboratories select quality indicators from the ISO 15189:2012 checklist, which is an international standard on laboratory accreditation, to develop their quality management system for assessing the competence of the laboratory. Laboratories that are accredited against ISO 15189:2012 standard are expected to monitor quality indicators continually, to improve their quality management system.

Quality indicators represent valuable tools for quantifying the quality of selected aspects by comparing them against selected criteria (Plebani 2014). A quality indicator supports accountability as well as helps support judgements and is used in the setting of priorities to enable comparison over time. Quality indicators are a management system tool and are used to monitor and control the quality of a laboratory. A quality indicator measures how well an organisation performs on their quality management system (Plebani 2014). The ISO 15189:2012 defines quality indicators as a measure of the degree to which a set of inherent characteristics fulfil requirements.

The international standard on laboratory accreditation does not specify the number of quality indicators to be monitored in a laboratory in a year. The laboratory, where the current study was conducted, chooses three quality indicators that would be monitored per that year, to improve and maintain the quality management system within the laboratory establishment. The selected quality indicators, which would be chosen from the ISO 15189:2012 checklist, would include pre-analytical, analytical, and post-analytical quality indicators. These are revised annually, with different analytical indicators monitored each year based on the areas that require attention. Choosing different quality indicators for monitoring within a particular year is viewed as would not adequately cover all aspects of the quality management system, since only selected

few quality indicators and not all within the ISO 151589:2012 guideline, would be monitored.

1.2 Rationale of the study

The purpose of the study was to determine whether the selected analytical quality indicators are sufficient to maintain the quality management system, since there are many areas on the analytical aspect in the laboratory that may require attention. Thus, the present study was to evaluate the effect of placing emphasis on selected analytical quality indicators and to assess whether this is sufficient to maintain the overall quality of the laboratory. The aim of the present investigation was to monitor the performance of analytical quality indicators on the quality management system of a medical laboratory, by comparing their performance over a two- year period. This was to be achieved by the evaluation of business quality reports of thirteen laboratories (comprising three main and ten peripheral laboratories) within a medical laboratory establishment. These indicators were pre-selected by the organisation on an annual basis between January 2017 and January 2019. Furthermore, a survey to determine the level of knowledge and perceptions on the use of quality indicators in a laboratory was conducted on medical technologists from a clinical pathology laboratory, which comprises the disciplines of Chemistry, Haematology and Microbiology.

Since there were no guidelines for identifying and developing quality indicators on the laboratory investigated, although the ISO 15189:2012 standard for medical laboratories requires the quality indicators to be monitored then the present study was to determine a set of guidelines that would assist medical technologists in maintaining the quality management system. Since the approved international guideline does not specify the number of quality indicators to be monitored in a laboratory in a given time, hence the risk of leaving it to the individual laboratories to decide on how many quality indicators they wish to adopt per time frame. The establishment of an evidence-based guideline of quality indicators that should be monitored each year, based on study findings that may highlight the problem areas, may assist in improving the quality management system. This in turn, may provide guidance to medical technologists who

are professionals that are responsible for sample analysis and ensuring that the laboratory tests of each patient are accurate, thereby enhancing the quality management system and making sure that clinicians receive quality results. Identifying a set of analytical quality indicators may improve the quality of service delivered to clinicians and provide confidence in the results generated. In our knowledge, there have been no published studies on the evaluation of using a few preselected ISO 15189:2012 quality indicators instead of monitoring all, within a quality management system in a medical laboratory.

1.3 Aim and Objectives

1.3.1 Aim of the study

The aim of the investigation was to evaluate the performance of preselected analytical quality indicators on the quality management system of a medical laboratory establishment over a two-year period from January 2017 to January 2019.

1.3.2 Research Objectives

1.To evaluate the performance of the pre-selected quality indicators from the quality reports in respect to compliance of the ISO:15189:2012 requirements as identified by the medical laboratory establishment on an annual basis.

2.To compare the performance of one identified analytical quality indicator among the main and the peripheral laboratories that form part of the medical laboratory establishment.

3.To determine the levels of knowledge, attitudes, and practises of medical technologists regarding the current use of quality indicators.

1.4. Summary of chapters

Chapter one: Background

This chapter includes the introduction and background to the study. This flows into discussions on the research problem, the aim and the objectives of the study. This chapter is concluded with the structural plan of the research report.

Chapter two: Literature Review

This chapter presents an in-depth literature review in which a range of literature related to quality indicators are covered. Diagrams and models relating to the quality management system and the monitoring of this which will provide a theoretical grounding of the topic were also provided in this chapter.

Chapter three: Methodology

The methodology describes the study design, population and the sampling strategy followed by a description of the data collection and the tool used and processes that were followed.

Chapter four: Results

This chapter contains the study results obtained from the survey and quality reports. The inferential statistics and the rest of the statistical analysis of data are presented and discussed.

Chapter Five: Discussion of findings

In this chapter the findings obtained from the survey and quality reports are discussed.

Chapter Six: Conclusion

In the final chapter, the study conclusions are stated.

1.5 Conclusion

This chapter introduced and presented an overview of the study and introduced the problem statement, research purpose and research objectives. In the following chapter a detailed literature review is presented.

CHAPTER TWO

Literature Review

2.1 Introduction

The aim of this study was to assess analytical quality indicators concerning the ISO 15189:2012 guidelines, which assist in the analytical aspect of laboratory testing. Providing laboratory test results in the quickest time and with the highest possible quality may both be useless when data are incorrectly interpreted (Mrazek 2020). Interpretation of laboratory test results must be performed considering clinical history, symptoms, and physical examination. The results are the deciding factor that predicts whether the clinical diagnosis is valid and eligible for patient care (Mrazek 2020). The present study aimed to evaluate the performance of a few pre-selected analytical quality indicators whether they can maintain and continuously improve the quality management system, to assist in achieving excellent patient care.

About the World Health Organization (2005), medical technologists must commit to meeting the quality needs and follow all quality assurance procedures and adhere to the requirements of the International Organization of Standards. The primary responsibility of medical technologists is to provide care to patients and place the welfare of patients above their own needs and desires (Kiani and Tavakkoli 2019). A medical technologist performs and analyses the results of tests on blood and body fluids. These highly trained professionals work in hospitals and laboratories using sophisticated procedures and equipment. Medical technologists should adopt a holistic approach to laboratory diagnosis and function in close coordination with clinicians to provide effective services for diagnosis of patients (Siddiqui, Lodhi and Uzma 2015).

Adoption of quality control in all phases of the diagnostic process is necessary to safeguard the interests of patients and deliver a quality service (Siddiqui, Lodhi and Uzma 2015). According to the World Health Organisation (2005) equipment management is one of the essential elements of a quality management system and this will reduce variation in test results and improve the technologist’s confidence in the accuracy of testing results and will determine a high level of laboratory performance.

Quality assessment demands that every step in the analytical process is performed correctly and accurately to ensure important decision making, therefore every risk or error not identified during this process will have a negative impact on patient care (Siddiqui, Lodhi and Uzma 2015).

As indicated by Barth (2011), there have been many changes with unpredictable improvements in analytical performance, patient tests and the ability to process large volumes of work due to the changing environment and the medical needs. As further suggested by Barth (2011) there is a growing awareness that the testing process starts from the time the clinician orders the tests until the samples reach the laboratory and until the clinician receives the patient report, and thus recommends that this whole process must be included in the quality assessment of the total testing process. It was concluded by Barth (2011) that service delivery should be patient-centred, timely, efficient, and equitable and should be molded to ensure that optimal outcomes are achieved. It is therefore imperative that an establishment have a quality management system in place that would ensure the quality of patient results are generated. The current study aimed to develop a generic guideline that would identify from the ISO standard set of quality standards that should be monitored in each annual review of indicators within the pre-selected list. This was expected to assist the establishment in maintaining the quality management system.

2.2 The role and responsibilities of a medical laboratory in ensuring reliable patient results

A significant view by Burnett (2013) suggests that a medical pathology laboratory plays a pivotal role toward patient-centered and patient care, therefore the laboratory should have measures in place to ensure that quality patient results are given to the clinicians for correct treatment and patient management. A further suggestion by Burnett (2013) indicates a need for consistent, specified, useful and evidence-based laboratory

processes and related quality and performance measures. These are important to health care outcomes and meaningful to healthcare stakeholders for which laboratories can be held accountable.

Medical laboratory services have been described as major processes that contribute to safe patient care in modern health care. The maintenance of high-quality in laboratory medicine is a guarantee that every step in the total testing process is correctly performed. This ensures valuable decision-making and effective patient care (Ambachew and Adane 2018). As claimed by the World Health Organisation (2005), laboratory quality can be defined as accuracy, reliability, and timeliness of the reported results. A laboratory needs to be as accurate as possible therefore all aspects of the medical laboratory operations must be valid, and reporting needs to be timely for this to be useful to the clinician. Laboratory results enable a physician and other health care professionals to make appropriate evidence based diagnostic decisions for patients. To achieve the highest level of accuracy and reliability of patient results, all processes and procedures need to be done in the best possible way. It is therefore important to have a quality management system in place to achieve good laboratory performance. Poor laboratory performance that leads to error and delays in the diagnosis and treatment is an obstacle to optimal patient care. It may result in patient harm. Identifying and evaluating errors in the total testing process by using quality indicators is mandatory (Ambachew and Adane 2018).

2.3 The usefulness of a quality management system in a medical establishment

Quality means meeting standards and is of paramount importance in medical laboratories. Quality is defined through a well-defined quality system and is aimed at ensuring consistency, reproducibility, traceability and efficiency of a system (WHO 2005). According to the World Health Organisation (2005), the purpose of establishing

quality standards is to ensure the accuracy of test results, increase the confidence in patients, clinicians and communities in the value of laboratory testing. International Standard of organisation (ISO) standards provide a technical base for health and safety as well as conformity assessment.

The ISO 15189:2012 standard defines quality indicators as a measure of the degree to which a set of inherent characteristics fulfil requirements, therefore quality indicators in a laboratory are a management tool for continual improvement for quality in a laboratory. A quality indicator represents a valuable tool for quantifying the quality of selected aspects by comparing it against established criteria (Burnett 2013). A quality indicator supports accountability, helps to make judgements, and set priorities, enabling comparison of quality over time. The process of monitoring quality indicators must be planned, and it includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement (Burnett 2013).

When a medical laboratory fulfil the ISO 15189 requirements, this confirms that the laboratory has met requirements for technical competence and the management system necessary for reliable delivery of technical and quality results (Leonard and Kinoti 2019). Organisations world-wide have defined various ways of ensuring that performance is enhanced to meet customer expectation of quality provided (Leonard and Kinoti 2019). The role and responsibilities of a medical laboratory therefore include the high standards that should be maintained in the practice of strict confidentiality of patient information and patient test results.

It is in the interest of patients, of society and those medical laboratories that operate at high standards of professional and technical competence. It is in the interest of laboratories that their competence is verified through a process of accreditation, which includes inspection and comparison against appropriate standards, as a confirmation of their good standing. The primary objective of laboratory accreditation is to ensure

that when a patient undergoes laboratory investigation, the results of those examinations are comparable irrespective of where they are performed (Burnett 2013). International Standard of Organisation (ISO) 15189:2012 defines accreditation as a procedure by which an authoritative body gives formal recognition that an organisation or a person is competent to carry out specific tasks (Burnett 2013). To achieve this improved performance, many laboratories have adopted the ISO standards either for certification or for accreditation, to improve confidence in their performance (Leonard and Kinoti 2019).

2.3.1 The impact of laboratory errors on the quality management system

Laboratory errors are defined as any defect from ordering tests to reporting of results; this comprises three phases namely pre-analytical, analytical and post -analytical variables (Siddiqui, Lodhi and Uzma 2015). Errors that occur during specimen testing are referred to as analytical errors (Siddiqui, Lodhi and Uzma 2015). They may occur due to many factors such as and not limited to either equipment malfunction, sample mix-up, interference, undetected failure in quality control, or procedures not followed correctly. Laboratory errors may lead to missed opportunities to make a correct and timely diagnosis. These may contribute to missed, wrong, or delayed diagnosis which may lead to harm from inappropriate treatment or delayed tests (Singh 2015). A study done by Lao and Garcia (2017) identifies that any failure in the processes in the laboratory can lead to consequences in patient safety.

Inaccurate results can provide consequences that can be significant and can result in unnecessary treatment of a patient, treatment complications, delay in correct diagnosis and unnecessary diagnostic testing (WHO 2005). Errors occur at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them (Plebani 2014). These can be minimised by implementing an effective quality management system that will assist the laboratory to

reduce such errors. There is an increased awareness of the importance of errors in laboratory practice and their negative impact on patient outcomes.

Errors prevail within the laboratory set up, and conscious efforts must be made to strive towards one hundred percent precision and accuracy in the whole testing cycle, including the periodic evaluation of the quality system to reduce or eliminate errors (Sakyi and Lang 2015). Laboratory errors can be reduced by increased cooperation with higher management authority and laboratory personnel and by implementing new strategies in quality improvement (Toshniwal and Shah 2016).

The most severe and costly type of errors should lead to the consideration for new strategies of achieving quality in all steps of the total testing process to improve patient safety (Plebani, 2014). Medical errors can no longer be seen as inevitable but as something that can be actively streamlined and prevented since they may cause harm to patients as well as result in huge medical costs (Hamerling 2012). Medical laboratory errors may lead to increased health care costs and decreased patient satisfaction (Plebani 2014).

Errors in the laboratory can be decreased by having a structured quality management system whereby quality indicators are being monitored (Burnett 2010). Quality indicators can be used to make an initial study of the risk of failures in an overall process or to confirm that the quality of a process is being maintained (Burnett 2010). Quality indicators will assist a laboratory in picking up errors and thus improving the quality management system of an establishment (Burnett 2010).

In view of this, the success of any attempt to reduce errors should be monitored by quality indicators to evaluate the effectiveness of the measures taken (Siddiqui

Lodhi and Uzma 2015). More studies in laboratory errors are required for effective patient care with increasing focus in achieving better analytical quality through improved laboratory equipment (Prabhakar and Stephen 2012).

2.4 The use of the International Standards of Organisation guidelines for medical laboratories

A study conducted by de Gruyter (2011) on eleven countries worldwide revealed that a quality indicator managed as an external quality assurance programme can serve as a tool to monitor and control the pre-, intra- and post- analytical activities. This may allow clinical laboratories to identify risks that lead to errors, resulting in patient care, identification and design of practices that eliminate medical errors. External quality assurance is the only one aspect that needs to be monitored as a quality indicator. The other aspects include, reporting of results, quality control, reporting critical results, review of results, turnaround time, continual improvement, and clinician satisfaction. Furthermore, de Gruyter (2011) suggested that initiatives must be undertaken such as involving accreditation bodies so that the model of quality indicators can be identified as a suitable tool complying with the ISO 15189:2012 standard requirement. Criteria to ensure that an appropriate list of quality indicators (number, typology, and frequency) of collection of data must be included in the model of quality indicators to ensure that laboratory performance is evaluated (Barth 2012).

The ISO 15189:2012 guideline stipulates analytic aspects that need to be monitored from a laboratory perspective. However, the medical establishment monitors only those quality indicators that would have been preselected for that year and does not monitor all the quality indicators mentioned in the guideline. Monitoring only a selected few quality indicators may negatively impact the quality management system of the medical establishment as not all aspects of the ISO 15189:2012 checklist would be monitored. If a laboratory does not monitor all quality indicators the quality in the

laboratory can be compromised thus, affecting the quality of patient results being evaluated.

The ISO 15189:2012 is available on purchase and it stipulates on how to measure quality indicators. However, more clinical laboratories need to participate in this quality indicator bench-marking programme to provide clear guidance on quality management. However, there are no studies to date on the successful implementation of quality indicators (Cadamuno and Gaksch 2018). To overcome this gap the European Federation of Laboratory Medicine established a task force on the performance specifications for the extra-analytical phase with the aim to identify reliable performance specifications (Cadamuno and Gaksch 2018). As further indicated by Cadamuno and Gaksh (2018) that there were no published studies that were noted for a successful implementation of quality indicators especially when a few are selected for monitoring and not all and hence, the current study needed to be conducted.

The focus of the current study was on analytical quality indicators as medical technologists are solely responsible for the analysis of patient samples. Analytical quality indicators were identified from the ISO 15189:2012 checklist for medical laboratories and were used to design a questionnaire to determine the levels of knowledge, attitudes, and practices of medical technologists regarding the current use of quality indicators in a clinical pathology laboratory. The ISO 15189:2012 checklist guides medical technologists and medical laboratories in the maintenance of quality. Medical laboratories use the ISO 15189:2012 checklist in developing their quality management system and assessing the competence of the laboratory. The study was based on the ISO 15189:2012 checklist which assists the laboratory in maintaining the quality management system. The analytical processes are internal quality control results, continual improvement and clinician satisfaction. validation and verification,

proficiency testing, result of reporting critical results and reporting of results (ISO 15189:2012 Checklist for Medical Laboratories). All these processes are found under different clauses in the ISO 15189:2012 guideline. Only the clauses that are part of the

analytical process were chosen for this study. The analytical process highlights what medical technologists are expected to perform in the medical laboratory.

The analytical processes were used such as internal quality control results (clause 4 management requirements), continual improvement and clinician satisfaction. (Clause 4 management requirements and resolution of complaints), validation and verification (clause 5), proficiency testing (clause 5 technical requirement and quality control materials), result of reporting (clause 5 technical Requirements and quality control data), reporting critical results (clause 5 technical requirements and report Attributes), reporting of results (clause 5 technical requirement review of results), (ISO 15189:2012 Checklist for Medical Laboratories).All these clauses or requirements are interrelated and all need to be fulfilled in order to achieve a well-maintained quality management system.

An ISO15189 model (Figure 2.1) describes the theoretical framework that medical laboratories can follow to gain competence and maintain quality to provide a service (Burnett 2013). This model denotes that the process of monitoring quality in a medical laboratory is cyclical; where the organisation and its management should ensure that quality management system is maintained as well as evaluated. The model was used in the current study as a theoretical framework to determine whether the quality management processes within the laboratory are interrelated and cyclical in maintaining the quality management system. This model proposes that any aspect that may not be followed in this cyclical process may result in non-attainment of high-quality patient care.

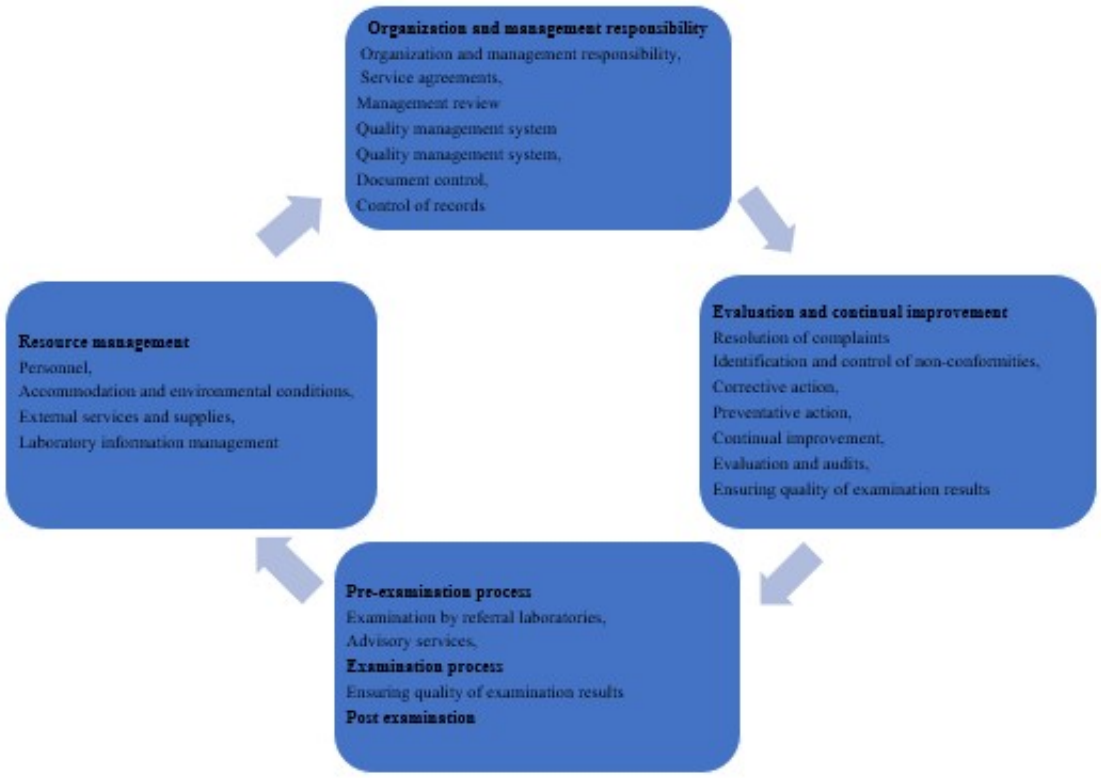

Figure 2.1 The ISO 15189 model, which indicates that the quality indicators are interrelated and cyclical in maintaining the quality management system. [Adapted from Burnett (2013)].

2.4.1 The evaluation of quality indicators toward quality improvement in a medical laboratory

A laboratory must establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post examination processes (Plebani 2016). The process of monitoring quality indicators must be planned, which should include establishing the objectives, methodology, interpretation and limit action plan and duration of measurement. A quality indicator measures how well an organisation performs on their quality management system. ISO 15189:2012 encourages full involvement and utilisation of the abilities of all employees at all levels to improve the organisation. In a laboratory accredited to the ISO 15189:2012 standard, the goal is continual improvement, and for staff members to know exactly what to do, how to do it, who is in charge of a process, and where to find all information

necessary to perform their jobs (Schneider and Mauer 2017). Quality indicators are an objective measure of laboratory practices (Sharma and Patgiri 2018). Laboratories implementing ISO 15189:2012 strive to create systems that are as failure resistant as possible, and will “catch” mistakes before they become a problem. Reducing errors is by getting things right the first time and identifying opportunities for improvement and empowering staff by involving them in the solving of problems and the implementation of solutions (Schneider and Mauer 2017). Monitoring quality indicators gives an organisation a snapshot view on the performance of the organisation. Harmonisation of quality indicators represents a fundamental step and therefore, the importance of quality indicators must be identified by developing appropriate guidelines at a national and international level (Plebani 2015).

It was deduced from the Plebani (2015) study that it is possible to compare laboratory functions with other laboratories by evaluating the prevalence of the various indicators. Laboratories should strive to reach set benchmarks to provide the best service to society. In the current investigation, it was to be determined whether there would be any gaps in choosing only a few quality indicators as opposed to the monitoring of all the quality indicators in the analytical aspect of the ISO 15189:2012 guideline each year. There are nine analytical quality indicators listed in the ISO 15189:2012 standard which include all the analytical aspects such as proficiency testing, reporting of results, quality control, reporting critical results, review of results, turnaround time, validation, verification, continual improvement and clinician satisfaction. Only three pre-selected quality indicators are monitored each year; however, this study was to evaluate whether monitoring only a few instead of all the quality indicators mentioned in the standard would be sufficient to maintain the quality management system. These shortfalls, if identified, were to indicate that the quality management system of the laboratory for the years investigated was negatively affected, and the integrity of laboratory results generated were compromised. Sharma and Patgiri (2018) suggested that when these quality indicators are developed, and monitored, then customer satisfaction is attained.

A study which investigated whether using quality indicators for internal and external quality control concluded that a high frequency of mistakes which raise alarms on the

importance of quality indicators to assess errors in the total testing process is vital in a laboratory environment (Ambachew and Adane 2018). This highlights the importance of monitoring all analytical quality indicators in a medical laboratory.

Furthermore, the Swetha and Raju (2019) study revealed the importance of assessing the performance of all quality indicators providing an insight into the efficacy of the quality assurance programme. Identifying the gaps in the quality assurance programme opens new avenues in quality improvement. This study by Swetha and Raju (2019) included a more exhaustive list for capturing different quality indicators in the respective phases for a comprehensive assessment of a quality management system which included critical results reported and internal quality control. It was further deduced in the study that it is possible to compare laboratory functions with other laboratories by simply evaluating the prevalence of the various indicators and furthermore laboratories should strive to reach these benchmarks to provide the best service to society. Notably, the current study had intended to formulate a suggested list of generic guidelines for monitoring quality indicators based on the study findings

2.5 The responsibility of medical technologists regarding the current use of quality indicators

A medical technologist is expected to comply with the whole total testing process using the quality indicators as a guideline of the quality management system and refocus on minimising the error rate in the analytical laboratory processes (Mrazek 2020). A medical technologist should exercise sound judgement in setting up, analysis, and assessment of laboratory testing (Kiani and Tavakkoli 2019). In addition, a medical technologist's ethical attitude safeguards the dignity and privacy of patients and provides accurate information to other health care professionals on the services that are provided (Kiani and Tavakkoli 2019).

In addition, the current study aimed to determine the levels of knowledge, attitudes, and practises of medical technologists in their role and responsibilities in monitoring analytical quality indicators and to ensure that accurate patient results are generated. Personal values and moral attitudes play a major role in clinical decision-making. Improving performances and behaviours of medical professionals require adequate

training and assessment of the levels of professionalism would be achieved (Kiani and Tavakkoli 2019). It was thus anticipated that findings of the present study would identify what could be included in a guideline of the analytical quality indicators in a medical laboratory, if developed.

The guideline would provide guidance to medical technologists who are professionals that are responsible for sample analysis and ensuring that the laboratory tests of each patient is accurate, thereby enhancing the quality management system and making sure that clinicians receive quality results. The guideline would ensure that the selection of the analytical quality indicators in a medical establishment provides a checklist for medical technologists. They would use this to maintain the quality management system of the laboratory and to ensure that clinicians receive quality results.

2.6 Conclusion

In this chapter, literature review on studies that have investigated the importance of quality indicators were discussed. The reviewed literature highlights that laboratories need to monitor quality indicators in order to maintain the quality management system. Furthermore, the theoretical framework that underpinned the study was presented in the form of a model. The model highlights that the analytical aspects are interrelated and is essential for all aspects of quality to be monitored and not just one aspect.

CHAPTER THREE

Research Methodology

3.1 Introduction

This chapter discusses the methodology that was used in the implementation of the study. It describes various aspects of the research including the study design, study setting, sampling, data collection and analysis.

3.2. Study design

This was a quantitative cross-sectional study consisting of retrospective and prospective components. The retrospective aspect included the evaluation of laboratory quality reports. The performance of pre-selected analytical quality indicators on the quality management system of a medical laboratory over a two- year period from January 2017 to January 2019 was evaluated using the quality reports. The prospective aspect consisted of a survey that aimed to determine the knowledge, attitudes, and practices of medical technologists regarding the current use of quality indicators, using a questionnaire.

3.3. Study setting

Ethical clearance was obtained from the Institutional Research and Ethics Committee (IREC) of Durban University of Technology with ethical clearance reference number 010/20 (Appendix A). Permission to conduct the study in the medical laboratory establishment was obtained from the Chief Executive Officer (Appendix B). The study was conducted in a private medical laboratory establishment based in Durban, KwaZulu-Natal, between January 2017 to January 2019. This establishment consists of three main laboratories and ten peripheral laboratories. All thirteen laboratories were included in the study. The main laboratories are responsible for additional routine work and tests that are not offered in a peripheral laboratory, while the peripheral laboratories are linked to hospitals that offer a stat/ emergency service to clinicians.

3.4. Sampling strategy

3.4.1 Retrospective data

All records on the analytical quality indicators were collected from the business unit's monthly quality reports for the period between January 2017 to January 2019. Laboratories are required to complete these reports monthly to determine whether the preselected quality indicator has been achieved in a particular year. This was extracted from the quality reports from the three main and ten peripheral laboratories, to determine whether one quality indicator is sufficient to maintain the quality system. In the current investigation, this information was expected to highlight whether there were any loopholes in choosing to monitor only a few quality indicators as opposed to all nine quality indicators. Any loopholes were to indicate whether the quality management system of the laboratory was negatively affected, and the integrity of laboratory results generated not compromised.

3.4.1.1 Inclusion criteria

All quality reports from the three main laboratories and the ten peripheral laboratories were included. There were a total of 156 quality reports that were evaluated for a two-year period (January 2017 to January 2019).

3.4.2 Prospective data

The survey that was to determine the level of knowledge, attitudes, and practices related to quality indicators was conducted among medical technologists with a minimum of three years' experience post qualification, working in the discipline of Clinical Pathology. The reason for including medical technologists in the investigation was that they are responsible for maintaining the quality of results generated in laboratories. Furthermore, those with three years or more work experience were expected to have more insight into the usefulness of the quality indicators. A total of

one hundred medical technologists are employed in the medical laboratory establishment, which is made up of three main laboratories and ten peripheral laboratories.

3.4.2.1 Sample size

To calculate the sample size, the formula used was based on a 95% confidence interval with a population size of 100 medical technologists, on the assumption of a 50% questionnaire response rate, with a 5% margin of error. From the three main and ten peripheral laboratories there were 100 medical technologists employment. The minimum sample size calculated, in consultation with a statistician was 80 medical technologists.

3.4.2.2 Inclusion criteria

Medical technologists with three or more years post qualification experience.
Those willing to participate and sign the informed consent form.

3.4.2.3 Exclusion criteria

Medical technologists that were qualified for less than three years.
Participants that participated in the pilot study were excluded from the main study.

3.5. Recruitment of study participants

A list of names of medical technologists that were qualified for three years or more was requested from a manager in each laboratory. Medical technologists were then approached by the researcher to invite them to participate in the study through email as well as giving them a letter of information which informed them about the study (Appendix C). The letter also informed them of their right to withdraw from the study if they so wish, without any prejudice.

All participants that were enrolled in the study had to have signed an informed consent form (Appendix D). On agreeing to participate, the participants were emailed the questionnaire (Appendix E). COVID-19 safety protocols were observed for those participants who chose to answer the questionnaire on computers in the laboratory during working hours. Social distancing and hand sanitization regulations were observed.

3.6 Pilot study

3.6.1 Selection of participants that participated in the pilot study

The pilot study was performed to assess the feasibility of the study as well as the efficiency of the data collection tool. The pilot study participants were made up of ten randomly selected medical technologists according to three years or more of experience after qualification. The questionnaire was piloted in a quality department in another province other than KwaZulu-Natal. The data from the pilot study was not used in the main study; however, the data was used to amend the questionnaire.

3.7. Data collection

3.7.1 Retrospective data

The business unit monthly reports were used to extract the pre-selected quality indicators to evaluate the performance to compliance of the predetermined targets set by the medical laboratory on an annual basis. Quality reports were reviewed over a two- year period on the analytical quality indicators, from January 2017 to January 2019.

3.7.2 Prospective data

For the survey, all respondents received the same questionnaire, which was administered electronically. The 80 medical technologists were placed in categories according to the number of years post qualification in three subgroups. The three subgroups were medical technologists qualified between three to five years, those qualified for between six to nine years and those qualified for ten years and more. An online survey was conducted to ascertain competence in quality, and this was extracted from the analytical aspect of the ISO 15189:2012 checklist for medical laboratories by the researcher. All 80 participants emailed back their responses to the questionnaire.

3.8. Validity and reliability

The researcher determined the validity of the questions in consultation with a statistician. A pilot study was conducted by experienced medical technologists to detect any shortcomings in the measuring instrument and to determine whether variables are measurable. The researcher adjusted the instrument for the reliability and validity of the results. Before the instrument tool was administered the research supervisors for constructive criticism and cohesiveness to ensure that the research questions were in line with the objectives of the study evaluated.

The two most important aspects of precision are reliability and validity. Reliability is computed by taking several measurements on the same subjects. A reliability coefficient of 0.60 or higher is considered “acceptable” for a newly developed construct. A Cronbach’s alpha score of 0.796 was obtained for all the items that constituted the questionnaire. The reliability score exceeded Cronbach's alpha value. This indicated a degree of acceptability consistent with the scoring for this section of the research.

3.9 Data analysis

The collected data was evaluated and analysed using descriptive and inferential statistical methods, in consultation with a statistician, using SPSS version 26.0. Descriptive statistical analysis for categorical data and continuous data were presented as frequencies, percentages, and range. The descriptive statistics were summarised in graphs and charts. Data reliability was determined using the Cronbach alpha test. Inferential techniques included the use of correlations and chi square test values, which were interpreted using the p-values.

The dependent t-test was the most appropriate statistical test for a comparison of the meanings. This tests any significant difference between two variables. Comparisons were done using Pearson's Chi square test, to determine the strength of the differences among the participant groups (Singh, 2015). Quality reports were reviewed over a two-year period on the analytical quality indicators from January 2017 to January 2019.

Data resulting from observations made on two different related categorical variables (bi-variate) were summarised using a table, known as a two- way frequency table or contingency table. The word contingency was used to determine whether there is an association between the variables. The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result was indicated with "$p < 0.05$".

3.10. Ethical considerations

Ethical approval was obtained from the Durban University of Technology Ethics Committee (IREC) and all the ethical principles were upheld throughout the entire research process, in line with the Durban University of Technology ethics ethos. Permission was obtained from the laboratory to conduct research (Appendix B). The laboratories and participants remained anonymous in this study as a measure of confidentiality. The use of numbers instead of using names of participants or

laboratories. No respondent was unjustly excluded based on race, age, sexual orientation, disability, religious beliefs, pregnancy, marital status and ethnic or social origin. Each medical technologist participating in the study was given a letter of information (Appendix C) which explained the purpose and implications of the research in a manner that was suitable to all participants. Upon accepting participation in the survey an informed consent form (Appendix D) was to be signed, to be enrolled into the study.

3.11. Conclusion

This chapter described the research procedure used in this study and provided information on how data was obtained and analysed. The next chapter presents the results and findings of the study.

CHAPTER FOUR

Presentation of results

4.1 Introduction

The previous chapter described the research methods used in this study. The current chapter presents the results obtained from the monthly business unit reports over a two-year period, from January 2017 to January 2019 and the questionnaire responses obtained from 80 participants. The data collected from the responses were analysed using SPSS version 26.0. The results present descriptive statistics in the form of graphs and figures for the quantitative data that were collected. Inferential techniques include the use of correlations and Chi square test values, which were interpreted using p-values.

The purpose of the study was to evaluate the performance of preselected analytical quality indicators on the quality management system of a medical laboratory establishment. This was to determine whether choosing to monitor only a few quality indicators as opposed to all nine analytical quality indicators among the main and the peripheral laboratories would be sufficient to maintain the quality management system. Furthermore, the study aimed to determine the levels of knowledge, attitudes, and practices of medical technologists within the medical laboratory establishment regarding the current use of quality indicators, to maintain the quality management system. The structure of this chapter has been divided into three areas, namely presenting the characteristics of the study participants, their evaluation of the quality indicators from the survey and lastly, reporting on the outcome of the evaluation of the quality monthly business reports.

4.2 Research Objectives

1. To evaluate the performance of the pre-selected quality indicators from the quality reports in respect to compliance of the ISO: 15189:2012 requirements as identified by the medical laboratory establishment on an annual basis.

2. To compare the performance of one identified analytical quality indicator among the main and the peripheral laboratories that form part of the medical laboratory establishment.

3.To determine the levels of knowledge, attitudes, and practises of medical technologists regarding the current use of quality indicators.

4.3 Summary statistics of the study participants

The demographic data of the participants that was collected using the questionnaire included age, gender, and racial distribution, as well as the years post qualification and experience of the medical technologists.

4.3.1 The age distribution of the study participants

The analysis of the demographic data revealed that the majority of the medical technologists 26.3% (n=21) were amongst the age group of 26 to 31 years old (Figure 4.1). Furthermore, those that were in the age group older than 45 years of age were noted to be 23.8% (n=19). Notably, only 5% (n=4) of the medical technologists were in the young adult age group, between 20 to 25 years of age.

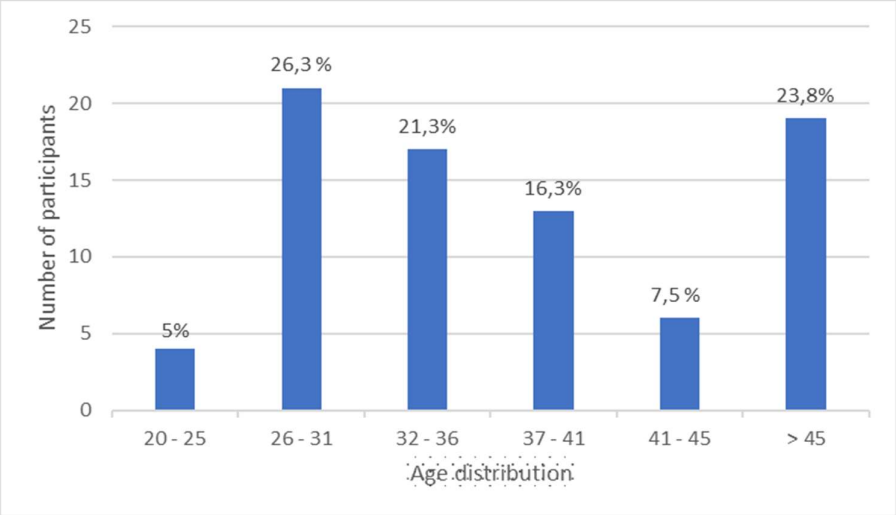

Figure 4.2 Age distribution of the participants

4.3.2 Gender distribution of the study participants

The analysed data depicted a gender composition amongst the participants, with females predominant in the medical laboratory establishment. The gender composition of the 80 participants that were investigated for the current study consisted of 70% (n=56) being females and males 30% (n=24) (Figure 4.2).

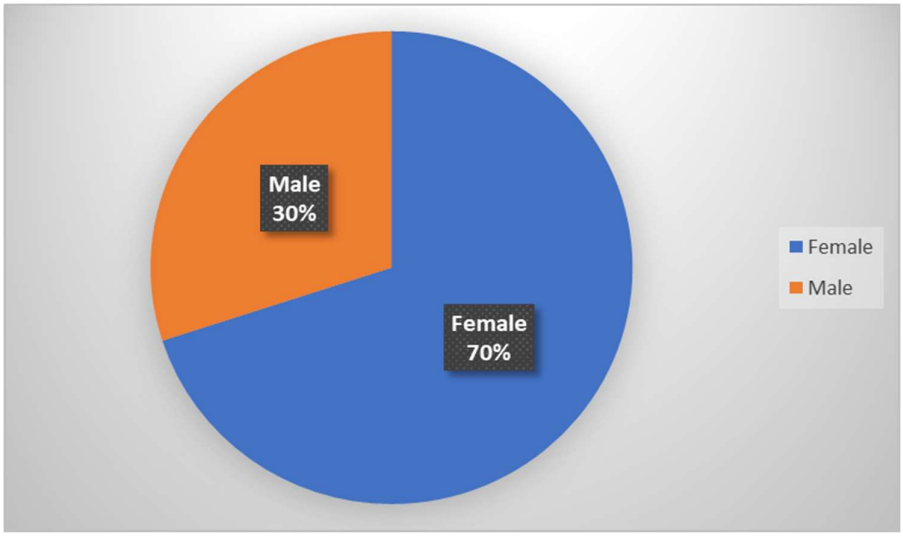

Figure 4.3 Gender distribution of participants.

4.3.3 The racial distribution of the study participants

The analysis of the race distribution of participants indicated that more than 50% of the medical technologists were Indian, being 66.3% (n=53). Whites constituted 16.3% (n=13), and Africans 15% (n=12), and Coloureds made up 1.3% (n=1) of the rest of the study population. Those who did not specify their race in the questionnaire, who were classified as other, were 1.3% (n=1) (Figure 4.3).

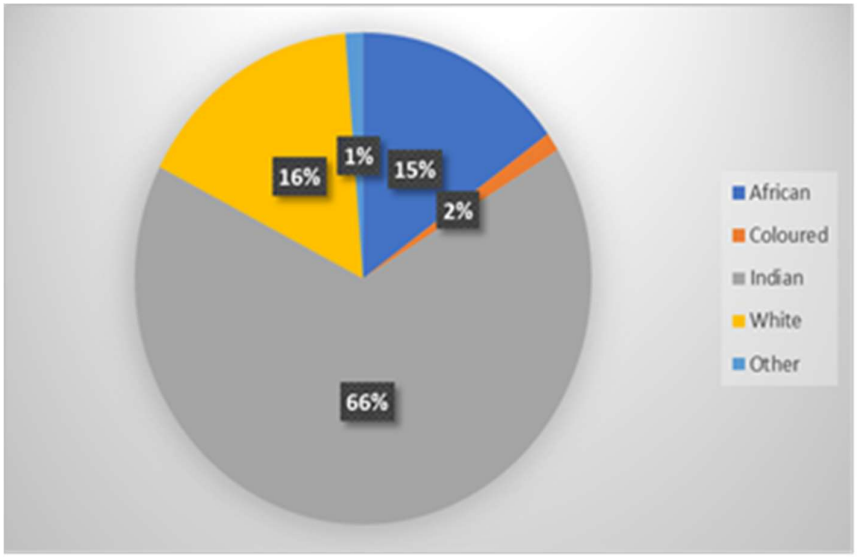

Figure 4.4 Race distribution of the study participants

4.3.4 The years of experience of the study participants

The results revealed that more than half of the participant population had working experience of greater than nine years post -qualification with 53.8% (n=43) observed. Those who had experience of between six and nine years were 36.3% (n=43) whereas 10% (n=8) had experience between three to five years (Figure 4.4).

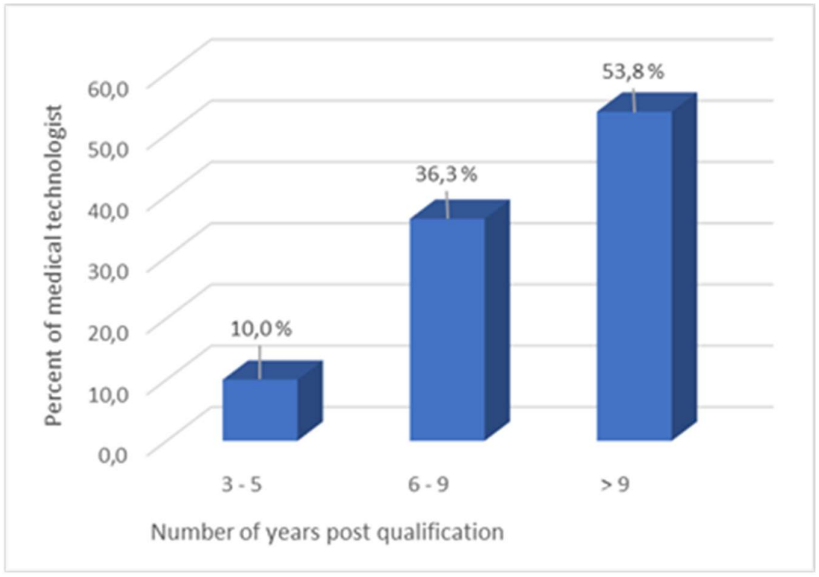

Figure 4.5 Experience of study participants in years post-qualification as Medical Technologists

4.4 The levels of knowledge, attitudes, and practises of the medical technologists regarding the current use of quality indicators

To address the objective that aimed to determine the levels of knowledge, attitudes and practices of medical technologists on the current use of the quality indicators, a questionnaire was administered to the participants. The expectation was that the participants' responses would highlight areas that should be recommended for inclusion in a set of guidelines, if it were to be developed, that would assist medical technologists in maintaining the quality management system. The questionnaire was tested for reliability and validity and Cronbach's alpha score of 0.796 was noted for all the items that constituted the questionnaire. A reliability coefficient of 0.60 or higher is considered acceptable for a newly developed construct and the reliability score for the questionnaire exceeded Cronbach's alpha value.

The questions in the questionnaire related to the knowledge, attitudes, and practices of medical technologists regarding the current use of quality indicators and were derived from the examination aspect of the ISO 15189:2012 guideline for medical laboratories. They were grouped into the following themes, namely: 1) validations and verifications of examination procedures; 2) measurement of uncertainty; 3) documentation of examination processes; 4) ensuring quality of examination results; 5) inter-laboratory and external quality control; 6) continual improvement; 7) evaluation of laboratory performance such as instrument maintenance; 8) evaluation of laboratory performance such as reagent, patient identification and 9) laboratory performance on quality results and improvement in the organisation (Table 4.1). Moreover, Table 4.1 illustrates the clustering of the questions into themes, indicating whether they were aimed to determine the levels of either knowledge, or attitudes or practices among the participants. This will be further presented in the section, which will indicate the correlations.

Table 4.1 The questions categorised into themes with an indication of whether they assessed levels of knowledge, attitudes or practises among the medical technologists

Themes that were derived from the ISO 15189 guideline	Levels Assessed
Validation and verifications of examination procedures (Questions 1 -5)	Knowledge
Measurement of uncertainty (Questions 6-9)	Knowledge
Documentation of examination procedures (Questions 10-13)	Practises
Ensuring quality of examination results (Questions 14-18)	Knowledge
Interlaboratory and external quality control (Questions 19-24)	Knowledge
Continual improvement (Questions 25-33)	Attitude
Evaluation of laboratory performance such as instrument maintenance (Questions 34 -37)	Practises
Evaluation of laboratory performance such as reagents (Questions 38-41)	Practises
Patient identification (Questions 42-43)	Practises
Laboratory performance on quality results (Questions 44 - 49)	Practises
Improvement in the establishment, peripheral laboratory and main laboratory (Questions 50 -52)	Attitude

In each section of the questionnaire (Sections B1 – B52), there were questions that required responses in Likert scale scoring, as well as others that required “yes” or “no” answers. The analysis of these responses revealed patterns of scoring, shown in Table 4.2. Additionally, there were open ended questions, which were analysed and are presented under each theme in section 4.4.1.

Table 4.2 Scoring patterns for Likert scale questions among participants, shown in percentage

Question	rongly Agree %	Agree %	e or disagree %	ly Disagree %	Disagree %	Yes %	No %	p-value
B1. Are instrument validations and verifications important in assisting in patient care	95	5	0	0	0			<0.001
B2. Data must be analysed using valid methods	97.5	2.5	0	0	0			<0.001
B3. Is it necessary to use medical decision levels for patients during the validation procedure						97.5	2.5	<0.001
B6. There should be factors in place that affect the measurement of uncertainty.						98	1.3	<0.001
B8. Measurement of uncertainty does not need to be calculated for manual assays.	3.3	11.3	0	41.3	31.3			<0.001
B10.I perform procedures in conjunction with standard operating procedures and working instructions	95	2.5	1.3	1.3	0			<0.001
B11. I will be able to perform my job if the laboratory procedures are not clearly documented	7.5	5	7.5	35	43.8			<0.001
B12 Standard operating procedures and working instructions must be written up and there is no need to review as procedures remain the same once its implemented						3.8	96.3	<0.001
B14. Internal quality control does not need to be run in order to validate a patient result.	1.3	98.8	0	0	0			<0.001
B16. If internal quality control is out of range, patient results can be generated	1.3	98.8	0	0	0			<0.001
B17. Is it important to pull Levy Jennings charts in the laboratory?						100	0	<0.001
B19. Inter laboratory comparison and external quality control does not need to be performed in the laboratory where I am employed as it is expensive.	87.5	0	0	0	12.5			<0.001
B21. Inter-laboratory comparison and external quality programmes chosen do not need to mimic patient samples	65	2.5	1.3	0	31.3			<0.001
B22 Inter-laboratory comparison and external quality programmes chosen must not mimic patient samples.	1.3	0	2.5	68.8	26.3			<0.001
B23. All staff involved in processing patient samples must also process interlaboratory and external quality control	87.5	10	0	0	2.5			<0.001
B24. Inter-laboratory programmes or external quality assurance is a clear indication of how patient results perform	55	36.3	2.5	0	25			<0.001
B25. There is no need to improve my current system as I am comfortable with the way the laboratory is organized.	32.5	67.5	0	0	0			<0.001
B27. Internal audits do not need to be performed as they are costly and time consuming	1.3	0	0	75	23.8			<0.001
B28. It is important for laboratories to have action plans for improvements						100	0	<0.001
B30. According to ISO 15189:2012, does the laboratory need to monitor quality indicators	0	12.5	0	87.5	0			<0.001
B32. Quality indicators are a continuous management-monitoring tool.	0	21.3	0	78.8	0			<0.001
B33.Quality indicators do not need to be reviewed periodically	51.3	3.8	0	1.3	43.8			<0.001
B34. Laboratory equipment does not need to be regularly maintained.	1.3	1.3	0	88.8	8.8			<0.001
B35. Quality control can be run if maintenance is not performed on laboratory equipment	7.5	16.3	0	52.5	17.5			<0.001
B36. Samples can be processed on laboratory equipment if maintenance errors are received	0	5	5	71.3	17.5			<0.001
B37. Instruments must be serviced periodically	82.5	11.3	2.5	3.8	0			<0.001
B38. Expired reagents and controls can be used in the laboratory for routine use	2.5	0	10	36.3	20			<0.001
B39. When reagents, controls and calibrator are opened for use, it is important to document on a reagent log	0	0	0	100	0			<0.001

B41 Reagents, controls and calibrators can be left at room temperature until loaded on to the analyser	30	16.3	33.8	15	5			<0.001
B42. Patient samples that are unsuitable for analysis can be analysed as it is unprofessional to contact the clinician for a re-bleed in order to process the test	5	0	2.5	73.8	18.8			<0.001
B43 Correct identification of patient samples is of vital importance in the laboratory	93.8	3.8	0	2.5	0			<0.001
B44. Tests that are not requested by the clinician can be processed and resolved.	0	5	5	63.8	26.3			<0.001
B45. Patients need to give consent to the laboratory in order to perform the relevant tests	62.5	23.8	0	3.8	7.5			<0.001
B46. The clinician does not need to be informed of an amended patient result.	91.3	0	0	0	8.8			<0.001
B47. Quality patient results are not important as long as a result is generated.	91.3	1.3	0	0	8.8			<0.001
B48. If patient results are life threatening, the clinician must be informed.	100	0	0	0	0			<0.001
B50. Would you as a patient expect the same quality result if the test was processed in the main laboratory versus the peripheral laboratory?	88.8	10	0	1.3	0			<0.001
B52. When answering the questionnaire did you find the need to refer to any documents.						48.8	51.3	<0.001

Shaded areas are not applicable

4.4.1. Assessing the levels of knowledge of medical technologists on the current use of quality indicators

Each theme that addressed the levels of knowledge of medical technologists will be presented in this section, which includes the levels of knowledge regarding (i) validations and verifications of examination procedures, (ii) measurement of uncertainty, (iii) inter-laboratory and external quality control. The Likert scale scores will be presented first, and thereafter the responses to the open-ended questions.

4.4.1.1 The responses of the questions that determined the levels of knowledge of the medical technologists in relation to validations and verifications of examination procedures

The statements in response to questions which determined the level of knowledge on the validations and verifications of examination procedures showed significantly higher levels of agreement ($p<0.001$). It was noted that 95.0% (n=76) of the medical technologists agreed that validations and verifications are important in assisting in patient care. In addition, 97.5% (n=78) of the participants agreed that data must be analysed using valid methods. Furthermore, 97.5% (n=78) of them agreed with the statement “It is necessary to use medical decision levels for patients during the validation procedure” and they were required to provide reasons for their answer. It was noted that 34.6% (n=27) gave the reason as clinical significance and 26.9% (n=21) indicated critical ranges covered as their answer. The remainder of the reasons are presented in Table 4.3.

Table 4.3 Reasons given by participants for the use of medical decision levels

Reason	n (%)
Clinical significance	27 (33.8)
Critical ranges covered	21 (26.3)
Laboratory performance	6 (7.5)
Clinical ranges	5 (6.3)
Patient ranges covered	3 (3.8)
Quality control treated as a patient	2 (2.5)
Reference range	2 (2.5)
Diagnostic decision making	2 (2.5)
Diagnostic therapeutic ranges	2 (2.5)
Clinical diagnosis	2 (2.5)
Interpreting results	2 (2.5)
Method valid	2 (2.5)
Sample treated as a patient	1 (1.3)
Precision check	1 (1.3)
Guideline	1 (1.3)
Bench mark	1 (1.3)

To further determine the levels of knowledge the only statement with a high level of disagreement was the “measurement of uncertainty does not need to be calculated for manual assays”, where 41.3% (n=33) of the participants strongly disagreed, and 31.3% (n=25) of them disagreed ($p<0.001$). Disagreement in this statement is directly related to the level of knowledge of the medical technologists.

The participants had to identify which procedures are used to check manufacturer’s instructions. The procedures identified by most of the participants (31.3%; n=25) were valid, whereas verification was identified by 23.8% (n=19). Lists of procedures identified by the participants that are used to check manufacturer’s instruction are listed in Table 4.4.

Table 4.4 Procedures indicated by participants to be used to check manufacturer's instructions

Procedure	n (%)
Validation	25 (31.3)
Verification	19 (23.8)
Calibration	3 (3.8)
External quality assurance	5 (6.3)
Internal quality assurance	12 (15)
Accuracy	6 (7.5)
Precision	2 (2.5)
Levy Jennings graphs	8 (10)
Quality control	16 (20)
Quality management system	3 (3.8)
Standard deviation	2 (2.5)
Standard operating procedure	1(1.3)
Work instruction	1(1.3)

4.4.1.2 The responses of the questions that determined the levels of knowledge of medical technologists in relation to measurement of uncertainty

The statements in response to the requirement for the participants to name three factors that they knew to affect measurement of uncertainty noted that 40% (n=32) of the participants listed the environment, with 36.3% (n=29) of them listing analytic. It is further noted that 27.5% (n=22) participants listed temperature ($p<0.001$). The rest of the named factors are shown in Table 4.5.

Table 4.5 Factors that were named by participants to affect measurement of uncertainty

Factors	n (%)
Environment	32 (40)
Analytic	29 (36.3)
Temperature	22 (27.5)
Pre-analytical	21(26.3)
Equipment	13 (16.3)
Calibration	12 (15)
Operator	9 (11.3)
Sample Integrity	8 (10)
Training	6 (7.5)
Systemic errors	4 (5)
Reagent stability	4 (5)
External quality assurance	4 (5)
Measurement	3 (3.8)
Stability	3 (3.8)
Quality	2 (2.5)
Error	2 (2.5)
Random error	2 (2.5)
Imprecision	2 (2.5)
Contamination	2 (2.5)
Coefficient of variation	1 (1.3)
Verification	1 (1.3)
Medical decision	1 (1.3)
Bias	1 (1.3)
Precision	1 (1.3)
Total allowable error	1 (1.3)
Variation	1 (1.3)
International standard	1 (1.3)

To further determine the levels of knowledge, the participants had to list tools that should be used to measure uncertainty of measurement. Most of the participants (31.3%; n=25) listed quality control and 27.5 (n=22) listed coefficient of variation. Other tools that the participants indicated are listed in Figure 4.5.

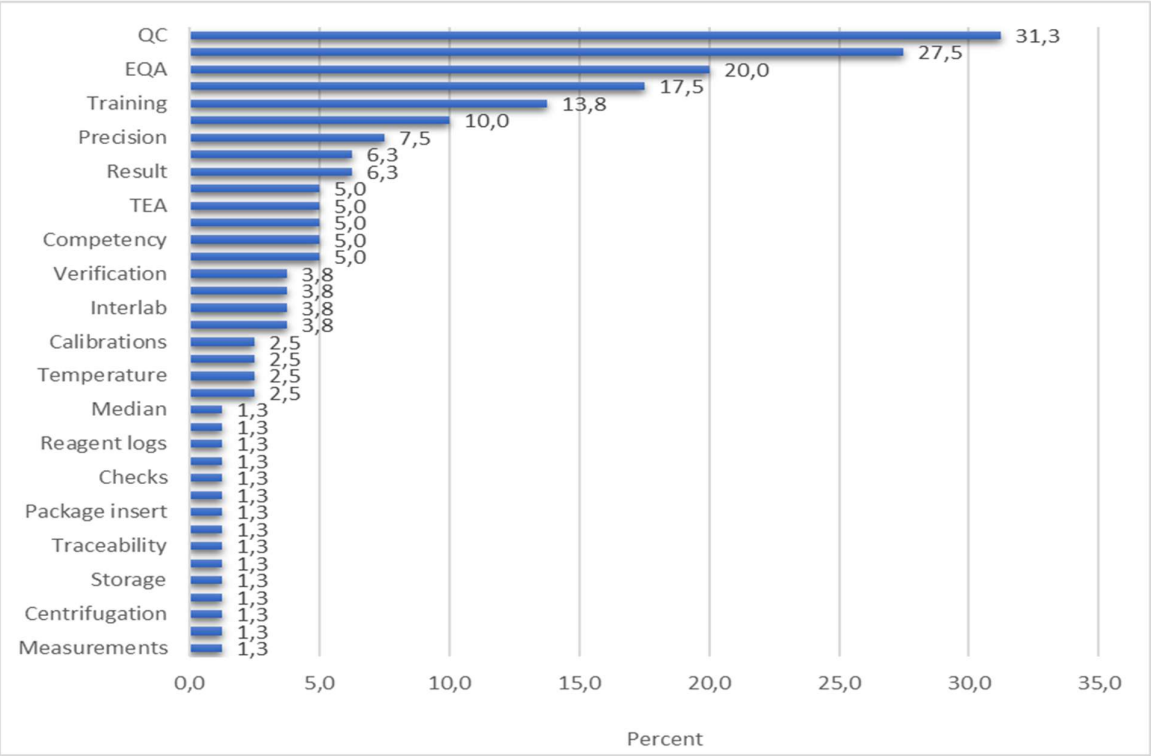

Figure 4.6 Tools listed by participants to be used to measure uncertainty of measurement

From the findings of the questionnaire, 98.8% of the respondents believed that quality control does not need to be run in order to validate patient results. The reasons given by 47.5% (n=38) of the participants was “instrument performance”, with 16% (n=20) of them indicating that it is “accurate results” and 12.5% (n=10) of them citing “validate results” as rather what needs to be considered when validating patient results. Further reasons noted from 7.5% (n=6) of the participants’ responses were “accuracy”, where 7.5% (n=6) indicated precision, and confidence in results noted from 2.5% (n=2) of them, and errors from 2.5% (n=2) participants. Notably, 1.3% (n=1) of the medical technologists further indicated each of the following reasons: assay performance, method performance, systematic errors, procedure correct and clinical range, in order to validate patient results.

Majority of the medical technologists (98.8%; n=79) that were investigated for the current study, answered yes to the following statement referring to the measurement of uncertainty “There should be factors in place that affect the measurement of uncertainty”.

All the medical technologists agreed that it was important to view Levy Jennings charts in the laboratory and had to provide an explanation for their answer. Only 18.8% (n=15) of the respondents believed that using Levy Jennings charts in the laboratory is used to monitor performance. Majority of the technologists (63.8%; n=51) answered “trends” and 56.3% (n=45) of them gave “shifts” as the reason. The rest of the responses are presented in Figure 4.6.

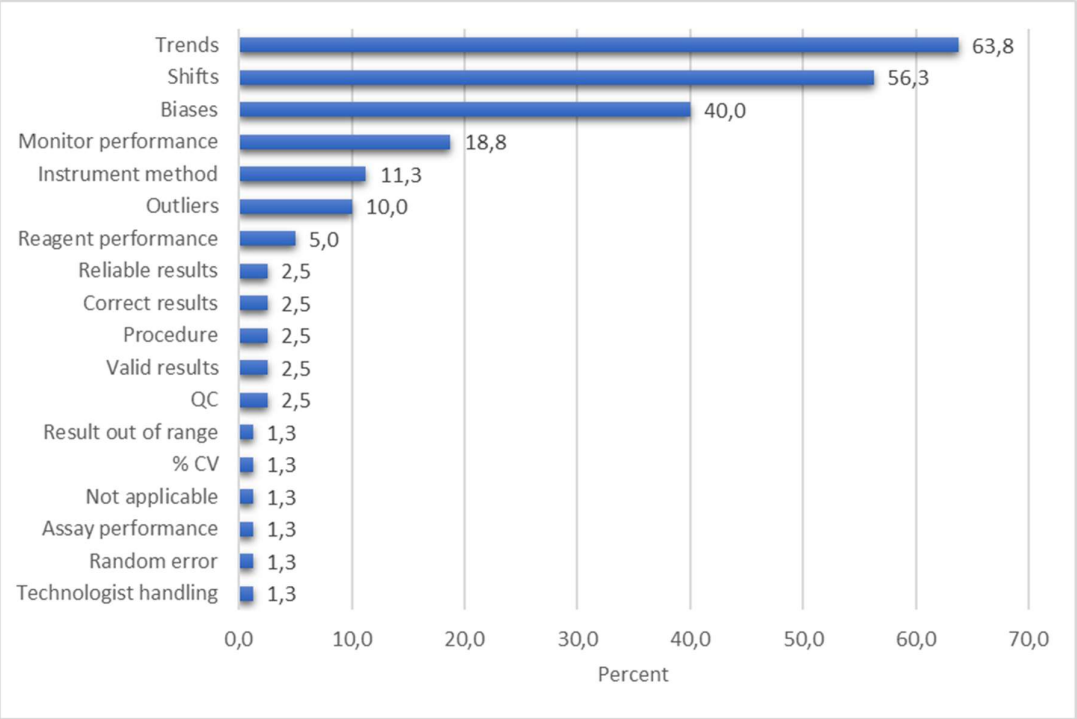

Figure 4.7 Importance of viewing Levy Jennings charts in the laboratory

All respondents agreed that it is important to compile Levy Jennings charts for the following reasons they stated, which included trends, shifts, biases, monitor performance, instrument method, outliers, reagent performance, quality control,

technologist handling, random error, assay performance, not applicable, percentage coefficient of variation and result out of range. All respondents 100% (n=80) answered

yes to the statement “Is it important to pull Levy Jennings charts in the laboratory?” From all the participants, 97.5% (n=78) answered yes to data analysis using valid methods. This further determined the participants’ level of knowledge.

4.4.1.3 The responses that assessed the levels of knowledge of medical technologists in relation to inter-laboratory and external quality control among the participants

Although participants had demonstrated high levels of knowledge in the other questions they had responded to, the majority of them (98.8%; n=79) indicated that quality control does not need to be run in order to validate patient results ($p<0.001$). It was further noted that 98.8% (n=79) participants believed that if the quality control is out of range patient results can be generated. Furthermore, 87.5% (n=70) of them responded that inter-laboratory comparison and external quality control does not need to be performed. It was further noted that 65% (n=52) of the participants agreed with the statement “that inter-laboratory and external quality programmes do not need to mimic patient samples” while 31.3% (n=25) of the participants disagreed with the statement. This suggested that they lacked knowledge in the aspects of inter-laboratory and external quality control.

It was further noted that a total of 68.8% (n=55) of them strongly disagreed with the statement “inter-laboratory comparison and external quality control programmes chosen must not mimic patient samples” (question 22). Responses that disagreed with this statement suggested lack of knowledge in this aspect of quality control Interestingly, this statement was similar to the one that had asked whether “inter-laboratory and external quality control should mimic patient samples” (question 21), where 65% (n=52) strongly agreed and 2.5% (n=2) agreed to the statement. It was noted that the participants’ responses to question 22 indicated knowledge compared to their responses in the same aspect in question 21 where they showed lack of knowledge.

87.5% (n=70) of the respondents that agreed that inter-laboratory comparison and external quality control does not need to be performed as it is expensive had to provide a reason for their answer ($p<0.001$). The reasons provided by 23.8% (n=19) of the

participants were “instrument performance”, with 22.5% (n=18) of them indicating “performance with other laboratories” and “accurate results” given by 15% (n=12). Some participants (8.8%; n=7) mentioned, “meet standard”, and (7.5%; n=6) mentioned “assay performance”, with “quality result” indicated by 7.5% (n=6) of them, with 5% (n=4) citing “external quality assurance”, and inter-laboratory indicated by 3.8% (n=3) of those. It was further noted that the following reasons were provided by one medical technologist each (1.3%): detect errors, acceptable performance, method and analytical testing. Although the response to the statement “inter-laboratory comparison and external quality control does not need to be performed as it is expensive” suggested lack of knowledge of some sort, these answers demonstrated that these participants had some understanding of inter-laboratory comparison and external quality control.

4.4.2 Assessing the practises of medical technologists on their current use of quality indicators

Each theme that addressed the practises of medical technologists will be discussed, which were in relation to (i) documentation of examination procedures, (ii) evaluation of laboratory performance such as reagents, patient identification, (iii) relation laboratory performance on quality results.

4.4.2.1 The responses that assessed the practises of medical technologists in relation to documentation of examination procedures among the participants

The responses to the “perform procedures in conjunction with standard operating procedures and working instructions” statement revealed that most of the participants performed good practice, since 95% (n=76) of them strongly agreed with the statement ($p<0.001$). It was further noted that the majority of the respondents (43.8%; n=35) disagreed and 35% (n=28) of them strongly disagreed with the statement that they would perform procedures despite them not being clearly documented.

For the statement “Standard operating procedures and working instructions must be written up and there is no need to review as procedures remain the same once implemented”, 96.3% (n=77) of the participants answered no to the statement. This revealed good practice by the participants. Of the 96.3% medical technologists that

disagreed, they had to provide a reason if they felt that it was not necessary to review standard operating procedures ($p<0.001$). It was noted that 70% (n=56) of them listed continuous improvement and 6.3% (n=5) listed guidance. It was further noted that 5% (n=4) of the participants provided “review procedures" and “reliable results" as reasons. The participants 2.5% (n=2) further provided the reasons as “accuracy” as well as “not applicable”. It was further noted that 1.3% (n=1) of the medical technologists provided the following reasons: changes, reference, experience, clear instructions, precision, standardisation and truth.

4.4.2.2 The responses that assessed the practises of medical technologists in relation to laboratory performance of instrument maintenance among participants

It was revealed that 88.8% (n=71) of the medical technologists strongly disagreed with the statement “laboratory equipment does not need to be maintained’ ($p<0.001$). This indicated good practice by the medical technologists. Further to this, 52.5% (n=42) disagreed with the statement that indicated that ‘quality can be run if maintenance is not performed on laboratory equipment’.

Only 1.3% (n=1) of the respondents strongly disagreed with the following statement: “Samples can be processed on laboratory equipment if maintenance errors are received” whereas 82.5% (n=66) of the respondents strongly agreed with the following statement “Instruments must be serviced periodically” ($p<0.001$). This indicated good practice.

4.4.2.3 The responses that assessed the practises of medical technologists in relation to laboratory performance of reagents among the participants

All respondents (n=80) agreed with the statement “When reagents, controls and calibrators are opened for use, it is important to document on a reagent log” ($p<0.001$). This was indicative of good practice. For the statement “Reagents, controls and calibrators can be left at room temperature until loaded on the analyser '', 33.8% (n=26) of the respondents neither agree nor disagree and 30% (n=24) strongly agree with the statement. This was indicative of poor practice. The results further revealed that 36.3%

(n=29) of the respondents strongly disagreed, 20% (n=16) disagreed, 10% (n=8) neither agree nor disagree with the statement the following statement 'Expired reagents and controls can be used in the laboratory for routine use'. This depicted bad practice. Medical technologists had to provide an explanation if they felt that it was important to document reagents on a reagent log. The explanations provided were traceability, troubleshooting, stability, stock control, stability, performance and standard operating procedure.

4.4.2.4 The responses that assessed the practises of medical technologists in relation to laboratory performance of patient identification among the participants

It was observed that 73.8% (n=59) of the respondents strongly disagreed with the statement "Patient samples that are unsuitable for analysis can be analysed as it is unprofessional to contact the clinician for a re-bleed in order to process the test" ($p<0.001$). This was indicative of a bad practice on the patient identification aspect. A total of 98.3% (n=75) of the respondents strongly agreed with the statement "Correct identification of patient samples is of vital importance in the laboratory". This showed that the majority of the participants had good practice.

4.4.2.5 The responses that assessed the practises of medical technologists in relation to laboratory performance of quality of results among the participants

All respondents (n=80) agreed with the statement "If patient results are life threatening, the clinician must be informed." ($p <0.001$). This was indicative of good practice by the participants. Furthermore, 62.5% (n=50) strongly agreed and 23.8% (n=19) agreed with the statement 'Patients need to give consent to the laboratory in order to perform the relevant tests', which demonstrated good practice

It was observed that 63.8% (n=51) of the respondents strongly disagreed and 26.3% (n=21) disagreed with the statement "Tests that are not requested by the clinician can be processed and resulted" ($p<0.001$). This indicated bad practice.

Only 91.3% (n=73) of the respondents strongly agreed that the clinician does not need to be informed of an amended patient result. This indicated a bad practice. It was further noted that 91.3% (n=73) of the respondents agreed with the statement “Quality patient results are not important as long as a result is generated ($p<0.001$). This indicated bad practice

4.4.3 Assessing the levels of attitudes of medical technologists on their current use of quality indicators

Each theme that addresses the attitudes of medical technologists will be discussed, from this it will determine what the levels of attitudes regarding (i) continual improvement, (ii) improvements in the establishment were. The Likert scale and open-ended questions will be discussed.

4.4.3.1 The responses that assessed the attitudes of medical technologists in relation to continual improvement among the participants

From the results, it indicated that 87.5% (n=70) of the participants strongly agreed and 12.5% (n=10) agreed that the laboratory needs to monitor quality indicators ($p<0.001$). This was indicative of a good attitude. The majority of the participants 75% (n=66) believed that audits must be performed even though they are costly and time consuming and only 23.8% (n=19) disagreed. This finding suggested that the majority of the participants showed a good attitude. It was further observed that 51.3% (n=41) of them believed that quality indicators need to be reviewed periodically, with few that agreed (3.8%; n=3) and only one that strongly agreed (1.3%). Although some of them disagreed (43.8%; n=35), however, majority of the participants had a good attitude towards quality indicators. Interestingly, 67.5% (n=54) of the participants agreed and 32.5% (n=26) strongly agreed that there was no need to improve their current quality management system as they were comfortable with the way the laboratory was organised. The medical technologists (n=80) as required to suggest improvements in the current system, provided suggestions, as listed in Table 4.6.

Table 4.6 Participants' suggestions for areas that need improvement in the current quality management system

Suggestions	n (%)
Continuous improvement	61 (76.3)
Internal quality assurance	4 (5)
External quality assurance	6 (7.5)
Inter-laboratory	7 (8.8)
ISO Standard	1 (1.3)
Improve system	4 (5.0)
Verification	1 (1.3)
Validation	1 (1.3)
Accreditation Status	2 (2.5)
SANAS audits	2 (2.5)
Internal audits	1 (1.3)
Laboratory needs	2 (2.5)
Procedures in place	1 (1.3)

The levels of attitude noted were generally good among the medical technologists, especially regarding continual improvement of the quality management system in the medical establishment.

Medical technologists listed the following continual improvement tools, in answering the question that required them to indicate what they understood as continual improvement tools. Majority of participants (33.8%; n=27) indicated "training", with some (21.3%; n=17) who indicated "audits", and 16.3% (n=13) who indicated "turnaround time". It was further noted that 12.5% (n=10) of them mentioned "monitoring", with 12.5% (n=10) who mentioned "quality control" and "communication" was stated by 8.8% (n=7) of them. "Improvement" was further indicated by 7.5% (n=6) of them, with 7.5% (n=6) who indicated "staff suggestion" and some noted "root cause analysis" (6.3%; n=5) as well as "external quality assurance" (5%; n=4) and complaints were mentioned by 5% (n=4) of the participants.

The following tools were mentioned by two medical technologist (2.5%) each: reliable results, preventative action, six sigma, re-assessment, trend analysis, error monitoring, risk assessment. Furthermore, each of the following tools were mentioned by one medical technologist (1.3%) each: laboratory safety, corrective action, contingency plans, methodology, quality assurance, management review, spot checks and transcription checks, amendments, pre-analytical and scope of tests and evaluation as

continuous improvement tools. The statement in response to the most common improvement tools identified from the respondents were training, audits, turnaround time, monitoring, quality control, communication, improvement, staff suggestion, root cause analysis, external quality assurance complaints.

The respondents further listed reliable results, preventative action, six sigma, re-assessment, trend analysis, error monitoring, laboratory safety, corrective action, contingency plans, methodology, quality assurance, management review, spot checks, transcription checks, amendments, pre-analytical and scope of tests as the most common improvement tools. This indicated a good attitude by the medical technologists as they indicated that they wanted to see improvement in the quality management system in their laboratory. Despite this, 78.8% (n=63) of them strongly disagreed with the statement “quality indicators are continuous monitoring tools” and only 21.3% (n=17) agreed.

Moreover, 88% (n=70) of the respondents strongly disagreed with the statement: “According to ISO 15189:2012, does the laboratory need to monitor quality indicators” ($p<0.001$). This was indicative of a poor attitude towards the current quality indicators.

4.4.3.2 The responses that assessed the attitudes of medical technologists in relation to improvement in the organisation among the participants

The results of the survey revealed that 88% (n=71) of the respondents would expect the same quality result if the test was processed in the main laboratory versus the peripheral laboratory. Notably, 51.3% (n=41) of them did not have to refer to any supplementary documents when answering the questionnaire however, 48.8 % (n=39) of them required to refer to the establishment’s quality documents when answering the questionnaire($p<0.001$). All the medical technologists (n=80) answered yes to the statement “It is important for laboratories to have action plans for improvements”. It is noted that 33.8% (n=27) of them suggested that there should be no improvements. The other responses from 16.3% (n=13) were quality training, with quality management systems constantly updated from 16.3% (n=13) of them and paperless systems from 15% (n=12) of them. The remainder of the responses are described in Figure 4.7.

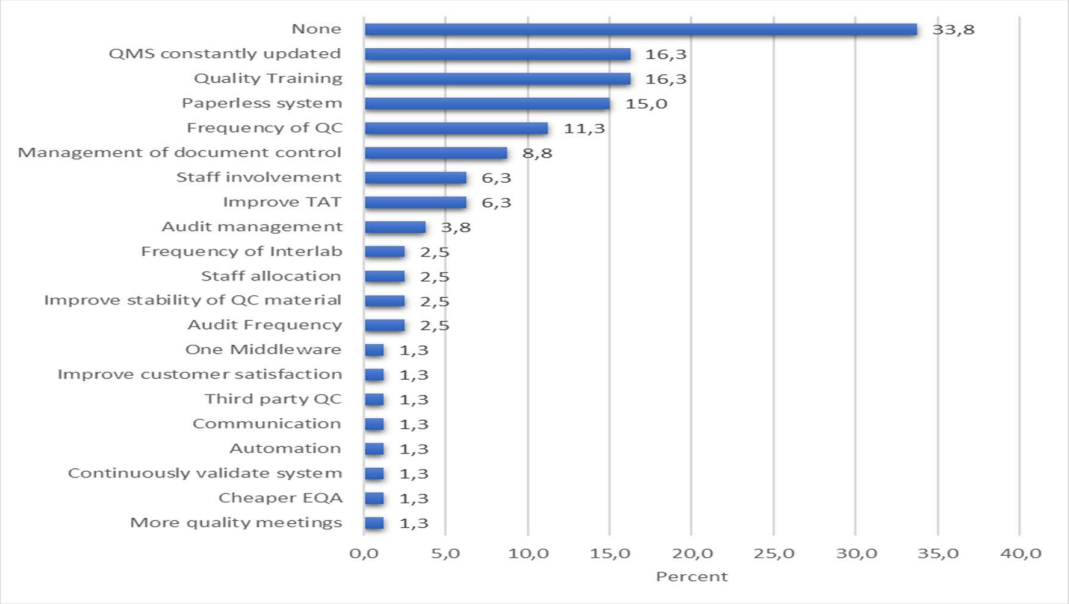

Figure 4.8 Improvements suggested in the current system

4.5 Participants recommendations towards a list of quality indicators to be monitored each year

The participants were required to recommend areas in quality indicators that should be included in a set of guidelines to be monitored each year, if it were to be developed, that would assist medical technologists in maintaining the quality management system. The participants were required to indicate what they consider as the most important quality indicator that needs to be monitored in a quality management system. The results revealed that the medical technologists (48.8%; n=39) indicated internal quality control and (43.8%; n=35) of them indicated external quality control as the most important quality indicator. Some of the other responses were as follows: “turnaround time” suggested by 25% (n=20) of them, and “analytical” by 21.3% (n=17) of them. Those that proposed “inter-laboratory” were 16.3% (n=13), and “post analytical” were 12.5% (n=10), with “amended reports” being 11.3 % (n=19). The remainder of the examples of quality indicators are described in (Table 4.7).

Table 4.7 A list of generic set of quality indicators suggested by participants

Quality Indicator	n (%)
Internal quality control	39 (48.8)
External quality assurance	35 (43.8)
Turnaround time	20 (25)
Analytical	17 (21.3)
Interlaboratory	13 (16.3)
Post analytical	10 (12.5)
Amended reports	19 (11.3)
Errors	8 (10)
Life threatening results	7 (8.8)
Submission of external quality assurance	5 (6.3)
Complaints	5 (6.3)
Safety	4 (5)
Competency test	2 (2.5)
Transcription check	2 (2.5)
Audits	2 (2.5)
Patient surveys	2 (2.5)
Shifts	2 (2.5)
Biases	2 (2.5)
Effectiveness	2 (2.5)
Verification	1 (1.3)
Uncertainty of measurement	1 (1.3)
Total allowable error	1 (1.3)
Validation	1 (1.3)
Cost	1 (1.3)
Training	1 (1.3)
Stability	1 (1.3)
Quality indicators	1 (1.3)
Inaccuracy	1 (1.3)

4.6 The evaluation of the pre-selected quality indicators from the business unit monthly reports

To address the objective to compare the performance of one identified analytical quality indicator among the main and the peripheral laboratories that form part of the medical laboratory establishment, the pre-selected quality indicators were evaluated over a two-year period. From the 156 business unit monthly reports evaluated on the performance of the pre-selected quality indicators, which were obtained from the three main and ten peripheral laboratories for the years 2017 and 2018, it was noted that all thirteen laboratories achieved 100% compliance on the pre-selected quality indicator that was identified by the medical establishment for the year 2017. The pre-selected quality indicator for 2017 was “turnaround time to be achieved at less than 5%”. All laboratories

ensured that the pre-selected quality indicator was monitored, evaluated and compliance achieved (Table 4.8). In addition, all thirteen laboratories achieved 100% compliance on the pre-selected quality indicator that was identified by the medical establishment for the year 2018. The pre-selected quality indicator for 2018 was that “85% of external quality assurance samples submitted to the external company for evaluation was acceptable”. All laboratories ensured that the pre-selected quality indicator was monitored, evaluated and compliance achieved (Table 4.8).

Table 4.8 pre-selected quality indicators for 2017 and 2018

Laboratory	Quality indicator 2017: (Turnaround time to be achieved <5%)	Pre-selected quality indicator 2018: (85% of external quality assurance samples submitted to the external company for evaluation)
Main laboratory 1	100% compliance	100% compliance
Main laboratory 2	100% compliance	100% compliance
Main laboratory 3	100% compliance	100% compliance
Peripheral laboratory 1	100% compliance	100% compliance
Peripheral laboratory 2	100% compliance	100% compliance
Peripheral laboratory 3	100% compliance	100% compliance
Peripheral laboratory 4	100% compliance	100% compliance
Peripheral laboratory 5	100% compliance	100% compliance
Peripheral laboratory 6	100% compliance	100% compliance
Peripheral laboratory 7	100% compliance	100% compliance
Peripheral laboratory 8	100% compliance	100% compliance
Peripheral laboratory 9	100% compliance	100% compliance
Peripheral laboratory 10	100% compliance	100% compliance

Further to the analysis of the performance of the pre-selected quality indicators on the business unit monthly reports evaluated for the two years, trends of “instrument malfunction”, “annual service of centrifuge not performed” and “quality control failure” were noted.

A trend is a laboratory error that occurs more than three times within a month. These trends were quality indicators that were not monitored in the mentioned study period, but their occurrences had been observed and only captured in the quality reports.

If these were preselected for the year, they would have been monitored as per the quality indicator, which would require a root cause analysis done and prevention of recurrence of error. However, since they were not preselected, the laboratory would not monitor the error monthly, but only capture it as a trend in the quality report. It was concerned that these trends were potentially posing a risk that may have had a direct negative impact on patient results.

To illustrate that there were loopholes in the monitoring of preselected quality indicators, Table 4.9 indicates the quality indicators that were monitored for the year 2017 in all the thirteen laboratories as well as those that were captured as trends but not monitored. The ticks (√) represent 100% compliance of the quality indicators that were monitored, whereas the dashes (-) indicate the quality indicators that were not monitored, although they are listed in the ISO 15189:2012 standard. In addition, the three quality indicators noted as trends in Table 4.10 were instrument malfunction, annual service of centrifuge not performed and quality control failure

Although the three main and ten peripheral laboratories monitored the pre-selected quality indicator for the year 2017, the following trends relating to other quality indicators that were not monitored were listed in the business quality report, namely (i) instrument nonconformity logs, (ii) instrument service/maintenance not done, (iii) equipment nonconformity logs (including pipettes, centrifuge, microscope), (iv) sample integrity (clotted and haemolysed samples), (v) turnaround time, (vi) outstanding container report, (vii) outstanding specimen report and other (which was not specified in the list).

Table 4.9 Quality indicators that were monitored as well as those that were not monitored in 2017

Quality indicator	Main laboratory 1	Main laboratory 2	Main laboratory 3	Peripheral laboratory 1	Peripheral laboratory 2	Peripheral laboratory 3	Peripheral laboratory 4	Peripheral laboratory 5	Peripheral laboratory 6	Peripheral laboratory 7	Peripheral laboratory 8	Peripheral laboratory 9	Peripheral laboratory 10
Turnaround time < %5	√	√	√	√	√	√	√	√	√	√	√	√	√
Internal quality control results fall within the medical decision levels of the assay	-	-	-	-	-	-	-	-	-	-	-	-	-
Measurement of uncertainty viewed on Levy Jennings graphs	-	-	-	-	-	-	-	-	-	-	-	-	-
Internal quality control within acceptable medical decision level of assay	-	-	-	-	-	-	-	-	-	-	-	-	-
Internal quality control within acceptable limits	-	-	-	-	-	-	-	-	-	-	-	-	-
External quality assurance within acceptable limits	-	-	-	-	-	-	-	-	-	-	-	-	-
Reagents not expired	-	-	-	-	-	-	-	-	-	-	-	-	-
Critical results phoned to clinician	-	-	-	-	-	-	-	-	-	-	-	-	-
Results correctly reported	-	-	-	-	-	-	-	-	-	-	-	-	-
Amended results	-	-	-	-	-	-	-	-	-	-	-	-	-
Clinician complaints	-	-	-	-	-	-	-	-	-	-	-	-	-
Instrument malfunction (Trend noted)		√				√		√			√		
Annual service not performed (Trend noted)					√								
Quality control failure (Trend noted)						√		√					

Table 4.10 indicates the quality indicators that were monitored for the year 2018 in all the thirteen laboratories and the ticks (√) represent 100% compliance, whereas the dashes (-) indicate the quality indicators that were not monitored although they are listed in the ISO 15189:2012 standard. Although the three main and ten peripheral laboratories monitored the pre-selected quality indicator for the year 2018. The following trends relating to other indicators were listed in the business quality report, namely (i) instrument nonconformity logs, (ii) instrument service/maintenance not done, (iii) equipment nonconformity logs (including pipettes, centrifuge, microscope), (iv) sample integrity (clotted and haemolysed samples), (v) turnaround time, (vi) outstanding container report, (vii) outstanding specimen report and other (not mentioned from the list). These were noted as trends since they were observed more than three times. Trends were noted for the following: (i) sample integrity, (ii) equipment malfunction, (iii) barcode errors, (iv) assay failing calibration and (v) turnaround time.

These trends were observed by the relevant laboratories however, they were not acted upon. There is a possibility that these trends may have had negative ramifications on the patient results generated. The sample integrity, equipment malfunction, barcode errors, assay failing calibration and turnaround time are analytical quality indicators that the medical technologists observed and recorded. Quality indicators that were not monitored were namely; 1) internal quality control results fall within the medical decision level of the assay, 2) measurement of uncertainty viewed on the levy Jennings charts, 3) updated document procedures, 4) internal quality control within acceptable limits of the assay, 5) external quality control within acceptable limits of the assay, 6) instrument maintenance performed, 7) reagents not expired, 8) critical results phoned to the clinician, 9) results correctly reported, 10) amended results, 11) clinician complaints (Table 4.10). Although a different pre-selected quality indicator was chosen and monitored for the years 2017 and 2018, namely turnaround time <5% and 85% of external quality assurance submission respectively, however only the pre-selected quality indicators were monitored and not the rest of the quality indicators that are in the analytical aspect of the ISO 15189:2012 standard.

Table 4.10 Quality Indicators that were monitored as well as those that were not monitored in 2018

Quality indicator	Main laboratory 1	Main laboratory 2	Main laboratory 3	Peripheral laboratory 1	Peripheral laboratory 2	Peripheral laboratory 3	Peripheral laboratory 4	Peripheral laboratory 5	Peripheral laboratory 6	Peripheral laboratory 7	Peripheral laboratory 8	Peripheral laboratory 9	Peripheral laboratory 10
85 % of External quality assurance submitted to the external quality assurance company for evaluation	√	√	√	√	√	√	√	√	√	√	√	√	√
Internal quality control results fall within the medical decision levels of the assay	-	-	-	-	-	-	-	-	-	-	-	-	-
Measurement of uncertainty viewed on Levy Jennings graphs	-	-	-	-	-	-	-	-	-	-	-	-	-
Internal quality control within acceptable medical decision level of assay	-	-	-	-	-	-	-	-	-	-	-	-	-
Internal quality control within acceptable limits	-	-	-	-	-	-	-	-	-	-	-	-	-
External quality assurance within acceptable limits	-	-	-	-	-	-	-	-	-	-	-	-	-
Reagents not Expired	-	-	-	-	-	-	-	-	-	-	-	-	-
Critical results phoned to clinician	-	-	-	-	-	-	-	-	-	-	-	-	-
Results correctly reported	-	-	-	-	-	-	-	-	-	-	-	-	-
Amended results	-	-	-	-	-	-	-	-	-	-	-	-	-
Clinician complaints	-	-	-	-	-	-	-	-	-	-	-	-	-
Sample integrity				√		√							
Equipment malfunction (Trends noted)			√		√			√		√			
Assay failing calibration (Trends noted)						√							
Barcode errors (Trends noted)							√						
Turnaround time (Trends noted)					√					√			

4.7 Correlations between levels of knowledge and practises among the medical technologists

The bivariate correlation result analysis indicated a pattern that denoted that the levels of knowledge of medical technologists on the quality indicators were directly proportional to their practises towards quality indicators. Directly related proportionality between levels of knowledge and good practises of medical technologists are illustrated from the analysis of responses (Table 4.10). The correlations were statistically significant when the p-value was $\underline{\geq}$ 0.05.

A positive correlation between “Instruments must be serviced periodically” and “Data must be analysed using valid methods” was statistically significant was noted ($r=0.320$; $p<0.001$), indicating a directly related proportionality. Respondents indicated that the more valid methods used are dependent on periodic instrument maintenance. This showed that medical technologists’ knowledge of using valid methods was directly proportional to their practises towards quality indicators.

A statistically significant positive correlation between “I perform procedures in conjunction with standard operating procedures and working instructions" and “Patient needs to give consent to the laboratory in order to perform relevant tests" was noted ($r=0.282$; $p<0.001$), indicating a directly related proportionality. Respondents indicated that patients need to give consent and they would perform procedures in conjunction with standard operating procedures. This depicts that the level of knowledge of medical technologists of document control is directly proportional to the way they practice good quality habits.

A statistically significant positive correlation between ‘Would you as a patient expect the same quality result if the test was processed in the main laboratory versus the peripheral laboratory “and “Data must be analysed using valid methods” was noted (0.443; $p<0.001$). That is directly related to proportionality. Respondents indicated that if valid methods were used, they would as a patient expect the same quality result if the test were processed in the main laboratory versus the peripheral laboratory.

This indicated that practises of medical technologists were directly proportional to the levels of knowledge.

Table 4.11 Correlation patterns suggested on the knowledge vs practises

Level of knowledge	Level of practises	Correlation coefficient	p-value
Quality indicators are a continuous monitoring tool	All staff involved in processing patient samples must also process interlaboratory and external quality control	r=0.457	p<0.001
Instruments must be serviced periodically	Data must be analysed using valid methods	r=0.320	p<0.001
I perform procedures in conjunction with standard operating procedures and working instructions"	Patient needs to give consent to the laboratory in order to perform relevant tests"	r=0.282	p<0.001
Would you as a patient expect the same quality result if the test was processed in the main laboratory versus the peripheral laboratory	"Data must be analysed using valid methods	r=0.443	p<0.001

Negative coefficient correlation values imply an inverse relationship between variables that have an opposite effect on each other. The negative correlations that were statistically significant are illustrated in Table 4.11.

A statistically significant negative correlation between "Internal audits do not need to be performed as they are costly and time consuming" and "Data must be analysed using valid methods" was noted (r=0,272; p<0.001). That is, the more emphasis there is on internal audits the less the need to analyse data using valid methods. This pointed to the fact that knowledge of internal audits was not correlating with practises in regards to the benefit of ensuring the use of valid methods in sample analysis.

A statistically significant negative correlation between "According to ISO 15189:2012, does the laboratory need to monitor quality indicators" and "Inter laboratory comparison and external quality control does not need to be performed in the laboratory where I am employed as it is expensive" was noted (r=0.314; p<0.001). This revealed that the knowledge of the fact that ISO 15189:2012 quality indicators need to be monitored was not correlating with the practises, where the emphasis on

the fact that the laboratory comparison and external quality control programme does not need to be performed as it is expensive.

A statistically significant negative correlation between “Tests that are not requested by the clinician can be processed and resulted” and “All staff involved in processing patient samples must also process inter-laboratory and external quality control” was noted (r= 0.270; p<0.001). This signified that the levels of knowledge in the fact that it is a requirement that inter-laboratory and external quality control programmes be processed to validate patients’ results was not correlating with practises in that what is not requested by a clinician should not be processed.

Table 4.12 Negative correlation patterns of knowledge vs practises

Levels of knowledge	Levels of practises	Correlation coefficient	P value
Internal audits do not need to be performed as they are costly and time consuming	Data must be analysed using valid methods	r= -0.272	p<0.001
According to ISO 15189:2012, does the laboratory need to monitor quality indicators	“Inter laboratory comparison and external quality control does not need to be performed in the laboratory where I am employed as it is expensive	r=-0.314	p<0.001
Tests that are not requested by the clinician can be processed and resulted”	All staff involved in processing patient samples must also process interlaboratory and external quality control	r=-0.270	p<0.001

4.8 Conclusion

The purpose of the study was to determine whether the pre-selected analytical quality indicators are sufficient to maintain the quality management system, since there are many areas on the analytical aspect in the laboratory that may require attention. Quality indicators were evaluated, and it was observed that not all that are in the ISO 15189:2012 standards were monitored and some trends that had been noted in the laboratory during each year had not been selected for monitoring in each of the two

years that were investigated. This was achieved by the evaluation of business quality reports of thirteen laboratories (from three main and ten peripheral laboratories).

Moreover, the levels of knowledge, attitudes, and practices of medical technologists on the quality management system were determined, noted to be varied. The research findings highlighted both positive and negative correlations between the levels of knowledge and practices as well as attitudes among the participants.

CHAPTER FIVE

Discussion of results

5.1 Introduction

In this chapter the findings of the business unit report, and the questionnaire are discussed. The discussion of the results is guided by the study objectives. Findings that are statistically significant, with a p value <0.05 are discussed. Recommendations and suggestions are based on the research investigation. The analysis of the data was done to satisfy the objectives of this study as stated in chapter one.

5.2 Discussion of results

From the study findings it was noted that the overall ratio of males to females was approximately 3:7, being 24 males and 56 females. Similarly, Mullah and Grant (2020), in a survey that investigated the working environment of medical technologists in South Africa found that only 20.8% of their respondents were male and 78.5% were female. Another survey on the profile, perceptions and future expectations of medical laboratory scientists in Namibia, Noden and Nowaseb (2015) revealed that 24% of the participants were male and 76% were female. Although very little research has been conducted on gender disparity amongst medical technologists in South Africa, the cited studies suggest that the profession may be less popular amongst males.

The analysed data further revealed that 53.8% of medical technologists had more than nine years of experience. This was viewed as a benefit to the establishment in experience regarding the dedication to the quality management system. As suggested by Schiender and Maurer (2017), involvement in ISO 15189:2012 quality standard is a journey that requires many years of commitment. Most often “things” become easier the longer the laboratory is following the ISO 15189:2012 standard. Schiender and Mauer (2017) further suggested that the culture of the laboratory changes gradually to warrant good thinking of “seeing” problems before they can occur, resulting in their

prevention. With increased years of experience, medical technologists may become proactive rather than reactive to the quality management system. Mullah and Grant (2020) found that medical technologists that were older than 35 years of age were happier with their profession due to the commitment and good job satisfaction. If staff are happy, they give off their best which will in turn give them job satisfaction and assist in refining good quality management systems (Mullah and Grant 2020).

The current study aimed to evaluate the performance of the pre-selected quality indicators from the quality reports in respect to compliance of the ISO: 15189:2012 requirements as identified by the medical laboratory establishment on an annual basis. The analysed data revealed that all thirteen laboratories maintained the pre-selected quality indicator for 2017 and 2018 respectively. However, this study observed that the effect of the current practice of placing emphasis on preselected analytical quality indicators for the three main laboratories and ten peripheral laboratories was not sufficient to maintain the overall quality of the laboratory as per the included study period.

In the year 2017, only ‘turnaround time’ as the pre-selected quality indicator was monitored. The other eight quality indicators such as proficiency testing, reporting of results, quality control, reporting critical results, review of results; continual improvement and clinician satisfaction were not monitored. Also, in the year 2018, the ‘submission of external quality assurance’ was the quality indicator monitored and the other eight quality indicators were not monitored. Instead, in some of the laboratories the following nonconformities were observed and documented as trends: (i) sample integrity, (ii) equipment malfunction, (iii) barcode errors, (iv) assay failing calibration and (v) turnaround time, however, they were not acted upon. The trends for the other nonconformities were laboratory errors that were noted over and above what had been pre-selected for monitoring in that year. As common practice within the laboratory, when a pre-selected quality indicator is not achieved in a particular month, its root cause is investigated in the following month and corrective measures put in place to

ensure that the pre-selected quality indicator is achieved in the following month.

However, the additional trends were not acted upon, as they were not previously identified as the pre-selected indicator for monitoring for the year, they were just observed and documented.

In this medical establishment, management review meetings are held to discuss performance areas that require attention and to identify quality indicators for the following year, based on the performance areas identified from the present year that require improvement. The quality indicators are chosen from the nonconformities that would have been observed nationally, to be monitored by all laboratories in the entire establishment. These nonconformities would have been those that were documented as trends. If the trends were identified in one province and not in others, then they would not be pre-selected for monitoring nationally. Hence, the trends that were observed in 2017 in some of the laboratories that were investigated in the current study were not chosen for the following year (2018) as a pre-selected quality indicator due to them not being picked up in other provinces. Therefore, a loophole was identified in the current quality management system of the medical laboratory establishment, as highlighted by the trends that were picked up but not monitored or used in deciding on which quality indicators to choose for monitoring in the following year.

There was a likelihood that these nonconformities that were noted as trends may have had adverse consequences on the generated patient results. Based on this finding, we propose that all the non-conformities that have been identified as trends be considered as quality indicators to be monitored in the following year. Furthermore, the current findings suggest that it was essential that more than one analytical quality indicator was selected to ensure that the maintenance of the quality management was successful, and that trends were not ignored. Although, a study by Plebani (2016) suggested that only five of the analytical quality indicators should be monitored each year: namely, 1) test not covered by internal quality control, 2) unacceptable performance of quality control, 3) test not covered by external quality control, 4) unacceptable performance of external quality control and 5) transcription errors,

however, the current study highlighted the need for monitoring of all the quality indicators and not just those pre-selected.

Although the 13 laboratories successfully monitored those quality indicators that were pre-selected, the nonconformities were identified and recorded as trends and corrective action was not taken on them by the quality department. Aita and Sciacovelli (2019) concur with our viewpoint that all quality indicators as listed in the ISO 15189:2012 standard must be monitored and not only those that would be pre-selected for the year. Aita and Sciacovelli (2019) have formed an International Federation of Clinical Chemistry and Laboratory Medicine bench-marking program that is formulating a model of quality indicators that would need to be monitored annually for the improvement of quality management systems. Several countries, including Spain (working group of the Catalonian Health Institute), Brazil (Brazilian Society of Clinical Pathology/Laboratory Medicine) and Australia (Royal College of Pathologists of Australasia) are included in this bench-marking program, and it is noted that South Africa has not been included in any of these studies.

Currently, there are nine analytical quality aspects listed under the examination clauses in the ISO 15189:2012 standard, which include all the analytical performance such as proficiency testing, reporting of results, quality control, reporting critical results, review of results, turnaround time, continual improvement, and clinician satisfaction (ISO 1589:2012 Medical checklist). However, the ISO standard does not specify the appropriate number of quality indicators to be monitored in a laboratory each time. The onus is on the individual laboratories to decide on how many quality indicators they wish to adopt per time. The current establishment however only monitors one analytical quality indicator per year which may not be sufficient to improve the quality management system since there are other analytical aspects that are not monitored in that year.

Vermeersch and Frans (2021) indicated that the intention of the ISO 15189:2012 is to guide laboratories to develop a quality management system that regulates all steps in the total testing process therefore, laboratory professionals often have an obligation to design their quality management in such a way that it also conforms to local regulations

regarding accreditation. Hence, monitoring only one aspect does not give a snapshot view of the entire quality management system. Since these guidelines are not specific about the number of quality indicators for a laboratory to monitor, the laboratory may want to take an easier route and only choose one quality indicator just to ensure they comply.

In addition, the analysed data on the levels of knowledge, attitudes, and practices of medical technologists on the current use of quality indicators revealed significantly high levels of knowledge in document control and instrument maintenance. As indicated by Schiender and Mauer (2017), document control is more than having procedures signed on time, and eliminating cheat sheets with outdated information. It includes writing and reviewing of work instructions and standard operating procedures. Schiender and Mauer (2017) further indicated that control of documents is important for the entire workforce such as staff including pathologists and medical technologists performing the task and they must always have the correct information needed in order to perform their job correctly. Also, from the study findings, medical technologists indicated that they maintain instruments to minimise analytical errors, thus improving the quality of the current system. About Mrazek (2020), this high level of knowledge is an important trait for medical technologists to demonstrate as errors in the analytical phase can also be operator dependent.

The results of the study further indicated that the majority of the participants performed procedures in conjunction with standard operating procedures and working instructions set out by the establishment. This revealed that most of the participants performed good practice due to their adequate levels of knowledge. Good practice would influence a good attitude towards the quality management system of the establishment. This view was based on the high levels of knowledge in respect to document control that the participants demonstrated. Interestingly, despite the high levels of knowledge that the participants demonstrated, it was noted that they had poor levels of knowledge in the use of the following quality indicators: 1) internal quality control, 2) inter-laboratory quality control, 3) validations, 4) verifications, 5) medical decision levels and 6) measurement of uncertainty.

The majority of the participants agreed that quality control does not need to be run in order to validate patient results and they believed that even when the quality control is out of range of the patient, results can be generated, whereas the expected response was that the quality of patient results is more important than the turnaround time. These responses suggested that the importance of inter-laboratory and external quality control was not fully understood by these medical technologists. As mentioned by Mrazek (2020), internal quality control and external quality assessment are the cornerstones of quality assessment in the analytical phase; therefore, laboratories must make sure that patient results cannot be released if internal quality control is out of range.

Badrick and Gay (2017) concurred with this viewpoint that external quality evaluation is the confirmation of results on a recurring basis; therefore, laboratory results must be in line with the excellence required for patient care. Furthermore, Aita and Sciacovelli (2016) indicated that in any analytical process, the use of internal and external quality control are continuous improvement tools. When quality control is not treated correctly, patient results will be directly impacted.

The results further determined that the level of knowledge of medical technologists was poor in respect to the validation and verification of methods. This is based on the participants not knowing the reason validations and verifications were important. This would have a direct impact on the patient results as validations and verifications play an important role in the success of a quality management system. Gunther (2020) stated that modern laboratories must confirm that the procedures used for specific tests are reliable and valid by performing validations. From the responses of the survey in the present study, it was deduced that the medical technologists knew that validations, verifications and medical decision levels of tests are important but the reason as to why they are important was not fully understood by the participants. The reasons provided were variable and not appropriate. Medical technologists who have been in employment for more than nine years would be expected to have high levels of

knowledge on the importance of validations and verifications, as sources of errors and interference can invalidate the results.

A study done by Amarsingha (2021) revealed that newly qualified medical technologists have higher knowledge than experienced medical technologists. More experience may not be useful unless new knowledge is gained. Amarsingha (2021) further indicated that education and new knowledge have a greater influence on understanding about quality than years of experience

When the participants were asked to suggest a list of different tools that should be used to measure uncertainty measurement, the list they supplied was inappropriate, indicating a lack of knowledge in the aspect of measurement of uncertainty. As noted by Brago and Pateghini (2019) measurement of uncertainty provides a quantitative estimate of the level of confidence that a laboratory has in the analytical precision of test results. It was further noted by Brago and Pateghini (2019) that estimation and checking measurement of uncertainty in medical laboratories is essential to determine its influence on measurement results.

When the levels of knowledge and attitudes were correlated, it revealed that knowledge was directly proportional to attitudes. Kiani and Tavakkoli (2019) suggested that when there is sufficient knowledge it would lead to a positive attitude towards performance. Hence, the poor levels of knowledge in the above-mentioned quality indicators would impact on the attitudes and practices of the medical technologists and affect their generation of patient results. Aita and Sciacovelli (2016) intimated that efforts must be made to empower laboratories to accumulate knowledge on the usefulness of quality indicators and manage their actions for continuous improvement.

To assess the levels of knowledge further, the participants had to provide reasons which were variable and indicated a lack of knowledge on the medical decision levels as being an important component for patient care. With reference to Ozarda and Higgins (2018), ISO 15189:2012 standard for clinical laboratory accreditation states that each laboratory should periodically re-evaluate its medical decision levels. The findings of the study concerning medical decision levels revealed that knowledge is not

adequate for critical decision-making on patient care. Ozarda and Higgins (2018) further suggested that medical decision levels are an important part of the information supplied by laboratories to clinicians to assist with the interpretation of patient results. Although the establishment had 100% compliance for monitoring of the pre-selected quality indicators, the participants demonstrated poor knowledge in certain areas, and this was postulated as due to them possibly needing to focus only on the pre-selected quality indicators rather than knowing the whole quality management system. A study done by Mamuye and Merga (2018) indicated that poor laboratory practice may affect negatively to attain the quality purpose and the study required educational and motivation activities to improve the practice on internal quality control.

If knowledge is improved on handling of reagents, they will practice with the knowledge they have attained. From the results of the survey, it denoted that medical technologists need to improve their practices on the laboratory performance quality results. Poor performance will result in increased errors. When the levels of knowledge and good practices were correlated, it was observed that good practice was directly proportional to knowledge and attitude. Medical technologists' knowledge of using valid methods was directly proportional to their practices towards quality indicators and the level of knowledge of medical technologists of document control is directly proportional to the way they practice good quality habits. However, the results revealed that less than half of the respondents strongly disagreed with the following statement 'Expired reagents and controls can be used in the laboratory for routine use'.

This indicated bad practice on handling reagents. From the analysed data, it noted that medical technologists poorly practice the handling of reagents. This would have a direct impact on the patient results generated therefore further training is suggested on reagent stability and handling, to enhance the knowledge of medical technologists in this establishment. A study conducted by Mohanty (2018) identified the following analytical quality indicators as necessary to maintain the quality management system: namely lot to lot of reagents, instrument efficiency, data entry.

Traits of bad practice were revealed when the majority of the respondents answered the questions on practice on the patient identification aspect as well as on amended results poorly. Lippi (2020) strongly points out that accurate identification of patients and the appropriate labelling of blood collection tubes are crucial steps for preventing diagnostic errors and inappropriate patient management. Lippi (2020) further indicated that misidentification can be prevented by having quality indicators in place. From the results obtained, it was denoted that the medical technologists needed to improve their practices on the laboratory performance of quality results. Poor performance would result in increased errors.

It was concerning that the majority of the respondents strongly agreed that the clinician does not need to be informed of an amended patient result. The expected response was that the clinician needs to be notified of any amended results so that patients can be treated accordingly. Mrazek (2020) suggested that when tests are rerun early, this gate-keeping approach will assist the clinician and the medical technologist in improving the quality of the patient's results. In spite of some traits of bad practice that the participants demonstrated, they, on the other hand, showed good attitude in wanting to see improvement in the establishment that they work in. Medical technologists suggested the following on what they thought would improve the current system: 1) quality training, 2) quality management system to be constantly updated, 3) paperless system, 4) frequency of quality control, 5) improved turnaround time, 6) staff involvement, 7) audit frequency, 8) staff allocation, 9) more quality meetings, 10) cheaper external quality control, 11) a continuously validated system, 12) automation, 13) communication, 14) third party quality control, 15) improved customer satisfaction and 16) one middleware.

They further indicated that if valid methods were used, they would, if they were a patient, expect the same quality result even if the tests were processed in the main laboratory versus in the peripheral laboratory. Bakotic and Rogosic (2017) concurred with some of these suggestions when they stated that employee involvement through different concepts such as employee training, communication, empowerment and rewards and recognition had a positive impact on the continual improvement.

Therefore, the suggestions by the medical technologists indicated a good attitude towards continual improvement. Our viewpoint is that it would benefit the medical establishment to consider these suggestions for continual improvement. Medical technologists should be committed to maintaining the quality management system. As indicated by Bhatia and Ranjana (2021) commitment of laboratory workers in accepting, sustaining and evaluating the quality management system data will lead to further reinforcing the current healthcare system.

It was further noted that the majority of the participants believed that audits must be performed even though they are costly and time-consuming, this further showed good attitude towards continual improvement of the quality management system. Sharma and Patgiri (2018) indicate that conducting audits or evaluating laboratory records is important to have as a goal or standard of performance.

The current study highlighted that it is essential that the medical establishment that was investigated identifies quality indicators for continual improvement of the quality management system, as well as that all of those identified indicators are monitored. Considering the critical role medical technologists play in the quality management system, it was noted as important that they have good attitudes and good practice traits. It was further observed that medical technologists' knowledge toward the current use of quality indicators has an impact on their attitudes and practices in the medical establishment.

A study by Dale (2021) which focused on the knowledge, attitudes and perceptions of medical technologists showed that although participants were familiar with quality assurance and practicing quality assurance as well as customer satisfaction, their levels of knowledge were measured as poor. This is similar to the current study findings, where although participants demonstrated poor knowledge on certain areas of the quality management system, their attitude was good in realising that they may contribute to the continual improvement of the same quality management system.

Medical technologists are professionals that are responsible for sample analysis and ensuring that laboratory test results of each patient are accurate in maintaining the

quality management system, and to ensure that clinicians receive quality results. As indicated by Aita and Sciacovelli (2019) laboratory professionals must maintain a high level of skills for achieving efficiency and effectiveness when delivering laboratory services. The knowledge, practices and attitude of medical technologists have a direct impact on maintaining this quality management system. If the knowledge of a medical technologist is improved by training and quality workshops, this will then in turn improve their practices and attitudes within the workplace. The current study findings concluded that the knowledge is directly related to the good attitudes and practices of medical technologists about quality indicators.

The current study concurs with the views of Aita and Sciacovelli (2019) that indicate that education and training designed to improve knowledge and skills to guarantee relevant competency is essential. The laboratory professionals should focus on the five-rights principle based on: appropriateness; personalised and patient-centred service; focus on outcomes, value-added, and diagnostic partnership (Plebani 2016).

5.3 Study Limitations

1. Selecting participants from a population size of 100, which form part of the Medical Technology staff complement within this investigated establishment Future studies should consider including other regions to participate in such an investigation. The sample size would be larger and would provide a wider indication of the knowledge, practices and attitudes of medical technologists. The study only viewed the perspectives of medical technologists, further studies should be done to investigate the perspectives of managers and other key decision makers on quality within a laboratory setting.

2. Only one geographical area was used in the investigation as the study was conducted in KwaZulu-Natal. This was regarded as a limitation. If more geographical areas were part of the study, a different outlook may have been obtained on the view of the knowledge, practices and attitudes of medical technologists regarding the use of analytical quality indicators. Future studies should consider including more than one geographical area. Similar studies to this current study are essential in other provinces of South Africa.

3. Another limitation was that only one medical establishment, which is private, was used in the study. If more establishments were included in the study, more information may have been gathered on how other establishments, public and private, monitor and evaluate the quality indicators, whether they pre-select quality indicators or if they are even monitored at all. A comparison could be determined whether the quality indicators are monitored and evaluated according to the ISO 15189:2012 standard. Future studies should be conducted with public and private medical establishments included. The results of such studies could be beneficial in enabling South African medical laboratories to determine their own bench-marking exercises for quality indicators.

4. The study period was only for the years 2017 and 2018, and this was a limitation. It may have provided more information especially with the nonconformities recorded as trends if the study period was for more than two years, to determine whether the observed trends may not have been noted by chance but may have occurred over many years.

CHAPTER SIX

Conclusion and recommendations

6.1 Concluding remarks

This current study, which investigated the usefulness of quality indicators in a medical establishment, was noted to be the first such study conducted in South Africa (SA). No evidence was noted in published data of any such study being investigated in SA. Despite the limitations highlighted in the previous chapter, the current study noted key findings, as follows:

1. The study revealed that the participants displayed significantly high levels of knowledge on document control and instrument maintenance. This had a direct impact on their attitudes and practices on the current use of quality indicators. The study findings underscored the direct proportionality between levels of attitude as well as level of good practices of the medical technologists to their high levels of knowledge.

2. The study highlighted the need for the monitoring of all the analytical quality indicators, as indicated in the ISO 15189:2012, and this was another key finding. More than one pre-selected analytical quality indicator is recommended, to maintain the quality management system of the establishment. It identified that the monitoring of just one analytical quality indicator per year is inadequate. This is based on the loopholes that were identified, where although all 13 laboratories investigated conformed to the preselected quality indicators however, nonconformities were noted as trends but were not actioned upon since they were not chosen for monitoring in a particular year.

3. The participants' suggested list of quality indicators for the continual improvement of the quality management system was a significant finding of this study. The participants suggested a list of quality indicators based on their views that they felt might assist the establishment in maintaining the quality management system. Some of these quality indicators they suggested, are not in the current ISO 15189: 2012 quality standard. The suggested list of quality indicators may ensure that the selection of the analytical quality indicators in a medical establishment provides guidance to medical technologists.

6.2 Recommendations

1. Notwithstanding the many years of experience that the participants have, it is however recommended that ongoing training, quality workshops and refresher courses be given to them, to improve their knowledge on the aspects in the quality management system that they demonstrated poor levels on. Training and quality workshops will assist in maintaining the quality standards set out in ISO 15189:2012.

2. To improve the quality management system, all analytical quality indicators listed in the ISO 15189:2012 standard should be monitored, and not just one pre-selected quality indicator. This would therefore incorporate the monitoring of unacceptable quality control results that may or may not have been noted as nonconformities/ trends.

3. Besides the quality indicators listed in the ISO 15189:2012 standard, some or all of the quality indicators that were recommended by the participants may need to be considered to be included for monitoring in the quality indicators annually.

4. The study findings highlighted a need for a generic guideline to be established in the medical laboratory establishment where the investigation was undertaken. This guideline would include some or all of the recommended quality indicators to improve the quality management system of the medical establishment.

5. The recommended list of quality indicators should have a follow up study done to evaluate these indicators in more depth, to determine if this improved list can enhance quality.

LIST OF REFERENCES

Aita, A. and Sciacovelli, L.2016.Performance criteria and quality indicators for the post analytical phase, *Journal o*f C*linical Chemistry* L*aboratory Medicine,* 54, 1169.

Aita, A. and Sciacovelli, L.2019.The silk wood to total quality in laboratory medicine, *Journal o*f C*linical Chemistry Laboratory Medicine,* 57, 812.

Amarsingha, A.2021. Knowledge and attitudes of laboratory technologists in the Southern Province on medical laboratory accreditation, *Department of Medical Laboratory Science,*3,1.

Ambachew, S. and Adane,K. 2018. Errors in the total testing process in clinical chemistry at University of Gondar hospital, *North West Ethiopian Journal of Health Science,28,2*.

Badrick, T. and Gay, S.2017.External quality assessment beyond the analytical phase: an Australian perspective. *Biochemical Medical,10,11613.*

Barth, JH. 2011. Clinical quality indicators in laboratory medicine, *Annals of Biochemistry.* volume 48 Issue 3. Pages 238-240.

Barth, JH. 2012 Selecting Clinical quality indicators for Laboratory medicine. Annals of Biochemistry. volume 49 Issue 3 March 2012.Pages 257-61.

Bakotic,D. and Rogosic ,A.2017.Employee involvement as a key determinant of core quality management practises. *Total quality management business executive*.2017.11-12.

Bhatia,M and Ranjana,R.2021. Analysis of trends of post analytical quality indicators in a clinical Bacteriology laboratory. *India Journal of Medical Microbiology*.2021.196-199.

Brago, F. and Panteghini, M. 2020. The utility of measurement of uncertainty in medical laboratories. *Journal of Clinical Chemistry Laboratory Medicine,* 2019, 1336.

Burnett, S. 2010.Medical engagement in organisation wide safety and quality improvement programmes: experience in UK safer patient initiatives. *Quality and safety healthcare*,10,1136

Burnett, D. 2013. *A practical guide to ISO 15189 in Laboratory Medicine,* London Inc: ACB Venture publications.

Chawla, R. G. and Singh, B. 2010. Evaluating laboratory performance with quality indicators. *Journal of Clinical Chemistry Laboratory Medicine,* 41, 297.

Cadamuno, J. and Gaksch, M.2018. Are laboratory tests always needed? Frequency and causes of laboratory overuse in a hospital setting. *Journal of Clinical Chemistry Laboratory Medicine,* 10, 1515.

Dale, D.2021. Knowledge attitudes and practises in laboratory quality assurance among medical technologists in selected level 111 hospitals in Davao city, *International journal of Progressive Research in Science and Engineering*,2,398.

de Gruyter, W. 2011. Quality indicators in laboratory medicine: from theory to practice. *Journal of Clinical Chemistry Laboratory Medicine,* 49, 835.

Gunther, V. S. 2020. Using Business Intelligence Tools to Support Medical Validation of Laboratory Tests. *European Federation for Medical Informatics*. 10.3233.

Hamerling, J.A.2012. A review of medical errors in laboratory diagnostics and where we are today. *Journal of Clinical Chemistry Laboratory Medicine,43,44.*

Kiani, M. and Tavakkoli, S.2019. Changes in ethical attitudes of clinical laboratory professionals after teaching them ethics using different methods. *Medical Journal Islam Republic Iran.*33,36.

Lao, E.G. and Garcia, A.S.2017. Errors of clinical laboratory and its impact on patient safety. *Open Journal of Social Sciences.* 243,253.

Leonard K.N and Kinoti F. 2019. ISO 15189 Accreditation projects and performance of medical laboratories in Naorobi City Country, Kenya. *International Academic Journal of Information Sciences and Project Management*. Volume 3, Issue 3, pp. 235-258.

Lippi, G. C.2020. Errors within the total laboratory testing, from selection to decision making, a review of causes, consequences, surveillance and solutions. *Biochemia Medica.* 30,502.

Mamuye, D. and Merga, Y. 2018. Assessment of knowledge attained and practice of medical laboratory professionals on the use of internal quality control for laboratory tests among selected healthcare centres in Addis Ababa Ethiopia. *Ethiopian Public health institute.*8-2.

Mrazek, C. 2020. Inappropriate use of laboratory tests, how availability triggers demand examples across Europe. *Journal of Clinical Chemistry Laboratory Medicine,* 506,107.

Mohanty, S.2018. Errors in laboratory medicine: The role of quality indicators. *International journal of clinical Biochemistry and Research.* 2397-6377.

Mullah, M and Grant, K.A.2020. A survey of the working environment of medical technologists in South Africa. *Journal of Laboratory Medicine Science and Technology,22,28.*

Noden. B, and Nowaseb. V.2015.Profile, perceptions and future expectations of medical laboratory scientists in Namibia. *The Authors Licence: Oasis Open Journal,10.4102.*

Ozarda, Y. and Higgins, V.2018.Verification of reference intervals in routine clinical laboratories: practical challenges and recommendations. *Journal of Clinical Chemistry Laboratory Medicine,*10,1515.

Plebani, M. 2014. Laboratory associated and diagnostic errors: a neglected link. Available https://doi.org/10.1515/dx-2013-0030 (Accessed 20.03.2018).

Plebani, M. 2015. Towards harmonisation of quality indicators. *International Journal of Clinical Chemistry and Diagnostic Laboratory Medicine*, 10,1515.

Plebani, M. 2016.Towards a new paradigm in laboratory medicine. *International Journal of Clinical Chemistry and Diagnostic Laboratory Medicine*, 54,1881.

Plebani, M. 2017. Quality indicators for the total testing process. *Journal of Clinical Laboratory Medicine,* 37, 187.

Prabhakar,E. and Stephen ,G. Laboratory errors in routine biochemical investigations. *Journal of Pharmaceutical and Biomedical Science*,22,22.

Sakyi, A.S. and Lang, E.F.2015.Evaluation of analytical errors in a clinical chemistry laboratory: A 3-year experience. *Annals of Medical and Health Science Research.*5,1.

Schneider, F. and Maurer, C.2017. International organisation for standardisation (ISO) 15189.*Annals of Medical and Health Science*. *37,365.*

Sharma, P. and Patgiri, D.2018. Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety. *Journal of Medical Society. 32,157.*

Siddiqui, J.A, Lodhi, A and Uzma,2015. Evaluation and control of Pre analytical errors in required quality Variables of Clinical Laboratory Services.*Journal of Nursing and Health Science* 2320–1940 Volume 4, Issue 3 PP 54-71.

Singh, H. 2015. Reducing misdiagnosis: Time for the next chapter in improving patient safety. *Baylor College of Medicine,* 10,1056.

Swetha, K.N and Raju N.S.2019. Quality assurance program in clinical biochemistry laboratory at a multi-speciality teaching hospital, with Special Reference to quality Indicators. *National Journal of Laboratory Medicine.* Vol-8(2): BO05-BO08.

Toshniwal, P. and Shah, R.2016.An insight view on pre and post-analytical errors in clinical chemistry laboratory of a tertiary care super speciality hospital. *National Journal of Laboratory Medicine.*10,14.

Vermeersch, P. and Frans, V.2020. How to meet ISO 15189:2012 requirements in a clinical laboratory? A consensus document. *Journal of Clinical Chemistry and Diagnostic Laboratory Medicine*, 54,2020.

World Health Organization. 2005. Laboratory quality management system. Available: https://www.who.int/quality . (Accessed 12.10.19).
World Health Organization. 2011. Laboratory quality management system. Available: https://www.who.int/quality management systems. (Accessed 12.12.20).

South African National Accreditation System .2015. Available: https://www.thedti.gov.za/agencies/sanas.jsp (Accessed 03.03.2018).

Kaiser-Meyer-Olkin measure of sampling adequacy. 2020. Available http://www-01.ibm.com/support/knowledgecenter/SSLVMB_20.0.0/com.ibm.spss.statistics.cs/factor_telco_howto_01.htm(Accessed03.03.2018).

Appendix A : Ethical clearance

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

P O Box 1334, Durban, South Africa, 4001

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

www.dut.ac.za

8 July 2020

Mrs N Hirjee
10 Gokal Road
Effingham Heights
Durban

Dear Mrs Hirjee

Evaluation of the performance of analytical quality indicators on the quality management system in a medical laboratory establishment
Ethical Clearance number IREC 010/20

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

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

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

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

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

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

Yours Sincerely,

Professor J K Adam
Chairperson: IREC

Appendix B : Permission to conduct study

PATHOLOGY LABORATORY SUPPORT SERVICES
Registration No.: IT190/92
AMPATH TRUST

166 Witch-Hazel Avenue, Highveld technopark, Centurion, Cl 57
Private Bag Highveld, 0169 lei: (01 2) 678-1 COO Fax: (012) 678-18 5
SERVICING DRS DU BUISSON, KRAMER, SWART, BOUWER Inc./Ing.

3/08/2018

To whom it may concern : Ampath Trust

Re: Permission to conduct a study on the analytical quality indicators

I am Nishani Hirjee student number 19551895, employee number 32761 am currently registered at the Durban University of Technology for a Masters Degree in Health science. My topic is the Evaluation of the performance of the identified analytical indicators on the quality management system in a medical laboratory. I would like to seek permission to use the information from the monthly business unit quality report on the analytical quality indicators for 2017 and 2018 for all laboratories in KZN. Confidentiality of the company will not be breached as the organisation will remain anonymous. A survey of Medical Technologists will be conducted and this will remain anonymous. All ethical considerations will be adhered to.Your permission will be highly appreciated

Researcher Name: Nishani Hirjee Researchers signature:

Approved by

Name and Surname : Dr Mick Forder

Signature :

Date : 03/08/2018.

Appendix C: Letter of information

LETTER OF INFORMATION

Dear Participant

My name is Nishani Hirjee, registered at Durban University of Technology for the Masters in Health Science. I am kindly requesting you to participate in my study titled "Evaluation of the performance of analytical quality indicators on the quality management system of a medical laboratory establishment.

The study aims to evaluate the performance of preselected analytical quality indicators on the quality management system of a medical laboratory over a two- year period between January 2017 to January 2019. This study intends to determine whether the pre-selected analytical quality indicators will be sufficient to maintain the quality management system in the laboratory. It also aims to determine a generic set of quality indicators established from the ISO 15189:2012 checklist to assist the laboratories to maintain the quality management system. The study will be a quantitative evaluation study consisting of a retrospective and a prospective component. The retrospective aspect will include the evaluation of the laboratory quality reports. It will evaluate the performance of preselected analytical quality indicators on the quality management system of a medical laboratory over a two- year period from January 2017 to December 2018.

The prospective aspect will consist of a questionnaire which will be given to eighty medical technologists to determine their knowledge, attitudes and practises regarding the current use of quality indicators. If you agree to participate and have signed an informed consent form, you will be required to complete an on- line survey which will be given to medical technologists according to years of being qualified. The survey will be completed in one and a half hours. Participation in this survey is voluntary. Medical technologists will be recruited by years of qualification, from three years to greater than nine years. The survey will take approximately forty minutes to complete. Confidentiality will be maintained as each questionnaire will be coded and your names will not be used.

There will be no risks or discomforts to you in association with the study. The benefits of the study will be publications of study and may be a generic set of quality indicators to improve the quality of the laboratory. Reason/s why you may be withdrawn from the Study may be due to non-compliance or illness. There is no

Remuneration from the study. There are no Costs implications of the Study Confidentiality of each medical technologist participating in the study will be given a letter of information (Appendix C) which will be added as a disclaimer at the beginning of the survey explaining the purpose and implications of the research in a manner that is suitable to you and accepting participation in the survey. There will be no Research-related Injury.

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

Dr B T Mkhize (PhD)	Dr P Pillay (PhD)	Ms N Hirjee
Main Supervisor	Co-Supervisor	Principal Investigator
0828794923	0844660916	0848781339
mkhizebt@dut.ac.za	pillay@dut.ac.za	nishanihirjee@webmail.co.za

Additional Contact info:

Institutional Research Ethics Administrator: Tel: 031 373 2375

Prof Z Ndakisa (DVC: Research, Innovation and Engagement)

Tel: 031 373 3007, Email: zenandeN@dut.ac.za.

Appendix D: Informed consent form

Consent

Statement of Agreement to Participate in the Research Study.

- I hereby confirm that I have been informed by the researcher, (Nishani Hirjee), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance: Number ___IREC010/20_____
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

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

Full Name of Researcher	Date	Signature
Full Name of Witness (If applicable)	Date	Signature
Full Name of Legal Guardian (If applicable)	Date	Signature

Appendix E Questionnaire

Instructions to commence with questionnaire:

- Answer all questions
- Place a cross X next to the most suitable answer

1. For paragraph questions answer briefly

Section A						
Demographics: (Participant: Please tick where relevant)						
Age:	20-25	26-31	32-36	37-41	41-45	>46
Gender	Female	Male				
Race	Black	Coloured	Indian	White	other	
Years qualified	3-5 years	6-9 years	>10 years			

Section B					
Key: 1 = Agree 2= Strongly Agree 3= neither agree or disagree 4= Disagree 5= Strongly Disagree, Yes and No					
	1	2	3	4	5
1.Are Instrument validations and verifications important in assisting in patient care					
2. Data must be analysed using valid methods					
3. Is it necessary to use medical decision levels for patients during the validation procedure	Yes		No		
4.If you have answered yes to question 3, give a reason for your answer					
5. What procedure in the laboratory is used to check if the manufacturers specifications are met					
6.There should be factors in place that affect the measurement of uncertainty	Yes		No		
7. If you have answered Yes to question 5 name 3 factors that affect measurement of uncertainty					
	1	2	3	4	5
8.Measurement of uncertainty does not need to calculated for manual assays					
9.List two tools that are used in the laboratory to measure uncertainty of measurement					

	1	2	3	4	5
10. I perform procedures in conjunction with standard operating procedures and working instructions					
11. I will be able to perform my job if the laboratory procedures are not clearly documented					
12. Standard operating procedures and working instructions must be written up and there is no need to review as procedures remain the same once it is implemented	Yes			No	
13. If you disagree with question 11 provide a reason for your answer					

	1	2	3	4	5
14. Internal quality control does not need to be run in order to validate a patient's result					
15. Give a reason for your answer					
16. If internal quality control is out of range, patient results can be generated					
17.Is it important to pull levy Jennings charts in the laboratory	Yes			No	
18. If you agree with question 17, provide a brief explanation					

	1	2	3	4	5
19.Inter laboratory comparison and external quality control does not need to be performed in the laboratory where I am employed as it is expensive.					
20. Give a reason for your answer					

	1	2	3	4	5
21. Inter-laboratory comparison and external quality programmes chosen do not need to mimic patient samples					
22. Interlaboratory comparison and external quality programmes chosen must not mimic patient results					
23. All staff involved in processing patient samples must also process interlaboratory and external quality.					
24. Inter-laboratory programmes or External quality assurance is a clear indication of how patient results perform.					
25.There is no need to improve my current system as I am comfortable with the way the laboratory is organised.					
26.Give a reason for your answer					

27.Internal audits do not need to be performed as they are costly and time consuming					
28.It is important for laboratories to have action plans for improvements.	Yes		No		
29. If you have answered yes to question 28, name three common improvement tools in the laboratory					

	1	2	3	4	5
30. According to ISO 15189:2012, does the laboratory need to monitor quality indicators					
31. List three examples of the three most important quality indicators that need to be measured in the laboratory					

	1	2	3	4	5
32. Quality indicators are a continuous management monitoring tool					
33. Quality indicators do not need to be reviewed periodically					
34. Laboratory equipment does not need to be regularly maintained					
35. Quality control can be run if maintenance is not performed on laboratory equipment					
36.Samples can be processed on laboratory equipment if maintenance errors are received					
37. Instruments must be serviced periodically					
38.Expired reagents and controls can be used in the laboratory for routine use					
39.When reagents, controls calibrators are opened for use, it is important to document on a reagent log	Yes		No		
40. If you agree with question 39, provide an explanation					

	1	2	3	4	5
41.Reagents, controls and calibrators can be left at room temperature until loaded on to the analyser					
42. Patient samples that are unsuitable for analysis can be analysed as it is unprofessional to contact the clinician for a re-bleed in order to process the test.					
43. Correct identification of patient samples is of vital importance in the laboratory					
44. Tests that are not requested by the clinician can be processed and resolved.					
45.Patients need to give consent to the laboratory in order to perform the relevant tests.					
46. The clinician does not need to be informed of an amended patient result.					
47. Quality patient results are not important as long as a result is generated.					
48. If patient results are life threatening, the clinician must be informed	Yes		NO		
49. If you answered yes to question 48, provide an explanation					

	1	2	3	4	5
50.Would you as a patient expect the same quality result if the test was processed in the main laboratory versus the peripheral laboratory					
51.If I had to change three things in the current quality system, what would it be					
1.					
2					
3					
52.When answering the questionnaire did you find the need to refer to any documents Yes NO					

Thank you for your participation